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Life Sciences 2025

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Contributing Editor
Lincoln Tsang
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Global Practice Guides

Life Sciences

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2025

Chambers Global Practice Guides

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INTRODUCTION

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Ropes & Gray LLP is home to one of the world's pre-eminent life sciences groups, with a global platform for innovators at every stage of the development life cycle. The firm's collaborative approach – spanning more than 25 practice areas and touching all offices around the world – offers one of the largest and most experienced industry-specific teams, comprising more than

300 lawyers, subject-matter experts and technical advisers who deliver sophisticated transactional, regulatory, IP, and litigation and enforcement strategies to position industry innovators and investors for success. The Ropes & Gray team is sought after to lead clients in navigating the complex legal landscape in which the life sciences industry operates.

Contributing Editor



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INTRODUCTION

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A Brave New World of Evolving Global Life Sciences Landscapes

Welcome to the 2025 edition of Chambers and Partners' Life Sciences Global Practice Guide. As the new contributing editor for this publication, I wish to express my gratitude to colleagues for their expert contributions to this Guide. They have collectively covered the latest developments in a wide range of regulatory compliance, legal and policy issues in their respective jurisdictions. In addition, I wish to take the opportunity to make a few opening remarks.

The life sciences and healthcare sector represents a major knowledge-based global economy. It is anticipated to grow to approximately USD4 trillion by 2033, poised for some breath-taking technological and medical transformations, driven by digitalisation and by the increasing convergence of biological, physical and computer sciences to expedite identification of novel therapeutic targets, novel materials, and new methodological approaches to evaluating the safety, quality, and clinical effectiveness of innovations.

Post-pandemic challenges

March 2025 marks nearly five years since the World Health Organization (WHO) officially declared the COVID-19 pandemic, beginning one of the most challenging periods in recent times. The pandemic also tested the resilience of the life sciences and healthcare sector at all levels. The sector has adapted its practices – and continues to do so – through increased agility and collaboration, spanning the full spectrum of R&D as well as healthcare delivery activities.

The industry has begun to stabilise after the WHO lifted the global public health emergency status for COVID-19, given that the disease is now considered to be ongoing and well established. Yet

now the world is confronted with a new wave of macroeconomic challenges such as high inflation and the rise in energy prices. Geopolitical friction is the new frontier that has contributed to the faltering of economic growth. Many economic commentators have remarked that high geopolitical risk has been associated with lower equity returns and higher forecast volatilities, as well as uncertainty in investment decisions. The Institute of International Finance has indicated that the global debt levels are extraordinarily high, with USD60 trillion added since 2020. The life sciences sector is not immune to these existential economic vulnerabilities.

Trade policy changes under new Trump administration

The second term of the Trump administration in January 2025 – overseeing the world's largest national economy and leading global trader – has started with some significant trade policy changes to achieve the USA's economic and trade-related objectives. The Trump administration has justified such trade measures as rebalancing the country's large and persistent annual trade deficit in goods, where closed markets abroad have reduced US exports and open markets in the USA have resulted in significant imports.

These changes have already sent shockwaves around the world, as the new trade policy has broken with decades of free trade policy – in recognition of globalisation, which involves increasing integration of economies around the world – by imposing tariffs on a number of key economic regions, including the USA's traditional allies. At the time of writing (April 2025), the new US President famously considered 2 April 2025 as the "tariffs day"/"liberation day" on which the new tariffs will be enacted unless the tariff and non-tariff barriers are equalised.

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EU countermeasures

The EU and the other US allies have already introduced a series of countermeasures. Trade measures and countermeasures were imposed by the EU (in 2018 and 2020 respectively) during the first Trump administration, primarily in response to the US tariffs on European steel and aluminium exports. These EU countermeasures were structured into two sets of measures, each affecting different product categories. The EU measures and countermeasures introduced in 2018 and 2020 were subsequently suspended until 31 March 2025 or otherwise will be reactivated on 1 April 2025 to give the USA and the EU the opportunity to work out a longer-term solution. In response to the new US trade measures on European goods of 12 March 2025, on the same day the EC defended European interests in response through two sets of countermeasures – namely, the reimposition of the suspended 2018 and 2020 rebalancing measures, and the imposition of a new package of additional measures.

The EU's trade countermeasures were initiated by the EC according to the EU Enforcement Regulation 2014, which enables the EU to suspend concessions or other obligations under international trade agreements with the intention of rebalancing concessions or other obligations in trade relations with third countries when the treatment accorded to goods from the EU is altered to such an extent that affects the EU's interests.

This rebalancing of concessions or other obligations is permissible under international trade law as now reflected in EU law. Specifically, a member of the WTO can apply a safeguard measure or seek an extension of a safeguard measure based on objective criteria (defined in EU law) in order to suspend tariff concessions and to

impose new or increased customs duties. These objective criteria set out in EU law are:

- effectiveness in inducing compliance of third countries with international trade rules;
- potential to provide relief to economic operators within the EU affected by third-country measures;
- availability of alternative sources of supply for the goods concerned in order to avoid or minimise any negative impact on downstream industries, contracting authorities, entities, or final consumers within the EU;
- avoidance of disproportionate administrative complexity and costs in the application of the measures; and
- any specific criteria that may be established in international trade agreements.

Impact on life sciences and healthcare sector

The uncertainty surrounding the trade tariffs will likely increase the costs on goods and hence increase price spikes, disrupt the supply chains, and bring about serious supply shortages. This is particularly impactful for the life sciences and healthcare sector, which has relied upon on international trade and an interconnected global economy in order to research, develop and manufacture healthcare products – particularly essential and critical medicines, as well as healthcare products that global citizens have taken for granted. Supply shortages will have seriously momentous consequences on public health and patient care. The COVID-19 pandemic also emphasised the increasing interdependency and interconnectivity of various geographical regions in providing raw materials for the manufacture and distribution of critical public health countermeasures for hospitals, including prophylactic vaccines and personal protective clothing.

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Moreover, the trade wars will hurt the ongoing global development of AI and digital health. Tariff and export control policies will have much larger effects on AI hardware supply chains.

Industry has already responded by urging the Trump administration and the EU to exclude medical products from expanding tariff wars, in the hope of avoiding price increases and supply shortages.

On 2 April 2025, President Trump issued an executive order (the Reciprocal Tariffs Executive Order) imposing a reciprocal tariff of 10% at baseline on all US trading partners, effective 5 April 2025. An additional reciprocal tariff will be imposed on 57 countries, effective 9 April 2025. Annex II to the Reciprocal Tariffs Executive Order excludes certain named medicines or categories of medicines – as well as key ingredients used in drug formulation – from the reciprocal tariffs. However, it is not apparent that the exclusion applies to medical devices and medical technologies – although semiconductor devices and semiconductor-based transducers are excluded. Tariff relief for pharmaceuticals could be short-lived, as the Reciprocal Tariffs Executive Order contemplates applying the so-called Section 232 investigation to pharmaceuticals alongside lumber, semiconductors, and other sectors. Sector-specific import duties could be on the horizon following such an investigation, given the declared Trump policy to strengthen the USA's pharmaceutical manufacturing capacity so as to avoid relying on imported medicines. Following the President's decision to pause many of the tariffs worldwide for 90 days, the EU suspended retaliatory counter-tariffs on 10 April 2025; however the interim measures do not remove the trade uncertainties.

The impact of commercial trade policies has not attracted a great deal of attention in the life sciences sector until very recently. This is largely because, since the late 1980s, key geographical regions – through the processes of the International Council for Harmonisation (in the case of pharmaceuticals) and the Global Harmonisation Task Force (now rebranded as the International Medical Devices Regulatory Forum) – have striven to promote harmonisation efforts to standardise regulatory requirements in order to minimise friction in the transboundary movement of medicines and healthcare products.

Changing role of USA in global public health

The WHO also has a pivotal role in promoting global public health and global harmonization. The USA has been by far the biggest financial contributor to the WHO's global health initiatives, contributing circa USD960 million. On 20 January 2025, the executive order by the President famously entitled "Withdrawing the United States from the World" gave official notice of the USA's intention to withdraw from the WHO, citing grounds arising from the WHO's mishandling of the COVID-19 pandemic and other global health crises, its failure to adopt urgently needed reforms, and its inability to demonstrate independence from the inappropriate political influence of WHO member states.

The significant leadership change in US health-care regulation will also likely result in potentially seismic legislative and policy regulatory policy changes, as well as challenge operational resilience in a number of key federal public health agencies. These can be globally impactful, given that the USA has significant influence on the global regulatory compliance landscape and has been instrumental in leading many international co-operative initiatives. Moreover, the new Trump administration has already declared its

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desire to trim down the government and reduce federal spending under the directions of the Department of Government Efficiency (DOGE). The new policy has already caused substantial rippling effects.

The question will remain as to whether the USA will continue to play a global leadership role and maintain the treasured internal scientific expertise to usher the global public health and patient safety agenda. Only time will tell.

AUSTRIA

Law and Practice

Contributed by:

Sonja Hebenstreit, Michael Cepic and Maximilian Kröpfl
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Herbst Kinsky Rechtsanwälte GmbH has become one of Austria's leading commercial law firms since its establishment in 2005. Its specialised and highly committed lawyers combine many years of experience gained abroad and in reputable Austrian law firms. The firm's practice covers a full range of services in all areas of commercial, corporate, civil and public law, including banking, insurance and capital mar-

kets, corporate and M&A, IP, IT and life sciences, antitrust and competition, data protection, real estate, dispute resolution and arbitration. Herbst Kinsky Rechtsanwälte has established a particularly strong presence in the field of life sciences and healthcare. The firm's clients range from large international privately held and publicly listed companies to SMEs, as well as start-ups.

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HERBST KINSKY

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Austrian law regarding medicinal products is heavily influenced by European Union legislation. The primary national legal framework for pharmaceuticals (referred to as “medicinal products”) intended for human use is the Austrian Medicinal Products Act (*Arzneimittelgesetz*, or AMG). This act incorporates the key provisions of EU legislation, particularly Directive 2001/83/EC.

As of 28 January 2022, medicinal products intended for veterinary use are regulated by the Regulation on Veterinary Medicinal Products (Regulation (EU) 2019/6). Starting in January 2024, the new Austrian Veterinary Medicinal Products Act (*Tierarzneimittelgesetz*) has supplemented this regulation in Austria.

Specific provisions in relation to medicinal products can also be found in other Austrian laws, such as the Austrian Pharmaceutical Products Import Act (*Arzneiwareneinfuhrgesetz*, or AWEG)

or the Austrian Prescription Act (*Rezeptpflichtgesetz*). Furthermore, the manufacture and distribution of medicinal products is governed by several national ordinances (*Durchführungsverordnungen*), which are based on the AMG, including the Medicinal Products Operations Ordinance (*Arzneimittelbetriebsordnung*, or AMBO).

Medicinal products law is also increasingly regulated by directly applicable EU regulations – for example, Regulation (EC) 726/2004 (see 3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices), Regulation (EU) 536/2014 (“Clinical Trials Regulation”, or CTR), and Regulation (EC) 1394/2007 (“Advanced Therapy Medicinal Products Regulation”, or ATMPR).

As of 26 May 2021, medical devices have mainly been governed by the Regulation (EU) 2017/745 (“Medical Devices Regulation”, or MDR), which is complemented by the Austrian Medical Devices Act 2021 (*Medizinproduktegesetz*, or MPG) providing for rules regarding the safety, functionality and quality of medical devices with regard to their construction, operation, use and main-

tenance. Since 26 May 2022, in vitro diagnostic (IVD) devices have been governed by Regulation (EU) 2017/746 (“In Vitro Diagnostics Regulation”, or IVDR), which is likewise complemented by the MPG. The MPG came into force on 1 July 2021 for medical devices and on 26 May 2022 for IVD devices.

The competent national authority for medicinal products, medical devices and IVD devices is the Austrian Federal Office for Safety in Healthcare (*Bundesamt für Sicherheit im Gesundheitswesen*, or BASG). The BASG is responsible for the approval and control of medicinal products in Austria and the control and approval of clinical trials (see **2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial**). Together with the competent European agencies, the BASG further monitors at the national level the medicinal products, medical devices, and IVD devices already on the market in terms of their efficacy, safety, production, transport, and storage.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions by regulatory bodies qualify as specific administrative acts (*Bescheide*), which can be challenged by the addressee – or by a (third) party having a legal interest, if applicable – by lodging an appeal with the regulatory body that issued the administrative act. The decision on the appeal is made by the competent administrative court.

Appeals against administrative acts must be made in writing and – unless the respective regulation provides otherwise – filed within four weeks of the date of the decision to be challenged. The appellant is not legally obligated to be represented by an attorney.

1.3 Different Categories of Pharmaceuticals and Medical Devices

In Austrian medicinal products law, various criteria exist based on which medicinal products are categorised and regulated differently. By way of an example, the AMG distinguishes between medicinal products available for the patient only upon prescription and over-the-counter (OTC) medicinal products available without prescription. Medicinal products requiring prescription may not be advertised to the general public (“laymen”) but, rather, only to healthcare professionals under the preconditions laid down in the AMG.

The AMG makes another relevant distinction between medicinal products that are, in principle, subject to marketing authorisation – known as “medicinal specialties” (*Arzneispezialitäten*) – and medicinal products not subject to such authorisation. Furthermore, the AMG differentiates on the basis of the material composition of a medicinal product (eg, biological medicinal products, herbal medicinal products, radioactive medicinal products, or homoeopathic medicinal products).

Likewise, the Ministry of Health may qualify medical devices as requiring a prescription or as only available through certain specialised dealers. Prescription-only medical devices may not be advertised to the general public, either. However, in practice, the vast majority of medical devices are freely available and not qualified as prescription-only or are exclusively available in specialist stores.

There is an important distinction between in-vitro diagnostic (IVD) devices, which are governed by the In Vitro Diagnostic Regulation (IVDR), and other medical devices, which fall under the Medical Device Regulation (MDR). Additionally,

the MDR and IVDR categorise devices based on their purpose or use, such as active devices, implantable devices, invasive devices, or single-use devices. They also classify devices according to their inherent risks:

- medical devices are classified into Classes I, IIa, IIb, and III; while
- IVD devices are categorised into Classes A, B, C, and D.

2. Clinical Trials

2.1 Regulation of Clinical Trials

As of 1 February 2022, the regulatory system for clinical trials of medicinal products underwent a comprehensive restructuring aimed at further harmonising the rules on the conduct of clinical trials within the EU member states. The legal framework of clinical trials on medicinal products is now essentially defined by the CTR, thereby replacing the former system for clinical trials based on Directive 2001/20/EC. Supplementary provisions for national implementation and within the scope of so-called opening clauses of the CTR have been introduced into the Austrian legal system through the AMG.

If genetically modified organisms (GMOs) are used for therapeutic purposes – as defined in Section 4(24) of the Austrian Gene Technology Act (*Gentechnikgesetz*, or GTG) – in the course of a clinical trial, a prior permit according to Section 74 of the GTG must also be obtained.

Clinical trials of medical devices (known as “clinical investigations”) are mainly regulated by the MDR and clinical trials of IVD devices (known as “performance studies”) are regulated by the IVDR. Supplementary provisions have been included in the MPG.

For non-interventional studies, the CTR and the MDR/IVDR provisions do not apply. Instead, there are specific national provisions in the AMG and the MPG for these studies, including provisions concerning data protection and inspections by the BASG. The following may also apply:

- general provisions of civil, criminal and data protection law; or
- specific rules for clinical research under, for example, the Austrian Hospital and Sanatoria Act (*Krankenanstalten- und Kuranstaltengesetz*, or KAKuG) or the Austrian University Act 2002 (*Universitätsgesetz*, or UG).

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Since 31 January 2023, all new applications for clinical trials of medicinal products must be submitted in accordance with the CTR. The authorisation procedure is initiated by the sponsor sending the application dossier to the EU member states concerned via the EU portal, known as the Clinical Trials Information System (CTIS). The reporting member state must then carry out a validation within ten days and notify the sponsor via the portal of the results. In Austria, the BASG is responsible for the validation procedure, whereby the ethics committee can issue an opinion on certain parts of the application (Section 31, paragraph 4 of the AMG). The validation procedure is followed by the evaluation procedure, which is divided into two parts.

- Part I is a co-ordinated assessment of the application between the reporting and concerned member states takes place, in which aspects of the clinical trial – such as whether it is minimally interventional, the expected therapeutic and public health benefits, and the risk of harm posed to the trial subjects – are evaluated. The assessment report must

be prepared and submitted within 45 days of validation; however, this term may be extended under certain conditions. The responsibilities regarding Part I of the assessment procedure are divided nationally between the BASG and an assessing ethics committee (Section 35 of the AMG).

- Part II of the evaluation procedure includes the aspects to be assessed nationally by each member state – for example, requirements for informed consent, patient recruitment, and subject insurance. The evaluation report must also be submitted within 45 days of validation. In Austria, the responsibility for preparing the assessment report in Part II is assigned to the evaluating ethics committee.

The decision to authorise the clinical trial must then be taken by each member state within five days of the conclusion of the evaluation procedure. If a timely notification is not made, the conclusion regarding Part I of the assessment report is automatically deemed to be the decision of the respective member state.

The approval of a clinical investigation into a medical device for the purposes of the conformity assessment referred to in Article 62, paragraph 1 of the MDR essentially follows the MDR. Depending on the type of investigation, different procedures are provided for (eg, authorisation procedure/notification procedure/instruction procedure).

An application for authorisation must be submitted electronically to the BASG. Upon receipt of the application, the BASG must carry out the validation within ten days.

With regard to Class I investigational devices or Class IIa/IIb non-invasive devices, the clinical investigation may be commenced immediately

after validation – provided that the BASG has confirmed proper notification and the ethics committee has given a favourable opinion (ie, notification procedure).

In the case of other investigational devices (Class III investigational devices or Class IIa/IIb invasive devices), the clinical investigation may only commence after notification of the authorisation by the BASG – again with the prerequisite that a favourable opinion by the competent ethics committee must be provided. The decision about the authorisation must usually be communicated to the sponsor within 45 days of validation (ie, authorisation procedure).

For clinical investigations of medical devices that already bear a CE marking, thereby confirming *conformité européenne* (“European conformity”), a different procedure applies under certain conditions (Article 74 MDR). The sponsor must notify the BASG of the conduct of such investigation at least 30 days before it begins. In this case, the BASG will confirm the notification without further subsequent assessment (ie, information procedure).

Clinical investigations of medical devices for other purposes than the demonstration of conformity are also subject to prior approval by the BASG if they have an impact on the diagnostics and/or therapy of a trial subject (Article 82 of the MDR, in conjunction with Section 13, paragraph 3 of the MPG); otherwise, it is only necessary to conduct an information procedure.

For performance studies on IVD devices, the provisions of the MPG are largely applicable *mutatis mutandis* – although there are certain exceptions (see Article 66 et seq of the IVDR and Section 36 of the MPG for comparison).

2.3 Public Availability of the Conduct of a Clinical Trial

For medicinal products, information on clinical trials initiated under the CTR as of 31 January 2022 (including the start and end dates of the trial, details of the sponsor, and trial results) is publicly available on the [EU Clinical Trials website](#). Information on clinical trials initiated under the former system of Directive 2001/20/EC (before 31 January 2022) may still be accessed via the [EU Clinical Trials Register](#).

No publicly accessible register is currently provided at the EU or national level for clinical investigations and performance studies under the MDR and the IVDR. However, information on such trials will be accessible via the EUDAMED database as soon as the entire EUDAMED system has been declared fully functional.

At the national level, the legislator did not exercise the option to provide for the maintenance of a (publicly accessible) register for non-interventional studies of medical devices via ordinance.

2.4 Restriction on Using Online Tools to Support Clinical Trials

In Austria, it is not generally prohibited to conduct the consent procedure remotely or to remotely supervise certain tasks/procedures carried out at home by a physician. Remote access to source data for the purpose of monitoring is also permissible; however, this only applies to original electronic medical records and where a correspondingly validated record system is being used.

In December 2022, the EU Decentralised Clinical Trial (DCT) project team published a recommendation paper on decentralised (remote) elements in clinical trials. The team comprises experts from the Clinical Trial Coordination Group, the

Clinical Trial Expert Group, European Medicines Agency (EMA) scientific committees, EMA working parties, and EMA staff. This document also includes guidance concerning national provisions on the use of online tools in clinical studies within the EU.

As regards special measures due to COVID-19, see **11.2 Special Measures Relating to Clinical Trials**.

2.5 Use of Data Resulting From Clinical Trials

Clinical studies involve the processing of patients' contact and health information, which qualify as personal data as defined by Article 4(1) of the General Data Protection Regulation (EU) 2016/679 (GDPR). To the extent that patients are identified or at least identifiable in data resulting from the clinical trial, these data sets must also be qualified as special categories of personal data (sensitive data).

The processing of personal data in the context of a clinical trial is generally based on the patient's consent pursuant to Article 6, paragraph 1(a) – in the case of sensitive data in conjunction with Article 9, paragraph 2(a) – of the GDPR. Accordingly, any disclosure of personal data to third parties must be covered by this consent.

Furthermore, personal data can also be processed in the course of scientific research on the basis of the Austrian Research Organization Act (*Forschungsorganisationsgesetz*, or FOG), provided that the processing methods mentioned there, such as anonymisation or pseudonymisation, are concerned (Article 2(2)(1) FOG).

2.6 Databases Containing Personal or Sensitive Data

The processing of personal data (including sensitive data) within databases is subject to compliance with the GDPR, (potentially) the FOG and the Austrian Data Protection Act (*Datenschutzgesetz*, or DSG).

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The distinction between medicinal products and medical devices is made in accordance with the product definitions as outlined in the AMG (Section 1, paragraph 1) and the MDR (Article 2(1)).

“Medicinal products”, within the meaning of the AMG, are substances or preparations of substances that either:

- are intended for use in or on the body and as agents with properties to cure or alleviate or prevent diseases or pathological complaints (so-called presentation medicinal products); or
- may be applied in or on the body or administered to a human (so-called functional medicinal products) with a view to either:
 - (a) restoring, correcting or modifying physiological functions by a pharmacological, immunological or metabolic action; or
 - (b) making a medical diagnosis.

According to the MDR, the term “medical device” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human

beings for one or more of the following specific medical purposes, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means:

- the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- the diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- the investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; and
- for providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

Furthermore, devices for the control or support of conception and certain products specifically intended for the cleaning, disinfection or sterilisation of devices will be deemed medical devices.

The distinction between medicinal products and medical devices can be made, in most cases, on the basis of the principal mode of action of the product (see Article 1, paragraph 6(b) of the MDR). A product with an essentially pharmacological, immunological or metabolic action should not be classified as a medical device. The principal mode of action of medical devices is mostly of a physical or mechanical kind.

In the case of diagnostic devices, distinction must be made on the basis of the nature of the product (substance/instrument, apparatus, etc) and the place of application (in vivo or in vitro).

In Austria, manufacturers of products (or their representatives) may initiate a procedure with the BASG, whereby questions concerning the product classification – including the demarcation between the medicinal product and the medical device status of the product – will be clarified (Section 10 of the MPG and Section 49a of the AMG).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Within the meaning of the AMG, the term “biological medicinal products” comprises:

- certain immunological medicinal products;
- certain medicinal products manufactured by using human blood or blood plasma as a starting material; and
- medicinal products listed in Annex I (1) and (1a) Regulation (EC) 726/2004, such as:
 - (a) medicinal products developed by means of recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes (including transformed mammalian cells), or hybridoma and monoclonal antibody methods; and
 - (b) ATMP.

Austrian law does not provide for a marketing authorisation procedure specific to biological medicinal products. However, for medicinal products listed in Annex 1(1) and (1a) Regulation (EC) 726/2004, a central marketing authorisation according to said regulation is mandatory. In addition, differences with regard to the required application documents may arise for different types of biological medicinal products.

Furthermore, the AMG contains specific provisions for certain immunological medicinal products, as well as medicinal products manu-

factured by the use of human blood or blood plasma. According to Section 7, paragraph 8 of the AMG, for example, blood and blood components intended for direct transfusion are exempt from the obligation to obtain a marketing authorisation. Also, a batch release may be required as a prerequisite for supplying certain biological medicinal products in national Austrian law (see Section 26 of the AMG). Lastly, specific provisions for so-called biosimilars can be found in Section 10, paragraph 6 of the AMG.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The BASG generally grants a national marketing authorisation of a medicinal product for a period of five years (Section 20, paragraph 1 of the AMG). An extension of the marketing authorisation (at the request of the marketing authorisation holder) is valid without a time limit unless the BASG again sets a time limit of five years for reasons of pharmacovigilance.

If an authorised medicinal product has not actually been placed on the domestic market within three years of the marketing authorisation being granted or has not been on the market for three consecutive years, the marketing authorisation may expire in accordance with Section 22 of the AMG (the so-called sunset clause). In certain cases, the marketing authorisation must also be revoked. Similar rules apply according to Regulation (EC) 726/2004 with regard to the period of validity of marketing authorisations for medicinal products authorised under the centralised procedure.

The placing on the market of medical devices is not subject to a marketing authorisation; however, the manufacturer must perform a conformity assessment procedure (see 3.4 Proce-

cedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices). According to Article 56 of the MDR, certificates of conformity issued by the notified bodies will be valid for the period they indicate, which must not exceed five years. Upon application by the manufacturer, the validity may be extended for further periods (of no more than five years), based on a re-assessment. The CE marking will be suspended, restricted or withdrawn if a notified body finds that the manufacturer no longer meets the requirements of the MDR.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Marketing Authorisation for Medicinal Products

There are, in practice, four different procedures for obtaining a marketing authorisation for medicinal products.

- Marketing authorisation must be obtained via the centralised procedure for medicinal products according to Annex I Regulation (EC) 726/2004 (eg, ATMP). Under certain conditions (see Article 3, paragraph 2), the centralised procedure is also available for other medicinal products. A marketing authorisation obtained under the centralised procedure is issued by the European Commission and is valid in all EU member states. Applications must be submitted to the EMA.
- For other medicinal products, marketing authorisation may be obtained under the national procedure according to Sections 7 et seq of the AMG via application to the BASG. The BASG is also the competent authority for issuing the national marketing authorisation, which is only valid on Austrian territory.
- Where a national authorisation already exists in a member state, it may be extended to the

territory of other member states through a mutual recognition procedure (Section 18a of the AMG).

- For medicinal products that cannot be authorised under the centralised procedure, marketing authorisation in different EU member states may be applied for through a decentralised procedure (Section 18a of the AMG).

Variations to marketing authorisations

Variations to marketing authorisations are governed by Regulation (EC) 1234/2008 for all types of authorisations. Depending on the degree of health risk and the impact on quality, safety and efficacy, either a simple notification procedure, a notification obligation with a prohibition reservation or a prior authorisation procedure is required. In contrast, applications for authorisation extensions (eg, in the case of relevant changes to the active substance) must be evaluated according to the same procedure as the application for the original authorisation.

Transfers of marketing authorisations

Transfers of marketing authorisations obtained through the centralised procedure must be requested from the EMA in accordance with the guidelines established in Regulation (EC) 2141/96. If this process is not followed, then Section 25 of the AMG applies. According to this section, a waiver declaration of the authorisation from the previous marketing authorisation holder and an acceptance declaration from the new holder (transferee) must be submitted to the BASG.

Medical Device and IVD Device Compliance

Placing medical devices and IVD devices on the market is not subject to obtaining a marketing authorisation; however, medical devices or IVD devices may only be placed on the market or

put into service if they comply with the MDR/IVDR. Specifically, they must meet the general safety and performance requirements, taking into account their intended purpose. Also, an assessment of the conformity of the device must be conducted, and a corresponding declaration of conformity must be issued. Depending on the risk classification of a medical device, a notified body must be involved in the process. The CE marking of the product indicates conformity with the applicable requirements. Transfers of CE markings are not provided for in the MDR/IVDR.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal Products

As far as medicinal products are subject to a marketing authorisation, such marketing authorisation is a prerequisite for lawful placing on the market in Austria. For this reason, opportunities to supply such medicinal products to patients without marketing authorisation are limited. Nevertheless, there are a number of exceptions to this principle. The following are among the exceptions to the authorisation requirement.

- Named Patient Use (Section 8, paragraph 1(2) of the AMG) – no marketing authorisation is needed if a physician or dentist authorised to practise independently in Austria certifies that:
 - (a) a medicinal product is urgently needed to prevent a threat to life or serious damage to the health of a specific patient; and
 - (b) this threat or damage cannot be prevented with an authorised and available medicinal product according to the state of the art.
- Compassionate Use Programmes (Section 8a of the AMG and Article 83 of Regulation (EC) 726/2004) – marketing authorisation is

not needed within Compassionate Use Programmes, which may be established (subject to prior approval by the BASG) for a defined group of patients suffering from a debilitating chronic or severe disease or whose disease is life-threatening and cannot be satisfactorily treated with an authorised and available medicinal product.

- Clinical trials (Section 8, paragraph 1(1) of the AMG) – medicinal products intended for the use in non-clinical or clinical studies or clinical trials do not need a marketing authorisation.
- Hospital exemption (Section 7, paragraph 4 of the AMG and Article 28 of Regulation (EC) 1394/2007) – ATMP that are manufactured on a non-routine basis in Austria on the basis of an individual medical prescription specifically for a particular patient, in order to be used on that patient in an Austrian hospital under the exclusive professional responsibility of a physician, are not subject to marketing authorisation.
- Official and magisterial medicinal preparations (Section 7, paragraphs 2 and 3 of the AMG) – certain medicinal products manufactured in pharmacies are not subject to marketing authorisation.

Further exemptions are listed in Sections 7 et seq of the AMG.

It should be noted that a marketing authorisation is a prerequisite for placing medicinal products on the market but not for their use. For this reason, medicinal products can, in principle, be used on patients beyond the scope of their marketing authorisation (off-label use). In this context, however, the physician has increased obligations to provide information to the patient.

Medical Devices and IVD Devices

With regard to medical devices and IVD devices, the MDR/IVDR provides exemptions from the obligation of CE marking for custom-made devices, investigational devices, and devices for performance studies (Article 20 of the MDR and Article 18 of the IVDR). Furthermore, the placing on the market and putting into service of a medical device for which no conformity assessment has been carried out may be authorised by the BASG in specific cases upon request for reasons of public health or patient health and safety (Article 59 of the MDR, Article 54 of the IVDR and Section 12 of the MPG).

As per the above-mentioned definition of Named Patient Use, if a physician or dentist authorised to practise independently in Austria confirms that a medical device is required for a specific patient in order to avert a danger to life or a serious impairment of health – and that the treatment cannot be expected to be successful with a medical device for which conformity assessment procedures have already been carried out – then such authorisation is not necessary. The same applies to medical devices used in connection with certain deployments of the Federal Armed Forces (Section 12, paragraphs 2 and 3 of the MPG).

Finally, under certain conditions, there are far-reaching exemptions from the MDR/IVDR obligations for in-house products manufactured and used only in healthcare facilities (Article 5, paragraph 5 of the MDR/IVDR and Section 9 of the MPG).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations Medicinal Products

Holders of a marketing authorisation for a medicinal product must operate a pharmacovigilance system (Section 75i et seq of the AMG). Within the framework of this system, the holder must, among other things:

- appoint a pharmacovigilance officer;
- keep a pharmacovigilance master file;
- operate a risk management system;
- monitor the results of risk minimisation measures;
- monitor pharmacovigilance data; and
- subject the pharmacovigilance system to regular audits.

The applicable law also provides for reporting obligations (Section 75j of the AMG, Article 28 of Regulation (EC) 726/2004 and Article 107 of Directive 2001/83/EC) and information obligations of the holder (Section 75m of the AMG). In addition, holders are obliged to regularly prepare periodic safety update reports (PSUR) and transmit them electronically to an archive maintained by the EMA.

Other obligations of the holder include the following, as outlined below.

- The holder must inform the BASG about the date of actual placing on the market of a medicinal product, as well as a temporary or permanent removal from the market (Section 21 of the AMG).
- The holder must ensure that complete documentation of all activities related to the marketing authorisation or the medicinal product is available at all times (Section 24b of the AMG).

- If concerns arise regarding the medicinal product's risks, the holder may face additional requirements or conditions imposed by the BASG, such as the performance of post-authorisation safety studies. If findings on the disease or clinical methodology indicate that previous assessments of efficacy may need to be significantly corrected, an efficacy study must be imposed (Section 19a of the AMG).

Medical Devices and IVD Devices

For medical devices and IVD devices, the MDR/IVDR require the manufacturer to plan, establish, document, implement, maintain and update a post-market surveillance system as part of the quality management system in a manner appropriate for the risk class and type of the product (Article 83 of the MDR and Article 78 of the IVDR). To this end, a post-market surveillance plan must be established (Article 84 of the MDR and Article 79 of the IVDR) and post-market surveillance reports must be prepared and updated (Article 85 of the MDR and Article 80 of the IVDR). Further obligations concern, for example, the preparation of PSUR (Article 86 of the MDR and Article 81 of the IVDR), the reporting and analysis of serious incidents and safety corrective measures (Articles 87 and 89 of the MDR and Articles 82 and 84 of the IVDR) and trend reports (Article 88 of the MDR and Article 83 of the IVDR).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

On an EU level, the EMA publishes a monthly list of medicinal products under current evaluation under the centralised procedure. A list of all medicinal products that have received marketing authorisation under the centralised procedure is provided in the "Union Register" published by the European Commission. This

register includes information on the name of a product, the registration number, name and address of the marketing authorisation holder, the active substance, the therapeutic indication, and relevant documents – as well as suspended, withdrawn or refused marketing authorisations.

On a national level, the BASG keeps a public register of all medicinal products for which a national marketing authorisation has been obtained (*Arzneispezialitätenregister*). Any granting, variation, cancellation and transfer of a marketing authorisation must be entered into this register. Entries regarding the granting of a marketing authorisation include information on the authorisation number, the name of the product, the authorisation holder, prescription-only or narcotic status, and the composition of the medicinal product.

Furthermore, the BASG operates an internet portal on medicinal products for public information purposes. In addition to information on the granting of marketing authorisation and the variation of a medicinal product, the BASG shall (inter alia) publish the technical information and approved directions for use, information on approved variations, and the conditions and constraints of marketing authorisations. Also, every expert opinion provided in the context of an application for marketing authorisation shall be published after all confidential information in the party's commercial interest has been removed.

Information on products authorised via a mutual recognition procedure can be found in the MRI Product Index. Information on medical devices and IVD devices (including summaries of safety and clinical performance) and their manufacturers and importers, as well as certificates, may be publicly accessed via the EUDAMED database.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

In case of an application for a centralised authorisation granted by EMA, applicants can ask for an “accelerated assessment”, which reduces the timeframe for the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) to review a marketing-authorisation application (from up to 210 days to 150 days). In order to be eligible for such accelerated assessment, applicants need to argue that the product is of major interest to public health and therapeutic innovation. The Austrian (national) regulatory landscape does not provide for a fast-track registration route.

Regarding medical devices, the MDR and IVDR currently do not provide for accelerated procedures.

4.2 Regulatory Reliance

Austria is a member of the European Union. An authorisation granted by the European Medicines Agency (EMA) through the so-called “centralised procedure” is valid throughout the EU, and the respective medicinal product may be marketed in all member states.

Further, where a national authorisation already exists in an EU member state, it may be extended to the territory of other member states through a mutual recognition procedure (Section 18a of the AMG). For medicinal products that cannot be authorised under the centralised procedure, marketing authorisation in different EU member states may be applied for through a decentralised procedure (Section 18a of the AMG). See also 3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices. Medical devices that have successfully

undergone a conformity assessment in accordance with the MDR or IVDR, as applicable, and carry a CE mark can be marketed throughout the European Union.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicinal products (including packaging, labelling and final release of the finished product) may only be carried out based on a manufacturing authorisation (known as an “operating licence”) to be applied for in accordance with the AMG.

The BASG grants the authorisation upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended manufacturing activity;
- the nature, size, equipment, dedication and location of the premises (as well as their furnishings and equipment);
- the nature of the technical equipment; and
- the appointed Qualified Person (QP) (*sachkundige Person*) who needs to be appropriately qualified, experienced and reliable.

Another prerequisite for the manufacturing licence is a trade permit for the manufacturing of medicinal products. This is issued, in accordance with the Trade Act (*Gewerbeordnung*, or *GewO*), by the Trade Authority – ie, the competent district administrative authority (*Bezirksverwaltungsbehörde*) at the intended manufacturing site. Such a permit requires the nomination of

a “managing director under trade law” (*gewerberechtlicher Geschäftsführer*) who is appropriately qualified (as further defined in the GewO).

The manufacturing licence will only be issued after a successful on-site inspection of the manufacturing premises by BASG, during which the authority checks compliance with the requirements of the AMBO and ensures that the quality of the medicinal products as required for the health and life of humans (or animals) is ensured on the basis of the provided facts. The statutory timeframe for issuing a manufacturing licence is 90 days from submitting a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock stop.

The manufacturing authorisation is granted for a specific site, for specific manufacturing activities and types of medicinal products as specified in the application, and – in principle – for an unlimited period. However, the authorisation remains subject to regular GMP inspections by the BASG, and can be withdrawn in the case of any detected and non-remedied deficiencies.

The manufacture of medical devices and IVD devices is not subject to a specific governmental authorisation. However, requirements as applicable to any manufacturing activity – for example, those under construction law and under trade law regarding operating plants – will apply.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

A wholesale dealer licence (WDL) (also called an “operating licence”) is required to carry out

wholesale distribution of medicinal products. Such a licence is required not only if the respective entity actually carries out physical handling and storage of medicinal products but also for selling and supplying medicinal products – even though the actual logistics are outsourced to a third party (likewise requiring a WDL itself).

The WDL is granted by the BASG upon application, in which the applicant must provide details of:

- the nature, scope and location of the intended distributing activity;
- the nature, size, equipment, dedication and location of the premises as well as their furnishings and equipment;
- the nature of the technical equipment; and
- the appointed responsible person (*fachkundige Person*) for wholesale distribution being appropriately qualified, experienced and reliable.

Furthermore, a trade permit is also required for the wholesale of medicinal products (see 4.1 **Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**). Such a permit requires the nomination of an appropriately qualified managing director under trade law.

The WDL may only be issued after the BASG successfully inspects the wholesale distribution site. The statutory timeframe for issuing a WDL is 90 days from the submission of a complete application. Any additional requests by the authority or missing information identified in the inspection will lead to a clock stop.

The WDL is granted for a specific site and for specific distribution activities as specified in the application and is in principle for an unlim-

ited period. However, the authorisation remains subject to regular Good Distribution Practice inspections by the BASG and can be withdrawn in the case of any detected and unremedied deficiencies.

No licence comparable to the WDL is necessary for the distribution of medical devices. However, a trade licence and an appropriately qualified managing director under trade law are necessary.

Finally, according to Section 67 of the MPG, registration in the publicly accessible Medical Devices Register is mandatory for all persons or entities responsible for placing medical devices on the market for the first time in the European Economic Area (EEA) and domiciled in Austria.

6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Different Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and transfer of “pharmaceutical products” (*Arzneiwaren*) is regulated under the AWEG. In this context, it should be noted that the term “pharmaceutical products” is not identical to the term “medicinal product” as defined in the AMG or Directive 2001/83/EC – rather, it is based on the customs tariff regulations of Regulation (EEC) 2658/87. The AWEG, therefore, does not apply to all medicinal products. Also, medi-

cal devices are explicitly excluded from its scope (Section 1, paragraph 2 of the AWEG).

Provisions for parallel imports of medicinal products are regulated in the AMG (in particular, Section 10c). Products that have been authorised for parallel import are exempt from the notification obligation under the AWEG. Furthermore, obligations for importers and exporters are provided by the AMBO (see, for example, Section 4a). Specific provisions for the importation of investigational medicinal products are regulated in the CTR (Articles 61 and 63). The transfer of investigational medicinal products within the EEA (and Switzerland) is exempt from the notification obligation under the AWEG (Section 6, paragraph 2 of the AWEG).

The BASG is competent in issuing import certificates, receiving notifications under the AWEG, and supervising compliance with the AMG, the AWEG, and the CTR. In addition, certain powers are granted to the customs administration under the AWEG.

General and specific obligations regarding the importation of medical devices and IVD devices are laid down in the MDR/IVDR (see, in particular, Articles 13 and 60 of the MDR and Articles 13 and 55 of the IVDR) and enforced by the BASG as the competent authority.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

According to Section 4 of the AWEG, the following entities are entitled to apply for an import permit or carry out an importation notification for pharmaceutical products:

- public pharmacies;
- hospital pharmacies; and

- companies authorised to distribute pharmaceutical products in a state within the EEA.

The entitlement to apply for a parallel import authorisation is granted to the following entities, according to Section 9 of the AMG:

- professionals authorised to manufacture or wholesale the medicinal product concerned;
- operators of domestic public pharmacies; and
- pharmaceutical companies established within the EEA that are authorised to place the medicinal product concerned on the market.

Depending on their activities (eg, repackaging), importers may be subject to the operating licence requirement of Section 63 of the AMG (see also **5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices** and **6.1 Wholesale of Pharmaceutical and Medical Devices**).

The MDR and the IVDR do not provide for specific legal requirements to act as the importer of record of medical devices or IVD devices. However, they define the importer as “any natural or legal person established within the Union that places a device from a third country on the Union market”. Importers must register in accordance with Article 28 of the MDR/IVDR.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Under the AWEG, pharmaceutical products imported from a state outside the EEA are subject to a prior importation permit issued by the BASG. Similarly, pharmaceutical products imported from a state within the EEA must be notified to the BASG in advance.

Section 11 of the AWEG, however, provides for extensive exceptions to these requirements, including exceptions for:

- medicinal products for which a marketing authorisation or an authorisation for parallel import has been obtained;
- medicinal products for Named Patient Use;
- medicinal products for use in a Compassionate Use Programme;
- medicinal products needed in the event of emergencies; or
- medicinal products for personal use, in an amount corresponding to the usual personal needs of the traveller concerned.

Parallel importation of medicinal products is subject to a prior authorisation by/notification to the BASG in accordance with Section 10c of the AMG (see also Article 57, paragraph 1(o) of Regulation (EC) 726/2004 for medicinal products authorised under the centralised procedure).

The importation of medical devices and IVD devices does not require any specific authorisation under the MDR/IVDR or the MPG.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The products subject to restrictions under the AWEG are determined based on the classification of goods according to the tariff and statistical nomenclature of the EU, as established by Regulation (EEC) 2658/87. Only those products that fall under the specific subheadings of the combined nomenclature listed in Section 2(1) of the AWEG – such as subheadings 3002 20, 3002 30, and 3004 – are considered “pharmaceutical products” within the context of the AWEG.

7.5 Trade Blocs and Free Trade Agreements

Austria is a member of the WTO. Furthermore, as a member state of the EU, Austria participates in free trade agreements concluded by the EU member states. It is worth noting that the current EU sanctions against Russia do not provide for trade blocs of medicinal products and medical devices.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

The price basis of a medicinal product is the manufacturer's factory or depot selling price (*Fabriksabgabepreis/Depotabgabepreis*, or FAP/DAP). Furthermore, the respective "mark-ups" (wholesale and pharmacy mark-ups, regulated by law) and VAT are added to this price. The FAP/DAP can be freely determined by the company authorised to distribute, and the Ministry of Health needs to be informed of this price.

For those medicinal products that are included in the list of reimbursable medicinal products, the so-called Reimbursement Code (*Erstattungskodex*, or EKO), the "EU average price" is relevant. This average price constitutes the maximum possible FAP/DAP for reimbursable products. For the purpose of calculating the EU average price, the Price Commission of the Ministry of Health considers the medicinal products with the same active ingredient, active ingredient strength, dosage form and identical (or approximately identical) package size.

The Price Commission determines the EU average price six months after the application for inclusion in the EKO is submitted. This is

repeated 18 months after the first price determination and 24 months after the second price determination. The Price Commission can initiate a new price determination 18 months after the third price determination.

In the case of medicinal products that are not included in the EKO but exceed an annual turnover of EUR 750,000 at the expense of public health insurance (based on the FAP in the previous 12 months), the Umbrella Organisation of the Austrian Social Insurance (Dachverband, or DVB) must immediately notify the Price Commission, which then has eight weeks to determine an EU average price for the medicinal product. If the determined EU average price is lower than the applied price, the company authorised to distribute must reimburse the difference to the social insurance institutions within six months of exceeding the sales threshold.

The DVB applies the principles of price determination in accordance with the rules of procedure for the issuance of the EKO, as well as the economic evaluation criteria of the Therapeutic Products Evaluation Commission, and negotiates the reimbursement price with the manufacturer on this basis. Once an agreement has been reached, the reimbursement price specified in the EKO is binding, albeit subject to adaptation in accordance with the EU average price. If, on the other hand, a medicinal product is removed from the EKO by the decision of the DVB, the companies authorised to distribute the drug have the option to appeal to the administrative court.

Furthermore, specific price regulations apply if a successor product with the same active ingredient (generic or biosimilar) is available in the EKO.

With regard to generics, the price of the first generic successor product must be at least 50% below the price of the original branded product whose patent protection has expired. The price of the second generic successor product must be 18% lower than the price of the first successor product, and the price for the third successor product must be 15% lower than that of the second successor product. The original product's price must be reduced by at least 30% within three months of the inclusion of the first generic product in the EKO. If there is a third successor product, all other providers must reduce the price to the price of the third product. Additional successors must offer price reductions of at least EUR0,10 in order to be included in the EKO.

With regard to biosimilars, the price of the first successor product must be at least 38% lower than the original product. The price of the second successor product must be at least 15% lower than that of the first successor product, and the price of the third successor product must be at least 10% lower than that of the second successor product. After that, the same regulation applies as for generics (ie, the original product must reduce its price by 30% within three months, etc).

In principle, no legal price control mechanisms are available for medical devices and IVD devices.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The price of a medicinal product can, in principle, be freely determined by the company authorised to distribute it but is limited by the EU average price of said product (as further detailed in **8.1 Price Control for Pharmaceuticals and Medical Devices**).

In principle, no legal price-control/price-setting mechanisms are available for medical devices and IVD devices.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Austrian General Social Security Act (*Allgemeines Sozialversicherungsgesetz*, or ASVG) states that, in case of illness, the insured person is entitled to health treatment comprising the provision of remedies (Heilmittel) – a term that includes medicinal products, in particular. According to the ASVG, medical treatment must be adequate and appropriate, but it should not exceed what is necessary.

Austria is one of the few EU countries where the costs of reimbursable medicinal products prescribed by a physician are, in principle, covered in full for the patients insured in the public insurance system. Patients only have to pay a flat fee (“prescription fee”) in pharmacies. Exemption from the prescription fee is possible under certain conditions.

Medicinal products included in the EKO can be prescribed at the expense of health insurance institutions (see **8.1 Price Control for Pharmaceuticals and Medical Devices**). Other medicinal products are only reimbursed in medically justified individual cases.

Regarding medical devices and IVD devices, no system comparable to the EKO exists. The Austrian Social Security Act does not refer to “medical devices” as such but to Heilbehelfe and Hilfsmittel (therapeutic aids), which are reimbursed – subject to a 10% deductible (or a current minimum of EUR 40,40) – if a physician prescribes them. Typically, medical device/IVD device manufacturers sign contracts with the

social insurance institutions in order to avoid the social insurance institutions requesting a cost estimate in advance regarding devices if no contract between the social insurance institutions and the manufacturer is in place.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Any entity authorised to distribute a medicinal product approved and available in Austria may apply for inclusion in the EKO. The medicinal products undergo a pharmacological, medical-therapeutic, and health-economic evaluation regarding their eligibility for reimbursement. In this process, the DVB is supported by the Medicines Evaluation Commission (*Heilmittel-Evaluierungs-Kommission*, or HEK), an independent advisory body that is not bound by instructions. The HEK's recommendations form the basis of the DVB's decisions.

The EKO is divided into three areas (known as “boxes”), which are outlined below.

- The Green Box contains medicines that the health insurance institutions reimburse to the socially insured without special authorisation. These are freely prescribable.
- The Yellow Box includes medicinal products that social insurance institutions consider to have a significant additional therapeutic benefit for patients but which were not included in the Green Box for medical or economic reasons. For these medicines, health insurers reimburse the insured if the prescription has been approved by their chief medical office (dark yellow area RE1). In some cases, a retrospective control is also accepted (light yellow area RE2).
- The Red Box contains medicinal products for a limited time while the company's request for inclusion in the EKO is being reviewed. During

this period, the costs are covered only if there is approval from the chief medical office of the social insurance institutions.

Finally, even the so-called “no-box” medicinal products – ie, products for which no application has been made to be included in the EKO – can be reimbursed if the individual prescription has been approved by the chief medical office. As this option is usually chosen for very expensive medicines, the Austrian legislator has introduced a requirement that the EU average price be relevant to these products if turnover exceeds EUR 750,000 (see 8.1 **Price Control for Pharmaceuticals and Medical Devices**).

Changes within the boxes and deletions from the EKO are possible at the request of both the company authorised to distribute the product and the DVB (supported by the HEK's recommendations).

If the social insurance institution refuses reimbursement in an individual case, the patient can file an action before the civil courts. In these proceedings, typically, the court reviews the social insurance institution's decision with the help of a specific expert, who is entitled to decide on the reimbursement. The court's decision may be challenged before the Higher Regional Court and, eventually, before the Supreme Court.

No system comparable to the EKO exists for medical devices and IVD devices. For reimbursement of medical devices and IVD, see 8.3 **Pharmaceuticals and Medical Devices: Reimbursement From Public Funds**.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Essentially, retailing of medicinal products (whether available only upon prescription or

freely available) may only be made by pharmacies. Medicinal products requiring prescription may only be provided to patients upon actual prescription by a physician.

So far, the *aut idem* rule has not been implemented into Austrian law. Pharmacists are required to dispense to the patient the medicinal product actually prescribed (even if, for example, a generic product is available). The pharmacist can only offer the patient a pharmaceutical equivalent if the prescribed product is at the respective point in time not available in the respective pharmacy.

Medical devices and IVD devices are not pharmacy-only products but distributors and retailers require a specific trade license for the sale of these products.

Trends and Developments

Contributed by:

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Herbst Kinsky Rechtsanwälte GmbH has become one of Austria's leading commercial law firms since its establishment in 2005. Its specialised and highly committed lawyers combine many years of experience gained abroad and in reputable Austrian law firms. The firm's practice covers a full range of services in all areas of commercial, corporate, civil and public law, including banking, insurance and capital mar-

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Life Sciences in Austria: An Overview

Austria is an active life sciences location that is internationally visible, has excellent research and development, and has a growing corporate landscape. Compared to other innovative sectors, the life sciences sector is by far the most innovative, has one of the highest research rates and significantly contributes to national value creation.

Austria provides for several public funding programs at national and regional levels specifically directed to support the life sciences sector. Funding is intended to enable and support the implementation of scientific discoveries into businesses. The Austrian Ministry for Labour and Economy has budgeted EUR45 million to fund life sciences projects as part of its transformation initiative. Applications can be submitted until 18 December 2026.

Over the last decade (2009-2021), the R&D activities in the life sciences sector have kept a good track, with the number of employees in the field increasing by 12.70% and the total R&D of business enterprises even more. Generally, this sector shows an upward trend with lots of

potential. Apart from its universities, Austria is home to the Austrian Academy of Sciences with 450 researchers and 38 ERC grants, the Institute of Science and Technology Austria, the Ludwig Boltzmann Society (LBG), the Vienna BioCenter and the Austrian Institute of Technology. Over the years, the number of business enterprises in the life sciences sector has increased to 982 with about 60.000 employees. Given that these numbers are referring to the year 2020, a much higher number is expected in the next national life sciences report, likely to be released in the first quarter of 2025 (Austrian Research and Technology Report 2024, 117).

The Austrian life sciences sector has always focused on basic research, often transitioning to applied research, translation and innovation through spin-offs, start-ups and investing pharmaceutical companies.

The formation of clusters and the expansion of research infrastructure also help to strengthen Austria as a business and research hub and promote cooperation between universities and non-university institutions. Examples include the Vienna BioCenter or the LISA Vienna.

Current Challenges

- In addition to the implementation of the numerous European directives and regulations in the life sciences field (see below), the new Austrian government will have to deal with the following major challenges in the life sciences sector, for example:
- regarding reimbursement of medicinal products (currently very low price level regarding off-patent medicines, on the other hand, in principle availability for reimbursement by the state sick funds of extremely expensive innovative medicines);
- ensuring that Austria remains an attractive location for research and clinical trials (eg, through safeguarding efficient and high-quality implementation of clinical trials in accordance with the Clinical Trials Regulation (CTR), optimisation of administrative processes in the operational implementation of clinical research projects and the extension of eligibility for research funding to multicenter clinical trials with Austrian participation); and
- public healthcare reform – guaranteeing access to healthcare by strengthening the private practice sector

European Initiatives Are Drivers of Development

European initiatives influence many developments in the Austrian life sciences sector. Below, you will find the currently most significant regulations and initiatives.

AI Act

The European Parliament passed the AI Act on 13 March 2024, and its directly applicable provisions will likely also influence life sciences-related AI applications, machine learning, and big data projects in Austria. Inventors and founders will have to take different precautions, taking

into account the expected risk that emanates from the prospective AI.

Both medical devices and IVD-medical devices fall under the scope of the AI Act as they are considered high-risk AI systems. Henceforth, developers and investors will need to examine whether their AI tool complies with the obligations of high-risk AI systems. These obligations cover a risk management system, data governance, technical documentation, transparency and information provision, robustness, accuracy and security, human oversight, conformity assessment, post-market monitoring, CE marking, registration with the EU's database and cooperation with authorities.

NIS-2-Directive

The NIS-2-Directive, a legislative act intended to strengthen cybersecurity, was due to be transposed into national law on 17 October 2024. The most recent legislative attempt failed because of a missing majority in the Austrian parliament. Notwithstanding, compliance with its obligations should already be achieved as the draft of the transposing law (*Netz- und Informationssystem-sicherheitsgesetz2024*) already exists, and the legal act is expected to be passed soon. The NIS-2 Directive applies to a broader range of entities than its predecessor (NIS Directive), targeting the following.

- Essential entities – larger organisations with critical roles, such as pharmaceutical companies, biotechnology firms, and healthcare providers.
- Important entities – medium-sized enterprises that provide significant services, such as clinical research organisations (CROs), diagnostic labs, and supply chain partners.

Organisations in life sciences will need to implement solid security measures, including the following.

- Risk management policies – ensuring cybersecurity risks are identified, assessed, and mitigated effectively.
- Incident response plans – developing and maintaining procedures to address and recover from cybersecurity incidents.
- Supply chain security – ensuring vendors and partners adhere to cybersecurity requirements.
- Access controls – protecting sensitive research data, intellectual property, and patient information through secure access management.

Critical Medicines Act

The European Commission has announced its intention to tackle the problem of shortage of essential medicines with a critical medicines act. The impact assessment is still outstanding, and it is uncertain whether the legislative proposal will be presented in the first quarter of 2025.

EU Biotech Act

The European Commission has announced a Biotech and Biomanufacturing Initiative for 2025 to help boost the biotech sector. The initiative is supposed to simplify market entry for newcomers by using regulatory sandboxes and establishing a new EU biotech hub.

European Health Data Space

While on hold for a while, the initiative to establish a European Health Data Space was boosted as, in Spring 2024, the European Parliament and the Council reached a political agreement on the Commission's proposal for the EHDS. The EHDS is intended to foster patients' portability of electronic health data, create a single market for

electronic health record systems and establish a uniform legal framework for the secondary use of health data. After being adopted by the European Parliament in December 2024, the EHDS proposal was also adopted by the Council of the EU on 21 January 2025. It will, therefore, soon enter into force.

Latest Developments at the National Level *Amendment to the Austrian Health Telematics Act (Gesundheitstelematikgesetz)*

- eVaccination card and full operation: Introduction of detailed regulations for the start of full operation of the eVaccination card.
- Restructuring of the electronic health records (ELGA) and eHealth support centers: Establishment of an "ELGA and eHealth support facility" with four sub-areas: ELGA ombudsman's office (existing), Appeals office (existing), Service line (existing), and new eHealth service point to ensure data quality and availability in the central vaccination register.
- Data security measures: Adaptation of the data security precautions laid down in the Austrian Health Telematics Act.
- Reducing prohibitions and simplifying through more general formulations to make ELGA and eHealth applications legally secure.

Reimbursement of digital therapeutics (DTx) in Austria

Digital therapeutics (DTx) are becoming increasingly attractive both in terms of commercialisation and clinical application. In Austria, DTx is typically referred to as "*Digitale Gesundheitsanwendungen*" (DIGAs). Austrian law provides for a system of compulsory health insurance. The legal basis for reimbursement of medical treatment for insured persons is laid down in the Austrian General Social Insurance Act ("ASVG"). Currently, no explicit provision is in place to govern the reimbursement of DTx. Therefore, reim-

bursement of such DTx is only possible if such reimbursement complies with the ASVG in its current version. According to Section 133 (1) ASVG, medical treatment which must be provided to the insured needing such treatment includes:

- medical assistance (“*ärztliche Hilfe*”);
- medicinal remedies (“*Heilmittel*”); and
- medical aids (“*Heilbehelfe*”).

The literature suggests that the current provisions of the ASVG also allow for reimbursement of DTx. However, it would be desirable for all stakeholders and patients that the respective provisions in the ASVG be adapted to clarify and facilitate reimbursement of DTx in Austria.

Ordinance on the stockpiling of “critical medicines”

The Austrian Federal Minister of Social Affairs, Health, Care, and Consumer Protection has issued an ordinance regarding the requirement for the stockpiling of (prescription requiring, not patent protected) medicinal products critical for the supply of patients in Austria (Verordnung: Bevorratung von Humanarzneispezialitäten, BGBl II 161/2024). The actual medicines concerned are listed in an annex to the ordinance. Marketing authorization holders are required to keep sufficient stocks of these medicinal products in Austria. These stock levels are based on the previous year’s numbers and must be maintained either directly by the marketing authorization holders or through authorized facilities. Exemptions apply in case of increased demand, force majeure, unforeseen circumstances or regulatory restrictions. The ordinance comes into

force on 20th of April 2025 and remains effective for three years.

Conclusion

Austria’s life sciences sector stands as a key driver of innovation, economic growth, and scientific progress. The sector continues to grow and evolve with public funding, a thriving research environment, and increasing business activity. It also holds many opportunities for business development. However, challenges such as pharmaceutical reimbursement, efficient and high-quality conduct of clinical trials, and regulatory compliance must be addressed to ensure Austria remains an attractive location for life sciences undertakings. On an individual level, the appropriate business and legal strategy naturally plays a crucial role in profiting from Austria’s life sciences economic environment.

European initiatives, including the AI Act, NIS-2 Directive, and the European Health Data Space, are set to shape the sector’s future by fostering digitalisation, security, and innovation. At the national level, recent legislative developments, such as amendments to the Austrian Health Telematics Act and discussions on digital therapeutics reimbursement, highlight ongoing efforts to modernise healthcare and research infrastructure.

Looking ahead, Austria’s ability to navigate regulatory challenges, leverage European opportunities, and support innovation through funding and collaboration among research institutions and private-sector enterprises will be crucial in maintaining its position as a leading life sciences location.

BRAZIL

Law and Practice

Contributed by:

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Kasznar Leonardos Intellectual Property has a century of professional experience and is recognised for its experience and excellence in the provision of services in all areas of intellectual property to clients of any size. The firm acts as attorneys in the prosecution of applications, as legal advisers on licensing and other contract matters, as lawyers in litigation and arbitration,

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices in Brazil are regulated by Federal Laws and Resolutions (known as *Resoluções* or RDCs) issued by ANVISA, the National Health Regulatory Agency.

Key legislation for pharmaceuticals includes:

- Law 5,991/1973, known as the Law of Sanitary Control of the Distribution and Sale of Medicines, which regulates the distribution, sale and control of medicines and related products;
- Law 6,360/1976, the primary statute for pharmaceutical products, covering production, commercialisation, advertising, labelling, quality control and penalties;
- Law 6,437/1977, which outlines penalties for violating federal sanitary statutes and regulations; and
- Law 9,294/1996, which imposes restrictions on the use and advertising of specific products.

Key legislation for medical devices includes:

- RDC 751/2022, amended by RDC 810/2023, which establishes rules for risk assessment, notification procedures, registration, labelling and use of medical devices;
- RDC 850/2024, which sets the validity term for medical device marketing approvals;
- RDC 830/2023, which establishes rules for in vitro diagnostic devices, including its instruments, complemented by IN 320/2024;
- RDC 657/2022, which regulates software as a medical device (SaMD); and

- Normative Instruction 290/2024, under the terms of RDC 741/2022, which establishes a procedure for analysing medical device registration petitions, utilising analyses by an Equivalent Foreign Regulatory Authority (AREE).

ANVISA operates independently within the Ministry of Health as the primary regulatory authority. It oversees the production, marketing and utilisation of health-related products and services, as well as supervising ports, airports and borders. ANVISA functions as a semi-autonomous agency, with administrative and financial autonomy but linked to the federal government (Ministry of Health). Oversight and budgetary control are provided by the Ministry, while ANVISA's board of directors, composed of technical experts, makes science-based decisions regarding regulations and approvals.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Regulatory decisions in the pharmaceutical and medical field can be contested through administrative appeals, either directly to the relevant regulatory authority or via lawsuits in federal courts.

The process for filing administrative appeals against ANVISA's decisions is governed by Law 9,784/1999, which regulates administrative procedures within the Federal Public Administration, and RDC 266/2019. ANVISA's decisions undergo a maximum of three instances:

- first instance – decisions by Organisational Units;
- second instance – Appeals Division (*Gerência-Geral de Recursos* or GGREC); and
- final instance – Collegiate Board of Directors (*Diretoria Colegiada* or DICOL)

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First instance appeals are directed against decisions issued by ANVISA's Organisational Units and must be addressed to the authority responsible. If unresolved initially, appeals are reviewed by the General Appeals Management at the second stage and, if necessary, escalated to the Appeals Division (GGREC) and ultimately to the Collegiate Board of Directors (DICOL).

Appeals must adhere to formal requirements outlined in RDC 266/2019, Article 4 onwards, and must be submitted in writing. The deadline for appealing an ANVISA decision is 30 days from the notification date.

Similar challenges can be applied to other regulatory matters under ANVISA's jurisdiction, such as food, cosmetics, sanitisers and tobacco derivatives.

1.3 Different Categories of Pharmaceuticals and Medical Devices

ANVISA categorises pharmaceutical products based on their active pharmaceutical ingredient (API) and innovative characteristics as outlined in RDC 753/2022, amended by RDC 948/2024, as can be seen below:

Pharmaceutical Categorisation (RDC 753/2022)

Primarily, but not exclusively:

- reference drug – an original, rigorously tested drug approved by ANVISA;
- generic drug – a cost-effective alternative drug with the same ingredients, form and effect;
- innovative drug – a drug that features new molecules, combinations or delivery methods;
- new drug – a drug that contains previously unapproved molecules; and

- similar drug – a drug that is similar to a reference drug with minor variations.

Medical Device Categorisation (RDC 751/2022 – amended by RDC 777/2023 and 810/2023)

Categorised by use and risk:

- active medical device – operates with external energy, alters density of gravity or converts energy;
- diagnostic and monitoring device – provides information on health states;
- therapeutic device – modifies, replaces or restores biological functions;
- single-use device – used once per procedure;
- implantable device – fully or partially inserted into the body;
- invasive device – partially or fully penetrates the body; and
- in vitro diagnostic device – analyses samples for diagnostic purposes.

Risk Classification

- Class I – low risk;
- Class II – medium risk;
- Class III – high risk; and
- Class IV – maximum risk.

2. Clinical Trials

2.1 Regulation of Clinical Trials Clinical Trials for Pharmaceuticals

- RDC 945/2024 establishes the guidelines and procedures for conducting clinical trials in the country with the aim of subsequently granting drug registration.
- CNS Resolution 251/1997 defines regulatory and bioethical guidelines.
- CNS Resolution 466/2012 establishes general rules for clinical trials.

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- RDC 505/2021 (amended by Normative Instruction 270/2023) governs clinical trials for advanced therapy medicinal products.

Clinical Trials for Medical Devices

- Law 14.874/2024 provides for research involving human subjects and establishes the National System of Ethics in Research with Human Subjects.
- RDC 837/2023 regulates medical device trials.
- RDC 751/2022 (in force but amended by RDC 777/2023 and 810/2023) defines risk classification, notification, labelling and use instructions.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Pharmaceuticals

For ANVISA approval of pharmaceutical trials, sponsors must submit a Drug Clinical Development Dossier (DDCM) as per RDC 945/2024. ANVISA's Co-Ordination of Research and Clinical Trials department (COPEC) assesses the DDCM for sanitary risks before approval. ANVISA aims to complete its analysis within 90 days. Sponsors must also provide detailed protocols to the Research Ethics Committee (CEP) before trials commence. Imported products for human research must also obtain ANVISA approval, with sponsors maintaining responsibility for data integrity and quality, even if functions are delegated to a Clinical Research Organisation (CRO).

It is worth noting that Law 14,874/2024 establishes a new deadline of 90 days for ANVISA's analysis of primary petitions for clinical trials with human beings.

Medical Devices

RDC 837/2023 simplified medical device clinical trials in Brazil, aligning with international stand-

ards and clarifying ANVISA approval requirements. This regulation eliminates the need for Clinical Research Process Consent and expedites approvals by consolidating documentation under a single Medical Devices Clinical Research Dossier (DICD) process. This streamlining removes the necessity for CEP opinions, simplifying paperwork. Only trials with results that could support Class III and IV medical device registration in Brazil necessitate ANVISA submission.

2.3 Public Availability of the Conduct of a Clinical Trial

ReBEC (*Registro Brasileiro de Ensaaios Clínicos*) is the official Brazilian Registry of Clinical Trials, operated by ANVISA. It is a public platform where anyone can find details about clinical trials conducted in Brazil, including study design, participant criteria and contact information.

The database contains information such as trial title, sponsor, investigational product, phase, primary and secondary endpoints, inclusion/exclusion criteria and participating research centres.

Health data is considered sensitive under National Research Ethics Committee (CONEP) Resolution 466/2012 and Law 13,709/2018, also known as the General Data Protection Law (*Lei Geral de Proteção de Dados Pessoais* or LGPD), mandating confidentiality for trial participants' data in both public and private institutions.

Sponsors must document and report adverse events, especially fatal or life-threatening ones, to ANVISA electronically within seven days of becoming aware of them (RDC 945/2024).

Section II, subsections I and II of RDC 945/2024, specify that sponsors must submit annual monitoring reports on the trial drug's progress, detail-

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ing all adverse events using subject codes. They also require a final report after the trial's completion across all participating countries, including information on withdrawn subjects and verified adverse events.

These reports must meet the minimum requirements outlined in Article 73 for annual reports and Article 74 for final reports. The annual report should be submitted within 60 days of the annual reference date (the trial's start date in Brazil), while the final report is due within 12 months of the trial's conclusion.

Law 14,874/2024 also establishes that the researcher is responsible for submitting the research documentation, including any amendments, to the CEP for approval, but the reporting of adverse events continues to be ANVISA's responsibility.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific regulations in Brazil that explicitly restrict the use of online tools for supporting clinical trials, such as for recruitment or monitoring purposes.

However, it is essential to ensure that any online tools used comply with CONEP Resolution 466/2012 and the LGPD, which clearly states that health data is considered sensitive, and confidentiality of trial participants' data is mandatory for both private and public institutions.

2.5 Use of Data Resulting From Clinical Trials

Building on the discussion above, health data is considered sensitive, necessitating strict confidentiality safeguards in both private and public institutions. According to Article 5, Item II of the LGPD, sensitive personal information includes

details regarding a natural person's racial or ethnic origin, religious beliefs, political views, union or other organisational memberships, health or sex life, and genetic or biometric data.

Transferring personal data from clinical trials to a third party or affiliate is possible but subject to stricter conditions outlined in Article 11 of the LGPD.

- Specific consent – explicit and informed consent from the data subject is mandatory, clearly explaining the recipient and purpose of the data transfer.
- Limited exceptions – the LGPD permits transferring sensitive data without consent in limited circumstances, such as legal compliance or protecting the data subject's life or safety. However, these exceptions are interpreted narrowly.

2.6 Databases Containing Personal or Sensitive Data

Following on from 2.5 **Use of Data Resulting From Clinical Trials**, data from clinical trials in Brazil faces strict data protection regulations due to its personal and sensitive nature. Before transferring such data to third parties or affiliates, explicit consent from participants, contractual agreements outlining data security protocols and potential data residency restrictions must all be considered.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Article 4 of RDC 751/2022 (in force but amended by RDCs 777/2023 and 810/2023) regulates the

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classification of medical devices as any instrument, apparatus, equipment, implant, in vitro diagnostic medical device, software, material or other article, intended by the manufacturer to be used, alone or in combination, in human beings, for some specific medical purpose, and whose principal intended action is not achieved by pharmacological, immunological or metabolic means in the human body, but which may be aided in its intended action.

For a product to be classified as a pharmaceutical (regarding Law 10,742/2003), it should be any pharmaceutical product, technically obtained or prepared, for prophylactic, curative, palliative or diagnostic purposes.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biologic products often involve complex manufacturing processes and unique safety considerations compared to traditional chemical drugs. Therefore, obtaining marketing authorisation for biologics in Brazil typically involves additional requirements beyond those for chemical drugs.

Comprehensive Dossier

Detailed information about the biologic product must be submitted to ANVISA. This dossier typically includes:

- product characteristics;
- manufacturing information;
- non-clinical studies – data from pre-clinical studies (in vitro and in vivo) assessing the product's safety and potential efficacy;
- clinical studies – data from well-designed and controlled clinical trials in humans to demonstrate the product's safety and efficacy for the intended use; and
- risk management plan – a comprehensive plan outlining potential risks associated with

the product and strategies to mitigate those risks.

Comparability Studies

For biosimilars (biologics that are similar to an already approved reference product), additional comparability studies demonstrating similarity to the reference product in terms of quality, safety and efficacy are often required.

Stricter Regulatory Requirements

Compared to chemical drugs, biologics might face stricter regulatory requirements related to manufacturing process controls, product characterisation and ongoing monitoring of safety post-marketing.

Additional Considerations

- Foreign clinical trials – clinical trials conducted outside Brazil might be accepted by ANVISA under certain conditions. However, specific requirements regarding data integrity and compliance with Good Clinical Practices must be met.
- Post-marketing surveillance – marketing authorisation holders are typically required to conduct post-marketing surveillance to monitor the safety and efficacy of their biologic product in the real-world setting.

The following are some of the main resolutions that relate to biological products.

- RDC 55/2010 (in force but amended by RDC 948/2024) regulates the registration of new biological products and biological products.
- RDC 913/2024 regulates post-registration changes and cancellation of registration of biological products.
- RDC 412/2020 establishes the requirements and conditions for conducting stability stud-

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ies for the purposes of registration and post-registration changes to biological products.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Marketing authorisations for pharmaceuticals and medical devices are valid for ten years from the date of their publication in the Brazilian Official Gazette (DOU). They can be renewed for successive ten-year periods.

Certain requirements must be met for renewal, for example, for medicines, the product must have been marketed for at least 80 months (two-thirds) of the ten-year period (120 months).

For medical devices, for example, revalidation of the registration must be requested no more than 12 months and no less than six months before the registration expires.

The registration of a product which is subject to health surveillance may be cancelled in the following situations.

- When the renewal of the product's registration has not been requested within the period specified by ANVISA.
- When it is proven that the product or manufacturing process may present a risk to the health of the consumer, patient, operator or third parties involved.
- When a request from the holding company is made when it no longer has any interest in marketing the product.
- When a request from the holding company is made when the registration is to be transferred to another company.

In addition, ANVISA can take preventive measures to protect public health during a health

risk assessment. These measures, authorised by Law 6,360/1976, Law 9,782/1999 and Law 9,784/1999, include inspection actions such as seizure, recall, prohibition and suspension of activities relating to the product or service in question (storage, marketing, distribution, manufacture, import, advertising and/or use).

Furthermore, ANVISA can utilise precautionary measures, which are also proactive administrative actions based on the terms of Law 6,437/1977. These measures aim to safeguard public health in situations of imminent risk, even before a formal hearing with the party involved. For example, a precautionary interdiction can be applied when there is clear evidence of product alteration or adulteration.

Once a health investigation is completed and an infraction is confirmed, ANVISA initiates the process of charging the responsible party. Penalties for sanitary infractions, as defined in Law 6,437/1977, can be applied individually or in combination.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The process for obtaining marketing authorisation for pharmaceuticals and medical devices in Brazil is overseen by ANVISA.

What follows is a summary of the steps.

- Pre-application:
 - (a) compile all necessary data and documentation; and
 - (b) evaluate risk classification and seek pre-submission consultations with ANVISA.
- Formal application:
 - (a) submit a comprehensive dossier electronically through ANVISA's online platform.

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- Technical evaluation:
 - (a) ANVISA experts assess safety, efficacy and quality; and
 - (b) inspections of manufacturing facilities or clinical trial sites may be conducted.
- Decision and issuance:
 - (a) ANVISA issues a final decision approving or rejecting. It is also possible that it may request further information for making such decision; and
 - (b) if approved, ANVISA issues a marketing authorisation document.

Variations to marketing authorisation:

- similar process, but typically less extensive; and
- complexity depends on the nature of the change: minor, moderate or major.

Transfer of marketing authorisation:

- eligibility is limited to specific corporate operations such as mergers or successions;
- procedures are outlined in RDC 903/2024;
- deadlines vary by product category; and
- no other changes are permitted in the transfer petition.

Steps for submitting a registration transfer request:

- petitioning;
- fees;
- protocol;
- statement of the corporate or commercial transaction carried out, as set forth in Annex I of RDC 903/2024;
- a certified copy of the operating licence or sanitary permit issued by the competent authority, updated to reflect the corporate or commercial change; and

- monitoring

Important points:

- the registration number follows a specific formation process; and
- the validity of the registration remains the same regardless of the transfer publication date.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In Brazil, patient access to pharmaceuticals and medical devices typically requires ANVISA's marketing authorisation. However, exceptions exist.

- Clinical trials – patients can join strictly regulated trials for new products. This requires informed consent.
- Compassionate use programmes – eligible patients with life-threatening conditions and no alternatives may access unapproved products under strict criteria:
 - (a) eligibility – determined on a case-by-case basis;
 - (b) physician request – detailed justification submitted to ANVISA;
 - (c) ANVISA approval – evaluation based on risks and benefits; and
 - (d) limited availability – access granted from a limited supply, often from the manufacturer.

Compassionate use is not guaranteed, and ANVISA holds final approval authority.

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3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The regulations concerning the obligation on the marketing authorisation for pharmaceuticals and medical devices are summarised below.

Pharmaceuticals (Medicinal Products)

Marketing authorisation (MA) process

- RDC 31/2014 (in force but amended by RDC 438/2020) defines procedures for obtaining an MA in Brazil, including documentation requirements and evaluation timelines.
- ANVISA (National Health Surveillance Agency) oversees the process.
- Phases include pre-clinical studies, clinical trials (Phases I-III) and post-marketing (Phase IV) studies.

Pharmacovigilance obligations (medicinal products)

RDC 658/2022 establishes General Guidelines for Good Manufacturing Practices for Medicines.

Post-marketing obligations

Phase IV trials may be imposed to monitor real-world safety and efficacy.

Medical Devices

RDC 751/2022 (in force but amended by RDC 777/2023 and 810/2023) regulates the risk classification, notification and registration regimes, labelling requirements and instructions for use of medical devices.

- Technovigilance obligations – manufacturers must actively participate in technovigilance.
- Post-marketing obligations – similar to pharmaceuticals, ongoing safety assessment is crucial.

The following are some resolutions regarding the control, inspection and monitoring of products and services:

- RDC 67/2009 (in force but amended by RDC 702/2022) – technovigilance standards applicable to health product registration holders in Brazil.
- RDC 551/2021 – obligation for registration holders to carry out and report field actions, meaning actions of a health product with the aim of reducing the risk of an adverse event related to the use of the health product already on the market of health products in Brazil.
- RDC 665/2022 – Good Manufacturing Practices for Medical Products and Diagnostic Products for In Vitro Use.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

In the realm of third-party access to pharmaceutical and medical device authorisations, regulation is governed by the Information Access Law (Law 12,527/2011). Despite the sensitivity and confidentiality of health products, interested third parties can request access to registration information under this Law.

Article 7 states that access to information includes obtaining data from records or documents produced by relevant bodies or entities, whether stored publicly or not, as well as information concerning public asset administration, resource usage, bidding and administrative contracts.

However, it is important to note that while all information regarding a registered health product may be requested, it may not always be provided by regulatory agencies such as ANVISA or

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the Chamber for the Regulation of the Medical Market (CMED).

The primary regulation safeguarding commercially confidential and individual-related information is the “secrecy law” (*Lei do Sigilo*). Additionally, trade secrets benefit from specific legislation protection, crucial for preserving proprietary knowledge and fostering competitiveness and innovation.

To safeguard trade secrets effectively, companies should implement practical measures:

- identification and classification – recognise and appropriately classify information deemed as trade secrets;
- access control – limit access to authorised personnel only;
- contracts and agreements – incorporate confidentiality clauses in contracts with partners, suppliers and employees;
- physical and digital security – implement measures to protect electronic documents and data physically; and
- training and awareness – educate employees on the significance of confidentiality and trade secret protection.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

In Brazil, the regulatory framework foresees routes for expediting the registration of medicines and medical devices. The optimisation of the registration proceedings has recently been enhanced by new rules regarding regulatory reliance enacted between 2022 and 2024. Additionally, for medical devices, the issuance of authori-

sations can be faster for products classified as Group 1 or 2 based on their risk level.

Pursuant RDC 751/2022, the category of medical devices is divided into four groups.

- Group 1 and 2 – classified as low risk. These devices are required to be notified to ANVISA, following a simplified process that demands the submission of fewer documents (on average, three documents).
- Group 3 and 4 – classified as high risk. For these devices, a full registration procedure is required with ANVISA, involving the submission of more comprehensive documentation (on average, five documents).

Regarding importation, there is a distinction between registered and notified medical devices. Imported medical devices subject to registration require the submission of proof of registration, a certificate of free sale or equivalent document, issued by the competent authority of the country of manufacture and sale, as well as a declaration from the legal manufacturer. On the other hand, notified medical devices only require the declaration issued by the legal manufacturer.

Finally, it is important to point out that in vitro medical devices have their own specific regulations, as set out in RDCs 830/2023 and 848/2024. Although they follow the same regulatory process of notification or registration, the documentation required for these devices differs from that applicable to others.

4.2 Regulatory Reliance

Brazil has embraced the notion of regulatory reliance. With RDC 741/2022, ANVISA recognises assessments by Equivalent Foreign Regulatory Authorities (AREEs). Normative Instructions (IN) 289/2024 and (IN) 290/2024 detail the

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procedures for utilising these assessments. IN 289/2024 applies to medicines, biological products, vaccines and active pharmaceutical ingredients, while IN 290/2024 specifically addresses medical devices.

The applicable AREEs for each sector are as follows.

Medicines, biological products and vaccines:

- European Medicines Agency (EMA);
- Health Canada;
- Swissmedic;
- Medicines and Healthcare products Regulatory Agency (MHRA);
- US Food and Drug Administration (FDA);
- Therapeutic Goods Administration (TGA); and
- World Health Organization (OMS)

Active Pharmaceutical Ingredients:

- World Health Organization (OMS); and
- European Directorate for the Quality of Medicines & HealthCare (EDQM)

Medical Devices:

- Australian Therapeutic Goods Administration (TGA);
- Health Canada (HC);
- US Food and Drug Administration (FDA);
- Japan Ministry of Health, Labour and Welfare (MHLW).

Brazil makes use of regulatory decisions of other jurisdictions to optimise its product registration procedures. Therefore, if a company has already obtained authorisations from internationally recognised jurisdictions, the issuance of ANVISA's authorisations can be expedited. The analysis conducted by AREE can be accepted

for the purpose of implementing an optimised analytical procedure facilitated by regulatory trust practices, such as collaborative work and mutual or unilateral recognition. The practice of the optimised analysis procedure will be based on the instructional documentation prepared by the Equivalent Foreign Regulatory Authority, as established in specific normative acts.

For the purposes of adopting the optimised analysis procedure, the instructional documentation of the Equivalent Foreign Regulatory Authority must:

- prove that the product subject to the instructional documentation is essentially identical to the one submitted for evaluation by ANVISA;
- have been prepared using standards consistent with those used by ANVISA, to ensure it has the same scope; and
- be presented in its complete form, including the questions and guidelines that were made during the analysis by the Equivalent Foreign Regulatory Authority, unless excepted in specific normative acts.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Both pharmaceutical and medical device manufacturing facilities in Brazil need a licence to operate, known as an *Autorização de Funcionamento* (AFE), issued by ANVISA.

The procedure for obtaining an AFE is outlined in RDC 16/2014 (in force but amended by RDC 860/2024).

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- Registration – the company and product must be registered with ANVISA.
- Documentation – detailed documentation should be submitted describing manufacturing processes, quality control measures and plant layout, complying with Good Manufacturing Practices (GMP) regulations (RDC 658/2022 for pharmaceuticals and specific RDCs for medical devices).
- Inspection – ANVISA conducts a facility inspection to verify compliance.
- Approval – If compliant, ANVISA issues the AFE.

Activities authorised by the AFE include manufacturing, storage of raw materials and finished products, and quality control procedures.

The AFE has no expiry date.

Additional notes:

- while a GMP certificate is not mandatory for the AFE, facilities must adhere to ANVISA's Good Manufacturing Practices.
- documentation requirements and inspections may vary based on product complexity and risk classification; and
- for certain products such as electrical medical devices, breast implants, rubber gloves and sterile disposable syringes, an INMETRO certificate confirming compliance with Brazilian standards is necessary.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale distributors of pharmaceuticals and medical devices in Brazil must be licensed by

ANVISA. The Authorisation to Operate Pharmacies and Drug Stores (AFE) permits the sale of industrialised medicines, including those under special control per Regulation SVS/MS 344/1998 and updates.

The application process, outlined in RDC 16/2014, Article 28, requires the submission of technical and formal documentation.

Once granted, the AFE for Wholesale allows commercialisation of various products such as medicines, pharmaceutical inputs, health products, cosmetics, personal hygiene items, perfumes and disinfectants between legal entities or to professionals.

The AFE has no expiry date.

6.2 Different Classifications Applicable to Pharmaceuticals

As mentioned in 1.3 Different Categories of Pharmaceuticals and Medical Devices, ANVISA categorises pharmaceutical products based on their API and innovative characteristics, as outlined in RDC 753/2022.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Law 6,360/1976 is the primary pharmaceutical law, governing production, marketing, advertising, labelling, inspection, quality control, penalties, importation and marketing authorisation of medicines, drugs, active ingredients and medical devices. Decree 8,077/2013 regulates it.

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To secure marketing authorisation for medicinal products, the applicant must be an authorised manufacturer or importer. ANVISA authorisation is mandatory for manufacturing/selling pharmaceuticals and/or importing them before market entry.

Various government agencies enforce import regulations for pharmaceuticals and medical devices.

- National Health Regulatory Agency (ANVISA):
 - (a) oversees health product import/export; and
 - (b) sets specific technical requirements/procedures via resolutions/directives.
- Federal Revenue Department (*Secretaria da Receita Federal do Brasil*):
 - (a) manages customs control at Brazilian borders; and
 - (b) collaborates with ANVISA to verify import documents, classify goods and collect duties/taxes.
- Ministry of Agriculture, Livestock and Supply (MAPA):
 - (a) participates in importing specific agricultural/veterinary medical devices; and
 - (b) collaborates with ANVISA on import procedures for these products.
- National Institute of Metrology, Standardisation and Industrial Quality (INMETRO):
 - (a) involved in importing certain medical devices meeting technical standards; and
 - (b) may require additional certifications/conformity assessments to meet Brazilian specifications.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

In Brazil, only a local legal entity can serve as the importer of record for pharmaceuticals and

medical devices. Specific requirements must be met.

Eligible importer of record:

- Brazilian legal entity – registered with the relevant commercial registry. This includes subsidiaries of foreign companies or wholly Brazilian-owned companies; and
- foreign company with a branch office – a foreign company can be the importer if it has a duly established and registered branch office in Brazil.

Importer of record requirements:

- valid CNPJ (National Registry of Legal Entities) – the company must possess a valid CNPJ, a unique identification number for Brazilian legal entities;
- qualified technical professional – the importer must employ a qualified technical professional responsible for the imported products, possessing relevant qualifications;
- permanent establishment – maintaining a physical establishment in Brazil with proper infrastructure for storage and distribution to ensure supply chain traceability; and
- ANVISA registration – the importer must be registered with ANVISA, allowing verification of regulatory compliance and import management capacity.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In Brazil, importing pharmaceuticals and medical devices requires prior authorisation from ANVISA.

Key regulations, including RDC 810/2023 amending RDC 751/2022 (in force with amendments), cover risk classification, notification,

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registration regimes, labelling requirements and usage instructions for medical devices. Additionally, RDC 18/2014 regulates communication to ANVISA regarding temporary or permanent discontinuation or reactivation of medicine manufacture or import.

Import Authorisation (AI) requirement:

- commercial imports typically require an AI from ANVISA;
- importers must apply for the AI before the shipment reaches Brazil; and
- ANVISA assesses applications and supporting documents to ensure product registration, technical compliance and adherence to GMP.

Exemptions may apply in certain cases.

- Donations – importing for public health programmes as donations may be exempt from AI, subject to specific ANVISA procedures and documentation.
- Emergency situations – temporary authorisations may be granted during public health emergencies.
- Clinical trials – authorised trials have specific import procedures for investigational drugs and medical devices.
- Personal use – limited exemptions may exist for small quantities for personal use, but travellers should verify guidelines with ANVISA or Brazilian customs to avoid penalties.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Brazil's non-tariff regulations and restrictions (NTRs) for imports, including pharmaceuticals and medical devices, ensure product safety, quality and compliance.

Basis for imposing NTRs:

- Harmonised System (HS) Tariff Code – determines NTR requirements based on product classification;
- technical description – product characteristics can dictate NTRs; eg, medical devices may need extra certifications; and
- regulatory category – ANVISA's classification influences NTRs, with high-risk products facing stricter regulations.

Laws and regulations listing products subject to NTRs:

- Law 13,097/2015 – governs import/export of health products, outlining ANVISA's role;
- ANVISA resolutions and directives – specify technical requirements, registration and import processes for different product categories; and
- other legislation – additional regulations from ministries such as MAPA or INMETRO may apply.

7.5 Trade Blocs and Free Trade Agreements

Brazil engages in trade agreements with provisions for trade and regulatory facilitation. Some include the following.

Trade Bloc

Mercosur was formed in 1991 with Argentina, Uruguay, Paraguay and associate members such as Bolivia, Chile, Peru, Suriname and Guyana. Mercosur promotes trade integration via tariff reductions and regulatory harmonisation.

Free Trade Agreements (FTAs)

Brazil has FTAs with various countries:

- Uruguay and Paraguay (Mercosur);
- Argentina (Mercosur);
- Bolivia (Mercosur);

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- Chile;
- Paraguay (bilateral);
- Israel;
- Palestine;
- Egypt; and
- South Africa

Trade/Regulatory Facilitation Provisions

FTAs often include the following.

- Mutual Recognition Agreements (MRAs) – recognising each other’s testing and certification procedures to reduce redundant testing.
- Harmonisation of technical standards – aligning regulations and standards to simplify compliance.
- Streamlined customs procedures – speeding up customs clearance and reducing paperwork.
- Transparency and information sharing – enhancing regulatory transparency and information exchange for smoother trade in regulated goods.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Brazil imposes price controls on pharmaceuticals and medical devices through CMED, regulating prices, fostering competition and setting price ceilings.

Key laws include:

- Law 10,742/2003 – establishes CMED and modifies previous legislation; and
- Decree 4,937/2003 – defines criteria for drug price adjustments.

Medical devices undergo economic monitoring per RDC 478/2021, with Normative Instructions 84/2021 and 119/2022 outlining monitoring details.

Drug Price Approval

The process involves submitting economic data and proposed prices based on drug categories outlined in CMED’s Resolution 2/2004.

CMED’s decision is subject to appeals, with final decisions potentially reviewed by federal courts.

Drug Price Categories (Resolution 2/2004)

- Categories I-VI – classify drugs based on novelty and therapeutic benefit, each with specific pricing rules.
- Omissive category – for drugs not fitting established categories.

Appealing Price Decisions

Companies can challenge CMED decisions internally and through federal courts if legal grounds exist.

Drug Price Classification

CMED classifies approved drug prices into three categories.

- Factory price (PF) – maximum price for companies selling drugs to pharmacies and the government.
- Maximum consumer price – highest price pharmacies can charge consumers.
- Maximum selling price to the government – price resulting from applying a mandatory discount (PAC) to the PF. The PAC is adjusted annually.

Price Adjustments and Industry Concerns

Annual price adjustments, criticised for lagging behind inflation, affect drug pricing, though

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actual market prices often fall below set ceilings, especially for generics.

8.2 Price Levels of Pharmaceuticals or Medical Devices

International reference prices indirectly influence drug pricing in Brazil, particularly in Category I, where they play a significant role. Resolution 2/2004 establishes a price basket comprising nine countries, serving as a benchmark for evaluating manufacturer prices, excluding taxes.

Category I, for new patented drugs offering substantial benefits, is directly influenced by international prices. The proposed PF cannot exceed the lowest PF practised for the same product in the basket of countries, ensuring competitive market entry.

However, drug pricing in Brazil is influenced by factors beyond international prices.

- Product characteristics – novelty, therapeutic benefit and patent status influence pricing.
- Cost-effectiveness analysis – companies must demonstrate the drug's cost-effectiveness compared to existing treatments.
- Public health needs– CMED may prioritise public health considerations, setting prices below international levels.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Brazil's healthcare system blends public and private financing for drugs.

Public System (SUS)

- SUS prioritises essential healthcare and medication access for citizens.

- SUS is government-funded to ensure universal health access (Article 196 of the Constitution).

Drug acquisition:

- public bidding – transparent, cost-effective drug procurement via public bidding;
- government may purchase patented drugs without bidding;
- productive development partnerships – strategic drug partnerships with private firms ensure reliable supply at set prices; and
- technology incorporation (CONITEC):
 - (a) evaluates new technology inclusion into SUS based on evidence and cost-effectiveness;
 - (b) stakeholder submissions undergo CONITEC review and final recommendation; and
 - (c) Law 14,313/2022 allows SUS reimbursement for off-label drug uses upon CONITEC approval.

Private System (Health Insurance)

Health insurance coverage:

- ANS oversees private health insurance, defining mandatory coverage; and
- ANS's List of Procedures mandates drug coverage based on contracted plans.

List of procedures:

- ANVISA authorisation – only ANVISA-approved drugs are included; and
- the list is updated every two years to include new technologies.

Judicialisation:

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- lawsuits ensure access to drugs not covered by SUS or private plans;
- Constitutional guarantee (Article 196) supports patient access, especially for rare diseases or cannabis-based products.; and
- Supreme Court guidelines consider ANVISA approval, alternative treatments and unreasonable delays in drug evaluation.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Brazil employs cost-benefit analysis (CBA) within Health Technology Assessment (HTA) processes for pharmaceuticals and medical devices, though its direct influence on pricing and reimbursement decisions varies.

HTA process and CBA:

- CONITEC manages Brazil's HTA process, considering factors such as clinical effectiveness, safety, budgetary impact, ethics and societal/public health effects; and
- CBA evaluates technology costs against expected health benefits.

Impact on pricing:

- while CBA informs negotiations for essential drugs on the RENAME list, it is not decisive; and
- government considers affordability, production costs, R&D expenses and reasonable profit margins, with international prices as negotiation benchmarks.

Impact on reimbursement:

- CBA heavily influences reimbursement decisions by SUS;

- SUS prioritises interventions with favourable cost-benefit ratios, ensuring significant health benefits at justifiable costs; and
- high-cost, low-benefit technologies may not be reimbursed by SUS.

Limitations of CBA:

- CBA complexities and uncertainties arise in calculating long-term health benefits and costs; and
- quantifying ethical considerations and improved quality of life in economic terms can be challenging.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Brazil has implemented regulations to oversee physician prescribing and pharmacy dispensing, aiming to ensure rational medication use and control pharmaceutical spending.

The Federal Council of Medicine and ANVISA provide guidance.

- The Federal Council of Medicine offers guides for medical prescriptions.
- ANVISA's RDC 44/2009 (RDC current with amendments) outlines Good Pharmaceutical Practices for pharmacies.

Prescription regulations:

- only licensed physicians and dentists may prescribe medications;
- prescriptions must adhere to a standard format set by the Ministry of Health;
- stricter rules govern controlled substances prescriptions; and
- electronic prescriptions, while not yet mandatory, are increasingly being utilised.

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Pharmacy regulations:

- only licensed pharmacists may dispense medications, ensuring proper prescription verification;
- pharmacists may substitute generics for brand-name drugs with patient consent;
- pharmacies must retain dispensed prescriptions for record-keeping; and
- some medications are available over the counter, with pharmacists providing guidance on usage and interactions.

Trends and Developments

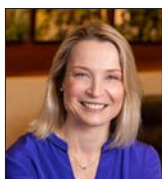
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porate groups to the freshest of start-ups. The firm's Life Sciences team supports clients to safely navigate the Brazilian regulatory framework, including: consulting on the regulatory frameworks of and representing clients before the Ministry of Health, ANS, ANVISA and MAPA; advising on permits, registration of products, and price adjustments; assisting with public bids and contracts; and reviewing advertising campaigns and product labels, as well as policies on compliance and corporate ethics.

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Introduction

The Brazilian life sciences market has experienced significant growth in recent years, driven by both domestic factors and global trends. With a robust pharmaceutical sector, expanding markets for dietary supplements and cosmetics, and growing interest in innovative healthcare solutions, Brazil is emerging as a key player in the global life sciences industry. This text explores the current market trends shaping the sector, including regulatory and legislative changes, technological advancements, and the increasing private collaboration that is fostering investment and growth. It highlights the key sectors, such as pharmaceuticals, cannabis, clinical trials and public-private partnerships, that are poised to drive future development and innovation in Brazil's healthcare landscape in the coming years.

Market Trends

The Brazilian pharmaceutical sector reached a significant milestone in 2023, following a period of consistent growth in the previous years. Despite global economic challenges, the market [posted](#) a solid revenue of USD68 billion, reflecting a nominal growth of 8.53% from 2022. Brazil remains the largest pharmaceutical market in Latin America, with a 50.7% market share, followed by Mexico (20.7%) and Argentina (10.4%).

Together, these three countries [account](#) for 82% of the region's total market.

In Brazil, the sector has benefited from a substantial increase in public health spending, particularly in 2022–2023, compared to the pre-pandemic period. According to [market insights](#), this surge has been supported by a rapidly expanding private healthcare segment, which is tapping into new markets like pet insurance and embracing digital channels in wholesale.

In addition, the Brazilian Federal Government legal framework and new regulation promises numerous investments in the health sector, with high expectations for the effective increase of partnerships between state-owned companies and national and/or foreign companies aiming for a bigger development and innovation in the health sector, especially in the field of pharmaceuticals.

In light of recent global trade dynamics, the Brazilian pharmaceutical market is poised to become an increasingly attractive destination for foreign companies. The US imposition of 25% tariffs on imports from Canada and Mexico, along with a 10% tariff on Chinese imports – one of the main markets of API – is [expected](#) to create new challenges for the pharmaceutical industry in North

America. As a result, companies may turn their focus to Brazil as a key region to expand their operations and develop their industry in a more favourable environment.

In addition to the pharmaceutical sector, the dietary supplements sector also appears promising, showing considerable growth since 2022 in merger and acquisition transactions. The [expectation](#) is that this market will generate more than BRL10 billion annually by 2028.

Another sector that is constantly expanding is the cosmetics and personal care industry. The Brazilian market is the fourth largest in the world and is continuously growing, with [projections](#) indicating that revenue will exceed USD44 billion by 2029. [Data shows](#) that the growth rate for this market is over 7%.

New policies currently under discussion in Congress and at federal regulatory agencies, such as the National Health Surveillance Agency (ANVISA) and the National Agency for Supplementary Health (ANS), are likely to play a crucial role in shaping the future of the industry. These regulatory changes, alongside continued investment in innovation and healthcare infrastructure, will provide new opportunities for both domestic and foreign companies, further fuelling the expansion of the Brazilian market.

Clinical Trials

Brazil's ethnic diversity, large population, highly trained professionals, and the credibility of its regulatory agency make it one of the most attractive countries in the world for the development of clinical trials. In response to the sector's constant demand for clearer regulations and faster procedures, the Brazilian government passed a law to regulate human clinical trials in the country.

Published in mid-2024, Federal Law 14.874 introduced significant changes regarding the responsibilities of sponsors during and after clinical trials and established defined timelines for the review and approval of research protocols by ethics committees. Although some specific regulations are still pending, the new legislation provides greater legal certainty for all parties involved. This is expected to foster increased investment from both national and international companies interested in developing their activities in Brazil.

Partnerships Between Public and Private Laboratories: PDPs and PDIL

Brazil is one of the few countries in the world that guarantees free access to the National Health System (SUS) for its entire population, covering everything from medical consultations and surgical treatments to the provision of expensive, continuous medicines. Due to this high demand for products such as surgical instruments and medications, Brazil operates public laboratories that manufacture these items to reduce government costs.

This public policy requires public laboratories to enter into partnerships with private companies for: (i) the transfer of technology (PDP – Partnership for Productive Development), enabling the public sector to manufacture products and make them available to SUS, or (ii) the development of innovative solutions for the public health sector (PDIL – Local Development and Innovation Program).

These partnerships are expected to grow significantly in the coming years, as the federal government aims for 70% of SUS's product demand to be met through local production by 2033. To achieve this goal, the government plans to invest more than BRL8 billion by 2027. Notably, the

signing of a PDP does not prevent the private company from continuing to market its products in Brazil. In the case of medicines, after the technology transfer is completed, the product manufactured by the public laboratory receives an independent registration.

Cannabis and Its Medicinal Use

The use of cannabis for medicinal purposes, both for humans and animals, has increasingly been advocated by Brazilian healthcare professionals, creating growing pressure for regulations regarding the cultivation of the plant within Brazilian territory. In some Brazilian states and municipalities, cannabis-based products are even provided free of charge through the SUS.

Since 2015, the use of cannabis-based products has been permitted in Brazil. In 2019, ANVISA regulated the importation, manufacturing and commercialisation of cannabis products by legal entities. While cultivation remains prohibited, this situation is expected to change after the second half of 2025.

A recent Superior Court of Justice order has mandated that the Brazilian government publish regulations concerning cannabis cultivation, with the deadline for compliance set for May. This regulation on medicinal cannabis cultivation is highly anticipated in the Brazilian market, not only by pharmaceutical companies but also by research institutions in fields like healthcare and agriculture. It is expected that once cultivation is authorised, the cannabis market will see significant growth due to the reduction in costs associated with importing raw materials.

[Studies](#) indicate that in 2024, the medicinal cannabis market grew by 22% compared to 2023, reaching a total of BRL852 million in revenue

in just the last year. This market is continually evolving.

Innovation in the Healthcare Sector – Regulatory Sandbox

The emergence of new business models and innovative technologies in the healthcare sector has created a need for ANVISA to lose certain regulations to enable the development of these groundbreaking solutions.

This need has led to the creation of “*regulatory sandbox*”, a type of “*experimental regulatory environment*”, where companies will receive a temporary licence from ANVISA to develop and test experimental techniques and technologies through a simplified process.

ANVISA’s sandbox will cover a wide range of healthcare products (medications, cosmetics, medical devices), and it represents a valuable tool for developing and testing innovations, including Software as a Medical Device (SaMD).

The first project to be launched in ANVISA’s regulatory sandbox will focus on personalised cosmetics, which are products whose formulation, characteristics, or presentation are tailored at the point of sale to meet the specific needs of each consumer.

Though still a new and challenging area, this initiative presents an excellent opportunity to explore solutions that currently challenge existing regulations but promise substantial benefits for the healthcare sector. There is high anticipation for the inclusion of SaMD projects in the experimental regulatory environment, which would allow solutions already in use internationally to be introduced to the Brazilian market.

Leveraging Foreign Authority Evaluations for Product Registration in Brazil and Simplified Registration for Companies Within the Same Economic Group

In an effort to strengthen international co-operation, standardise approval processes, and accelerate the registration of drugs, biologics and raw materials in Brazil, ANVISA has begun to leverage evaluations from foreign regulatory authorities (reliance).

This approach significantly reduces the time required for the registration and post-registration processes with the Brazilian regulatory agency when a product has already been approved by foreign authorities.

As a result, companies that have already received approval from agencies such as the US Food and Drug Administration (FDA), the Medicines and Healthcare products Regulatory Agency (MHRA), the European Directorate for the Quality of Medicines & Healthcare (EDQM), the European Medicines Agency (EMA), Health Canada, the Swiss Agency for Therapeutic Products (Swissmedic), or the World Health Organization (WHO) gain a significant advantage when introducing the same product into Brazil.

Additionally, Brazil offers a simplified registration process for medicines that allows companies within the same economic group to register and market the same medicine under different names, with a faster approval process. This procedure is known as the “*clone registration process*”.

The clone registration process is designed for medicines that share the same manufacturer, production line, technical and clinical reports, and the same composition as a medicine already registered through the standard process in Brazil. This mechanism is widely used by economic groups that have companies dedicated to marketing only similar or generic medicines, as the time for granting a clone registration is much shorter than in the regular process.

Conclusion

The Brazilian life sciences market is already one of the most significant in the world and is constantly evolving and improving to meet emerging innovations. With an active and competent regulatory agency, Brazil’s increasing interaction with regulatory agencies from other countries is becoming more commonplace, providing greater legal certainty and confidence for domestic companies seeking to explore international markets, as well as for international companies looking to tap into the Brazilian healthcare market.

As seen, the expected expansion spans across all life sciences sectors, with notable growth in cannabis products, cosmetics, public-private partnership for the transfer of technology, and clinical research.

CHINA

Law and Practice

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Global Law Office (GLO) has become one of the largest, leading Chinese law firms, with more than 500 lawyers practising in its Beijing, Shanghai, Shenzhen and Chengdu offices. Its life sciences and healthcare practice group was one of the first in China and provides “one-stop” legal services for every area of the industry, including M&A, investment and funding, licence-in and out, daily operation, IP protection, and advice on compliance, including internal and government investigations as well

as anti-bribery matters and dispute settlement. Under a changing regulatory environment, the firm’s team has the perfect combination of international experience and local knowledge to support various innovation or pilot projects, including digital healthcare and MAH/cMAH trial cases. The team participates in the formulation of local codes of conduct and benchmark policies/rules and also co-operates closely with associations such as the CPIA and the RDPAC.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary statute regulating pharmaceuticals in the People's Republic of China (the "PRC") is the Drug Administration Law (the "DAL"). Together with its implementing rules, the DAL governs various drug-related activities, including drug development, registration, manufacturing and distribution.

In order to address statutory requirements under the DAL, good practice (GxP) rules on laboratory, clinical trials, manufacturing, distribution and pharmacovigilance have also been enacted, as well as administrative measures on drug registration, manufacturing, distribution and recall, etc. Product-specific laws, rules and guidelines, such as the Vaccine Administration Law and the Administrative Measures on Blood Products, also apply to the respective products.

The draft Medical Devices Administration Law (the "MDAL Draft") was released for public comment on 28 August 2024. The MDAL Draft introduces chapters related to medical device standards and classification, R&D, import and export and use to emphasise the life cycle management of medical devices. It is noteworthy that the content of the MDAL Draft is subject to further revisions and reviews and upon the official release of the final document, the Medical Devices Administration Law (the "MDAL") will be the first basic law in the PRC to regulate medical devices, with its legal hierarchy higher than the effective Regulations for the Supervision and Administration of Medical Devices (the "RSAMD"). The development, registration/filing, manufacturing and distribution of medical devices are, like pharmaceuticals, regulated by GxP rules and administrative

measures. Product-specific rules and guidelines have also been released and implemented.

Furthermore, the Administrative Measures on the Registration and Record-filing of Medical Devices (the "*Device Registration Measures*") and the Administrative Measures on the Registration and Record-filing of In Vitro Diagnosis (IVD) Reagents were released to update and specify the regulatory procedure and requirements for medical device and IVD reagent registration and filing, respectively.

Regulatory Bodies

State Administration for Market Regulation (SAMR)

The SAMR is the national authority for the market supervision, administration and law enforcement of pharmaceuticals and medical devices, in the areas of anti-monopoly, product quality safety, food safety, fair competition and commercial bribery, the issuance of business registrations, and certifications and accreditations, among others.

National Medical Products Administration (NMPA)

As a national bureau operating under the supervision of the SAMR, the NMPA regulates the registration, post-market risk management, administration of safety and quality, formulation of industrial/national standards, and supervision and inspection of pharmaceuticals and medical devices.

The NMPA also supervises permit/filing receipt issuance and law enforcement on pharmaceuticals and medical devices on the provincial level, while the local administrations for market regulation (the "AMR") are in charge of certain permit issuance and law enforcement on pharmaceu-

ticals and medical devices at city and county levels.

National Health Commission (NHC)

The NHC is mainly responsible for national health policies, reform of the medical and healthcare system, disease prevention and control, national drug policies and the national basic drug system. It supervises the National Administration of Traditional Chinese Medicine and the National Disease Control and Prevention Administration.

National Healthcare Security Administration (NHSA)

The NHSA is mainly responsible for the preparation and implementation of regulations and policies related to basic medical insurance (BMI), including policies regarding reimbursement, pricing and procurement for pharmaceuticals and medical services.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

The decisions of the regulatory bodies that apply and enforce pharmaceuticals and medical devices regulations can be challenged through an administrative review or administrative litigation. These procedures also apply in general vis-à-vis administrative regulatory bodies for other regulated products.

Administrative review is a procedure to challenge regulatory body decisions. If the decisions made by the reviewing body are unacceptable, a lawsuit before the court could be filed, unless the administrative review decisions are final as prescribed by law. Alternatively, proceedings may be instituted directly with a court, except in certain circumstances in which an administrative review must first be applied for. Once the

court accepts the case, no further administrative review can be sought.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

The DAL classifies drugs as prescription drugs and non-prescription (over-the-counter or OTC) drugs under different supervision requirements. A patient must present prescriptions when purchasing prescription drugs, while OTC drugs can be bought without prescriptions. China further subdivides OTC drugs into Class A and Class B, according to their safety level.

Medical Devices

The RSAMD classifies medical devices into three classes according to their risk levels and expected purposes, structural features, methods of use and other qualities. Class III medical devices have the highest risk level and their safety and effectiveness should be ensured through strict controls.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The DAL and the Administrative Measures for Drug Registration establish the primary principles and statutory requirements for clinical trials. Guidance and technical review standards such as the Good Clinical Practice (GCP) for Drug Trials and the Pharmaceutical Research Information Guide for Phase III Clinical Trials of Innovative Drugs (Chemical Drugs) provide guidance detailing the obligations of the parties involved, operational procedures, technical requirements, etc.

In June 2024, the Centre for Drug Evaluation (the “CDE”) released the Technical Guidelines for the

Evaluation of Adverse Event Relatedness in Drug Clinical Trials (“*Trial Implementation*”) to provide a reference for sponsors, investigators, regulatory agencies and other relevant personnel in conducting surveillance, identification, assessment and control of adverse reactions in drug clinical trials. For clinical trial institutions, the Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (“*Trial*”) tailor the rules on supervising compliance with the GCP for drug trials and other relevant rules by the institutions in the process of filing and clinical trials.

The Administrative Measures stipulate that provincial medical products administration (MPA) may employ various inspections to supervise clinical trial institutions. The MPA will require those institutions found to be non-compliant to suspend any new clinical trials for drugs. Notably, the NMPA issued new regulations in 2024 to optimise the review and approval procedures for clinical trials of innovative drugs, including reducing the standard review period to 30 days, and launched pilot programmes in Beijing and Shanghai.

The Frequently Asked Questions on Rapid Reporting of Safety Data during Drug Clinical Trials was updated to version 2.0 in 2023, aiming to align with the relevant International Council for Harmonisation regulations.

Likewise, the RSAMD and the Device Registration Measures set out the legal framework on whether and how clinical trials of medical devices should be conducted, while an array of review standards and guidance, such as GCP for medical devices trials, further specify operational guidance and technical requirements for conducting clinical trials. For clinical trial institutions, in line with the regulatory approach for drug clinical trials, the NMPA issued regulations on the

supervision and inspection of medical device clinical trial institutions in June 2024. For clinical trials for IVD reagents, the NMPA provides special principles with a separate guideline.

The Trial Measures for the Review of Sci-tech Ethics Clinical requires that entities engaged in the life sciences, medicine and other scitech activities set up a scitech ethics review committee to assess the scitech ethics risks, conduct an ethical review, etc. As such, clinical trials for drugs and medical devices must comply with the relevant ethical review requirements.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical trials for drugs are generally required before the sponsor applies for marketing authorisations, unless otherwise exempted by law (such as certain generic drugs and IVD). A clinical trial must be authorised by the CDE of the NMPA before its implementation. The general steps for securing pharmaceutical clinical trial authorisation are as follows.

- A review by an ethical committee prior to initiation.
- A sponsor may need to apply for a pre-consultation meeting with the NMPA.
- The sponsor may conduct a clinical trial if it has not received any objection or query from the CDE within 60 days of acceptance of the clinical trial application. For pilot projects that meet the requirements, the CDE will complete the review and approval process within 30 days after receiving the application and will notify the applicants of the approval or rejection decision through its website. Applicants must wait for this notification before proceeding with subsequent work.
- If there is no objection from the CDE, the sponsor may implement the clinical trial after

the 60-day period, which will be recalculated if supplementary documents are required.

- If the CDE issues an objection, the sponsor may reply in writing concerning all issues raised by the CDE and reapply for approval of the clinical trial. The CDE will further review and determine whether to approve that clinical trial within 60 days of receiving the reapplication, and the sponsor is only allowed to implement the clinical trial upon receipt of the CDE's written approval.

Clinical trial requirements for medical devices vary according to the relevant classification. Specifically, Class I medical devices are exempted from clinical evaluations, while Class II and III medical devices may undergo clinical evaluations or clinical trials subject to their safety and effectiveness.

- Clinical evaluation: unless otherwise exempt from a list issued by the NMPA, Class II and III medical devices are subject to clinical evaluation conducted by the NMPA.
- Clinical trial: if the existing clinical literature and clinical data are insufficient to demonstrate the safety and effectiveness of a medical device, a clinical trial should be implemented instead. The MDAL Draft proposes shortening the approval period for medical device clinical trials from 60 days to 30 days.

2.3 Public Availability of the Conduct of a Clinical Trial

The Drug Clinical Trial Registration and Information Platform (www.chinadrugtrials.org.cn) hosted by the NMPA is a public database providing detailed information regarding clinical trials of pharmaceuticals for the purpose of registration. The Specifications for Drug Clinical Trial Plan Submission and Review reiterate that an appli-

cant register the drug clinical trial plan on the platform prior to conducting a drug clinical trial.

There is no publicly available database for clinical trials of medical devices in the PRC.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions on using online tools to support clinical trials. Using these tools is subject to generally applicable laws and regulations concerning personal information protection, online advertising, etc.

2.5 Use of Data Resulting From Clinical Trials

Raw data generated from clinical trials may include trial subjects' personal information, health data, genetic resources, etc.

The Personal Information Protection Law (the "PIPL") provides a legal framework for the administration of handling personal information. During clinical trials, sites, principal investigators, sponsor-designated monitors and other third parties may access trial subjects' personal information. However, sponsors will generally only receive anonymised data from the trial. Moreover, the sharing and transferring of personal data is subject to other statutory requirements, such as the receipt of data subjects' consent, restrictions on cross-border data transfer, etc. In March 2024, the Cyberspace Administration of China issued the Provisions on Promoting and Regulating Cross-border Data Flow, which refines the specific requirements for cross-border data transfer.

Human genetic resource (HGR) samples and data are governed by the Biosecurity Law and the Administrative Regulation on Human Genetic Resources (the "HGR Regulation"). Foreign parties are currently only permitted to use Chinese

HGR upon filing/approval by the HGR authority and are strictly prohibited from collecting or storing Chinese HGR in the PRC and transferring the Chinese HGR overseas. Failure to obtain the filing/approval may result in administrative liabilities or even criminal liabilities. The Implementation Rules on the HGR Regulation provide specific guidance on determining foreign parties and a more specific scope of HGR, excluding clinical data, imaging data, protein data and metabolic data from the scope of the HGR Regulation.

2.6 Databases Containing Personal or Sensitive Data

In addition to the statutory requirements set out in 2.5 Use of Data Resulting From Clinical Trials, the Guidelines for Clinical Trial Data Management issued by the NMPA set out the basic standards for the responsibility, qualification and training of parties responsible for data management, and requirements for the design of data management systems, the standardisation of clinical trial data, quality control and the assessment of clinical data.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The DAL defines “*drug*” as a substance used to prevent, treat or diagnose human diseases and intended to regulate human physiological functions, for which usage and dosage are specified for indication/primary treatment. The list of types of drugs includes traditional Chinese medicines, chemical drugs and biological products. The CDE evaluates drug marketing authorisation applications submitted by manufacturers or development institutions.

The term “*medical devices*” refers to instruments, equipment, appliances, IVD reagents and calibrators, materials and other similar or related articles (including computer software) that can be used directly or indirectly with human bodies to achieve specified purposes (such as diagnosis, prevention and monitoring) and whose effectiveness is primarily achieved by physical or other similar means rather than by pharmacological, immunological or metabolic means (or under circumstances where these latter means only serve auxiliary functions).

The Center for Medical Device Evaluation (the “*CMDE*”) of the NMPA is responsible for the technical evaluation of medical devices. The NMPA has released the Announcement on Standardising the Identification of the Classification of Medical Device Products, outlining procedures to apply for the classification of newly developed medical devices which have never been classified before or where provincial MPA finds it hard to identify the device. The NMPA has issued and been constantly updating the Medical Device Classification Catalogue, indicating its commitment to maintaining the regulatory environment with the rapid development of medical device technologies and the industry.

The following applies to products containing both a drug and a device (ie, a combination product).

- Applicants should apply for its registration as a drug if the product mainly acts as a drug, and as a medical device if the product mainly acts as a medical device.
- If the major utility of a combination product cannot be easily identified, the applicant will apply for the product attribute identification with the NMPA and submit a registration application accordingly.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Marketing authorisation applications for biologic medicinal products generally follow a similar process outlined in **3.1 Product Classification: Pharmaceuticals or Medical Devices**. Having said that, it is compulsory to conduct verification and examination on manufacturing sites and pre-market GMP inspections for biologic medicinal products being registered, while the verification and examination of other drugs is subject to the CDE's discretion.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Marketing authorisations for drugs and Class II and III medical devices are valid for five years and can be renewed for another five years. Marketing authorisations for Class I medical devices (ie, filing receipts) do not expire.

The NMPA can revoke a marketing authorisation for reasons such as:

- the conducting of clinical trials without pre-approval;
- the use of unapproved package materials or containers; and
- the use of unapproved labels or instructions, bribery, obtainment of a marketing authorisation by fraudulent means, etc.

Conversely, the NMPA could cancel the marketing authorisation if an approved product lacks effectiveness, has material adverse effects or poses risks to human health.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

There are three types of registration applications for drugs:

- drug registration applications;
- re-registration applications; and
- supplemental applications.

Drug Registration

The following steps are generally required in a drug registration:

- study prior to clinical trials;
- clinical trials;
- submission of a drug registration application;
- registration verification and examination; and
- registration inspection.

Re-Registration

This is applicable when renewing a valid drug marketing authorisation before expiry. The NMPA has promulgated detailed application procedures and documents for re-registration of drugs.

Supplemental Applications

These are generally required for changes to drugs with marketing authorisation, such as material changes in the drug manufacturing, changes related to drug effect and risks in the instructions, changes of the marketing authorisation holder (the "MAH"), registration standards, etc. Notably, when changing the MAH, the transferee must be capable of quality management, risk prevention and control, and of providing liability compensation to ensure drug safety, effect and quality control. For approved changes, the MAH may be granted a grace period of up to six months from the date of approval to implement

the change, except for changes related to drug security.

The NMPA issued the Administrative Measures for Drug Standards in 2023, requiring the MAHs to submit the proposed standards for drug registration during their applications or supplemental applications. Any change to registration standards requires a supplementary application, filing or report, depending on the risk levels.

In 2024, the General Office of the State Council promulgated certain opinions, requiring relevant authorities to improve the quality and efficiency of the review and approval of drugs and medical devices, such as shorter review and approval time, less inspection quantity and batches. Detailed measures are to be issued by the NMPA.

Medical Devices

Class II and III medical devices are administrated by the registration process, while Class I medical devices are administrated by the filing process.

The following processes are generally required to obtain a new marketing authorisation:

- submission of a technical product testing report;
- submission of the clinical evaluation for the clinical data to confirm safety and effectiveness, if required by law;
- examination of the quality management system, which will comply with good manufacturing practices;
- submission of the registration application documents; and
- regulatory review by the CMDE and the NMPA/provincial MPA.

Changes to these marketing authorisations are divided into modification registration item variations (eg, change of product specification or technical requirements) and filing item variations (eg, change of the MAH's name or address). Both currently need to be approved by the NMPA/provincial MPA. Changes to modification registration items may trigger an additional technical review by the CMDE. There is no definitive regulation to permit the transfer of the marketing authorisation of medical devices. Having said that, the MDAL Draft expressly allows the medical device registrant, namely the MAH, to transfer the registration certificate upon approval by the competent MPA, provided that the transferee is capable of quality management and risk prevention and control. It remains uncertain whether the transfer will also be allowed in the final version.

Regarding the application for Class I devices, the provincial MPA (for domestic devices) or the NMPA (for imported devices) will be provided with the filing materials, which are generally the same as those for Class II and III medical devices administrated by the registration process. The MAH must file any changes to the filing items of Class I devices with the original filing authority.

Subject to these procedures, the NMPA has required registration applications for drugs and certain medical devices to be conducted via the electronic system since 2022. In order to facilitate applicants, the CDE continues to optimise and update the software for the production of electronic application materials.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The DAL explicitly establishes an expanded access programme allowing physicians and

patients access to pre-approval, investigational drugs if the drug:

- is in a clinical trial;
- is used for diseases that threaten life but lack effective treatment;
- has potential effectiveness based on medical observations;
- usage complies with ethical principles;
- usage has been reviewed and the patient's informed consent has been obtained; and
- is only used within the clinical trial site and is used on patients outside the clinical trial setting but with similar conditions.

In addition to these requirements under the DAL, certain regions have introduced regional rules for expanded access programmes. Both Tianjin and Shenzhen have issued Regulations on the Promotion of Cell and Gene Industries, which permit expanded access programmes regarding cell and genetic drugs held in Tianjin and Shenzhen Special Economic Zone on certain grounds, such as approval for expanded clinical trials and submission of the marketing authorisation application to the CDE for these drugs.

The RSAMD also has similar requirements for an expanded access programme for investigational medical devices. Moreover, the Regulations for the Emergency Use of Medical Devices specify an emergency use system that permits the use of medical devices without marketing authorisations in public health emergencies, including implementing authorities and their responsibilities, detailed procedures for expert verification, etc.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

A drug MAH (and its local MAH deputy, if it is an overseas MAH) has the following post-marketing obligations under the DAL and relevant regulations:

- implementing a pharmacovigilance system;
- conducting regular post-market launch appraisals;
- establishing a release process for drug market launches;
- establishing and implementing a drug-tracking system; and
- establishing an annual report system.

The NMPA has promulgated Guidelines on Pharmacovigilance Inspections and Good Practice for Pharmacovigilance Systems to guide a drug MAH in establishing a pharmacovigilance system.

To refine the quality and safety management throughout the entire drug life cycle and clarify the key responsibilities of a MAH, the NMPA subsequently issued Provisions on the Supervision and Administration of Drug Marketing Authorisation Holder Implementation of the Main Responsibility of Drug Quality and Safety in 2023 to summarise relevant provisions previously scattered across the DAL and other laws and regulations.

A medical device MAH is also responsible for post-marketing obligations, including:

- establishing and maintaining a quality management system;
- setting up and implementing the post-marketing research and risk management and control plan;

- monitoring and re-evaluating medical device adverse events; and
- establishing a tracking and recall system.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The official websites for the CDE (for drugs), the CMDE (for medical devices) and the NMPA (for both drugs and medical devices) enable third-party access to certain information regarding pending, rejected and approved marketing authorisations.

Pharmaceuticals

For drugs pending approval, information such as acceptance number, drug name, drug type, application type, registration category, company name, accepted date and registration application status is publicly available on the CDE's official website. The public can also access granted marketing authorisation information such as approval number, manufacturing enterprise with production site, approved date, dosage form and specification via the relevant database on the NMPA's official website. Third parties can access refused application information on the NMPA's official website.

Medical Devices

Third parties can access less information about medical devices compared to drugs. The pending marketing authorisation information is only available to applicants. Refused marketing authorisation information for refused devices, including acceptance number, device name, the applicant and its local deputy (if it is an overseas medical device), can be accessed on the NMPA's official website. Marketing authorisation information for permitted devices is publicly available on the NMPA's official website, including the marketing authorisation number,

the MAH's name and address, the manufacturing site, the device's name, type, specifications, structure, components, applicable scope and intended use, the approval date, the effective date and modified information.

The government is prohibited from disclosing any commercial secrets (such as manufacturing processes, key technical parameters, know-how, tests and data) or personal privacy accessed during review and examination, unless the rights-holder has granted its consent or unless non-disclosure will have a material adverse effect on public interests.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The NMPA provides four kinds of special procedures to shorten the time or facilitate the registration review of drugs, as follows:

- registration for drugs with breakthrough effects;
- registration for drugs with additional approval conditions;
- fast-track registration for drugs with obvious clinical values; and
- registration for drugs that are required to confront public health emergencies.

Specifically, the CDE has issued specifications on facilitating the registration review of marketing authorisation applications for innovative drugs that are specific to children, used for the treatment of rare diseases or applicable to special procedures for drugs with breakthrough effects. These specifications clearly outline the timeframe for communications (30 days) and

registration review (130 days) for innovative drugs that fall within their scope.

Likewise, there are certain special procedures to shorten the time or facilitate the registration review of medical devices, under relevant regulations, including the following.

- A registration procedure for an innovative medical device.
- A priority registration procedure for medical devices that:
 - (a) have obvious clinical advantages for certain diseases or are in urgent clinical demand without homogeneous approved medical devices; and
 - (b) are listed in the national key R&D projects.
- An emergency registration procedure for medical devices required in public health emergencies.

4.2 Regulatory Reliance

In terms of medical products that have obtained authorisations in other jurisdictions, China has introduced special rules for the registration of these medical products to strengthen international exchanges and co-operation.

For drugs that have been authorised to market from internationally recognised jurisdictions, supporting documents (with notarised instruments and Chinese translations) proving the overseas permits for marketing should be submitted for the application for market authorisation in the PRC. Drugs that have already been marketed overseas are classified into different categories (ie, Class 5 for chemical drugs, and Class 3.1 and 3.2 for prophylactic/therapeutic biologics), and applications are submitted based on different registration classifications and declaration documents.

Overseas research information and data could be used to support drug registration in the PRC if the sources, research institutions or laboratory conditions, quality system requirements, and other management conditions are in line with the prevailing principles of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (the “ICH”), and comply with the relevant requirements for the administration of drug registration in the PRC. Compared with the general review time limit of 200 days, the review time limit for rare disease drugs with urgent clinical needs that have been marketed overseas but are yet to be marketed in the PRC would be shortened to no more than 70 days.

An application for imported medical devices is required to be submitted to the NMPA for the filing (Class I)/application for review (Class II and Class III). Supporting documents are also of the essence when submitting the application to prove that competent authorities permit the marketing of these medical devices. In terms of the timeframe for acceptance, technical review, verification and approval of registration, there is no specific process for accelerated approval for the filing/registration of imported medical devices.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceutical manufacturing plants are required to obtain drug manufacturing licences, even for MAHs that lack manufacturing capac-

ity and outsource manufacturing work to other manufacturers. In the event of outsourcing the manufacturing and/or sub-packaging, the manufacturing enterprise that carries out the manufacture and/or sub-packaging also has to obtain the corresponding manufacturing licence, which is valid for five years and is renewable for another five years and six months before it expires.

To further implement the responsibility of MAHs in ensuring the quality and safety of outsourced drug manufacturing, since October 2023 the NMPA has imposed more stringent and detailed requirements in terms of licensing, quality management and supervision of outsourced drug manufacturing. The NMPA has developed corresponding on-site inspection guidelines, which ensure that MAHs and manufacturing enterprises have more detailed reference criteria. In recent years, the NMPA continuously issued drafts for comments in the regulations to supervise the manufacturing of exported drugs, outlining the fundamental compliance requirements for the manufacturing of exported drugs.

Medical Devices

In line with the Measures for the Supervision and Administration of Medical Device Production (2022 revision), the types of authorisation for medical device manufacturers differ depending on the classification of devices.

- Class I devices: the manufacturer will conduct a filing with the provincial MPA for the manufacturing of Class I devices.
- Class II and III devices: a manufacturing licence will be granted by the provincial MPA following the result of the review and on-site examination.

A filing for Class I devices does not specify the duration of authorisation, while a manufacturing

licence for Class II and III devices is valid for five years and can be renewed for another five years within 30 to 90 working days prior to expiry. To ensure the quality and safety of contract manufacturing of medical devices, the NMPA has established detailed requirements for quality management and supervision of contract manufacturing of medical devices since June 2024, which aims to fully implement the responsibilities of medical device registrants.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

In support of the revised DAL (2019), the SAMR officially implemented the Measures for the Supervision and Administration of Drug Quality in Operation and Usage in January 2024, and the NMPA issued the Announcement on Further Improving the Supervision and Administration of Pharmaceutical Distribution in April 2024. These measures further clarify the conditions, procedures and quality management requirements for obtaining a drug distribution licence.

Generally, a wholesale drug distributor must maintain a drug distribution licence, with an exception for drug MAHs that sell their drugs as a wholesaler without obtaining a drug distribution licence. The licence is valid for five years and can be renewed two to six months before expiry. The relevant provincial MPA will review the application, conduct on-site examinations and decide whether to approve it.

An application for changes to licensed matters of a drug distribution licence must be submitted to the issuing authority, which will make its decision within 15 days from the date of receiv-

ing the change application. In addition, a wholesale drug distributor must have a self-operated warehouse that is appropriate for its range of products and scale of operations.

If a wholesale drug distributor (including a MAH) is an online seller, it will report to the provincial MPA by filing an information report form.

Medical Devices

The wholesale distribution of Class I devices does not require authorisation. For Class II devices, a distributor should maintain a distribution filing receipt from the provincial MPA, which will grant receipt if all the required documents are submitted. The wholesale distribution of Class III devices requires a distribution licence from the provincial MPA, which will review the application, conduct examinations when necessary and decide whether to approve the application.

A filing receipt for Class II devices does not specify a validity period, while a distribution licence for Class III devices is valid for five years and can be renewed for another five years, subject to an application for renewal within 30 to 90 working days before expiry.

Any violations of the Quality Management Standards for the Operation of Medical Devices may lead to the revocation of the wholesale medical devices distribution licence due to the impact on product safety and effectiveness. A wholesale medical device distributor is therefore also required to comply with the revised Quality Management Standards for the Operation of Medical Devices, which officially came into effect on 1 July 2024. This includes new requirements related to the establishment and improvement of the distribution quality management system.

If a medical device distributor (including a MAH) is an online seller, it will complete the medical device online sales information form. This form requires pre-filing with the relevant provincial MPA, providing information such as the medical device manufacturing licence, the medical device distribution licence or medical device filing certificate number, etc. Any changes to the filed information should be promptly notified.

6.2 Different Classifications Applicable to Pharmaceuticals

For the different classifications that apply to pharmaceuticals (such as “*available only on prescription*”), see **1.3 Different Categories of Pharmaceuticals and Medical Devices**. Additionally, a drug retailer will not offer free prescription drugs or Class A OTC drugs for purchase or commodity.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices are subject to the Customs Law of the PRC, the DAL and various relevant regulations.

The SAMR, the NMPA, the NMPA’s designated drug test institutions, the Ministry of Commerce of the PRC (the “MOFCOM”) and China Customs all have the power to enforce relevant laws and regulations. The NMPA and its local counterparts govern the administration of the use of imported pharmaceuticals and medical devices.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of record of pharmaceuticals and medical devices is required to conduct a filing with China Customs as the customs declaration enterprise (either as a customs broker or as a consignee of imported/exported goods).

If the importer of record concurrently acts as the applicant for the NMPA's import filing (see 7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices) and port inspection for imported pharmaceuticals, it must maintain a drug distribution licence or a drug manufacturing licence (for active pharmaceutical ingredients and intermediate agents).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Prior Authorisations for Importation of Pharmaceuticals

The following require prior authorisation:

- in general, imported pharmaceuticals must obtain marketing authorisations from the NMPA prior to importation. An additional import permit issued by the NMPA is required for narcotic drugs and psychotropic drugs;
- in exceptional cases, pharmaceuticals can be imported by means of a special approval from the NMPA;
- a small number of drugs to be imported by a hospital and used for specific medical purposes due to urgent clinical needs;
- drug samples for drug registration purposes; and
- comparator drugs (except narcotic drugs and psychotropic drugs) for the purposes of drug registration or consistency evaluation of generic drugs.

Individuals bringing drugs to China for their personal use are exempted from these requirements.

Prior Authorisations for Importation of Medical Devices

The following applies:

- imported medical devices will first be filed/registered with the NMPA and obtain marketing authorisations;
- if the imported medical devices fall into the Catalogue of Products Subject to the Compulsory Product Certification System, a Chinese compulsory certification is required;
- if the imported medical devices fall into the Catalogue of Commodities Subject to the Automatic Import Licence Administration, an automatic import licence is required; and
- if medical devices are imported for emergency use, an approval from expert evaluation organised by the CMDE of the NMPA is required.

To meet peoples' needs for pharmaceuticals and medical devices, more and more policies have been issued by local governments to optimise import approval procedures for designated medical institutions to apply for drugs and medical devices in urgent clinical needs, such as nine cities in the Guangdong Province-Hong Kong-Macao Greater Bay Area, Beijing and Hainan Boao Lecheng International Medical Tourism Pilot Zone. A tax exemption is also applicable.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The importation of drugs or medical devices is subject to registrations/permits, compulsory national or industrial standards and specific regulations. To guarantee the public's safe use of pharmaceuticals and medical devices, the laws

and regulations specify several reasons for prohibiting importing, including but not limited to:

- uncertain curative effect;
- serious adverse reaction;
- harm to the human body;
- expired;
- invalid;
- obsolete; or
- used.

7.5 Trade Blocs and Free Trade Agreements

China has signed and acceded to various trade blocs and free trade agreements, including the Regional Comprehensive Economic Partnership, the Framework Agreement on Comprehensive Economic Cooperation with ten members of the Association of South-East Asian Nations, the Preferential Trade Agreement (the Asia-Pacific Trade Agreement) and 18 bilateral free trade agreements (FTAs). Based on the official website of the China FTA Network, several other FTAs are also being negotiated and considered.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

The prices of most drugs are mainly determined by market competition, while the prices for narcotic drugs and Class I psychotropic drugs that are listed in the Central Pricing Catalogue are capped by the government.

Nonetheless, government policies may have a significant effect on the pricing of drugs. For example:

- prices for drugs reimbursed by the BMI funds are determined by authorities, including the NHSA, and prices for certain drugs covered by the BMI funds are fixed through negotiations between the NHSA and suppliers thereof;
- the government centralised procurement, which offers strong bargaining power to the procuring side, gives a favourable procurement price to hospitals and drug stores participating in centralised procurement, and may set pricing rules for manufacturers and wholesalers;
- the “two-invoice system” eliminates multi-tiered distribution channels and lowers drug prices; and
- the enforcement of “zero mark-up policy” means that public hospitals may not add any mark-up when selling drugs to patients.

Medical Devices

There is no nationwide regulation or policy specifically and directly controlling the pricing of all medical devices. However, the pricing of medical devices may be significantly influenced by the following regulatory factors:

- the pricing of certain medical devices is indirectly restricted because national and local rules limit the amount that a public hospital may charge patients for medical services, and the cost of medical devices used in these services may be included in those charges;
- the procurement of certain costly medical devices by hospitals is strictly controlled by planning at the central and provincial levels; and
- centralised procurement, the “two-invoice system” and the “zero mark-up policy” may also be applied to the procurement of certain high-value medical consumables by public hospitals, etc.

8.2 Price Levels of Pharmaceuticals or Medical Devices

PRC law does not require the prices of pharmaceuticals and medical devices to be benchmarked or otherwise set in reference to the prices of the same products in other countries. However, the NHSA does monitor drug prices at home and abroad for the purpose of making timely warnings of any abnormal changes to drug prices and supply. Prices in other countries might also be used as reference points during negotiations between the NHSA and drug suppliers with respect to BMI funds coverage.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Pharmaceuticals

The NHSA and the Ministry of Human Resources and Social Security (the “MOHRSS”) jointly issued the latest version of the National Reimbursement Drug List (the “NRDL”) in 2024. Under the NRDL, pharmaceuticals are classified into Class A and Class B, with each class being reimbursed differently by the BMI funds. Patients assume full costs for drugs excluded from the NRDL.

The latest effective NRDL, officially implemented on 1 January 2025, reiterates that all provincial authorities will implement the same NRDL with limited exceptions, including ethnic medicines, preparations of medical institutions and Chinese medicine tablets.

Medical Devices

Medical consumables may be considered “*diagnosis and treatment items*” or parts of these items for BMI funds reimbursement purposes. Certain local healthcare security administrations at the provincial level have promulgated effec-

tive lists of medical consumables that local BMI funds can reimburse.

At the end of 2024, the General Office of the State Council issued the Opinions on Comprehensively Deepening the Reformation of Pharmaceuticals and Medical Devices Supervision and Promoting the High-Quality Development of the Pharmaceutical Industry, providing guidance on studying and standardising the lists of medical consumables and medical service for medical insurance, and incorporating eligible innovative drugs and medical devices into the medical insurance coverage.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Pharmaco-economic analysis would be employed when assessing which drugs are to be included in the NRDL and the price for NRDL negotiations. Pharmaco-economic materials may be required to be submitted by applicants to add a drug into the NRDL or to adjust its reimbursement coverage.

A cost-benefit analysis would also be considered when assessing which medical consumables are to be covered by BMI funds.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Physicians and pharmacists must follow the principles of safety, effectiveness and economy when issuing or dispensing prescriptions.

A physician may decide what drugs are to be prescribed based on the physician’s professional judgement that the prescription is rational and appropriate to a patient’s condition. In no event will the prescription be formulated by artificial intelligence (AI). The quantity of drugs a physician may prescribe is specifically limited for each

prescription, to avoid wasting medical resources or taking advantage of the BMI funds.

Government policies may affect or guide a physician's prescription decisions.

- The BMI funds indirectly require physicians to consider the BMI budget when prescribing drugs and to use medical consumables reimbursed by the BMI funds.
- Hospitals are required to prioritise drugs and medical consumables that are centrally procured.
- Diagnosis-related group (DRG) payment methods and the big data diagnosis-intervention package (DIP) are aimed to be fully implemented and expanded to all medical institutions by the end of 2025 and will pressure hospitals to control medical expenses so may influence physicians' prescription behaviours. The NHSA is building an intelligent monitoring system for BMI fund supervision of the DRGs and DIP payment methods.
- Local authorities of the NHSA, along with other departments, conduct examinations of the

use of BMI funds through diverse inspections, such as daily supervision, special inspections, joint inspections, unannounced inspections and inspections based on whistle-blowing. The increasingly severe punitive measures imposed on designated medical institutions and drug retailers contracting with the agencies of the BMI, as well as the mechanism and rewards for reporting noncompliant use of BMI funds, aim to restrain fraudulent activities in the use of BMI funds. The special rectification campaign to crack down on BMI fund fraud led by the NHSA focuses on acts of obtaining insurance benefits in a deceptive manner and monitors how the BMI funds are reimbursed on key drugs and medical consumables with top billing.

A pharmacist will dispense prescription drugs according to a physician's prescription. The examination of a prescription by an eligible pharmacist focuses on the appropriateness, rationality and correctness of a drug's use, rather than economic considerations.

Trends and Developments

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Han Kun Law Offices

Han Kun Law Offices is a leading full-service law firm in China, with over 800 professionals located in eight offices in Beijing, Shanghai, Shenzhen, Haikou, Hong Kong, Wuhan, Singapore and New York City. The firm's main practice areas include: private equity; mergers and acquisitions; international and domestic capital markets; investment funds; asset management; antitrust/competition; banking and finance; aviation finance; foreign direct investment; compliance; private client/wealth man-

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Introduction

In 2024, China's pharmaceutical industry entered a recovery phase, marking a rebound from a period of stagnation. Despite the continued cautious attitude of investors and the tightened regulations surrounding initial public offerings (IPOs), the industry began to show promising signs of revival. Notably, the development of antibody-drug conjugates (ADCs) and bi-specific/multi-specific antibodies emerged as focal points of pharmaceutical innovation where China's pharmaceutical industry has demonstrated remarkable capabilities in engineering innovation and operational efficiency.

Pharmaceutical Industry Transactions in 2024 IPOs

In 2024, the pharmaceutical industry continued to experience a decline in IPOs. Only five pharmaceutical companies were listed on the Chinese A-shares market, compared to 22 in the previous year, the lowest number since 2008. Additionally, at least 24 pharmaceutical companies announced the withdrawal of their IPOs or the suspension of the IPO review process. The slowdown was primarily due to stricter regulatory scrutiny, with a focus on financial perfor-

mance, promotional expenses and technological innovation. These developments indicate a shift toward increasing regulatory complexity within the industry due to more rigorous market entry standards.

VC/PE financing

In 2024, securing VC/PE financing in China's primary market became even more challenging, with companies likely to attract funding limited to those in high-growth fields or holding leading market positions. Throughout the year, a total of 652 companies completed financing rounds in the primary market, of which 550 disclosed their financing amounts. The cumulative financing reached RMB51.315 billion, representing a 35% decline from RMB79.203 billion in 2023.

The average financing amount per deal stood at RMB93 million, a 15% decrease from the RMB109 million in 2023. Most financings in 2024 were concentrated in early funding rounds, particularly around Series A. The combined proportion of seed, Series A and Series B financing events accounted for 82.4% of all deals. Investors showed a greater preference for early-stage

investments, aiming to reap higher returns when the market recovers.

License-in/out

In 2024, innovative Chinese drug companies continued to achieve remarkable milestones in license-out transactions, setting new records in both the number of deals and the total transaction value. A total of 76 license-out deals were concluded, which is three times the number of concurrent license-in deals (26 deals). In terms of transaction amounts, from January to October 2024, the upfront payments for license-out deals amounted to approximately USD3.16 billion, with the total transaction value reaching USD51.1 billion. This figure surpassed the total amount of license-out deals for the whole of 2023.

Half of the license-out transactions (38 deals) were related to antibodies and conjugated drugs, with a particular focus on bi-specific antibodies and ADC drugs. Meanwhile, the cell and gene therapy drug area witnessed a total of five license-out transactions, which is expected to emerge as another promising subsector for innovative Chinese drug development, with the potential to gain global market recognition in the future.

Multinational corporations (MNCs) have become the primary purchasers in license-out transactions. The 24 deals involving MNCs accounted for 55.4% of the total license-out transaction value and 71.5% of the total upfront payments. This trend underscores the recognition by MNCs of the robust R&D capabilities of innovative Chinese drug companies. As a result, innovative Chinese drug assets have become a crucial source for MNCs to sustain and enhance their own innovative capabilities.

Newco model

The newco model, which gained significant industry attention in 2024, has emerged as a novel pathway for innovative Chinese drug companies to expand globally. The newco model involves granting the overseas rights of a Chinese company's core products to a newly established overseas entity (ie, a newco), while simultaneously introducing overseas funds and assembling an international management team, with the ultimate goal of exiting through the newco's overseas listing, merger or acquisition.

In May 2024, Hengrui Pharmaceuticals launched the first notable newco transaction in the Chinese market, by licensing the global rights of its GLP-1 product portfolio outside the Greater China Region to Hercules CM, a company jointly funded by Bain Capital and other investors. Beyond the approximately USD6 billion in upfront payments, milestone payments and sales milestone payments, Hengrui Pharmaceuticals also acquired a 19.9% stake in Hercules CM.

From May to November 2024, six newco transactions took place, with a total transaction value of USD8.23 billion and a combined upfront payment of about USD200 million. With market participants actively exploring the potential of the newco model, it is anticipated that this will become one of the predominant models for cross-border co-operation and transactions in the coming years.

Mergers and acquisitions

With the tightening of domestic IPOs and policy support from Chinese authorities, mergers and acquisitions are gradually emerging as the preferred exit strategy in the Chinese market. In 2024, 35 domestic merger and acquisition (M&A) events occurred in the pharmaceutical

industry, involving a total transaction amount of RMB112.58 billion. M&A activity in 2024 was predominantly characterised by reorganisations within industry chains, with a notable trend being the acquisition of innovative drug assets by major pharmaceutical companies. Out of the 35 M&A events in 2024, ten involved the acquisition of innovative biotechnology start-ups, and the transaction amounts of these ten events accounted for 61.1% of the total disclosed M&A transactions.

Regulatory Trends

In 2024, the Chinese regulatory authorities introduced a series of pivotal updates to laws and regulations in the life sciences sector. Key changes included easing some of the key restrictions on foreign investment, the nationwide implementation of regulations on investigator-initiated trials (IIT), updated human genetic resource (HGR) regulations, and enhanced oversight of drugs and medical devices.

China initiated pilot programmes to gradually ease foreign investment restrictions in the life sciences sector in 2024. On 8 September 2024, three governmental bodies in China jointly issued the Notice on Carrying Out Pilot Programmes to Expand Opening-Up in the Healthcare Sector. The Notice permits foreign-invested enterprises to participate in the development and application of stem cell, gene diagnosis and therapeutic technologies in four free trade zones (FTZs) or ports in Beijing, Shanghai, Guangdong and Hainan. This initiative is expected to stimulate growth and international collaboration in numerous industries including iPSCs, CAR-T, TCR-T, CAR-NK, TILs, mRNA, gene sequencing and IVD/LDT. More detailed measures in the FTZs are expected to be introduced soon.

Regarding IITs, the release of the Measures for the Administration of IITs (the “*IIT Measures*”) in 2024 marked a new phase in China’s IIT regulations. Under the IIT Measures, all IITs are required to only use marketed drugs approved by the National Medical Products Administration (the “*NMPA*”), except for IITs of stem cells and somatic cells. The IIT Measures apply nationally, in contrast to pilot regulations implemented in 2021 in selected regions (the “*Pilot Regulations*”). The IIT Measures further simplify the process for initiating observational studies and strengthen the role of clinical research management committees while retaining many key provisions from the Pilot Regulations, including IIT protocol signing requirements and research filing.

In terms of the updates to the HGR Regulations in 2024, the State Council issued an order to amend the Administrative Regulations of HGRs to designate the National Health Commission (the “*NHC*”) as the regulatory authority for HGR, replacing the Ministry of Science and Technology. These amendments highlight that HGR remains China’s key regulatory focus. In January 2025, the administrative guidelines for HGR approval and filing requirements were further amended, reflecting ongoing refinements in regulatory implementation.

In 2024, the State Council issued its Opinion on Deepening Drug and Medical Device Regulation Reform to Promote High-Quality Development of the Pharmaceutical Industry, focusing on improving regulatory efficiency, supporting innovation and strengthening compliance. It also advocates for extending the data protection period, enhancing the market exclusivity system, shortening clinical trial approval timelines and optimising the import approval process for drugs and medical devices.

In addition to these key regulatory updates, there have been other regulatory highlights for drugs and medical devices, respectively as follows.

Drug highlights

In 2024, several regulations were introduced to strengthen the marketing authorisation holder (MAH) system. For example, to strengthen compliance enforcement for MAHs of imported drugs, the NMPA issued the Interim Provisions on the Administration of Domestic Responsible Entities Designated by Overseas MAHs, providing specific obligations and procedural requirements for MAH domestic responsible entities.

Several regulations were also released to regulate the manufacture and promotion of drugs. In April 2024, the NMPA issued the Announcement on the Optimisation of Registration Application Procedures for the Transfer from Overseas Manufacture to Domestic Manufacture for Marketed Drugs in China. The Announcement provides a feasible pathway to localise the production of imported drugs and clarifies the requirements for these transfers.

For the manufacture of biological products, the NMPA released the Pilot Work Plan for Segmented Production of Biological Products in October 2024, suggesting the feasibility of cross-provincial and cross-border production of some specific biological products. With respect to promotions, the NMPA released the Draft Measures for the Administration of Pharmaceutical Representatives in November 2024, which would regulate the conduct of pharmaceutical representatives and ensure compliance for promotional activities in pharmaceutical academic settings.

China also released multiple guidelines to address anti-monopoly issues in the pharmaceutical industry. In August 2024, the State Admin-

istration for Market Regulation (the “SAMR”) issued the Draft Anti-Monopoly Guidelines for the Pharmaceutical Industry, which aim to prohibit monopolistic practices and promote fair competition specifically within the pharmaceutical market.

Medical device highlights

China made significant breakthroughs and landmark developments in the medical device regulatory framework in 2024. In August, the NMPA released the draft Medical Device Administration Law (the “draft MDAL”) for public consultation. This is a remarkable milestone, which has been achieved within one year of its inclusion in China’s legislative agenda. The draft MDAL introduces several significant reforms, including establishing clear pathways for medical device marketing approval transfers, strengthening oversight of domestic responsible entities, streamlining clinical trial approval processes and proposing the establishment and enhancement of a vigilance system.

China has also updated its regulations for innovative medical device importation. In July 2024, the NMPA and the NHC issued the Announcement on the Temporary Import and Use of Clinically Urgent Medical Devices for Medical Institutions. This Announcement establishes and refines a nationwide framework for the importation of clinically urgent medical devices, while also integrating insights from local pilot programmes. It has paved the way for the temporary importation of medical devices that lack equivalent products marketed in China, facilitating the entry of innovative solutions into China.

As for the regulations covering medical device clinical trials, in March 2024, the NMPA released the Regulations on the Supervision and Inspection of Medical Device Clinical Trial Institutions

(For Trial) (Draft for Comment) and the Key Points and Determination Principles for the Supervision and Inspection of Medical Device Clinical Trial Institutions (Draft for Comment). The two drafts provide comprehensive guidance on the stringent inspection criteria and procedures for clinical trial institutions. Once finalised, they are expected to significantly strengthen regulatory oversight and improve the integrity of medical device clinical trials.

Compliance Practices

Following the stringent anti-corruption measures in 2023, rectification actions in the pharmaceutical industry continued to intensify in 2024. From legislation to enforcement, these efforts underscore China's determination to combat corruption in the life sciences and healthcare industries.

Commercial bribery in life sciences and healthcare

In 2024, Chinese regulators remained keenly focused on anti-bribery and anti-corruption, publishing a number of documents to maintain strong oversight of commercial bribery in the life sciences and healthcare sectors and to provide further compliance guidelines.

Effective 1 March 2024, the Amendment (XII) to the Criminal Law of the People's Republic of China adopted a more severe stance toward bribery in the healthcare sector. It explicitly outlined standards for "*aggravated penalties*" under various circumstances, with the maximum penalty against the offenders being life imprisonment.

On 11 October 2024, the SAMR issued the Guidance on Preventing Commercial Bribery Risks for Pharmaceutical Enterprises (Draft for Comment). On 10 January 2025, the Guidance on Preventing Commercial Bribery Risks for Pharmaceutical Enterprises (the "*Guidance*") was officially

released by the SAMR and took effect immediately. The Guidance aims to assist pharmaceutical and medical device enterprises in effectively preventing and addressing commercial bribery risks during their daily operations, ensuring compliance with relevant laws and regulations.

On 25 December 2024, the Standing Committee of the National People's Congress released the draft Anti-Unfair Competition Law of the PRC (the "*2024 Draft*") for public comment. The 2024 Draft would make significant revisions regarding commercial bribery, emphasising prohibitions against accepting bribes. Additionally, it would increase the maximum fine for commercial bribery from RMB3 million to RMB5 million and introduce personal penalties for legal representatives, primary executives and directly responsible personnel of entities engaging in commercial bribery. The 2024 Draft would also add provisions for administrative penalties for those who offer bribes.

Meanwhile, anti-corruption enforcement and judicial actions in the pharmaceutical industry were strengthened nationwide in 2024. This again emphasises that both recipients and offerors of the bribe may be subject to punishment.

On 27 May 2024, the NHC, the SAMR, the Ministry of Public Security, the National Audit Office and ten other departments jointly issued the Key Work Points for Rectifying Malpractices in the Procurement and Sales of Pharmaceuticals and Medical Services in 2024. This document specifically targets illegal activities such as bundled sales and "*kickback sales*" disguised as conferences, donations, research collaborations and trial promotions.

Strengthened regulation of medical insurance fund usage

On 28 February 2024, the Supreme People's Court, the Supreme People's Procuratorate and the Ministry of Public Security jointly issued the Guidance on Several Issues Concerning the Handling of Criminal Cases Involving Medical Insurance Fraud. Effective from the date of issuance, this document aims to legally punish medical insurance fraud crimes, safeguard the security of medical insurance funds and protect the legitimate rights and interests of the public with respect to medical insurance.

On 2 April 2024, the National Healthcare Security Administration (the "NHSA"), together with multiple national departments, issued the Notice on Conducting Special Rectification Work on Illegal and Non-Compliant Issues of Medical Insurance Funds, initiating a nationwide special rectification campaign targeting illegal and non-compliant issues in medical insurance funds.

In April 2024, the NHSA, along with four other national agencies, issued the Notice on Conducting Unannounced Inspections of the Medical Insurance Fund in 2024, officially launching unannounced inspections of the use of the National Medical Insurance Fund for 2024.

Intellectual Property

Continued growth in patent applications related to life sciences and healthcare

The number of invention patent applications in China continued to grow. According to national statistical reporting, by the end of 2024, the total number of patents granted in 2024 reached 1.045 million, representing a year-on-year increase of 13.5%. In 2024 a total of 67,000 patent re-examination and invalidation cases were concluded, and the number of high-value invention patents per 10,000 people in China reached 14.

Consistent with this trend, patent applications related to life sciences and healthcare in China also continued to increase. In 2024 alone, the number of published patent applications related to life sciences and healthcare (including chemical drugs, biopharmaceuticals, traditional Chinese medicines and medical devices) exceeded 252,000, including 176,000 medical device-related patent applications and 76,000 drug-related patent applications. This represents a year-on-year increase of more than 30% compared to the 58,000 drug-related patent applications in 2023.

Changes in patent examination and patent industrialisation

Guided by the principle of "quality over quantity", the government strengthened control over patent examination and prosecution procedures in 2024. For example, when examining healthcare-related patent applications, the number of citations of integrity clauses and notices identifying abnormal application behaviour significantly increased compared to previous years. This has had a significant impact on improving patent quality.

According to data disclosed by the China National Intellectual Property Administration, the patent industrialisation rate of valid invention patents held by Chinese enterprises reached 53.3%. The number of recorded patent transfer and licensing transactions throughout the year exceeded 613,000, representing a year-on-year increase of 29.9%. Among these, the number of recorded transfer and licensing transactions by universities and research institutions reached 76,000, representing a year-on-year increase of 39.1%. From January to November 2024, the total import and export value of intellectual property royalties nationwide reached RMB356.41 billion, representing a year-on-year increase of 6.6%.

Corresponding to the trend of increased patent industrialisation, the pharmaceutical industry in China completed 102 transfer and licensing deals in 2024, with a total upfront payment of USD3.16 billion and a total transaction value exceeding USD51.1 billion.

Judgments in pharmaceutical patent infringement litigation with significant impact

In 2024, China's Supreme People's Court delivered a landmark judgment in a patent infringement case involving sitagliptin metformin tablets. The Court clarified that if a generic drug manufacturer submits an application to the NHTA to include its generic drug in the national medical insurance catalogue during the patent protection period of the original drug, such an act is not considered an offer to sell. Therefore, this behaviour does not infringe upon the patent rights of the original drug manufacturer.

In contrast, in 2023, the Supreme People's Court rendered a judgment in a patent infringement case involving the online listing for sale of vildagliptin tablets. The Court held that the act of a generic drug company participating in the centralised drug procurement bidding process and listing its products online during the valid patent term of the original drug constituted an offer to sell, which infringed upon the original drug manufacturer's patent rights. The ruling explicitly stated that during the patent protection period, generic drug companies may not engage in certain sale preparation activities, such as bidding, without the permission of the patent holder.

The judgments in these 2023 and 2024 Supreme Court rulings together serve as typical cases to help clarify legal boundaries and reduce infringement disputes arising from legal ambiguity. They also demonstrate a legislative goal of balancing intellectual property protection for innovative

pharmaceutical companies and market access opportunities for generic drug companies.

Tax Concerns

As one of the most encouraged sectors in China currently, healthcare and life sciences companies may enjoy a wide range of tax incentives, mainly including the following preferential tax treatments.

High and new technology enterprises (HNTE)

The HNTE policy offers a reduced 15% corporate income tax rate (as opposed to 25% for normal enterprises). Many life sciences companies find it relatively easy to qualify for this tax incentive, although certain others may encounter difficulties, particularly Chinese subsidiaries of MNCs, due to a lack of People's Republic of China or PRC-generated IP. Over the last few years, more pharmaceutical companies, particularly biotechnology start-ups, have devoted themselves to developing first-in-class or best-in-class drug products, which places them in a better position to enjoy HNTE tax incentives.

However, in 2024, there were some notable instances where life sciences companies (including listed companies) had their HNTE status withdrawn due to compliance issues and other factors. This serves to underline the importance of legal compliance for companies that obtain this tax incentive.

R&D expense super deduction

The PRC's R&D expense super deduction policy is similar to those of many other jurisdictions, which allows an extra deduction for qualified expenditures. Life sciences companies are qualified to enjoy a 100% extra deduction by being recognised either as “*manufacturing enterprise*” or “*small and medium technology enterprise*”.

Input VAT refunds

In terms of VAT treatment, a major incentive is the input VAT refund mechanism, under which small-scale or manufacturing life sciences companies can have their qualified accumulated input VAT refunded. This is particularly beneficial for life sciences companies that incur significant input VAT out of payments due to R&D or licence activities during their early stages when they have no chance to book revenue.

From a transactional perspective, it is also important to have a proper understanding of the relevant tax implications. For example, for license-in deals, apart from the potential input VAT refunds, one of the key tax considerations is the identification of a permanent establishment for overseas licensors that plan to assign personnel to work in the PRC for the licence project. The entire revenue package of the licensor may be subject to a corporate income tax rate of 25% if it is deemed to have set up a permanent establishment in the PRC.

Tax incentives extended

Since 2023, the economic environment in the PRC has proven to be mixed. In order to promote business development, the government and tax authorities have extended many tax incentives including those designed for small and medium-sized companies. These incentives are not only applicable to life sciences companies but reduce the tax burden for start-up companies significantly as well.

License-out tax matters

In 2024, we observed more PRC-based life sciences companies license-out IP to overseas companies. Proper design of transaction structures is needed to avoid triggering a significant tax burden for these PRC-based licensors, especially with respect to foreign withholding taxes.

FRANCE



Law and Practice

Contributed by:

Emmanuelle Trombe, Anthony Paronneau, Anne-France Moreau and
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McDermott Will & Emery

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companies on complex FDA/regulatory, transactional, intellectual property and litigation matters. The team offers solid experience and creative solutions and the firm represents 75% of the top 20 biopharmaceutical companies globally.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices are governed by various pieces of legislation and regulations arising from different sources. There is no uniform body of law, although there is an increasing number of rules being set at the European Union (EU) level, which tend to harmonise – although not completely – the regime applicable across EU member states.

In France, pharmaceuticals are mainly governed by the Public Health Code, which implements and complements the EU Directive on the Community code relating to medicinal products for human use (Directive 2001/83/EC) and the EU Regulation on the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Regulation 726/2004). A new directive and regulation (collectively known as the “*EU Pharmaceutical Package*”) are currently being discussed to revise the EU regime of pharmaceuticals.

Medical devices are also governed by the Public Health Code, which implements and complements the EU regulations on medical devices (Regulations 2017/745 called “*MDR*” and 2017/746 called “*IVDR*” and, to some extent, the previous Directives). The medical device regulatory framework is also in the midst of a significant legislative reform.

Beyond the Public Health Code, relevant rules are also included in the Social Security Code, Environmental Code, and more generally the Civil Code, Commercial Code and Consumer

Code, not to forget codes of conduct and guidelines set by trade associations.

In correlation with this diversity of legislative and regulatory sources, there are also several regulatory bodies that apply and enforce these rules.

For pharmaceuticals, the European Medicines Agency (EMA) and the French National Agency for Medicines and Health Products Safety (*Agence nationale de sécurité du médicament et des produits de santé*, ANSM) would be key entities. The EMA is an EU institution and the ANSM is a public establishment under the authority of the French Ministry of Health.

With respect to medical devices, “*notified bodies*” are also essential as they are in charge of assessing compliance of medium- to high-risk medical devices prior to and post-market. These bodies are independent from central administration and must undergo a regulatory accreditation process.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions made by the regulatory bodies are primarily administrative acts that can be challenged through the following avenues.

- Administrative appeal. This involves filing an objection with the regulatory body that issued the act (*recours gracieux*) or with its higher authority (*recours hiérarchique*). This administrative appeal is a complaint addressed to the authorities asking them to change a decision they have taken, whether explicitly (eg, refusal) or implicitly (eg, lack of reply). In certain cases, this appeal may be compulsory prior to lodging a judicial claim.

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- Judicial appeal. This allows the regulatory decision to be challenged before the competent Administrative Court.

These challenge procedures also apply in general for administrative acts covering other regulated products (eg, food products).

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are multiple categories of pharmaceuticals and medical devices that are regulated differently. As health products, each of their characteristics affects the rules applicable to them.

For instance, pharmaceuticals may be subject to compulsory prescription. They require a doctor's prescription to be issued. There may also be restrictions on the prescription process itself due to the level of risk of the product (eg, limited to hospital settings or requiring mandatory particulars).

Other pharmaceuticals may be subject to optional prescription. They require a doctor's prescription only to be reimbursed by statutory health insurance (SHI). Medical devices may also be subject to optional prescription for reimbursement purposes.

In addition, there is a pharmacy monopoly on the dispensing of pharmaceuticals and certain medical devices (eg, most in vitro diagnostic medical devices). Some pharmaceuticals are offered over-the-counter, meaning that they are freely accessible by purchasers in the pharmacy, while others may only be within the pharmacist's reach. In addition, some pharmaceuticals and medical devices may only be dispensed in hospital settings.

Pharmaceuticals are regulated differently depending on (i) their preparation (princeps, generic, hybrid or biosimilar pharmaceuticals) which determines the applicable marketing authorisation procedure and delivery conditions, (ii) their reimbursement status (which notably affects advertising requirements) and (iii) their therapeutic interest (pharmaceutical companies are required to maintain a minimum safety stock for products of major therapeutic interest).

Medical devices are classified according to the level of risk they present for users, which is set by law. They are also subject to various rules depending on their intended use (eg, implantable or sterile) or composition (eg, software-based).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of pharmaceuticals and medical devices are regulated both by EU law and domestic rules.

Clinical trials of pharmaceuticals are mainly regulated by the EU Regulation on clinical trials on medicinal products for human use (Regulation 536/2014), fully applicable since January 2025.

Clinical trials of medical devices, called investigational studies or performance studies, are mainly regulated by the MDR and IVDR and complementing provisions of the Public Health Code.

Clinical trials must also comply with domestic and international guidelines, such as the ANSM Guidelines on Good Clinical Practices, the International Conference on Harmonization Guidelines on Good Clinical Practice or the Declara-

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tion of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to undertake a clinical trial of a pharmaceutical and a medical device is essentially as follows.

Pharmaceuticals

For pharmaceuticals, applications must be submitted to the ANSM via the Clinical Trials Information System (CTIS), a centralised EU-wide electronic platform introduced by the CTR, and must include all information listed in EU law.

Upon submission to the ANSM, the application undergoes a validation review completed within ten days from the date of receipt. If the application is incomplete, the sponsor is granted ten additional days to provide the missing information. Upon receiving additional documents, the ANSM has five days to review updates and notify the sponsor of validation or rejection.

Once validated, the application undergoes a scientific assessment by the ANSM and ethical assessment by the competent ethics committee in France, within 45 days. In the event of requests for additional information, the evaluation period is extended by a maximum of 31 days. For multinational trials, the scientific assessment is a joint decision among the health authorities of the involved EU member states.

The final decision is notified to the sponsor via CTIS within a maximum of five days following the later date between the scientific assessment report and the ethical assessment report.

Medical Devices

For medical devices, clinical trials are mandatory for Class III and implantable devices (unless exempt).

Applications must be submitted electronically to the ANSM, together with the documents referred to in EU law. The new application procedure under the MDR, which mandates submission via the European Database on Medical Devices (EUDAMED) using the Clinical Investigations and Performance Studies Module, is not yet applicable as the module remains non-operational. Until its implementation, national procedures remain in effect.

Upon submission, the application undergoes a validation review co-ordinated by the ANSM, completed within ten days from the date of receipt. If the application is incomplete, the sponsor is granted ten additional days to provide the missing information. Upon receiving additional documents, the ANSM and the ethics committee have five days to review updates and notify the sponsor of validation or rejection.

Once validated, the application undergoes a scientific assessment by the ANSM and ethical assessment by the ethics committee, within 30 to 65 days, depending on the category of clinical trial (which is determined primarily based on the purpose and status of the medical device). The final decision is notified to the sponsor.

2.3 Public Availability of the Conduct of a Clinical Trial

Pharmaceuticals

Since January 2025, all clinical trials on pharmaceuticals must be registered in the CTIS. Sponsors are required to submit trial results within one year of completion, after which the data is published on CTIS. Clinical trial information

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was previously available in the EU Clinical Trials Register.

Medical Devices

On the other hand, there is currently no publicly accessible database for clinical trials on medical devices. However, once the Clinical Investigations and Performance Studies module of EUDAMED becomes operational, mandatory registration will be required. This requirement will take effect six months after the module is officially declared operational, as announced in the Official Journal of the EU by the European Commission.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The use of online tools to support clinical trials (eg, for recruiting or monitoring purposes) is not fully regulated in France, although there are guidelines at the EU level. Restrictions however apply on the processing of patient data (see 2.5 Use of Data Resulting From Clinical Trials and 2.6 Databases Containing Personal or Sensitive Data).

2.5 Use of Data Resulting From Clinical Trials

Data resulting from clinical trials usually relate to both participants and investigating personnel, thereby qualifying as personal data under Article 4 of the General Data Protection Regulation (EU) 2016/679 (GDPR). More specifically, data relating to clinical trial participants often reveals details about their health status and generally falls within the category of “*data concerning health*” (GDPR, Article 4(15)), which is part of the broader classification of sensitive data.

Even when pseudonymised, such data remains classified as personal data, as pseudonymisation does not irreversibly prevent the re-iden-

tification of individuals, unlike anonymisation, which is the determining factor for data to be considered non-personal.

The transfer of health data to affiliates or third parties may occur under the established GDPR framework, provided that participants are informed and that the processing is based on one of the exemptions outlined in Article 9 of the GDPR, which serves as the legal basis for processing sensitive health data. In the context of clinical trials, such processing generally relies either on consent or on public interest, as defined under Article 9 of the GDPR and Article 44, 3° of the French Data Protection Act (*Loi No 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés*, or LIL).

Where processing is grounded on consent, the transfer of data is permissible only if explicitly addressed in the consent form signed by the participants. Where the processing is based on public interest, the data controller must obtain prior authorisation from the French Data Protection Authority (CNIL) or adhere to a reference methodology. In addition, such authorisation or reference methodology must identify the third party or the affiliate as an authorised recipient.

When the recipient is located outside the European Union, additional requirements come into play. The data controller must ensure that the transfer is subject to an adequacy decision by the European Commission or, failing that, is governed by standard contractual clauses or binding corporate rules. Furthermore, the data controller may need to conduct an impact assessment to evaluate the adequacy of the third country's legal framework in safeguarding the rights of data subjects.

2.6 Databases Containing Personal or Sensitive Data

In addition to the usual conditions for processing of sensitive data under the GDPR and French law (see 2.5 Use of Data Resulting From Clinical Trials), databases containing personal or sensitive data can be subject to the requirements applicable to Health Data Warehouses. The CNIL considers that databases designed for facilitating secondary use of health data (eg, research, studies and in some cases, AI training), named “*Health Data Warehouses*”, qualify as autonomous health data processing and should be grounded on one of the exemptions of Article 9 of the GDPR. In practice, the legal grounds for such Health Data Warehouses are either the explicit consent from data subject or a CNIL authorisation. A standard CNIL authorisation can be granted for organisations which comply with the framework on Health Data Warehouses – however, this framework is designed for Health Data Warehouses justified by a public interest mission.

The data protection requirements imposed by GDPR can be supplemented by health law requirements, mainly from the French Public Health Code (FPHC), if the databases contain medical data. Organisations hosting personal health data collected in the course of preventive, diagnostic, care or medico-social monitoring activities (“*HDS data*”) on behalf of a data controller must hold a specific *Hébergeurs de données de santé* or HDS certification (Article L.1111-8 of the FPHC). Processing of medical information is also frequently subject to a strong duty of confidentiality (“*medical secrecy*”) under Article L.1110-4 of the FPHC.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The classification of a product as either a pharmaceutical or a medical device is determined by its intended purpose and mode of action, in accordance with EU law. In essence, classifications are as follows.

- A product is classified as a pharmaceutical product if it is intended to be used for medical purposes through pharmacological, immunological or metabolic means. This includes substances or combinations of substances used to treat or prevent diseases, restore, correct or modify physiological functions, or make medical diagnoses.
- A product is classified as a medical device if it is intended to be used for medical purposes without relying on pharmacological, immunological or metabolic means. Medical devices include instruments, apparatus, appliances, software, implants, reagents, materials or other articles used alone or in combination for medical purposes.

Some products may have characteristics of both pharmaceuticals and medical devices, known as “*borderline*”, “*hybrid*” or even “*combination*” products. In such cases, the ANSM may assess the product on a case-by-case basis to determine the applicable regulatory framework. This assessment considers the product’s intended purpose, its mode of action and the claims made by the manufacturer.

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3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

French law does not provide for specific marketing authorisation procedures for biologic medicinal products (apart from the difference in supporting scientific data).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Marketing authorisations are granted for five years for pharmaceuticals.

- They may be renewed at the end of the first five years at the request of the marketing authorisation holder, for an unlimited period unless the ANSM decides on a five-year renewal, based on a reassessment of the pharmaceutical's positive therapeutic effects in relation to the risks to patient health or public health, linked to its quality, safety or efficacy.
- They may be revoked if the product to which it relates has not been marketed for three consecutive years or if the marketing of the product already placed on the market is suspended for three successive years.

The ANSM may, in exceptional circumstances, grant a derogation from this rule:

- for public health reasons;
- when the pharmaceutical cannot legally be marketed during the period in question;
- when the pharmaceutical is exclusively intended for export to a state that is not party to the European Economic Area (EEA) agreement; or
- when the pharmaceutical is marketed in at least one other EU member state or party to the EEA, in which it has obtained an authorisation pursuant to a mutual recognition

procedure or a decentralised procedure for which France is designated as the reference member state and at least one different dosage or pharmaceutical form of this medicinal product is marketed in France.

Marketing authorisations may also be suspended or revoked if legal requirements for the authorisations are not met or are no longer met. This includes, in particular, the following reasons:

- the pharmaceutical is harmful;
- the pharmaceutical does not produce therapeutic results;
- the risk-benefit balance is unfavourable;
- the pharmaceutical does not have the declared qualitative and quantitative composition; or
- the manufacturing process does not comply with the applicable good practices.

Medical devices are subject to pre-market certification, which is valid for five years. Every medical device must bear the CE-marking following a conformity assessment with the general safety and performance requirements set out by EU law. Lower risk devices may be self-certified but medium to high-risk devices must obtain a CE certificate from a notified body to bear the CE-marking and be placed on the French market.

The notified body may narrow the scope, suspend or withdraw a certificate if the conditions for its issuance are not fulfilled or are no longer maintained.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The procedure for obtaining a marketing authorisation for pharmaceuticals and medical devices is essentially as follows.

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Pharmaceuticals

For pharmaceuticals, a marketing authorisation may be obtained through the following procedures:

- a centralised procedure to obtain an authorisation valid in all EU countries, co-ordinated by the EMA and its Committee for Medicinal Products for Human Use (CHMP), and ending with a decision by the European Commission;
- a mutual recognition procedure, which allows the extension of a marketing authorisation already granted by a member state to one or more EEA countries;
- a decentralised procedure, which allows a marketing authorisation to be granted simultaneously in two or more EEA countries on the basis of identical documentation; and
- a centralised procedure to obtain a marketing authorisation valid only for the French market.

To initiate one of these procedures, the applicant must submit an application to the competent authority (ie, the ANSM or the EMA), together with a dossier containing the information required by EU law.

The procedures for variations to the terms and conditions of a marketing authorisation are laid down in Commission Regulation (EC) No 1234/2008. These procedures differ according to the type of variation requested (variation types IA, IB and II).

- Type IA variations, which have little or no impact on the quality, safety and efficacy of the medicinal product (such as the change of contact details of the marketing authorisation holder) can be implemented even before being notified to the competent authorities (within 12 months of the implementation of the variation).

- Type IB variations (such as a change in the medicinal product name) must be notified by the marketing authorisation holder prior to implementation. The holder must wait 30 days to ensure that the variation is considered acceptable by the competent authority (by implicit authorisation) before implementing the variation.
- Type II variations (such as the addition of a therapeutic indication) require prior approval from the competent authority before implementation.

The transfer of a national marketing authorisation from one holder to another is possible and subject to the approval of the ANSM. In the case of a merger or a partial transfer of assets, the companies involved may submit an application for the transfer of marketing authorisations before the merger or transfer is finally completed. In support of their request, they must submit the letter of intent or agreement on the merger or contribution.

Medical Devices

For medical devices, these are classified into risk groups based on the risk during use, and their placing on the market requires the CE marking to be affixed to the device after the manufacturer has conducted a conformity assessment with all applicable general safety and performance requirements set out by EU law.

Manufacturers of Class I medical devices and class A in vitro diagnostic medical devices (the lowest risk class) can self-certify that their devices meet all applicable requirements. For all other Classes (and Class I medical devices that are supplied sterile, have a measuring function or are reusable surgical instruments), the involvement of a notified body is required to conduct

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the conformity assessment and issue the corresponding certificate of conformity.

In general, any variations to the approved device require a new approval by the notified body that issued the certificate of conformity, if they may affect the safety and performance of the device or the conditions of use prescribed for that device.

EU regulations do not provide for the transfer of the CE marking. The new manufacturer of the medical device must fulfil all the necessary requirements to obtain certification for the device under their own name.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The supply to patients of pharmaceuticals and medical devices that are not subject to a marketing authorisation is generally not permitted, unless they are a candidate in a clinical trial. However, derogations apply.

Pharmaceuticals

For pharmaceuticals, there are two main derogatory pathways:

- early access (*accès précoce*) for pharmaceuticals intended to treat serious, rare or disabling diseases when the following conditions are met:
 - (a) the product addresses an unmet therapeutic need;
 - (b) the product is presumed to be innovative;
 - (c) the treatment cannot be delayed; and
 - (d) the efficacy and safety of the product is strongly presumed in view of the results of therapeutic trials;
- compassionate use (*accès compassionnel*) for pharmaceuticals in specific therapeutic

indications when the following conditions are met:

- (a) the product is not the subject of research involving human subjects for commercial purposes;
- (b) there is no appropriate treatment; and
- (c) the efficacy and safety of the product are presumed with regards to the available clinical data.

Medical Devices

For medical devices, the ANSM may authorise, by way of exception, the placing on the French market of a device which does not bear the CE marking, but whose use is in the interest of public health or in the interest of patient safety or health. Some derogatory pathways exist to facilitate access by patients to innovative devices (eg, *Forfait Innovation*).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Marketing authorisation (or CE-marking) holders are bound by strict post-market surveillance obligations.

Pharmaceuticals

For pharmaceuticals, marketing authorisation holders must conduct pharmacovigilance by recording suspected adverse reactions in detail and reporting those classified as serious with the highest degree of urgency. This information must be collected and submitted to competent authorities in the form of periodic safety update reports.

The holder is also required to implement a pharmacovigilance system and, in particular, to:

- respect the good practices on pharmacovigilance;

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- have an adequate pharmacovigilance system and a risk management system;
- have a suitably qualified person responsible for pharmacovigilance in both the EU and France;
- monitor the results of risk mitigation activities;
- monitor pharmacovigilance data; and
- conduct periodic audits of the pharmacovigilance system.

The ANSM may also require the MA holder to conduct:

- a post-authorisation safety study if there are concerns about the safety risks posed by an authorised product; and
- a post-authorisation efficacy study when the understanding of the disease or clinical methodologies indicate that previous efficacy assessments may need to be significantly revised.

More generally, the holder must contribute to the product's proper use, in particular by ensuring that it is prescribed in accordance with its MA. In the event of prescriptions that do not comply with proper use, it must take all appropriate measures to inform health professionals and immediately inform the ANSM.

The holder is further required to inform the ANSM immediately of any prohibition or restriction imposed by the competent authority of any country in which the product is marketed and of any other new information that may influence the evaluation of the benefits and risks.

Lastly, the holder must immediately inform, specifying the reasons, the ANSM of any action taken in France or in another EU member state to suspend or terminate the marketing of the medicinal product, to request the withdrawal of

the authorisation or not to apply for the renewal of the authorisation for the medicinal product.

Medical Devices

For medical devices, economic operators and in particular manufacturers are required to submit vigilance reports to the ANSM for all the incidents of which they have become aware in France involving their devices.

Manufacturers must also take appropriate safety action when required and communicate on all the corrective actions that have been undertaken to avoid or reduce the risks associated with the use of a medical device.

In addition, manufacturers of medical devices are subject to a number of obligations under the EU legislation, such as keeping the technical documentation of the device up to date, appointing a person responsible for regulatory compliance and complying with vigilance reporting obligations.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Third parties may access certain pieces of information about pending applications for marketing authorisations for pharmaceuticals and medical devices.

Pharmaceuticals

At the EU level, the EMA issues every month a list of “*pharmaceuticals under evaluation*” by the CHMP.

At the national level, pending applications for marketing authorisation are not made publicly available. Third parties only have access to information on pharmaceuticals published by the ANSM on the database *Répertoire des*

spécialités pharmaceutiques and the relevant documents (ie, the summary of product characteristics and the patient information leaflet). Otherwise, the ANSM publishes the summary report of the assessment carried out for each new medicinal product as well as the decisions to grant, suspend or withdraw marketing authorisation. The ANSM also publishes the agendas and minutes, with details and explanations of votes (including minority opinions), of the meetings of its commissions, committees and expert collegial bodies, excluding any information covered by business or medical secrecy.

Medical Devices

For medical devices, information may be publicly accessed via EUDAMED, which is currently being deployed by gradual roll-out. Once fully functional, EUDAMED will ultimately be composed of six modules:

- actor module;
- unique device identification (UDI) and device module;
- notified bodies and certificates module;
- market surveillance module;
- vigilance and post-market surveillance and vigilance module; and
- clinical investigations and performance studies module.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The French regulatory framework does not specifically foresee fast-track registration routes for pharmaceuticals and medical devices. Only pharmaceuticals subject to the centralised procedure (at EU level) may benefit from expedited reviews, namely those of major public health

interest for public health and therapeutic innovation or those addressing diseases with a high unmet need, based on less comprehensive clinical data than normally required.

4.2 Regulatory Reliance

France has not exactly embraced the notion of regulatory reliance.

Nevertheless, the ANSM is participating in pilot programmes of mutual regulatory reliance managed by the EMA designed to assess the impact of using the results of regulatory inspections carried out by the regulatory authorities of third countries that are members of the Pharmaceutical Inspection Co-operation Scheme and by the United States Food and Drug Administration.

Moreover, the EU has entered into a number of mutual recognition agreements with non-EU countries that define the conditions under which the EU member states will accept conformity assessment results (such as testing or certification) performed by conformity assessment bodies designated by another non-EU member state and vice versa.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing plants of pharmaceuticals are subject to an authorisation, while plants manufacturing medical devices are generally not.

Pharmaceuticals

Manufacturing plants of pharmaceuticals must be licensed as pharmaceutical establishments

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(*établissement pharmaceutique*) by the ANSM. Any company that includes at least one pharmaceutical establishment must be owned by a pharmacist or a company in which a pharmacist participates in the management or general direction.

- Manufacturers must submit a detailed application covering all manufacturing operations, including raw material procurement, production, quality control, batch release, and storage, in compliance with Good Manufacturing Practices (GMP).
- Applications must be submitted via an online platform (*Démarches Simplifiées*). The ANSM reviews the application and conducts an on-site inspection. If all regulatory requirements are met, the authorisation is granted and published in the EudraGMDP database. If the Director General of the ANSM does not issue a decision within 90 days of receiving the application, the request is automatically considered denied by default.
- Each authorisation is issued per facility, requiring separate applications for each production site. However, a single authorisation may cover multiple manufacturing activities within the same establishment.
- The authorisation remains valid indefinitely, provided the facility complies with GMP regulations and updates its authorisation in case of major modifications. In cases of non-compliance with the applicable regulations, the ANSM has the authority to suspend or revoke the authorisation.
- Each manufacturer must also appoint a qualified person (*pharmacien responsable*) responsible for ensuring continuous compliance with quality and safety standards.

Medical Devices

Manufacturing plants of medical devices are generally not subject to prior authorisation, but they are required to register themselves on EUDAMED. However, pending the full operability of EUDAMED, manufacturers can use a national form provided by the ANSM. In this case, national declarations are only valid in France. Manufacturers of custom-made medical devices must also declare their activity to the ANSM before making such devices available on the national market. This declaration must include details of the type of activity performed and the devices concerned.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

The establishments engaged in wholesale of pharmaceuticals are subject to an authorisation, while those engaged in wholesale of medical devices are generally not.

Pharmaceutical Wholesalers

Pharmaceutical wholesalers (including acquisition, storage, supply or export, but excluding direct sales to the public) must be licensed as pharmaceutical establishments by the ANSM.

The license process follows the same steps as for manufacturers (see 5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices). The applicant must submit a detailed application describing its distribution activities and demonstrating compliance with Good Distribution Practice (GDP), which is then reviewed by the ANSM and followed by an on-site inspection.

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However, unlike for manufacturers, the absence of a decision from the ANSM within 90 days of receiving the application results in tacit approval, meaning that the authorisation is considered granted.

Medical Devices Wholesalers

Medical devices wholesalers generally do not require prior authorisation or specific registration. Distributors making medical devices available on the French market, excluding direct sales to the public, must however declare their activity to the ANSM.

6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Different Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and exportation of pharmaceuticals are mainly regulated by dedicated provisions of the Public Health Code.

Importation and exportation of medical devices are mainly regulated by EU law (MDR and IVDR) and dedicated provisions of the Public Health Code.

The ANSM is responsible for applying and enforcing regulations on the import and export of pharmaceuticals and medical devices.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Companies or organisations licensed as pharmaceutical establishments by the ANSM may act as importers of record of pharmaceuticals (see 5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices).

With respect to medical devices, any natural or legal person can act as an importer of record. EU law assigns specific regulatory obligations to importers, particularly when the manufacturer is located outside the EU and has not appointed an authorised EU representative.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

The importation of pharmaceuticals and medical devices is subject to prior authorisations.

Pharmaceuticals

The importation of pharmaceuticals into France, including from another EEA country, requires prior authorisation from ANSM, which may be granted for:

- a single import operation (valid for up to three months); or
- a series of imports over one year for a specified quantity.

Import authorisation requests must be submitted via an online platform ([Impexweb](https://impexweb.ansm.fr/)). If the ANSM does not respond within 45 days, the request is considered rejected. The ANSM may suspend or revoke an authorisation at any time. Except in urgent cases, such decisions can only be taken after allowing the authorisation holder to submit observations.

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However, there are exemptions from the prior authorisation requirement, namely for:

- individuals importing medicines for personal use;
- medicines with a valid marketing authorisation in France, provided they are presented in compliance with the approved authorisation (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**);
- homeopathic and traditional herbal medicines registered in France, provided they are presented in compliance with their registration;
- medicines authorised under early access or compassionate use;
- medicines required for an authorised biomedical research study in France;
- medicines imported from an EU member state and stored in a licensed pharmaceutical facility, provided they are intended exclusively for export to non-EU countries;
- medicines imported by a sports team physician for team use, whether transported personally or through other means; or
- medicines in external transit or moving through French territory as part of intra-EU exchanges.

Medical Devices

The importation of medical devices from non-EEA countries into France does not require prior governmental authorisation. However, imported devices must fully comply with EU regulatory requirements, including a valid CE marking and an EU Declaration of Conformity, which confirm compliance with essential safety and performance standards and enable free circulation within the EU.

If the manufacturer is based outside the EEA and has not appointed an authorised representative,

the importer assumes regulatory responsibility for ensuring the device's conformity, traceability and compliance with post-market obligations.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The import of products into the EU is governed by a standardised classification system that categorises products based on their tariff codes (Harmonised System, Union Combined Nomenclature and Community Customs Tariff). This classification helps to identify and regulate products that are being imported, ensuring that duties, taxes and restrictions are properly applied. Additionally, the applicable non-tariff regulations depend on whether an imported product meets the statutory product definition (medical devices or pharmaceuticals).

The types of products subject to import regulations in the EU are outlined in various laws and regulations such as EU Regulation No 952/2013 laying down the Union Customs Code or Regulation No 952/2013 laying down the Union Customs Code.

7.5 Trade Blocs and Free Trade Agreements

France, as a member of the EU, participates in the EU's free trade agreements and applies the principle of free movement of goods and services within the EU single market.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Prices for pharmaceuticals and medical devices are strictly controlled in France if such products are reimbursed by SHI.

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The rules governing price setting are mainly outlined in the French Social Security Code and Framework Agreements entered into between the governmental body in charge of fixing prices (*Comité économique des produits de santé* or CEPS) and industry trade associations.

Pharmaceuticals

The price of products used in hospitals is negotiated between the pharmaceutical company and the hospital, within the framework of the Public Procurement Code. France has implemented an activity-based tariff system for hospitals.

However, the price of (i) expensive and innovative pharmaceuticals included in the list of pharmaceuticals chargeable in addition to hospital stays (*liste en sus*), for which payments are made in addition to the hospitalisation price, and (ii) pharmaceuticals available in pharmacy hospitals for direct sale to outpatients, included in the list of pharmaceuticals prescribed on a retrocession basis (*liste de restitucion*), is negotiated between the CEPS and the pharmaceutical company. The ministers responsible for Health and Social Security may set a maximum sale price for pharmaceuticals with a risk of unjustified spending or for pharmaceuticals that are particularly costly for institutions.

The price of reimbursed pharmaceuticals prescribed to outpatients is determined through negotiations between the pharmaceutical company and the CEPS, based on various factors, including:

- the improvement in medical benefit of the pharmaceutical;
- the results of health economic assessment;
- the prices of other pharmaceuticals in the same therapeutic field;
- the expected or actual sales volumes;

- the expected and actual conditions of use of the pharmaceuticals; and
- the security of supply to the French market guaranteed by the location of production sites.

If no agreement is reached between the CEPS and the pharmaceutical company, the CEPS has the authority to unilaterally set the price. The Ministers of Health, Social Security and the Economy may oppose this decision within 15 days.

When generic or biosimilar pharmaceuticals enter the market, specific discount rates are applied by the CEPS to determine their price, and the prices of the reference pharmaceuticals are reduced accordingly.

The Ministers of Economy and Health may also control the margins of reimbursed pharmaceuticals. Discounts, rebates and any other commercial and financial benefits, including service fees, on reimbursed pharmaceuticals, granted by a supplier to pharmacists, cannot exceed, per calendar year and per product line for each pharmacy, 2.5% of the manufacturer price excluding tax. For generic pharmaceuticals, this is capped at 40% of the manufacturer's price.

Medical Devices

Rules applicable to medical devices used in hospitals are the same as for pharmaceuticals used in hospitals or healthcare institutions.

For medical devices prescribed to outpatients, the maximum price that the public can be charged and the tariff on which SHI reimbursement is based are determined through negotiations between the pharmaceutical company and the CEPS. The determination of the tariff primarily takes into account:

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- the medical benefit or the improvement in medical benefit of the medical device;
- if applicable, the results of the medico-economic assessment of tariffs of comparable products or services;
- the planned or observed sale volumes;
- planned or observed amounts reimbursed by SHI, and
- the estimated conditions of use.

If no agreement is reached between the CEPS and the pharmaceutical company, the CEPS has the authority to unilaterally set the price. The pricing of reimbursed medical devices may be reviewed at the initiative of the CEPS.

The Ministers of Economy and Health may set the margins of reimbursed medical devices. Discounts, rebates and any other commercial and financial benefits, including service fees, granted by any supplier to retailers of reimbursed MDs, may soon be capped under French law. A ministerial order is expected to limit such discounts, rebates and benefits, per calendar year and per product line, to a percentage of the product price (excluding tax) for each retailer, not to exceed 50% of the operator (*exploitant*) price. The implementing act for this provision is expected to be issued by the end of the year.

8.2 Price Levels of Pharmaceuticals or Medical Devices

When setting and reviewing the price of reimbursed pharmaceuticals and the tariff of reimbursed medical devices, the CEPS may take into consideration the existence of lower prices or tariffs in Germany, Spain, Italy and the United Kingdom.

The Framework Agreement between the trade association representing the pharmaceutical industry and the CEPS establishes the possi-

bility of benefiting from a pre-tax list price that cannot be lower than one of the prices applied in Germany, the United Kingdom, Italy and Spain for a pharmaceutical providing an ASMR I, II or III (see 8.4 **Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**) and whose main manufacturing stages (active ingredient, finished product, packaging) are carried out in France.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The costs of pharmaceuticals and medical devices may be reimbursed from public funds at a variety of levels and under different pathways.

Pharmaceuticals

Pharmaceuticals used in hospitals are primarily financed through hospital stays. However, expensive and innovative pharmaceuticals, for which payments are made in addition to the hospitalisation price, are included in the list of pharmaceuticals chargeable in addition to hospital stays (*liste en sus*) and are reimbursed by the SHI based on invoices issued by hospitals.

Pharmaceuticals used in ambulatory settings are reimbursed subject to registration on a positive list (*liste des spécialités pharmaceutiques remboursables*). Access to reimbursement and reimbursement rate defined by the National Union of Sickness Insurance Funds (*Union nationale des caisses d'assurance maladie*) are based on the therapeutic value of the pharmaceutical (*service médical rendu*) assessed by the HAS (see 8.4 **Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**). The final decision on reimbursement is taken by the Minister of Health by legal order.

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Medical Devices

Medical devices for individual use in hospitals are primarily financed through hospital stays. Expensive and innovative medical devices are financed separately, in addition to the hospitalisation price. In such cases, they are included in the list of products and services chargeable in addition to hospital stays (*liste en sus*) and are reimbursed based on an invoice issued by hospitals.

Medical devices for individuals used in ambulatory settings may be reimbursed subject to registration on a specific list called “*List of Reimbursable Products and Services*” (*Liste des Produits et Prestations Remboursables* or LPPR). Access to reimbursement is based on the therapeutic value of the medical devices assessed by the HAS (see **8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**).

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In France, cost-benefit analyses play a significant role in determining both the price and the reimbursement status of pharmaceuticals and medical devices.

The HAS (Transparency Committee for the pharmaceuticals and The National Committee for the Evaluation of Medical Devices and Health Technologies for medical devices) is responsible for conducting such health technology assessment.

After reviewing the dossier submitted by the company and the other available scientific data, the HAS publishes a scientific opinion evaluating the actual clinical benefit and the clinical added value of the product.

Reimbursement decisions are based on the rating and, while the rating is not the only factor, it is the primary criterion which supports the pricing by the CEPS (see **8.1 Price Control for Pharmaceuticals and Medical Devices**).

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

To ensure cost efficiency in pharmaceutical prescribing and dispensing:

- physicians are required to prescribe pharmaceuticals using the Non-Proprietary Name, which is the globally recognised name for the active substance; and
- pharmacists are allowed to substitute branded pharmaceuticals with generic/biosimilar pharmaceuticals, under certain conditions, unless the physician writes on the prescription that the pharmaceutical cannot be substituted for medical reasons.

GERMANY

Trends and Developments

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D+B Lawyers



D+B Lawyers was established in 1997 as Dierks + Bohle and has since grown into a legal firm with seven equity partners and over 30 lawyers fully dedicated to life sciences and healthcare law. As part of a collective experience within the firm, each partner contributes to its expertise and continuity. Specialising solely in life sciences and healthcare law, the firm's team offers advisory services, focusing particularly on areas such as statutory health insurance, data protection and digital health. The firm's clients include

pharmaceutical companies, medical technology firms, healthcare practitioners and governmental bodies. The firm operates across three core departments: pharmaceuticals and pharmacies; panel doctor legal affairs; and hospital law. Headquartered in Berlin, with additional offices in Düsseldorf and Brussels, its lawyers aim to expand their national and international reach, continually strengthening its network and team to address legal needs.

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An Introduction to the German Life Sciences Industry in 2025

Overview of Germany's healthcare system

For more than 100 years, Germany's healthcare system has been based on statutory health insurance (*gesetzliche Krankenversicherung* or GKV). Today, approximately 74 out of 84 million inhabitants are covered by statutory health insurance, whereas only ten million patients are privately insured. In 2024, statutory health insurance funds spent more than EUR300 billion per year on services for their insureds. Statutory health insurance funds therefore have an important impact on all stakeholders in the life sciences industry. This leads to a highly regulated life sciences sector, with a major emphasis on the cost-benefit ratio of services provided.

Impact of statutory health insurance

In addition to the density and quantity of regulations, life sciences is one of the most complex and rapidly changing regulatory branches. An almost disruptive change to the statutory health insurance system, in particular, was observed in the legislative period between mid-2017 and the end of 2021 when Jens Spahn was Minister of Health. Since 2020, the COVID-19 pandemic situation has emerged as the main catalyst for action by the legislator. While there was a refresh

by the Minister of Health, Professor Karl Lauterbach, who was installed at the end of 2021, the pace of change has significantly slowed compared to the previous legislative period. It will be very interesting to see which new legislation will be introduced with a new government to be formed in spring 2025.

Digitalisation initiatives and regulatory changes

The focus is still on the acceleration of digitalisation, including installing e-health records or e-prescriptions. The further development of digital health applications (DiGA) continues to raise a lot of specific questions following their introduction at the end of 2019, particularly with regard to reimbursement schemes. However, the implementation of the main digitalisation instruments faced a lot of resistance in the last few years.

Finally, the e-prescription system has been fully applicable since the start of 2024. With the adoption of the Health Data Use Act (the "*Gesundheitsdatennutzungsgesetz*" or GDNG) and the Digital Act (the "*Digital-Gesetz*" or DigiG) in February 2024, the German legislator took two further important steps on its digitalisation path.

Focus on financial stability and medicinal supply

The focus is also still on the financial health of the statutory health insurance system, which has worsened in the last few years. At the end of 2022, the legislator therefore introduced a strict law, the GKV Financial Stabilisation Act (the “*GKV-Finanzstabilisierungsgesetz*” or GKV-FinStG) to stabilise statutory health insurance funding by avoiding a permanent rise in the premiums paid by its members.

This had a number of impacts, particularly on the lower reimbursement of medicinal products in Germany. As statutory sick funds are still facing growing deficits it seems likely that new laws will be introduced in the upcoming legislative period.

Influence of EU directives on regulation

Additionally, the focus is on the maintenance of a sustainable availability of medicines (specifically, generic), which again is something that has worsened in recent years. At the start of 2023, the legislator therefore published the Drug Delivery Shortage Control and Supply Improvement Act (the “*Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz*” or ALBVVG).

Current developments and challenges for the industry

The regulatory framework for the life sciences industry is heavily influenced by EU directives and regulations, especially concerning the marketability of pharmaceuticals and medical devices. All in all, legal advice must cover many areas. This obviously includes legal know-how and expertise on life sciences regulations but also extends to, inter alia, M&A, antitrust and competition, public procurement and data protection.

Evolution of market access and reimbursement

Manufacturers of pharmaceuticals have to deal with frequently amended regulations on market access and reimbursement of their products without losing sight of the fact that prices in Germany are also a relevant reference point for prices in many European countries, as well. The benefit assessment by the Federal Joint Committee (the “*Gemeinsamer Bundesausschuss*” or G-BA), based on the Act on the Reform of the Market for Medicinal Products (the “*Arzneimittelmarkt-Neuordnungsgesetz*” or AMNOG) has the greatest influence on the reimbursement prices.

Impact of legislative changes on pharmaceutical pricing

Nevertheless, the GKV-FinStG of 2022 could essentially change the established system, which is mainly based on the benefit of the respective medicinal product as assessed by the G-BA. Instead, the GKV-FinStG widely introduces a schematic price corridor system linked to comparator drugs. According to the first evaluation at the end of 2023, the legislator currently does not deem it necessary to reconsider its “*new approach*”, however.

One piece of good news is that with the Medical Research Act (the “*Medizinforschungsgesetz*” or MFG) of 29 October 2024, the legislator at least introduced an exception to this price corridor system in the event that the pharmaceutical company performs – briefly summarised – 5% of its clinical studies in Germany. The *Medizinforschungsgesetz* (MFG) further introduced the opportunity to agree on confidential reimbursement prices – to avoid negative reference impacts – for the first time after long years of discussion, but with a lot of limiting requirements.

Adaptations for Advanced Therapy Medicinal Products

Furthermore, Regulation 2021/2282 on Health Technology Assessment (the “HTA Regulation”) by calling for a more collaborative framework in the EU, gets closer to improving business predictability and avoiding duplication of work and discrepancies between HTA mechanisms. The HTA Regulation has been applicable since 12 January 2025, starting with cancer medicines and ATMPs. It will expand to cover OMPs in 2028 and to cover all centrally authorised medicinal products in 2030.

The European-wide orientation includes huge challenges for the German life sciences industry. On 8 March 2025, the German national implementing rules in the Ordinance for the Benefit Assessment of Medicinal Products (the “AM-NutzenV”) adopted by the Federal Ministry of Health (the “BMG”), entered into force.

Challenges in clinical trials and regulatory simplification

In terms of clinical trials, the implementation of the Clinical Trials Regulation (the “CTR”) and the Clinical Trials Information System (the “CTIS”), in particular, is still causing many practical issues for the industry. However, the legislator has taken a first step to improving the legislative conditions to perform clinical studies in Germany. With the MFG, simplifications of the regulatory framework for clinical studies were introduced, eg, the facilitation of the regulatory process for clinical studies affecting the Radiation Protection Law or the shortening of the processing time for the authorisation of mono-national clinical trials with medicinal products. Furthermore, the concept of common standard contractual clauses for clinical trial agreements found its way into law for the first time.

Anticipating the EU pharmaceutical law package

The “next big thing” for pharmaceutical entrepreneurs at a European level, beyond the further legislative progress of the regulation introducing the European Health Data Space (the “EHDS”), surely lies in the new EU pharmaceutical law package. On 26 April 2023, the EC presented the following legislative proposals for the revision of the EU medicinal products legislation:

- first, a proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use; and
- second, a proposal for a Regulation of the European Parliament and of the Council laying down EU procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency.

The proposals intend to repeal several pieces of EU legislation, including Directive 2001/83/EC and Regulation (EC) 726/2004. This revision is part of the implementation of the Pharmaceutical Strategy for Europe and aims to promote innovation while reducing the regulatory burden and environmental impact of medicinal products.

This will also undoubtedly have a huge impact on the pharmaceutical industry in Germany and the proposals have already been heavily discussed. Not surprisingly, the different Commission and Parliament drafts (2024) affect the appropriate provision of regulatory data protection. Council discussions are currently ongoing.

Challenges for medical device manufacturers under the Medical Devices Regulation

Manufacturers of medical devices still face the challenge of adapting to the Medical Devices

Regulation (the “MDR”), which sets the regulatory framework for the marketability of their products. This demands an understanding of the new legal requirements and the implications for the certification process and the design of quality management systems.

The industry in Germany was also relieved by the news that, after months of discussions, the transitional provisions of the MDR were extended. However, even with more time, the preparation for stricter regulations remains challenging for the industry, with many questions still unanswered. Correspondingly, new proposals for further facilitations in practical terms have already been submitted.

GREECE

Law and Practice

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ALG Manousakis Law Firm is a law firm established in 2011 by Ioannis and Alexandros Manousakis. Based in Athens, ALG is an international law firm with lawyers qualified in 6 EU jurisdictions and Switzerland. ALG's team consists of 50 lawyers and 25 paralegals. With deep expertise in corporate and commercial law, the firm offers tailored solutions across various industries. Their client base includes 30

pharmaceutical/biotech and five medical device companies, supported by the firm's lawyers in contracting negotiation, ensuring compliance, and developing robust data privacy frameworks. The firm has a proven commercial and administrative litigation track record, with a high rate of success, especially in commercial claims and tax and administrative litigation.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices Pharmaceuticals

European Legislation

- Directive 2001/83/EC (“*Directive*”) on the Community code relating to pharmaceutical products for human use, as amended and in force.

National Legislation

- Legislative Decree 96/1973 (Government Gazette A’ 172/3/8.8.1973) on the trading of pharmaceutical and cosmetic products.
- Law 1316/1983 (Government Gazette A’ 3/11/11.1.83) on the establishment, organisation and competence of the National Organization for Medicines (EOF, as per its Greek acronym).
- Joint Ministerial Decision DYG 3a/32221/2013 (“*JM Decision*”) (Government Gazette B’ 1049/29.04.2013) on the implementation of Directive 2001/83/EC of the European Parliament and the European Council on the Community Code relating to pharmaceutical products for human use.

Medical Devices

European Legislation

- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices (“*MDR*”).
- Regulation (EU) 2017/746 of the European Parliament and Council of 5 April 2017 on in vitro diagnostic medical devices (“*IVDR*”).

National Legislation

- Joint Ministerial Decision DY8d/130648/2009 on “*Medical Devices*” (Government Gazette B’ 2198/02.10.2009), for the harmonisation

of national legislation with the provisions of Directive 93/42/EEC “*on Medical Devices*”, as amended by Directives 98/79/EC, 2000/70/EC, 2001/104/EC, 2007/47/EC and Regulation (EC) 1882/2003.

- Joint Ministerial Decision DY8d/130644/2009 on “*Active Implantable Medical Devices*” (Government Gazette B’ 2197/2.10.2009), for the harmonisation of national legislation with the provisions of Directive 90/385/EEC “*on the approximation of the laws of the Member States relating to Active Implantable Medical Devices*”, as amended by Directives 93/42/EEC, 93/68/EC, 2007/47/EC and Regulation (EC) 1882/2003.
- Joint Ministerial Decision DY8d/3607/892/2001 on “*In Vitro Diagnostic Medical Devices*” (Government Gazette B’ 1060/10.8.2001), for the harmonisation of national legislation with the provisions of Directive 98/79/EC of the European Parliament and of the of 27 October 199 “*on In Vitro Diagnostic Medical Devices*”.

Regulatory Bodies

The competent national authority with regulatory oversight over pharmaceutical products and medical devices is EOF, established by Law 1316/1983 (Government Gazette A’ 3/11/11.1.83) as an entity of public law.

Within the framework of its mission, EOF is responsible for:

- receiving and approving applications for marketing authorisations;
- receiving and approving applications for clinical trials and monitoring clinical trials;
- approving and monitoring manufacturing facilities in order to ensure compliance with Good Manufacturing Practices (GMP);

- monitoring the quality, safety and efficacy of products within its competency;
- receiving applications for pricing of pharmaceutical products and proposing pricing to the Ministry of Health; and
- approving and monitoring wholesale facilities.

EOF, in the scope of its mission, is autonomous, and the Ministry of Health can only revoke its decisions based on a legally justifiable basis.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Pharmaceuticals

When a marketing authorisation for a pharmaceutical product is rejected, the applicant can appeal to the Committee for Medicinal Products for Human Use (under Article 49 of the JM Decision). The Committee will issue a decision on the appeal within 60 days of the submission. If the applicant's appeal is denied, they can further contest this decision by appealing to the Administrative Court of First Instance.

Additionally, objections to the price bulletin issued by the Ministry of Health can be raised through a petition for annulment submitted to the Conseil d'État (Council of State (ΣτΕ)).

Objections against the decision of the Ministry of Health for non-inclusion in the Reimbursement List may be raised by a petition of annulment before the Three-Member Administrative Court of Appeal.

Medical Devices

In Greece, the EOF is responsible for overseeing the marketing of medical devices. This includes ensuring that these devices comply with the legal requirements outlined in the Joint Ministerial Decision DY8d/130648/2009, as amended

by Ministerial Decision YA A4g/88159/2017. This framework appoints the EOF as the authority overseeing medical devices in Greece and outlines the applicability of the MDR and IVDR within the country. The relevant legal provisions also include Article 2, Paragraph 2; Article 3, Paragraph 1; and Article 6, Paragraph 2 of Law 1316/1983 (Government Gazette A' 3/11/11.1.83), along with the applicable provisions of the MDR and IVDR.

If EOF decides to withdraw a medical device from the market, the manufacturer has the right to appeal this decision at the Administrative Court of First Instance for annulment.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

Prescription-only medicines require a doctor's prescription for purchase, are dispensed by pharmacies, and are subject to stricter regulations regarding their distribution and marketing.

Following their approval, OTC products can be sold without a prescription.

Medical Devices

The MDR and the Joint Ministerial Decision DY8d/130648/2009 (Article 9 and Annex IX) classify medical devices as follows:

- Class I requires only self-certification by the manufacturer;
- Class IIa involves a notified body for conformity assessment;
- Class IIb requires the involvement of a notified body and a more rigorous assessment (eg, clinical evaluation and performance data are required); and
- Class III requires a full assessment from the notified body (including design dossier

review, robust clinical data requirement, and clinical trials).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Pharmaceuticals

The legal framework applicable to clinical trials in Greece is laid down in the Regulation (EU) No 536/2014 (“CTR”) on clinical trials on pharmaceuticals for human use.

The provisions of the CTR were transposed in the Greek legislation by the Joint Ministerial Decision G5a/59676/2016 (Government Gazette B’ 4131/22.12.2016).

In order to conduct a clinical trial in Greece, prior approval from EOF is required following an application submitted via the EU portal.

The application, the clinical trial protocol, the information material addressed to patients, the informed consent form, the labelling, the patient cards, and the insurance contract must be submitted in Greek. The rest of the file documentation may be submitted in English.

Medical Devices

The legal framework applicable to clinical investigations (or performance studies in the case of in vitro diagnostic medical devices) is set out in Section VI of the MDR, as well as in Section VI of the IVDR on in vitro diagnostic medical devices, as the case may be. In Greece, the MDR and the IVDR are directly applicable in conjunction with the Joint Ministerial Decision DY8d/130648/2009 (Article 15 of the said Decision specified the clinical-related rules).

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Pharmaceuticals

Clinical trials are subject to scientific and ethical evaluation and are approved in accordance with Article 8 of the CTR. The EOF conducts a scientific evaluation of the clinical trial. If EOF has been granted the status of ‘reporting’ member state, it notifies the sponsor and other member states concerned via the EU portal within six days of submitting the application file (Article 5 of the CTR).

Ethical evaluation is carried out by the National Ethics Committee, which drafts an assessment report in accordance with the procedure laid down in Article 7 of the CTR.

A positive scientific (by EOF) and ethical (by National Ethics Committee) assessment of the clinical trial is required for its approval.

Medical Devices

According to articles 62 of the MDR and 58 of the IVDR, both clinical investigations and performance studies are subjected to an authorisation by the Member State in which the clinical investigation or the performance study is to be conducted, following a scientific and ethical review, the latter being performed by an ethics committee, according to the national law. As per above, competent authorities are EOF and the National Ethics Committee.

2.3 Public Availability of the Conduct of a Clinical Trial

Greece has no national database for clinical trials of medicines or medical devices. A central European database (EudraCT) exists, as provided in article 80 of the CTR.

2.4 Restriction on Using Online Tools to Support Clinical Trials

In Greece, there are no explicit restrictions on the use of online tools in clinical trials. However, the use of these tools must comply with both national and European legislation. This includes the CTR, Ministerial Decision No G5a/59676/2016 on Clinical Trials, and EU Regulation 2016/679 (General Data Protection Regulation – GDPR), along with its implementation of Greek Law 4624/2019. Additionally, guidance from EOF must be followed to ensure the protection of clinical trial participants' data privacy rights.

More specifically, Ministerial Decision No. G5a/59676/2016 (Articles 8, 13 and 24) describes the processes throughout the clinical trial course in Greece and the obligations assigned to sponsors and clinical research organisations (CROs) regarding protecting the participant's data, including using appropriate security measures.

In addition, a Data Protection Impact Assessment has to be conducted; appropriate privacy-related information must be provided to individuals concerned, and data processing agreements (DPAs) are required between sponsors, investigators, and tool providers. The Hellenic Data Protection Authority (HDPa) oversees the enforcement of data protection regulations in Greece. While the HDPa has not issued specific guidance on the use of online tools in clinical trials, sponsors and investigators must ensure that any digital platforms used for recruitment or monitoring purposes implement appropriate technical and organisational measures.

2.5 Use of Data Resulting From Clinical Trials

Data from clinical trials is classified as sensitive health-related information regarding an individu-

al's past, present, or future physical and mental health (Article 4(15) GDPR).

Transferring clinical trial data to third parties or affiliates is allowed under specific conditions:

- Within the EU/EEA – It is allowed, provided that clinical trial participants have been duly informed through the informed consent form and processing is in accordance with the trial's approved protocol.
- Outside the EU/EEA (International Transfers) – If data is transferred to a third country (eg, the US), additional safeguards are required:
 - (a) the recipient country must have an adequacy decision from the European Commission (eg, under the EU-US Data Privacy Framework);
 - (b) if no adequacy decision exists, Standard Contractual Clauses (SCCs) or Binding Corporate Rules (BCRs) must be used; and
 - (c) additional security measures (eg, encryption, pseudonymisation) may be required.

To ensure compliance, before transferring clinical trial data to third parties or affiliates, the sponsor must execute a Data Processing Agreement (DPA) (along with the execution of the appropriate Standard Contractual Clauses if applicable for international transfer) with third-party vendors or enter into an intragroup data transfer agreement with its affiliates.

2.6 Databases Containing Personal or Sensitive Data

Below, you will find requirements applying to the creation of database containing personal or sensitive data (in accordance with GDPR and Law 4624/2019).

A Data Protection Impact Assessment (DPIA) (GDPR art. 35) is mandatory if the processing of personal data is likely to result in a high risk to individuals' rights. For example, this will be the case if:

- there is large-scale processing of special categories of data;
- there is involvement of high-risk data processing; or
- there are systematic and extensive processing activities, including profiling.

Adherence to data protection principles such as the data minimisation and purpose limitation principles is required, as the database should only contain the minimum amount of data necessary for the specific purposes for which it was created (Articles 5-11 GDPR).

Appropriate security and access controls (eg, encryption & pseudonymisation, access restrictions, data retention policies, and rules to protect data from unauthorised access, breaches, or leaks) must be implemented.

The appropriate legal basis must be assessed (as per Articles 6 & 9 of the GDPR for plain and special categories of personal data such as health-related).

It is essential to provide relevant information to the individuals involved. This information should include the purposes for processing their data, the identity and contact details of the data controller, any recipients or categories of recipients who will receive the personal data, and the privacy-related rights of the individuals, among other necessary details.

If third parties access the database, data processing agreements must be executed, along

with Standard Contractual Clauses (SCCs), as applicable for international transfers.

In case the database involves automated processing of personal data, prior consultation with the Hellenic Data Protection Authority (HDPa) may be required. The HDPa may also review international data transfers or secondary uses of the data.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The process for classifying a product as either a pharmaceutical or a medical device depends on its intended use, primary mode of action and composition. The primary distinction is their mode of action. Pharmaceuticals exert their effects through chemical or biological mechanisms, while medical devices operate primarily via physical or mechanical means.

Pharmaceuticals

Pharmaceuticals are governed by Directive and relevant national laws, such as Legislative Decree 96/1973 and Law 1316/1983 in Greece. The approval process for pharmaceuticals involves submitting an application to the regulatory authority (EOF in Greece), including information about composition, manufacturing standards, and pharmacovigilance practices. Once approved, marketing authorisation holders (MAHs) must comply with stringent post-marketing obligations, including pharmacovigilance reporting.

Medical Devices

The MDR and the IVDR regulate medical devices. National Joint Ministerial Decisions, along with guidance issued by the EOF, provide additional oversight. Medical devices are designed to assist bodily functions and can operate mechanically, physically, or through software without producing direct pharmacological effects. Examples include surgical instruments and diagnostic software. Manufacturers must complete a conformity assessment to demonstrate compliance with safety and performance standards. The product obtains CE marking through a notified body or the national authority before it can be marketed. Devices are classified based on their risk level and intended purpose, with post-marketing vigilance responsibilities ensuring continued safety and effectiveness. In Greece, the responsible notified body for the conformity assessment and the CE marking (granting of CE 0653 in Greece, which shows compliance with the applicable legislation) of medical devices is the National Evaluation Center of Quality and Technology in Health (EKAPTY).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In Greece, biologic medicinal products require marketing authorisation through either the national procedure (EOF) or, more commonly, the centralised procedure under Regulation (EC) No 726/2004, where approval is granted at the EMA level.

There are no differences in the approval process between pharmaceutical (chemical) and biological products.

Biosimilars, or generic biological products, must be similar but not identical to the reference product. This contrasts with traditional chemical

pharmaceuticals, which require identical characteristics for approval.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Validity and Renewal

Pharmaceuticals

Marketing authorisations are valid for five years from the date of approval. If a renewal is approved, the authorisation lasts indefinitely unless further safety monitoring is necessary, in which case the renewal is for an additional five-year period.

Medical devices

A CE certificate necessary for the marketing of medical devices is issued by a notified body for a five-year term (as per Article 56 paragraph 2 of the MDR). Manufacturers must provide updated clinical evaluations, performance data, and post-market surveillance reports to renew the CE certificate. The said CE certificate is issued by a notified body (ie, the organisation responsible for the CE certification issuance and conformity assessment procedures as per Article 1, paragraph 2ie), Article 11 and 16 of the Joint Ministerial Decision DY8d/130648/2009 – their specific requirements are set out in Annex VII of the MDR, in Greece, Ministry of Health is responsible for their compliance as per Article 3 of the Ministerial Decision A4g/88159/2017).

Revocation, Variation, Suspension or Withdrawal

Revocation by EOF or EMA if:

- the product is not placed on the market within three years of authorisation;
- the product is not marketed for a continuous period of three years; or

- if new pharmacovigilance data show an unacceptable risk-benefit ratio.

Modification of a marketing authorisation is applicable if new data on safety or efficacy is discovered.

Temporary suspension is applied in case of unresolved safety issues.

For medical devices, the CE marking certification can be:

- revoked if the device is not placed on the market within three years from the issuance of the certificate;
- suspended or withdrawn if there is an increase in adverse events and the risk level is high; and
- modified if additional safety measures are needed.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Obtaining an Authorisation

Pharmaceuticals

The regulatory process for national marketing authorisation by EOF is outlined in detail in the JM Decision (Article 7 et seq), and it is fully aligned with the centralised process (marketing authorisation from EMA) provided for in the Regulation (EC) No 726/2004. The application for a national marketing authorisation for a medicinal product intended for human use is submitted to EOF.

Medical devices

The manufacturer of medical devices is required to submit all relevant data to the EOF for the identification of these products before they are marketed (including the CE marking and the

instructions for use). This requirement is outlined in Article 14 of Joint Ministerial Decision DY8d/130648/2009, Article 10a of Joint Ministerial Decision DY8d/130644/2009, and Article 10 of Joint Ministerial Decision DY8d/3607/892/2001.

The rules regarding conformity assessment and CE marking of medical devices also depend on their classification as category I, category IIa, category IIb and category III medical devices, made-on-order medical devices or active implantable medical devices. In particular, every manufacturer of category I or on-order medical devices that sells in the Greek market under its name or via an authorised representative based in Greece (when the manufacturer's registered office is outside the EU) is registered in the Register of Manufacturers of the EOF, to affix the CE marking on the medical devices (Article 14 of Joint Ministerial Decision DY8d/130648/2009).

Every manufacturer of category IIa, IIb, and III medical devices, of active implantable medical devices, as well as of in vitro diagnostic medical devices, submits a technical dossier of the products to a Notified Body within the EU, which assesses their compliance with the legal requirements and issues a CE marking certificate (Article 16 and Annex XI of Joint Ministerial Decision DY8d/130648/2009, Article 9 and Annex II of Joint Ministerial Decision DY8d/130644/2009, as well as Article 9 and Annex II of Joint Ministerial Decision DY8d/3607/892/2001).

Variation of an Authorisation

Pharmaceuticals

According to Article 43 of the JM Decision, any changes to an existing marketing authorisation are determined by the EOF. An application providing a specific form that follows the template set by the EMA must be submitted to the EOF to initiate a variation.

Variations are categorised based on their impact on safety, quality, and efficacy, and the process aligns with EU rules for minor and major variations (EU Regulation 1234/2008). Minor changes may require just EOF's notification (eg, change in labelling – such as a font size change), moderate changes require EOF's approval before implementation (eg, change of labelling which is linked with safety), major changes necessitate an evaluation before implementation (eg, change in therapeutic indication, formulation).

Medical devices

EOF has not made publicly available a template form to be submitted for variations concerning specifically medical devices; however, based on the rules and guidance provided by EMA, the following details are expected to be requested:

- device(s) identification and classification;
- name of the device and brief description;
- intended purpose;
- classification;
- serial number;
- manufacturer details;
- notified body details;
- proof of fee paid; and
- details regarding the variation.

Transfer of an Authorisation

Pharmaceuticals

The process involves a joint transfer application to EOF, which includes:

- details about the product concerned
- details about the existing and the new MAH;
- confirmation that there are no changes to the product; and
- description of the pharmacovigilance system.

Medical devices

For medical devices, the rights regarding the CE marking can be transferred by:

- updating the CE certificate holder details with the Notified Body;
- ensuring continued compliance with the MDR and EOF's guidance by the new holder; and
- updating EOF's registration regarding the new owner's details.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Pharmaceuticals

Compassionate use programmes: In Greece, compassionate use programmes are regulated by the Joint Ministerial Decision DYG3(a) 85037/10/2011, which provides early access/compassionate use of medicinal products which either constitute the subject of a marketing authorisation application before EOF or EMA or are at stage III of clinical trials and more specifically at the stage of analysis of clinical trial data. Conditions are:

- approval by EOF; and
- certification from a doctor of the respective speciality that the existing treatments do not exist.

Two types of programmes may be approved:

- a group early access; and
- an individual early access,
- with a maximum duration of one year for both programmes.

In the first case, the applicant is the applicant for the marketing authorisation before the competent authority or the sponsor of the clinical trial,

while in the second case, the applicant is the treating physician.

Emergency and public health exceptions

EOF can authorise a temporary supply of unapproved medicines as follows.

- According to paragraph 5 of Article 8 of Legislative Decree 96/1973, EOF may, in case of a public health emergency, proceed with the import of any pharmaceutical product with no limitations in terms of quantity and quality.
- According to paragraph 6 of Article 8 of Legislative Decree 96/1973, EOF may permit importing unapproved medicinal products in limited quantities and for specific purposes.

Medical Devices

According to Article 59 of the MDR and as per Article 11 paragraph 13 of the Joint Ministerial Decision DY8d/130648/2009, any competent authority (EOF for Greece) may authorise the import of a specific device for which the procedures for placement in the market have not been carried out but the use of which is in the interest of public health or patient safety or health.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations Pharmaceuticals

MAH's ongoing obligations are described in Article 36, 38, 39 and 40 of the JM Decision.

Article 36 of the JM Decision provides that EOF may impose on MAH the obligation to conduct either:

- a post-marketing safety study, if there are issues relating to the risks of a medicinal product; or

- a post-marketing efficacy study when the knowledge of the disease or the clinical methodology suggests that previous efficacy assessments may need a significant revision.

Furthermore, according to Article 38 of the JM Decision, the MAH immediately informs EOF of any prohibition or restriction imposed by the competent authorities of any other country and any new information that might influence the pharmaceutical product's risk-benefit balance.

Article 39 of the JM Decision provides that the MAH notifies EOF of the exact date of the placement of the medicinal product in the Greek market. The MAH notifies EOF of any discontinuation (temporary or permanent) of commercialisation of the product at least three months before discontinuation.

Article 12A of the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973) provides that any MAH of medicinal products shall ensure the adequate and continuous supply of products to the market in order to meet the needs of patients in Greece.

The electronic submission of individual case safety reports (ICSRs) in the Eudravigilance database is mandatory for MAHs either through the centralised procedure of Regulation 726/2004 or through the national procedure of Directive, as well as for clinical trial sponsors.

Medical Devices

Post-marketing vigilance. The competent authority in Greece, the EOF, has adopted the White Card system. Manufacturers are obliged to report to EOF all serious adverse events taking place in Greece by submitting in English the following two types of reports:

- the Manufacturers Incident Report (MIR) form; and
- the Field Safety Corrective Action (FSCA) form. The following are reportable to EOF:
 - (a) any malfunction or deterioration in the characteristics and/or performance of a product, as well as any deficiency in the labelling or instructions for use, which may cause or have caused the death or serious deterioration in the health of a patient; and
 - (b) any technical or medical event relating to the characteristics or performance of a product which has led to the manufacturer's systematic withdrawal from the market.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices Pending Applications

Third parties have limited access to information in pending marketing authorisation applications. The information included in the application dossier (such as proprietary formulations, clinical trial data, regulatory status or information that might reveal competitive strategies) is not publicly accessible unless there is an overriding public interest in disclosure (Article 81, paragraph 5 of the CTR).

For medical devices, no public registry of pending applications exists.

Granted Authorizations

Pharmaceuticals

The following information becomes public:

- product name & active substance;
- MAH;
- summary of product characteristics;
- public assessment report;

- approval date and therapeutic indications; and
- package leaflet & labelling.

Medical devices

EOF may release basic registration details (eg, name of the manufacturer, general device use, approval date), but full technical documentation remains confidential. Article 20 of the Joint Ministerial Decision DY8d/130648/2009 sets out what is considered non-confidential information. Moreover, the National Electronic Registry of Medical Devices (GREMDIS) can only be accessed if there are dedicated credentials and is not publicly available, while for EUDAMED (the EU medical device database), in order to check for device registration/certifications, specific fields need to be completed (eg, manufacturer; notified body; certificate number and status; risk class; device type, etc).

Refused Authorisations

Pharmaceuticals

EMA publishes details of refused, withdrawn, or suspended authorisations, including the reasons for refusal. Information on national refusals (EOF decisions) is not published but can be obtained upon request.

Medical devices

If a CE certification is refused, the manufacturer is not obligated to disclose it.

Rules on Protecting Commercially

Confidential Information and Personal Data

There are confidentiality obligations regarding commercially confidential information (eg, manufacturing processes, regulatory strategies, proprietary research) and the protection of personal data (eg, clinical trial participants' personal data and individual adverse event reports) as set out in EU legislation (eg, Regulation EU 1049/2001

– Access to EU Documents, 679/2016 GDPR, Regulation EU 1725/2018 for processing of personal data by the Union institutions, bodies, offices and agencies; Directive, etc).

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes Pharmaceuticals

EMA provides mechanisms such as accelerated assessment (Regulation 726/2004 Article 14 paragraph 9 and Directive) and conditional marketing authorisations (Regulation 726/2004 Article 14a in conjunction with Regulation 507/2006 and Directive) for products that address unmet medical needs or serious conditions. For accelerated assessment, the authorisation application is assessed in 150 days instead of 210 days, and the applicant submits a full set of clinical data and data proving that the medicine is of major interest to public health.

Conditional marketing authorisation allows approval of the product before full submission of the clinical trial results, provided that the benefit of the immediate availability on the market outweighs the risk when additional data are still required.

Medical Devices

For medical devices, Article 11 paragraph 13 of the Joint Ministerial Decision DY8d/130648/2009 and Article 59 of the MDR provide expedited pathways in specific cases where any competent authority may authorise, on a duly justified request, the placing of a specific device on the market, the use of which is in the interest of public health. EOF may grant temporary emergency use authorisation or national exemption before EU-wide approval.

4.2 Regulatory Reliance Pharmaceuticals

EU-based reliance

If a medicine has received a marketing authorisation from EMA, it is automatically valid in all EU member states, including Greece.

If another EU national competent authority grants an authorisation via Mutual Recognition Procedure or Decentralised Procedure, EOF relies on that decision and does not reassess the application dossier.

Non-EU reliance

EOF may consider World Health Organization (WHO) pre-qualification medicines in case of global health emergencies.

EOF does not automatically accept non-EU approvals (eg, FDA, MHRA, etc), however:

- companies can submit foreign regulatory approvals as supportive data;
- EOF may expedite the local review.

Medical Devices

If a device is already CE-certified by an EU Notified Body, EOF does not conduct an additional review. Registration with EOF is still required for local market entry. In general, as per Article 20, paragraph 1 of the MDR, medical devices in conformity with the rules of the MDR bear the CE marking of conformity, which means that they can be marketed in all member states.

EOF does not automatically accept non-EU approvals (eg, FDA), but companies can submit foreign approvals to strengthen applications.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceuticals

Manufacturing facilities must obtain a manufacturing license from EOF. According to Article 58 of the JM Decision, each manufacturing facility has to obtain a manufacturing license, which is granted under the following conditions:

- specify the medicinal products to be manufactured, as well as the place of manufacture;
- ensure suitable and adequate premises, technical equipment, and control facilities; and
- appoint at least one qualified person.

Furthermore, according to Articles 9 of both Joint Ministerial Decision DYG3a/7567/2008 and Joint Ministerial Decision YA D3(a)/14709/2018, the manufacturer must ensure that manufacturing plants and equipment are sited, designed, constructed and maintained in such a way that they perform the functions for which they are intended. Additionally, they must be arranged and used in such a way as to minimise the risk of error and to permit effective maintenance in order to avoid direct and cross-contamination and any undesirable effect on product quality. EOF conducts on-site inspections to verify compliance with EU GMP standards.

Medical Devices

For medical devices, the decision issued by EOF 0–1016/22nd/15.12.2008 (Ministerial Decision 6209/2009) sets out the rules regarding good manufacturing and control rules for medical devices in order to ensure appropriate implementation of a quality system. As per Article 3

of the said decision, among others, the manufacturer of a medical device must have the following in place:

- appropriately qualified and trained personnel;
- adequate facilities and premises;
- appropriate equipment and services;
- appropriate materials, containers and labels;
- approved procedures and instructions;
- appropriate storage; and
- written records of manufacture and distribution with which the history of the batch can be traced.

Following the approval of the application, EOF grants the manufacturing authorisation for the medical device as per Article 2 of the Joint Ministerial Decision DY8d/130648/2009.

Manufacturing licenses for pharmaceuticals and medical devices typically remain valid indefinitely, provided that the manufacturer complies with ongoing regulatory requirements. These include:

- adherence to GMP rules and issuance of a relevant GMP certificate of compliance, which is valid for three years unless specific circumstances reduce or increase this period; and
- adherence to relevant quality management standards (eg, ISO 13485 for medical devices that must be renewed every three years).

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesalers must obtain a wholesale license issued by EOF. Application to EOF includes company details, warehouse location, description of storage and handling facilities, list of medicinal

products to be handled and responsible person certificate.

Upon evaluation and on-site inspection to verify GDP standards, EOF grants a wholesale license, which gives the right to procure, store, distribute and supply pharmaceuticals/devices to pharmacies and hospitals.

Pharmaceuticals

The Wholesale License is issued for a specific region and is valid for five years. If MAH or its local representative has a manufacturing license, no wholesale license is needed to distribute and sell products.

The conditions for granting a wholesale license are outlined in Article 105 of the JM Decision and the Presidential Decrees 194/1995 and 88/2004.

According to Article 105 of JM Decision, the applicant must:

- have appropriate and sufficient premises and equipment;
- employ staff, including a qualified person (QP) who meets the requirements set forth in the applicable legislation;
- fulfil the obligations outlined in Article 106 of JM Decision; and
- satisfy the remaining conditions of Presidential Decree 88/2004, *“Organization and Operating Specifications of a Pharmaceutical Warehouse.”*

Medical Devices

For medical devices, the validity period is not explicitly set under MDR/IVDR, but compliance with regulations is continuously monitored, and EOF may revoke the authorisation if the wholesaler fails to comply with regulatory obligations. Any certification which verifies compliance with

regulatory standards must be renewed every three years.

6.2 Different Classifications Applicable to Pharmaceuticals

The classifications are described in the Directive (Directive Title VI), national laws (3457/2006 & 3816/2010), and JM Decision (Article 95). According to Article 70 of the Directive and Article 95 of the abovementioned Decision, pharmaceuticals are classified as:

- a pharmaceutical subject to medical prescription; and
- a pharmaceutical not subject to medical prescription.

Based on the above, in Greece, the classification of pharmaceuticals is as follows:

- Prescription-only medicines (POM) require a prescription from a licensed healthcare professional and are dispensed in pharmacies. Furthermore, according to Directive Article 70 paragraph 2, EOF has to classify further when labelling the following pharmaceuticals:
 - (a) pharmaceuticals subject to a medical prescription;
 - (b) pharmaceuticals subject to special medical prescription; and
 - (c) pharmaceuticals subject to *“restricted”* medical prescription reserved for use in hospitals.
- Over-the-counter (OTC) medicines can be purchased without a prescription. Regulated under EOF guidelines and still subject to quality & safety controls.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Pharmaceuticals

Directive 2001/83 (IV Section) along with the JM Decision and EU Directive 2011/62 along with Joint Ministerial Decision D3(q)41169/19/8-7-2020 (for the prevention of the entry into the legal supply chain of falsified medicinal products) set out the rules for importation and exportation of pharmaceuticals.

Medical Devices

MDR is the legal framework for importing and exporting medical devices, while IVDR is the legal framework for in vitro diagnostic medical devices.

Competent Bodies

- EOF is the competent authority.
- To ensure an adequate supply of products in the market, the EOF has banned the export of certain medicines. Additionally, through Circular No 66718/2011, the EOF requires wholesalers to submit monthly intra-EU export data. In line with this, the Greek Customs Code (Law 2960/2001) and the EU Customs Code (Regulation (EU) No 952/2013) have introduced a monitoring system, as outlined in Circular No 24151/2012, to track the domestic distribution of pharmaceuticals at the customer level for all wholesalers.
- In response to COVID-19 supply chain challenges, EOF, in coordination with EMA, imposed temporary bans on parallel exports and intra-EU distribution.

- Greek Customs Authority (Independent Authority for Public Revenue – AADE):
 - (a) controls import duties, VAT, and customs clearance;
 - (b) works with EOF to intercept counterfeit or illegal imports; and
 - (c) ensures compliance with tariff codes and EU single market rules.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

In Greece, an importer can be:

- a MAH;
- manufacturers with import licenses (if importing their own products); and
- licensed wholesale distributors of medicines and medical devices.

IFET (the national Greek public wholesaler) handles the import of medicines that are not commercially available in Greece and require special approval for pharmacies and hospitals

Pharmaceuticals

According to the JM Decision (Government Gazette B' 1049/29-04-2013), which aligns Greek law with the Directive, an importation licence from EOF is required. Obtaining the licence requires filing an application, which must include the specific medicines to be imported, the place of their production, the relevant premises, technical equipment, and control capabilities for the importation process. Additionally, the application must designate at least one qualified individual responsible for these activities, as outlined in the aforementioned Ministerial Decision.

Key requirements:

- Import Permit by EOF for controlled substances (pharmaceuticals containing narcotics);
- Wholesale Distribution Authorisation from EOF;
- Marketing Authorisation or Parallel Import License; and
- Customs Registration & VAT Compliance (AADE & Greek Customs Authority).

Medical Devices

According to guidance issued by EOF, importers of medical devices are required to notify their details to the National Electronic Registry of Medical Devices GREMDIS. Required documents are:

- CE Marking Certificate (for high-risk medical devices) or certificate of the competent authority of the EU Member State where the products were registered (for low-risk Categories);
- manufacturer's Declaration of Conformity;
- outer packaging;
- and
- instructions for use.

Key requirements:

- registration with EOF as an importer;
- CE Marking & Declaration of Conformity from the manufacturer
- quality compliance certification (eg, ISO 13485); and
- Customs and VAT Registration (AADE & Greek Customs Authority).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In Greece, the importation of pharmaceuticals and medical devices requires prior authorisation from the National Organization for Medicines (EOF). Import licenses are necessary only for products brought in from non-EU countries. This is in accordance with the EOF Circular on the Import and Distribution of Pharmaceuticals (EG-18013-2013) and the regulation allowing the free movement of goods within the EU (DYG 3a 82161/12, Article 40).

Importation of Pharmaceuticals

According to the JM Decision (Government Gazette B' 1049/29-04-2013), an importation license from EOF is required as follows.

- Import Capability License:
 - (a) company application with requested forms;
 - (b) operating license from Authorities;
 - (c) layout of required spaces; and
 - (d) list of microbiological/chemical lab instruments (if self-testing).
- Pharmaceutical Product Import License:
 - (a) application specifying manufacturer, packaging, control site, origin, formulation, strength, and packaging;
 - (b) Import Capability License for the requested form;
 - (c) marketing authorisation; and
 - (d) GMP Certificate issued by an EU/EEA Authority for the product or manufacturer.

Importation of Medical Devices

Distinction between based on CE mark:

- CE-Marked Medical/In Vitro Diagnostic Devices (MDR/IVDR compliant); the importer must be registered with EOF; and

- Non-CE-Marked Devices (not registered in Greece): EOF must provide specific import approval.

Custom-made medical devices (eg, prosthetics) may be exempted from standard import requirements but must still be registered with EOF.

In order to place their products on the Greek market, medical device importers are required to notify the National Electronic Registry of Medical Devices GREMDIS of their details. Required documents are:

- CE Marking Certificate (for higher-risk medical devices) or Certificate of the competent authority of the EU Member State where the products were registered (for low-risk medical devices);
- Manufacturer's Declaration of Conformity;
- outer packaging; and
- instructions for use.

Exceptions

Personal use

Patients can import small quantities of prescription medicines for personal use, but the provision of the doctor's prescription and patient declaration to customs is mandatory.

Emergency public health situations

During pandemics, disasters, or shortages, pharmaceutical products may be imported following a decision of EOF (Paragraph 5 of Article 8 of Legislative Decree 96/1973)

Named patient programmes & compassionate use

Importation of unapproved medicines for individual patients or for a group of patients following EOF decision. For individual patients, the

treating physician proposes (and EOF issues) an individual decision.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

In Greece, non-tariff regulations and restrictions on the importation of pharmaceuticals and medical devices are imposed based on their regulatory category and classification under the Combined Nomenclature (CN) Code, which is based on the Harmonized System (HS) Code.

The Greek Customs Code (Law 2960/2001), in alignment with the EU Customs Code (Regulation (EU) No 952/2013), provides that if the pharmaceutical product or the medical device meets the requirements of the applicable legislation for its manufacturing and production, it may be imported into Greece or any other European jurisdiction.

Pharmaceuticals, governed by Directive, implemented in Greece through JM Decision, require authorisation from the EOF. Products must meet provided qualitative and quantitative composition standards, and batch testing may be required upon their termination.

Medical devices are regulated under MDR and IVDR for in vitro diagnostic devices. All imported devices must bear the CE mark and be registered in the EUDAMED database. Customs authorities check for technical documentation, conformity assessments, and labelling compliance.

Additionally, specific restrictions from countries on specific products may be provided in the EU TARIC database, which determines additional requirements, restrictions, or prohibitions.

Laws and Regulations governing these restrictions are outline below.

- Greek Customs Code (Law 2960/2001) – Establishes the general import framework.
- EU Customs Code (Regulation (EU) No 952/2013) – Sets import procedures across the EU.
- Directive & JM Decision – Regulates pharmaceutical imports.
- MDR & IVDR – control medical device imports.

7.5 Trade Blocs and Free Trade Agreements

Greece is a member of the European Union (EU), which operates as a trade bloc and has established multiple Free Trade Agreements (FTAs) and Mutual Recognition Agreements (MRAs) with third countries.

The EU's FTAs with Japan (EPA), South Korea, and the UK (TCA) provide duty-free access for pharmaceutical exports, eliminating tariffs entirely. In the case of the FTA with Canada (CETA), 99% of tariffs on pharmaceuticals have been abolished. The EU also has an FTA with Switzerland, where pharmaceutical trade benefits from tariff-free movement due to Switzerland's participation in the EU Single Market. Once ratified, the pending EU-MERCOSUR trade agreement is expected to bring tariff reductions for pharmaceutical exports.

As a member of the World Trade Organization (WTO) since 1995, Greece adheres to global trade rules that promote transparency, fair market access, and lower trade restrictions. Its participation in the WTO FTA reduces shipping times and administrative costs, which benefits pharmaceutical exports.

Mutual Recognition Agreements (MRAs) with Canada, Switzerland and the UK facilitate market access by eliminating duplicate testing,

expediting regulatory approvals, and accelerating entry into highly regulated markets.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices Pharmaceuticals

According to Legislative Decree 96/1973 and Ministerial Decisions D3(a)/6295/2024 and D3(a) 59308/2024, the maximum prices for prescription-only medicinal products – specifically the retail price, wholesale price, hospital sale price, and ex-factory price – are determined using Price Bulletins issued by the Minister of Health. This process follows a proposal by the EOF, as stated in Article 17 of Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973), and requires an application from the Marketing Authorization Holder (MAH). OTC medicinal products are excluded from this pricing structure.

Original medicinal products are priced in accordance with a median of the two lowest prices of the two Member States of the Eurozone. The same applies to off-patent medicinal products (original products following the expiration of their market exclusivity). Generic products are priced at 65% of the original product's price, while biosimilars are priced using the same method as their originals (the two lowest prices in the Eurozone). Non-prescribed pharmaceutical products (OTC) are priced in accordance with a median of three lowest prices of three EU Member States, and this price is indicative for pharmacies but mandatory for sales to hospitals. The final price of all the above categories of products is the ex-factory price on which the wholesale margin and the retail margin are added when the product is

sold through a pharmacy. When the products are sold to a hospital, the ex-factory price is reduced by 8.74%.

Medical Devices

There is no legislation in Greece controlling their prices. EOPYY (National Organization for Health Care Services) sets maximum reimbursement limits for certain categories of devices. Prices are primarily controlled through hospital tenders and reimbursement policies rather than direct price caps.

8.2 Price Levels of Pharmaceuticals or Medical Devices

Pharmaceuticals

Original medicinal products are priced in accordance with a median of the two lowest prices of the two Member States of the Eurozone.

The same applies to off-patent medicinal products (original products following the expiration of their market exclusivity).

Generic products are priced at 65% of the original product's price, while biosimilars are priced with the same method as their originals (the two lowest prices in the Eurozone).

OTCs are priced in accordance with a median of the three lowest prices of the three EU Member States. This price is not obligatory for the retail channel (pharmacies) but is mandatory when sales are made to public hospitals.

Medical Devices

For medical devices, Greek legislation does not explicitly tie, their price to other countries under general pricing rules but relies on EOPYY reimbursement rules considering costs across the EU.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Pharmaceuticals

According to Article 1 (paragraph 2) of Law 3457/2006 (Government Gazette A 93/8.5.2006), the medicinal products that are classified as OTC are not reimbursed by social security funds. The reimbursement rules regarding prescription-only products are contained in Article 12 of Law 3816/2010 (Government Gazette A' 6/26.01.2010), as well as in Article 247 et seq of Law 4512/2018 (Government Gazette A' 5/17.01.2018).

For the latter products to be reimbursed, they need to be approved on the positive list of reimbursed products (Article 12 of Law 3816/2010). The inclusion of a medicinal product requires a Decision of the Minister of Health, following the opinion of the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use (Evaluation Committee – Article 247 of Law 4512/2018), which opinion is issued following an application from the MAH.

The Evaluation Committee, in order to evaluate the cost-effectiveness ratio and the impact on the state budget, refers for an opinion to the Drug Price Negotiation Committee (Negotiation Committee) and is responsible for negotiating the prices or discounts of medicinal products which are going to be reimbursed (and often concludes separate agreements including further discounts).

The Negotiation Committee initiates and concludes the negotiation process for the medicinal product by issuing a justified opinion. The Evaluation Committee takes into account the justified opinion of the Negotiation Committee for its final opinion.

Medical Devices

The reimbursement of medical devices is regulated under Article 108 of Law 4461/2017 (Government Gazette A' 38/28.03.2017). In particular, for the reimbursement of medical devices for special medical purposes (FSMPs), the importer/manufacturer/representative of these products must submit to EOPYY a declaration stating that:

- the items are registered in the registers of EOF and in the registers of reimbursable products of EOPYY if the product is registered in the latter; and
- that the product is marketed in at least three countries of the European Union.

The reimbursement price of the product is determined by a maximum of the average of the three lowest prices in the countries of the European Union.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In Greece, Health Technology Assessment (HTA) plays a significant role in reimbursing pharmaceuticals and medical devices.

Currently, the country has established the Committee for Assessment and Reimbursement of Medicines for Human Use, effectively functioning as an HTA body, which evaluates new products as follows (Article 245 of Law 4512/2018):

- clinical benefit – assessing the therapeutic value and efficacy of the medicine;
- comparison with existing therapies – evaluating how the new medicine compares to treatments already available and reimbursed;
- data reliability – ensuring the robustness and credibility of the submitted clinical and economic data;

- cost-effectiveness – analysing the economic value of the medicine in relation to its therapeutic benefits; and
- budget impact – estimating the financial implications of including the medicine in the reimbursement list.

The assessment process begins with the MAH submitting a dossier. For products receiving a positive initial assessment, the Pricing Negotiation Committee (as per Article 254 of Law 4512/2018) evaluates their budget impact and negotiates pricing and discounts with the MAH.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Prescription and Dispensing by Physicians

According to Law 3892/2010, physicians are required to issue prescriptions through the Electronic Prescription System, a centralised platform managed by IDIKA SA (e-Government Center for Social Security Services). IDIKA S.A. maintains a database of all insured individuals in all social insurance funds based on the unified Social Security Registry Number (AMKA Registry). This system monitors prescribing practices and ensures compliance with national guidelines.

According to the provisions of Laws 4052/2012 and 4093/2012, doctors must prescribe exclusively based on the active substance's International Nonproprietary Name (INN). Doctors are required to select the appropriate medication in compliance with the therapeutic protocols of EOF. Also, physicians are legally obligated not to exceed prescription limits for patients.

Pharmacy Sales

Pharmacies, according to law 4316/2014, are required to dispense the pharmaceutical product with the lowest retail price for each active sub-

stance from the drugs listed in the positive list unless the consumer insists on a brand-name drug and pays the price difference in addition to a co-payment which is typically 0%-25% of the drug cost.

Also, pharmacies are linked to the national e-prescription system, ensuring real-time tracking.

Law 4052/2012, as amended, provides for a claw-back mechanism imposing a specific budget for pharmaceutical sales to public health-care entities. As a result, any amount exceeding the budget is recovered by the payors from the MAHs of pharmaceutical products.

Trends and Developments

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ALG Manousakis Law Firm

ALG Manousakis Law Firm ALG Law Firm was established in 2011 by Ioannis and Alexandros Manousakis. Based in Athens, ALG is an international law firm with lawyers qualified in 6 EU jurisdictions and Switzerland. ALG's team consists of 50 lawyers and 25 paralegals. With deep expertise in corporate and commercial law, the firm offers tailored solutions across various industries. Their client base includes 30

pharmaceutical/biotech and five medical device companies, supported by the firm's lawyers in contracting negotiation, ensuring compliance, and developing robust data privacy frameworks. The firm has a proven commercial and administrative litigation track record, with a high rate of success, especially in commercial claims and tax and administrative litigation.

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Pharma-Related Trends in Greece *Greek Government's incentivisation of pharmaceutical companies' investments in clinical research*

A recent legal initiative provides that pharmaceutical companies may offset the amounts owed as claw-back to the state (amounts paid for exceeding the budget of the Ministry of Health) against their expenditure on research activities. This measure is now financed by the Recovery and Resilience Fund (RRF), which is part of the NextGeneration EU program, a European financial instrument aimed at economic recovery and strengthening the resilience of EU member states following COVID-19. The inclusion of this measure in the RRF aims to promote investments and create a favourable environment for innovation in Greece's pharmaceutical sector.

The “claw-back” system is a mechanism that was established in Greek legislation, according to Annex 5 of the Memorandum for certain economic policy conditions of 2012. Article 11 of Law 4052/2012 states that “*the monthly expenditure for pharmaceutical products by social security funds (SSFs) cannot exceed 1/12 of the amount recorded in the annual social budget allocated to pharmaceutical care*”. Based on the limits of the monthly/yearly expenditure, an automatic recovery system is linked to the establishment of “closed budget” for pharmaceutical products.

The amounts that each Marketing Authorization Holder (MAH) is required to pay in the case of claw-back are determined based on:

- the percentage contribution of each drug to pharmaceutical expenditure;
- the market share of each drug within its therapeutic category on the reimbursement list; and
- the comparative consumption of each drug relative to the market share it held during the corresponding period of the previous year.

Initially, the aforementioned obligation was imposed due to the financial crisis, with the decision 668/2012 of the Plenary Session of the Conseil d'Etat (ΣΤΕ/Supreme Administrative Court), exclusively on a budget of the drugs sold through pharmacies and reimbursed by the Greek national payor of pharmaceutical products (EOPYY) for a limited period of time (eg, 2012-2015). It was essentially a corrective mechanism used to balance public spending. Subsequently, due to the continuing economic strain, the Greek government decided to extend the claw-back provisions for another three years (ie, 2015-2018) and to the in-hospital expenditure for pharmaceutical products. It becomes clear that the budget limitation will not be a temporary one but a permanent one, as Law 4837/2021 extended the claw-back until 2025.

The constitutionality of the “*claw-back*” mechanism has been repeatedly challenged. Pharmaceutical companies challenged the implementation of the claw-back before the Conseil d’Etat on the grounds that it restricts their freedom to operate independently and restricts their financial freedom. However, The Conseil d’Etat ruled that these restrictions are constitutionally justified from the public interest perspective in saving pharmaceutical costs and the long-term sustainability of the social security system. Regarding orphan drugs, the Conseil d’Etat, in its decision 162/2020, ruled that imposition of claw-back in orphan drugs is unconstitutional because these medicines constitute a special category, as they are used for the treatment of rare diseases and, furthermore, because they concern an extremely small number of patients, who are already known in advance, compared to medicines used for the treatment of other severe diseases (ie, the government cannot impose budget restrictions when the budget for those drugs should have been calculated due to the limited number of patients). Additionally, despite the fact that under Regulation 141/2000, EU member states must provide incentives to encourage the circulation of these medicines, Greek legislation on automatic reimbursement does not provide any form of special treatment for these medicines. As a result, the consequences become disproportionate to the intended purpose of the state in reducing pharmaceutical expenditure and, for this reason, constitute an excessive restriction on the companies that market orphan drugs.

In order for the Greek government to mitigate the financial impact of the “*claw-back*” mechanism and promote research and development (R&D), it enacted Law 4633/2019, which allows pharmaceutical companies to offset the amount of the claw-back with eligible R&D and investment expenses. The Joint Ministerial Decision

4577/24-1-2020 sets out the procedure and specific terms and conditions under which the claw-back obligation may be offset with R&D expenses for the development of pharmaceutical products. The amounts owed under the claw-back provisions may be offset with R&D expenses, including preclinical and clinical trial expenditures for original products. In 2020, the total amount available for offsetting was EUR50 million and in 2023, it was EUR150 million. The inclusion of this measure in the RRF aims to promote investments and create a favourable environment for innovation in Greece’s pharmaceutical sector.

This is the first time that such a law has been implemented, providing investment incentives for pharmaceutical companies while ensuring fiscal responsibility in public healthcare spending. This initiative aims to stimulate research and development, foster innovation in the pharmaceutical sector, and ultimately improve public health outcomes.

Increase in the use of generic pharmaceutical products

Greece was one of the bottom countries in the European ranking of generic drug use in 2010, where only 15% of the medicinal products sold were generic or biosimilar products. Following extensive changes in the legislation, a sustained and steady increase in the use of generic medicines has been observed from 2010 to 2022, and the total consumption reached 32.6%, with an increase rate of 8.5% during 2022.

In Greece, until the outbreak of the fiscal crisis at the end of 2009, pharmaceutical expenditure was unsustainable due to legislation reimbursing any brand-name drug. Following the signing of the First Memorandum and the First Economic and Financial Adjustment Program

in May 2010, broader reforms were foreseen to improve the management of the state budget and the efficiency of the entire healthcare sector. These measures sought to manage the previously uncontrolled pharmaceutical expenditure. One of the initial steps was the introduction of a requirement for Healthcare Professionals (HCPs) to prescribe based on the active substance instead of the brand name of the drug, thereby annulling previous legislation providing for the latter (Decision 3802/14 of the Plenary Session of the ΣΤΕ). More specifically, since 2012, doctors have been required to prescribe the corresponding international non-proprietary name (INN) of the active substance instead of the brand name. However, brand-name prescribing is allowed for up to 15% of the total annual prescription value in exceptional cases involving certain diseases.

Despite the total consumption of generic drugs reaching 32.6% in 2022, with an annual increase rate of 8.5%, the fact that they were “imposed” as a memorandum-related economic measure lead citizens-patients to face them with suspicion – mainly, during the early years of the financial crisis (2010-2014). However, the aforementioned scepticism has been eliminated in recent years thanks to the continuous bioequivalence reports of generic drugs conducted by the Hellenic Medicines Organization (EOF). This ensures their equivalence to the original reference drugs and dispels any doubts regarding the quality and safety of generics.

As a matter of fact, an additional significant factor that contributed to the increase in the use of generics was the more rational legislative approach regarding their pricing and reimbursement. In Greece, the maximum price of generics is set at 65% of the price of the corresponding reference products when the market exclusivity period expires (10 years from the market authori-

sation issuance). Moreover, from 2014, as provided in Ministerial Decision 38733/29.4.14, an increased patient co-payment is foreseen when the cost of the medicine exceeds the reimbursement price, which fosters the use of generics, since the reimbursed amount for generics equals the reimbursement price, while the price of the original product exceeds, most of the times, the reimbursement price.

As a result, in Greece, the widespread use of generic medicines in recent years has brought a plethora of advantages: pharmaceutical expenditure is reduced, competition in drug pricing intensifies, and research for new drugs is encouraged, as generics limit the monopoly profits from brand-name drugs whose patent protection has expired, due to the decline in their sales.

Significant investment by mostly Greek-owned generic drug producers in building manufacturing facilities in Greece

Large manufacturing units have been built and begun operating in Tripoli and Attica during the past three years, a development not very common during the past twenty years.

In recent years, Greece has witnessed significant investments in pharmaceutical manufacturing, particularly in regions like Tripoli and Attica. This trend marks a departure from the past two decades, during which such developments were relatively uncommon.

The industrial area of Tripoli, located in the central Peloponnese, is rapidly transforming into a centre for pharmaceutical research and production. Several factors contributed to this development, including investment incentives provided through the “*Just Transition Development Plan*” following the phase-out of coal in nearby

regions like Megalopolis and Tripoli's proximity to Athens. Taking advantage of the investment claw-back program enacted by the government, four of the largest pharma manufacturing companies are investing in new production facilities. Their collective efforts aim to establish ten new factories and 56 production lines, along with 14 new research structures, creating approximately 5,500 new jobs. These initiatives are expected to meet over 50% of Greece's medication needs for oncology patients, contribute to savings in pharmaceutical expenditure and enhance both national and European self-sufficiency in pharmaceutical production.

More specifically, one of the largest pharmaceutical companies of parenteral solutions (IV fluids) in Europe and a prominent player in the Greek pharmaceutical industry has announced an ambitious investment plan worth EUR356 million for the period 2021-2027. This plan includes constructing four new production units in Tripoli's Industrial Area. Additionally, it is expanding its finished pharmaceutical product manufacturing capabilities by building six new production units at its Tripoli complex, aiming for a capacity of 250 million finished products annually.

Another leading Greek pharmaceutical company, known for its respiratory medications and cardiovascular products, contributes to the industry's growth with significant investments of EUR170 million in research and development, especially in the Attica region. The company operates a state-of-the-art Experimental Research Center and has been actively developing both original and generic pharmaceutical products for the Greek and international markets.

Another Greek pharmaceutical company, with a history of over 70 years, produces a wide range of pharmaceutical and non-pharmaceutical products covering various therapeutic categories, such as osteoporosis, hypertension, infertility and parathyroid disorders. Along with two large pharmaceutical companies, it is planning the construction of a new research and manufacturing facility for injectable and biotechnological drugs in the Industrial Zone of Tripoli. Reports indicate that the total investment for the three pharmaceutical companies in the area will exceed EUR180 million.

Finally, in the Attica region, another multinational pharmaceutical company that manufactures veterinary, respiratory, cardiovascular, and neurological products operates a major industrial production facility in Koropi, marking it as the only multinational pharmaceutical company with a manufacturing facility in Greece. In 2020, the pharmaceutical company announced further multi-year investments of EUR120 million in Koropi, intending to transform this site into a new production hub for its innovative medications.

INDONESIA



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Santoso, Martinus & Muliawan Advocates (SMMA) is an Indonesian law firm with global exposure and local expertise. The firm's partners are alumni of major international law firms who have represented FTSE 100 and US Fortune 500 companies as well as Asia's largest companies in high-profile transactions and cases. Examples of relevant recent work include representing an S&P 500 provider of specialty medical devices in setting up an entity in Indonesia, representing a European multinational

pharma and biotechnology company in its antitrust compliance exercise in Indonesia, representing a NASDAQ 100 company on a compliance exercise in Indonesia, representing an S&P 500 global supplier of life sciences solutions in its compliance exercise in Indonesia, assisting a European medical device innovator in a tender submission with the Ministry of Health, and representing a US medical device company in its anti-bribery investigation and employment matters.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices Legislation and Regulation

The primary legislation governing pharmaceuticals and medical devices is Law No 17 of 2023 on Health (“*Law 17/2023*”). This legislation is implemented through regulations on pharmaceuticals issued by the Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan*, or BPOM) as well as regulations on medical devices issued by the Minister of Health (MOH). On 26 July 2024, the government issued Government Regulation (GR) No 28 of 2024 on Implementing Regulation of Law Number 17 of 2023 on Health (“*GR 28/2024*”).

Pharmaceuticals

Key regulations for pharmaceuticals include:

- BPOM Regulation No 8 of 2024 on Procedures for the Approval of Clinical Trials Implementation (“*BPOM 8/2024*”)
- BPOM Regulation No 27 of 2022 on Supervision of Drug and Food Imports into Indonesia, as amended by BPOM Regulation No 28 of 2023 (“*BPOM 27/2022 as amended*”)
- BPOM Regulation No 2 of 2021 on Guidelines for Drug Advertising Supervision (“*BPOM 2/2021*”)
- BPOM Regulation No 14 of 2024 on the Supervision of Drugs and Food Distributed Online (“*BPOM 14/2024*”)
- BPOM Regulation No 7 of 2024 on Good Manufacturing Practice for Pharmaceuticals;
- BPOM Regulation No 10 of 2021 on Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Drug and Food Sector;

- Head of BPOM Regulation No 24 of 2017 on Criteria and Procedures for Drug Registration, as last amended by BPOM Regulation No 15 of 2023 (“*H.BPOM 24/2017 as amended*”) and
- MOH Regulation No 98 of 2015 on the Provision of Information on Maximum Retail Price of Medicines (“*MOH 98/2015*”)

Medical devices

Key regulations for medical devices include:

- MOH Regulation No 14 of 2021 on Standards for Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Health Sector, as lastly amended by MOH Regulation No 17 of 2024 (“*MOH 14/2021*”)
- MOH Regulation No 51 of 2014 on the Importation of Medical Devices through the Special Access Scheme as amended by MOH Regulation No 7 of 2020 (“*MOH 51/2014 as amended*”)
- MOH Regulation No 24 of 2022 on Medical Records (“*MOH 24/2022*”)
- MOH Regulation No 20 of 2019 on the Implementation of Telemedicine Services between Healthcare Facilities (“*MOH 20/2019*”)
- MOH Regulation No 62 of 2017 on Marketing Authorisation for Medical Devices, In Vitro Diagnostic Medical Devices, and Household Health Supplies (“*MOH 62/2017*”)
- MOH Regulation No 63 of 2017 on Good Clinical Practice for Medical Devices (“*MOH 63/2017*”)
- MOH Regulation No 17 of 2017 on Action Plan for the Development of the Pharmaceutical and Medical Equipment Industry (“*MOH 17/2017*”)
- MOH Regulation No 76 of 2013 on Advertising of Medical Devices and Household Health Supplies (“*MOH 76/2013*”)

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- MOH Regulation No 20 of 2017 on Good Manufacturing Practices for Medical Devices and Household Health Supplies (“MOH 20/2017”)
- MOH Regulation No 1189/MENKES/PER/VIII/2010 Year 2010 on Production of Medical Devices and Household Health Supplies as partially revoked by MOH Regulation No 26 2018 on Electronic Integrated Business Licensing Services in the Health Sector (“MOH 1189/2010”) and
- MOH Regulation No 4 of 2014 on Good Distribution Practice for Medical Devices (“MOH 4/2014”).

Regulatory Bodies Pharmaceuticals

The BPOM is the primary regulatory body responsible for the supervision and regulation of pharmaceuticals in Indonesia. The BPOM operates under Presidential Regulation (PR) No 80 of 2017 on Indonesian Food and Drug Authority (“PR 80/2017”) and is a non-ministerial government institution tasked with overseeing drug control. Under PR 80/2017, the BPOM operates under and is accountable to the President through the MOH.

Medical devices

The MOH is the primary regulatory body responsible for the supervision and regulation of medical devices in Indonesia. As part of the central government, it operates under PR No 161 of 2024 on Ministry of Health (“PR 161/2024”). Under PR 161/2024, the MOH formulates and enforces health policies, including those related to medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Under Law No 5 of 1986 on the State Administrative Court, as lastly amended by Law No 51 of 2009 (“Law 5/1986 as amended”), there exists a legal avenue for challenging administrative decisions. This legislation allows any party who believes that their rights have been infringed upon by a state administrative decision to file a lawsuit in the State Administrative Court (*Pengadilan Tata Usaha Negara*, or PTUN).

For a decision to be the object of a PTUN lawsuit, it must meet the criteria of being concrete, individual and final. The BPOM is a governmental agency responsible for regulating and controlling drugs and food products, whereas the MOH is responsible for regulating and controlling medical devices. As such, the BPOM’s and the MOH’s decisions are considered state administrative decisions. These decisions can be challenged in the State Administrative Court, provided they meet the aforementioned criteria.

To challenge a BPOM and MOH decision, the claimant must demonstrate that the decision directly affects their legal rights or interests and is flawed either procedurally or substantively. The lawsuit must be filed within 90 days from when the decision was issued or became known to the claimant. The State Administrative Court will then review the case to determine the legality and justification of the decision. If the court deems the decision unlawful, it can annul the decision and order corrective actions.

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1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

Under Law 17/2023 and GR 28/2024, drugs are categorised into prescription-only drugs and non-prescription drugs.

Prescription-only drugs consist of potent drugs, narcotics, and psychotropics, which must be dispensed exclusively by licensed pharmacists operating within a pharmaceutical service facilities. Non-prescription drugs, which are further divided into OTC drugs and limited OTC drugs, may be obtained from pharmaceutical service facilities or other facilities in accordance with laws and regulations.

Law 17/2023 provides that certain potent drugs may be dispensed by a pharmacist without a prescription. Under GR 28/2024, these drugs are specified in a list issued by the MOH and reviewed based on developments in healthcare needs, science, and technology.

In addition to these categories, Law 17/2023 also delineates the classification of natural medicines into traditional herbal remedies (*jamu*), standardised herbal medicines, phytopharmaceuticals, and other natural medicines.

Medical Devices

Based on the risk posed to patients by the use of medical devices, MOH 62/2017 categorises medical devices into Class A (low risk), Class B (low-to-moderate risk), Class C (moderate-to-high risk) and Class D (high risk).

For in vitro diagnostic medical devices, MOH 62/2017 provides classification based on the risk posed by misinterpretation of diagnostic results to individuals and the public – ie, Class A (low risk both to individuals and the public), Class

B (moderate risk to individuals but low risk to the public), Class C (high risk to individuals but moderate risk to the public), and Class D (high risk both to individuals and the public).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Pharmaceuticals

Under BPOM 8/2024, clinical trials of pharmaceuticals are differentiated into pre-marketing clinical trials and post-marketing clinical trials. Conducting both types of clinical trials requires prior approval from the head of the BPOM (except for post-marketing clinical trials that are specifically undertaken in Indonesia for educational purposes). Such approval is valid for two years from the date of issuance.

Medical Devices

Similarly, MOH 63/2017 differentiates clinical trials of medical devices into pre-marketing clinical trials and post-marketing clinical trials. Conducting pre-marketing clinical trials requires prior approval from the MOH. Such approval is valid for two years from the date of issuance. In contrast, a notification to the Director General of Pharmaceuticals and Medical Devices (DGPMD) under the MOH will suffice for conducting post-marketing clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Pharmaceuticals

To secure authorisation to undertake a clinical trial of a pharmaceutical, the applicant must first submit an electronic application to obtain approval from the head of the BPOM through the official BPOM website by filing the prerequisite documents and paying the service fees. The BPOM will then evaluate the documents

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and may request for a correction to be made and/or additional data to be provided. If the BPOM deems no correction and/or additional data is necessary, the BPOM will issue either an approval or a refusal of the application within 20 working days from the date of service fees payment. Approval from the head of the BPOM to undertake a clinical trial will only be given after an approval from the Health Research Ethics Committee is obtained.

Medical Devices

Pre-marketing clinical trials

To secure authorisation to undertake a pre-marketing clinical trial of a medical device, the applicant must first submit a written application to attain approval from the MOH by filing the pre-requisite documents to the DGPMD under the MOH and paying the service fees. If the documents are deemed to be complete, the DGPMD will then form an evaluation team that will conduct an evaluation of the documents and deliver the result of the evaluation to the DGPMD. The DGPMD will issue an approval, refusal or deferment for the application within 20 working days from the date of the receipt of the documents filed. An approval from the Health Research Ethics Committee must be obtained prior to submitting a pre-marketing clinical trials application.

Post-marketing clinical trials

To secure authorisation to undertake a post-marketing clinical trial of a medical device, the applicant must first submit a written notification to the DGPMD under the MOH by filing the pre-requisite documents. The DGPMD will then give a response to the notification within 20 working days from the date of the receipt of the documents filed. If the DGPMD does not provide a response within the stipulated time, the applicant may draw up a statement confirming readiness to undertake the post-marketing clinical.

Approval from the Health Research Ethics Committee must be obtained prior to submitting a post-marketing clinical trials notification.

2.3 Public Availability of the Conduct of a Clinical Trial

The conduct and results of a clinical trial both for medicines and medical devices will not be listed in any publicly accessible database. The data generated by clinical trial institutions (eg, hospitals, research centres, and universities) is safeguarded and retained exclusively within these entities, ensuring that no external party is authorised to access such information.

In practice, the release of clinical trial data requires the explicit consent of all parties involved. For instance, in the event of a serious adverse incident, the data may be disclosed solely by mutual agreement for evidentiary purposes. The dissemination of such data is strictly confined to the directly involved parties, maintaining the integrity and confidentiality of the clinical trial process.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials (eg, for recruiting or monitoring purposes).

2.5 Use of Data Resulting From Clinical Trials

If the data generated from clinical trials can be used to identify an individual, it is deemed as personal data under Law No 27 of 2022 on Personal Data Protection (“Law 27/2022”). Under Law 27/2022, any transfer of personal data to an external entity is strictly prohibited unless consent has been obtained from the data subject.

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Additionally, Article 1(9) of BPOM 8/2024 and Article 1(6) of MOH 63/2017 affirm that the confidentiality of information relating to individuals participating in clinical trials of pharmaceuticals and medical devices is part of the Good Clinical Practice standard (*Cara Uji Klinis Yang Baik*), which must be complied with in conducting clinical trials.

2.6 Databases Containing Personal or Sensitive Data

Under Law 27/2022, the creation of a database containing personal information requires the explicit consent of the data subject.

Further, GR 28/2024 provides that health information system providers must store health data and health information in a database that is located in a safe place and is not damaged or easily lost by using electronic and/or non-electronic storage media. These databases may utilise servers, cloud computing systems, or other storage media in accordance with technological development. Such database must be hosted in a data centre located within the territory of Indonesia. Although storage services and facilities owned by a third party may be used, such arrangements must adhere to the following conditions:

- the storage must be implemented within Indonesia's jurisdiction;
- a formal co-operation agreement must be in place, which contains at least provisions on confidentiality, service level, and service level target;
- the health data and information are owned and fully controlled by the health information system provider; and
- the data processor must fulfill all data processor obligations under Indonesian law.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Under Law 17/2023, medical devices are defined as instruments, apparatus, machines, equipment, implants, in vitro reagents and calibrators, software, and materials or similar that are used on humans for medical purposes and do not achieve their primary action through pharmacological, immunological, or metabolic processes.

In contrast, drugs are defined as substances or mixtures thereof (including biological products) that are intended for human consumption to influence or examine physiological systems or pathological conditions for the purposes of diagnosis, prevention, treatment, recovery, health improvement, and contraception.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological products (eg, vaccines) fall within the definition of drugs and thus fall under the same regulations.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Marketing authorisation for pharmaceuticals is issued with a maximum validity period of five years. Renewal of marketing authorisation for a pharmaceutical must be submitted no earlier than 12 months and no later than two months before the current authorisation expires. Marketing authorisations for pharmaceuticals can be suspended and/or revoked in the event of:

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- violation of the obligation to make and send a production report or import report of imported drugs to the BPOM in accordance with laws and regulations;
- revocation of the industrial licence of the marketing authorisation owner; or
- the marketing authorisation owner committing a violation in the field of production, distribution, promotion, and/or drug labelling.

Medical Devices

Marketing authorisation for medical devices is issued with a maximum validity period of five years. Renewal of marketing authorisation for a medical device must be submitted no earlier than nine months before the current authorisation expires. Marketing authorisation for medical devices can be revoked in the event of:

- the medical devices causing consequences that may endanger health;
- the medical devices not meeting the criteria in accordance with the data submitted at the time of the application for the marketing authorisation registration;
- the product certificate is revoked;
- the medical device distribution licence is revoked; or
- termination of appointment as sole agent/sole distributor/exclusive distributor and/or authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices Pharmaceuticals

To obtain a marketing authorisation for pharmaceuticals, the registration process must be conducted with the BPOM through the Risk-Based Approach Online Single Submission (RBA OSS) system. Only pharma manufacturing companies

established in Indonesia can apply for registration.

The registration process for new products is classified into three categories:

- category 1 covers new drugs and biological products, including biosimilars;
- category 2 covers generic drugs and branded generic drugs; and
- category 3 covers other drug-containing products with special technology (eg, transdermal patches, implants and beads).

For new product registration of category 1, risk management planning is mandatory. The procedures and requirements for registration are outlined in H.BPOM 24/2017 as amended.

The registration process for variation is classified into three categories:

- category 4 covers major variations – ie, variations that have a significant effect on the efficacy, safety and/or quality of the drug;
- category 5 covers minor variations – ie, variations that do not fall under the category of either major variation or notification variation registration; and
- category 6 covers notification variations – ie, variations that have minimal or no effect on the efficacy, safety and/or quality of the drug.

The registration process for the foregoing generally consists of two stages – namely, the pre-registration phase and the registration phase. The pre-registration phase filters the registration process by determining the registration category, evaluation track, evaluation fee, and required documents.

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Medical Devices

Applications to obtain marketing authorisations for medical devices and in vitro diagnostic medical devices are submitted online through the RBA OSS system and the MOH electronic system. The application includes submission of administrative and technical requirements, including a certificate of production/medical device distribution licence, certificate of free sale, quality management system document, and product information.

The MOH then evaluates and verifies the administrative and technical requirements of the application. If the medical devices involve new technology, active substances, or uncommon claims, a review by a designated expert team may be required.

If the administrative and technical requirements are fulfilled and the documents are complete, the marketing authorisation is issued electronically within a specified timeframe. Otherwise, the MOH will issue a refusal letter. If additional information is required, the MOH will notify the applicant to provide the necessary details or documents.

Variation in the marketing authorisation must be conducted in the event there is a variation in:

- the size, packaging or marking of the product;
- accessories/attachments to the marketing authorisation; or
- the name or address of the representative authorised by the manufacturer.

If there are variations other than the foregoing, the marketing authorisation holder must apply for a new marketing authorisation.

Applications for a variation in the marketing authorisation for medical devices are submitted online through the MOH electronic system and fulfil administrative and technical requirements.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In principle, medical devices and in vitro diagnostic medical devices that are produced, imported, assembled, and/or repackaged must have a marketing authorisation to be distributed within Indonesia. However, MOH 62/2017 provides specific exemptions to this requirement:

- medical devices that enter Indonesia through a special access scheme (SAS) in accordance with laws and regulations;
- certain medical devices and in vitro diagnostic medical devices produced by household companies; and/or
- medical devices and in vitro diagnostic medical devices for certain reasons determined by the MOH.

Pharmaceuticals that enter Indonesia through the SAS in accordance with laws and regulations are exempted from the requirement for a marketing authorisation. In the event of a public health emergency, the marketing authorisation may be in the form of an emergency use authorisation (EUA), which is only effective for use of drugs during the public health emergency and for patient medications in accordance with laws and regulations.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmaceuticals

A holder of a marketing authorisation for pharmaceuticals is required to submit production

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reports or import reports to the BPOM. They are also obliged to monitor the efficacy, safety and quality of the drug and report the result to the BPOM. Such data can trigger the BPOM to conduct a drug reassessment, which can result in:

- change of label;
- revision of composition/formula;
- provision of limitation of use;
- change in classification of the drug;
- withdrawal of the drug from circulation;
- suspension or revocation of the marketing authorisation.

Medical Devices

Manufacturers and distributors of medical devices or in vitro diagnostic medical devices that will be distributed must include markings and information on the medical devices in accordance with laws and regulations. The information that must be provided includes safety, usefulness, instructions for use, and/or other necessary information, such as trade name, marketing authorisation number, product specification, expiration date and – if applicable – “*For Professional Use Only*” warning label.

Additionally, if applicable, information on net content, composition and levels of active ingredients, contraindications, cautions and warning signs or serious adverse events/side effects must be included in the marking and information. The marking and information are prohibited from including certain contents – for example, using superlative words such as “*very*”, “*top*” and “*super*” and mentioning the name of the test lab.

Holders of a marketing authorisation must submit reports including production reports or distribution reports to the MOH. They must also

submit an adverse event report if an adverse event occurs.

Manufacturers and distributors of medical devices and in vitro diagnostic medical devices must supervise their products and ensure conformity to standards of quality, safety, and usefulness. The supervision can take the form of audit, re-examination of products to determine serious adverse events, and reporting serious adverse events to the government.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Information relating to pending applications for marketing authorisations both for pharmaceuticals and medical devices is not made available to, and thus cannot be accessed by, third parties. Specifically with regard to pharmaceuticals, Article 27(4) of H.BPOM 24/2017 as amended provides that any information submitted to the BPOM for the purpose of applying for marketing authorisation is strictly confidential and may only be used solely for evaluation purposes by authorised parties.

The BPOM provides a website where third parties can access information concerning the status of marketing authorisations (ie, whether the said authorisation is active, suspended, or has been revoked).

Article 1(9) of BPOM 8/2024 and Article 1(6) of MOH 63/2017 affirm that the confidentiality of information relating to individuals participating in clinical trials of pharmaceuticals and medical devices is an integral part of the Good Clinical Practice standard, which must be adhered to when conducting clinical trials. Additionally, the Appendix to BPOM 8/2024 and the Appendix to MOH 63/2017 further clarify that clinical tri-

als must keep confidential all information relating to individuals participating in clinical trials. Researchers may also be instructed to maintain the confidentiality of any information relating to pharmaceuticals and medical devices.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes Medical Devices

In Indonesia, there is no fast track registration route for medical devices. The registration process must adhere to the procedures set forth by MOH 62/2017. The regulation requires all devices to undergo evaluation based on their risk classification (Class A, B, C, or D), with corresponding timelines and requirements.

For domestically produced devices, the evaluation timelines are as follows:

- Class A (low risk) – maximum ten days;
- Class B (low-to-moderate risk) – maximum 20 days;
- Class C (moderate-to-high risk) – maximum 20 days; and
- Class D (high risk) – maximum 30 days.

For imported devices, the evaluation timelines are as follows:

- Class A (low risk) – maximum 15 days;
- Class B (low-to-moderate risk) – maximum 30 days;
- Class C (moderate-to-high risk) – maximum 30 days; and
- Class D (high risk) – maximum 45 days.

After all administrative and technical requirements are deemed complete and compliant,

the MOH will issue the marketing authorisation within ten days. In practice, the above timelines can be longer.

Notably, during the COVID-19 pandemic, a temporary fast track registration process (EUA) was introduced under the COVID-19 EUA Guidelines issued by the MOH in 2021. Under the COVID-19 EUA Guidelines, the evaluation timeline for Class A, Class B and Class C would only be ten days. However, this process only applied to certain types of medical device products determined under the COVID-19 EUA Guidelines, such as N95 masks, surgeons' gloves, oxygen masks, and portable oxygen generators. However, as the pandemic emergency has resolved, the registration process has reverted to the standard procedures outlined in MOH 62/2017.

Pharmaceuticals

For pharmaceuticals, although no fast track mechanism exists, the BPOM embraces the notion of regulatory reliance (see 4.2 Regulatory Reliance), which streamlines the authorisation process for pharmaceuticals.

4.2 Regulatory Reliance Pharmaceuticals

Indonesia has embraced the notion of regulatory reliance to streamline its drug authorisation process. Under BPOM 24/2017, the evaluation for registration of a medicine can take 300 business days. However, if the medicine has been approved in at least one country with a well-established evaluation system, the evaluation for registration of such medicine can be expedited to only 120 business days. This expedited timeline applies specifically to registrations of new medicines and registration of major variations with new indications or posology for biological products and new chemical drugs.

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Medical Devices

Indonesia does not embrace the notion of regulatory reliance for the medical device authorisation process. Consequently, despite having obtained authorisations in a country with a well-established evaluation system, all products and establishments must still undergo local authorisation processes in adherence to MOH 62/2017.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceuticals

The manufacturing of pharmaceuticals is subject to authorisation from the Ministry of Industry (MOI) and the BPOM. Companies must obtain a standard certificate from the MOI and a Good Manufacturing Practice for Pharmaceuticals (*Cara Pembuatan Obat yang Baik*, or CPOB) certificate from the BPOM. The process to obtain both authorisations is conducted online through the RBA OSS system. For the standard certificate application, the RBA OSS system will then redirect to the MOI electronic system. For the CPOB certificate application, the RBA OSS system will redirect to the BPOM electronic system. The standard certificate and the CPOB certificate authorise the company to conduct manufacturing of pharmaceuticals pursuant to their Indonesian Business Classification Code (*Klasifikasi Baku Lapangan Usaha Indonesia*, or KBLI).

The period of validity of both the standard certificate and the CPOB certificate is five years and can be extended.

Medical Devices

The manufacturing of medical devices is subject to an authorisation. Companies must obtain a Good Manufacturing Practice for Medical Devices (*Cara Pembuatan Alat Kesehatan yang Baik*, or CPAKB) certificate and a manufacturing licence. The process to obtain a CPAKB certificate and a manufacturing licence is conducted online. The CPAKB certificate and the manufacturing licence authorise the company to conduct the manufacturing of medical devices pursuant to their KBLI. The period of validity of both the CPAKB certificate and manufacturing licence is five years and can be extended.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Pharmaceuticals

The wholesale of pharmaceuticals is subject to authorisation from the BPOM and the MOH. Companies must obtain a Good Distribution Practice for Pharmaceuticals (*Cara Distribusi Obat yang Baik*, or CDOB) certificate from the BPOM and a wholesaler licence from the MOH. The process to obtain a CDOB certificate is conducted online through the RBA OSS system and the BPOM electronic system, whereas the process to obtain a wholesaler licence is conducted through the RBA OSS system and the MOH electronic system. The CDOB certificate authorises the company to conduct the wholesale of pharmaceuticals pursuant to their Indonesian KBLI. The period of validity of both the CDOB certificate and the wholesaler licence is five years and can be extended.

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Medical Devices

The wholesale of medical devices is subject to authorisation from the MOH. Companies must obtain a Good Distribution Practice for Medical Devices (*Cara Distribusi Alat Kesehatan yang Baik*, or CDAKB) certificate and a distribution licence from the MOH. The process to obtain a CDAKB certificate and a distribution licence from the MOH is conducted online through the RBA OSS system and the MOH's electronic system. The CDAKB certificate and the distribution licence authorises the company to conduct the wholesale of medical devices pursuant to their KBLI. The period of validity of both the CDAKB certificate and the distribution licence is five years and can be extended.

6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Different Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceuticals and medical devices in Indonesia are primarily overseen by the Minister of Trade (MOT), the MOH, and the BPOM.

The primary regulation for imports is the MOT Regulation No 36 of 2023 on Import Policy and Provisions, as lastly amended by MOT Regulation No 8 of 2024 (“*MOT 36/2023 as amended*”), which outlines the requirements and procedures for importing goods into Indonesia. For exports,

the primary regulation is MOT Regulation No 23 of 2023 on Export Policy and Provisions, as lastly amended by MOT Regulation No 21 of 2024.

In the health sector, the MOH and the BPOM play crucial roles in applying and enforcing the import regulations of pharmaceuticals and medical devices. For instance, the BPOM is responsible for issuing marketing authorisations for pharmaceuticals and oversees the adherence to these authorisations at the point of entry and beyond.

At the point of entry, the Indonesian customs collaborates with the MOT, the MOH, and the BPOM to inspect and verify the compliance of imported pharmaceuticals and medical devices with all relevant regulations. After entry, the BPOM and the MOH continue to monitor and enforce compliance through routine inspections and market surveillance.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Any legal entity with a valid import business licence can act as the importer of record for pharmaceuticals and medical devices. However, the import of certain products requires specific documents issued by the relevant authorities (see 7.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

The import of pharmaceuticals and medical devices requires marketing authorisation of the products (see 3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations). The import of pharmaceuticals also requires an import certificate (*surat keterangan impor*, or SKI) from the BPOM. Additionally, certain products require an import approval and/

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or surveyor report under the MOT 36/2023 as amended.

BPOM 27/2022 as amended provides that pharmaceuticals without marketing authorisation may be imported into Indonesia for certain purposes, such as:

- personal use;
- research;
- product and/or scientific development;
- donation;
- sample for marketing authorisation applications;
- clinical trials for registration requirements, product development, and/or scientific purposes;
- government programmes;
- urgent national interests;
- special use for healthcare services that cannot be produced domestically; and
- exhibitions.

MOH 14/2021 provides that the MOH may issue statement letters addressed to the Indonesian customs to explain that the imported products are raw materials, spare parts, or samples that will be used for the purpose of applying for marketing authorisation. Further, please note that – in importing such products – a statement letter from the MOT may also be required.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Non-tariff regulations and restrictions in Indonesia are imposed based on the harmonised system (HS) codes of the goods. The types of products subject to non-tariff regulations and restrictions are listed in the Ministry of Finance (MOF) regulation – specifically, MOF Regulation No 26/PMK.010/2022 of 2022, as amended by MOF Regulation No 10 of 2024.

7.5 Trade Blocs and Free Trade Agreements

Indonesia is a member of the Association of Southeast Asian Nations (ASEAN) and the following free trade agreements that contain provisions on trade/regulatory facilitation. Three notable examples include:

- the ASEAN Trade in Goods Agreement (ATIGA);
- the ASEAN–Australia–New Zealand Free Trade Agreement (AANZFTA);
- the Regional Comprehensive Economic Partnership (RCEP).

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices Pharmaceuticals

The prices for pharmaceuticals in Indonesia are regulated to ensure affordability and accessibility, primarily governed by MOH 98/2015. Under this regulation, pharma industries are required to provide information on the highest retail price on the drug's label – either as a nominal value in Indonesian rupiah or as a formula, depending on the type of drug. This regulation covers generic drugs listed in the e-catalogue for government procurement, generic drugs not listed in the e-catalogue, and drugs other than generic drugs.

For generic drugs not listed in the e-catalogue and drugs other than generic drugs, the highest retail price must be in the form of a nominal value. The highest retail price is 128% of the HNA (*harga netto apotek*, or pharmacy net price), which is the price given by the pharmaceutical wholesaler to the pharmacies plus VAT.

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For generic drugs listed in the e-catalogue, the highest retail price will be in the form of a formula of the highest retail price.

Pharmacies, drug stores, and hospital or clinic pharmaceutical installations are required to sell drugs at prices equal to or lower than the highest retail price indicated on the label. If the price provided on the label is no longer valid, they must adjust accordingly to comply with current regulations.

Medical Devices

There is no specific regulation on pricing for medical devices.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The price levels of pharmaceuticals and medical devices in Indonesia do not generally depend on the prices for the same products in other countries but rather are mainly determined by the production cost and the variables introduced by the importation process. The government has previously expressed concerns about the high price of certain imported pharmaceutical materials, which is caused by the fluctuating exchange rates, in the Appendix to MOH 17/2017.

In 2023, the MOH conducted a focus group discussion regarding access to and production of innovative drugs, comparing drug prices in Indonesia with those in other countries.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

While there is no specific regulation directly addressing the reimbursement of pharmaceuticals and medical devices, the public healthcare system is effectively managed by BPJS Health (*Badan Penyelenggara Jaminan Sosial Keseha-*

tan), an independent authority established to administer the national health insurance programme.

BPJS Health mandates that every Indonesian citizen participates in the health security programme, regardless of any existing health insurance policies they may hold. It collects periodic contribution fees from all enrolled participants. These contributions are structured based on income levels.

BPJS Health's coverage encompasses a wide range of health services, including the costs associated with pharmaceuticals and medical devices.

The extent and circumstances under which these costs are reimbursed from public funds are determined by the policies and operational guidelines set forth by BPJS Health.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

There is no specific regulation that governs the application of cost-benefit analysis in determining what price should be paid for pharmaceuticals or medical devices or in determining whether pharmaceuticals or medical devices should be reimbursed.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

The regulations concerning prescriptions by physicians and dispensing by pharmacies are not aimed at curbing spending on pharmaceuticals but, rather, at ensuring the safety of patients and protecting the community from the circulation of unsafe drugs.

Pursuant to Article 320 of Law 17/2023, there are three types of drugs where a prescription is

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mandatory – namely, potent drugs (*obat keras*), narcotics, and psychotropics. The dispensing of prescription drugs that circumvent the prescription requirement risks imprisonment of up to 12 years and fine of up to IDR5 billion. Additionally, the illegal distribution of narcotics and psychotropics carries a severe penalty, whereby the death penalty may be imposed in certain circumstances.



Law and Practice

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Reinhold Cohn Group is one of the leading IP firms in Israel and specialises in litigation and legal counselling relating to IP rights – including patents, patent term extensions, trade marks, designs, copyrights, trade secrets and plant breeders' rights – as well as in IP-related fields. With years of professional experience, Gilat, Bareket & Co has been recognised for success-

fully litigating landmark cases and representing local and international clients. As part of the Reinhold Cohn Group, the firm works in close co-operation with the patent and trade mark attorneys of Reinhold Cohn & Partners, creating a unique and effective platform for maximising the value of IP assets and securing optimal protection.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

In Israel, pharmaceuticals and medical devices are regulated by various legislative acts and regulatory bodies. What follows is a summary of the main legislation and regulatory bodies.

- The main legislations for pharmaceuticals are the Pharmacists Ordinance of 1981 and the Pharmacists Regulations (Preparations) of 1986.
- The Minister of Health and the Ministry of Health (MoH) are the main regulatory bodies. The MoH is the government agency responsible for public health policy and regulation in Israel. It oversees and regulates pharmaceuticals and medical devices, as well as healthcare (providing services through state, mental health and geriatric hospitals), and issues guidelines relating to the various matters for which it is responsible.
- The Pharmacy Department of the MoH oversees the regulation of pharmaceuticals. This includes registration and monitoring of pharmaceutical preparations or medicinal drugs, manufacturing plants, importation/exportation, advertisements, and clinical trials.
- The main pieces of legislation dealing with medical devices are the Medical Device Law of 2012 and the Medical Devices Regulations (Registration of Medical Equipment in the Register and its Renewal) of 2013. Although the Medical Device Law of 2012 has yet to formally enter into force, the relevant actors are conducting themselves in accordance with it.
- The MoH's Medical Device Division (AMAR) oversees the regulation of medical devices, including registration and monitoring.

- In addition, Israel's National Health Insurance Law of 1994 and those regulations and orders issued in accordance therewith ensure funding for a standardised healthcare package. This package encompasses a range of medical products and services and is regularly updated.
- All Israeli residents are covered by one of four statutorily organised Health Maintenance Organisations (HMOs), based on personal choice, which serve both as insurers and providers of these healthcare services. Some HMOs also manage public hospitals.
- Additional relevant legislation is the Public Health Ordinance of 1940, which relates to clinical trials, epidemics, and more.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions made by Israeli regulatory bodies are subject to various legal and administrative challenges.

Although there is no process similar to the United States Food and Drug Administration (FDA) citizen petition procedure in Israel, the applicable law provides procedures to challenge decisions (administrative procedures) in certain instances. By way of example, a registered pharmaceutical preparation owner may object to the MoH's decision not to renew the registration thereof before the MoH's director (or others in the MoH who are authorised by the director to hear such claims). Another example is individuals seeking funding for treatments not covered by the standard healthcare package (eg, for off-label or compassionate use), who may apply to their HMO's special committee. Decisions made by these committees can be appealed before the labour courts.

In addition, any Israeli citizen has the right to file an administrative appeal with the administrative courts against the decision of any authority, provided that the decision pertains to matters outlined in the Administrative Matters Courts Law of 2000. In the healthcare sector, decisions subject to challenge may include those entered under the Pharmacists Ordinance of 1981, the National Health Insurance Regulations of 2012, the Organ Transplantation Law of 2008, the Public Health Protection (Food) Law of 2015, and any authority's decision concerning importation under any law, including specific decisions regarding importation licences.

Moreover, governmental decisions can be challenged before the Supreme Court. The Supreme Court also hears appeals and applications for leave to appeal lodged against decisions of the district courts serving as administrative matters courts.

In January 2025, the MoH published a draft bill titled the *"Healthcare Services Quality Assurance Law 2025"* for public opinions and comments. The bill aims to improve compliance, enhance the MoH's regulatory role, and strengthen enforcement by introducing measures such as a broader authority to demand information, levying financial penalties, and the expansion of the MoH's oversight of HMOs and medical institutions.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are two main categories of pharmaceuticals and medical devices in Israel – namely, registered and non-registered. These can be divided into further categories, as described here.

Registered Pharmaceuticals

"preparation" or *"medicinal drug"* should be registered in the Israeli Drug Registry according to the MoH's requirements (see **3.1 Product Classification: Pharmaceuticals or Medical Devices**). Registered preparations can be further categorised as follows.

- **Prescription Only (Rx)** – prescription-only preparations may be provided only to consumers with a prescription at pharmacies and by certified pharmacists.
- **OTC Medicines – P (Pharmacist)** – a preparation whose provision does not require a prescription yet is provided only in pharmacies by certified pharmacists.
- **OTC – General Sale List (GSL)** – non-prescription preparations that may be provided to consumers not by pharmacists and outside pharmacies, according to the Pharmacists Regulations (sale of a preparation without a prescription not in a pharmacy or not by a pharmacist) of 2004 and the MoH guidelines of 2011. The regulation includes a list of the active pharmaceutical ingredients (APIs) that may be included in GSL preparations.

Non-Registered Pharmaceuticals

The general rule is that it is not possible to provide consumers with a preparation unless it is registered. This is also the case for off-label uses of registered preparations, as was determined by the Israeli Supreme Court in the Tibet case of 1984.

However, the MoH may allow specific preparations to be imported, manufactured or marketed without registration or in an off-label manner for uses such as research or essential treatments or for export purposes, provided the MoH determines it will not negatively impact public health. Such allowances may also be made in cases

of non-commercial quantities for personal use, preparations made in Israel or imported for registration purposes, preparations intended for treating epidemics, and registered preparations for off-label use by medical institutions for their patients. The MoH's guidelines provide more details on such cases (see also **3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations**).

Registered Medical Devices

Medical devices should be registered in AMAR's Medical Device Registry.

Non-Registered Medical Devices

The Medical Device Law of 2012 allows the Minister of Health to issue regulations that exclude certain types of medical devices from the registration requirement for purposes such as R&D, export, emergency, and more. A draft of such regulations was published in August 2023 for public comments but has not yet been enacted.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The Public Health Ordinance of 1940 and the Public Health Regulations (Medical Experiments on Humans) of 1980, which apply the Declaration of Helsinki, are the main legal acts overseeing clinical trials in Israel. In addition, several MoH guidelines and circulars apply. For actors interested in conducting trials in Israel, the main guideline is Guideline 14 on Medical Experiments on Humans (2020), which governs the submission and approval of clinical trials.

The guidelines include the requirement that the principal investigator adhere to international Good Clinical Practice (GCP) guidelines and ISO

14155 (Clinical Investigation of Medical Devices for Human Subjects).

In addition, legislation relevant to the realm of the specific research may apply, such as the Physicians Ordinance of 1976, the Patients' Rights Law of 1996, the Genetic Information Law of 2000, privacy laws, the Medical Device Law of 2012 and standards, the Prohibition of Genetic Intervention Law (Human Cloning and Genetic Modification of Reproductive Cells) of 1999, and the Dangerous Drugs Ordinance of 1973.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to conduct clinical trials in Israel is outlined in the Public Health Regulations (Medical Experiments on Humans) of 1980 and MoH Guideline 14 on Medical Experiments on Humans (2020), as described in **2.1 Regulation of Clinical Trials**. The approval process entails a dual scrutiny mechanism involving assessment by both the medical institution's Helsinki Committee and the MoH. In many kinds of "*specialised medical trials*", as defined in the Public Health Regulations (Medical Experiments on Humans) of 1980 (eg, trials on registered preparations and medical devices), approval by the institution's director is sufficient.

Trials relating to human genetics, non-natural female fertilisation, and others determined by the MoH require the opinion of the Higher Helsinki Committee. This committee may also approve urgent medical cases where the informed consent of a trial participant cannot be given.

Trials on existing data or questionnaires also require approvals and have specific instructions in the guidelines.

Multi-centre trials are evaluated by a dedicated national committee, according to MoH Guideline 168 of 2023.

2.3 Public Availability of the Conduct of a Clinical Trial

According to MoH Guideline 14 on Medical Experiments on Humans (2020), the initiation of a clinical trial is contingent upon its registration within the MoH's MyTrial website. The information presented on the MyTrial website includes details of the disease/medical condition, the intervention being tested and how the trial is conducted, as well as criteria for inclusion and exclusion, a list of the centres where the trial is conducted, and contact details for obtaining further information.

Exemptions from registration on the MyTrial website can be requested from the Helsinki Committee. They can be based on reasons of IP in feasibility trials, as long as the trial was not registered on the USA's National Institutes of Health (NIH) website.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The use of digital means in the process of obtaining informed consent is regulated under MoH Guideline 169/01. The guideline refers to the use of digital means in presenting the information to the participants and verifying their understanding, as well as the use of such means in obtaining informed consent and documenting the process. The use of such digital means requires the approval of the Helsinki Committee as part of the approval of the trial.

In addition, restrictions under additional laws and regulations exist, such as those outlined in

2.5 Use of Data Resulting From Clinical Trials

The informed consent forms provided in MoH Guideline 14 on Medical Experiments on Humans (2020) state that the consent to participate in the trial also includes consent for medical and personal information collected during the trial to be transferred to an external party for data processing. The information is to be transferred in an encoded form, free of identifying details, with the link between the code and the identifying details being kept securely by the Principal Investigator in Israel. Changes in these forms require the approval of the Helsinki Committee.

In addition, to the extent that the resulting data from the trials amounts to a database containing identifying information about an individual (eg, their health status), it should be considered a database of "*sensitive data*" according to the Protection of Privacy Law of 1981. The use of such a database is subject to the provisions outlined in the law and regulations – examples of which include the following.

- If an external service provider needs access to the database in order to provide a service, the agreement with such service provider must include provisions set forth in the Protection of Privacy Regulations (Data Security) of 2017 (such as provisions referring to the data security implementation, confidentiality, and annual reports).
- Transfer of data from such a database to a third party outside Israel is governed by the Protection of Privacy Regulations (Transfer of Data to Databases Outside the State Borders) of 2001. These regulations set out conditions for transferring data abroad – for example, the transferee must undertake to comply with the conditions for data retention and use applying to a database located in Israel, or the trans-

freee must be a corporation under the control of a database owner that has assured the protection of privacy after the transfer.

Two MoH circulars from 2018 relate to secondary uses of health data and collaborations based on such data. The circulars include various measures to protect the data, such as de-identification, requirements for approvals, and security measures.

2.6 Databases Containing Personal or Sensitive Data

If the data in the database is identifying, then the database should be subject to the provisions of the Protection of Privacy Law of 1981 and its regulations, including those described in **2.5 Use of Data Resulting From Clinical Trials**. This may require registration of the database if sensitive information such as health conditions are included, more than 10,000 persons are included in the database, or for other reasons defined in the law. Such inclusion may also require the implementation of adequate security measures stipulated in the Protection of Privacy Regulations (Data Security) of 2017. Amendment No 14 of the Privacy Protection Law of 1981 – currently under legislative procedure – seeks to revise the definition of “*sensitive data*” to encompass, inter alia, medical data as defined in the Patients’ Rights Law of 1996 and genetic data as defined in the Genetics Information Law of 2000.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

According to the Pharmacists Ordinance of 1981, “*preparation*” or “*medicinal drug*” is any

form of substance that has properties for curing or preventing a disease or for the treatment of a disease – or that is presented as having such features that cause (or is given for the purpose of causing, restoring, replacing, repairing or changing) a physiological action in the body through pharmacological, immunological or metabolic action – and is given (or can be given) for medical diagnosis.

The Medical Device Law of 2012 excludes preparations (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**) from the definition of “*medical device*” but includes any of the following:

- a device used for medical treatment, as well as a device or computer software required for operating such a device – for this purpose, “*device*” includes an accessory, chemical substance, biological product, or biotechnological product;
- contact lenses; and
- an electrical device that emits ionising or non-ionising radiation used for cosmetic treatment.

Additionally, in 2002 (a decade before the Medical Device Law of 2012 was enacted), the MoH issued a guideline classifying medical products that combine preparations and medical devices or whose classification is unclear/disputed (MoH Guideline 47). The guideline includes rules on how to classify the product, as well as the classifications of specific products (such as bandages containing medical material, biological glue, ultrasound gels, condoms, and more).

Requests for early designation may be filed with the medical assistant at the Preparations Registration Department or AMAR in the MoH.

Appeals are made to the deputy general director of the MoH.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In general, registration of original biologic medicinal products (which makes it possible to market those products – see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**) requires that a quality certificate be obtained from the MoH for that product.

Where a biosimilar – namely, a pharmaceutical comprising a biological active ingredient that is similar to the active ingredient of an already-registered original biologic pharmaceutical – is concerned, MoH Guideline PRA-127/03 is applied. The guideline adopts the European Medicines Agency (EMA)'s policy regarding registration – with changes – and registration is usually dependent on showing actual registration for the biosimilar (or a positive opinion regarding it) from one of several foreign countries, as well as on the provision of data proving that there is no significant difference in aspects of quality, safety and efficacy between the biosimilar and the original biologic medicinal product.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The basic requirement for marketing pharmaceuticals and medical devices is their registration. The initial period of validity for such registration is typically no more than five years and is subject to renewals. In certain circumstances, the MoH may prohibit the marketing of a preparation or medical device, revoke its registration, and take any action required to ensure public health.

Pharmaceuticals

In general, retail marketing of preparations can only be done by pharmacists in pharmacies. Wholesale marketing of preparations can be carried out only by “*pharmaceutical trading houses*”, which store, distribute, and transport preparations or raw materials.

According to the Pharmacists Regulations (Preparations) of 1986, the first registration of a preparation must not exceed five years. A renewal may be limited or unlimited in time, depending on quality, efficiency, or safety reasons.

A registered preparation marketed for the first time must receive marketing authorisation from the MoH for the first batch. Marketing of any further batches requires the authorisation of a responsible pharmacist in a business that has received authorisation from the MoH to act as such.

A preparation whose registration has not been renewed, or has been cancelled, may continue to be marketed for a period not exceeding one year from the expiration of the registration.

Medical Devices

The general rule for the first registration of a medical device is the same as for preparations – ie, it shall not exceed five years. This is according to the Medical Devices Regulations (Registration of Medical Equipment in the Register and its Renewal) of 2013. The registration may be renewed.

According to the Medical Device Law of 2012, a medical device whose registration has not been renewed or has been deleted or cancelled may continue to be marketed for a period not exceeding two years from the expiration of the registration.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Pharmaceuticals

The basic requirement for marketing pharmaceuticals and medical devices is their registration, as noted in 3.3 **Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices**.

To register a preparation, apart from adhering to the Pharmacists Ordinance of 1981 and the Pharmacists Regulations (Preparations) of 1986, applicants must submit an application to the Preparations Registration Department of the MoH. This application is exclusively available to Israeli residents or registered Israeli corporations and should be filed by a pharmacist approved by the MoH for such a purpose.

The procedure adheres to MoH Circular No 08_2012 (*"Application Submission Guideline for the Registration of Medical Preparations (Including Changes and Renewals)"*) (last updated in 2015). The circular classifies pharmaceutical preparations into six groups, including new APIs, generics, and biosimilars – each with specific requirements.

Any change in a registered preparation should be brought to the attention of the MoH and the circular includes procedures for changing the registration (such as changes in indication, dosage, and manufacturing plant). Another circular, No EX-009/04, relates to changes from a quality perspective and is based on the EC guidelines (mainly EC 1234/2008).

MoH Guideline No 36 delineates the procedure for changing the registration holder. This process necessitates the manufacturer's declaration regarding the new registration holder, including

their unrestricted access to all confidential information contained within the product file.

Medical Devices

To register a medical device, applicants must complete an application, which is to be submitted to AMAR according to the relevant guidelines. This application must include valid regulatory approvals, encompassing safety and efficiency certifications issued by recognised certifying bodies abroad (eg, FDA, *Conformité Européenne* (CE), and International Organization for Standardization (ISO) approvals), or documentation corresponding to the device's class.

In 2024, the MoH published guidelines for fast track registration of medical devices (see 4.1 **Fast Track Registration Routes**). This is part of a reform in the registration procedure for medical devices that was published in August 2023 and is aimed at shortening the registration times of medical devices in Classes I and II.

Requests to transfer registration to another holder must be submitted along with, inter alia, a letter of consent from the current registration holder, declarations from the manufacturer and the importer, and other requirements detailed in the MoH's guidelines.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Preparations and medical devices that are not registered may be supplied in specific circumstances, as detailed here.

Pharmaceuticals

The Pharmacists Regulations (Preparations) of 1986 delineates certain exceptions to the regular requirements for preparations (such as registration and batch approvals), subject to

MoH approval/requirements. These exceptions include materials used without any process or change, preparations in non-commercial and small quantities, personal use of such, use for research, local manufacture for export purposes, use for epidemic purposes, and registered preparation for off-label use.

The MoH published several guidelines concerning the exceptions, which include various requirements, forms and approvals.

Medical Devices

The Medical Device Law of 2012 grants authority to the Minister of Health to establish regulations governing exceptions to the registration requirement under specific circumstances outlined in said law. Such regulations have not yet been enacted. However, in August 2023, the MoH released draft regulations, which proposed allowing the use of unregistered medical devices in the following cases:

- essential medical treatment and urgent care in the absence of a registered, marketed and available alternative;
- compassionate treatments;
- research, development and production of medical equipment not intended for marketing purposes;
- emergency preparedness;
- export-only purposes;
- conducting clinical evaluations of a limited number of patients; and
- personal use of customised medical equipment by a therapist.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

“*Pharmacovigilance*” is defined here as the pharmacological science relating to the detection,

assessment, understanding and prevention of adverse effects – in particular, the long-term and short-term side effects of medicines.

“*Technovigilance*” is defined here as the science relating to the detection, assessment, understanding and prevention of adverse incidents – in particular, the long-term and short-term side effects of medical devices.

Pharmaceuticals

The preparation registration owner must maintain a drug monitoring system – for which, a physician/pharmacist with at least two years’ experience will be responsible.

The preparation registration owner must notify the MoH of any change in the registration file. MoH Guideline No 6 (“*Reporting Adverse Events and New Safety Information*”) details which information should be provided and additional relevant requirements. Among other things, the MoH’s guidelines require creating a system for monitoring side effects and new safety information for the registered preparation (pharmacovigilance system), providing Periodic Benefit-Risk Evaluation Reports (PBRER) or Periodic Safety Update Reports (PSUR), post-marketing spontaneous reporting of individual case safety reports, and follow-up on serious side effects.

The MoH may impose additional conditions on registration or renewal of the preparation, such as requiring regular and ongoing supply of the preparation.

Medical Devices

Section 7 of the Medical Device Law of 2012 outlines the parameters that the MoH may impose during the registration phase of medical devices. These include requirements for transportation and storage, the regular supply of the medical

device in question, and others. Renewals may also require the filing of information regarding ongoing obligations.

The Medical Device Law of 2012 also authorises the Minister of Health to establish quality control regulations. However, these regulations have not yet been issued.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Pending applications for marketing authorisations for pharmaceuticals and medical devices remain confidential until registration. Basic information only (such as name, active ingredients, indications, dosage forms, and other details) becomes accessible to third parties upon completion of the registration process. The Israeli Drug Registry is available on the MoH's website, which also features additional information such as information on preparations that are no longer marketed in Israel and notices regarding certain defects and side effects.

The MoH may use data to authorise generics only after the market exclusivity period ends.

Medical Devices

Registered Israeli medical devices are public and available on the MoH's website. At this stage, the information available online is not complete.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Israel's regulatory framework offers fast track registration routes both for medicines and medical devices, as detailed here.

Medicines

In February 2024, the MoH published a temporary framework for the approval of generic or biosimilar drug imports under Regulation 29 of the Pharmacists Regulations (Preparations) of 1986. This framework introduces expedited regulatory pathways by allowing conditional import approval for up to ten pharmaceuticals that meet the predefined criteria.

The approval process requires, inter alia, that:

- the pharmaceutical must be generic or bio-similar;
- the pharmaceutical must be registered in recognised regulatory markets (such as the USA, the EU and the UK);
- the original pharmaceutical must be already registered in Israel; and
- there must be two or fewer registered pharmaceuticals for the same active ingredient in Israel.

Applications to import such drugs can only be submitted by HMOs, with a permit being granted automatically after 45 working days, unless the MoH decides otherwise. Once issued, the permit is valid for up to one year, and extendable based on compliance with registration requirements. The framework aims to facilitate patient access to essential medications while ensuring regulatory oversight and cost-effectiveness, with the savings being used to improve healthcare in Israel.

Medical Devices

In 2024, the MoH published two guidelines for fast track registration of medical devices, introducing simplified procedures for Class I and Class II devices. The first guideline, published in January 2024, established an expedited route for low-risk devices (Class I and IVD Class A),

allowing them to be registered based solely on a declaration from the registration holder or the importer. This route applies only to devices that are already registered and marketed in recognised countries (including the USA, Canada, Australia and the UK, as well as EU member states such as France and Germany). Applications must include a completed form, a signed declaration, regulatory certificates, and supporting documents. No fees are required. Additionally, annual renewal declarations must be submitted by October 1 of each year to maintain registration.

In June 2024, a second guideline was introduced to enable fast track registration for Class II and in vitro diagnostic (IVD) medium-risk devices. This procedure applies to Class II, IIa, IIb, and IVD B/C devices that are already registered in recognised countries. The registration process under the guideline is simplified, requiring proof of marketing history (four to six months), regulatory certificates, and a declaration from the registration holder. Processing times vary, as new registrations for Class IIb and IVD C devices may take up to 60 days, whereas renewals may take up to ten days. There are no fees required. These two guidelines aim to streamline the registration process in Israel, ensuring that pre-approved medical devices can enter the market efficiently while regulatory oversight is maintained.

4.2 Regulatory Reliance

Israel has embraced the concept of regulatory reliance, both for pharmaceuticals as well as for medical devices.

Where pharmaceuticals are concerned, the registration of a new pharmaceutical for the purposes of obtaining a market approval may only begin after it has been registered in other recog-

nised countries. The same is true for biosimilars and generics as well.

Additionally, according to the Medical Device Law of 2012, the MoH may register a medical device even if the conditions outlined in the law are not fully met, provided that the device is registered in a recognised country or authorised for marketing and actively marketed in that recognised country.

Moreover, the Medical Devices Regulations (Registration of Medical Equipment in the Register and its Renewal) of 2013 set forth that – during the registration process – medical devices that are already registered or marketed in a recognised country do not require additional documentation such as risk analysis, clinical evaluation, clinical trial summaries, and expert opinions. If a device is equivalent to a device that is already registered in Israel or in a recognised country, it can follow the same simplified registration process.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing of Pharmaceuticals

The manufacturing of pharmaceuticals is regulated by the Pharmacists Ordinance of 1981 and the Pharmacists Regulations (Preparations) of 1986, as well as by specific regulations relating to production conditions for preparation and by the MoH's guidelines. Among other things:

- the plant should be operated by skilled professionals, including a quality assurance

- manager, a lead pharmacist, and a business manager;
- the preparations should be manufactured according to good manufacturing practices (GMP) and the principles of EU Directive 2003/94/EC for human preparations;
- the APIs used in manufacturing the preparation should be manufactured according to GMP and the principles of EU Directive EC/2001/83;
- the MoH must audit the business according to the EMA's *"Compilation of Community Procedures on Inspections and Exchange of Information"*; and
- the plant must have a business licence pursuant to the Business Licensing Law.

Manufacturing of Medical Devices

The manufacturing of medical devices is regulated by the Medical Devices Law of 2012, the Medical Devices Regulations (Registration of Medical Equipment in the Register and its Renewal) of 2013 and the MoH's guidelines.

The manufacturing plant's GMP should meet the requirements of ISO 13485, as well as have a business licence pursuant to the Business Licensing Law of 1968.

Transportation conditions must meet the requirements of ISO9001. Businesses also require an appropriate business licence for the storage and transportation of medical devices pursuant to the Business Licensing Law of 1968.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale marketing of preparations can be done only by *"pharmaceutical trading houses"* that store, distribute and transport preparations or raw materials (as noted in 3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices and 3.8 Rules Against Illegal Medicines and/or Medical Devices). The pharmaceutical trading houses should be managed by a pharmacist approved by the MoH according to MoH Guideline 139.

Wholesale is also allowed by institutions that have been acknowledged by the Minister of Health. The Minister of Health is also authorised to allow wholesale in other cases for necessary treatment, research or registration, provided such actions do not pose any detriment to public health.

Distribution and storage should be according to MoH Guideline 126 and MoH Guideline 130.

Non-prescription medicines may be sold subject to approval by the district pharmacist according to the Pharmacists Regulations (sale of medicine without a prescription not in a pharmacy or not by a pharmacist) of 2004 and under MoH Guideline 56.

Medical Devices

The sale of medical devices necessitates registering the equipment in the registry – although exceptions may exist (see 3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices and 3.5

Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations).

6.2 Different Classifications Applicable to Pharmaceuticals

In Israel, there are two main categories of pharmaceuticals. The first is registered pharmaceuticals and the second is non-registered pharmaceuticals. For a detailed explanation, please see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of products are mainly governed by the Import and Export Ordinance of 1979, the Customs Ordinance of 2014, and the Free Import Order of 2014. In addition, specific regulations and MoH guidelines exist for the importation and exportation of pharmaceuticals and medical devices; these make it necessary to obtain approvals from the Import of Pharmaceuticals and Drugs Department or AMAR. MoH Guideline 33 governs the submission and handling of applications for import approval. MoH Guideline EX-015/02 outlines the procedures for granting, renewing, updating, suspending and revoking approvals for importers of pharmaceuticals.

At the point of entry, the customs authorities are responsible for enforcing import regulations. Following entry into the country, ongoing enforcement and oversight are maintained by various

entities within the MoH, such as the Pharmaceutical Administration and AMAR.

A proposal for an amendment to the Patents Law of 1967 is currently pending. According to Amendment No 14 (Increasing Competitiveness in the Israeli Economy), 5781-2021, third parties shall be allowed to manufacture an otherwise infringing medical device or pharmaceutical during the period of a patent term extension (PTE) order – provided that the exploitation of the invention is made for export purposes or made for stockpiling and marketing in Israel during the final six months of the period of the PTE.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

There is no official definition of “*importer of record*” in Israel.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Importers of pharmaceuticals and medical devices are generally required to obtain prior authorisations from the MoH, as mentioned in **7.1 Governing Law for the Importation and Exportation of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies**. The Pharmacists Ordinance of 1981 defines “*marketing*” as including importation; therefore, any approval required for marketing is also applicable for importation (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices** and **6.1 Wholesale of Pharmaceuticals and Medical Devices**).

Exemptions exist, according to Regulation 29 of the Pharmacists Regulations (Preparations) of 1986 (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**). In addition, in view of the war in Gaza, the MoH published a donation outline for medical devices that allows

the importation of specific medical devices without MoH import authorisation under certain conditions.

The Pharmacists Ordinance of 1981 permits the parallel import of a product equivalent to a registered preparation by entities other than the registration holder, provided it is identical to the registered item and meets regulatory storage and delivery conditions. Except for the requirement of registration itself, all rules applicable to the registered preparation also apply to the imported equivalent on a comparable basis.

As of January 2025, and according to Amendment to the Pharmacists Ordinance (Amendment No 37) of 2024, Israel's "*What is Good for Europe is Good for Israel*" reform allows importers (registered as "*proper importers*") to bring in cosmetic products legally marketed in EU member states, Switzerland or the UK through a streamlined process. The reform aims to facilitate imports, increase competition, and reduce consumer prices while maintaining product safety standards.

From an IP perspective, importing a product protected by a local patent for purposes such as production, use, sale, or offering for sale is regarded as exploitation of the invention. Therefore, if a medical device or pharmaceutical has a related registered patent/s in Israel, the importer is obligated to obtain consent from the patentee prior to importing the product.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The Import and Export Ordinance of 1979, the Customs Ordinance of 2014, and the Free Import Order of 2014 include various non-tariff regulations and restrictions imposed upon importation.

7.5 Trade Blocs and Free Trade Agreements

Israel has signed many free trade agreements and trade pacts with multiple countries and economic blocs, including the USA, the EU (including the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA)), the European Free Trade Association (EFTA), the UK, South Korea, China, the Eurasian Economic Union, India, Mercosur (a South American trade bloc comprising Argentina, Brazil, Paraguay and Uruguay), and neighbouring/regional countries such as Jordan, Egypt, Turkey, and UAE.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Although the prices of medical devices are not controlled, the prices of pharmaceuticals are. Specifically, the Supervision of Prices of Commodities and Services (Maximum Prices for Prescription Preparations) Order of 2001 determines maximum prices for prescription preparations, as elaborated on in 8.2 Price Levels of Pharmaceuticals or Medical Devices.

As for preparations sold without prescriptions, the Supervision of Prices of Commodities and Services (Application of the Law on Preparations) Order of 2001 provides that the prices of such preparations may not be raised without their sellers first obtaining governmental approval.

When it comes to GSL preparations, the same order provides that the registrants of such are to provide a biannual report to the MoH in which they are to detail the prices of all preparations they are selling, as well as provide an annual

report regarding their profitability from the sales thereof.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The prices of medical devices are not controlled. As regards pharmaceuticals, the Supervision of Prices of Commodities and Services (Maximum Prices for Prescription Preparations) Order of 2001 noted in 8.1 **Price Control for Pharmaceuticals and Medical Devices** provides that the maximum price of prescription preparations is to be determined as an average of the lowest three prices for that preparation in the following countries: Belgium, the Netherlands, Hungary, Spain, France, the UK, and Germany.

The order further provides that where that prescription preparation is not sold in three of the above-mentioned seven countries, the price of a given preparation would be set as the average of the prices thereof in the two countries in which it is being sold. Finally, where the preparation is sold in only one of the seven countries referenced by the order, that price alone would be used to set the maximum price for that preparation in Israel.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

As mentioned in 1.1 **Legislation and Regulation for Pharmaceuticals and Medical Devices**, Israel nationalised its healthcare system in 1994 when it enacted the National Health Insurance Law of 1994. This law provides a lengthy list of all the healthcare services to which all residents of Israel are entitled, which is formally known as the “*Health Service Basket*” or – more commonly – the “*Health Basket*”.

Once a given medical device or pharmaceutical has been introduced into the Health Basket, it is subsidised by the State of Israel and provided by HMOs. In particular cases, patients may request reimbursement for pharmaceuticals or medical devices that are not included in the Health Basket. Such requests are evaluated on a case-by-case basis by healthcare providers, who consider factors such as medical necessity, lack of alternative treatments, and clinical justification.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The Health Basket is updated on a yearly basis, according to the recommendations of a public committee, which are then assessed by the government before a decision is made. Given that the annual budget for this purpose is always limited, a cost-benefit analysis is always carried out. Specifically, the public committee must consider the benefits offered by a given preparation or device against the costs thereof – both at the individual and the national level – and rank these prospective additions accordingly. In certain cases, negotiations are carried out between the State of Israel and the companies to secure hedges, which would place a cap on the total cost incurred as a result of a company’s product being included in the Health Basket.

A cost-benefit analysis is also carried out in a way whereby the maximum prices for prescription preparations are concerned. As noted in 8.1 **Price Control for Pharmaceuticals and Medical Devices**, it is permissible to set a higher price than that which would have otherwise been set if setting a lower price might cause the preparation not to be marketed in Israel.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

The Physicians Regulations (Provision of Prescription) of 1981 lists the details to be included in a prescription and allows such to be issued digitally. When it comes to dispensing prescriptions, the Pharmacists Ordinance of 1981 provides that – unless the physician clearly states that the preparation is not to be switched – the pharmacist may provide a generic product thereof and must advise the patient which additional generics for that preparation are available at the dispensing pharmacy.

In practice, HMOs instruct their physicians – when possible – to not include such clear statements in their prescriptions so that pharmacists dispense generic preparations rather than reference preparations, thus curbing spending.

JAPAN

Law and Practice

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Nagashima Ohno & Tsunematsu is widely recognised as one of Japan's leading international law firms, specialising in all aspects of business and commercial law. The firm represents domestic and foreign clients involved in every major industry sector, including many of the largest and most influential companies, funds and organisations in Japan. The firm has structured and negotiated many of Japan's largest and most significant corporate and finance transactions, and has extensive expertise across all its

practice areas. The pharmaceutical and healthcare team is based in the Tokyo office and consists of more than 14 lawyers, including eight partners. Key areas of the firm's practice relating to the life sciences sector include pharmaceutical and healthcare, risk and crisis management/compliance, corporate/M&A, data protection and privacy, IP, antitrust/competition, consumer law (consumer litigation), dispute resolution, and labour and employment.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the “*Pharmaceuticals Law*”), together with related cabinet and ministerial orders, is the primary law that governs pharmaceuticals and medical devices in Japan. Under the Pharmaceuticals Law, pharmaceuticals and medical devices are in principle subject to the same level of regulation in order to maintain the safety and efficacy of these products. Details of the regulations applicable to pharmaceuticals and medical devices are set out in ministerial orders, administrative guidelines and cabinet orders as explained in the next paragraph.

The Ministry of Health, Labour and Welfare (MHLW) is the principal regulatory body for pharmaceuticals and medical devices. The MHLW is the national government body that issues most of the Pharmaceuticals Law-related ministerial orders and administrative guidelines, and drafts relevant cabinet orders. Prefectural governments (ie, independent local governments such as the Tokyo Metropolitan Government) are primarily responsible for monitoring pharmaceutical and medical device marketers, manufacturers and distributors in their respective jurisdictions on behalf of the MHLW. Various business licences for pharmaceutical and medical device marketers, manufacturers and distributors are also issued by the prefectural governments, while marketing authorisations and other product-related approvals are generally handled directly by the MHLW. The Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese independent administrative agency that receives financial support from the Japanese government to cov-

er its operational costs, also plays a key role in reviewing marketing authorisation applications for new pharmaceutical and medical devices. Applications for new pharmaceutical marketing authorisations are first reviewed and commented on (if any) by the PMDA. Therefore, communication with PMDA officials is key to obtaining new pharmaceutical marketing authorisations.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

If a pharmaceutical or medical device firm violates the Pharmaceuticals Law or any related regulation, the MHLW or a prefectural government may issue an administrative order to that firm. The recipient may challenge the administrative order through an administrative complaint review process provided under the Administrative Complaint Review Act. A pharmaceutical or medical device firm served with an administrative order may also commence a legal action for the revocation of the administrative order with a competent court in accordance with the Administrative Case Litigation Act. These challenge procedures are also generally applicable in cases involving the issuance of administrative orders for violations of laws concerning other regulated products (eg, certain food products). Recently, a few leading generic drug manufacturers received business suspension orders due to their violations of pharmaceutical regulations, resulting in significant shortages in certain sectors of the generic drug market in Japan.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into two classes: prescription pharmaceuticals and OTC pharmaceuticals. Prescription pharmaceuticals may only be used by doctors or used in accordance with a doctor's prescription. OTC pharmaceuti-

cals can be purchased at drug stores or other non-licensed stores. OTC pharmaceuticals are further classified into several sub-categories and, depending on the relevant sub-category, may have certain sales restrictions.

- Class one OTC pharmaceuticals – can only be sold by a licensed pharmacist, with a mandatory explanation of the key points relating to such pharmaceuticals to be given by the pharmacist to a purchaser at the time of sale.
- Class two OTC pharmaceuticals – can only be sold by a licensed pharmacist or a registered seller (who has passed a registered seller examination held by a prefectural government), and explanation of such pharmaceuticals at the time of sale is recommended.
- Class three OTC pharmaceuticals – can be sold without the presence of a licensed pharmacist or a registered seller, and explanation of such pharmaceuticals by the seller is not legally required or recommended.

Medical devices are categorised into three classes:

- specially controlled medical devices (medical devices that are highly invasive to the patient, and, if a problem were to occur, there is a risk that it would directly affect the patient's life or pose a relatively high risk to the human body; classes III and IV of the Global Harmonisation Task Force (GHTF) international classification structure);
- controlled medical devices (medical devices for which the risk to the human body, even if a problem were to occur, is considered to be relatively low; class II of the same); and
- ordinary medical devices (medical devices for which the risk to the human body, even if a problem were to occur, is considered to be extremely low; class I of the same).

Depending on the relevant class of medical devices, a marketer and a distributor will need to obtain different business licences, as appropriate. A distributor of the specially controlled medical devices is required to obtain a business licence for each of its distribution offices. A distributor for the controlled medical devices is required to submit a notification of its distribution activity for each of its distribution offices. A distributor of only ordinary medical devices is not subject to such business licensing or notification requirement.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The Pharmaceuticals Law, together with the Good Clinical Practice (GCP) ministerial order issued by the MHLW, is the principal law regulating clinical trials. The MHLW and the PMDA are the main regulatory authorities that oversee clinical trials.

The MHLW generally requires all drugs to be tested in clinical trials conducted in Japan and operated by hospitals located in Japan, and to be subject to marketing authorisations in Japan. Even new drugs that have undergone clinical trials and received marketing approval in foreign jurisdictions are required to undergo separate clinical trials in Japan in order to verify such drug's effectiveness and safety when given to Japanese people. Even for COVID-19 vaccines supplied to Japan, the Japanese government required that a limited number of separate clinical trials be performed in Japan based on this policy. The MHLW insists that such clinical trials are necessary and that they must be carried out in Japan in order to study the differences in pharmacology due to race, lifestyle, etc, in Japan with those in a foreign country.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, an applicant (a pharmaceutical or medical device marketer) must prepare a protocol and receive approval for such protocol from an institutional review board (IRB). A protocol must cover, among other things, the subject material, purpose, design, methods, statistical considerations and organisation of the proposed clinical trials. The applicant is also required to register the protocol with the MHLW through the PMDA. In practice, the applicant consults with the PMDA informally about its draft protocol before formally registering the protocol with the MHLW.

2.3 Public Availability of the Conduct of a Clinical Trial

The website of the National Institute of Public Health discloses certain basic information regarding clinical trials conducted in Japan, including:

- the title of the study;
- the subject material of the study;
- a brief summary of the study;
- information about the monetary sponsor, the relevant IRB, and other organisations involved;
- contact information for the parties involved; and
- a summary of the results.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There is no apparent prohibition on using online tools to support clinical trials, which are generally required to be conducted by doctors or hospitals and include in-person interviews with, and written informed consents from, clinical trial subjects. Recruiting clinical trial subjects can be conducted online. In addition, under a guideline

from the MHLW, if an approved protocol for a clinical trial provides for online medical checks in the clinical trial, such medical checks can be conducted on an online virtual examination basis.

2.5 Use of Data Resulting From Clinical Trials

Raw data obtained from clinical trials is considered to be sensitive data of clinical trial subjects. Therefore, clinical trial data obtained by a doctor or hospitals (investigators) is usually converted into a form that prevents the identities of clinical trial subjects from being discoverable and only such anonymised information or data is provided to the sponsor of the clinical trial. Furthermore, upon commencement of a clinical trial, investigators must obtain an informed consent letter from each trial subject regarding the use and treatment of such subject's sensitive personal data as well as potential risks associated with the trial subject's participation.

2.6 Databases Containing Personal or Sensitive Data

As mentioned in 2.5 *Use of Data Resulting From Clinical Trials*, it is common practice for resulting data to be anonymised, and in such form the data is not regulated as strictly as sensitive data. Disclosure of original, non-anonymised data (raw data) is heavily regulated as sensitive information under the Act on the Protection of Personal Information (APPI). In applying the APPI regulations, data of clinical trial results that “*can identify specific individuals through easy matching with other information*” (easy matching) is generally considered to be non-anonymised and sensitive personal data. The Federation of Pharmaceutical Manufacturers' Associations of Japan issues the Guidelines for the Proper Handling of Personal Information by Pharmaceutical Companies. Such Guidelines note that

in order to ensure the reliability of clinical trial data collected by medical institutions conducting clinical trials, pharmaceutical companies may sometimes be required to directly inspect medical records, etc, for monitoring or auditing purposes. Whether or not such inspection by pharmaceutical companies comparing clinical trial data managed by subject identification codes with medical records, etc, falls within the category of easy matching, is considered to be *“consistent with the actual situation, and easy matching is recognised when matching is possible regardless of whether the name, address, etc, is intentionally visible or not.”*

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The term *“pharmaceutical”* is defined under the Pharmaceuticals Law as:

- items listed in the Japanese Pharmacopoeia;
- items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals; or
- items that are intended to affect the structure and functioning of a human’s or animal’s body.

However, quasi-pharmaceutical products and cosmetics are excluded from the definition of pharmaceutical.

The term *“medical device”* is defined under the Pharmaceuticals Law as appliances, instruments or similar items that are intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals – or that are

intended to affect the structure or functioning of the bodies of humans or animals – and that are specified by cabinet order.

The relevant cabinet order specifying medical devices is so broadly worded that it is not clear whether each and every medical appliance, instrument or similar item is classified as a medical device. Software that is intended for use in the diagnosis, medical treatment or prevention of disease in humans or animals can also be classified as a medical device.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market a pharmaceutical or medical device, the initial marketer is required to obtain marketing authorisation. Key factors that are taken into account when reviewing an application for marketing authorisation or marketing certification are:

- the quality, effectiveness and safety of the pharmaceutical or medical device;
- the applicant’s marketing business licence;
- the manufacturer’s manufacturing business licence; and
- the manufacturer’s compliance with the good manufacturing practice (GMP) regulation.

Biological pharmaceuticals are generally considered to be proteins or polypeptides produced by the culture of recombinant or non-recombinant cell protein expression systems, highly purified, and characterised by a range of appropriate analytical methods, as well as derivatives thereof or pharmaceuticals containing them as a component. To obtain marketing authorisation for a biological pharmaceutical, certain additional requirements must be fulfilled, such as:

- a manufacturer of a biological pharmaceutical must comply with more stringent management and safety requirements; and
- packaging/packaging inserts of a biological pharmaceutical must indicate that it is a biological product.

The MHLW believes that in the manufacturing of biological pharmaceuticals, it is important to establish appropriate quality control methods to ensure that the intended clinical efficacy and safety are achieved, and it is necessary to conduct a wide range of quality characteristic analyses as a basis for this. Among the quality characteristics, those that may affect efficacy and safety are managed using a combination of various control methods, including raw material control, process parameter control, in-process testing, specifications and test methods, etc, to ensure that the final product quality falls within the target range. The PMDA and the MHLW emphasise the importance of checking these points when reviewing an application for marketing approval of a biological product.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of a marketing authorisation is not indefinite. An authorisation for a new pharmaceutical is generally subject to re-examination eight years after the initial authorisation. However, depending on the type of pharmaceuticals, this may be four to ten years after the initial authorisation. Additionally, the MHLW occasionally conducts a re-evaluation of pharmaceuticals based on the recommendation of its advisory board.

A marketing authorisation can be revoked by the MHLW and other competent authorities, when, for example, it is found that:

- the relevant pharmaceutical does not have the efficacy or produce the effects indicated in the application; or
- the relevant pharmaceutical has no value because the harmful effects associated with such product outweigh the efficacy or beneficial effects.

Additionally, a marketing authorisation can be revoked if the responsible party has not marketed the relevant authorised pharmaceutical or medical device for three consecutive years without any reasonable justification. The MHLW may vary parts of a marketing authorisation for pharmaceuticals and medical devices if, in the MHLW's view, it is necessary to do so in light of health or hygiene considerations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Submission of Application

An application for marketing authorisation must be submitted to the MHLW or – in the case of certain pharmaceuticals and all medical devices (other than medical devices with a GHTF classification of class IV) – to the relevant prefectural government or a particular registered certification body. With regard to an application for a pharmaceutical or medical device that must be submitted to the MHLW, the application must be submitted through the PMDA. The MHLW's review of applications for marketing authorisation for new medicinal products is substantially outsourced to the PMDA. Once the PMDA is satisfied with the application, the application is forwarded to the MHLW, which then obtains a recommendation from the Council of Pharmaceutical and Food Sanitation before approving the application.

Required information

A marketing authorisation application must include, as an attachment, data concerning the results of clinical trials and other pertinent data – except where the application is for a medicine that is subject to a conditional early approval for market authorisation (an expedited process).

Variation of a marketing authorisation

Variation of a marketing authorisation – such as a change in the therapeutic indication, formulation, dosage, patient population, packaging or labelling – requires the marketing authorisation-holder to complete a formal process. Depending on the materiality of the change, the variation may require approval from the relevant authority or the mere submission of a report.

Transferral of a marketing authorisation

It is permissible for market authorisation to be transferred from the current marketing authorisation-holder to a transferee. A transferee of a marketing authorisation must notify the relevant authority of the transfer, evidenced by providing the application for transfer addressed to the MHLW, at least one month prior to the date of transfer. The transferee must attach a document evidencing the transfer of the marketing authorisation from the transferor (eg, a short-form sale and purchase agreement) and a supply agreement with a foreign manufacturer if the product is imported from the foreign manufacturer. The transferee must, in addition to obtaining marketing authorisation, obtain a business licence to market the pharmaceuticals. In the case of a transfer of the marketing business of a pharmaceutical product, the business transferee is required to apply for the marketing business licence well in advance so that it is issued on or before the effective date of the business transfer.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The Pharmaceuticals Law provides for an exceptional procedure to allow the importation of a pharmaceutical or medical device that has received foreign marketing authorisation for compassionate use if:

- the foreign marketing authorisation was obtained in a country with a marketing authorisation system equivalent to the system in Japan;
- immediate use of the pharmaceutical or medical device is necessary to prevent a pandemic that could cause death or serious harm to the health of Japanese citizens; and
- the pharmaceutical or medical device is specifically designated under an administrative order.

This special procedure was once used to import an influenza vaccine produced by a foreign manufacturer. It is also used for vaccines and therapeutic drugs for COVID-19 that are produced by foreign manufacturers and supplied for use in Japan.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

After the marketing of a pharmaceutical or a medical device commences, the marketing authorisation-holder is required to conduct post-marketing pharmacovigilance and technovigilance. If any issue relating to the effectiveness or safety of the marketed pharmaceutical or medical device is discovered during the post-marketing authorisation surveillance period, the marketer must conduct a pharmaceutical or medical device recall campaign, report the discovery to the PMDA, issue public notices,

and take other appropriate measures to prevent patients suffering further damage or losses.

An applicant for a marketing authorisation must typically complete all clinical trials first and then submit its application with the complete accompanying data. However, in the case of conditional early approval for market authorisation for an innovative product exempted for a part of its clinical trials, post-marketing phase IV clinical trials must be performed.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

In general, third parties can access information about applications for marketing authorisations by making a request under Japan's information disclosure law. Under the Act on Access to Information Held by Administrative Organs, anyone may request the disclosure of administrative documents held by an administrative organ.

Under this law, the MHLW is essentially required to disclose an application for marketing authorisation if properly requested. However, the application for marketing authorisation may include or refer to the IP or confidential information of an applicant, and the disclosure of such information to a third party may result in serious damage to an applicant's rights and competitiveness. Therefore, disclosure of an application is usually made after the relevant sensitive information contained in it has been redacted or masked so that the IP and/or confidential information of an applicant is protected.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

In the case of orphan drugs and certain other products that are considered to have particularly high medical needs, the examination of the marketing authorisation application for the product can be granted priority over examination of other products by the examining authority. Products that are eligible for this priority examination route include, for example, pharmaceuticals that are designated by the MHLW as products with unmet medical needs pertaining to paediatric diseases and antimicrobial resistance, as well as pharmaceuticals and medical devices that are designated by the MHLW as innovative products.

The Pharmaceuticals Act also provides for an exceptional abbreviated marketing authorisation application process for certain designated pharmaceuticals and medical devices that satisfy certain criteria prescribed by law, including, for example, that (i) there is urgent need to use the product to prevent the spread of disease or other health hazards that may pose serious effects on the lives and health of the general public, and (ii) there is no other appropriate method available other than to use such product. Currently, the MHLW has designated drugs pertaining to COVID-19 as the products eligible for such abbreviated application process. In the abbreviated application process, the MHLW has the authority to grant the applicant an extended grace period for submitting certain information and documents required for ordinary marketing authorisation application.

4.2 Regulatory Reliance

As part of the marketing authorisation application documents, the applicant is required to pro-

vide information regarding the use of the product outside of Japan, including whether a marketing authorisation for the product has already been obtained outside of Japan. However, such information is one of the various factors to be considered in the course of the MHLW's marketing authorisation application examination process. The MHLW does not necessarily expedite the issuance of the marketing authorisation in Japan even if marketing authorisation for the product has already been obtained outside of Japan.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices Pharmaceutical Manufacturers

A manufacturing business licence is required in order to manufacture pharmaceuticals in Japan. If a manufacturer of an imported product is located outside Japan, that manufacturer will be required to obtain accreditation as a foreign manufacturer. A manufacturing business licence is granted by the relevant prefectural government and such accreditation is granted by the MHLW. Once an application for a manufacturing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's manufacturing premises. The period of validity of a manufacturing business licence and an accreditation is five years.

Medical Device Manufacturers

Unlike pharmaceutical manufacturers, a medical device manufacturer – whether located in Japan or outside Japan – is only required to satisfy a prior registration (ie, registration with the MHLW

as a medical device manufacturer). The registration must be renewed every five years.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

In order to market pharmaceuticals or medical devices, the initial marketing entity must hold a marketing business licence and have marketing authorisation for each of the relevant products. A marketing business licence is granted by the relevant prefectural government. Once an application for a marketing business licence is formally submitted, the prefectural government reviews the application and – in most cases – conducts an on-site inspection of the applicant's office or factory.

Marketing business licences are generally valid for five years; however, the actual validity period will depend on – among other things – the type of pharmaceutical or medical device to be distributed by the applicant. Wholesalers and retailers of pharmaceuticals and medical devices are also required to obtain a distribution business licence.

6.2 Different Classifications Applicable to Pharmaceuticals

There are two types of marketing business licences for pharmaceuticals: Type 1 and Type 2. A Type 1 marketing business licence is required for marketing prescription pharmaceuticals. A Type 2 marketing business licence is required for marketing other pharmaceuticals (ie, non-prescription ethical pharmaceuticals and OTC pharmaceuticals).

There are three types of marketing business licences for medical devices:

- a Type 1 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class III or IV;
- a Type 2 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class II; and
- a Type 3 medical device marketing business licence is required for marketing medical devices with a GHTF classification of class I.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The Pharmaceuticals Law governs the import and export of pharmaceuticals and medical devices. Imports of pharmaceuticals and medical devices from outside Japan are, in principle, subject to the same marketing regulations applicable to products manufactured in Japan. Importers of these products are subject to requirements regarding marketing authorisation, marketing business licences and accreditation as a foreign manufacturer.

A manufacturing business licence is required for the manufacture of pharmaceuticals or medical devices that are to be exported from Japan. Although marketing authorisation is not necessary, a separate registration for manufacturing pharmaceuticals or medical devices for export is required.

The relevant prefectural government regulates marketing business licences, whereas the MHLW regulates accreditations for foreign manufacturers.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

In principle, an importer of pharmaceuticals or medical devices must obtain a marketing business licence, and is required to present certificates of the marketing business licence and the marketing authorisation for each particular imported product to the relevant customs house. The Pharmaceuticals Law provides for exceptions to these requirements, such as where an individual imports small amounts of these products for their personal use.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In principle, import of pharmaceuticals or medical devices is not permitted unless the importer on record possesses a marketing business licence and a marketing authorisation for each particular imported product. The Pharmaceuticals Law provides for exceptions to these requirements, such as where small amounts of these products are imported by an individual for their personal use. As regards permitted exceptions in the case of emergency situations, see **3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations.**

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

In addition to obtaining a marketing business licence and marketing authorisation when importing pharmaceuticals or medical devices, it may be necessary to change the product's packaging to conform to product description and information requirements provided under the Pharmaceuticals Law. By way of an exam-

ple, packaging and product labelling – and the explanatory written material provided with the products (such explanatory information is usually available online) – must be provided in Japanese and satisfy the requirements under the Pharmaceuticals Law. Changing a product's packaging is considered part of the manufacturing of the product and, as such, the entity responsible for performing such changes is required to possess a manufacturing business licence.

7.5 Trade Blocs and Free Trade Agreements

As of January 2025, Japan has signed 21 economic partnership agreements/free trade agreements with other countries. Among others, Japan is a signatory to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP) and the Regional Comprehensive Economic Partnership (RCEP), as well as economic partnership agreements with such countries as the United States, the United Kingdom, Singapore, Mexico, India, Peru, Switzerland, Thailand and Indonesia.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Prices for the substantial majority of medical services provided and prescription pharmaceuticals sold in Japan are reimbursed by the Japanese universal healthcare system, and the substantial majority of legal residents of Japan participate in and are covered by Japan's national health insurance system. The cost of prescription pharmaceuticals to be paid through the national health insurance system corresponds to the prices for the relevant pharmaceuticals listed on the drug tariff.

Listing of a prescription pharmaceutical's price on the drug tariff is based on the Health Insurance Act and is a separate procedure from the marketing authorisation procedure provided under the Pharmaceuticals Law. The profit margin of the hospitals and the pharmacies is usually the difference between the prices for the relevant pharmaceuticals listed on the drug tariff and the prices at which the pharmaceuticals are purchased by the hospitals and the pharmacies (such price is usually lower than the price listed on the drug tariff).

In the case of medical devices, typically, it is not the medical devices themselves, but the medical services provided using the medical devices, that are reimbursable under the Japanese health insurance. However, certain medical device products that are designated by the MHLW are reimbursable under the Japanese health insurance.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The listing of pharmaceuticals on the drug tariff and the price designated for each of the pharmaceuticals listed are determined by the MHLW after reviewing the applications submitted by the market authorisation-holders of such pharmaceuticals. The price of the same product in other countries is one element of background information considered when determining the listing price. The drug tariff is reviewed and updated basically every two years. Recently, an “*interim*” review and update of the drug tariff is conducted after one year, which essentially means that the drug tariff is generally reviewed and updated every year.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical treatments is covered by the health insurance scheme. For the majority of Japanese residents, 70% of these costs are covered by health insurance.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The MHLW considers cost-benefit analysis as a key factor when evaluating new pharmaceuticals. Whether or not pharmaceuticals, medical devices and medical treatments are reimbursed by the Japanese health insurance, and the reimbursement price of such products and services under the Japanese health insurance, are determined and reviewed periodically by the MHLW, upon taking into consideration various factors including cost-benefit analyses.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Historically, Japanese hospitals prescribed and dispensed pharmaceuticals themselves. However, in an effort to address excessive pharmaceutical-related spending, the MHLW began incentivising hospitals to separate the prescription and dispensing of pharmaceuticals functions so that pharmaceuticals are not prescribed unnecessarily. Furthermore, under the Japanese health insurance regulations, Japanese hospitals are prohibited from instructing patients to purchase prescription drugs at a specific pharmacy.

MEXICO



Law and Practice

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Baker McKenzie has a healthcare and life sciences industry group that is active in matters throughout the whole life cycle of products, from research and development to manufacturing and commercialisation. It provides industry-focused and integrated advice in the fields of regulatory, data privacy, IP, transactional and M&A, foreign trade, antitrust, compliance, tax and litigation. The firm acts for leading indus-

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The legal framework regulating pharmaceuticals and medical devices is largely federal in Mexico, and includes the following laws and regulations:

the General Health Law (GHL);

- the Health Supplies Secondary Regulations (*Reglamento de Insumos para la Salud*, or RIS);
- the Health Services Secondary Regulations;
- the Health Advertisement Secondary Regulations;
- the Clinical Research Secondary Regulations (CRSR); and
- several official Mexican standards on specific technical aspects (eg, good manufacturing practices, labelling and stability).

In Mexico, the legal and administrative nature of the Federal Commission for the Protection against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*, or COFEPRIS) is that of an autonomous agency, under the administrative structure of the Ministry of Health (MoH). The GHL created COFEPRIS and gave it administrative, technical and operational autonomy.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of the regulatory bodies that apply and enforce pharmaceutical and medical device regulations may be challenged through the following optional appeal proceedings:

- an initial administrative review, decided by the same authority that issued the appealed administrative decision;
- an annulment trial, decided by the Federal Administrative Tribunal; and
- an *amparo* trial, decided by a judicial body, a judge or a court (depending on the nature of the decision being challenged).

The formal requirements for challenging a decision vary depending on the nature of the decision being challenged, but generally the appeal lawsuit will include:

- identification of the affected party;
- identification of the challenged decision;
- identification of the authority that issued the decision;
- a description of the facts; and
- the available evidence.

However, the most important element for successfully litigating regulatory decisions is in-depth understanding of life sciences regulations and public law, so that the science and the law can be properly understood, aligned and argued in each case.

In the last couple of years, there has been a significant increase in litigation relating to decisions taken by health regulators. Litigation has always existed in this area – traditionally in relation to sanctions. There is now a lot of litigation in relation to the system of authorisations and the interpretation of technical regulations. As the regulatory system has evolved into a more complete set of legal rules, and as regulatory work is now being undertaken not only by pharmaceutical chemists but also by lawyers, companies have better understood their rights and have felt increasingly confident in challenging regulatory decisions that affect their interests.

For a whole decade following the creation of COFEPRIS in 2000, regulatory work was highly technical and was mainly handled by pharmaceutical chemists, both in companies and in regulatory agencies. The health law and regulation did not evolve as quickly as the science and the market. The government's regulatory decisions were frequently taken based not on existing legal rules but exclusively upon technical criteria, which led to a highly discretionary system. Although decisions were always legally vulnerable, the concern of companies was that legally challenging a decision on one product would affect other decisions pending over other products. At the same time, public affairs actions were rather successful in achieving results without the need to litigate.

Two COFEPRIS administrations (2010–18) then brought the legal framework up to date, bringing in lawyers to key positions and modernising the administrative system. This helped to trigger a trend for in-house lawyers and external counsel specialising in the field. At the same time, compliance controls tightened, forcing companies to evaluate, enforce and defend their rights and obligations on the one hand and to put pressure on the area of public affairs on the other.

Finally, the actions of the two most recent COFEPRIS administrations (2018–20 and 2020–23) deliberately isolated the agency from the industry by restricting contact with the regulated industries, replacing experienced examiners and reducing the number of available examiners, leading to a huge backlog that disrupted commercial operations. This created strong incentives for companies to litigate all kinds of pending approval applications.

Taken together, the foregoing has resulted in a significant and sustained increase in litigation,

year after year, for the past decade. This led to the creation of the Specialised Chamber for Regulatory Matters within the Federal Administrative Tribunal, which heard 300 cases against COFEPRIS in 2020. Currently, there is significant litigation against a lack of response on new authorisations, renewals, modifications, rejections and inspection procedures, in addition to the litigation of sanction decisions. In 2022, the total number of all types of litigation cases against COFEPRIS skyrocketed to 12,000.

The previous administration (2023–24) partially restarted communication with the regulated industries via the Commissioner for Health Promotion, through technical sessions and goodwill meetings. Both schemes are confidential, non-binding and not regulated by applicable regulations. Nonetheless, these schemes represent an alternative means for the industry to understand COFEPRIS' interpretation of regulations and requirements. How this new administration (2025–31) will tackle the regulated industries and the severe administrative backlog it has inherited remains to be seen.

1.3 Different Categories of Pharmaceuticals and Medical Devices

The GHL contains many relevant classifications for medicines, including reference and generic/biocomparable drugs, prescribed and non-prescribed drugs, standard and controlled drugs, and so on.

Medical devices are divided into three classes according to the risk they pose to human health, as follows:

- class I – devices that are recognised in medical practice, have proven safety and efficacy, and are generally not introduced into the human body;

- class II – devices that are recognised in medical practice, can vary in the way or volume in which they are manufactured and are regularly introduced into the human body (remaining in situ for less than 30 days); and
- class III – new products, or those recently accepted by medical practice or that are introduced into the human body and remain in situ for more than 30 days.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are regulated by the following key instruments:

- the GHL;
- the CRSR;
- Technical Standard NOM-012-2012-SSA3;
- the Guidelines for Good Clinical Practice published by COFEPRIS; and
- the Decree for the Operation of Ethics Committees, co-ordinated by the National Bioethics Commission.

In general, clinical trials (Phases I–IV) must be:

- preceded and supported by preclinical data;
- conducted in accordance with scientific and ethical principles;
- performed with the informed consent of the participating human subjects;
- executed under a research protocol;
- overseen by a principal investigator; and
- performed in licensed health institutions.

In addition, they must obtain the relevant approvals from a health institution, an ethics committee and COFEPRIS.

Historically, the operation of ethics committees was largely self-regulated and based on international best practice. There was also a lack of co-ordination between COFEPRIS and the National Bioethics Commission (ConBioetica). However, the Decree for the Operation of Ethics Committees (2012) provides a clearer legal framework for ethics committees, establishing their structure and objectives, the role of their members and the requirement to be registered with ConBioetica and COFEPRIS. Unfortunately, ConBioetica has accumulated enormous regulatory delays, forcing serious consideration of litigation of the lack of response.

Notably, the Guidelines for Good Clinical Practice (2012) make clear reference to international best practice, including standards developed by the International Conference on Harmonisation. These good clinical practices will be the basis of a move towards a certification system, for which COFEPRIS has already started to conduct inspections of research sites.

The operation of contract research organisations (CROs) is not fully regulated, with references only found in the guidelines, but there are ongoing initiatives to address this, including the draft PROY-NOM-262-SSA1-2024 on good clinical practices.

Other regulatory measures have been introduced to promote Mexico as a place for conducting clinical research, including the following.

- An important amendment to the RIS – Article 170 of the RIS originally required a certificate of free sale of the country of origin to be submitted as part of an application for obtaining marketing authorisation (MA) for a drug produced abroad, such that it was not possible to have Mexico as the first country

of registration. In 2012, however, this rule was changed to make it possible to submit a clinical trial report instead, provided that the Mexican population was included in the trial.

- The creation of third authorised parties for clinical research – COFEPRIS has authorised several public hospitals with extensive experience in clinical research to conduct a pre-evaluation of research protocols. If their report is positive, approval times at COFEPRIS are reduced significantly.

The same rules regulate medical devices and pharmaceuticals.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

The procedure for securing authorisation to undertake a clinical trial of a pharmaceutical or a medical device is comprised of three basic steps, which are sequential and cannot be applied for in parallel, as follows:

- favourable opinion of the research protocol by the ethics committee of the health institution where the trial is to be conducted, which – according to the Decree for the Operation of Ethics Committees – must take place within 30 business days of filing;
- authorisation of the research protocol by the director of the health institution where the trial is to be conducted, which must take place under its relevant internal rules; and
- approval of the research protocol from COFEPRIS, which – according to the Federal Law on Administrative Proceedings – must take place within three months of filing.

2.3 Public Availability of the Conduct of a Clinical Trial

After their protocols have been authorised by COFEPRIS, most trials are currently recorded

in the National Registry of Clinical Trials (*Registro Nacional de Ensayos Clínicos*, or RNEC). The information contained in the RNEC is collected by COFEPRIS in collaboration with those responsible for conducting the clinical trial (ie, a sponsor, CRO or healthcare institution). The RNEC publishes an electronic database that includes only general information about clinical trials. Although limited, this database has seen significant progress; until very recently, almost no local information was made publicly available. Confidential information is not included in the RNEC, and nor is the health information of patients, which will be regarded as sensitive personal information under data protection laws and will be protected accordingly.

On the other hand, there is no binding provision to disclose or publish the results of clinical trials, although the Code of Ethics of the Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) does contain a specific obligation for sponsors to disseminate the positive and negative results of trials, particularly the adverse events.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no specific restrictions regarding online clinical trial platforms. However, it would be important for a platform to comply with the regulations regarding the recruitment of and interaction with patients enrolled in a clinical trial if those functionalities are included in that platform. There could also be other regulatory implications, such as in relation to the advertising of health inputs, services and privacy protection, so it is important that platform content be reviewed on a case-by-case basis.

The data resulting from a clinical trial would be considered personal if the patients enrolled

therein are identified. If the results of a clinical trial are presented without providing information or images that could lead to the identification of the patients, such results would not be considered personal data.

2.5 Use of Data Resulting From Clinical Trials

It is permissible to transfer the data resulting from a clinical trial to a third party or an affiliate, if the privacy notice states that a transfer will occur and identifies a justifiable purpose for that transfer. When sensitive personal data is involved, the data controller must obtain express written consent for its processing through a signature, an electronic signature or any authentication mechanism established for that purpose.

2.6 Databases Containing Personal or Sensitive Data

The creation of databases that contain sensitive personal data must be justified, and must follow legitimate and concrete purposes that correspond to the activities and explicit objectives of the data controller. These kinds of databases are not subject to authorisation before operations commence.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The GHL provides a general definition for pharmaceuticals, and any product that falls under such definition should be considered a pharmaceutical. According to the GHL, a medicine is any substance or mixture of substances of natural or synthetic origin that has any therapeutic, preventative or rehabilitative properties,

is presented in any pharmaceutical form and is identified as such for its pharmacological activity and physical, chemical and biological characteristics.

On the other hand, the new definition of medical device contained in Section 3.41 of Standard NOM-241-SSA1-2021 (NOM-241) is broader: *“Medical device, instrument, apparatus, utensil, machine, software, implantable product or material, diagnostic agent, material, substance or similar product, to be used, alone or in combination, directly or indirectly in human beings; with any of the following purposes of use:*

- *diagnosis, prevention, surveillance or monitoring, and/or aid in the treatment of diseases;*
- *diagnosis, surveillance or monitoring, treatment, protection, absorption, drainage, or aid in the healing of an injury;*
- *substitution, modification or support of the anatomy or of a physiological process;*
- *life support;*
- *control of conception;*
- *disinfection of medical devices;*
- *disinfectant substances;*
- *provision of information through an in vitro examination of samples taken from the human body, for diagnostic purposes;*
- *devices incorporating tissues of animal and/or human origin; and/or*
- *devices used in in vitro fertilisation and assisted reproductive technologies,*

as well as those whose main purpose of use is not through pharmacological, immunological or metabolic mechanisms; however, they can be assisted by these means to achieve their function. Medical devices include supplies for health in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnos-

tic agents, supplies for dental use, surgical and healing materials, and hygienic products”.

Initially, any product that falls into this definition should be considered a medical device.

It is also important to remember the list of products that, due to their nature, characteristics and uses are not considered medical devices. Products included on this list are excluded from the medical devices regulation.

There are other categories that are recognised in practice (eg, combination products) but not formally regulated through mandatory instruments.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

In general, there is only one type of MA for pharmaceuticals for human health and for medical devices, which is granted by COFEPRIS. The same requirements of quality, safety and efficacy apply, regardless of whether the product is allopathic, homeopathic, herbal or a vitamin pharmaceutical.

However, there is a significant difference between the extent and scope of safety and efficacy data that would be required for an innovator product compared with a subsequent product, and a specific requirement for releasing biologic products after importation. Biotech drugs are also subject to a pre-submission regulatory meeting with the COFEPRIS' New Molecules Committee.

Please also note that a new class of approvals was introduced during the COVID-19 pandemic (albeit without a legal basis therefor): emergency authorisations. These expired once the health emergency was declared to be over, with regular market authorisations subsequently being required instead.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The period of validity of any MA for pharmaceuticals and medical devices is five years. After this period, MAs may be renewed every five years. In contrast, a recognition letter for orphan drugs (the equivalent of an MA) lasts for two years only.

Also, any authorisation may be revoked by COFEPRIS at any time – for instance, when a new risk to human health is found, if an infringer repeatedly disregards safety measures, or if false information is submitted. MAs may be cancelled if companies fail to submit renewal applications on time.

A recent change to the RIS means that the second and subsequent renewals of MAs – both for medicines and for medical devices – will only be subject to a notification, not to an authorisation.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

In general, the procedure for obtaining an MA for pharmaceuticals includes filing the MA application form at COFEPRIS, along with evidence of the following:

- the payment of governmental fees;
- a manufacturing licence or equivalent;
- notice of appointment of a qualified sanitary officer;
- draft labels;
- the information to prescribe;
- certificates of good manufacturing practices for the finished product, its active ingredients and its additives;
- the draft distinctive name;
- the quantitative and qualitative formula;
- quality information; and

- preclinical studies, including pharmacodynamics, pharmacokinetic and toxicology studies.

For products manufactured abroad, it is also necessary to file a representation letter granted to the holder.

The application to obtain an MA for medical devices must be submitted with the following:

- the payment of governmental fees;
- the technical and scientific information that proves the security and efficacy standards;
- draft labels;
- instructions;
- a general description of the manufacturing process;
- a description of the structure, materials, parts and functions;
- certificates of good manufacturing practices for the finished product;
- laboratory tests; and
- bibliographic references, if such are required.

For products manufactured abroad, it is also necessary to file the following:

- a free sale certificate;
- a representation letter issued by the manufacturer of the product;
- a certification of analysis;
- sanitary notification of the distribution warehouse; and
- notification of the sanitary official of the distribution warehouse.

Approval times are as follows:

- for pharmaceuticals that include active and therapeutic indications already registered in

Mexico, the decision must be granted within 180 days;

- for pharmaceuticals whose active ingredients are not registered in Mexico but are registered and sold freely in their country of origin, a decision shall be taken within 240 days;
- for new molecules, after a prior technical meeting between applicants and the New Molecules Committee of COFEPRIS, the decision shall be taken within 180 days;
- for homeopathic, herbal and vitamin pharmaceuticals, decisions shall be taken within 45 days; and
- for biotechnological drugs, applications must be resolved within 180 days.

These approval times can be extended if COFEPRIS requires additional information.

For class I medical devices, the decision must be granted within 30 days; for class II, the decision shall be taken within 35 days; and for class III, the decision shall be taken within 60 days.

As with pharmaceuticals, these approval times can be extended if COFEPRIS requires additional information.

There is no mandatory requirement to conduct clinical trials in a paediatric population nor to obtain a waiver from this requirement in relation to individual pharmaceuticals; this is completely optional and subject to stricter requirements.

The modification of MAs can be classified as administrative or technical. Technical modifications are those relating to changes in the formulation, indication or manufacturing process. Administrative modifications include changes to the corporate name or address of the holder, or to the information to prescribe. The assignment of an MA is regarded as an administrative modi-

fication. Each application to modify an MA must contain the technical and legal documentation supporting the relevant change.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

There are a limited number of cases where an unauthorised product can be imported into the country and supplied to patients, including low-prevalence diseases, donations (eg, in natural disasters), personal use, experimental products for clinical research and medical use.

In addition, if the relevant product is included on the list of products that, due to their nature, characteristics and uses are not considered medical devices, it would not be considered as a medical device and consequently would not require an MA.

The third wave of equivalency decrees introduced the import without registration route. This route was designed to secure the supply of medical products by requiring importers to apply for marketing authorisation within ten days after importing the first batch of the product.

The import of medicines and medical devices that do not have an MA in Mexico is permitted provided they have an MA from certain recognised jurisdictions, that the medicine or medical device is included in the national tender of medical products consolidated by *Laboratorios y Reactivos Biologicos Mexicanos*, S de R L de CV (BIRMEX) and that an MA application is filed after the first import of the product.

This route allows some companies faster market access, bypassing costly and time-consuming regulatory requirements, but risks patent violations, as the patent linkage system may be

overlooked. This could impact third-party patent rights during COFEPRIS's review of a market authorisation application under the official decree.

Unequal market access and potential patent breaches could violate free trade agreements and enable counterfeit medical products. Likewise, a company can access the market faster through the import without MA route, but if the application is denied, the company risks breaching its public contract and facing economic penalties.

The importation of medicines and medical devices without an MA was previously authorised during the pandemic, in the third wave of equivalency decrees published by the MOH on 28 January 2020 and 22 June 2021. To activate the importation without MA under these decrees, a prior declaration of necessity issued by multiple authorities was required. Both decrees have since been amended and their mechanisms substituted by the current 4 December 2024 decree.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Holders of MAs must comply with good manufacturing practices and stability, pharmacovigilance or technovigilance and labelling standards and regulations; they must also comply with the advertising regulations that apply to pharmaceuticals or medical devices. Product recall obligations have also become relevant of late.

In general, pharmaceuticals and medical devices are subject to post-approval vigilance. These obligations are developed in technical standards, which generally specify the rights and obligations for holders of MAs, distributors, research sites, health institutions, physicians

and patients to monitor adverse events or incidents, and to investigate and report them. It is also necessary to have a pharmacovigilance or technovigilance unit, someone responsible for pharmacovigilance and someone responsible for technovigilance, and a pharmacovigilance or technovigilance manual.

However, Phase IV data is only required for more complex products (eg, complex biologics or biotech drugs), as decided by the New Molecules Committee.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

COFEPRIS has periodically published lists of applications and lists of granted or rejected MAs. However, these lists are not updated regularly, and frequently contain limited information that excludes confidential information. Full access to individual files is only granted to the applicant.

Although third parties have long been able to file public information requests in relation to any file held by COFEPRIS under the mechanisms overseen by the National Institute for Access to Public Information and Data Protection (*Instituto Nacional de Transparencia, Acceso a la Información y Protección de Datos Personales* INAI), COFEPRIS historically resisted providing access to most of the files of MAs, which it regarded as being confidential in their entirety. Nevertheless, through several INAI decisions, an increasing number of data elements can now be accessed. Fortunately, COFEPRIS has now begun to populate a public database on its website that displays key data contained in the MAs for pharmaceuticals.

Confidential information is protected by several special laws, including those related to privacy,

IP and administrative procedures, and labour and criminal law.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Mexico's regulatory framework for medicines and medical devices includes fast-track registration through agreements with 42 global regulatory agencies via the equivalencies registration route.

Mexico signed its first equivalency agreements with Australia, Canada, Switzerland, the European Union and the United States on 10 March 2012. On 29 March 2019, the agreements were expanded to include medicines and vaccines prequalified by the World Health Organization, covering Argentina, Brazil, Canada, Chile, Colombia, Cuba and the United States.

During the COVID-19 pandemic in 2020 and 2021, the equivalencies registration route was expanded to ensure a stable local supply of medical products. This third expansion acknowledged members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and countries with products prequalified by the World Health Organization.

Thus, the equivalencies registration route established a 60-business day (three-month) fast-track period, as opposed to the traditional registration route applicable to local medical products and subject to a 240-calendar day (eight months) period for COFEPRIS to issue a resolution on MA applications.

The three waves of equivalency decrees are mostly similar, with minor differences. The

inclusion of WHO-prequalified medicines and vaccines was logical both scientifically and economically, but the reasoning for extending equivalence to members of PIC/S (the third group) is unclear.

4.2 Regulatory Reliance

Regulatory reliance refers to the practice of relying on regulatory decisions made by other jurisdictions, which are recognised as trusted regulatory authorities, to approve new medical products.

Regulatory reliance can be applied to the extent determined by the health regulator, either through an abbreviated process for medical products already authorised by another regulatory authority or by directly recognising the regulatory decision.

COFEPRIS aims to use reliance as a method to improve efficiency in supervising medical products. It has adopted the concept of reliance to achieve regulatory alignment with other regional authorities by collaborating with the Pan American Health Organization (PAHO).

This effort resulted in strategies for regulatory certainty for medicines and medical devices, as well as the modernisation of technical regulations such as NOM-241 on good manufacturing practices for medical devices and NOM-177-SSA1-2013 on the interchangeability of medicines. Additionally, several other existing technical regulations are being modified, including NOM-059-SSA1-2015 on good manufacturing practices for medicines.

As mentioned, COFEPRIS can legally expedite market authorisations if a company has approvals from recognised jurisdictions. However,

expedited resolutions for such applications are rarely seen in practice.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

A pharmaceutical manufacturing plant is subject to a licence, and a medical device manufacturing plant must submit a notice of operation. COFEPRIS is the authority responsible for granting the manufacturing licence and receiving the notice of operation.

To secure a manufacturing licence, a certificate of good manufacturing practices (“GMP certificate”) must be obtained. For that purpose, a COFEPRIS inspection visit to the manufacturing plant must first be requested, to review whether the plant complies with Technical Standard NOM-059-SSA1-2015 on good manufacturing practice for pharmaceuticals. If COFEPRIS determines in the inspection visit that the facility is in compliance, it will grant a certificate, which must be included in the manufacturing licence application. Once the application is submitted, COFEPRIS will take no more than 60 business days to grant the manufacturing licence. The activities typically approved by the manufacturing licence are the manufacture and warehousing of pharmaceuticals in the same facility. The operation licence does not have an expiry date.

The notice of operation for a medical device manufacturing plant only needs to be submitted to COFEPRIS and becomes valid the moment it is filed. The notice of operation requires the appointment of a sanitary officer, who shall be in

charge of the facility. The typical activities covered by the notice of operation are the manufacture and warehousing of medical devices in the same facility. The notice of operation does not have an expiry date. With the recent issuance of the new NOM-241 on good manufacturing practice for medical devices, a GMP certificate must be obtained. This new version of NOM-241 has been a source of controversy, as it also applies to manufacturing sites dedicated exclusively to exporting, which are covered by the Manufacturing Industry, Maquiladora, and Export Service (*Industria Maquiladora, Manufacturera y de Servicios Exportadores IMMEX*) programme.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

As a general rule, establishments involved in the wholesale of pharmaceuticals and/or medical devices are only required to submit a notice of operation to COFEPRIS. The notice of operation enters into effect at the moment of filing and does not have an expiry date.

The exception to the general rule is warehouses dedicated to the wholesale of controlled pharmaceuticals (eg, psychotropic and narcotics) and/or biological products for human use, which are subject to a licence.

6.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are divided into the following six sections in relation to their prescription status:

- section I – prescription pharmaceuticals that can only be acquired by a special prescription

or permit issued by the regulatory authority (eg, controlled substances);

- section II – prescription pharmaceuticals that require a prescription to be collected and retained in the pharmacy as well as registration in the pharmacy control books;
- section III – pharmaceuticals that can only be purchased with a prescription that may not be supplied more than three times and that must be recorded in the control book and retained in the pharmacy after the third supply;
- section IV – pharmaceuticals that require a prescription, but which can be supplied as many times as directed by the physician (eg, antibiotics);
- section V – non-prescription pharmaceuticals, authorised for sale only in pharmacies; and
- section VI – pharmaceuticals that do not require a prescription and can be supplied in any establishments other than pharmacies (eg, OTC products).

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

A vast body of law, including secondary regulations, technical standards and administrative decrees, controls the area of foreign trade and customs law. These are not necessarily co-ordinated with the health regulation, creating frequent issues for companies in the pharma and medical devices sectors.

By way of example, product classifications can differ to the extent that a product may be classified from a customs perspective as a cosmetic

for importing purposes and as a medical device from a regulatory perspective for commercialisation purposes. This can in turn have a tax impact on the applicable rate of value added tax.

Depending on the timing and the type of regulation to which the goods are subject, the following authorities could be involved:

- the Tax Administration Service;
- the National Customs Agency of Mexico;
- the MoH, through COFEPRIS;
- the Ministry of Economy, mainly through the General Direction of Standards and the Federal Consumer Protection Agency (*Procuraduría Federal del Consumidor* PROFECO); and
- the Attorney General's Office.

Depending on the type of good, enforcement may also be in the remit of the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence, the Federal Commission of Telecommunications, etc.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Imports must be carried out by an individual or legal entity that is registered in the Importers' Registry, which is administered by the Tax Administration Service.

Depending on their tariff classifications, certain goods – including certain chemical products, radioactive goods, chemical precursors and essential chemical products – may be subject to registration in specific sectors of the Importers' Registry. This registration is subject to additional requirements, which depend on the sector in which the importer is to be registered.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Imports of all pharmaceuticals and some medical devices are subject to the obligation of securing specific import permits.

While such imports are normally administered by the MoH through COFEPRIS, depending on the type of product they may also be subject to other types of import or export permits, including those imposed by the Ministry of Economy, the Ministry of Agriculture, Livestock and Natural Resources, the Ministry of Defence and the Federal Commission of Telecommunications.

Among others, the following exceptions to the obligation to secure an import or export permit may apply, but only for non-commercialisation purposes:

- importing for personal use;
- importing for donations;
- importing for experimental use; or
- importing for low-prevalence diseases.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

In Mexico, non-tariff regulations and restrictions – such as import permits and licences – are imposed based on the tariff classification (harmonised tariff schedule (HTS) code) and the description of the goods to be imported or exported.

Pursuant to the Mexican Constitution, the executive power may regulate or restrict the importation or exportation of products, provided that Congress grants it such authority. The use of that authority needs to be approved by Congress at the end of each year.

Under the Foreign Trade Law, Congress grants this authority to the executive power, with the condition that – in order for a non-tariff regulation or restriction to be imposed – the corresponding decree or administrative regulation must be published in the *Federal Official Gazette*, and the goods subject to such regulation or restriction must be listed by tariff classification and description.

When products are subject to sanitary import permits, which in many cases require a marketing authorisation, if the product is subject to inspection upon customs clearance or after importation and the importer cannot demonstrate compliance with these permits (which are non-tariff regulations), a fine ranging between 70% and 100% of the commercial value of the products can be imposed, and title to the goods would pass to the Federal Treasury. If the importer has already disposed of the goods, an additional sanction equivalent to the commercial value of the goods can be imposed.

7.5 Trade Blocs and Free Trade Agreements

Mexico has entered into 14 free trade agreements with more than 50 different countries.

Mexico is an active party to the Pacific Alliance (along with Chile, Colombia and Peru). The Pacific Alliance and its framework agreement have specific provisions on regulatory co-operation and product-specific annexes, covering cosmetics, medical devices, dietary supplements and cleaning products. This has started a very promising regulatory harmonisation/convergence process in the region.

Mexico is also party to the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (the revised Trans-Pacific Partnership

Agreement), which contains promising provisions on the regulatory co-operation side, as well as product-specific annexes.

The United States–Mexico–Canada Agreement (USMCA) entered into force in July 2020 and contains several regulatory annexes for pharmaceuticals, medical devices, chemical substances, cosmetic products and food products.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

In Mexico, the private and public markets for medical products have separate rules depending on whether the products are patented. However, this mainly applies to pharmaceuticals and has changed during the new federal administration.

The very general legislative bases of the dual system are contained in two laws: the GHL (Article 31) and the Federal Economic Competition Law (Article 9). However, the rest of the rules are largely contained in separate regulatory instruments of lower hierarchy, including the Addendum to the Agreement for Drug Pricing Co-ordination signed in 2004 between the Ministry of Economy and the National Chamber of the Pharmaceutical Industry, and the technical standard for the labelling of drugs (NOM-072-SSA1-2012).

Private Market

Patented drugs for the private market are subject to a hybrid system that is largely self-regulated and voluntary. Under this system, companies compile their own information about their prices in other jurisdictions and submit that to

the authority, which monitors the accuracy of the data.

The manufacturer is required to stamp the price on the label of the product at the end of the manufacturing process. PROFECO verifies that the prices at the point of sale (ie, at pharmacies) do not exceed that price.

Generic drugs, off-patent products and medical devices in general are not part of this pricing regulation, being subject to direct price competition in the market. Newly launched products are initially exempted, as explained here.

Public Market

Until very recently, patented pharmaceuticals for the public market were subject to a different process of annual negotiation. For ten years, such negotiations were held with the Co-ordinating Commission for Negotiating the Price of Medicines and other Health Inputs (*Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud CCPNM*), which was created in 2008 and encompassed all major public institutions buying drugs in Mexico, as well as the Ministries of Public Administration, Finance, Economy and Health. However, the last federal administration, which took office on 1 December 2018, introduced two major changes.

First, it eliminated the CCPNM, transferring the whole pricing process to the public procurement system. That change eliminated the prior distinction between pricing and acquisition, which are now defined in the same process for patented medicines.

The estimated price for generic and off-patent products was initially defined by those public institutions co-ordinating the public procure-

ment exercise, based on their market research. However, the price would also be influenced by the discounts offered by the participating bidders and would ultimately be determined in the acquisition award and contract.

The administration then changed the rules again, by means of issuing a new version of the Secondary Regulations for the National Compendium, creating a national formulary from which public health institutions must – in principle – acquire the medical products they need. The new version incorporated new provisions under which a company must provide a maximum price as part of the process to add products; if the addition is approved, that maximum price will become the basis for any public acquisition mechanism.

8.2 Price Levels of Pharmaceuticals or Medical Devices

Newly launched pharmaceuticals for the private market are initially exempted from the maximum retail price (MRP) system – given that, in principle, they would not have a comparator. The manufacturer can set the initial price, subject to a re-evaluation three months after the product launch. The review is conducted to verify whether the product exists in the international market. If this is confirmed, an MRP will be estimated, and the price of newly launched products will be influenced by prices for the same product in other countries but not based on a health technology assessment. The price regulations for medicines do not apply to medical devices.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The Mexican system operates not through a model of reimbursement, but through a model of public procurement of drugs and medical devices.

There is a comprehensive legal regime for public procurement in Mexico, which is overseen by the Ministry of Antibribery and Good Government in co-ordination with the purchasing entity. On 22 December 2023 and 29 October 2024, a presidential decree was published that ordered BIRMEX to consolidate public procurement processes for the public health care sector, which encompasses the Mexican Institute of Social Security (*Instituto Mexicano del Seguro Social*; IMSS), the Institute for Social Security and Services for State Workers (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado* ISSSTE), IMSS-Bienestar, national health institutes and federal reference hospitals. Under this decree, the Vice Ministry of Health was tasked with preparing a diagnostic of necessities and plan the consolidated purchase of medical products. Thus, BIRMEX now conducts the public procurement process on behalf of the healthcare institutions, under the instructions of the Vice Minister of Health. The first consolidated public procurement process under this scheme began in December 2024 and was still on-going in February 2025, as challenges in its implementation arose.

In general, public procurement operates through three mechanisms:

- public bidding, with a national or international scope;
- invitation to at least three persons; and
- direct awards.

Although public bidding is the general rule, purchasing by invitation or direct award is allowed under certain circumstances, which are listed in the Federal Law for Procurement, Leases and Services of the Public Sector. One of the exemptions refers to cases where there are no substi-

tute products, there is only one possible supplier or the required product is patent-protected.

Accessing the public market for pharmaceuticals does not begin directly with public procurement. Other key regulatory steps must first be met, given that public procurement works through product codes included in the National Compendium for Medical Products. A product can only become part of a public procurement exercise once it has been allocated a code, which – in the case of medicines – is assigned per active ingredient. Note that on 8 November 2022, a national compendium of medical products replaced the basic formulary and several institutional formularies.

Regulations for the national compendium were issued on 22 November 2022, bringing several changes to the system – including one that has been a source of controversy and litigation, relating to the introduction of a new requirement. The new rules now state that an application to add a product must first obtain and submit a sponsoring letter from one of the public payors, representing an access barrier.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Previously, the methodology for determining price was quite clear and included cost-benefit analyses. However, it is no longer clear, and it is also not currently clear whether the new administration will be open to exploring value-based proposals.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

The regulatory framework links the rules of prescription and dispensing with those of substitution at the point of sale. There are two scenarios for the private and public markets.

- For the private market, the first rule is that prescribing according to the active ingredient or generic name is mandatory, and that the use of the distinctive name or trade mark of the product is optional for health professionals. The second and perhaps most important rule is that if the prescription contains only the generic name, pharmacists are allowed to substitute the product. Conversely, if the product is prescribed under its distinctive name, then substitution at the point of sale is forbidden.
- For the public market, although the basic rule structure is the same, there is no reference to the option of prescribing by trade mark – meaning that substitution is always allowed. At the same time, it has also been a long-held practice in the public sector to prescribe using the product code allocated in the national compendium, which is based on the active ingredient as well. There are provisions allowing prescriptions to be made under different conditions, but the respective institution would need to authorise such decisions, which is not common.

Trends and Developments

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Galicia Abogados, SC has an unmatched culture that fosters collaboration and excellence. Galicia has cultivated an environment where the sharpest minds come together to solve complex legal challenges. The firm's unique market offering sets it apart, blending precise and renowned transactional and regulatory expertise with the strategic acumen required for high-stakes liti-

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Equivalence Agreements and Importation Without Marketing Authorisation

Regulation of equivalence agreements in Mexico

In Mexico, the Ministry of Health (*Secretaría de Salud*) has the authority to issue general provisions recognising that the requirements, tests and evaluation procedures used by foreign health authorities can be equivalent to those required by Mexican law for the approval of health products. These foreign evaluations are considered sufficient if they ensure that the products meet the same standards of quality, safety and effectiveness that are mandated in Mexico. As a result, products that have been approved in countries with similar regulatory systems can be fast-tracked for approval in Mexico, avoiding the need for a full re-evaluation. This approach ensures that drugs and medical devices meet the necessary standards while facilitating a more efficient process for obtaining sanitary registration in Mexico (Article 161 bis of the Health Input Regulations (*Reglamento de Insumos para la Salud* RIS)).

One of the key mechanisms through which this process is facilitated is the equivalence agreements established by the Federal Commission for the Protection against Health Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios* COFEPRIS). According to public records, COFEPRIS still has equivalence agreements with the sanitary regulatory agencies of the following countries (as well as the European Medicines Agency; EMA): Germany, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, Cyprus, Colombia, Korea, Cuba, Denmark, Slovakia, Slovenia, Spain, Estonia, Finland, France, Greece, Netherlands, Hong Kong, Hungary, Ireland, Italy, Japan, Iceland, Latvia, Lithuania, Malta, Norway, Poland, Portugal, the United King-

dom, the Czech Republic, Romania, Singapore, Sweden, Switzerland and the USA.

By leveraging equivalence agreements, COFEPRIS enables drugs and medical devices that have already been evaluated and approved by these regulatory agencies to be marketed in Mexico without undergoing the entire approval process again, since it is considered that these agencies comply with the same quality, safety and effectiveness standards required in Mexico.

The use of equivalence agreements not only reduces the time it takes for products to reach the Mexican market but also reduces the administrative costs for COFEPRIS by avoiding the need to reprocess the technical and scientific information of the products.

Regarding the United States, it is important to note that even though – through an executive order from President Donald Trump – the United States withdrew from the World Health Organization (WHO) on 20 January 2025, this withdrawal has no impact on the equivalence agreements executed between COFEPRIS and the Food and Drug Administration (FDA), since such agreements are independent from any international affiliations between both countries. With respect to medical devices, the equivalence agreement between Mexico (COFEPRIS) and the FDA was published in the *Official Gazette of the Federation* (the “*Official Gazette*”) on 26 October 2010, while the equivalence agreement between Mexico (COFEPRIS) and the FDA for medicines was published in the *Official Gazette* on 11 November 2012.

Background to importation without marketing authorisations under equivalence agreements

The Mexican government has the authority to allow the importation of drugs and medi-

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cal devices into the country without the prior requirement for a marketing authorisation issued by COFEPRIS in the following circumstances (Article 132 of the RIS):

- when a contingency arises;
- when required by sanitary policy;
- for purposes of scientific research, registration or personal use; and
- for laboratory tests.

Equivalence agreement for drugs issued in 2020

Although the ability to import drugs and medical devices without marketing authorisation has been in place for several years, it was not until recently (during the administration of former President Andres Manuel Lopez Obrador) that Mexico's government started to use this mechanism to import drugs and medical devices expeditiously, arguing that allowing a greater number of drug suppliers into Mexico would help reduce prices. As a result, an equivalence agreement was issued in the *Official Gazette*, permitting the importation of drugs for any disease or condition as long as they were aimed at public health institutions and authorised by the following regulatory authorities (the "2020 Equivalence Agreement") the Swiss Agency for Therapeutic Products (Swissmedic), the European Commission, the US FDA, the Health Ministry of Canada, the Therapeutic Goods Administration of Australia and reference regulatory agencies of the Pan American Health Organization (PAHO)/WHO, prequalified by the WHO's pre-qualification programme for medicines and vaccines or regulatory agencies that are members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

This agreement allowed the importation of foreign drugs without a marketing authorisation

from COFEPRIS, as long as these products had the necessary authorisations for commercialisation in their country of origin and were aimed at public health institutions. These commercialisation authorisations had to come from one of the regulatory authorities listed in the 2020 Equivalence Agreement. However, although drugs could be imported without a marketing authorisation issued by COFEPRIS, they still had to obtain their corresponding marketing authorisation in order to access the market. This process included a resolution period of 60 business days, which is shorter than the timelines for "ordinary" applications not covered by the 2020 Equivalence Agreement.

At the time, one of the most common criticisms of the pharmaceutical industry was that the publication of the 2020 Equivalence Agreement sought to align Mexico's regulatory standards with those of certain agencies that have more lenient requirements. Critics argued that this could put the Mexican population at risk by allowing the importation of medicines that might not meet the safety, efficacy and quality standards set by Mexican law. However, under Article 222 of the General Health Law, marketing authorisations in Mexico are granted only to drugs that demonstrate that they meet safety, efficacy and quality standards. This includes adherence to good manufacturing practices for both the drug and its active ingredients, among other requirements.

Amendment to the 2020 Equivalence Agreement

On 22 June 2021, an amendment to the 2020 Equivalence Agreement was published in the *Official Gazette* allowing importation of foreign medical devices without a marketing authorisation from COFEPRIS, as long as these products had the necessary authorisations for commer-

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cialisation in their country of origin and were aimed at public health institutions. These commercialisation authorisations came from regulatory authorities – the US FDA, the Health Ministry of Canada and the Ministry of Health, Labor and Welfare of Japan – allowing the commercialisation of medical devices within their respective territories, as well as from the Japan Pharmaceuticals and Medical Devices Agency, the European Commission, the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, the Ministry of Food and Drug Safety of Korea, the Therapeutic Goods Administration of Australia and the National Health Surveillance Agency of Brazil.

Similar to drugs, once imported into Mexico, medical devices had to undergo the required application process to obtain marketing authorisation from COFEPRIS. This process included a resolution period of 60 business days, which is shorter than the timeframes for ordinary applications not covered by the 2020 Equivalence Agreement.

Termination of the 2020 Equivalence Agreement for importation

On 11 September 2024, an agreement was published in the *Official Gazette* revoking the 2020 Equivalence Agreement and its amendments, thereby terminating the provisions that allowed the importation of drugs and medical devices without a marketing authorisation issued by COFEPRIS (the “*Termination Agreement*”). However, it also established that any procedures initiated before the Termination Agreement could continue based on the applicable provisions. At the time, this meant that it was no longer possible for foreign products to participate in tenders without marketing authorisation.

The 2024 Equivalence Agreement for the importation of drugs and medical devices

The current equivalence agreement, published in the *Official Gazette* on 4 December 2024, allows the importation of certain drugs and medical devices without a marketing authorisation issued by COFEPRIS, provided they have commercialisation authorisation from recognised regulatory agencies (the “*2024 Equivalence Agreement*”).

The provisions of the 2024 Equivalence Agreement regarding drugs will apply only to the following types of drugs – ie, excluding those classified as psychotropics or narcotics, as well as vaccines:

- new molecules indicated in Article 2, Section XV of the RIS;
- generics;
- innovative biotechnology;
- biocomparable biotechnology; and
- biological products.

Additionally, to obtain import permits for drugs under the terms of this agreement, applicants may submit commercialisation permits and marketing authorisations issued by the regulatory authorities of the following countries: Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Netherlands, Norway, Portugal, Japan, Singapore, Spain, Sweden, Switzerland, the United States of America, Canada, Australia and the United Kingdom. In addition to the above, commercialisation permit and marketing authorisations issued by the EMA and obtained through a centralised process may be submitted.

To obtain import permits for medical devices under the terms of this agreement, applicants may submit commercialisation permits and marketing authorisations issued by the regula-

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tory authorities of the following countries: the United States of America, Canada, Japan, the United Kingdom, Brazil, Australia, the Republic of Korea, Singapore and Switzerland. In addition to the above, commercialisation permits and marketing authorisations issued by the European Commission may be submitted.

It is important to note that the above-mentioned commercialisation permits and marketing authorisations, issued by the regulatory authorities and used in the application of the 2024 Equivalence Agreement, must have undergone a thorough and independent review by the respective regulatory bodies. This review process must meet the comprehensive standards set by the issuing authority to ensure that the product complies with the safety, efficacy and quality requirements established in their jurisdiction.

Only authorisations granted through the standard approval process can be used for the import permit request under the terms of the 2024 Equivalence Agreement. Specifically, authorisations that stem from alternative approval pathways – such as expedited or accelerated approval, conditional approval, emergency authorisation, court-ordered approval or any other non-standard evaluation process – are not eligible for submission under the 2024 Equivalence Agreement.

Current application of the 2024 Equivalence Agreement for participating in consolidated public procurement

The main purpose of the 2024 Equivalence Agreement is to facilitate the importation of certain drugs and medical devices intended for the consolidated public procurement carried out by BIRMEX (*Laboratorio de Biológicos y Reactivos de México, SA de CV*), a state-owned company in charge of consolidating the entire purchase of several federal governmental entities, such as

the Ministry of the Navy (*Secretaría de Marina*), the Mexican Social Security Institute (*Instituto Mexicano del Seguro Social*), the Institute of Security and Social Services for State Workers (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*), the Health Services of the Mexican Social Security Institute for Welfare (*Servicios de Salud del Instituto Mexicano del Seguro Social para el Bienestar*), national health institutes (*institutos nacionales de salud*), federal reference hospitals (*hospitales federales de referencia*) and other health service institutions integrated into the consolidated contracting process, in accordance with the applicable provisions.

The consolidated contracting process is a form of centralised procurement that allows the Ministry of Health and BIRMEX to consolidate the purchasing of health inputs such as drugs, medical devices and other essential supplies across various government health institutions. This system ensures that multiple organisations can access high-quality products through a co-ordinated and streamlined process. It also ensures that all products, regardless of the supplier, meet the required regulatory standards and are authorised by recognised authorities.

How to participate in the procurement process through the 2024 Equivalence Agreement

For foreign bidders to participate in the procurement process for drugs or medical devices without a marketing authorisation issued by COFEPRIS, it is necessary to submit the following applications and comply with the requirements set forth below.

Drugs

Applications for import permits for drugs (“COFEPRIS-01-009-C sanitary permit for importation of

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raw materials, or for drugs that are not or do not contain narcotics or psychotropic drugs, which have marketing authorisation, Modality C”) must include:

- proof of payment of governmental fees;
- a valid sanitary licence for the manufacturing plant or laboratory of medicines or biological products intended for human use;
- “*sanitary responsible notice*”;
- a commercialisation permit and marketing authorisation, which is in force, issued by any of the regulatory Authorities established in the 2024 Equivalence Agreement (apostilled or legalised by the country of origin, as applicable);
- a public instrument proving the legal personality of the promoter, or a letter containing the procedure number and the legal representative’s name, signature and scope of powers;
- a letter in which the holder of the drug’s marketing authorisation abroad, along with their legal representative in Mexico, commits to complying with the provisions set forth in the agreement – the letter should also include the award number from the acquiring public institution; and
- the original label, prescribing information and instructions, attached as applicable, along with a simple translation into Spanish and the electronic address where they can be accessed.

Medical devices

Applications for import permits for medical devices (“COFEPRIS-01-014-A *Sanitary permit for importation of medical devices with marketing authorization that are not or do not contain narcotics or psychotropic drugs Modality A.- Importation of medical devices that have marketing authorization (such as: medical equipment,*

x-ray devices, heart valves, internal prostheses, pacemakers, prostheses, dental supplies, surgical materials, healing and hygienic products with marketing authorization”) must include:

- proof of payment of governmental fees;
- an operation notice with the relevant medical device classification;
- a commercialisation permit and marketing authorisation, which is in force, issued by any of the regulatory authorities established in the 2024 Equivalence Agreement (apostilled or legalised by the country of origin, as applicable);
- a public instrument proving the legal personality of the promoter, or a letter with the procedure number and the legal representative’s name, signature and scope of powers;
- a sworn letter in which the holder of the drug’s marketing authorisation abroad, along with their legal representative in Mexico, commits to complying with the provisions set forth in the agreement – the letter should also include the award number from the acquiring public institution; and
- the original label and instructions for use, or the manual, as appropriate, with a simple translation into Spanish and the electronic address where they are available.

It is important to note that, in accordance with the Federal Administrative Procedure Law, COFEPRIS is required to resolve the matter within a maximum of three months. If this time limit expires without a resolution, the outcome will be considered a rejection (*negativa ficta*). This principle is typically applied when the authority needs to conduct a thorough review before granting approval, ensuring that silence is not mistakenly interpreted as implicit approval.

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Conclusion

In conclusion, Mexico has implemented equivalence agreements to streamline the process of importing drugs and medical devices. These agreements recognise the regulatory standards of agencies whose requirements align with Mexico's safety, efficacy and quality standards, thus expediting market entry and reducing COFEPRIS's administrative burden.

The 2024 Equivalence Agreement issued by COFEPRIS represents the most recent development in the regulation of the importation of drugs and medical devices without marketing authorisation (although such products will need to obtain a marketing authorisation in order to be commercialised in Mexico). It encourages greater participation in consolidated public procurement, providing foreign suppliers with a clear pathway to engage in Mexico's healthcare system while ensuring that imported products comply with COFEPRIS's regulatory standards.

POLAND



Trends and Developments

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Kiełtyka Gładkowski KG Legal is a Polish law firm with offices in Warsaw and Krakow, and with an address in New York. The team comprises more than 30 lawyers. Kiełtyka Gładkowski KG Legal mainly handles cross-border cases. It has a dedicated corporate and private client desk and advises international and domestic clients on the basis of Polish law, and in litigation and non-contentious matters. The firm's particular focus is on cross-border and multi-jurisdictional matters, primarily within the technology; fintech and blockchain; cybersecurity; media and telecom; healthcare and life sciences; digital health;

financial institutions; DeFi; defence; real estate, construction and infrastructure; transport and logistics; manufacturing; retail and distribution sectors; as well as standard areas of expertise like corporate, commercial, antitrust and competition, bankruptcy, commercial litigation, energy and employment. The firm represents domestic and international clients regardless of the size, stage of development or scope of their business, including investors, start-ups, entrepreneurs, seed and angel venture funds, growing companies, small and mid-size companies and large global corporations.

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Since January 2025, Poland has assumed the presidency of the Council of the European Union, a fact of key importance for the healthcare system and the pharmaceutical market. Currently, a pharmaceutical package is being finalised, the European Health Data Space is being implemented and the health technology assessment (HTA) and so-called European biopharmaceutical strategy are being reformed. These activities will be of significant importance for Europe's competitiveness in the area of healthcare.

The healthcare market in Poland is investing in necessary innovations, which will require the supplementation of EU legislation and the creation of new legal and investment frameworks. An example of this is investment in artificial intelligence (AI) factories in line with Council Regulation (EU) 2021/1173 of 13 July 2021 on establishing the European High-Performance Computing Joint Undertaking, aimed at the creation of supercomputers implementing state-of-the-art generative AI models to drive progress in AI applications (apps) in various sectors, such as healthcare.

Healthcare Cybersecurity

To counter cyber-attacks, advanced cybersurveillance and espionage tools, such as rootkits, as well as investment in cybersecurity operations and databases belonging to healthcare entities are key. The Polish healthcare sector is highly valuable for foreign IT service providers, providing data protection solutions. Polish law generally focuses on establishing responsibility for the security of healthcare market entities, the internal procedures of such entities and the associated complex data processing. Polish regulations cover due diligence procedures, penalisation and the distribution of liability in case of advanced cyber-attacks on the critical infrastructure of public healthcare entities.

Salt Typhoon is a well-known threat actor, but above all, ransomware – malicious software that infects computer systems and then encrypts the data stored therein, making it inaccessible to the owners of the systems – must be countered.

In the healthcare sector, the Polish justice system currently uses legal tools that are aimed at protecting data and IT systems and counteracting cybercrime. Article 267 of the Penal Code is increasingly used for cybercrime, penalising unauthorised access to computer systems (eg, through password capture or overcoming system security to illegally obtain protected information). In Poland, there is also a ban on creating and distributing malicious software, as specified in Article 269b of the Penal Code. This includes computer viruses, spyware and tools that allow the bypassing of security and attacking of IT systems, which is the most common form of attack on medical data.

In the civil sphere in Poland, as in the rest of the EU, the basic legislation regulating civil liability for data breaches, including medical data, is the General Data Protection Regulation (GDPR), with the key articles being Article 82 (liability for data leakage) and Article 32 (required technical measures). This Regulation forces healthcare entities to implement information security management standards, such as the International Organization for Standardization (ISO) 27001 standard.

The most recent example of a cyber-attack in the healthcare sector in Poland is an incident involving one of the country's largest hospitals, which was targeted by a ransomware cyber-attack that disrupted the facility's computer systems. The attack involved the use of malicious software that encrypted files stored on the hospital's servers, posing a high risk of unauthorised access

and potential theft of patients' and employees' personal data.

Use of Artificial Intelligence in the Life Sciences Sector

Regarding AI use in life sciences, the most important legal acts are Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 on the establishment of harmonised rules on AI and the Act of 6 September 2001 – Pharmaceutical Law (*Journal of Laws of 2024*, item 686, as amended). In the context of the use of AI in the development of new medicines, the provisions on high-risk AI systems are important. High-risk systems are systems that meet the conditions specified in Article 6, paragraph 1 of the Regulation, as well as those listed in Annex III of the Regulation as systems posing a significant risk of damage to health, safety, fundamental rights (eg, privacy) or the environment. The Regulation separately specifies the obligations of suppliers of high-risk systems (primarily in Article 16 et seq) and the entities using such systems (Articles 26–27). Suppliers of high-risk systems will also have to undergo a procedure assessing their compliance with the requirements of the Regulation.

As alluded to above, AI systems used in the healthcare sector, including for the development and testing of new drugs, can be classified as high risk. In practical terms, by using an AI system to process registration documentation, companies will be able to speed up drug approval procedures during the necessary registration processes. In addition, AI algorithms will be able to help analyse large data sets, including pre-clinical and clinical documentation. AI can also facilitate the conduct of clinical trials, including through automatic analysis of clinical data and selecting patients for clinical trials and subsequently monitoring them. Moreover, AI systems

can promote pharmacovigilance: algorithms can analyse adverse event reports and identify potential risks to patients. However, it should be remembered that any implementation of AI must comply with the principles of good manufacturing practice (GMP) and good clinical practice (GCP), and with EU regulations.

Introducing modern technologies into the regulated pharmaceutical environment is associated with challenges related to ensuring quality and compliance with applicable regulations. In this context, Good Automated Manufacturing Practice (GAMP) 5 is one of the most important tools for managing the life cycle of computer systems in the pharmaceutical and biopharmaceutical industries, including systems based on AI.

GAMP 5 is a set of guidelines developed by the International Society for Pharmaceutical Engineering (ISPE) to assist pharmaceutical companies in ensuring compliance with regulations concerning the quality and security of computer systems. This document presents a comprehensive approach to managing the life cycle of computer systems, including the validation, design, implementation, operation and retirement of systems that are used in environments requiring high quality standards, such as the pharmaceutical industry.

Medical Device Conformity Assessment

Significant regulations and trends can be observed in medical device conformity assessments for regulatory purposes. In this context, guidelines for technical and legal classification and certification of medical products and diagnostic devices, performed before they are placed on the market by a notified body assessing conformity in accordance with Regulation 2017/745, as well as the ISO 13485 standard –

Quality Management System for Medical Devices, are important.

ISO 13485 specifies the requirements for a quality management system that can be used by organisations engaged in the design, development, production, installation and servicing of medical devices and the provision of related services.

The current EU regulations on medical devices, active implantable medical devices and in vitro diagnostic medical devices, which place greater emphasis on proving efficacy and safety, conducting clinical trials and detailed assessment before placing devices on the market, are important for medical device market participants. The key regulations are Medical Devices Regulation (EU) 2017/745 on medical devices and active implantable medical devices and In Vitro Diagnostic Medical Devices Regulation 2017/746.

The key changes introduced by these regulations include:

- the introduction of the European Database for Medical Devices (EUDAMED), which facilitates the tracking of medical devices;
- extension of market surveillance and product surveillance (Articles 84–93);
- clarification of the roles and responsibilities of economic operators (Articles 10–30);
- the introduction of unique device identification (UDI) codes and implant cards (Articles 18 and 27);
- new rules on clinical evaluation and clinical trials (Articles 55–61); and
- changes to safety and effectiveness requirements (Annex I).

Problems Encountered by Foreign Drug Manufacturers Conducting Clinical Trials in Poland

Foreign drug manufacturers are very active on the Polish market, testing the effectiveness of their newest drugs for serious and complicated diseases. According to Eurostat, drug creation accounts for up to three-quarters of the drug cycle, and only one in several thousand chemical compounds meets the regulatory and economic conditions for commercialisation and entry into the market as a finished drug product. Clinical trials represent the final phase of drug creation and are critical for validating the many years of effort expended by a drug manufacturer, which usually begins with the formula being covered by patent protection. Poland, as a member of the EU, is subject to the highly restrictive Regulation 536/2024, which regulates the entire process of clinical trials, including the actors therein, supervision and even IT infrastructure. In the Polish legal system, Regulation 536/2024 is supplemented primarily by the Pharmaceutical Law, encompassing several thousand implementing acts and the Act of 9 March 2023 on clinical trials of medicinal products for human use. Despite the extensive experience of regulatory bodies and the large number of regulations, there is unfortunately no regulation for the release of a drug after a clinical trial if a foreign pharmaceutical company decides not to enter into the sales process (ie, does not commercialise the drug). In Europe, this is referred to as “*compassionate use*”, which is not regulated in Poland.

It is important to anticipate the possibility of not entering the market with a given drug after the completion of a clinical trial given that, in Poland, foreign sponsors have occasionally made reference to very detailed changes in Polish pharmaceutical law in their clinical trial plans – associated with the introduction of the compassionate

use procedure – which unfortunately did not come to fruition.

Investments in the Life Sciences Sector in Poland and Financing Models

Changes have occurred in the way biotechnology companies and investment funds operate. In recent years, many biotechnology companies have used technologies based on genetic information to create so-called biomolecular platforms. These platforms intervene at different points in the biomolecular information chain to modify the processes that cause diseases. The software-based nature of this approach to drug development allows for the design of many new therapies on a single platform that contains instructions for modifying the molecular hardware associated with the diseases. A biomolecular platform, in contrast to the traditional approach of focusing on a single technology, allows for the development of multiple therapies simultaneously. Companies with a biomolecular platform start working on a therapeutic solution by building a platform and designing experiments to demonstrate its usefulness as a source of therapeutics (eg, vaccines). They then identify diseases, therapeutic areas or groups of biologically related diseases that can be treated with these therapeutic tools, and finally prioritise drug discovery and development for selected diseases. Digital/IT solutions are an integral part of the biomolecular platform-based model at every stage of the project, from drug discovery and the preclinical phase to clinical trials and manufacturing.

Another important trend is the application of the portfolio model to the financing and management of biotechnology R&D. The portfolio model is an innovative business model in which a portfolio manager controls a set of companies or projects spanning multiple technologies and

therapeutic areas. Rather than focusing on a single technology, the portfolio manager draws on experience in fundraising, investing, venture creation, R&D, manufacturing, commercialisation, management systems and credibility building – as well as relationships with key stakeholders – to assemble a portfolio of investments, each of which is assigned to a unique drug programme. In the portfolio model, investors allocate capital to a central management team that offers a competitive advantage through its expertise in managing a variety of different companies and organisations. The new model allows the portfolio manager to raise capital from a broader group of investors. There is evidence that the portfolio model is an effective mechanism for managing R&D in the life sciences sector in Poland.

Access to Medicinal Products for Patients: Architecture of the Pharmaceutical Law in 2025

Poland, as one of the 27 members of the EU, has a very large number of regulations pertaining to the quality, efficacy and safety of drugs and drug marketing authorisation. In the following, trends in this area set to continue in 2025 are detailed.

Greater information requirements

The Pharmaceutical Law focuses on regulating the release of medicinal products prescribed by a doctor to a patient. Currently, the regulations take into account the progress of a prescription through the IT system and documentation of the patient's need for a drug. A recent example is a regulation that specifies that more information is required for the release of a drug to a patient, based on communication between the doctor and a pharmacist. This is associated with the new principle whereby it is not necessary to fulfil the entire prescription in one pharmacy (amendment to the Act of 27 August 2004 on healthcare services financed from public funds; *Journal of*

Laws of 2024, item 146, as amended). Another example is the requirement for more information about the drug use amount associated with long-term (eg, annual) prescriptions, effective from August 2024. These examples reflect a clear trend towards greater control over the amount of a drug that a patient takes, partly attributable to problems with target and parallel imports in Poland.

Tetrahydrocannabinol

There is a trend towards greater patient access to consciousness-altering substances. Attitudes regarding whether psychoactive substances should be restricted vary within the EU. As an example, tetrahydrocannabinol (THC) is available in Poland on prescription as medical cannabis, in line with a national procedure for introducing pharmaceutical raw materials to the market, compliance with GMP documentation requirements and an amendment to the Pharmaceutical Law excepting medical cannabis from anti-drug laws (primarily Article 33a of the Act of 29 July 2005 on Counteracting Drug Addiction). The Pharmaceutical Law is currently aimed at limiting access to medical cannabis to physical pharmacies and tightening the requirements for issuing prescriptions thereof. This is because the Polish government views the popularity of online platforms combining medical advice with prescription services as an undesirable attempt to circumvent the law on medical cannabis, such that THC can be used for purposes other than pain management. As the problem of abuse of narcotic and psychotropic drugs is growing, the Polish Ministry of Health has decided to introduce further restrictions to significantly reduce the over-prescription of drugs subject to special controls. The latest Regulation of 30 October 2024 specifies substances for which prescriptions can no longer be obtained in Poland as part of an online service – ie, via so-called prescrip-

tion machines/platforms and private teleconsultations. In accordance with this Regulation, from 7 November 2024, a doctor is obliged to consult with their patient in person before writing a prescription for fentanyl, morphine, oxycodone, non-fibrous hemp (including dried herbs and medical cannabis extracts) or pharmaceutical tinctures. The Regulation provides for one exception, where these drugs can be prescribed via a teleconsultation only as a continuation of treatment by a primary care physician (excluding night and holiday care).

Over-the-counter drugs

The sale of over-the-counter (OTC) drugs in places other than pharmacies (eg, large grocery stores, multi-sector stores, railway stations, petrol stations) is supervised by the Polish authorities, requiring restrictions and constant supervision. According to publicly available data, OTC sales are worth PLN9 billion gross for pharmacies, versus PLN0.5 billion outside of pharmacies (ratio of 1:18). The Pharmaceutical Inspector makes the decisions regarding the OTC (without prescription) sale of specific drugs outside of pharmacies. This can be very complicated for manufacturers, with the procedure being administrative in nature and depending on arguments that do not necessarily have a legal basis, instead being related to distribution and GMP.

Another problem related to the distribution of OTC drugs outside of pharmacies concerns the classification of suspensions not as drugs, but rather as dietary supplements or medical devices. Distributors and manufacturers are looking for easy and legal sales models, and the classification of a product as a drug, supplement or medical device gives rise to frequent disputes between manufacturers and pharmaceutical market supervisory authorities.

New Regulations for Health Apps (Digital Therapeutics)

The Polish Ministry of Health is currently promoting free apps for monitoring the health of patients. Apps will be eligible to receive the “*Ministry of Health-Certified Application*” accreditation for a period of 24 months. According to the new regulations, the aim of the certification programme is to recognise health apps that can not only provide information about health but also safely store data, where their software will be classified as “*medical device*”. A health app is an app that is used to monitor health. Some apps may be recognised as medical devices if they meet the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. The certification is designed to show that the app is a safe and reliable tool that can be used by patients and medical personnel. For developers, the certification may be useful for promoting apps by providing proof of their effectiveness. Currently, two apps in the health app portfolio have been certified: the first was created by doctors to assess symptoms and their causes, and the second was designed for people struggling with allergies.

Through the certification programme, apps are verified in terms of their content, functionality, ease of use, innovation and information security. The programme is scheduled to finish in November 2026 and, according to the Ministry's announcements, may be the first step towards medical apps in Poland being issued to patients on prescription.

Current Problems in Creating and Distributing Life Sciences Products: Selected Examples

Concerning the creation and distribution of medicines (including OTC medicines), medical devices for treatment and in vitro diagnosis, dietary supplements, novel foods and “*border-*

line” products, challenges are arising in relation to the rapid changes in regulations and the need to adapt production to a relatively short vacatio legis.

For example, the regulations that help ensure products are fit for use over the long term are changing in relation to specific chemical compounds and food preservatives. The large distribution chains of functional foods, such as energy bars, are not keeping up with the bans on the use of preservatives and certain colorants. Current trends point to poor labelling practices and the use of substances included in the Rapid Alert System for Food and Feed (RASFF) database.

Under Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, the RASFF was established as a notification system for foods that pose a direct or indirect danger to human health. Based on product testing and notifications via the RASFF, non-compliant products posing a risk to humans are withdrawn from the market. The RASFF is thus an important source of information on product safety, identifying substances in imported products that, if consumed by humans, may have serious negative health effects. In Poland, in accordance with Article 85 of the Act of 25 August 2006 on food and nutrition safety, the Chief Sanitary Inspectorate manages the RASFF.

It should be remembered that the producer (or other entity, such as the importer) that introduces a product to the market is responsible for food safety in Poland. It is their responsibility to ensure procedures and safeguards that minimise the risk of contamination are in place.

When a food that may pose a health risk is in circulation and/or in the possession of consumers, the Chief Sanitary Inspectorate informs the pub-

lic by publishing warnings on the office website, including the name and type of food; the name of the manufacturer, batch number and expiry date; the nature of the risk and the preventive measures taken; and recommendations for the consumer.

Technology Transfer in the Life Sciences Sector

A noticeable trend in the Polish life sciences sector associated with regulatory changes is cross-border technology transfer. The process of creating, for example, a medical device requiring algorithms and hardware components is a complex, multi-year procedure often supported by EU funds and sometimes based on co-operation with scientists. Regulatory changes may preclude the legal sale of such products, not only because of intellectual property protections but also because of the tightening of data processing rules, sensitive data protections and concerns around patient welfare.

Therefore, new opportunities for the sale or transfer of technology to entities outside the health sector are being sought in order to give technologies new life as double use technologies. Technology transfer involves various legal vehicles, and the transfer model must take into account all issues associated with a given technology, including industrial property rights, R&D results, patent protection, potential future value, settlements with entities involved in the technology's creation and the protection of algorithms that, in some cases, may qualify as medical devices.

The life sciences sector accounts for a very large share of the cross-border economic turnover in Poland. In 2023, the value of the healthcare market, excluding medicines, amounted to PLN191 billion, with an average annual growth of 8.3% forecast in the period 2023–28. In the context of an aging society, the growing prevalence of chronic diseases and the increased wealth of citizens, the healthcare sector in Poland offers numerous investment opportunities.

PORTUGAL



Law and Practice

Contributed by:

Eduardo Nogueira Pinto, Hugo Monteiro de Queirós,
Eliana Bernardo and Ricardo Rocha

PLMJ

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PLMJ is a law firm based in Portugal that combines full service with bespoke legal craftsmanship. For more than 50 years, the firm has supported clients in all areas of the law, often with multidisciplinary teams and always acting as a business partner in the most strategic decision-making processes. **PLMJ** has specialist lawyers who know the sectors and markets in which they work well and keep close contact with the regulators for each sector. The firm created **PLMJ Colab**, a collaborative network

of law firms spread across Portugal and other countries with which it has cultural and strategic ties. **PLMJ Colab** makes the best use of resources and provides a bespoke response to clients' international challenges. International co-operation is ensured through firms specialising in the legal systems and local cultures of Angola, Cabo Verde, China/Macau, Guinea-Bissau, Mozambique, São Tomé and Príncipe, and Timor-Leste.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The rules on medicines for human use come from Decree-Law 176/2006 of 30 August 2006, while the rules on medical devices come from Decree-Law 189/2000 of 12 August, Decree-Law 145/2009 of 17 June, Decree-Law 29/2024 of 5 April, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (the Medical Devices Regulation – MDR) and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (In Vitro Medical Devices Regulation – IVMDR). There are also several sets of regulations that implement decree laws in different matters.

The regulatory body that applies and enforces pharmaceutical and medical device regulation is INFARMED (the National Authority of Medicines and Health Products, IP), which is part of the State's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

As a rule, the Minister of Health takes decisions regarding expenditure on medicines and medical devices, who may delegate these decisions to INFARMED.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

INFARMED's decisions regarding medicines and medical devices may be challenged through administrative and/or judicial channels within a given period.

Individuals and entities affected by these decisions can react against them, mainly on the grounds of breach of the law. These means of reaction are common to decisions that affect other products (eg, food supplements and cosmetics), although there may be specific details.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Certain categories of medicines and medical devices are subject to specific regulations. As an example, medicines containing psychotropic and narcotic substances are regulated by Decree-Law 15/93 of 22 January 2022, Decree-Regulation 61/94 of 12 October 1994, Law 33/2018 of 18 July 2018 and Decree-Law 8/2019 of 15 January.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Different pieces of legislation regulate clinical trials of medicines and clinical studies of medical devices.

Medicines

Regulation regulates clinical trials of medicines (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 (*"Clinical Trials Regulation"*) and Law 21/2014 of 16 April 2014 (*"Clinical Trials Law"*).

The entry into force of the Clinical Trials Regulation on 31 January 2022 involved the entry into force of the Clinical Trials Information System (CTIS), through which all clinical trial submission, assessment and supervision processes in the EU are to be submitted. The three-year transition period provided by the Clinical Trials Regulation has elapsed on 31 January 2025, after which all

ongoing trials will have to be transferred to the CTIS under the Clinical Trials Regulation.

Medical Devices

The rules regarding clinical studies of medical devices are found in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and in DL 29/2024, implementing MDR in Portugal.

In Vitro Medical Devices

The legal rules applicable to clinical studies of in vitro medical devices are established in Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) and in the Clinical Trials Law.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicines

Since 31 January 2025, authorisation to conduct a clinical trial of medicine needs to be obtained through the CTIS, pursuant to the Clinical Trials Regulation.

Applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS, under the terms provided by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials of medicinal products for human use. In this case, applications must be submitted through the CTIS, and the sponsor should propose a reporting member state that will be responsible for the analysis of the application.

Medical Devices

Applications to conduct clinical investigations as defined in the MDR must be submitted by the sponsor to the member state(s) where the clinical investigation will be conducted. The applica-

tion must be submitted through the electronic system referred to in the MDR, accompanied by the documents referred to in Chapter II of Annex XV of the MDR.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical trials of medicines and clinical studies of medical devices are available on the National Clinical Trials Register website at www.rnec.pt. The results of clinical trials and clinical studies of medical devices are not available in publicly accessible databases.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The recruitment methods for clinical trials of medicines and clinical studies of medical devices must follow the legally prescribed rules. In addition to physical advertising methods, digital means can be used for this purpose. These means may also be used for monitoring purposes, provided that they do not jeopardise the purpose and safety of the trial.

2.5 Use of Data Resulting From Clinical Trials

Data from clinical trials of medicines and clinical studies of medical devices may qualify as personal data in the sense of sensitive data. However, if the data is fully anonymised (and not merely pseudonymised), it is no longer personal data, and subsequently, it does not fall within the category of sensitive data. Anonymisation implies that the data subject's identity is unobtainable, which makes the data anonymous.

If the data resulting from processing is still classified as personal data, it may be shared with third parties or affiliates. However, this transfer must adhere to the requirements of the General Data Protection Regulation (GDPR). This

includes obtaining consent, fulfilling information obligations, ensuring the security of the processing, establishing joint controllership or sub-processing agreements, and complying with regulations regarding international data transfers. If the resulting data is anonymised, then those GDPR requirements do not apply.

2.6 Databases Containing Personal or Sensitive Data

The GDPR requirements regarding the processing of health data apply to the grounds for the lawfulness of processing, transparency, and security measures.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified through the definition of medicine (function and/or presentation) and the definition of medical device provided in the applicable legal provisions. In the case of borderline products, the purpose intended by the manufacturer of the product in question and the mechanism through which the main desired effect is achieved is considered.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Medicines developed by means of one of the following biotechnological processes must be subjected to the centralised community procedure:

- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and

- hybridoma and monoclonal antibody methods.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices Medicines

In the case of medicines, the MA is valid for five years; after the first renewal, it is valid indefinitely or, if considered necessary, for a second five-year period. The renewal of the MA is subject to a specific renewal procedure.

An MA may be revoked, suspended or amended whenever there is non-compliance with the applicable legal and regulatory provisions or with the conditions of the MA in question. This includes when it is concluded that the risk-benefit balance is unfavourable, the medicine is harmful or the manufacturing process does not comply with the applicable good practices.

Medical Devices

No authorisation is required to place medical devices on the market. The manufacturer must submit the medical device to a conformity assessment and notify the competent authority that the medical device has been made available on the market. INFARMED may withdraw a product from the market or may suspend, restrict or subject to certain conditions the placing on the market and putting into service of a device or group of medical devices under certain conditions – namely when the use of medical devices could compromise the health and safety of patients or other persons, or for public health reasons.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

The marketing of a medicine may follow one of these procedures:

- a national procedure, if the medicine is intended to be approved only for placing on the Portuguese market;
- a mutual recognition procedure, in which an authorisation obtained in a member state is used to apply for authorisation in a new member state;
- a decentralised procedure, when the application is submitted in several member states simultaneously and when the medicine does not have an MA in any member state; and
- a centralised procedure, managed by the European Medicines Agency (EMA), leading to an MA that is valid in all member states.

Any change in the terms of an MA must be subject to an application for a variation of the MA, including changes to the summary of product characteristics and any conditions, obligations or restrictions affecting the MA or changes to the labelling or package leaflet in connection with changes to the summary of product characteristics.

An MA may be transferred to a new holder by submitting a transfer application by the MA holder.

The placement of a medical device on the market does not require authorisation (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicines without an MA or without an MA that is valid in Portugal may be made available to patients through the exceptional use authorisation, under which patients can access them through early access programmes, which have a specific regulation issued by INFARMED.

Regarding medical devices, INFARMED may authorise the placing on the market or putting into service of a medical device for which no conformity assessment procedures have been carried out but the use of which is in the interest of public health or patient safety or health.

Compassionate use also takes place in the context of clinical trials.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

The MA for a medicine may be granted subject to the subsequent conduct of additional studies or compliance with special rules regarding safety and the reporting of all incidents associated with the use of the medicine and the measures to be taken, the conduct of a post-authorisation safety or efficacy study, or the fulfilment of other obligations established by INFARMED.

After the granting of an MA, INFARMED may require its holder to conduct a post-authorisation safety study if there are doubts about the risks of the authorised medicine or if knowledge about the disease or clinical methodology indicates that previous efficacy evaluations may need to be significantly revised.

The holder of an MA is obliged to comply with the obligations provided for by law – namely,

to comply with pharmacovigilance obligations and to make this or other data proving that the benefit-risk relationship of the medicine remains favourable available to INFARMED.

Manufacturers of medical devices other than investigational devices must report any field safety corrective action to INFARMED, as well as any serious incident or any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected to have undesirable side effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices
INFARMED publishes information on the status of an MA application and its assessment report on its website. It suppresses any commercially confidential information and allows access to the summary of product characteristics, the package leaflet, and information on the medical devices placed on the market.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Fast-track procedures for the registration of medicines and medical devices may be created and applied in very specific circumstances, such as those caused by the COVID-19 pandemic. However, the Portuguese regulatory framework does not generally provide for a specific fast-track mechanism for the registration of medicines and medical devices.

In the case of medicines, the applicant may submit a reasoned request for the accelerated assessment procedure, which reduces the assessment period of the application, based on a major public health interest, in particular from the perspective of therapeutic innovation, as provided for in Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004.

4.2 Regulatory Reliance

INFARMED has not issued authorisations based on specific Portuguese regulatory reliance rules. Nevertheless, as an EU member, Portugal is covered by the mutual recognition agreements between EU and third-country authorities concerning the conformity assessment of regulated products. Such agreements contain a sectoral annex on the mutual recognition of good manufacturing practice inspections and batch certification of human and veterinary medicines.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicines, experimental medicines and medical devices requires authorisation from INFARMED.

The manufacture of medicines requires the existence of facilities licensed for the purpose and compliance with good manufacturing practices. The facilities are subject to periodic inspections by INFARMED, which certifies their compliance and issues a certificate of good manufacturing practices, valid for three years.

For medical devices, facilities must obtain an industrial activity licence in accordance with the applicable legislation and have an industrial activity code associated with the categories of medical devices produced in conjunction with the respective manufacturing activities performed.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

INFARMED issues authorisation for the wholesale of medicines. It covers supplying, holding, storing, or delivering medicines for processing, resale, or use in medical services, healthcare facilities, and pharmacies, excluding the supply to the public. It specifies the facilities from which distribution is carried out and is subject to the validity of the certificate of good distribution practices, which must be renewed every five years.

The wholesale of medical devices is subject to prior notification to INFARMED. It covers supplying, holding, storing or supplying medical devices for resale or use in medical services, healthcare facilities, pharmacies and other points of sale to the public, excluding supply to the public.

6.2 Different Classifications Applicable to Pharmaceuticals

For dispensing to the public, medicines are classified into prescription-only medicines (MSRMs) and non-prescription medicines (MNSRMs). The former can also be classified as renewable, special or for restricted use in specialised monitored conditions, and the latter as MNSRMs for dispensing only in pharmacies.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of medicines is regulated by Decree-Law 176/2006 of 30 August 2006 and by related legislation on good practice in transportation and distribution. The MDR and Decree-Law 29/2024 apply to medical devices.

INFARMED is the entity responsible for monitoring compliance with these regulations.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Any natural or legal person can be an importer of medicines and medical devices if they are duly authorised and licensed for that purpose by INFARMED.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

The import and export of medicines and medical devices require the economic operator to be licensed by INFARMED for that purpose. For personal use, medicines can be transported only for the necessary period, provided that they are accompanied by a medical prescription, when necessary. In the case of emergencies or donations, INFARMED will assess each case individually.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The following regulations are to be considered upon the importation of any products into the Portuguese territory, which is part of the customs territory of the European Union:

- Regulation (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013, which approves the Union Customs Code;
- Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015; and
- Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015.

7.5 Trade Blocs and Free Trade Agreements

Portugal is part of the EU and a single European market. It applies the principle of free movement of goods and services and has harmonised regulatory rules for medicines and medical devices.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Price Control for Medicines

Non-reimbursed medicines have free pricing arrangements, but all other medicines are regulated and subject to maximum price rules or notified price rules. They cannot be sold unless the MA holder obtains a retail price (RP).

The RP of the medicine is composed of:

- the ex-factory price (EFP), which is the maximum price at the stage of production or import and has fixed rules for its determination;
- the wholesalers' and retailers' selling margins, as fixed by ministerial order;
- the tax on the sale of medicines; and
- value-added tax (VAT).

MSRMs intended to be dispensed and used in National Health Service (NHS) establishments

are also subject to maximum price rules. Their final price is composed of the EFP, the sales tax, and the VAT.

The prices of medicines subject to the maximum price rules are reviewed annually. The pricing rules for medicines are set out in Decree-Law 97/2015 of 1 June 2015 and regulated by several Ministerial Orders (in particular, Ministerial Order 195-C/2015 of 30 June 2015 and Ministerial Order 154/2016 of 27 May 2016).

Requests for price authorisation and price revision communications follow their own procedures and are submitted to INFARMED by the MA holder.

Price Control for Medical Devices

As a rule, medical devices financed by the State have fixed maximum prices. Medical devices not financed by the State have free pricing.

The pricing rules for medical devices are set out in Decree-Law 97/2015 of 1 June 2015, and there are Ministerial Orders that define the maximum prices applicable to certain devices or groups of medical devices, which usually include the marketing margins and VAT. In these cases, the RP proposed is indicated by the manufacturer at the time of the request for reimbursement to INFARMED, which follows its own procedure.

8.2 Price Levels of Pharmaceuticals or Medical Devices Medicines

The price of medicines is generally set and reviewed based on the prices in the reference countries with comparable GDP per capita or lowest price level, which are defined annually among EU countries.

Ministerial Order 293/2024/1 of 15 November has defined Spain, France, Italy and Belgium as reference countries in 2025.

Medical Devices

Medical device prices do not depend on the prices applied in other countries.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Public financing of medicines and medical devices depends on an application to INFARMED by the MA holder or the manufacturer, respectively. This public financing may be full or partial and differs according to various factors, such as pathologies or special groups of patients, therapeutic indications, the prevalence of certain diseases in the population, etc (see **8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**).

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices Medicines

As a rule, State funding of medicines is cumulatively subject to prior technical-scientific demonstration of therapeutic innovation or equivalence for the therapeutic indications claimed, as well as demonstration of the economic advantage of the medicine. These factors are not decisive in fixing the price of medicines, given that these prices tend to be fixed, taking into account the prices in the reference countries – see **8.1 Price Control for Pharmaceuticals and Medical Devices** and **8.2 Price Levels of Pharmaceuticals or Medical Devices**.

Medical Devices

A cost-benefit analysis is also carried out in the financing of medical devices by the State, considering the therapeutic innovation demonstrated for the clinical purposes claimed and the demonstration of an economic advantage – see **8.1 Price Control for Pharmaceuticals and Medical Devices**.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

In order to ensure the sustainability of the NHS, the prescribing of reimbursed medicines is made using the international non-proprietary name and may only include the commercial name of the medicines in the exceptional cases listed in the law. Pharmacies must inform the patient about the medicine that, in compliance with the prescription, has the lowest price. These rules apply to reimbursed medical devices with the necessary adaptations.

Trends and Developments

Contributed by:

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Eversheds Sutherland

Eversheds Sutherland is an innovative, international, multidisciplinary firm with more than 30 years of experience. The firm has approximately 80 professionals and 22 partners, with three offices in Portugal (Lisbon, Oporto and Faro) that collaborate closely with EVC Advogados/Eversheds Sutherland in Angola and AG Advogados/Eversheds Sutherland in Mozambique. The life sciences team provides comprehensive legal support beyond technical aspects, working closely with clients' regulatory departments. Eversheds Sutherland advises on agreements with public entities and patient associations,

compliance with industry and ethical codes, SOPs, clinical trials (including GDPR and insurance matters), sponsorships, transparency disclosures and pharmacovigilance. The firm's expertise extends to OTC launches, food supplements, medical devices, product labelling, advertising claims, prize promotions and compliance with MedTech and EFPIA ethical codes. With deep industry knowledge, Eversheds Sutherland provides strategic, tailored guidance for its clients in all life sciences regulatory and commercial matters.

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Upcoming Challenges for Life Sciences in an Ever-Changing World

The world is constantly changing, and the law is no exception. In a society where innovation and technology are the watchwords, there is an increasing need for the law to keep up with developments, particularly in the area of health.

The challenges are manifold: technological advances occurring at breakneck speed, regulatory changes and the increase in cyberthreats are just some of the issues in the healthcare and pharmaceutical sectors. It is crucial to address these fundamental issues in order to strike a balance between patient access to innovative health technologies and safe and ethical promotion of sustainable of health systems.

The future of medicine and artificial intelligence

It is impossible to talk about challenges and not mention artificial intelligence (AI). We are witnessing a revolution in various industry sectors owing to AI, with life sciences being one of the most exciting in this respect.

AI could play a role in drug discoveries, improvements in disease diagnosis, clinical research, support for patient care during treatment and even increased productivity when carrying out administrative tasks. However, although AI is here to stay, concerns remain. The increased use of AI raises both ethical and legal questions, which explains why the European Union has attempted to regulate this new technology, albeit with some difficulties.

Currently, AI is notoriously flawed. We know that it is biased, can have hallucinations, makes classification or prediction errors, provides allegedly reliable results based on non-existent sources and is characterised by a lack of transparency

regarding its design, development, evaluation and use. Questions also arise about how to determine responsibility when AI makes mistakes. Is the system itself to blame, or is it the person who developed the software, the health professional accompanying the patient or even the healthcare institution?

The European Union has endeavoured to address these issues, notably through the AI Act (Regulation (EU) 2024/1689), which applies risk-based regulatory frameworks to AI applications – ie, it provides for a uniform legal regime for developing AI and placing it on the market, and for putting AI systems into service and use in Europe, using a classification based on the risks posed to citizens' health, safety and/or fundamental rights.

The law classifies AI systems used in critical infrastructure that could jeopardise the lives and health of citizens as high risk; therefore, such systems are subject to a set of strict requirements that must be met before they can be used.

In this context, *Serviços Partilhados do Ministério da Saúde*, EPE (SPMS) published a white paper entitled *Inteligência Artificial na Saúde em Portugal: Regulamentação, Impactos e Perspetivas de Futuro* (Artificial Intelligence in Health in Portugal: Regulations, Impacts and Future Prospects) in February 2025, providing a glimpse of the state of the art in Portugal in the use of AI technologies, as well as some recommendations and good practices identified as important for the application of AI solutions in the healthcare area.

Furthermore, as a rule, the use of AI in the health sector involves the processing of a special category of data: “sensitive” health data. Therefore, now more than ever, compliance with the rules of

the General Data Protection Regulation (GDPR) is essential, particularly with regard to the rules on data minimisation, obtaining unequivocal consent from the data subject for the processing of data as required, automated profiling – which, because sensitive data is involved, requires that appropriate measures be applied to safeguard the rights and freedoms and legitimate interests of the data subject – and the international transfer of data. Accordingly, it is necessary to ensure that those who develop AI solutions, as well as the health institutions themselves, implement systems to guarantee compliance with the legislation, not least because in Portugal the national supervisory authority, the National Data Protection Commission (*Comissão Nacional de Protecção de Dados CNPD*), is increasingly vigilant; fines of up to EUR20 million or 4% of worldwide annual turnover, whichever is higher, can be imposed for violating the GDPR.

Alongside the aforementioned AI Act, the Council of the European Union adopted the Regulation on the European Health Data Space (the “*EHDS Regulation*”), which aims to improve people’s access to and control over their personal electronic health data, facilitating the international exchange of health data between health service providers located in various member states. The EHDS Regulation distinguishes two health data infrastructures: primary use of data (clinical context) and secondary use of data (for research, decision-making, etc).

With the application of the EHDS Regulation, it is expected that people will have easier access to their electronic health data, regardless of where they are located (ie, in their country of origin or in any other member state). Therefore, each country in the European Union will have to designate at least one e-health authority, which

will be responsible for implementing these new provisions.

The interoperability of data is also fundamental to the quality of AI, since the higher the quality of the data used to train AI systems, the more likely it is that the algorithms will provide accurate and reliable results. A structured, organised and accurate database will give AI systems greater capacity for analysis, reducing the risk of biased decisions and gross errors in healthcare.

In Portugal, Order No 3030/2025 of 7 March designated the SPMS as the entity responsible for co-ordinating the preparatory work for the implementation of the EHDS Regulation. As such, the SPMS will co-ordinate an interdisciplinary working group to monitor and follow up the implementation and development of electronic health record systems, in line with European guidelines.

Electronic health record systems are essential if the EHDS Regulation is to be implemented effectively in Portugal, bearing in mind that citizens’ health information not only includes that which is collected and used within the scope of the National Health Service (NHS), but also that collected in other sectors. As such electronic health records must be operationalised for health operators in all sectors that keep electronic clinical records.

Although the EHDS Regulation is ambitious and has the positive aim of promoting a true single market for electronic health record systems, it does present some obstacles that the companies to which it applies must be aware of. As well as intellectual property, sensitive commercial information is at stake, so it is of great importance for the organisations concerned to adapt accordingly.

More recently, after a period in which various European laws were published, and in contrast to other major world powers such as the United States of America, the European Union apparently realised that there was a need to slow down its regulatory activities.

Notwithstanding its virtues and legitimate objectives, it is clear that the proliferation of European legislation has disincentivised innovation in some sectors, as well as investment and the deployment of venture capital, due to the number of requirements and demands imposed on companies and technology creators. For many observers, Europe now seems to be trying to find a middle ground, promoting the updating of legislation while not jeopardising change and innovation.

Cybersecurity

Attacks on hospital computer systems, data breaches and medical device hacking are all threats that healthcare organisations must be increasingly careful about and prepared for. The concern should not be if they will be attacked, but rather when they will be attacked, since it is impossible to completely eliminate the risk of all possible types of attacks in the face of asset vulnerabilities, no matter how robust the information security system.

With this in mind, the regulatory power of the European Union will again play a key role, highlighting the importance of Directive (EU) 2022/2555 – commonly referred to as Network and Information Security Directive 2 (NIS2) or Security of Network and Information Systems 2 (SRI2), to use the nomenclature of the National Cybersecurity Centre – which introduces more stringent cybersecurity requirements for the life sciences sector.

NIS2 has changed the cybersecurity paradigm, widening the scope of application of Directive (EU) 2016/1148 – also called the Network and Information Security (NIS) Directive (now NIS1 or SRI1) – to healthcare providers, manufacturers of medical devices and entities that carry out research and development activities for medicines as “*essential entities*” or “*important entities*”. Organisations identified as such must ensure that improved cybersecurity measures are in place, carry out risk assessments and ensure that any cybersecurity incidents are reported within 24 hours.

If organisations fail to comply with the NIS2 standards, fines of up to EUR10 million euros or 2% of the annual worldwide turnover, whichever is higher, can be imposed.

In Portugal, as in several other European Union countries, the deadline for transposing NIS2 has long since passed. However, the Portuguese government presented a draft law to transpose the Directive – which was subject to public consultation during December 2024, leading to its revision and the presentation of a new draft law – with a vote on the approval of this second law by the Assembly of the Republic scheduled for 20 March 2025; this would give the government the power to pass the transposition law.

However, because Portugal will hold an election again on 18 May 2025, the vote has been withdrawn, and the transposition of NIS2 will thus occur during the next parliamentary term. At the moment, it is not known when the Directive will be transposed, and it is possible that the European Union will impose sanctions because of the delay in transposition.

Despite this legislative delay in Portugal, companies and public organisations to which NIS2

applies should start preparing for its application. Healthcare providers, manufacturers of medical devices and organisations carrying out research and development activities in relation to medicines – and which, due to their size and turnover, will be required to comply with NIS2 – should implement robust information security systems.

Alongside NIS2, and reflecting the European Union's concern, in January this year the European Commission presented an action plan aimed at strengthening cybersecurity for hospitals and healthcare providers. The European Union intends to give high priority to this plan, as it is a fundamental step towards protecting the health sector from the various cyberthreats.

The European Union is sensitive to the issues that digitalisation can cause, showing awareness that cyberattacks can delay medical procedures, create bottlenecks in emergency rooms and disrupt vital services that, in serious cases, can have a direct impact on the lives of Europeans. Accordingly, the action plan has four main priorities:

- reinforce prevention;
- improve threat detection and identification;
- respond to cyber-attacks in order to minimise their impact; and
- dissuade the entities responsible for cyberthreats in order to protect European health systems.

It is expected that the plan will be progressively implemented, this year and next, by healthcare providers, member states and the cybersecurity community.

Regulatory matters

Value-based healthcare

With an increasingly ageing population, fewer specialised healthcare staff and growing inequalities in access to healthcare, the value-based healthcare (VBH) financing model is gaining greater prominence in Europe, as it makes it possible to constrain, and above all rationalise, healthcare expenditure.

The VBH model is, in practice, a financing model centred on measurable results and incentives linked to quality. As its name suggests, the VBH model focuses on providing high-quality healthcare with better-controlled costs, linking reimbursement or payment to the outcome of the patient's treatment.

However, the concept of “value” is indeterminate, and it is difficult to quantify value in healthcare since patients' experience and treatment outcomes can differ.

It is essential to devise study programmes to measure patient satisfaction throughout the treatment and recovery process, and thus provide a baseline to determine whether a particular treatment falls below or exceeds the minimum acceptable threshold. In turn, this will make it possible to remunerate according to the value generated.

The VBH model can aid the exchange of personal data between healthcare providers, insurers and regulatory bodies. The GDPR, in this context, poses a challenge to the exchange of information, which must obviously comply with the applicable legal standards. This is clearly an area where innovation can thrive in the absence of regulation. Therefore, once again, there is a need to avoid complicating European and national rules, or to make them more flexible, in order

to allow new models for costing and financing healthcare, particularly the NHS, to be studied and implemented. The balance between ensuring that innovation is possible while regulating the sector is an issue that the European Union will increasingly face in the future.

Another challenge related to the VBH financing model is its compatibility with public procurement, since in Portugal this sector is very rigid, and there are doubts and difficulties regarding how to operationalise a VBH-based payment model in the context of public procurement.

In Portugal, some pilot projects introducing value-based payments models have already been implemented. A white paper published by Health Cluster Portugal in June 2023 even refers to the crucial role that the legislator and the government have in developing legislation to encourage healthcare providers to focus on improving treatment outcomes.

To integrate the VBH financing model, several regulatory changes, both in Europe and in Portugal, would be desirable; even though it is already possible to implement VBH projects, there are difficulties and uncertainties related to the existing legislation. The European Union is currently harmonising the various regulations in this area, but each European jurisdiction will also have to individually adapt its health systems. In summary, the VBH model will certainly see strong growth in the coming years.

Extraordinary contribution to the pharmaceutical industry

Another pressing issue in the health area that the pharmaceutical industry hopes will soon be addressed by the regulators in Portugal concerns a concept introduced by Law No 82-B/2014 of 31 December (the “2015 State Budget Law”),

namely “*extraordinary contribution to the pharmaceutical industry*”, with the ultimate aim of financing the NHS.

Extraordinary contribution to the pharmaceutical industry is predicated on the sales of medicines in Portugal. The contribution varies between 2.5% and 14.3% and is calculated according to the total value of sales of:

- medicines reimbursed by the state;
- medicines subject to prescription restrictions;
- medicines with exceptional use authorisation or exceptional authorisation;
- medical gases and derivatives of human blood and plasma;
- other medicines whose packaging is intended for hospital use; and
- orphan drugs.

It transpires, however, that this contribution was provisional, yet the regime has been included in all successive state budget laws for more than ten years.

The extraordinary contribution to the pharmaceutical industry regime is applicable to entities that make the first sale of medicines for human use in Portugal. These entities include:

- holders of marketing authorisations or registrations;
- representatives, intermediaries and wholesale distributors; and
- marketers of medicinal products under exceptional use authorisation or exceptional authorisation.

However, the law provides for the possibility of an agreement between the Portuguese state and the pharmaceutical industry – through the Portuguese Association of the Pharmaceutical

Industry (*Associação Portuguesa da Indústria Farmacêutica APIFARMA*), the local industry association, on the one hand and the National Authority for Medicines and Health Products (*Autoridade Nacional do Medicamento e Produtos de Saúde INFARMED*), the local medicine supervisory authority acting on behalf of the state that sets the maximum amounts of public spending on medicines and the contribution (according to the sales volume) of pharmaceutical companies, on the other hand. In this way, APIFARMA's member companies provide the state with a contribution that is, as a rule, lower than that which would result from applying the above-mentioned rates.

Companies in the pharmaceutical industry that are not APIFARMA members have been able to declare their adherence and sign an agreement with INFARMED on an individual basis, thus being exempted from making contributions at the above-mentioned rates. However, such companies that do not join the scheme voluntarily are obliged to contribute on the basis of the rates laid down in the State Budget Law, and there is no indication as to when this obligation will be lifted.

The foregoing shows how a scheme that was provisional has in fact been treated as definitive for the last ten years, and although VBH models for rational NHS cost contributions and payments are being discussed, the pharmaceutical industry is still being asked to essentially finance the NHS.

Conclusion

Healthcare in Europe, and more specifically in Portugal, has undergone major changes in recent years, and this evolution is accelerating through the use of new technologies and innovations. With the emergence of new issues, however, it is essential for healthcare providers and other organisations involved in the healthcare sector to be up to date with respect to cybersecurity and to maintain an environment in which personal data is effectively protected.

Along with technological innovation, Portugal also has several regulatory issues that the pharmaceutical industry hopes will soon be resolved, although the unstable political situation places the country at something of a disadvantage.

SERBIA

Law and Practice

Contributed by:

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BDK Advokati

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BDK Advokati is a full-service commercial law firm for corporate, institutional and high net worth clients with multiple specialisations and with offices in Serbia, Montenegro, Bosnia and Herzegovina and North Macedonia. The firm advises clients on deals, supports and represents them in contentious situations and provides legal advice in support of their business. The firm's focus is on prime expert work and complex cross-border deals, but it is also able to work on bread-and-butter matters in an efficient manner due to institutionalised know-how

and organised processes. BDK Advokati's Life Sciences and Healthcare Group has assembled lawyers with different areas of expertise of relevance to these industry sectors, and has advised leading multinational companies on commercial, competition, data protection, disputes, employment, M&A and industry regulations. Present and former clients from the industry include Aspen Pharma, Biotest AG, Genesis, GlaxoSmithKline, Hoffmann-La Roche, Merck, Mylan, Hemofarm and Farmalogist.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices Applicable Legislation

Pharmaceutical products in Serbia are regulated in the Medicines and Medical Devices Act of 2010 (as amended) (Medicines Act). The sections of the Medicines Act regulating medical devices have ceased to apply and medical devices are now regulated separately in the Medical Devices Act of 2017. A considerable number of by-laws regulate in more detail different matters governed by the Medicines Act and Medical Devices Act.

Competent Bodies

Competences for implementation and enforcement of pharmaceutical and medical devices legislation are shared between three governmental bodies:

- the Agency for Medicines and Medical Devices (ALIMS), the regulatory body tasked with enforcement of pharmaceutical and medical devices legislation for pharmaceuticals for human and veterinary use. The ALIMS is an independent regulatory body established by law;

- the Ministry of Health has certain competences with respect to the area of pharmaceuticals and medical devices for human use, particularly with respect to licensing and administrative oversight; and
- the Ministry of Agriculture, Forestry and Water Management is competent for matters concerning the pharmaceutical products intended solely for veterinary use.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation Right to Appeal

Decisions of the ALIMS can be challenged before the competent ministry – ie, the Ministry of Health with regard to medicines and medical devices for human use, and the Ministry of Agriculture, Forestry and Water Management with regard to medicines for veterinary use.

A party to the proceeding before the ALIMS, or any person whose rights, obligations or legal interest may be affected by the outcome of the proceedings, may submit an appeal. An appeal may also be submitted if the ALIMS fails to adopt a decision within the statutory deadline.

Appeal Procedure

A party may submit an appeal against the ALIMS's decision to the competent ministry through the ALIMS. The deadline for submitting an appeal is 15 days from adoption of the first-instance decision or, in the case of failure to adopt a decision, within a year from the expiry of the statutory deadline. Decisions of the competent ministry upon appeal, as well as first-instance decisions of the ministries in the matters from their competence, are final and may be challenged only before the Administrative Court.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Classification of Pharmaceuticals

Pharmaceuticals are classified into pharmaceuticals for human use and those for veterinary use. Furthermore, pharmaceutical products are classified into (i) prescription-only, and (ii) over-the-counter (OTC) pharmaceuticals. The ALIMS carries out the classification in the process for issuing marketing authorisations. Prescription-only and OTC pharmaceuticals are subject to different regimes with respect to pricing, advertising, dispensing and sale.

Classification of Medical Devices

Medical devices are classified into (i) general medical devices, (ii) in vitro diagnostic medical devices, and (iii) active implantable medical devices.

General medical devices are classified according to the degree of risk for the users into:

- Class I – medical devices with a low degree of risk for the user;
- Class IIa – a low-to-medium degree of risk for the user;
- Class IIb – a medium-to-high degree of risk for the user; and

- Class III – medical devices with a high degree of risk for the user.

A notified body carries out the classification of medical devices. As an exception, the manufacturer classifies class I medical devices and others as in vitro medical devices.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical Trials for Pharmaceuticals

The Medicines Act is the principal piece of legislation regulating clinical trials of pharmaceuticals. Additionally, the Healthcare Act of 2019 and the Rulebook on Clinical Trials for Medicines for Human Use (2022, as amended), set out detailed rules related to ethics committee approval and performance of clinical trials. In October 2023, the government introduced amendments to the Clinical Trials Rulebook to limit the phase I (I, Ia, and Ib) clinical trials in Serbia only to public healthcare institutions. However, in December 2024, the government introduced further amendments to the Clinical Trials Rulebook. These changes eliminated the requirement for principal investigators to have prior clinical trial experience and removed the restriction that limited private healthcare institutions to conducting only phases II and III clinical trials, allowing them to participate in all three phases. Additionally, import approval for medicines undergoing clinical trials will now be granted simultaneously with clinical trial approval. When reviewing clinical trial documentation, ALIMS will consider decisions from the EMA and other relevant international bodies, such as ICH, to enhance the efficiency of the approval process. To ensure transparency, ALIMS will also publish information on all approved clinical trials on its website.

Clinical trials of pharmaceuticals are conducted in accordance with the Ministry of Health's guidelines on Good Manufacturing Practice (2017), Good Laboratory Practice (2008), and Good Clinical Practice (2017).

Clinical Trials for Medical Devices

The Medical Devices Act and the Rulebook on Clinical Trials for Medical Devices of 2018 (as amended) regulate clinical trials for medical devices.

Clinical trials of medical devices are conducted in accordance with the guidelines of the Good Clinical Practice.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Clinical Trials Subject to Approval

Sponsors must request simultaneous authorisations for conducting a clinical trial from the ALIMS and the Ethics Committee of Serbia, a government-appointed expert body that takes care of the provision and implementation of healthcare at the national level, in the case of:

- clinical trials for medicines which do not have a marketing authorisation or for which a different use from the one prescribed in the approved summary of product characteristics is proposed, or medical devices for which a conformity assessment has not been carried out; and
- an interventional post-marketing clinical trial, where the medicinal product is applied in accordance with the conditions prescribed in the marketing authorisation, but requires additional diagnostic procedures, as well as the monitoring procedures defined by the clinical trial protocol, or where a medical device has been subject to conformity assessment, but the clinical trial is conducted

for a purpose that is absent from the conformity assessment.

Clinical Trials Subject to Notification Only

Sponsors must only notify the commencement of a trial to the ALIMS if they wish to conduct a non-interventional post-marketing clinical trial of a pharmaceutical or a medical device in accordance with an approved summary of product characteristics of a pharmaceutical for which a marketing authorisation has already been issued, or a clinical trial of a medical device for which a conformity assessment has already been carried out.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical Trials Database

Basic information on all clinical trials conducted at a given moment in Serbia are publicly available within the database kept by the ALIMS on the e-government Portal. The information includes the date and number of the relevant decision on approval of the clinical trial, the protocol number, the names of the sponsor and the client, and the title of the trial, as well as its basic description.

Publication of Clinical Trial Results

Sponsors of clinical trials do not have an obligation to make the results of clinical trials publicly available. They must submit to the ALIMS, within one year of completion of the clinical trial, the report containing detailed results, both positive and negative, obtained through the trial.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials, either for recruiting or monitoring purposes. Sponsors must, however, undertake all adequate measures to provide

information to, and secure the consent of, the subjects and to protect their personal data.

2.5 Use of Data Resulting From Clinical Trials

In accordance with the Data Protection Act (2018), data resulting from clinical trials is personal data, specifically special category data (health data), as long as a particular individual is identifiable from that data. As it follows from an opinion of the Data Protection Commissioner, expressed in its ninth publication Protection of Personal Data: Opinions and Stances of the Commissioner (2024), the Commissioner considers clinical trial data identifiable (and therefore, personal) as long as any party, whether the controller or a third party, can identify the data subject.

Data processing of the resulting data, including sharing the data with third parties or affiliates, may be permitted, however, the supervisory authority and courts have not given any clarification as to which legal bases and conditions for the processing are applicable. In particular, the Commissioner has not opined on whether consent from clinical trial participants can be freely given and thus serve as a legal basis for the processing of their personal data.

Clinical trial data may be transferred abroad to countries that are members of the Council of Europe Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data, and to countries determined by the European Union to provide an adequate level of protection. Transfer to other countries is allowed if the data exporter applies one of the prescribed safeguards, such as the conclusion of controller-to-processor standard contractual clauses, adopted by the Commissioner, with the data importer. Controller-to-controller clauses

are not available in Serbia because the Data Protection Act does not authorise the Commissioner to adopt them. Alternatively, data transfer may occur in specific situations outlined in the Data Protection Act, such as transfer based on explicit and informed consent.

2.6 Databases Containing Personal or Sensitive Data

Creation of a database with the resulting data from the clinical trials would require carrying out a data protection impact assessment, in line with the Decision of the Serbian Data Protection Commissioner on the list of categories of data processing activities for which a data protection impact assessment must be carried out.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

An assessment of whether a product should be classified as a pharmaceutical or as a medical device is carried out by the ALIMS in the process of issuing of a marketing authorisation for a pharmaceutical product or registration of a medical device. The Medicines Act and the Medical Devices Act contain the criteria for classification.

The main criterion for differentiating between pharmaceuticals and medical devices is the following: pharmaceuticals are applied to humans or animals with the intention to restore, improve or modify physiological function by pharmacological, immunological or metabolic action, or by setting up a medical diagnosis; however, medical devices do not fulfil their principal intended purpose in or on the human body by pharmacological, immunological or metabolic means,

but the medical device may be assisted in its function by such means.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Biological medicinal products must meet the same quality, safety and efficacy criteria as other medicinal products to receive marketing authorisation. Biosimilars, however, may benefit from the short-form procedure for the granting of marketing authorisation, equivalent to the one available to generic medicinal products.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Validity and Renewal of Marketing Authorisation

Marketing authorisation is valid for five years. It may be renewed based on the reassessment of the risk/benefit ratio of the medicine. If, on the basis of the available pharmacovigilance data, the ALIMS determines that a pharmaceutical is safe, it grants a permanent marketing authorisation. In the event that the ALIMS determines that the pharmaceutical product is not safe, it will refuse to grant a permanent authorisation. Instead, the ALIMS will decide on whether to renew an authorisation for an additional period of five years. A marketing authorisation may be renewed for an additional period of five years only once. If the ALIMS still has justified doubts with respect to product safety, it will terminate the already issued marketing authorisation.

Revoking of a Marketing Authorisation

The ALIMS will revoke a marketing authorisation if it determines that the product is not safe for the life and health of humans and animals. The ALIMS will revoke the marketing authorisation if:

- the medicinal product is harmful under normal conditions of use;
- the medicinal product has no therapeutic efficacy;
- the risk-benefit ratio is not favourable under typical application conditions;
- the qualitative and quantitative medicinal product composition does not match the declared composition of the medicinal product;
- the marketing authorisation was issued on the basis of incomplete or false information, or if data is not amended in accordance with the law;
- the marketing authorisation-holder no longer meets the prescribed requirements; and/or
- the medicinal product was not marketed in Serbia for three years from the date of marketing authorisation issuance or was withdrawn from the market in Serbia for three consecutive years.

The ALIMS may vary, suspend, or revoke a marketing authorisation on the basis of data on adverse drug reactions collected within the scope of its pharmacovigilance activities.

Medical Devices

If the Ministry of Health determines that a medical device constitutes an unacceptable risk to public health and/or safety, or does not meet the statutory requirements, the Ministry may order the manufacturer or its authorised representative to take all appropriate and justified preventive or corrective measures. The Ministry may also prohibit or restrict the placing of a medical device on the market, set specific requirements for the placement of a medical device on the market, or order the withdrawal of a medical device from the market.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Pharmaceuticals

The Medicines Act and a series of implementing by-laws govern the granting of a marketing authorisation. The ALIMS is the competent authority for issuing marketing authorisations. A medicinal product may be granted a marketing authorisation after undergoing pharmaceutical (pharmaceutical, chemical, and biological), pharmaco-toxicological and clinical trials and provided that it has the required quality, safety and efficacy. The ALIMS conducts a formal review of an application for marketing authorisation within 30 days. The substantive review must be completed within 210 days. If the ALIMS requests additional documents from the applicant, the deadline is paused until submission of those documents. There is also an accelerated procedure for obtaining a marketing authorisation, for a medicinal product which obtained a marketing authorisation in accordance with the EU centralised procedure, and for medicines for human use of utmost importance for public healthcare. The accelerated procedure may last no longer than 150 days from receipt of a complete application.

Medical Devices

Medical devices are not subject to marketing authorisation and may be placed on the market or in use if they comply with essential requirements set out in the Medical Devices Act regarding conformity assessment, labelling and supporting documents, if they are properly procured, installed and maintained, and used in accordance with their purpose. A manufacturer or its representative must submit the application for registration of a medical device to the ALIMS before placing it on the market or putting it to use. The Medicines Act contains a limited

list of medical devices which do not need to be registered in order to be placed on the market or put to use (ie, medical devices for approved clinical trials or research and development, custom-made devices, devices for the personal use of a patient previously treated abroad, devices imported on a temporary basis for medical fairs, and those manufactured in medical institutions for in-house use).

Variations

A request for a variation is submitted to the ALIMS. Marketing authorisation-holders are obliged to:

- report IA-type variations within 12 months from the moment of application (*“do and tell”* procedure);
- report IAIN variations without delay following their application for the purpose of continuous monitoring of the medicinal product;
- request the ALIMS’s approval for IB-type and type-II variations before their application (*“tell, wait and do”* procedure); and
- submit a new request for marketing authorisation for variations related to changes of the active ingredient or changes in strength, pharmaceutical form, or manner of application of the medicine, and for variations of veterinary medicines for animals used in human alimentation.

The ALIMS conducts a formal assessment of the application within 15 days from the day of the application and the substantive review within 90 days from the day when the application is deemed complete. The pharmaceutical product must be marketed in accordance with the approved variation at the latest within 12 months from the delivery of the ALIMS’s act on approval of the variation.

Transfer of a Marketing Authorisation

A marketing authorisation may be transferred to a new marketing authorisation-holder at the request of the existing one submitted to the ALIMS. The ALIMS will assess whether the prospective new holder meets the requirements prescribed by the law. The ALIMS conducts a formal assessment of the application within 15 days from the day of the application and the substantive review within 60 days from the day when the application is deemed complete.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

General Conditions

An importer may submit to the ALIMS a request for importation of a pharmaceutical for which a marketing authorisation was not issued in Serbia if:

- there is no registered pharmaceutical of the same international non-proprietary name (INN), strength, pharmaceutical form and packaging size on the market in Serbia;
- the pharmaceutical is intended for treatment of rare diseases in humans;
- it is necessary to ensure sufficient quantities and types of a pharmaceutical in the case of epidemics, natural disasters, or other emergency situations; or
- when the safe provision of healthcare is impeded, meaning when there are insufficient quantities and types of medicines on the market for which a marketing authorisation has been issued due to production or distribution problems, if in Serbia there are insufficient quantities of a medicine with the same INN, strength, pharmaceutical form, and packaging size as the medicine for which an import request has been submitted.

Compassionate Use Programme

In addition to the import of unregistered pharmaceuticals under the general conditions previously described, import is also permitted on the basis of a compassionate use programme. The purpose of such a programme is to treat specific patients or a group of patients who are afflicted by life-threatening diseases such as AIDS, cancer and other malignant or auto-immune diseases. Import is organised as a donation or humanitarian aid to a health institution, provided that such pharmaceuticals are not subject to clinical trial in Serbia at the moment of the submission of request for import, and provided that they:

- are undergoing an advanced stage (Phase III) of clinical trial procedure in an EU country or in a country with similar requirements to Serbia regarding issuance of a marketing authorisation;
- have completed a clinical trial procedure in that country;
- are currently subject to a centralised marketing authorisation procedure in the EU; or
- have received a marketing authorisation in the EU centralised procedure.

Exceptionally, a patient or a group of patients who are not eligible to participate in the ongoing clinical trial for that medicinal product in Serbia may receive a donation or humanitarian aid in the form of unregistered pharmaceuticals or registered pharmaceuticals for an unregistered indication, which are at that time subject to clinical trial in Serbia.

Import of Unregistered Medical Devices

The ALIMS may also authorise the import of a medical device not registered in Serbia. This is permissible if that import is intended for a particular patient or group of patients, or comes as a donation or humanitarian aid, or the subject-

matter of the import is a medical instrument for scientific research or for emergency situations. In order to be imported, these medical devices must have undergone a conformity assessment.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance of Medicinal Products

In the post-marketing phase, marketing authorisation-holders must ensure continuous monitoring of adverse drug reactions to a pharmaceutical product (pharmacovigilance), namely:

- the continued monitoring of adverse drug reactions (ADRs), and have a full-time employee with adequate qualifications responsible for pharmacovigilance;
- keep records on all suspected ADRs notified in Serbia, EU countries or any third country, and provide the ALIMS with electronic reports;
- keep records of all suspected serious ADRs reported by health or veterinary professionals, or records of ADRs that MAHs can reasonably be expected to be aware of, and to report this information promptly to the ALIMS, no later than 15 days following the receipt of information;
- submit to the ALIMS periodic drug-safety reports at six-month intervals if the marketing authorisation was conditional or under special circumstances; and
- submit periodic drug-safety reports every six months for a period of two years following the placing of the pharmaceutical on the market, then annual reports for another two years and finally submit reports at three-year intervals.

Vigilance of Medical Devices

A manufacturer of medical devices or its authorised representative must employ a person responsible for vigilance and continuously monitor the medical device on the market, with the aim of identifying any need for corrective or preventive measures.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

The Agency and the competent Ministries must treat as confidential all the data in the documentation enclosed within an application for the issuance of a marketing authorisation, variation or a renewal. This obligation applies in particular in relation to trade secrets – ie, when the following cumulative conditions are met:

- the data is confidential – ie, not generally known or easily available to persons usually dealing with that kind of information;
- the data has commercial value due to its confidentiality, during the period of confidentiality; and
- an applicant for a marketing authorisation, variation, and/or renewal, under the circumstances, takes reasonable measures to keep that data confidential.

Information from the documentation submitted during the procedure of obtaining a marketing authorisation, as well as in other procedures handled by the Agency and/or relevant Ministries, may only be disclosed to third parties with the consent of the applicant, or if the data is already available to the general or professional public for the purpose of providing information necessary for use or handling of a pharmaceutical or a medical device, or required for the protection of health in humans and animals.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The Medicines Act provides for a fast-track procedure for obtaining a marketing authorisation for (i) medicines for human use of utmost importance for public healthcare, particularly with respect to therapeutic innovations, and (ii) for a medicinal product which obtained a marketing authorisation in accordance with the EU centralised procedure.

The Rulebook on the content of application and documentation and the method of obtaining a marketing authorisation for placing the medicine on the market lays down the conditions for issuing the marketing authorisation through fast-track procedure. For medicinal products for human use of utmost importance for public healthcare, particularly with respect to therapeutic innovations, the applicant must first obtain an opinion on priority determination from a special commission formed by ALIMs, determining whether a medicinal product is of the highest public health interest in order to apply through the accelerated marketing authorisation procedure. A request on this basis may be submitted for:

- the first generic application of a medicinal product or the next generic application if a generic medicinal product with the same INN has marketing authorisation in Serbia but is not on the market, with a limit of three generic applications based on the order of priority requests or marketing authorisation applications;
- applications related to the transfer of medicinal product manufacturing in Serbia;

- applications for products manufactured in Serbia that are intended exclusively for export;
- applications for medicinal products whose unavailability in Serbia poses a public health risk, particularly vaccines for mandatory immunisation;
- applications for medicinal products included in the Positive List of medicines reimbursed from the national health insurance fund, but without a marketing authorisation in Serbia (D List) at the time of the priority determination request;
- applications for medicinal products developed, manufactured or marketed with state funding; and
- applications for medicinal products of strategic importance as determined by official acts of Serbia and programmes implemented by the Ministry of Health, where applicable.

With respect to conditions and documentation for fast-tracking of medicines approved through the EU centralised procedure, please see the answer to **4.2 Regulatory Reliance**.

The Agency is required to issue a decision on granting the marketing authorisation through the fast-track procedure, or a decision on rejecting the application, no later than 150 days from the date of receipt of a complete application, based on the evaluation of the documentation regarding the quality, safety and efficacy of the medicinal product. If the application for a marketing authorisation under the fast-track procedure is incomplete, the Agency notifies the applicant in writing, requesting the submission of the missing information within 30 days from the date of receipt of the written notification. The request for outstanding information stops the clock until the applicant completes the application.

4.2 Regulatory Reliance

Since 2023, Serbia has been progressively introducing the concept of regulatory reliance. The reliance strategy employed by the ALIMS is based on a risk- and science-driven approach, carefully selecting where to apply reliance while considering public health needs and priorities, available resources and expertise, the type and source of the evaluated product, and the opportunities for reliance.

Regulatory reliance for centrally authorised medicinal products (CP) was introduced in January 2023, both for the issuance of initial marketing authorisations and for post-approval changes (ie, renewals and variations). In 2024, ALIMS initiated a pilot project aimed at expanding the reliance framework to cover medicines previously approved in the EU via the decentralised procedure (DCP) and mutual recognition procedure (MRP).

Reliance for Medicinal Products Approved Through CP in the EU

As at the time of writing, no legislative amendments have been made to formally incorporate reliance into Serbia's regulatory framework. Instead, reliance for centrally authorised medicinal products has been introduced through an interpretation of the existing provisions governing the accelerated procedure for initial marketing authorisations (which has a 150-day timeline, as outlined in 4.1 Fast Track Registration Routes).

ALIMS employs the European Medicines Agency (EMA) as its reference regulatory authority, relying on EMA assessment reports while retaining full independence, responsibility and accountability in its decision-making process. The reliance procedure involves requesting various EMA assessment reports to enable an informed

reliance approach, taking advantage of EMA's transparent evaluation processes.

ALIMS applies reliance to both issuance of marketing authorisations and post approval changes (renewals and variations) for centrally authorised medicinal products. The reliance-based regulatory pathway follows three key steps: (i) verification of the sameness of dossier submitted to Serbia and approved in the centralised procedure before EMA; (ii) confirmation of the applicability of the assessment outcomes of EMA for regulatory decision-making in the national context; and (iii) abridged review.

The reliance pathway is detailed in the ALIMS Internal procedures and Standard Operating procedures (SOPs), which outline the steps for processing reliance applications, the corresponding regulatory procedures, and the requirements that applicants must meet. ALIMS also employs a distinct template for abridged review applications, separate from full review applications.

Documentation Required for Initial Marketing Authorisation Through Reliance

Documentation to support reliance for initial marketing authorisations includes:

- confirmation of approval (Commission Decision; Approval Letter/CHMP Opinion; eCPP);
- statement regarding product sameness submitted in Serbia and approved in CP;
- list of variation submitted and approved in CP;
- questions and answers, interim assessment reports and unredacted final CHMP assessment report (before publishing) generated by EMA;
- approvals (acknowledgement of receipt/notification/CHMP Opinion) and assessment

- reports (type IB i II) for all variations implemented in submitted dossier;
- the complete product dossier (CTD M2-5) as approved by EMA; and
- the latest set of documents approved in the centralised procedure for the initial MA or variations, including the composition of the medicinal product with specification for the active substance(s), SPC, PIL, text for inner and outer packaging, EURMP (European Risk Management Plan), finished product specifications, specification release and shelf-life for the product, and flow chart approved in the centralised procedure).

Documentation Required for Post-Approval Changes Through Reliance

Documentation to support reliance for post approval changes includes the package of variation documentation approved in the centralised procedure, variation approval in centralised procedure, and assessment report in centralised procedure for variations type IB and II.

Reliance Pathway on DCP/MRP Approved Medicines Pilot Project

In 2024, ALIMIS launched a pilot project to refine and expand the reliance strategy to cover medicines approved under the DCP and MRP. This project focuses on initial marketing authorisations and post-approval changes for recently approved medicines (no later than 2022) to incorporate the latest scientific and regulatory requirements, such as risk assessments for nitrosamine and elemental impurities.

Currently, there are no national regulations explicitly governing reliance for medicines approved via the DCP/MRP. However, upcoming legislative changes in Serbia's medicinal product regulations are expected to introduce formal provisions for this type of reliance. In the

meantime, the documentation required for reliance on DCP/MRP-approved medicines aligns with that for CP-approved medicines.

Other Projects Regarding Reliance and International Co-Operation

ALIMS actively participates in the WHO Regulatory Systems Strengthening (RSS) programme for National Regulatory Authorities (NRAs) under WHO Resolution 67.20. Serbia's regulatory system underwent benchmarking in 2019 and was classified as Maturity Level 3 (stable, well-functioning, and integrated) for vaccines. By the end of 2025, ALIMIS aims to achieve Maturity Level 4 (advanced level of performance and continuous improvement) for vaccines and expand this evaluation to cover other medicines.

ALIMS is also striving to be designated as a WHO Listed Authority (WLA), which recognises regulatory agencies operating at an advanced level of performance as globally trusted authorities for reliance and work-sharing procedures. As part of these efforts, in 2024, ALIMIS participated in its first pilot project for post-approval changes (CMC variation), with the objective of reducing global approval and implementation timelines while minimising country-specific regulatory requirements.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Manufacturing of Pharmaceuticals

The manufacturing of pharmaceuticals is subject to a licence issued by the Ministry of Health to legal entities. The application for a manufactur-

ing licence must contain information and documents regarding the location and premises of the manufacturing site, equipment, personnel, medicines to be produced, relevant procedures, as well as other information required by the law. The Ministry issues a licence for a particular manufacturing site and certain forms of pharmaceutical manufactured at that site. The licence may include an entire manufacturing process or only a part of the process. The licence is valid for an indefinite period.

Manufacturing of Medical Devices

Manufacturers of medical devices may be both legal entities and individuals. A manufacturing licence is necessary only for class I medical devices (other than Is and Im class), other in vitro diagnostic medical devices, medical devices for which no conformity assessment has been performed, those not covered by the sign of conformity, custom-made devices for a particular patient, and medical devices for clinical trials, as well as a system or a kit. The Ministry of Health issues a manufacturing licence for medical devices, which is valid for five years.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale of medicines and medical devices includes purchase, storage, distribution, imports and export. A wholesale licence is issued by the Ministry of Health for an indefinite period for pharmaceuticals, and for medical devices for a period of five years.

The exception from obtaining a wholesale licence applies to (i) manufacturers of medicines for products from their production programme,

(ii) manufacturers of medical devices with a registered seat in Serbia, who must obtain a manufacturing licence for medical devices from their production programme, and (iii) entities performing only import or export activities on behalf of and for the account of a medicines wholesale licence-holder.

Applicants for a wholesale licence must provide information and documents regarding the legal entity, location and premises, supply territory, products for which the wholesale licence is sought, personnel, equipment, a plan for an urgent withdrawal of products from the market, as well as the other information of relevance for the issuance of the wholesale licence.

6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Product Classification: Pharmaceuticals or Medical Devices relating to different categories of pharmaceuticals.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The import and export of pharmaceutical and medical devices in Serbia are governed by the Medicines Act and the Medical Devices Act, respectively. Import and export constitute the wholesale of medicines and medical devices and as such are additionally regulated in the rule books governing the wholesale of medicines and medical devices.

Depending on whether the product is intended for human or veterinary use, the Ministry of Health or the Ministry of Agriculture issues a pharmaceutical wholesale licence. The ALIMS issues (i) opinions on the import of cell or tissue samples for clinical trials' procedures of medicinal products, (ii) approvals for the import of medicines for clinical trials, and (iii) approvals for the import of medicines without a marketing authorisation.

Customs officials check if all the conditions are met in each case.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

An importer of record for pharmaceuticals or medical devices may be a legal person with a relevant wholesale licence.

Furthermore, a pharmaceutical or a medical device manufacturer may import products from its production programme, raw materials and substances for production, interim products, and semi-finished products, in accordance with the manufacturing licence, medicinal products marketing authorisation, or a subcontracting agreement.

Manufacturers of medical devices with a registered seat in Serbia who do not need a manufacturing licence must obtain a wholesale licence for medical devices from their production programme.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

The import and export of pharmaceuticals and medical devices is subject to a prior issuance of a medicinal product wholesale licence, subject to exceptions described under **7.2 Importer of**

Record of Pharmaceuticals and Medical Devices.

A legal entity that performs only the activities of import and export may perform these activities without a medicinal product wholesale licence if it conducts the import and customs clearance activities on behalf of and for the account of a wholesale licence-holder to the site of the goods' free marketing, in accordance with the customs regulations.

Generally, only medicinal products with a valid marketing authorisation and medical devices registered in the ALIMS's registry of medical devices may be imported. Exceptionally, the ALIMS may approve import of medicinal products without a marketing authorisation in Serbia or unregistered medical devices under conditions prescribed for compassionate-use programmes, donation or humanitarian aid, or the emergency situations described in **3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations**.

Persons entering or leaving Serbia may carry medicinal products in the amount not exceeding their six-month requirement within one calendar year, for their personal usage or for an animal travelling with them, depending on the type and length of the underlying illness. They have to provide to the Customs Authority the approval of a competent Serbian ministry for bringing in or carrying out medicinal products for personal use.

The transfer of medicinal products across the border in the amount not exceeding the 15-day requirement of an individual is not subject to any approval.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Although Serbia is not yet an EU member state, nor a member of the World Trade Organization (WTO), Serbia has, to a large extent, harmonised its legislation with the EU *acquis* and WTO agreements. Therefore, non-tariff restrictions are rare and imposed only in particularly justified situations, in line with the general principles of the EU and WTO to limit the use of non-tariff restrictions.

Non-tariff regulations and restrictions are imposed based on the Harmonized Tariff Schedule (HTS) Code. The products that are subject to those restrictions (usually quotas) are listed for example in specific international agreements which Serbia has concluded.

7.5 Trade Blocs and Free Trade Agreements

Serbia is a party to the Stabilisation and Association Agreement with the EU, the Central European Free Trade Agreement, and the Agreement with EFTA, as well as a number of bilateral free-trade agreements.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

The prices of pharmaceuticals are controlled by the government only with respect to prescription-only pharmaceuticals. The government determines the criteria for the pricing of pharmaceuticals, and calculates their maximum prices at the joint proposal of the ministries competent for health and trade. The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals.

The pricing of prescription-only medicines is governed by the Medicines Act, the Decree on Criteria for Forming of Prices of Prescription-Only Pharmaceuticals for Human Use, and the Decision on Maximum Prices of Prescription-Only Pharmaceuticals for Human Use. Prescription-only pharmaceuticals for which the government did not determine the maximum wholesale price may not be placed on the market.

Once the government decides on the maximum permitted wholesale price of the pharmaceutical, marketing authorisation-holders may apply to include the pharmaceutical into the positive reimbursement list of medicines (*“Positive List”*), to be prescribed and issued at the expense of the compulsory health insurance. Wholesalers of pharmaceuticals, as well as pharmacies, must align the prices of pharmaceuticals that they have in stock with the maximum prices determined by the government on the same day as the relevant decision on maximum prices enters into force.

However, marketing authorisation-holders are free to determine the prices of over-the-counter medicines and must only notify the Ministry before March 1st of the current year of the price for the previous year.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The Ministry of Health calculates the maximum wholesale price for prescription-only pharmaceuticals based on a number of criteria. One of these criteria is price parity – ie, the comparable wholesale prices of pharmaceuticals in reference countries, namely, Slovenia, Greece and Italy, and the current wholesale price in Serbia, in addition to other applicable criteria.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

For the cost of a pharmaceutical to be reimbursed, the product must be included in the Positive List. The general criteria for adding a pharmaceutical to the List are, as follows:

- pharmaco-therapeutic justification of the pharmaceutical;
- pharmaco-economic justification of the pharmaceutical; and
- financial resources provided by the annual financial plan of the National Health Insurance Fund.

In cases when there are not sufficient resources to include in the Positive List all pharmaceuticals which comply with the general criteria, the National Health Insurance Fund further considers two special factors: (i) the existence, if any, of a managed entry agreement, and (ii) the priority for adding the pharmaceutical to the list according to the following criteria:

- the lack of a pharmaceutical from the same pharmaco-therapeutic group on the Positive List for a particular medical indication;
- the significance of a pharmaceutical for public health; and
- ethical aspects.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Within the scope of the process for inclusion of pharmaceuticals into the Positive List of pharmaceuticals to be reimbursed from the national health insurance, the Central Medicines Commission established by the National Health Insurance Fund conducts the health technology assessment of medicines when reviewing the applications for inclusion of pharmaceuticals on the List.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Dispensing and sale of pharmaceuticals is regulated only with respect to prescription-only medicines. The ALIMIS decides whether a medicine is to be dispensed only on prescription in a marketing authorisation procedure. Prescriptions and dispensing of pharmaceuticals are regulated in the Rulebook on Form and Content of Medical Prescription, Manner of Issuing and Prescription of Pharmaceuticals. Healthcare professionals are obliged to observe the recommendations from Good Practice in Prescribing of Pharmaceuticals.

A pharmacy may replace the prescribed brand-name medicine with its generic equivalent only if the patient consents after being adequately informed by the pharmacist, and under the condition that the physician did not prohibit replacement on the prescription.

Trends and Developments

Contributed by:

Bisera Andrijašević

BDK Advokati

BDK Advokati is a full-service commercial law firm for corporate, institutional and high net worth clients with multiple specialisations and with offices in Serbia, Montenegro, Bosnia and Herzegovina and North Macedonia. The firm advises clients on deals, supports and represents them in contentious situations and provides legal advice in support of their business. The firm's focus is on prime expert work and complex cross-border deals, but it is also able to work on bread-and-butter matters in an efficient manner due to institutionalised know-how

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In recent years, the Serbian government has been working towards positioning the country as a global hub for biotechnology and artificial intelligence in healthcare. This strategic focus aims to drive innovation and attract investment in these rapidly evolving fields. On the other hand, these objectives must be supported by legislative changes and regulatory capacities, which are still lagging behind. The process of digitalisation in healthcare is progressing, although there is still much work left ahead.

Overview of the Pharmaceutical Market in Serbia

The Serbian pharmaceutical market continues to evolve, with total market value reaching EUR1.2 billion in 2022. Healthcare spending accounts for approximately 10% of the country's GDP, with public funding covering 61% of total healthcare expenditure and out-of-pocket contributions accounting for 39% (data for 2021).

Despite ongoing efforts to improve patient access to modern treatments, the availability of innovative therapies remains insufficient. Over the past seven years, 96 new innovative medicines have been introduced into the reimbursement system. However, as of November 2024, more than 80 innovative medicines were still awaiting inclusion in the positive reimbursement list. A step forward was made in 2024, when 16 new innovative medicines for additional indications were added to the list, but further progress is needed to ensure timely access to cutting-edge treatments for Serbian patients.

Following the introduction of the procedure for off-label prescription of medicines in December 2022, in 2023 the Serbian government introduced the rules for reimbursements from the Health Insurance Fund for off-label use of medicines.

Legislative Changes

Expected new Medicines Act

The applicable Medicines and Medical Devices Act was adopted in 2010. As of 1 December 2018, the provisions related to medical devices ceased to apply as the separate Medical Devices Act entered into force. A new Medicines Act has been announced several times since 2021, however, despite long-standing discussions, a draft of the new law has yet to be published.

The new Medicines Act should additionally align Serbian medicines legislation with EU regulations, including the EU Transparency Directive, and introduce clear and shorter deadlines for regulatory procedures. It should eliminate unnecessary administrative barriers, better regulate pharmaceutical trade, and allow the registration of advanced therapies like gene and stem cell treatments. Provisions on patent protection, pricing mechanisms, and inclusion in the reimbursement list also need revision to improve and facilitate market access. Improvements in clinical trial regulations, pharmacovigilance, and advertising approval processes are also necessary.

Amendments to the Medicines Act should also include changes to the regulation of sales channels for over-the-counter (OTC) medicines. Currently, online sales of medicines are prohibited by law, restricting modern access to medications. However, this ban is widely violated through the sale of counterfeit drugs and medicines without marketing authorisation in Serbia, with regulatory authorities acting only upon complaints rather than proactively. Additionally, there is no capacity for effective oversight of online drug sales, highlighting the need for both regulatory reform and improved monitoring mechanisms.

Implementing by-laws which regulate applications for marketing authorisations, as well as the approval of variations, need urgent amendments in order to remove unnecessary administrative barriers and further expand the use of reliance procedure in approval of marketing authorisations and post-approval changes.

Recent amendments to the clinical trial regulation

In 2023 and 2024 there were turbulent regulatory changes in the clinical trials sector. In August 2023, the government introduced stringent amendments to the Clinical Trials Rulebook, which were largely reversed in October due to the outcry from the industry. Nonetheless, restrictions remained on Phase I (Ia and Ib) clinical trials, limiting them to public healthcare institutions. A new requirement was also introduced, stipulating that chief investigators must be full-time employees of a healthcare institution, except for those serving as professors at higher education institutions.

Following a continued discussion between the government and the industry, further amendments to the Clinical Trials Rulebook were made in December 2024, lifting the restriction on private healthcare institutions, allowing them to conduct Phase I trials in addition to Phases II and III. The requirement for prior clinical trial experience for principal investigators was also removed. Additionally, import approval for medicines subject to clinical trial will now be granted simultaneously with clinical trial approval, streamlining the process. To improve efficiency, the Medicines and Medical Devices Agency of Serbia (ALIMS) will take into account decisions from the European Medicines Agency (EMA) and other international regulatory bodies, such as the International Council for Harmonisation (ICH), when reviewing clinical trial applications. ALIMS

will also publish information on all approved clinical trials to enhance transparency.

Efforts to Expedite Regulatory Procedures

ALIMS is significantly behind the legally prescribed deadlines for issuing, renewing and amending marketing authorisations for medicines, as well as approving promotional materials. These delays result in longer patient wait times for new therapies, disruptions in the continuity of medicine supply, and additional costs due to failed procurement processes. ALIMS struggles with prolonged timelines for reviewing applications, exceeding legally prescribed deadlines. Limited administrative capacity and unclear regulatory interpretations contribute to bottlenecks, making it difficult for manufacturers to plan supply chains efficiently. Companies operating in Serbia frequently face inconsistent requirements compared to EU markets, further complicating compliance.

In 2024, ALIMS made progress in streamlining the processing of marketing authorisations, variations and renewals by optimising internal procedures and reorganising its operations. However, given the backlog across all procedures, full compliance with legal deadlines for certain processes is unlikely to be achieved quickly. ALIMS has been making significant efforts to accelerate its processes, particularly the issuance and renewal of marketing authorisations, as well as the approval of variations and promotional materials for medicinal products. There are indications that simplified procedures could be introduced for medicines already approved in the EU via decentralised and mutual recognition procedures, in addition to the already available fast-track procedure for medicines approved through the EU centralised procedure. By the end of 2026, ALIMS is expected to process

applications within the legally prescribed timeframes.

Shortcomings in the Inclusion of Medicines on the Reimbursement List

The current provisions governing the inclusion and removal of medicines from the positive reimbursement list of the National Health Insurance Fund lack clear and detailed criteria, creating uncertainty in the selection process for medicines covered by mandatory health insurance. While some progress has been made, the decision-making process remains opaque. Each application for reimbursement should be subject to greater transparency, with a mandatory explanation of the final decision and the right to appeal.

The process and dynamics of updating the positive list is inconsistent. The absence of a predictable and structured update process creates challenges for business planning, disrupts the stability of medicine supply, and limits patient access to essential therapies. To address these issues, the legislative amendments should establish clear timelines and procedures for regular updates of the positive list.

In 2023, the by-law on criteria for forming prices for prescription medicines was updated to introduce Greece as a reference country for pricing, alongside Italy and Slovenia, which is expected to reduce prices of medicines.

Increased Scrutiny by the Serbian Competition Authority

Increased scrutiny of exclusive distribution arrangements

The Serbian Competition Authority has tightened its review of agreements submitted for individual exemption in the pharmaceutical sector. In July 2024, the Commission issued a decision reject-

ing a request to extend a previously granted individual exemption of an exclusive distribution agreement between a major pharmaceutical company and its Serbian distributor. This marks the second time that the Commission has denied an individual exemption request, having previously refused to extend another exclusive distribution agreement in 2023. This signals a stricter stance by the Commission in this area. The medicines in question were used exclusively in inpatient healthcare institutions and procured through public tenders organised by the Republic Health Insurance Fund.

In its relevant market analysis, the Commission determined that each medicinal product covered by the agreement constituted a distinct relevant market, as the product markets had to be defined at the level of individual molecules. Consequently, the manufacturer held a 100% market share for each product. Given that these medicines were procured solely through public tenders, with no inter-brand competition in the relevant markets, the Commission found that the only potential competition was intra-brand, through multiple suppliers of the same medicine. The exclusive distribution arrangement, if concluded, would eliminate or at the very least significantly restrict this form of competition.

Sector inquiry into pharmaceutical sector

Most recently, on 10 January 2025, the Commission announced that it had launched a sectoral inquiry into the pharmaceutical market for medicines for human use in Serbia. The focus of the inquiry is on prescription medicines financed by the Serbian Health Insurance Fund, with a particular emphasis on how the prices of medicines are determined at the retail level. The Commission aims to assess the competitive conditions in the market, including market shares, vertical relations between wholesalers and pharmacies,

and potential barriers to market entry. As part of the inquiry, the Commission has already begun sending out questionnaires to larger pharmacy chains to gather the necessary data for its analysis.

The inquiry follows a growing concern about market practices in the pharmaceutical sector, which had also been expressed by the Serbian Prime Minister in October 2024. Additionally, the inquiry may be spurred by the ongoing consolidation in the retail pharmacy market, as larger pharmacy chains acquire smaller ones, potentially fostering an environment where price collusion could occur. The goal of the inquiry is to identify measures and recommendations to improve market competition, which the Commission may present to relevant authorities and market participants. The inquiry might also result in initiation of concrete infringement proceedings, which often follow sector inquiries conducted by the Commission.

Centre for the Fourth Industrial Revolution and BIO4 Campus

A significant step in positioning Serbia as a regional and European biotechnology hub was the establishment of the Centre for the Fourth Industrial Revolution in Serbia, launched in March 2022 as a joint initiative between the government and the World Economic Forum. This Centre is the first of its kind in the region and only the third in Europe, following Oslo and Moscow. Its primary objective is to advance biotechnology and AI applications in healthcare by fostering collaboration between science and industry. The Centre will support research in biotechnology, molecular biology and medicine, ensuring their practical implementation in healthcare solutions.

To further strengthen Serbia's biotechnology sector, construction of the BIO4 Campus in

Belgrade began in late December 2023, with completion expected by the end of 2026. This state-of-the-art hub will facilitate the development of innovative therapies by bringing together research centres from companies working in biomedicine, biotechnology, bioinformatics and biodiversity. The government has already signed memoranda of understanding with several leading global pharmaceutical companies to encourage investment and collaboration. Additionally, the Campus will include a start-up accelerator to support Serbian biotech companies.

Digitalisation of Healthcare

ALIMS is continuing to expand the use of the Regulatory Information Management System (RIMS) for the regulatory applications and requests from its competence. RIMS is a centralised software platform designed to streamline the management of regulatory information throughout a product's lifecycle and enables efficient tracking of regulatory activities, including product applications, registrations and submissions, thereby enhancing compliance and operational efficiency.

Requests are now being submitted through the RIMS system for a range of pharmaceutical and clinical trial-related procedures. This includes applications for the issuance of marketing authorisations for medicines, such as drug categorisation, expert opinions on packaging and approval of promotional materials for both the general and professional public. Also included are requests for the importation of unregistered medicines, reference standards and expert opinions on the country of origin of a medicine. The system facilitates requests for clinical trial approvals, including registration, amendments and notifications on the completion of clinical trials. Requests for the importation of medicines and medical devices for clinical trial purposes,

as well as the import of biological samples for clinical trial testing, are also processed. Additionally, quality control documentation submissions for medicines and requests for the suspension of procedures are managed through RIMS. The system is centralising and streamlining these processes to enhance efficiency and transparency.

Furthermore, the Health Documentation and Records Act, adopted in 2023, introduced the electronic medical record (e-File), which is a unique and centralised registry of data and documents from mandatory medical documentation of patients. This system should enable the efficient tracking of patients' medical history and treatment across health centres, hospitals, and both public and private practices. The e-File is planned to be used in the provision of healthcare services, the exercise of rights under mandatory health insurance, as well as for analytics, reporting, healthcare planning and scientific research purposes. Access to the data will be granted to the patient's chosen physician, specialist, emergency medical services, medical commission, or any doctor to whom the patient grants access. This should streamline the patient's journey through the healthcare system, prevent unnecessary repetition of tests, and reduce the need for referrals back to primary care doctors. However, the e-File system has not yet been implemented, and full implementation was expected to begin as of January 2025.

The creation of the Republic Integrated Health Information System is ongoing, which will unify data on all healthcare resources and provide electronic services for healthcare institutions and patients. By integrating digital records, automating administrative processes, and enabling real-time data access for healthcare professionals, this system has the potential to improve treatment efficiency and resource allocation. However, for full effectiveness, the system must be regularly updated, interoperable across institutions, and supported by comprehensive training for medical staff.

SOUTH KOREA

Law and Practice

Contributed by:

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Lee & Ko



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for the quality of the firm's legal services. Lee & Ko's healthcare practice group of more than 70 professionals focuses on providing legal services expertly tailored to meet the needs of clients with specific concerns around healthcare and related matters, including pharma, bio, medical devices, food and beverage products, medical data with AI application, genome analysis, DTC, tobacco and cosmetics.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing pharmaceuticals in Korea is the Pharmaceutical Affairs Act (PAA). The Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biological Products (AABP) regulates cutting-edge biopharmaceutical products such as cell therapy, gene therapy, and tissue engineered products. The Medical Devices Act and the In-Vitro Medical Devices Act (collectively, MDA) regulate medical devices. All Acts, together with related presidential decrees, regulations and guidelines, are promulgated by the Office of the Prime Minister and the Ministry of Food and Drug Safety (MFDS).

On a related note, the Digital Medical Product Act was newly enacted on 23 January 2024. It aims to define and regulate digital medical products, including digital medical devices, digital integrated drugs, and digital medical/healthcare support devices. Such products were previously governed by the existing PAA, Medical Device Act, In Vitro Diagnostic Medical Devices Act, their subordinate regulations, and MFDS guidelines. The Digital Medical Product Act will now have precedence over those regulations. It will first be effective for digital medical devices and digital integrated drugs on 24 January 2025, and sequentially for digital medical/healthcare support devices on 24 January 2026.

The Ministry of Health and Welfare (MHW) and the MFDS (which is overseen by the MHW) are the main regulatory bodies in relation to pharmaceuticals and medical devices, and they are responsible for issuing and enforcing most of the regulations, guidelines and administrative orders

for pharmaceuticals and medical devices. Local governments (such as the Seoul Metropolitan government) also monitor pharmaceutical and medical device entities within their jurisdiction.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative orders issued by the MFDS, MHW or local governments to entities in violation of the PAA, AABP or MDA may be challenged via an administrative appeal to the competent administrative appeals commission under the Administrative Appeals Act, or via administrative litigation to the competent court under the Administrative Litigation Act. In most cases, either action will request that the competent commission or court revoke or declare null the administrative order. Rulings rendered by an administrative appeals commission may also be appealed to the competent court.

In general, these challenge procedures are applicable to other regulated products, such as food products.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are categorised into over-the-counter (OTC) drugs and prescription drugs. In principle, all pharmaceuticals must be delivered to patients by licensed pharmacists at pharmacies, except in some cases such as administration of pharmaceuticals to patients by doctors within medical institutions. While prescription drugs require a prescription from physicians, OTC drugs can be supplied to consumers without a prescription. Additionally, the MHW has designated certain OTC drugs as emergency drugs to treat light symptoms in urgent situations at patients' discretion, and such OTC drugs may be sold at 24-hour convenience stores by non-

pharmacists after such stores' registration with the local government.

Medical devices are classified into Classes I to IV, based on their intended use and the risk level associated with the device. Class I devices present the lowest risk, while Class IV devices are considered the highest risk and are subject to the greatest scrutiny.

The Digital Medical Product Act, implemented for digital medical devices and digital integrated drugs as of 24 January 2025, and for digital medical/healthcare support devices, to be implemented as of 24 January 2026, separates digital medical products into the categories of digital medical devices, digital integrated drugs, and digital medical/healthcare support devices. This allows the MFDS to classify digital medical products into different tiers depending on their purpose, function, and potential risk, among other factors.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The PAA, the MDA, the Bioethics and Safety Act (BSA) and relevant regulations govern clinical trials of medicinal products and medical devices, and the MFDS oversees approval for clinical trials.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

To conduct a clinical trial, the relevant clinical trial protocol must be reviewed and approved by an institutional review board (IRB) of the MFDS. The materials required to be submitted by the applicant for clinical trial approval include the following:

- for medicinal products, the clinical trial protocol, development plan, investigator's brochure, material on manufacturing and quality of the investigational drug, preclinical trial data, materials on medical institution conducting the clinical trial, institute analysing the clinical trial sample, and the investigator and Contract Research Organisation (CRO), policies and forms regarding the clinical trial subjects, etc; and
- for medical devices, the clinical trial protocol, materials proving that the clinical trial medical device is being manufactured in accordance with the facility, manufacturing and quality management system standards, purpose of use, working principle and technical documents to verify performance and safety.

Once approved, clinical trials must be conducted in accordance with the protocol and standards regarding good clinical practice for medicinal products and medical devices, as applicable.

2.3 Public Availability of the Conduct of a Clinical Trial

All clinical trials are registered with the MFDS. Basic information regarding clinical trials such as sponsor information, information on the clinical trial including its title, purpose and use, information of drug used, plan for clinical trial, method to arrange the participants subject to experimental group or control group, the status of the clinical trial (eg, on-going, completed), method to administer and evaluate the clinical test (eg, primary and secondary end point), and subject inclusion and exclusion criteria can be searched at the medicinal products comprehensive information system, which is a [website](#) of the MFDS.

2.4 Restriction on Using Online Tools to Support Clinical Trials

No restriction exists on using online tools to support clinical trials. However, it is generally required that clinical trials are to be conducted by doctors or hospitals with in-person interviews, and written informed consents from clinical trial subjects. Recruitment of clinical trial subjects can be conducted online.

When a crisis alert level of serious magnitude or higher is declared, and if deemed necessary to protect patients, medical personnel, and medical institutions from the risk of infection, the protocols allowing provisional “*untact*” medical care (a term coined by a research team in Korea for non-face-to-face contact) under Article 49–3 of the Infectious Disease Control and Prevention Act may be implemented. This may apply to clinical trials, where the treatment for and monitoring of patients during clinical tests may be converted to untact treatment and monitoring.

2.5 Use of Data Resulting From Clinical Trials

The data from clinical trials is considered as personal and sensitive data and the institutions conducting clinical trials are subject to the Personal Information Protection Act (PIPA) for the collection, use, provision, etc, of such personal and sensitive information. In addition, information with respect to the participant’s identity or sponsor’s intellectual property, etc, shall not be disclosed to third parties unless there is explicit permission granted to access that information. Further, in order to protect the clinical trial subjects’ identity, unique identity numbers need to be assigned to subjects instead of their name.

When obtaining consent on the clinical trial from its subjects, the medical institution conducting the clinical trial must explain that the records

of subjects’ personal information will be kept confidential, stipulate the same in writing, and make it clear that such personal information shall be maintained confidential even if results of the clinical trial become publicly available. It further needs to inform that the records relating to clinical trial including the subjects’ medical record can be accessed by the sponsor’s monitoring agent or inspector through an institutional review board (IRB) of the medical institution, and that the MFDS may also access and review such information and relevant materials.

2.6 Databases Containing Personal or Sensitive Data

In addition to the requirements described in 2.5 Use of Data Resulting From Clinical Trials, according to clinical trial management standards, such database needs to have a security system which prevents unauthorised persons from accessing the information, and matters as prescribed by the chief of MFDS for proper management of electronic records must be complied with. The sponsor also has to use identifier code for clinical trial subjects.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Under Article 2 of the PAA, “*drugs*” are defined as those other than quasi-drugs, among the articles listed in the Korean Pharmacopoeia, or articles, other than appliances, machinery or equipment, used for the purposes of diagnosis, treatment, alleviation, care or prevention of diseases of human beings or animals, or used for the purpose of exerting pharmacological effects

upon the structure or functions of humans or animals.

“medical device” is defined under the MDA as an instrument, machine, apparatus, material, software or any other similar product specified in the following:

- a product used for the purpose of diagnosing, curing, alleviating, treating or preventing a disease;
- a product used for the purpose of diagnosing, curing, alleviating or correcting an injury or impairment;
- a product used for the purpose of testing, replacing or transforming a structure or function; and/or
- a product used for the control of conception.

With regard to medical devices, sometimes it is difficult to distinguish medical devices from personal healthcare products (which do not require medical device approval) even when considering the purpose of use and the risk to the human body. In such case, guidance or administrative interpretation from the MFDS may be requested.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

To market biological drugs in Korea, the initial marketer is required to obtain marketing approval the same as that for chemical drugs. Key factors to consider when reviewing an application for market approval are:

- data on origin or discovery and development process;
- data on structure and physicochemical properties;
- data on stability;
- toxicological data;
- data on pharmacological mechanism;

- data on clinical trial results; and
- data on domestic and overseas usage and approval status.

For some biologics such as the botulinum toxin, additional strict requirements on use, transfer, etc, apply. Meanwhile, unlike generic drugs, a bioequivalence test does not replace data on stability and efficacy in order to obtain market approval for biosimilars.

On the other hand, cell therapy products (medicine manufactured by physical, chemical, or biological manipulation, such as cultivation, proliferation, or screening of living cells of humans or animals *in vitro*), gene therapy products (medicine containing genetic material or drug-containing cells into which genetic material has been modified or introduced), tissue-engineered products (medicine manufactured by applying engineering technology to living cells or tissues of humans or animals for the purpose of regenerating, restoring or replacing tissues), advanced bio-convergence products (cell therapy products, gene therapy products, tissue engineered products, and medicinal products formed through physical and chemical combination (including fusion, complex, combination) with medical devices under the MDA) are regulated by AABP, and marketing authorisation must be obtained accordingly. (For those not regulated by AABP, PAA applies.)

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

Under the PAA, marketing authorisation for pharmaceuticals is valid for five years, and renewal is required after five years. For renewal, safety data, domestic manufacturing/import data, and a GMP compliance certificate must be submitted to the MFDS at least six months before the

expiration date. If the marketing authorisation holder does not file the application for renewal or fails to meet the requirements, the marketing authorisation is cancelled.

In the case of medical devices, no renewal system existed previously, but since 8 October 2020, marketing authorisation for medical devices is to be valid for five years from the marketing authorisation date. Similar to pharmaceuticals, for medical devices, data proving that safety and efficacy has continued to be the same since the initial issuance of the marketing authorisation, and data on production/import performance, etc, must be submitted for renewal at least 180 days before the expiration date.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Data proving safety and efficacy, such as clinical trial results, must be submitted to the MFDS for obtaining marketing authorisation. In some cases, such as generic drugs or incrementally modified drugs, however, safety and efficacy data can be replaced with bioequivalence test result data.

The procedure for assessing marketing authorisation on medical devices varies depending on the risk they pose to human bodies. In the case of high-risk medical devices (Class III/IV), a higher level of scrutiny will apply, such as requesting and reviewing more data, including clinical data proving the efficacy and safety, compared to low-risk medical devices (Class I/II) where various data such as clinical trial data is exempted.

In the event that the indications for drugs or medical devices are changed after marketing authorisation, it is possible to file an approval

for change, and the procedure is similar to the procedure for new marketing authorisations.

It is also possible to transfer a market approval from one market approval holder to another.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In Korea, even if no marketing authorisation has been obtained, investigational drugs can, after relevant clinical trials are implemented and approved, be used as part of a compassionate use programme. The compassionate use programme is permitted only in the following cases:

- when treating patients with life-threatening conditions such as an end-stage cancer or acquired immunodeficiency syndrome (AIDS);
- when treating emergency patients, such as those in a critical condition or for whom there are no alternative treatment options; and
- when attempting to use investigational drugs for research or analysis (referring to research or analysis not involving human subjects).

In addition, certain orphan drugs and drugs for the treatment of rare diseases that are directly imported and distributed by the Korea Orphan & Essential Drug Center (KOEDC), as well as drugs that the MFDS admits for urgent introduction for the treatment of patients, are exempted from the requirement for obtaining marketing authorisation.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Effective as of 21 February 2025, the existing re-examination system for pharmaceuticals will be abolished, and the safety management system for pharmaceuticals will be integrated into

a comprehensive Risk Management Plan (RMP) system.

According to the PAA, those who wish to apply for market approval (or notification, as applicable) for new drugs, orphan drugs, advanced biopharmaceuticals, already approved drugs, or prescription drugs with a different type or combination ratio of active ingredients, must establish and submit a comprehensive drug safety management plan, known as the Risk Management Plan (RMP), which includes items for which information on safety and efficacy needs to be collected, or other types of risk mitigation methods as applicable. Those who have received market approval must conduct risk management according to the RMP and regularly submit the relevant results to the MFDS.

The MDA stipulates that the head of the MFDS may conduct safety and efficacy investigations for at least four years and no more than seven years on newly developed medical devices, orphan medical devices, and medical devices equivalent to newly developed medical devices.

Approved pharmaceuticals or medical devices may be subject to re-evaluation if the MFDS finds it necessary to re-evaluate the safety and efficacy of the product. To re-evaluate, the MFDS reviews not only documents and materials submitted before the marketing authorisation, but other post-approval information, including side-effect data since launch, status in other countries and amendments to the marketing authorisation made in relation to safety and efficacy.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Under the PAA and MDA, if the applicant files a request in writing to protect information or

data contained in the application for marketing authorisation against disclosure, such information or data should not be disclosed unless otherwise required by the public interest. The PAA and MDA even impose criminal penalties for breaching the non-disclosure obligation above.

Further, the Korean Criminal Act (KCA) punishes a public official or former public official who divulges secrets obtained in the course of performing their official duties.

While the contents of the application are not disclosed, third parties may infer from the following circumstances that certain marketing authorisations may be granted shortly:

- clinical trial approval status for drugs is published on the MFDS website; in particular, it can be inferred that generic drugs are scheduled to be released from the clinical trial approval status, since the submission of bioequivalence test results is required for approval of generic drugs; and
- the MFDS notices the DMF registration of APIs on its website.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The expedited (priority) review of pharmaceuticals is primarily governed by the PAA, the Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals, and the Special Act on the Promotion of Development and Emergency Supply of Medical Products for Public Health Crisis Response.

Under the PAA, the MFDS can designate a drug for priority review based on the applicant's

request if it falls into one of the following categories: (i) a drug used for treating serious or rare diseases with no alternative available, or one expected to significantly improve safety and efficacy compared to existing alternatives; and (ii) a new drug developed by an innovative pharmaceutical company designated as such by the MHW. Such designated drugs must be reviewed within 90 days, barring exceptional circumstances.

According to the Act on the Safety and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals, drugs can be designated for expedited processing upon the request of the developer if any of the following conditions is met: (i) for the treatment of life-threatening diseases like cancer with no alternatives; (ii) for the treatment of rare diseases as defined by the Rare Diseases Management Act; or (iii) for the prevention or treatment of bioterrorism-related or other pandemic infectious diseases. These expedited drugs will be prioritised over other non-designated product approvals.

The Special Act on the Promotion of Development and Emergency Supply of Medical Products for Public Health Crisis Response mandates that preliminary crisis-response medical products, designated by the head of MFDS for preventing or treating infectious diseases posing a serious threat to public health, should be reviewed within 40 days barring exceptional circumstances.

For medical devices, an expedited review system exists for orphan medical devices, innovative medical devices, and those under the integrated review of approval and new medical technology assessment. The MDA stipulates that orphan medical devices, designated by the head of MFDS for their special utility value for

rare diseases, can be reviewed and approved expeditiously. The Medical Device Industry Enhancement and Innovative Medical Device Support Act allows for advanced technological devices, significantly improving upon existing devices or treatments, to also receive expedited review. Regulations for the Integrated Operation of Medical Device Approvals and Assessments aim to shorten the market entry period by concurrently reviewing device approval, insurance benefit eligibility, and new medical technology assessments.

4.2 Regulatory Reliance

South Korea does not have a system in place for the expedited approval of pharmaceuticals that have been approved in other countries. However, there are regulations that allow for the submission of clinical trial data conducted abroad when applying for market approval (or notification, as applicable) of pharmaceuticals.

According to the PAA, foreign clinical trial data can be submitted in place of safety and efficacy data for Koreans during the domestic approval process. However, due to ethnic differences, it is challenging to only use foreign clinical data. Therefore, the law requires that simplified clinical trial data obtained from studies conducted specifically on Koreans be submitted together with the foreign clinical data.

Regarding medical devices, the MDA stipulates that clinical trial data related to the safety and efficacy of the medical devices must be submitted during the approval process. Submission of foreign data generated by institutions recognised for their reliability and determined to have been generated in accordance with medical device clinical trial management standards is allowed. While submission of bridging data is not explicitly mandatory for medical devices, the

MFDS may request additional data from domestic trials if it is deemed difficult to directly apply foreign clinical trial data.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

A manufacturing plant of pharmaceutical products is subject to an authorisation for manufacturing pharmaceuticals under the PAA, and a manufacturing plant of medical devices needs an authorisation for manufacturing medical devices under the MDA. The MFDS grants such authorisation. When a person, who intends to manufacture pharmaceuticals or medical devices, prepares and files the application for manufacturing authorisation and necessary documents with the local district of MFDS to which the manufacturer belongs, such local district MFDS reviews whether the applicant for manufacturing approval (in the case of a company, the representative) is qualified, whether all necessary documents are satisfied, and assesses whether the applicant has necessary facilities and labour force, and if appropriate, it grants authorisation. Once authorisation is granted, it will be valid without any other special renewal procedure unless grounds for revocation occur under the PAA or the MDA.

Of note, separate from MFDS's authority under PAA/MDA with regard to requirements for facilities and labour force, other licences/authorisations will be required for plant construction (such as those related to environment and safety).

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesale of pharmaceuticals is subject to authorisation from the head of Si/Gun/Gu (ie, the local government) in Korea. To obtain such authorisation, the applicant should meet qualifications and have a business place, warehouse and other facilities as prescribed by Presidential Decree of the PAA. The authorised wholesaler is in principle required to employ a pharmacist to manage the relevant tasks. Such authorised wholesaler can sell or acquire pharmaceuticals for sales purposes which comply with the standards for quality management of pharmaceuticals in distribution. There is no validity period for the authorisation of wholesale of pharmaceuticals.

For the wholesale of medical devices, the wholesaler should file a notification of distribution with the competent Special Self-Governing Mayor, Special Self-Governing Province Governor, or the head of a Si/Gun/Gu. Once such notification of distribution is accepted, the person can distribute medical devices and there is no period of validity for wholesale notification.

6.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals are classified into OTC drugs and prescription drugs under the PAA.

OTC drugs refer to any of the following drugs, which meet the standards determined and publicly notified by the Minister of Food and Drug Safety, following consultations with the Minister of Health and Welfare:

- a drug, the misuse or abuse of which is of little concern, and whose safety and efficacy

can be expected even when used without a prescription by a physician;

- a drug that may be used to treat a disease without a physician's or dentist's professional knowledge; and/or
- a drug which has a relatively small side effect on human bodies in light of their dosage form and pharmacological action.

Emergency drugs among the OTC drugs are used mainly for minor symptoms at the sole discretion of patients, and are publicly notified and prescribed by the Minister of Health and Welfare. Such emergency drugs can be purchased at places other than pharmacies. Conversely, prescription drugs mean drugs which are not OTC drugs and require a physician's prescription.

Meanwhile, orphan drugs mean either drugs used for the purposes of diagnosis or treatment of rare diseases under the Rare Disease Management Act or drugs with rare subject of application, whose alternative drug does not exist or whose safety or efficacy has been significantly improved compared to its alternative drug, which are designated by the Minister of Food and Drug Safety.

Other than the above, drugs essential for health and medical treatment, whose stable supply is difficult based only on market function, are designated and managed as national essential drugs.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The PAA and MDA are the primary laws governing the import and export of pharmaceuticals and medical devices, while the Customs Act and Integrated Public Announcement promulgated by the Ministry of Trade, Industry and Energy (MOTIE) pursuant to the Foreign Trade Act, apply the requirements of the PAA and MDA to the actual customs process.

In principle, pharmaceuticals and medical devices manufactured abroad are subject to the same regulations as those manufactured domestically. The importers of such products are responsible for obtaining the necessary licences from the MFDS, such as import business licences and marketing authorisation for particular products, and complying with all obligations under the PAA or MDA, such as quality testing. In addition to the above, importers also need to register overseas manufacturing facilities and undergo inspections of those facilities.

A manufacturing business licence and manufacturing authorisations for particular products are required for the manufacture of pharmaceuticals or medical devices, whether for domestic use or export. However, manufacturing authorisations for pharmaceuticals or medical devices that are only exported, and not sold or distributed domestically, are exempted from certain requirements and do not require renewal.

The MFDS regulates licences and authorisations for both pharmaceuticals and medical devices,

while the Korean Customs Service enforces the relevant regulations at the point of entry for imports.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Only those with an import business licence from the MFDS for pharmaceuticals or medical devices can act as their importer of record.

In order to receive an import business licence for either pharmaceuticals or medical devices, the entity applying for the licence must fulfil certain requirements, such as having the required storage facilities, quality testing facilities and equipment, and personnel such as import managers and safety managers. Additionally, local presence is required in order to hold an import business licence for pharmaceuticals and medical devices.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In principle, only entities with an import business licence and marketing authorisation for the particular imported product can import pharmaceuticals or medical devices into Korea.

Exceptions of varying degrees to this rule include imports for the treatment of rare diseases, emergency use, clinical trials, research and testing, and personal use.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

The Customs Act requires those who import products required by law to have approval, licence, labelling or fulfil other requirements for their importation to show proof of the fulfilment of such conditions to the head of the competent customs office, which for pharmaceuticals and medical devices are the requirements imposed

by either the PAA (for pharmaceuticals) or the MDA (for medical devices), see 7.1 **Governing Law for the Import and Export of Pharmaceuticals and Medical Devices** and Relevant Enforcement Bodies to 7.3 **Prior Authorisations for the Import of Pharmaceuticals and Medical Devices**.

Whether the imported product is subject to the regulations and requirements of either the PAA or MDA would be determined by whether the product satisfies the criteria for pharmaceuticals or medical devices as defined in the respective acts.

7.5 Trade Blocs and Free Trade Agreements

As of February 2025, Korea has entered into 22 economic partnership agreements and free trade agreements with other countries, all 22 of which (the RCEP and FTAs with Chile, Singapore, EFTA, ASEAN, India, the European Union, Peru, the United States, Türkiye, Australia, Canada, China, New Zealand, Vietnam, Colombia, MERCOSUR, the United Kingdom, RCEP, Israel, Cambodia, Indonesia and Philippines) are in force.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

The government's price control for pharmaceuticals is based on the relevant laws such as the National Health Insurance Act (NHIA), the Rules on the Standards of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Drugs. Also, the government's price control for medical devices is in accordance with NHIA, the Rules on the Standards

of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Activity and Medical Materials for Treatment, etc. The MOHW, the Health Insurance Review and Assessment Service (HIRA) and national healthcare insurance system (NHIS) control the price of pharmaceuticals and medical devices.

Prices for the majority of medical services provided and pharmaceuticals sold in Korea are reimbursed by the Korean NHIS, and most legal residents of Korea are insured by NHIS. NHIS classifies the items subject to reimbursement into the following categories: pharmaceutical products, therapeutic procedures, and treatment materials. Here, treatment materials refer to consumable medical devices used in therapeutic procedures.

If a medical service or a pharmaceutical product is covered by NHIS, a patient cannot be charged more than the co-payment amount corresponding to the maximum reimbursement price published by the MOHW. If a medical service or pharmaceutical is not covered by NHIS, the healthcare provider is free to determine the price of such product or service.

For pharmaceuticals and medical services to be reimbursed, the HIRA and the MOHW determine whether to reimburse the costs for medical services or pharmaceuticals after evaluating clinical efficacy, cost-effectiveness, and other factors.

Regarding medical devices covered by the NHIS, the device may be subject to its own maximum reimbursement price, or the cost of the medical device may be included in the maximum reimbursement price for the relevant medical service that utilises such a device.

8.2 Price Levels of Pharmaceuticals or Medical Devices

For drugs, foreign prices may be referenced in the negotiation of the drug's maximum reimbursement price. In general, the economic evaluation for pharmaceuticals takes precedence over such external price referencing in determining the price of drugs. Foreign prices have direct effect only when deciding the price of drugs whose economic evaluation can be exempted under relevant pricing regulations.

Meanwhile, in the case of pricing of medical devices (ie, pricing of the device or the medical service that utilises such a device), foreign prices are not referenced but the import price or the price of listed products with similar function are considered.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

A substantial part of the costs of pharmaceuticals and medical services (using medical devices) is covered by the national health insurance scheme. However, even when covered by the national health insurance scheme, the full amount is not paid by the health insurance, as the patient is responsible for the applicable co-pay amount.

Rules on the Standards of National Health Insurance Medical Benefits, and the Standards for Decision or Adjustment on Drugs define the items not subject to reimbursement. Such items include procedures, drugs, or treatment materials that are performed or used in cases where there is no hindrance to work or daily life, are not intended to improve essential bodily functions, or are preventative treatments not directly aimed at treating diseases or injuries.

There is a difference in the way pharmaceuticals and medical services are covered by health insurance. In the case of pharmaceuticals, products not listed on the reimbursement list are not covered by health insurance (positive-listing system). When a manufacturer or importer submits a request for reimbursement for a pharmaceutical product that has obtained marketing authorisation (MA), the product undergoes an evaluation of reimbursement appropriateness by HIRA. Subsequently, negotiations with the NHIS determine the maximum reimbursement amount. This process establishes the product's eligibility for health insurance coverage, the criteria for such eligibility, and the maximum reimbursement amount. Finally, the MOHW includes the product on the reimbursement list. However, in the case of medical services, the MOHW stipulates medical services not covered by health insurance (negative-listing system).

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Where drugs are concerned, it is the principle of the positive listing system to determine the eligibility for reimbursement and reimbursement amount on the basis of HTA (health technology assessment – ie, cost-utility analysis). In the case of pharmaceuticals for treatment of cancer or orphan diseases, however, economic evaluation may be omitted if certain criteria are met.

Meanwhile, for medical devices, the cost-effective analysis would play a minor role only to a limited extent in determining the eligibility for reimbursement and reimbursement amount.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

After the separation of prescribing and dispensing in 2000, only physicians can prescribe drugs in hospitals, and only pharmacists can dispense drugs in pharmacies (this applies to the case of outpatient only, and dispensing drugs in pharmacies within the hospital is possible for inpatients). In order to prevent the over-prescription of narcotic or psychotropic drugs such as propofol, monitoring of prescription details is performed through HIRA's big data management system.

Trends and Developments

Contributed by:

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Lee & Ko

Lee & Ko has become one of Korea's premier full-service law firms, widely recognised for its leadership and outstanding success in every area of legal practice. As has been confirmed in numerous reviews conducted by Korea's major media outlets, as well as ratings produced by international law firm rating services, Lee & Ko enjoys one of the highest levels of client satisfaction and a particularly excellent reputation

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SOUTH KOREA TRENDS AND DEVELOPMENTS

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Introduction

Patentees holding patent rights relating to pharmaceutical products often aim to extend their market exclusivity by obtaining Patent Term Extension (PTE) of patents covering their products. Conversely, generic companies seeking prompt market entry have a vested interest in opposing PTE.

Given these dynamics, the key points of dispute between patentees and generic companies are: (i) which patents are eligible for PTE (“*PTE eligibility*”) (ii) how long the term should be extended under PTE (“*PTE period*”) and (iii) what scope of rights should be granted during the extended patent term (“*PTE scope*”).

The Korean government has been attempting a statutory harmonisation with global standards while balancing innovation-fostering patent protection rights with the public interest served by lower-priced generic products. The PTE system, which emerged from these policy considerations, represents one of the most dynamic and constantly evolving areas of Korea’s patent policy.

For example, the Korean National Assembly recently passed a bill proposing to introduce additional requirements for PTE eligibility and the PTE period, and the Korean Intellectual Property Office (KIPO) is currently reviewing changes to the appellate system for rejected PTE requests.

This article examines the current status of Korea’s PTE system and the latest trends that patentees should keep in mind for a global IP strategic framework.

Overall Status of the Korean PTE System

Similar to policies in other areas of IP, patent offices worldwide are seeking to harmonise their PTE systems.

In Korea, KIPO introduced the so-called new substance-first approval requirement in 2013 as for PTE eligibility. This 2013 requirement is comparable to the notion of “*first commercialisation*” in the United States PTE policy and the European SPC systems. Under the amended Korean Patent Act (KPA) that will come into effect later this year, patentees should choose a single patent among multiple patents covering the approved pharmaceutical product, which is similar to the approach used in the United States PTE system.

Despite these amendments, however, there are still significant differences between the Korean PTE system and those of the United States and Europe with regard to the PTE period and the scope of the extended rights.

As for PTE period, in the leading Betmiga® case, the Korean Supreme Court ruled that the length of the PTE period under Article 89 of the KPA is “*the time period during which the patented invention could not be practiced*”. The Korean Supreme Court further defined the PTE period as the time period from the initiation of a marketing approval (MA) process (usually, the start date of clinical trials) or the patent registration date, whichever is later, to the MA date. This PTE period interpretation is akin to the definition under the Japanese PTE system. Despite this technical definitional similarity, however, the average length of PTE periods granted in Korea is much shorter than those in other jurisdictions, including Japan, because the KIPO takes a restrictive approach in calculating the PTE period. For PTE calculation purposes, only the periods during which clinical trial organisations and the Minis-

try of Food and Drug Safety were conducting related activities count toward the PTE period. In practice, the statutory PTE period – defined as *“the time period during which the patented invention could not be practiced”* will be determined according to the Public Notification on the Administration of the Patent Term Extension (the *“Public Notification”*) from KIPO rather than the Supreme Court’s interpretation of the statute.

As for PTE scope, in the leading Vesicare® case, the Korean Supreme Court held that the scope of rights should be determined by focusing on the sameness of the active ingredient, the medicinal use, and therapeutic effects. Based on these standards, the court found that the PTE scope of a compound patent covers different salt forms of the approved product. This ruling on the enforceable scope regarding API is similar to the enforceable scope of patent right by PTE/SPC in the United States and Europe. The Korean system differs significantly from its United States and European counterparts, however, in that the majority view takes the position that the PTE right should be limited to the first approved use (indications) as well as the approved API. That is, in the United States and Europe, any medicinal uses approved for the product at issue without any limitations thereon can be protected by the patent extended by PTE/SPC.

Recent Trends of Korea’s PTE System

PTE eligibility

First, according to the amended KPA, the single-patent selection requirement, whereby only one patent among multiple patents covering an approved product may receive PTE, will be implemented in the second half of 2025. According to the new statute, applicants (patentees) should select only one patent to benefit from PTE among the patents that are eligible for PTE since the related marketing approval is granted

after the implementation of the amended KPA. Accordingly, patentees should carefully determine which patents should be extended.

Second, regarding PTE eligibility, a recent Supreme Court decision in the Plegridy® case (wherein the API of the approved drug product at issue is a pegylated drug) highlights another key issue. The Supreme Court ruled that a pegylated drug may not be eligible for PTE as long as the active moiety is found to be the same (having the same medicinal use/effect despite different PK profiles, such as long retention time of drug in blood due to pegylation) as the earlier approved drug (a non-pegylated form).

Although the *“new substance-first approval”* requirement is similar to the *“first commercialization”* requirement in the United States and Europe, the Korean Supreme Court ruling in the Plegridy® case suggests that the PTE eligibility for pegylated drugs will be different from the United States and Europe where a pegylated product is generally considered a new active substance.

Under this Korean Supreme Court interpretation, the KIPO is expected to reject PTE applications based on pegylated forms of biologics. In fact, we are already seeing cases in Korea where the KIPO has rejected PTE applications under the Korean Supreme Court’s reasoning.

Therefore, patentees who own patents directed to pegylated pharmaceutical products need to show different medicinal uses/effects of their pegylated drugs from the earlier approved unmodified forms if they aim to secure PTE of their patents.

Although the above Supreme Court ruling implies that a pegylated drug is not eligible for

PTE, pegylation may result in a clearly different medicinal use/effect in some cases. In these specific cases, patentees may still argue for new active substance status even in the face of the Korean Supreme Court ruling. The Korean Supreme Court's decision was grounded on the foundation that the pegylated drug in question merely offered a different pharmacokinetic profile while maintaining the same medicinal use.

PTE period

The KIPO's calculation of the PTE period based on its Public Notification rules and regulations is notably restrictive and results in much shorter PTE periods compared to other jurisdictions.

It is important to note, however, that it has not always been calculated that way. Earlier KIPO public notifications allowed for a wider range of PTE periods, and, through a string of amendments to its public notifications, the KIPO has established a practice of increasingly limiting PTE periods.

Currently, in the Galvus® PTE case, the disputed issues are closely related to the KIPO's amendment to the calculation method of the PTE period. In that case, the PTE of the patent at issue was granted under the KIPO's public notification, issued in 2000 ("*KIPO's Former Public Notification*"), and the granted PTE period is being hotly contested.

Since the PTE period under the KIPO's Former Public Notification was substantially the same as that of the Japanese PTE system, the granted PTE period was longer than the period allowable under the current Public Notification. This PTE disparity was what prompted some generic companies to challenge the validity of the PTE of the Galvus® patent.

After more than eight years of twists and turns, the case is now pending before the Korean Supreme Court. Since the IP High Court found all periods granted for PTE to be valid, if the Supreme Court upholds this appellate decision, the KIPO's practice on PTE period calculation and the relevant provisions of the Public Notification may be amended going forward to expand the allowable time periods for PTE purposes.

Such a move will be welcome news for global patent owners with Korean patent interests.

On a separate but related issue regarding Korea's PTE period, according to the amended Patent Act, from the second half of 2025, Korea, like the United States, will be subject to a 14-year cap if the term of the extended patent exceeds 14 years from the date of approval of the drug product. The requirement for patentees to select only one patent to file a PTE application will be implemented in conjunction with this 14-year cap.

If the expected PTE term of each patent is the same as each other and is not limited by the 14-year cap, a longer exclusivity may be expected by the PTE of a later patent. In general practice, formulation or crystalline-form patents have a later term expiry date. Like many other jurisdictions around the world, the substance/compound patent is generally the strongest in terms of validity of rights.

Thus, in connection with the above two requirements, which will be newly implemented from the second half of 2025, pharmaceutical patent holders in Korea should comprehensively consider various factors from the perspective of pharmaceutical patent protection, including the degree of strength of each patent right that

can be extended and the length of the possible extension period, when pursuing a PTE application.

PTE Scope (enforceable scope of patent right during extended patent term)

The scope of rights during the extended patent term by PTE is stipulated by Article 95 of the KPA. It provides that the PTE scope is limited to only practising the approved product for its approved medicinal uses.

In this regard, the Korean Supreme Court clarified in the Vesicare® case that the PTE scope should be determined by focusing on the active ingredient, its medicinal use and therapeutic effect of the approved product. The Korean Supreme Court then found that any salt-modified forms can be covered by the compound patent extended based on the MA of the approved product at issue and where the API is a different salt.

Although the Supreme Court provided some clarity about how to assess the sameness of the active ingredients, uncertainties remain regarding how to interpret “the approved use”. These uncertainties are currently stirring controversy in Korea.

The following key points are worth pondering regarding “the approved use”: (i) whether the use should be the first approved uses; and (ii) whether the use means the specific approved indications or general concept of the medicinal use.

As at the time of writing, the latter is being disputed and tested in many cases, but patentees need to raise the former issue before moving to the latter one.

With respect to the former issue (referred to as “Issue 1”), although the majority view in Korea is that the PTE right should be limited by the first approved uses as well as the first approved API, the language of Article 95 of the KPA does not clearly limit the use to be that approved first for the product. The statute merely states that the scope of patent right is limited to practising the approved product for its approved uses. Historically, the PTE system was first established in the United States, and the relevant provision in 35 USC §156 (b)(1) also states that the scope of rights is limited to any approved use.

The limitation to approved medicinal uses was introduced in line with the original purpose of the PTE, which was to extend patent rights directed to a pharmaceutical product.

No matter how broad the scope of the patent, the scope of rights during the patent term extended by the PTE was limited to the approved API, and there was no rational reason to further narrow this limited scope based on the first approved medicinal use.

Accordingly, patentees may need to raise questions regarding Issue 1 and the proper interpretation and purpose of Article 95 of the KPA in terms of PTE history.

Regarding the latter issue (referred to as “Issue 2”), one common strategy taken by generic companies had been to change the API of the patented product, such as changing the salt, to claim non-infringement of the PTE scope. With the Supreme Court decision in the Betmiga® case blocking this strategy, local generics in Korea are turning to another strategy by claiming differences in approved medicinal use.

Currently, hundreds of scope confirmation action cases against a product patent extended based on the approval of the K-cab® product are pending before the IP High Court. In the first instance, the IPTAB ruled in favour of the patentee, and the IP High Court also ruled in support of IPTAB's decision. Specifically, the IPTAB held that:

- although the specific indications asserted by the generics are different from the first-approved indications of the patented drug, all of them are based on the same pharmacological mechanism, which has been known before the patent at issue;
- the PTE scope is limited to practising the invention directed to the approved product, which does not mean practising exactly the same pharmaceutical product as the approved product; and
- the asserted indications are deemed substantially identical to the first-approved indications in terms of medicinal use and effect.

Implications of the PTE Trends in Korea for Pharmaceutical Patent Holders

In the important field of PTEs, depending on the interests at stake, there will inevitably be arguments between patentees favouring broad interpretation of rights and generic companies advocating for narrow constructions.

Due to the competing policy aspects of the PTE system, the Korean PTE system is rapidly changing and creating an environment where legal disputes are constantly arising in connection with ambiguities in Korea's interpretation of the law.

While the direction of some previous Korean amendments may be favourable to patentees, the recent amendments to the KPA introduce more restrictive requirements for granting PTEs to patentees in Korea. However, further discussions regarding amendments to the Korean PTE system are ongoing. These evolving trends in the PTE system signify that the direction of the improvements or revisions is not set in stone and Korea remains open to hearing various views.

Therefore, pharmaceutical patent holders and the stakeholders in the pharmaceutical industry are encouraged to examine proactively whether the current and forthcoming amendments to the PTE system are moving in the right direction. In the end, a balanced IP and legal policy approach in Korea should be in line with the purpose and intent of the PTE system.

SPAIN



Law and Practice

Contributed by:

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Faus Moliner

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Faus Moliner is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. Faus Mo-

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices Key Legislation

The following legislation governs medicinal products and medical devices in Spain.

- General pharmaceutical legislation:
 - (a) Law 14/1986 (the “*General Law on Public Health*”)
 - (b) Law 16/2003, of 28 May, on the cohesion and quality of the National Health System; and
 - (c) Royal Legislative Decree 1/2015, which approves the consolidated version of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices.
- The authorisation, registration and distribution of medicinal products:
 - (a) Royal Decree 1345/2007, which regulates the authorisation, registry and dispensation conditions of medicinal products for human use prepared industrially for human use;
 - (a) Royal Decree 477/2014, which regulates the authorisation of medicinal products for advanced therapies not prepared industrially;
 - (b) Royal Decree 824/2010 on pharmaceutical companies, manufacturers of active ingredients, foreign trade of medicinal products and investigational medicinal products;
 - (c) Royal Decree 1785/2000 on the intra-community trade of medicinal products for human use; and
 - (d) Royal Decree 782/2013, which regulates the distribution of medicinal products.
- Medical devices:
 - (a) Royal Decree 192/2023, which regulates medical devices;
 - (b) Royal Decree 1616/2009 on active implantable medical devices (partially repealed); and
 - (c) Royal Decree 1662/2000 on in vitro diagnostic medical devices.
- Clinical studies, pharmacovigilance and access to medicinal products in special situations:
 - (a) Royal Decree 1090/2015, which regulates clinical trials, ethics committees for research on medicinal products and the Spanish registry for clinical trials;
 - (b) Royal Decree 967/2020, which regulates observational studies of medicinal prod-

- ucts for human use;
- (c) Royal Decree 577/2013, which regulates pharmacovigilance in relation to medicinal products for human use;
- (d) Law 14/2007 on biomedical research; and
- (e) Royal Decree 1015/2009 on access to medicinal products in special situations.
- Price, reimbursement and promotion:
 - (a) Royal Decree 271/1990, which regulates the prices of medicinal products reimbursed by the National Health System;
 - (b) Royal Decree 177/2014, which regulates the reference price system and homogeneous groups of medicinal products in the National Health System and information on the reimbursement and prices of medicinal products and medical devices;
 - (c) Royal Decree 823/2008, which establishes the margins, deductions and discounts corresponding to the distribution and dispensation of medicinal products for human use;
 - (d) Royal Decree 1416/1994, which regulates the advertising of medicinal products, and provisions established in Articles 38–40 of Royal Decree 1594/2009, which regulates medical devices (partially repealed by Royal Decree 192/2023); and
 - (e) Royal Decree 870/2013, which regulates online sales to the public of non-prescription medicinal products.

Regional authorities (Spain is divided into 17 autonomous regions) may also enact and enforce regulations that are applicable at their level and within their scope of competence (eg, pharmacy offices or healthcare provision).

Furthermore, there is a self-regulatory framework established by trade associations (eg, Farmaindustria, Fenin and Aeseg) that enforce their own codes of practice. These codes of practice have

a binding effect on their members and primarily govern advertising and interactions with healthcare organisations, healthcare professionals and patients' organisations. Although adherence to these trade associations or their codes of practice is not mandatory, authorities often reference them as a reflection of the current social reality and take them into account in practice.

Regulatory Authorities

At the national level, the main regulatory authorities responsible for applying and enforcing regulations on medicinal products and medical devices are the Ministry of Health (MOH) and the Spanish Agency for Medicines and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios* AEMPS). Among other functions, the MOH is responsible for drafting and implementing the rules on pricing and reimbursement of medicinal products. The AEMPS is responsible for the issuance of marketing authorisations (MAs) for medicinal products in Spain, which includes overseeing the authorisation process through national, mutual recognition and/or decentralised procedures, amongst other matters.

At the regional level, regional regulatory authorities enforce regulations in the above-mentioned areas and enact rules within their scope of competence. Moreover, regions participate in the MOH's committee responsible for evaluating pricing and reimbursement applications for medicinal products. High-level co-ordination among all regional healthcare systems mainly occurs through the National Health Service (NHS) Interterritorial Council, which comprises the national Minister of Health and the 17 regional ministers of health.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of regulatory bodies may be challenged through both administrative appeal and judicial review. In some cases, the administrative appeal is mandatory, and it must be filed within one month from receiving notice of the decision.

After administrative proceedings, the interested party may go to court within two months of receiving notice of the decision; if no notice is received, the deadline is six months from the presumed rejection date.

1.3 Different Categories of Pharmaceuticals and Medical Devices Medicinal Products

Article 8.1 of Royal Legislative Decree 1/2015 distinguishes between four types of medicinal products:

- medicinal products for human and veterinary use that are industrially manufactured, or in the manufacture of which an industrial process is involved;
- magistral formulae;
- official preparations; and
- special medicinal products (eg, vaccines and other biological medicinal products, advanced therapy medicinal products, radiopharmaceuticals, homeopathic medicinal products or medicinal gases).

In relation to prescription and dispensing conditions, Royal Legislative Decree 1/2015 contemplates the same classification set forth in Article 70 of Directive 2001/83/EC.

Medical Devices

Medical devices are classified into four classes (III, IIb, IIa and I), as are in vitro diagnostic medi-

cal devices (A, B, C and D). Devices are ranked considering their level of invasiveness according to Regulation (EU) No 2017/745 on medical devices and Regulation (EU) No 2017/746 on in vitro diagnostic medical devices. Additionally, medical devices can be categorised based on their intended purpose, following the classifications outlined in European regulations.

2. Clinical Trials

2.1 Regulation of Clinical Trials

In Spain, clinical trials with medicinal products are mainly regulated by Royal Legislative Decree 1/2015 and Royal Decree 1090/2015, whereas clinical investigations with medical devices are governed by Royal Decree 192/2023.

Moreover, the AEMPS has issued a document of instructions for the conduct of clinical trials with medicinal products in Spain and guidelines for conducting clinical investigations with medical devices, both of which are regularly updated.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial Medicinal Products

To initiate a clinical trial with medicinal products, the following will be required:

- prior authorisation by the AEMPS, after a scientific and ethical evaluation in accordance with Regulation (EU) No 536/2014;
- a favourable opinion issued by an ethics committee for research on medicinal products (*comité de ética de la investigación con medicamentos* CEIm) in Spain; and
- a written agreement between the sponsor and the sites (clinical trial agreement; CTA).

The sponsor may select any CEIm within Spain to review the study and issue a favourable opinion. With respect to the CTA, there is no standardised template for all Spanish sites. In practice, each hospital/region usually has its own template. The sponsor may sign the CTA before obtaining the required authorisations (Article 17 of Royal Decree 1090/2015). In such cases, the CTA will become effective once both AEMPS and CEIm approvals are in place.

Medical Devices

Two different situations can be distinguished for clinical investigations involving medical devices:

- clinical investigations involving medical devices without European Conformity (*Conformité Européenne* CE) for conformity assessment, as well as those with CE marking used outside the scope of their intended purpose, require a favourable CEIm opinion, AEMPS approval and a written agreement between the sponsor and the sites; and
- clinical investigations involving medical devices that have CE marking and are used in accordance with their instructions for use, and within the approved intended purpose when the CE marking was issued, require a favourable CEIm opinion and a written agreement between the sponsor and the sites – AEMPS approval is exempted.

In the first situation, the sponsor must submit the documentation described in Chapter II of Annex 15 of Regulation (EU) No 2017/745. The AEMPS shall evaluate the documentation submitted and decide to either authorise or reject the clinical investigation.

Additionally, if patients will undergo procedures beyond those applied under normal conditions of use, and these procedures are invasive or

burdensome, the sponsor shall notify this to the AEMPS through the database for clinical investigations involving CE-marked medical devices (NEOPS).

2.3 Public Availability of the Conduct of a Clinical Trial

The Spanish Registry of Clinical Studies (*Registro Español de Estudios Clínicos* REec) is a public database containing information on all clinical trials with medicinal products authorised by the AEMPS in Spain. It can be accessed through the AEMPS website.

The sponsor must publish the results of the clinical trial, whether positive or negative, preferably in scientific journals before disclosure to the general public, as well as in the REec.

For medical devices, there is currently no publicly available database specific for Spain.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The decentralisation of clinical trials (including the use of online tools for monitoring purposes) began with the COVID-19 pandemic, when the AEMPS amended its document of instructions to introduce exceptional measures regarding:

- patient visits for ongoing clinical trials during the pandemic;
- access to trial medicinal products;
- the transfer of patients between sites; and
- the procedure for obtaining patients' informed consent.

In view of the positive experience acquired, it has been considered convenient to facilitate the use of these decentralised aspects in clinical trials beyond the COVID-19 pandemic period. In November 2024, the AEMPS published a guide

for the implementation of decentralised elements in clinical trials, providing a series of recommendations on procedures performed with online tools to support clinical trials, such as online recruitment, electronic informed consent and telemedicine for remote monitoring. The use of these online tools is subject to appropriate safeguards to ensure participant safety and protect their rights. For example, the patient information sheet must clearly detail any decentralised elements, identify potential additional risks, and specify the measures in place to protect patient privacy.

2.5 Use of Data Resulting From Clinical Trials

Provided that it is not aggregated or anonymised, the data resulting from clinical trials is recognised as a special category of personal data and is therefore subject to restrictive guarantees by the personal data protection regulations applicable in the EU (ie, the General Data Protection Regulation; GDPR) and Spain (ie, Law 3/2018 on the Protection of Personal Data).

Generally, personal data resulting from clinical trials may not be transferred to a third party, or an affiliate, in a country that does not provide an adequate level of protection without complying with the provisions of Chapter V of the GDPR. In such cases, the sponsor must adopt one of the safeguards set out in Article 46 of the GDPR.

In those cases where there is an intention to use participants' data for future research or outside the protocol of the clinical trial (secondary use), data processing must be grounded in one of the lawful bases set forth in the GDPR. Additional Disposition 17 of Law 3/2018 has established specific provisions for secondary use of health data. In this regard, the re-use of data from previous studies is considered lawful and compatible

with clinical investigation purposes, provided that the new research is related to the scientific area of the original study for which consent was obtained. In such cases, the site or the sponsor must publish the information established by Article 13 of the GDPR in an easily accessible place on its website and notify the data subjects. In addition, a prior favourable report from a CEIm is required.

2.6 Databases Containing Personal or Sensitive Data

Databases containing personal data (eg, health data) are subject to the GDPR and Law 3/2018. In this regard, it is necessary to obtain the patient's informed consent prior to entering their data in the database, or to rely on another lawful basis for the processing of the data (Article 6.1 of the GDPR), as well as a valid exception to the prohibition of processing health data (Article 9.2 of the GDPR).

It is important to note that if a database involves the collection of information on medicinal products prescribed to patients, it may fall under the scope of observational studies involving medicinal products, as regulated by Royal Decree 967/2020, and thus be subject to the requirements established therein.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Products are classified as medicinal products or medical devices on a case-by-case basis.

According to Directive 2001/83/EC and Royal Legislative Decree 1/2015, a product shall be

classified as a medicinal product if it achieves its intended effect by means of a pharmacological, immunological or metabolic action (medicinal product by function), or if it is presented as having therapeutic properties typical of medicinal products (medicinal product by presentation). These are alternative conditions, meaning that a given substance or combination will be considered a medicinal product if either or both definitions apply to it.

The AEMPS is responsible for attributing the status of a medicinal product to a substance in Spain. This can occur within the framework of a national marketing procedure or, subsequently, within the scope of the market surveillance functions of the AEMPS.

However, in the centralised procedure, it is the European Medicines Agency (EMA) that determines whether a substance is a medicinal product. Moreover, the EMA has the power to intervene in disputes arising during decentralised authorisation procedures.

The AEMPS is also responsible for the qualification and classification of medical devices in Spain.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The granting of an MA for biologic products is governed by the same obligations as for other medicinal products. Biosimilar medicinal products have to demonstrate comparability in efficacy, safety and quality through an abbreviated clinical and non-clinical development programme. Biological and biosimilar medicinal products developed by means of biotechnological processes, as described in Regulation (EU) No 726/2004, must be authorised by the European Commission through the centralised pro-

cedure. Other biological and biosimilar medicinal products may optionally undergo the centralised procedure or decentralised/national procedures.

Advanced therapy medicinal products (which can also be biologic products) that are non-industrially manufactured are regulated by Royal Decree 477/2014, which sets out that their individual use and manufacture must be authorised by the AEMPS on a case-by-case basis.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices Medicinal Products

The MA of a medicinal product is valid for an initial period of five years. The marketing authorisation holder (MAH) may apply for MA renewal, pursuant to Article 27 of Royal Decree 1345/2007, at least nine months before expiration.

Once renewed, the MA will be valid for an unlimited period, unless the AEMPS requires an additional five-year renewal based on duly justified pharmacovigilance-related reasons. An MA shall be revoked if the product it refers to is not marketed for three consecutive years (ie, sunset clause).

Once the MA is granted, Royal Decree 1345/2007 imposes an obligation on the MAH to keep the market duly supplied. In practice, each October the MAH shall declare whether they intend to market the product during the following year. If they do not do so, they will be deemed to have requested a suspension of the validity of the MA.

Royal Decree 1345/2007 also empowers the AEMPS to keep MAs in force for reasons of public health interest, such as the creation of a treatment gap, either in the market in general or in the pharmaceutical provision of the NHS.

This could contravene the provisions of Directive 2001/83/EC, which allows marketing cessation if notified two months in advance. In practice, AEMPS has adopted a rather strict position on this matter and is taking actions against companies that cease supplies or that are not able to meet market demand if they cause a therapeutic gap.

Medical Devices

The certificate of conformity for medical devices issued by the notified bodies is valid for a maximum of five years, in line with provisions set out at the EU level. The validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment conducted in accordance with the applicable conformity assessment procedures.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Medicinal Products

The AEMPS is in charge of granting MAs in Spain, which are regulated by Royal Decree 1345/2007. Some provisions of the Royal Decree also affect medicinal products authorised by the European Commission pursuant to the centralised procedure.

The AEMPS shall authorise a specific product if it:

- fulfils the established quality requirements;
- is safe under normal conditions of use;
- is effective in the therapeutic indications;
- is correctly identified; and
- provides the patient with the necessary information.

The positive therapeutic effects of the medicinal product shall be assessed from a risk-benefit perspective.

The key stages of the authorisation procedure are as follows:

- submission of the application to the AEMPS;
- validation and acceptance of the submission;
- issuance of the evaluation report; and
- resolution of the application and granting, where appropriate, of the MA.

The maximum period to notify the applicant about the resolution of the authorisation procedure is 210 calendar days.

The main requirements for the different types of variations of MAs of medicinal products (ie, types IA, IB and II, and extensions) are regulated in Royal Decree 1345/2007.

Applications for variations must be submitted to the AEMPS, which has 30 days to approve or deny type IA and type IB variations, and 60 days for type II variations.

Transfers of MAs require prior authorisation by the AEMPS. The application is to be conducted through the RAEFAR platform, where the data and documentation supporting the proposed transfer must be uploaded.

Medical Devices

Medical devices are divided into four classes (III, IIb, IIa and I) depending on the risk posed by the device, which is mainly determined according to its level of invasiveness, the part of the body it is in contact with and the duration of such contact, according to the classification rules of Annex VIII of Regulation (EU) No 2017/75. In vitro diagnostic medical devices can also be classified into

four classes (A, B, C, D), taking into account the intended purpose of the devices and their inherent risks, in light of the classification rules in Annex VIII of Regulation (EU) No 2017/746.

Except for custom-made devices, medical devices must bear the CE marking to be placed on the market in Spain, which provides evidence of the device's conformity with the applicable requirements. The evaluation and variation approval of medical devices are governed at the EU level in accordance with Regulation (EU) 2017/745.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Medicinal Products

Spain has two national exemption schemes, implemented under Article 5(1) of Directive 2001/83, which permit the importation of and patient access to medicinal products that do not have a valid MA in Spain – the so-called compassionate use and foreign use of medicinal products – both of which are regulated under Royal Decree 1015/2009 on access to medicinal products in special situations.

Compassionate use is allowed for patients with serious or life-threatening conditions when no authorised and commercialised alternatives are available; in such cases, the medicinal product must either be subject to an MA application or be part of a clinical trial. In practice, the AEMPS takes the view that, when a medicinal product already has a valid MA and is commercialised in Spain, no compassionate use programme can be opened for indications under investigation. This may raise issues in practice if companies wish to offer units of the commercialised product to be used for such unauthorised indication free of charge. Meanwhile, the foreign use regime enables the import of medicinal products

approved in other countries but not yet authorised in Spain.

Both the compassionate use and the foreign use regimes require prior approval from the AEMPS, which manages these programmes with high efficiency through its website for medicines in special situations (*medicamentos en situaciones especiales* MSE), allowing physician and healthcare centres to submit requests for individual or group patient access. Furthermore, under Spanish law, such uses are carried out under the exclusive responsibility of the physician and require prior informed consent from the patient or their legal representative, a clinical report justifying the need for the treatment and approval from the healthcare centre where it will be administered. The price of the product concerned is fixed by the importer, normally after negotiation with the pharmacy service of the healthcare centre. In compassionate use cases, the AEMPS, hospitals and regional authorities frequently put pressure on the company to supply the product free of charge. However, for the time being, Spanish law does not require that the supply be free of charge.

Finally, off-label use of medicinal products is accepted when there are no authorised alternatives for the patient. Off-label use does not require AEMPS approval and may be accomplished under the healthcare provider's authority.

Medical Devices

Medical devices without CE marking, and those used outside of a clinical investigation or for conditions not included in the instructions for use, may be permitted under a compassionate use programme in accordance with the conditions established in Circular 7/2004 issued by the AEMPS. According to this Circular, the compassionate use of medical devices is car-

ried out under the exclusive responsibility of the physician and requires prior informed consent from the patient or their legal representative, a clinical report justifying the need for the treatment, approval from the healthcare centre where it will be administered and authorisation from the AEMPS.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Medicinal Products

Royal Decree 577/2013 imposes the following main pharmacovigilance obligations on MAHs:

- respect the good practices on pharmacovigilance published by the AEMPS;
- have an adequate pharmacovigilance system;
- have a suitably qualified person responsible for pharmacovigilance in both the EU and Spain;
- submit periodic safety reports to the EMA;
- have a risk management system for each medicinal product;
- notify and record suspected adverse reactions;
- monitor scientific literature worldwide;
- carry out post-authorisation studies of efficacy and safety; and
- perform a continuous evaluation of the risk-benefit parameters of the medicinal product.

The MAH shall conduct the post-authorisation efficacy studies required by member states or the European Commission in the following circumstances:

- as a condition of the MA, where questions about the efficacy of the medicinal product arise that can only be resolved after the product has been placed on the market; and

- subsequent to the granting of an MA, where knowledge of the disease or clinical methodology indicates that previous assessments of efficacy may need to be significantly revised.

Products subject to additional monitoring requirements must include a black inverted triangle in their package leaflet and data sheet, accompanied by the sentence *“this medicinal product is subject to additional monitoring”*.

Medical Devices

Manufacturers, authorised representatives and importers or distributors of medical devices must notify the AEMPS of:

- any malfunction or alteration of the characteristics of the device, as well as any inadequacy in the labelling or instructions for use that could lead to death or serious damage to health; and
- any reason of a technical or health-related nature linked to the characteristics or performance of a device that has led the manufacturer to take systematic action on devices of the same type.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Medicinal Products

Royal Decree 1345/2007 establishes the confidentiality/transparency regime that the AEMPS must follow in MA procedures for new medicinal products. Article 15 of Royal Decree 1345/2007 guarantees the absolute confidentiality of MA applications and the expert reports attached to such applications.

Royal Decree 1345/2007 also requires that the AEMPS must have a public database with information on authorised medicinal products

in Spain. This database must include the evaluation report issued by the AEMPS during the authorisation procedure (or a link to the one issued by the EMA), as well as the summary of product characteristics (SmPC), the patient leaflet and any other relevant information (risk management of the product, usage restrictions, post-authorisation studies, etc).

All this information is included in a publicly accessible online database called CIMA (*Centro de Información de Medicamentos* Drug Information Centre), which incorporates all information regarding medicinal products authorised in Spain (through both the national and centralised procedures), as well as those whose MA has been revoked or temporarily suspended. This database does not display information on medicinal products with pending MA decisions or MA applications rejected by the AEMPS.

It is important to note that the activity of the AEMPS is subject to the provisions of Law 19/2013 on transparency and access to public information. This law states that any interested party may submit requests for access to public information. Based on this regulation, it is possible to request that the AEMPS report on the number of pending MA applications for a specific active substance.

Based on the authors' experience with such requests, AEMPS provides information regarding the number of pending MA applications for a given active substance, the submission date of such application, the validation date, the pharmaceutical form, the registration status and the anatomical therapeutic chemical (ATC) code. However, the AEMPS does not disclose details regarding the name of the medicinal product or the applicant company, arguing that this information is confidential and that its disclosure

could affect the economic and commercial interests of the applicants, as it forms part of their regulatory strategy.

The same rationale applies to requests regarding MAs that have been rejected by the AEMPS. The names of medicinal products whose MAs have been denied, as well as the name of the applicant company, remain confidential.

Medical Devices

Finally, concerning medical devices, the AEMPS does not maintain a public database of all medical devices marketed in Spain. The AEMPS only publishes three specific lists of medical devices, indicating the date of notification, the trade name, the composition, the manufacturer and the distributor. These lists refer to:

- filler implants used for plastic, reconstructive and aesthetic purposes with CE marking marketed in Spain;
- medical devices considered platelet-rich plasma collection systems; and
- medical devices that were specifically used during COVID-19 and were found by the AEMPS to be non-compliant with regulations while on the market.

Additionally, Royal Decree 192/2023 created a registry for medical device distributors, requiring companies engaged in distribution activities to register. However, this registry is not yet operational. This Royal Decree also created the AEMPS Marketing Registry, where all medical devices placed on the market, except class I devices, must be registered. This registry is currently only operational for economic operators and is not public.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

Fast-track registration routes are available for AEMPS-listed strategic medicinal products. While not explicitly established by law, these mechanisms have been implemented in practice by the AEMPS. The AEMPS regularly publishes and updates the strategic medicinal products list on its website, which includes medicinal products that meet two key criteria: criticality (ie, importance of the therapeutic indication) and vulnerability (ie, availability of alternative treatments).

The list of strategic medicinal products includes clinically essential but under-represented treatments in Spain, particularly those containing World Health Organization (WHO) essential active ingredients and those selected by the Food and Drug Administration (FDA). It also includes medicinal products for which cancellation or suspension requests have been denied due to their critical healthcare impact, as well as those authorised through the mutual recognition procedure to address supply shortages.

Additionally, the list includes vulnerable medicinal products essential for national clinical practice. Products from the European List of Critical Medicinal Products that meet Spain's national criteria are also considered, along with those that have a high market concentration (over 70% share) and are manufactured nationally. Medicinal products still under market protection are excluded, as their availability is guaranteed through other mechanisms.

There are no fast-track registration routes in place for medical devices.

4.2 Regulatory Reliance

Spain embraces regulatory reliance, particularly within the European Medicines Regulatory Network. The AEMPS operates within the EMA-coordinated network, contributing to centralised and mutual recognition procedures for MAs.

Furthermore, the AEMPS adheres to the mutual recognition agreements (MRAs) established between the EU and third-country authorities concerning good manufacturing practice (GMP) inspections and batch certification for human and veterinary medicinal products. In this context, the AEMPS regularly publishes communications detailing the procedures to be followed in Spain in alignment with the MRAs.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices Medicinal Products

Any manufacturer or importer of medicinal products, and those involved in processes such as fractionation, packaging and presentation for sale, must be authorised by the AEMPS (Article 63 of Royal Legislative Decree 1/2015). This authorisation is also required if the medicinal product is for export only. To obtain the authorisation, the manufacturer must:

- apply to the AEMPS through the website of the Spanish Agency for Medicines and Health Products (*Agencia Española de Medicamentos y Productos Sanitarios* LABOFAR), specifying the medicinal products and pharmaceutical forms to be manufactured or imported,

as well as the location and facilities where the manufacturing or control will occur;

- have suitable premises and technical and control equipment for the activity intended to be carried out; and
- have a technical director, manufacturing manager and quality control manager with sufficient qualifications.

The AEMPS will verify that the application meets the formal requirements within ten days and conduct an inspection at the facilities. The AEMPS will then issue the authorisation resolution, notifying the autonomous regions. The maximum time for notification of the resolution is 90 days from the receipt of the application. The authorisation is valid indefinitely, unless revoked.

Medical Devices

Companies engaged in the manufacture, importation, grouping or sterilisation of medical devices, as well as the facilities where these activities are carried out, require a prior operating licence from the AEMPS.

The AEMPS will review the submitted application and notify its decision within three months from the application date. Operating licences might be refused, suspended or revoked if the documentation provided or inspection reports do not guarantee that the appropriate facilities, means, procedures and personnel are in place. Operating licences are valid for a maximum of five years.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medicinal Products

In Spain, the distribution of medicinal products can be carried out by entities holding a wholesale distribution authorisation (WDA), or directly by the MAH or its local representative (LR). Notably, an LR that only purchases (acquires) and sells (invoices) the product, without physically handling it, is not required to hold a WDA. This distinction is important for two reasons. First, it highlights the priorities of the AEMPS regarding WDAs. AEMPS is primarily concerned with the physical flow of products and ensuring that any entity handling them holds the necessary regulatory permits. It places less emphasis on financial transactions, such as product ownership transfer and invoicing. Second, in practice, foreign MAHs often rely on an LR that does not physically handle the product.

Typically, the MAH appoints a Spanish company within its group as the LR, entrusting it with all responsibilities related to marketing the product, including invoicing hospitals. At the same time, the LR contracts a third-party logistics provider (3PL) to receive and physically deliver the product to hospitals. In such cases, ownership of the product usually transfers to the LR (from the MAH or another authorised entity) just before hospital delivery, allowing the LR to invoice under its VAT number. From a regulatory perspective, the 3PL must hold a WDA since it physically handles the product, whereas the LR does not require one.

Wholesalers and contract warehouses must obtain a WDA from the health authority of the autonomous region where the warehouse is

located. This authorisation will specify the distribution activities the entity is authorised to perform, in accordance with the European format. Additionally, these entities must notify the AEMPS before starting their activities.

To grant this WDA, the regional authority will verify that such entities have the appropriate personnel, material and operational means to guarantee the correct development of their activity, as well as the capability to provide a quality service. In addition, a physical inspection of the premises will be carried out. The regional authority must notify its decision within 90 days of receiving the application. If no decision is made within this period, the applicant can consider their application approved.

The authorisation is valid indefinitely. However, it may be suspended in the following circumstances:

- if the entity does not fully, effectively and continuously carry out all the distribution activities for which it has been authorised one year after the authorisation is granted; or
- when the entity no longer meets the requirements that were considered to grant such authorisation or fails to comply with the legally established obligations.

Medical Devices

Distributors and other entities engaged in the sale of medical devices must submit prior notification of the start of their activity to the health authority of the autonomous region where the company's registered office is located. They must also notify the health authority of the region where the warehouses are located, if they are in different regions. The notification must include:

- identification of the distribution establishment;
- the types of products it distributes or sells; and
- identification and qualification of the responsible technician, where applicable.

In addition, the distributor must be registered in the AEMPS Marketing Register prior to the start of its activity. This register is currently in the design phase and is not operational. When the European Database on Medical Devices (EUDAMED) is fully functional, all devices, except custom-made medical devices, will be reported in the new Medical Device Market Register.

6.2 Different Classifications Applicable to Pharmaceuticals

Concerning the importer of record of pharmaceuticals and medical devices, please see 1.3 Difference Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importation and exportation of medicinal products and medical devices is governed by Royal Legislative Decree 1/2015 (in particular, Articles 72 and 73, relating to exports) and Royal Decree 824/2010.

The AEMPS applies and enforces regulations regarding the import, export and intra-community trade of medicinal products and medical

devices. In the exercise of its duties, the AEMPS has issued the following guidelines:

- Circular 1/2015 on the foreign trade of medicinal products; and
- Circular 2/2012 on the prior notification of shipments of medicinal products to other member states.

Parallel imports of nationally authorised medicinal products (ie, those which are distributed in Spain by an entity other than the MAH) are regulated by Royal Decree 1785/2000.

7.2 Importer of Record of Pharmaceuticals and Medical Devices Medicinal Products

Any individual or legal entity can apply for an import licence from the AEMPS if it complies with Article 63 of Royal Legislative Decree 1/2015. Requirements to obtain the import licence are the same as those listed for the application for manufacturing authorisations – please see **4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices** for more details.

Medical Devices

The importation of medical devices is subject to obtaining a prior licence from the AEMPS. Importers of medical devices established in Spain and class I or custom-made medical devices must be included in the registry of responsible persons.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Prior authorisation is required for the importation of medicinal products into the EU customs territory, as established in Circular 1/2015. The duration of the import authorisation granted by the AEMPS depends on the type of medicinal

product. For finished medicinal products, investigational medicinal products, those used in special situation programmes, advanced therapy medicinal products and hemoderivatives, import authorisations are valid for one year and may be carried out in several dispatches.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Imports of healthcare products are controlled by the Pharmaceutical Inspectorate at customs, which will verify that the products comply with the requirements established in applicable European legislation, and that the importer has an operating licence.

Ministerial Order SPI/2136/2011 lays down the procedures for health control at the border by the Pharmaceutical Inspectorate and regulates the computerised pharmaceutical inspection system for border health controls. Annex I contains a non-exhaustive list of the headings subject to control. The products are classified according to the combined nomenclature (CN) code, according to Council Regulation (EEC) No 2658/87.

7.5 Trade Blocs and Free Trade Agreements

The import authorisation referred to in **6.2 Importer of Record of Pharmaceuticals and Medical Devices** is not required if the product originates from another EU country (intra-community trade), or from Norway, Iceland or Liechtenstein, by virtue of the agreement for the European Economic Area (EEA) recognising the free movement of goods between the contracting parties, signed in Porto on 2 May 1992. In this case, a distribution licence is sufficient. For more information on distribution requirements, please see **5.1 Wholesale of Pharmaceuticals and Medical Devices**.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Medicinal Products

Reimbursed medicinal products have a maximum ex-factory price (*precio de venta laboratorio*; PVL) set by the Interministerial Committee for the Price of Medicines (ICPM), a committee of the MOH. The PVL is the maximum price for the units of the reimbursed product that will be reimbursed by the Spanish NHS. To determine the PVL, Spain has always followed a cost-plus system, under which the maximum PVL should correspond to the cost of the product plus a given profit margin; this is what Royal Decree 271/1990 contemplates in accordance with the provisions of Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use. As a matter of practice, however, the price-approval process entails negotiation with the authorities, where the cost and profit margin are not the main variables considered. In the firm's experience, companies should be prepared for prices to be determined based on:

- a comparative pharmaco-economic evaluation of the medicinal product and its competitors; and
- the price of the medicinal product in other EU member states.

Companies must also be ready for the authorities to consider other issues, such as the activities performed by the company in Spain (eg, R&D, manufacturing) and any relationship with a local company through a co-marketing or licensing arrangement. Reimbursed medicinal products also have a so-called notified price, which is the price at which the MAH may market such reim-

bursed product outside the Spanish NHS (eg, units supplied on a patient-payment basis). The notified price is in fact free, although according to Article 94.4 of Royal Legislative Decree 1/2015, it must be notified to the MOH, who may oppose to it on the grounds of protecting the public interest. The notified price is, by definition, higher than the PVL.

Finally, the MOH is working on an update of the rules governing the price and reimbursement of medicinal products. At the end of 2024, the MOH launched a public consultation on this matter.

Medical Devices

Unlike medicinal products, the vast majority of medical devices used at NHS hospitals do not have a maximum PVL determined at the national level. Instead, the price of such products is determined/negotiated on a case-by-case basis in public procurement proceedings.

Furthermore, certain medical devices/products for non-hospitalised patients (eg, bandages, gauze, catheters, urine collection bags) have a specific reimbursement regime laid down in Royal Decree 9/1996, which includes determination of the maximum PVL at the national level. This Royal Decree is expected to be replaced in the near future by a new one that is currently being drafted by the MOH (a first draft was released in late 2024).

8.2 Price Levels of Pharmaceuticals or Medical Devices

As per Spanish regulations, the MOH is not allowed to reference international prices. International referencing was contemplated in the Law on Medicinal Products before 2012, but Royal Decree-Law 16/2012 of 20 of April removed any reference to this practice in 2012; subsequently, international referencing had no legal basis in

Spain, and the judgments of the Supreme Court of 28 October 2015 and 11 November 2015 confirmed this.

However, in practice, external reference pricing influences price rulings in Spain. The fact that this practice has no legal basis makes it quite difficult to identify precisely how the MOH factors in international prices, and the sources from which these prices are obtained. In any case, as per the firm's experience in dealing with the MOH, it has become clear that the MOH requests the MAH to provide information about how the medicinal product has been priced in other EU countries, and that EU prices operate as a cap for Spanish prices, meaning that prices in Spain are rarely fixed above the price of the same medicinal product in other EU countries.

In relation to medical devices, the current regulation does not provide for price comparisons with other European countries. However, it is important to highlight that the draft of the new Royal Decree on the financing of medical devices for non-hospitalised patients does mandate, as a requirement for obtaining public reimbursement, that the company marketing a device submit, along with the price request, documentation regarding the status and price of the medical device in the EU member states where it is marketed. Additionally, the offering company must provide information, if available, on the prices of similar medical devices marketed by the company, both in Spain and in other EU countries.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Medicinal Products

For the reimbursement of medicinal products, two hurdles must be overcome. First, the product must not be specifically exempt from reim-

bursement; such products include those that are not subject to medical prescription; are not designed to cure a specific illness; are considered cosmetics, dietetics, mineral waters, elixirs, dentifrices or other similar products; are indicated for syndromes or illnesses of minor severity; or do not meet current therapeutic needs.

Second, a price and reimbursement proceeding must be completed before the MOH, in which the decision to reimburse a given product is taken considering the following criteria (Article 92 of Royal Legislative Decree 1/2015): (i) the severity, duration and sequelae of the different pathologies for which the product is indicated; (ii) the specific needs of certain groups; (iii) the therapeutic and social value of the medicinal product and its incremental clinical benefits, taking into account its cost-effectiveness; (iv) the rationale for public expenditure; (v) the existence of medicines or other therapeutic alternatives for the same condition/s at a lower price or with a lower treatment cost; (vi) the degree of innovation of the medicine; (vii) the contribution of the product to Spain's gross domestic product; and (viii) return mechanisms that may be proposed by the MAH (discounts, price reviews).

It must be acknowledged that item (vii) in the foregoing list is rather peculiar, as it suggests that local manufacturing or development operations could influence price and reimbursement decisions, which would be entirely contrary to EU law principles. Nevertheless, in the authors' experience, this criterion is occasionally applied by the Spanish authorities.

Item (viii) in the foregoing list reflects the growing significance of risk-sharing schemes in Spain. Many companies, particularly those with high-budgetary-impact products, are required to propose specific arrangements to obtain reim-

bursement. These arrangements may take various forms, including caps on the number of units reimbursed by the NHS and charge-backs if pre-defined therapeutic outcomes are not satisfied.

Medical Devices

Royal Decree 1030/2006 and Ministerial Order SCO/3422/2007 regulate the process of updating the package of benefits provided within the NHS. The rules state that any new technique, technology or process cannot be included in the NHS's package of benefits unless it contributes effectively to the prevention, diagnosis or treatment of diseases; to the maintenance or improvement of life expectancy; to self-resilience; or to the elimination or reduction of pain and suffering. Moreover, an improvement in safety, efficacy, effectiveness, efficiency or usefulness over other currently available alternatives must be demonstrated.

Royal Decree 9/1996, as mentioned in the foregoing, is the relevant legislation for the reimbursement of specific devices/products for non-hospitalised patients. Under this legislation, the reimbursement of such products must be guided by the same criteria used for medicinal products.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices Medicinal Products

Spanish law does not make any reference to cost-benefit analyses when it comes to the reimbursement of medicinal products. However, Article 92 of Royal Legislative Decree 1/2015 includes a reference to “cost effectiveness” as one of the criteria to be considered in reimbursement decisions. Cost-effectiveness ratios are commonly used in price and reimbursement proceedings, but unlike in other jurisdictions, no official cost-effectiveness threshold (eg, the maximum amount a decision-maker is willing

to pay for a unit of health outcome) applies in Spain.

With respect to the type of economic evaluation to be performed, Spanish law provides no guidance. However, the Spanish National Health System's Advisory Committee for Pharmaceutical Financing (*Comité Asesor para la Financiación de la Prestación Farmacéutica del Sistema Nacional de Salud* CAPF) has recently published a guideline on this matter, which the MOH has informally confirmed will be used as a reference. In the guideline, it is stated that “*Cost-utility analysis (CUA) will be prioritized*” and that “*In cases where a CUA is not feasible, justifications must be provided, and a cost-effectiveness analysis (CEA) will be conducted*”.

Finally, in 2024, the MOH launched a public consultation for a new Royal Decree pertaining to health technology assessment within the framework of the NHS. This legislation, which has not yet been approved, will be the main legislation governing health technology assessment (HTA) in Spain. The first draft of the Royal Decree submitted for public consultation established that economic evaluations of health technologies “*will provide useful information for decision-making... through a robust evaluation that considers the value of the medical technology from the perspective of relative effectiveness, the social value of the medical technology, and the impact on health-related quality of life. This information will identify the efficiency of the new technology compared to available alternatives, as well as analyse its budgetary impact*”.

Medical Devices

As with medicinal products, Spanish law does not refer to cost-benefit analysis in the regulation of the reimbursement of services or technologies other than medicinal products. Royal

Decree 1030/2006, however, does specifically require that any new technique, technology or process that aspires to be eligible for reimbursement must “*bring about an improvement, in terms of safety, efficacy, effectiveness, efficiency or proven usefulness, over other currently available alternatives*”. Notably, this requirement is much stricter than the one applying to medicinal products in Article 92 of Royal Legislative Decree 1/2015, which states that “*cost effectiveness*” analysis “*shall be taken into account*”.

Further, it is worth mentioning that the MOH may impose “*singular dispensation reserves*” on medicinal products, under which the affected products may only be dispensed by NHS hospital pharmacy services – ie, not by community pharmacies.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Royal Legislative Decree 1/2015 governs the prescription and dispensing of medicinal products. The general rule is that prescriptions in the NHS should be based on the active ingredient/s. Prescriptions based on trade name are possible if the principle of greater efficiency for the NHS is respected, and for medicinal products considered non-substitutable (eg, biological medicinal products). When the prescription is made based on the active substance/s, the pharmacist shall dispense the lowest-priced medicinal product in the so-called homogeneous groups – ie, lists of products available for substitution.

Trends and Developments

Contributed by:

Joan Carles Bailach, Lluís Alcover, Laia Rull and Pablo Mansilla

Faus Moliner

Faus Moliner is a modern boutique law firm based in Barcelona that specialises in advising the pharmaceutical industry and companies that operate in the life sciences sector. The firm was founded in 1997 and currently has 15 members. It focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. Faus Mo-

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At the end of 2024, the Spanish Government approved its Pharmaceutical Industry Strategy 2024-2028 (the “Strategy”), a long-anticipated development for Spain’s pharmaceutical sector.

The Strategy is a government action plan within the framework of the Recovery, Transformation, and Resilience Plan. With the involvement of four ministries (Health, Treasury, Industry and Tourism and Science, and Innovation and Universities), it aims to steer innovation towards addressing public health needs. The Strategy seeks to create a sector that not only contributes to the population’s well-being but also enhances competitiveness, fosters economic development and ensures the sustainability of the National Health System (NHS).

The Strategy focuses on three key areas: equitable access to medicines, the sustainability of the NHS and promoting innovation and competitiveness in the pharmaceutical industry. The Spanish government aims to foster an ecosystem where innovation, production, access and sustainability are integrated.

One of the Strategy’s key pillars is improving access to new medicines in Spain while managing the budgetary impact. A set of global meas-

ures is proposed to enable the system to adopt efficient access mechanisms and control pharmaceutical expenditure through more proactive monitoring of this spending.

The measures and actions included in the Strategy stem from the need to create a system for evaluating the efficiency of healthcare technologies, and for financing and pricing medicinal products, which will provide essential resources for Spain.

In parallel to building this evaluation system, the Strategy proposes other necessary changes to ensure quick and sustainable access to innovation, while also guaranteeing the supply of essential and strategic products within the NHS.

Among the measures, actions to improve timely access to medicinal products throughout their life cycle are included – specifically focusing on compassionate use and access between the stages of authorisation and decisions pertaining to pricing and reimbursement – without compromising price negotiations or sustainability. Additionally, the Strategy considers modification of the pricing and reimbursement procedure to provide, among other things, clear criteria, predict-

ability for stakeholders and clear rules regarding usage or non-usage during management.

Regarding the reference pricing system, the Strategy deems it necessary to introduce transparency and flexibility, thereby eliminating the current imbalances in the system and reducing the risk of associated supply problems. Finally, other actions are outlined related to the public procurement of medicinal products, the promotion of generic and biosimilar medicinal products and new economic return mechanisms to mitigate the impact of the growing budgetary expenditure dedicated to pharmaceutical services.

To implement these measures, the Spanish Ministry of Health (MOH) has been active in amending the regulations governing medicinal products and medical devices throughout 2024. It has also continued the reforms initiated by the previous government. Most of these regulations aim to provide a legal framework for realising the Strategy's objectives. These efforts have made 2024 a productive year for legislation, with many reforms expected to be finalised in 2025.

The main legislative amendments passed so far, and those expected to progress in 2025, are as follows.

General Pharma Legislation

The MOH opened a public consultation on the first draft of the law that will amend Royal Legislative Decree 1/2015 ("RDL 1/2015"). The associated published document indicated that the proposed reform aimed to address three specific matters.

Public financing of medicinal products

The MOH document outlines new measures for rational pharmaceutical expenditure and

rational use of public funds. It proposes modifying the reference price system by introducing elements that increase competition and value, representing an incremental benefit of the use of medicines. Additionally, the document suggests changes to the co-payment system to protect those in greater need, though it does not address whether co-payments could also be used to modulate demand for certain products. The document also announces measures to increase pressure on the pharmaceutical industry, including the possibility of quarterly contributions to medicines dispensed in health-care centres.

COVID-19 and the impact of new technologies

The COVID-19 pandemic highlighted limitations in the availability of medicinal products and medical devices. The MOH aims to consolidate the non-presential dispensing of medicines and telepharmacy within the NHS.

Implementation of EU law

The MOH document also proposes amendments to incorporate Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

The government was expected to provide a first draft law around Q4 2024. However, the draft prepared by the MOH, including all its amendments, was leaked.

While acknowledging the caution merited when analysing a leaked (unofficial) draft, the text nonetheless reveals a more substantial reform than initially anticipated. The text provides interesting ideas in relation to the criteria for reimbursement of medicinal products and medical devices, measures to speed up access to medicinal products, innovative measures in rela-

tion to public procurement and measures aimed at guaranteeing the supply of essential and strategic medicinal products.

The official draft is expected to be published during Q1 2025, allowing all interested parties to submit comments or objections. Subsequently, the government will need to approve the final proposal and forward it to Parliament (Congress and the Senate) for debate and final approval. Further changes may be made during the parliamentary process. Final approval of the new law is not expected in 2025.

Pricing and Reimbursement of Medicinal Products

The MOH launched a public consultation on the draft Royal Decree on the pricing and reimbursement of medicinal products, which seeks to repeal Royal Decree 271/1990 and establish an updated regulatory framework.

This new regulation is intended to regulate the inclusion and exclusion of medicinal products from pharmaceutical provisions, establish special reserves and financing conditions, establish a system for revising the minimum ex-factory price (*precio de venta al público* PVL) and provide new indications, among other things.

Although this public consultation is very welcome, representing another step towards the much-needed revision of the regulations of the public funding of medicines, holding the consultation before the approval of the new RDL 1/2015 (and even before the official publication of its draft via a public hearing) is not, in the authors' opinion, the most appropriate approach. As explicitly stated in the consultation, the objective should be to implement the new RDL 1/2015. Logically, the public consultation and the drafting process for the Royal Decree should take

place once RDL 1/2015, establishing the basic framework, has been finalised. Therefore, in the authors' view, conducting the public consultation after the publication of RDL 1/2015 publication would be more appropriate. It is expected that the draft of this new Royal Decree will be published during 2025.

Pricing and Reimbursement of Medical Devices for Non-Hospitalised Patients

A draft of the new Royal Decree on the financing of medical devices for non-hospitalised patients has also been published. This new Royal Decree aims to repeal Royal Decree 9/1996 and update the regulatory framework for these products.

The objectives of this regulation are twofold:

- to set the retail price of funded medical devices and margins for the activities of wholesale distribution and dispensing to the public; and
- to update the pharmaceutical provisions by including new medical devices and excluding those that are not marketed.

It is expected that this new Royal Decree will be approved during 2025.

Health Technology Assessment

The MOH published the draft of the new Royal Decree on health technology assessment (HTA) in August 2024. This new Royal Decree was a response to the judgment of the Spanish National High Court that declared void the "*Plan for the Consolidation of the Therapeutic Position Reports*".

The MOH proposes the creation of an HTA system separate from the price and reimbursement system, such that health technology evaluations will be separated from the decision-making process.

A health technology evaluation includes evaluation of both clinical and non-clinical aspects, with the latter including economic, environmental, ethical and patient quality of life issues. The guidelines that will be used to prepare the evaluation reports will be developed later by the MOH.

Once completed, the positioning group will make a final assessment of the clinical and non-clinical evaluation reports for a given health technology, and issue a recommendation thereon that will provide a basis for decision-making in respect to reimbursement.

One element of the draft Royal Decree that has raised concerns at the national industry level is the obligation for health technology developers to provide the *“reliable costs of production, research and development, as well as the sources of financing to cover these costs, whether public or private”*, given the difficulty of obtaining such information – especially considering that research and production can be done in other countries.

This new Royal Decree is expected to be approved during 2025.

Cannabis

In October 2024, the MOH published a draft Royal Decree establishing the conditions for the elaboration and dispensation of the standardised magistral formulas of standardised cannabis preparations. The purpose is to establish the conditions for the prescription, preparation, dispensing and use of standardised cannabis-based magistral formulas.

This proposed Royal Decree stems from a mandate from the Health and Consumer Affairs Committee of the Congress of Deputies, which in 2021 requested the creation of a subcommit-

tee to study experiences in the regulation of cannabis for medical use. One of the conclusions reached by the subcommittee was that there is a need to adopt measures to make standardised cannabis preparations available, to in turn address the needs of certain patients for whom authorised treatments have not been effective.

The MOH proposes to allow the use of standardised cannabis-based magistral formulas. These formulas would be prepared by hospital pharmacy services in response to a medical prescription, under the supervision of a pharmacist and in compliance with applicable good preparation practices.

The National Formulary, which contains standardised magistral formulas, will include monographs for the use of standardised cannabis preparations. These monographs will establish the uses and indications for these magistral formulas, allowing them to serve as alternatives when other therapeutic options have failed.

For now, the MOH intends for the monograph to cover four indications: chronic pain refractory to other treatments, spasticity related to multiple sclerosis refractory to other treatments, epilepsy refractory to other treatments and intractable vomiting refractory to other treatments related to chemotherapy in cancer patients. For these four indications, the use of cannabis would be authorised as a last-line treatment.

This Royal Decree is expected to be approved during 2025.

Advertising of Medicinal Products and Medical Devices

In April 2023, a public consultation on the new Royal Decree on the promotion of medicinal products for human use was launched. This

new regulation is intended to replace the current regulations, dating from 1996.

The proposed draft is aimed at addressing digital advertising, the use of social media and audio-visual modalities, the distribution of competencies between the state and regions and obligations for accessibility for individuals with sensory disabilities.

Regarding medical devices, the MOH published a draft Royal Decree governing the advertising of medical devices in March 2024. This draft encompasses several elements, such as streamlining the process for obtaining prior approval for the public promotion of medical devices, a new requirement for responsible advertising of specific devices and the prohibition of hospitality in relation to promotional meetings, except professional-scientific events. The draft also explicitly bans off-label promotion and offers detailed guidelines on permissible and prohibited content in advertisements directed at the public.

This Royal Decree is expected to be approved during 2025.

Transparency

One of the hottest topics at present is transparency and confidentiality in relation to the price and reimbursement conditions of medicinal products in Spain.

Following freedom of information requests from citizens, several court rulings were issued in 2023–24 obliging the MOH to provide access to the price and reimbursement conditions of certain medicinal products. These rulings are not final and have been appealed. A Supreme Court ruling is expected in the coming years.

So far, the MOH has maintained a firm stance in defending the confidentiality of this information, arguing that disclosure thereof would be detrimental to its ability to negotiate with companies when setting prices for medicinal products, thus undermining the economic sustainability of the NHS.

Despite some messages from the MOH at the beginning of 2024 that point to a potential change in criteria, in reality the MOH's position remains unchanged. Indeed, the leaked draft of the new RDL 1/2015 reinforces the confidentiality of the price and reimbursement conditions.

SWITZERLAND



Law and Practice

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Swiss healthcare regulation is spread over various statutes, ordinances and guidelines, including self-regulatory instruments such as best practice codes and references to international provisions. This makes navigating the life sciences landscape depend in large part on legal and regulatory expertise, as well as extensive practical industry experience.

The following key acts provide the principles of the national regulation of pharmaceuticals and medical devices, whereby the legal terminology in Switzerland refers to “*therapeutic products*” as the generic term encompassing both “*medicinal products*” (pharmaceuticals) and “*medical devices*”.

- Medicinal products – these are regulated by the Therapeutic Products Act (TPA), the Ordinance on Medicinal Products (OMP), the Medicinal Products Licensing Ordinance (MPLO), the Ordinance on the Requirements of Marketing Authorisation of Medicinal Products (OMAMP), the Ordinance on Medicinal Products Advertising (OMPA), and the Ordinance on Integrity and Transparency (OIT).
- Medical devices – these are regulated by the TPA, the Medical Devices Ordinance (“*MedDO*”) and the Ordinance on In Vitro Diagnostic Medical Devices (“*IvDO*”). Switzerland recently revised its medical devices law to align it with Regulation (EU) 2017/745 on medical devices (“*EU-MDR*”) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (“*EU-IVDR*”).

Duties and responsibilities for Swiss healthcare are divided among the federal, cantonal and municipal authorities, whereas this Global Practice Guide focuses on the federal level. As part of the Federal Department of Home Affairs (FDHA), the Federal Office of Public Health (FOPH) is responsible for public health in Switzerland. The Swiss Agency for Therapeutic Products (“*Swiss-medic*”) is the Swiss authority responsible for the authorisation and supervision of therapeutic products. As a federal public law institution, Swissmedic is autonomous with regard to its organisation and management.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Administrative decisions of regulatory bodies are usually issued in the form of a ruling and can be challenged in administrative procedures or administrative court proceedings. The appropriate legal action depends on whether a federal or a cantonal regulatory body has issued the decision. If issued by a federal authority, decisions can be appealed to the Federal Administrative Court. Decisions of the Federal Administrative Court are subject to further appeal to the Federal Supreme Court.

These challenge procedures in general also apply to other regulated products. In certain areas, such as public procurement or social security, special provisions may apply. Besides, criminal procedure rules may apply to administrative and criminal sanctions issued by regulatory bodies.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Medicinal products are divided into four dispensing categories:

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- category A – medicinal products that may be dispensed on a one-time basis on a physician's prescription (Article 41 of the OMP);
- category B – medicinal products that require a prescription and can be obtained several times, whereby medicinal products on list B+ can also be dispensed without a prescription (Article 42 of the OMP);
- category D – medicinal products that may be dispensed without a prescription, but after specialist advice (Article 43 of the OMP); and
- category E – medicinal products that may be dispensed without a prescription and without specialist advice (Article 44 of the OMP).

The assignment to a particular category determines who is authorised to dispense, prescribe and use the medicinal product (Articles 24 et seq of the TPA). Non-prescription medicinal products, known as OTC medicinal products, are intended for self-medication. The classification into the different categories is made by Swissmedic (Article 23a of the TPA).

The TPA further contains special provisions for blood and blood products (Articles 34 et seq of the TPA) as well as for veterinary medicinal products (Articles 42 et seq of the TPA).

Medical devices are divided into different categories (classes I, IIa, IIb, III) – for which, different conformity assessment procedures apply. The classification follows the respective regulation in the EU-MDR (Article 16 paragraph 1 of the MedDO) and is based on the intended purpose and the associated risk. Certain medical devices may be classified as intended for use by health-care professionals (HCPs) only.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials are mainly governed by the TPA, the Human Research Act (HRA), the Human Research Ordinance (HRO), the Clinical Trials Ordinance ("*ClinO*") and the Ordinance on Clinical Trials with Medical Devices ("*ClinO-MD*"). In principle, clinical trials with therapeutic products require prior authorisation from Swissmedic (Article 54 paragraph 1 of the TPA) and the competent ethics committee (Articles 24 et seq of the ClinO and Articles 9 et seq of the ClinO-MD). Regarding medicinal products, Swissmedic examines whether the good manufacturing practice (GMP) and safety requirements are met (Article 54 paragraph 4 lit a of the TPA). Regarding medical devices, the assessment includes the conformity of the products with the safety requirements (Article 54 paragraph 4 lit b of the TPA and Article 45 paragraphs 1 and 3 of the TPA).

Clinical trials must be conducted in line with the rules of good clinical practice as set out, with regard to medicinal products, in the International Council for Harmonisation (ICH) Guideline on Good Clinical Practice of 9 November 2016 and the World Medical Association (WMA) Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (Article 5 paragraph 1 of the ClinO and Article 3 of the ClinO-MD). With regard to medical devices, the applicable rules on good clinical practice were incorporated into Swiss legislation by way of reference to Article 72 and Annex XV Chapters I and III of the EU-MDR, as well as in EN ISO 14155.

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2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

In order to secure authorisation for the conduct of a clinical trial, the investigator must submit an application to the ethics committee in the canton in whose territory the study is conducted (Articles 24 et seq of the ClinO and Articles 10 et seq of the ClinO-MD). This is followed by:

- acknowledgment of receipt/possible deficiencies' notification within seven days (medicinal products) or ten days (medical devices); and
- decision within 30 days (medicinal products) or 40 (medical devices) days and information of Swissmedic in the event that an authorisation by Swissmedic is necessary – in case of multi-centre clinical trials with medicinal products, the deadline is extended to 45 days.

The submission of the application to Swissmedic is made by the sponsor – following which:

- acknowledgement of receipt/possible deficiencies' notification within seven (medicinal products) or ten (medical devices) days respectively;
- as a general rule, decision within 30 days (medicinal products) or 45 days (medical devices); and
- in certain circumstances, Swissmedic must obtain the opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) or the FOPH before granting the authorisation.

2.3 Public Availability of the Conduct of a Clinical Trial

Sponsors of authorised clinical trials with medicinal products are subject to registration obligations (Articles 64–67 of the ClinO). Before conducting a clinical trial with medicinal products, the sponsor must enter the clinical trial either

in a primary register recognised by the World Health Organization (WHO) or in the register of the National Library of Medicine of the United States of America as well as in the supplementary Swiss federal (from March 2025: cantonal) database using a Swiss national language.

The publicly accessible portal SNCTP (Swiss National Clinical Trials Portal) displays studies that are being conducted in Switzerland as soon as they have been approved by the cantonal ethics committee and released for publication by the researchers. The data originates from the cross-cantonal application submission platform BASEC (Business Administration System for Ethics Committees) and the international study database International Clinical Trials Registry Platform (ICTRP) (WHO database comprising 17 worldwide primary registers).

The data listed in Annex 5 number 2.1 to 2.14 of the revised ClinO (*“revClinO”*) will be made automatically accessible to the public at the latest within six months from the grant date of the trial authorisation (Article 64 paragraph 5 of the revClinO). This will include a brief description of the clinical trial, the site(s) where the clinical trial is conducted, the criteria for the participation in the clinical trial, the disease category, and the health condition investigated, as well as an indication of whether the clinical trial includes rare diseases.

The Registry of All Projects in Switzerland (RAPS) of the Swiss Association of Research Ethics Committees (*“swissethics”*), the umbrella organisation of cantonal ethics committees, also publishes clinical trials that have been approved by an ethics committee.

Sponsors of clinical trials must, in principle, register a summary of the results of the clinical trial

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in the respective trial registry (Article 64 paragraph 1 of the ClinO and Article 65a paragraph 1 of the revClinO), as well as a lay summary in the cantonal database within a year from completion or discontinuation of the trial (Article 65a paragraph 2 of the revClinO).

Sponsors of clinical trials of medical devices are subject to analogous registration obligations (Article 41 of the ClinO-MD).

Public access to the results of clinical trials of medical devices must be ensured by the sponsor by publication in one of the registries listed in Article 64 paragraph 1 of the ClinO (Article 42 of the ClinO-MD).

2.4 Restriction on Using Online Tools to Support Clinical Trials

Personal data held for research purposes must be protected by appropriate operational and organisational measures (cf Article 5 paragraph 1 of the HRO). The applicable ICH Guideline explicitly refers to the increasingly widespread use of electronic data handling and remote electronic trial data systems and outlines the additional requirements that must be met by the sponsor when using such tools (see Section 5.5.3 of the ICH Guideline for Good Clinical Practice E6(R2) of 9 November 2016). In addition, the use of online and electronic tools is subject to the limitations imposed by Swiss data protection law (in particular, the Federal Act on Data Protection (FADP) and the respective ordinance (Data Protection Ordinance, or DPO) – both of which have been completely revised as of 1 September 2023).

2.5 Use of Data Resulting From Clinical Trials

Health data is considered personal data requiring special protection. The HRA regulates in

detail the further use and disclosure of health data that falls within its scope of application. In principle, the disclosure of health data is permissible both within an organisation and to third parties depending on the type of health data, the intended further use, and the assignability to a specific person. The data protection provisions do not apply to anonymised and pseudonymised data, insofar as the data subjects are no longer identifiable.

2.6 Databases Containing Personal or Sensitive Data

According to the HRA and its implementing provisions (Article 43 of the HRA and Article 5 of the HRO), anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent the unauthorised use thereof, and must fulfil certain operational and professional requirements.

Since 2016, the Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks has complemented the Declaration of Helsinki.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The decisive criterion for the classification of a product as a therapeutic product (ie, as a medicinal product or as a medical device) is the intended purpose of the product, which – considering all objective (nature of a product) and subjective (designation and promotion of a product) circumstances of the individual case –

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must be the medical effect or application on the human organism.

As regards the distinction between medicinal products and medical devices, the decisive factor is not the material composition of the product, but whether its intended main effect in or on the human body is caused by pharmacological, immunological or metabolic means (medicinal products) or rather through mechanical, physical or physico-chemical effects (medical devices) (Article 4 paragraph 1 lit a and b of the TPA; BVGE C-2093/2006, E 3.5).

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

No specific requirements need to be met for the authorisation of biologic medicinal products (Article 2 paragraph 1 lit d of the Ordinance on the Simplified Marketing Authorisation Procedures (OSMA)). However, it is necessary that an equilateral black triangle standing on its apex is included in the package leaflet and information and is accompanied by the statement that this medicinal product is subject to additional monitoring (Article 14a paragraph 1 lit b of the OMAMP).

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

The authorisation of medicinal products is initially valid for a period of five years and is subject to subsequent renewal upon application (Article 16 paragraph 2 of the TPA and Article 16b paragraph 1 of the TPA). If a medicinal product is not placed on the market within three years of the granting of the authorisation, or if it is no longer actually on the market during a period of three consecutive years after it has been placed on the market, Swissmedic may revoke the authorisation (Article 16a paragraph 1 lit a of the TPA).

Medicinal products must fulfil their authorisation requirements for each production unit during the entire distribution period, whereby such requirements may only be modified, extended or restricted by a formal amendment procedure. Swissmedic may at any time review the authorisation, adapt it to changed circumstances, or revoke it (Article 16c of the TPA).

Regarding medical devices, the necessary certificates of conformity (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**) are valid for a maximum of five years and are extended following a re-assessment (Article 26 of the MedDO). If a designated body finds that a manufacturer no longer fulfils the requirements of the MedDO, it must set a deadline for correction and otherwise suspend, revoke or restrict the certificate (Article 27 of the MedDO).

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

An authorisation to place medicinal products on the Swiss market is granted based on a respective application (Article 11 of the TPA) and after a detailed examination by Swissmedic. Applicants must hold a manufacturing, import or wholesale licence issued by Swissmedic (see **4. Manufacturing of Pharmaceuticals and Medical Devices**), have a registered address, office or branch office in Switzerland, and must prove that the medicinal product is of high quality, safe and effective (Article 10 of the TPA).

Different authorisation procedures apply depending on the characteristics and the application of the medicinal product, as follows:

- ordinary procedures for first authorisations of new active pharmaceutical ingredients (APIs)

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- and major deviations (Article 9 paragraph 1 of the TPA and Articles 11 et seq of the TPA);
- compassionate use authorisations of medicinal products (in a simplified procedure, Articles 14 et seq of the TPA) for a limited period – ie, for life-threatening or debilitating diseases – if the medicinal products are compatible with the protection of health, their use is expected to have a major therapeutic benefit, and no authorised, alternative or equivalent medicinal product is available in Switzerland (Article 9a of the TPA and Articles 18 et seq of the OSMA);
 - fast track procedures for first authorisations of new APIs and major deviations on request, available for promising therapies for the prevention or treatment of a severe, debilitating or life-threatening disease where there is a high therapeutic benefit and where the standard treatment is either unavailable or unsatisfactory (Article 7 of the OMP) (see **4.1 Fast Track Registration Routes**);
 - simplified procedures for certain categories of medicinal products where this is compatible with the quality, safety and efficacy requirements and where there is no conflict with Swiss interests or international agreements – in particular, for generics (but not for biosimilars), orphan drugs, and certain categories of medicinal products authorised and/or used in foreign countries (Articles 14 et seq of the TPA and Articles 12 et seq of the OSMA); and
 - the authorisation procedure on the basis of a notification – in particular, for certain complementary medicines without indications and other medicinal products with a low-risk potential (Article 15 of the TPA).

Changes to an authorisation that have no or only minimal consequences for the quality, safety or efficacy of a medicinal product must be communicated to Swissmedic within 12 months of

their implementation (Article 21 of the OMP). Substantial variations require an additional marketing authorisation procedure. Marketing authorisations are in principle transferable upon approval of a respective application by Swissmedic.

Medical devices do not require an authorisation by a public authority prior to being placed on the Swiss market. Instead, they must bear a respective conformity (MD or CE) marking testifying the conformity of the device with the general safety and performance requirements.

The conformity assessment procedure is based on Articles 52 and 54 and Annexes IX-XI of the EU-MDR (Articles 21 et seq of the MedDO and Articles 17 et seq of the IvDO). Depending on the risk qualification of the medical device (see **1.3 Different Categories of Pharmaceuticals and Medical Devices**), the conformity is either to be declared by the manufacturer or by a private body certified to conduct conformity assessments.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

In principle, ready-to-use medicinal products may only be placed on the market after they have been authorised (Article 9 paragraph 1 of the TPA). However, there are a number of exceptions to this general rule.

- Medicinal products for which a review of the ordinary approval requirements (safe, effective, and of high quality) is not necessary or useful – eg, formula magistralis, officinalis and hospitalis products or products intended for clinical trials – may be placed on the market before they have been authorised (Article 9 paragraphs 2 et seq of the TPA).

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- Orphan use – the use of medicinal products for the treatment of diseases that are so rare that there is hardly any incentive for a regular marketing authorisation that may be approved in Switzerland for a limited period in a simplified approval procedure is permissible (Article 9a of the TPA and Article 14 paragraph 1 lit f TPA).
- Temporary authorisation for use outside of clinical trials – Swissmedic may temporarily authorise the use of as yet unauthorised medicinal products intended for clinical trials outside the scope of a clinical trial (Article 9b paragraph 1 of the TPA and Articles 52 et seq of the MPLO).
- Temporary authorisation to bridge temporary unavailability – medicinal products may be temporarily or quantitatively authorised by Swissmedic to bridge the unavailability of an identical medicinal product in Switzerland, provided that they are authorised in another country with an equivalent medicinal product control and no essentially identical medicinal product is authorised and available in Switzerland (Article 9b paragraph 2 of the TPA).
- Off-label use (eg, the use of a (properly) authorised medicinal product for other indications) is generally permissible within the scope of Articles 3 and 26 of the TPA.
- Unlicensed use – an unlicensed medicinal product may be imported under the restrictive requirements of Article 20 paragraph 2 of the TPA and Articles 48 et seq of the MPLO.

Manufacturers of medical devices must generally carry out a conformity assessment before placing the device on the market (see **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices**). However, in the interest of public health or patient safety or health, Swissmedic may – upon application – grant an authorisation even though

the relevant conformity assessment procedure has not been carried out (Article 22 paragraph 1 of the MedDO and Article 18 paragraph 1 of the IvDO).

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Holders of marketing authorisations for medicinal products, as well as medical device manufacturers, must have a post-market surveillance system (ie, pharmacovigilance and materiovigilance plans) in place (Article 11 paragraph 2 lit a no 5 of the TPA, Article 56 of the MedDO, and Article 49 of the IvDO).

Holders of marketing authorisations for medicinal products with a new API or a biosimilar must automatically file periodic safety update reports (PSURs) with Swissmedic on the safety and risk-benefit ratio for four years after authorisation (Article 60 of the OMP). With its marketing authorisation, Swissmedic may impose additional conditions or obligations on the applicant, including further product evaluations (eg, in Phase IV clinical trials). Depending on the classification of a medical device, its manufacturer has similar trend report, periodic summary report and PSUR obligations to the designated body involved in the conformity assessment (Articles 59 et seq of the MedDO and Articles 52 et seq of the IvDO).

As for incident notification requirements, manufacturers of medicinal products, distributors of ready-to-use medicinal products, and HCPs must notify Swissmedic of adverse events, adverse drug reactions, and quality defects within 15 days in the event of serious adverse reactions and within 60 days in the event of non-serious reactions. Similarly, anyone placing medical devices on the Swiss market must

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report to Swissmedic all serious incidents as well as all field safety corrective actions that are undertaken in Switzerland (Article 66 of the MedDO and Article 59 of the IvDO).

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

Authorities must, in principle, treat all data collected within the framework of the TPA and its implementing regulations as confidential, including all data communicated to the authorities in the context of a marketing authorisation application (Article 62 of the TPA). Granted marketing authorisations for medicinal products are published in the monthly *Swissmedic Journal*, together with essential information about the medicinal product. Swissmedic publishes an assessment report (SwissPAR) for all medicinal products with a new API – as well as for transplant products – for which a decision to approve or reject authorisation has been issued. The SwissPAR includes the evaluation results of the application for new authorisation or additional indication of a medicinal product, but not the applicant's commercial or manufacturing secrets or personal data.

Regarding medical devices, the conformity assessment procedures by Swiss or European assessment bodies are not accessible to third parties. The successful completion of a conformity assessment is made public together with the issuance of the declaration of conformity for the respective product (Article 90 lit f of the MedDO).

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes Medicinal Products

For the approval of a human medicinal product, a fast track procedure may be conducted. Unlike the standard procedure, the fast track procedure requires a previously approved request for the implementation of this procedure. Once such a request is received, Swissmedic will determine within 30 days whether the criteria for the fast track procedure are met (Article 7 of the OMP) (see Section 5.3 of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).

To qualify for a fast track authorisation procedure for a human medicinal product, the following criteria must be met.

- The medicinal product must provide promising prevention or treatment for a severe, disabling, or life-threatening disease (Article 7 lit a of the OMP).
- No currently authorised medicinal product exists for the condition, or existing treatments are unsatisfactory (Article 7 lit b of the OMP). Authorised medicinal products may be deemed unsatisfactory owing to various factors, including limited effectiveness, safety concerns, or the absence of an established standard treatment (see Section 5.1 of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).
- The new medicinal product must offer a significant improvement based on new clinical evidence. To provide a comparative basis, applicants must evaluate efficacy and safety data against existing authorised medicinal products available in Switzerland (see Section 5.1.c of Swissmedic guidance document *"Fast-Track Authorisation Procedure"*).

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Medical Devices

For medical devices, Switzerland currently does not explicitly provide a fast track registration route, meaning there is no expedited conformity assessment procedure. However, in exceptional cases, Swissmedic may – upon a duly justified request – authorise the placing on the market and use of a specific medical device in the interest of public health or patient safety, even if the full conformity assessment has not been completed (eg, because the device has not undergone a complete conformity assessment procedure or the certificate for a device for the device has been declared invalid) or the language requirements are not met (Article 22 paragraph 1 of the MedDO and Article 18 paragraph 1 of the IvDO).

Article 22 paragraph 2 of the MedDO and Article 18 paragraph 2 of the IvDO permit the placing on the market and use of individual devices without valid certificates in an individual case if the following conditions are fulfilled:

- the device serves to avert life-threatening conditions or to prevent the permanent impairment of a bodily function or, in the case of in vitro diagnostic medical devices, is used to test samples with the aim of averting or treating life-threatening conditions or permanent impairments of a body function;
- no conforming device is available for this specific intended purpose;
- the device is used exclusively by HCPs either directly on an individual patient or in a laboratory setting for patient-specific sample testing;
- the HCP using the device or providing treatment has informed the patient about the non-conformity of the device and the associated risks; and

- the patient concerned has provided consent for the use of the device.

The decision to use a non-conforming device must be based on a thorough risk-benefit assessment for the specific case. A Swissmedic authorisation is not required for these cases (see Swissmedic information sheet “*Derogation MEP*”). However, the exemption is limited to the manufacturer or importer making the device available to the user for the first time. Devices authorised under these exceptional provisions must not be traded or made widely available on the market. To ensure compliance with Article 22 paragraph 2 of the MedDO and Article 18 paragraph of the IvDO, the responsible HCP must document compliance with the specified conditions and retain all relevant records for regulatory verification.

4.2 Regulatory Reliance Medicinal Products

Swissmedic may expedite the approval process for certain medicinal products if they have already been authorised by internationally recognised regulatory bodies, such as the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), or others.

Applicants seeking authorisation, an extension, or a variation for a medicinal product or procedure that has already been approved in a country with a comparable regulatory system may benefit from Swissmedic’s reliance on foreign assessment results (Article 13 of the TPA) – provided the following conditions are met.

- The submitted foreign authorisation documents, including all variations, must be no older than five years and reflect the product’s current approval status abroad (Article 16 lit a of the OMP). Minor deviations from the

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foreign submission are permissible if they are justified (Article 16 paragraph 2 of the OMP). Such differences may, in particular, concern a different name for the medicinal product, a different pack size, or a different secondary packaging.

- The full and final assessment reports from the foreign regulatory agency must be available (Article 16 lit b of the OMP).
- The documentation must include all necessary information for Switzerland, particularly medicinal product information and labeling texts (Article 16 lit c of the OMP).
- The documentation must be provided in an official Swiss language or in English. If a translation is submitted, the applicant must confirm that it is correct (Article 16 lit d of the OMP).

Articles 16–20 of the OMP provide detailed provisions on the application of Article 13 of the TPA and Swissmedic has issued a respective guidance document on the procedure (*“Authorisation Human Medicinal Product Under Art. 13 TPA”*). The current list of countries recognised by Swissmedic as having comparable regulatory oversight for human medicinal products (Article 16 paragraph 4 of the OMP) is available on the Swissmedic website. In practice, the Article 13 TPA procedure can significantly reduce approval timelines – saving several months compared to the standard process.

In addition, Article 14 of the TPA provides for certain simplified authorisation procedures, which may apply when a medicinal product has already been approved by international regulatory authorities (see Swissmedic guidance *“Authorisation in Accordance with Art. 14 paragraph 1 abis-quarter TPA”*), as follows.

- A medicinal product may qualify for simplified authorisation if its active substances have been used in an approved medicinal product for at least ten years in an EU or European Free Trade Agreement (EFTA) country and if it is comparable to a foreign-authorised product in terms of indication, dosage (strength and recommendation), and route of administration (Article 14 paragraph 1 lit abis and Article 14a paragraph 1 lit a in conjunction with Article 17a and 17b of the OSMA).
- Furthermore, a non-prescription medicinal product with a stated indication may qualify for simplified authorisation if it has been medically used for at least 30 years, including at least 15 years in EU or EFTA countries (Article 14 paragraph 1 lit ater of the TPA and Article 14a paragraph 1 lit b of the TPA, in conjunction with Article 17c of the OSMA).

Finally, Switzerland has entered into multiple mutual recognition agreements (MRAs) that allow for respective products to be placed on the Swiss market and within the territory of the contracting party with as few obstacles as possible. For medicinal products, Switzerland has signed MRAs under which each contracting party recognises the results of GMP inspections conducted by the competent inspectorates of the other party. Additionally, these agreements provide for the mutual acceptance of manufacturing authorisations issued by the respective regulatory authorities, thereby reducing the need for duplicate inspections and authorisations. A comprehensive list of all MRAs is available on the Swissmedic website.

Medical Devices

Regarding medical devices, Swiss law currently allows only a limited regulatory reliance. Following the expiration of the MRA between Switzerland and the EU, Switzerland unilaterally

recognises conformity certificates (CE markings) issued by recognised bodies in EU/European Economic Area (EEA) countries (Article 25 paragraph 4 of the MedDO and Article 21 paragraph 4 of the IvDO), provided additional requirements are met. These additional requirements include the appointment of an authorised representative in Switzerland, who is responsible for ensuring compliance with both formal and safety-related requirements and who must be registered with Swissmedic (Articles 51 and 55 of the MedDO and Articles 44 and 48 of the IvDO).

In terms of recent developments, in 2022, the two Swiss parliamentary chambers adopted a motion mandating the Swiss Federal Council to amend the current legislation so that medical devices conforming to non-European regulatory systems (including FDA-approved devices) can be placed on the market in Switzerland by way of unilateral recognition. The FOPH is currently examining how this motion can be implemented.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

The manufacture of medicinal products in Switzerland is subject to a mandatory licence (Article 5 paragraph 1 lit a of the TPA). The same applies to anyone withdrawing blood from humans for the purpose of transfusion or the manufacture of therapeutic products or for supply to a third party (Article 34 of the TPA). The licence is issued if Swissmedic has successfully verified during an inspection that the necessary technical and operational conditions have been fulfilled and an appropriate system of quality assurance exists

(Article 6 of the TPA and Articles 3 et seq of the MPLO). The licence is issued for an unlimited period of time, whereby Swissmedic performs periodic inspections and may revoke licences if the requirements are no longer fulfilled.

Manufacturers of medical devices are not subject to licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland who is responsible for the related formal and safety-related aspects and is registered with Swissmedic (Articles 51 and 55 of the MedDO, Articles 44 and 48 of the IvDO, Article 11 of the EU-MDR/EU-IVDR).

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Any person engaged in the wholesale trade of medicinal products must possess a licence (Article 28 paragraph 1 of the TPA). The licence is issued following an inspection by Swissmedic (Article 28 paragraph 2 of the TPA and Articles 11 et seq of the MPLO).

No licences are required for the wholesale (Article 4 paragraph 1 lit i of the MedDO and Article 4 paragraph 1 lit h of the IvDO) of medical devices. Foreign manufacturers, however, need to appoint an authorised representative domiciled in Switzerland (see **5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices**).

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6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Different Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Importation and exportation of medicinal products and medical devices are mainly governed by the TPA, the MPLO, the MedDO and the Swiss customs legislation. At the point of entry, the responsibility for the application and enforcement of the respective regulations lies with the Federal Office for Customs and Border Security (FOCBS). The competent governmental authority for any subsequent market surveillance is Swissmedic. The FOCBS and Swissmedic co-operate closely in their joint areas of competence (cf Article 65 of the MPLO).

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Any person that professionally imports medicinal products intended for distribution or dispensing must possess a licence issued by Swissmedic (Article 18 paragraph 1 lit a of the TPA) following an inspection confirming that the necessary technical and operational conditions have been fulfilled and that an appropriate system of quality assurance exists (Article 19 paragraph 1 of the TPA and Articles 11 et seq of the MPLO).

Importers of medical devices (Article 4 paragraph 1 lit h of the MedDO and Article 4 paragraph 1 lit g of the IvDO) are not subject to

licensing requirements in Switzerland. However, if a manufacturer is not established within Switzerland, its devices may only be placed on the market if it has appointed an authorised representative in Switzerland that is responsible for the related formal and safety-related aspects and if the importer is registered with Swissmedic and is assigned a CHRN (Swiss Single Registration Number) (Article 55 of the MedDO and Article 48 of the IvDO) (see 5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In principle, only medicinal products that have been granted a marketing authorisation by Swissmedic can be imported into Switzerland (Article 9 of the TPA) and importation is subject to a specific licence (Article 18 paragraph 1 lit a of the TPA). Subject to certain exceptions – in particular, in connection with an official batch release from a foreign control authority belonging to the Official Control Authority Batch Release Network (OCABR) – anyone wishing to import immunological medicinal products or blood and blood products generally requires a special licence for each individual shipment (Article 44 of the MPLO). Under certain circumstances, ready-to-use medicinal products without a marketing authorisation in Switzerland may be imported in small amounts by persons for private use or by HCPs (cf Articles 48 and 49 of the MPLO).

While no licence for the import of medical devices is required (see 7.2 Importer of Record of Pharmaceuticals and Medical Devices), medical devices must – prior to their placing on the Swiss market – undergo a conformity assessment to ensure that general safety and performance requirements are met (Articles 6 and 21 et seq of the MedDO and Articles 6 and 21 et

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seq of the IvDO). Certifications of conformity (CE markings) issued by bodies from EU/EEA countries are unilaterally recognised in Switzerland (Article 25 paragraph 4 of the MedDO and Article 21 paragraph 4 of the IvDO).

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Non-tariff restrictions are set forth in the Swiss customs tariff. The entries in the relevant Harmonised Tariff Schedule (HTS) line will determine which market surveillance authority is competent to examine and approve import. The product-related laws and implementing ordinances set out the restrictions in detail.

7.5 Trade Blocs and Free Trade Agreements

Switzerland is a member of the EFTA and is, among others, signatory to the free trade agreement with the EU of 1972 as well as to a network of currently 33 free trade agreements with 43 partners. The EU has unilaterally ceased the application of the MRA as regards medical devices. As a result, exportation of medical devices from Switzerland into the EU has become more burdensome. Negotiations are currently taking place between Switzerland and the USA on a free trade agreement concerning the pharmaceuticals sector, which is intended to facilitate market access for Swiss pharma companies.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Under Swiss law, prices of therapeutic products are controlled to the extent that they are reimbursed by the compulsory health insurance. With regard to therapeutic products not reimbursed

by compulsory health insurance, manufacturers, wholesalers and retailers are, in principle, not restricted in their pricing.

Pharmaceuticals are reimbursed subject to a listing on the Specialties List (SL) where ready-to-use medicinal products are included. Medicinal products that are manufactured in a pharmacy are reimbursed if their APIs are included in the List of Medicines with Tariff (LMT). The requirements for price fixing are mainly contained in the HIA, the Health Insurance Ordinance (HIO), and the Ordinance on the Benefits under the Mandatory Health Insurance (OBHI). The SL determines the ex-factory price as well as the public price, which is the maximum amount (including VAT) that must be reimbursed by health insurers.

The FOPH decides on the inclusion of a medicinal product on the SL after consultation with the Federal Drugs Commission (*Eidgenössische Arzneimittelkommission*, or EAK), except in the case of certain medicinal products, such as generics and new galenic forms or package sizes of already-listed medicinal products (Article 31 paragraph 2 lit a of the OBHI). An accelerated procedure applies in the case of an accelerated market authorisation (Article 31a of the OBHI). The procedure is initiated by the market authorisation holder (Article 31 paragraph 1 lit a of the OBHI). Medicinal products can only be included in the SL if the criteria of efficacy, appropriateness and cost-effectiveness are met (Article 32 paragraph 1 of the HIA). The prices are reviewed every three years (Article 65d of the HIO) and additional reviews take place upon patent expiry and in the event of the authorisation of further indications.

The List of Items and Tools (LIT) determines which devices are covered by the compulsory health insurance. Unlike the SL, the LIT does not

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fix the ex-factory and public price, but only sets the maximum reimbursement amount. In principle, higher prices may be charged and the difference is borne by the patient. There are specific provisions governing the application for inclusion on the LIT. The FDHA decides upon consultation of the Federal Commission for Analyses, Instruments and Tools (FCAIT) on the addition, change, or delisting (cf Articles 21 et seq of the OBHI). The criteria of efficacy, appropriateness and cost-effectiveness also apply to medical devices.

8.2 Price Levels of Pharmaceuticals or Medical Devices

When setting and reviewing the prices of the medicinal products included in the SL, the FOPH relies on the following comparisons:

a therapeutic comparison in which the effectiveness of the medicinal products is assessed in relation to other medicinal products used for the same indication (Article 65b paragraph 1 lit a of the HIO); and

a price comparison with the same medicinal product abroad (cf Article 34a of the OBHI and Article 34b of the OBHI). The two comparisons are given the same weight. The latter comparison is carried out according to the guidance of the EAK, taking into account foreign countries whose pharmaceuticals sector is economically comparable with that of Switzerland.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Under the compulsory health insurance, insurers must reimburse costs for prescribed medicinal products listed in the SL and the LMT at the maximum amount set out therein. The reimbursement may be restricted to specific indications, quanti-

ties or durations. Reimbursement is, in general, only granted for listed medicinal products under the condition that they are used in connection with indications approved by Swissmedic and within approved quantities. Exceptions from this general rule apply on a case-by-case basis subject to the conditions set out in Article 71a of the HIO. In addition, there is also room for reimbursement in individual cases of medicinal products not yet authorised, not yet included in the SL, or used outside their marketing authorisation (Articles 71b-d of the HIO).

Medical devices applied by the patient are reimbursed under the condition that they belong to a specific group of medical devices in the LIT, are prescribed by a physician or chiropractor, and are dispensed by an authorised provider. The reimbursement of listed medical devices may be restricted to specific medical indications, quantities or durations. Case law has not yet addressed the question of whether the provisions of Article 71a-d of the HIO are also applicable to medical devices by analogy.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Among the conditions for the inclusion of medicinal products on the SL are their efficacy, appropriateness and cost-effectiveness, and the existence of these conditions must be periodically reviewed (Article 32 of the HIA). Medicinal products that no longer meet these criteria are removed from the SL by the FOPH. The same applies to medical devices (to be) included in the LIT.

It is usually undisputed that an authorised medicinal product is effective and appropriate. In practice, the main focus is therefore on the criterion of cost-effectiveness, including the respective comparisons with other medicinal

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products and markets (see 8.2 Price Levels of Pharmaceuticals or Medical Devices).

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Although the main purpose of the prescribing and dispensing regulations is to safeguard patient welfare and safety in the dispensing and use of medicinal products by requiring that only HCPs with sufficient education, training and continuing education are involved (Articles 24–26 of the TPA), HCPs are required by their professional duties and corresponding provisions in their self-regulations to also observe the aspect of economic efficiency. Furthermore, the legal provisions on the advertising of medicinal products explicitly provide for the inadmissibility of advertising (including to HCPs) that may encourage the excessive use of medicinal products (cf Article 32 paragraph 1 lit b of the TPA). Lastly, the integrity provisions (cf the OIT and Article 55 of the TPA) prohibit the excessive prescribing of medicines.

In general, physicians may prescribe any authorised medicinal product for a given indication without regard to its price and they are not obliged to propose a more affordable (generic) alternative. That said, if the SL contains different medicinal products containing the same API, the cost share that must be borne by the patient may vary. Physicians must inform their patients accordingly. Equally, for medicinal products that are not included in the SL or that are used off-label or off-limitation, HCPs must inform the patients that the costs might not be reimbursed under the compulsory health insurance. According to Article 52a of the HIA, pharmacists are allowed – but not obliged – to substitute a prescribed original medicinal product listed on the SL with a generic unless there is an explicit request by the prescribing physician or chiropractor to dispense the original.

Trends and Developments

Contributed by:

Tobias Meili and André Berne

Wenger Plattner

Wenger Plattner has been advising and representing clients in all aspects of business law for over 40 years, with more than 100 employees at its offices in Basel, Zurich and Bern. The firm's lawyers identify practical, workable solutions and help clients implement these to achieve the best possible commercial outcomes. Many of Wenger Plattner's experts are involved in decision-making as members of public authorities

and other bodies, which gives them an in-depth understanding of client needs. As a fully integrated partnership, the firm places a strong emphasis on teamwork and co-operation. Wenger Plattner's clients have access to dedicated, highly experienced specialists who offer top-level advice so that clients can meet their specific objectives efficiently and effectively.

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Initiatives and Challenges Impacting the Development of the Swiss Life Sciences Sector

In Switzerland, key legislation at federal level relating to the healthcare system is subject to federal referendums. This leads to a high level of acceptance in the population. In substance, the Swiss healthcare system is not only characterised by the high quality of its medical services but also by a persistent rise in costs and a generally high expenditure level. In Europe, Switzerland spends both the highest proportion of GDP and the most financial resources per capita on healthcare, which is reflected in constantly increasing cost pressure and rising patient demands.

Regarding innovation, Switzerland is one of the world's foremost innovators in biomedical research and life sciences technology. The chemical and pharmaceuticals industry is Switzerland's largest export sector and contributes approximately 5% to the country's GDP. There are about 1,000 companies active in this industry, with Novartis and Roche (both headquartered in the life sciences hub of Basel) being among the top ten global pharma companies. Most products in the Swiss life sciences sector are exported to the EU, which is why the EU regulatory framework is highly relevant.

Given that Switzerland's largest trading partner is the EU, the Swiss legislator strives for a far-reaching harmonisation of Swiss and EU legislation. Consequently, developments in the Swiss life sciences sector often mirror EU regulatory developments. Thus, various EU regulations significantly inform Swiss legislation, even though Switzerland is not a member state of the EU.

Considering these aspects, the Swiss life sciences sector is currently undergoing significant changes. This overview highlights some recent initiatives in the sector.

Ongoing revision of the Federal Therapeutic Products Act

The Federal Therapeutic Products Act (TPA), which contains the most basic regulations on the handling of medicinal products (ie, pharmaceuticals) and medical devices, entered into force in 2002 and is currently being revised. The revision draft was presented in December 2023 and the consultation period ended in March 2024. Once the results of the consultation process have been analysed, the Swiss legislator will tackle the drafting work. The main focuses of attention in the revision are the implementation of e-prescriptions and the improvement of patient medication safety, as well as drug safety in paediatrics. These strategic thrusts serve to

advance the digitisation of the healthcare system – something that plays a central role in cutting healthcare costs, as well as meeting patient demands, and must be further strengthened.

A priority for this revision is to establish a legal basis for the electronic issuance and digital transmission of prescriptions for medicinal products. The exclusively digital transmission of e-prescriptions aims to guarantee better legibility and thus contribute to increasing patient safety. Electronic prescriptions aim to prevent prescription forgeries and unauthorised duplicate prescriptions in the future. The framework conditions under which the e-prescription will be used are specified in the TPA. Nonetheless, patient autonomy and unrestricted pharmacy selection ought to be upheld.

The revision also aims to create a legal basis for a mandatory electronic medication plan and for the implementation of medication reconciliation when prescribing, dispensing or using medicinal products. The proposed law empowers patients to request a printed copy of their medication plan or receive it electronically. The objective is to improve medication safety, acceptability, and treatment compliance, in addition to fostering greater openness and information sharing among all treating healthcare providers.

Children's medication is another significant challenge. Few medications are specifically approved for use in children; however, dosages must be determined for each child based on age, weight, body size, and other pertinent considerations. The Swiss federal government has already issued a national directory with standardised dosage recommendations for the use of pharmaceuticals in paediatrics (Article 67a of the TPA). However, this does not include a calculator function for individual dosage calculations. To

avoid calculation errors as far as possible and thus increase the safety of the use of medicines in children, the revision aims to make the use of electronic systems for calculating drug dosages mandatory.

Furthermore, reflecting the high pace in the development of advanced therapy medicinal products (ATMPs) and their importance in medical practice, ATMPs are also to be regulated more specifically in the TPA. In the EU, ATMPs are regulated in a separate regulation (Regulation (EC) No 2007/1394) and include gene therapy medicinal products, somatic cell therapy medicinal products, bioengineered tissue products, and combinations of ATMPs and medical devices. Not being a member state of the EU, Switzerland nonetheless seeks to mirror EU law as far as possible in the TPA to guarantee Swiss patients access to novel, high-quality treatments and products. The EU and Swiss markets should become more competitive and compatible as a result, and an equivalent level of safety should be established.

Finally, the last area of revision is also due to developments in the EU aimed at avoiding trade barriers, preventing the emergence of antibiotic resistance, and guaranteeing market access to cutting-edge veterinary medicine therapies. The EU has revised and modernised its regulation in the area of veterinary medicinal products (Regulation (EU) No 2019/6), which entered into force on 28 January 2022. Thus, amendments to Swiss law are required to preserve the safety of the country's veterinary medicine supply as well as the ability to export animals and animal products to the EU. Amendments include modifications concerning antimicrobial active substances and – in this context – resistance-reducing measures, as well as modifying the duration of the authorisation for veterinary medicinal prod-

ucts. In addition, market access to novel and innovative therapies in veterinary medicine is to be guaranteed.

Other current legislative revisions

Effective 1 January 2025, the principle of voluntary blood donation has been codified (Article 33a of the TPA). It forbids any remuneration or advantages associated with blood donations, aligning with the principle of voluntary donation for organs, tissues and cells already established in the Federal Constitution. In addition, a prohibition on discrimination has been established to guarantee that individuals cannot be barred from donating blood due to their sexual orientation (Article 36(2bis) of the TPA).

Furthermore, the amendment to the Federal Ordinance on Research Involving Human Beings (the “*Human Research Ordinance*”, or HRO) came into force in November 2024. It is aimed at enhancing the protection of research participants and improving research conditions, especially via digitisation. Consent may now be provided electronically (new Article 8c of the HRO) and further amendments have been made, inter alia, to meet data protection and data security requirements (Article 4(1)(d) of the HRO). Finally, researchers are to engage pertinent demographic groups – such as women and the elderly – more extensively.

Another significant legislative revision that came to an end recently is the uniform financing of inpatient and outpatient medical services regulated by the Federal Health Insurance Act (HIA), which was approved by referendum on 24 November 2024. Thus, starting in 2028, outpatient and inpatient acute services will be uniformly financed, with care services to follow four years thereafter. To date, 55% of inpatient expenses have been jointly financed by the can-

tons (ie, the taxpayers) and 45% by health insurance funds (ie, the premium payers).

Conversely, outpatient expenses have been entirely covered (ie, 100%) by health insurance funds – something that has led to misplaced incentives. An unnecessarily large number of inpatient treatments have been carried out, even though outpatient treatments would have been often medically more appropriate and less expensive. Hence, both methods of treatment will in future be financed according to a uniform distribution mechanism.

Implementation of the Care Initiative

As in other Western countries, the population of elderly citizens in Switzerland is rising. The population of persons aged 100 and above has increased from 61 in 1970 to 2,086 in 2023, according to a survey recently published by the Swiss Federal Statistical Office. The demographic ageing of society is concurrently escalating the demand for nursing personnel. As the population of elderly persons rises, the prevalence of diseases such as cancer, diabetes, and cardiovascular conditions – as well as increasing multimorbidity – is expected to increase in the forthcoming years. This exacerbates the current shortage of qualified care staff in the healthcare sector.

In November 2021, 61% of Swiss voters approved an initiative to improve working conditions for care staff (the “*Care Initiative*”) and hence mitigate the shortage of care staff. As a result of this initiative, legislative measures will be implemented to:

- enhance the training of care staff at the tertiary level;
- enhance the granting of care degrees by higher technical colleges (*Höhere Fachschu-*

- *len*, or HF) and universities of applied sciences (*Fachhochschulen*, or FHs); and
- authorise care staff to directly bill specific medical services to social insurance funds, thereby eliminating the need for a doctor's prescription.

Additional measures are currently under consideration.

In addition, a national monitoring programme for care staff has been introduced that aims to systematically assess the impact of measures implemented based on the Care Initiative over an extended duration. This aims to provide to the federal government, cantons, and employers with a specific management instrument that determines the conditions within the various care sectors and to monitor in detail the consequences of the measures. The data recorded includes the number of vacancies, completed training courses, attrition rate, care staff count, and patient-perceived quality of care.

Continued development of digitisation of Swiss healthcare system

Telemedicine solutions thrive and are widely recognised in Switzerland. Many companies are active in this sector and provide telemedicine solutions, telemedical consultations, and remote monitoring of vital parameters. Hence, an important part of Swiss population has already been exposed to telemedicine. By way of example, numerous providers of telemedicine services offer health insurance companies the opportunity to serve as their policyholders' family doctors and/or medical gatekeepers. It is to be expected that the spreading of telemedicine services will continue and that telemedicine companies operating in Switzerland will aim for European expansion in the medium term.

A further digitisation of the Swiss healthcare system is to be carried out with the programme "*DigiSanté*", which was launched on 1 January 2025. The programme consists of approximately 50 distinct projects, all designed to advance digital transformation in the healthcare sector. These projects encompass legislative initiatives, software development, and the establishment of nationally co-ordinated guidelines for standardisation. Given that data constitutes a central element of digital transformation, standardised data structures and content shall be implemented to ensure that systems work together smoothly (ie, are interoperable) and that information only needs to be recorded once (the "*once-only principle*"). *DigiSanté* aims to establish specific regulations for data access and utilisation by various stakeholders, alongside the digitisation and co-ordination of governmental services and the provision of centralised services, including registers, interfaces, and identifiers.

Such measures will be implemented not only when providing medical services but also in their billing procedures. Thus, envisaged amendments to the HIA that are currently undergoing the consultation process aim to uphold the once-only principle in matters of social insurance law as well. Service providers of inpatient hospital care shall in the future be obliged to centrally transmit certain data to a platform managed by the Swiss Federal Statistical Office. As the once-only principle has not been consistently applied so far, hospitals frequently need to submit identical data multiple times to various authorities. By establishing the once-only principle in the future, the revision aims to eliminate redundant surveys, to organise data flows more transparently, and to enhance and access potential applications of the data.

Electronic patient records

To promote the use of electronic patient records (EPRs), the Federal Electronic Patient Record Act (EPRA) came into force in April 2017. The purpose of the law is to ensure that, in the future, all patient records are maintained exclusively in digital format and that all essential health documents (eg, nursing and hospital reports, examination results, and x-rays) are centrally stored and securely shareable among healthcare professionals. To implement this, all hospitals are required to join a state-certified parent organisation that provides EPRs to private individuals.

However, the use of an EPR is currently voluntary both for physicians and the general public. Consequently, implementation is advancing only incrementally – although there is great public interest and extensive media coverage. According to the Swiss Federal Office of Public Health, only 72,000 EPRs have been opened until August 2024. Therefore, to further promote EPRs, the EPRA is currently undergoing a revision with the aim of mandating all healthcare providers to use EPRs. Thus, it is envisaged that all Swiss residents subject to compulsory health or military insurance will automatically get an EPR. However, individuals may contest the issuance of an individual EPR (opt-out). The implementation date of the revision remains undetermined.

Organ donation

Digitisation also affects organ donation. In a referendum held on 15 May 2022, voters approved an amendment to the Transplantation Act introducing an opt-out system. As soon as the law comes into effect, it will in principle be possible to remove organs, tissues and cells from persons after their death, provided that they did not object to this during their lifetime (nevertheless, numerous exceptions will persist).

Digitisation plays an important role, as an electronic register will be established to document objections or consents to organ donation. The electronic identity (“e-ID”) will ensure the reliable and accurate identification of each registered individual. However, the implementation of such identification method – and thus the register – is contingent upon the enactment of the Federal Act on Electronic Identity, which is currently scheduled for 2026.

Increasing costs of Swiss healthcare system

The healthcare system in Switzerland is based on a social health insurance system – according to which, every Swiss resident is required to be insured with a compulsory health insurance provider. This system is designed to guarantee high-quality care at the lowest possible cost while also fostering greater solidarity between those who are ill and those who are healthy. However, this also means that all Swiss citizens are equally affected by cost increases in the Swiss healthcare system in the form of higher insurance premiums.

Insurance premiums have been rising continuously for the past 15 years. For 2025, health insurance premiums rose by an average of 6% compared to the previous year, even though inflation is low compared to other European countries. Thus, in recent years, these ongoing cost and premium hikes have become a significant economic challenge and political topic. In addition to the above-mentioned uniform financing of outpatient and inpatient treatments in an effort to reduce disincentives, the federal government addresses this issue through a cost-containment programme, whereby various stakeholders of the healthcare system convene biannually to collaboratively formulate specific cost-containment strategies. During an initial meeting in November 2024, stakeholders con-

curred on the objective of achieving annual savings of approximately CHF300 million starting in 2026, which corresponds to 1% of health insurance premiums.

Additionally, by 2026, the TARMED tariff framework for outpatient medical services – instituted in 2004 and serving as the principal basis for invoicing outpatient medical services – will be replaced by a new TARDOC single-service tariff framework and a flat-rate tariff structure.

Relationship with EU

As already mentioned, the EU is Switzerland's largest trading partner. Thus, Switzerland and the EU entered into a mutual recognition agreement (MRA) in relation to conformity assessment. The MRA is designed to remove technical barriers to the trade of industrial goods between the parties and applies, inter alia, to good manufacturing practices (GMP) inspections of medicinal products and to the certification of batches. Consequently, in the case of medicinal products, each party recognises the results of inspections conducted by the competent authorities of the other party at the premises of manufacturers, as well as recognising the production authorisations provided by the competent authorities of the other party. In addition, foreign authorities are permitted – under certain conditions and after notifying the Swiss Authority for Therapeutic Products (“*Swissmedic*”) – to audit Swiss companies active in the life sciences sector.

The MRA also applies, inter alia, to medical devices. Conformity assessments of medical devices authorised in the territory of a party are therefore, in principle, also acknowledged within the jurisdiction of the other party. In view of the recent changes to the EU regulatory framework on medical devices, it is necessary to revise the MRA's provisions on medical devices to guar-

antee mutual recognition of certificates of conformity, facilitation of reciprocal market access, co-ordinated market surveillance, and information sharing between authorities. However, the EC ties such update to further progress in the stalled political negotiations with Switzerland, which were interrupted between May 2021 and March 2024.

As a result of this impasse, the EU currently (still) treats Switzerland as a third country in terms of medical devices, requiring Swiss companies to incur higher administrative efforts to place medical products on the EU market. To counteract these negative impacts, in May 2021 the Swiss Federal Council amended the legal framework regarding medical devices to provide unrestricted access to EU-certified medical devices and to establish long transitional periods, therefore reducing supply issues in Switzerland.

With the negotiations between Switzerland and the EU having resumed in March 2024 and the substantive negotiations being concluded in December 2024, a political breakthrough seems possible – albeit still subject to the uncertainty of a legislative referendum. The achieved agreement focuses on health security, including full access of Switzerland to the EU's health security mechanisms, the European Centre for Disease Prevention and Control (ECDC) and the crisis preparedness area in the EU's multi-year programme (currently “*EU4Health*”). Thus, it remains an open question whether the compromise will also unblock the impasse regarding the MRA on medical devices.

Outlook

Switzerland's life sciences sector has faced significant challenges in recent years due to technological progress, developments in the EU, cost increases, regulatory amendments, and

SWITZERLAND TRENDS AND DEVELOPMENTS

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policy changes. The trends and developments discussed in this overview will continue to have a strong influence on the future development of the Swiss life sciences sector.



Law and Practice

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Arnold & Porter is an international law firm at the intersection of business, law and regulatory policy, serving clients whose business needs require expert US and/or European cross-border regulatory, litigation and transactional services. The firm has a particularly high reputation for advising on UK and EU law relating to pharmaceuticals, biotechnology and healthcare

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

On account of Brexit, the UK is no longer subject to EU single market rules or the EU legislative framework. However, under the EU–UK Withdrawal Agreement’s Protocol on Ireland and Northern Ireland, Northern Ireland continues to follow EU rules. However, this was somewhat narrowed by the entry into force of the EU-UK Windsor Framework on 1 January 2025, which allows for the UK-wide licensing of novel medicines, pursuant to domestic legislation, by the Medicines and Healthcare products Regulatory Agency (MHRA). Pre-existing domestic legislation that implemented EU law continues to have effect in the UK.

UK regulation of medicinal products derives from EU legislation, principally Directive 2001/83/EC (EU Directive 2001/83) and Regulation (EC) 726/2004 (EU Regulation). The key UK legislation is the Human Medicines Regulations 2012 (SI 2012/1916), as amended (HMRs).

Similarly, UK regulation of medical devices derives from three EU Directives (the Medical Device Directives):

- Council Directive 93/42/EEC on Medical Devices;
- Council Directive 90/385/EEC on Active Implantable Medical Devices; and
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD).

These directives are implemented in UK domestic law through the Medical Devices Regulations 2002/618, as amended (UK Medical Devices Regulations). The more recent EU Regulations

on medical devices – Regulation (EU) 2017/745 on medical devices (EU MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR) – do not apply to Great Britain, but do to Northern Ireland. The UK government intends to bring the UK Medical Devices Regulations up to date through a series of Statutory Instruments. The first of these regarding post-market surveillance requirements will come into force on 16 June 2025.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency sponsored by the Department of Health and Social Care (DHSC). The MHRA has the statutory responsibility to apply and enforce laws governing pharmaceuticals and medical devices in the UK.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Decisions of the MHRA can be challenged by way of judicial review in the Administrative Court, King’s Bench Division or through statutory review proceedings, although this is rarely used.

For a judicial review, an application must be made promptly, and in any event within three months of the decision to be challenged, and the applicants must be able to show a sufficient interest in the matter to which the application relates.

The court’s permission is required to proceed with a claim for judicial review.

The grounds for judicial review can be summarised as:

- illegality;

- irrationality;
- procedural unfairness; and
- legitimate expectation.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are three categories, or legal classifications, of medicinal products, which determine the level of control over supply. In part, classification rests on how much healthcare professional (HCP) input is needed to diagnose and treat the conditions for which the medicine might be used. The three legal classifications are:

- prescription-only medicines (POMs) – these have to be prescribed by a doctor or other authorised HCP and have to be dispensed from a pharmacy or from another specifically licensed place;
- pharmacy (also known as P, over the counter or OTC) – these have an intermediate level of control and can be bought only from pharmacies and under a pharmacist's supervision; and
- general sales list (GSL) – these may be bought from general retail stores or vending machines.

Medical devices are given a classification depending on the level of risk associated with their use. This relates to the regulatory pathway for the product rather than the conditions on supply. How a medical device is classified will depend on factors such as:

- the intended purpose of the device;
- how long it is intended to be in use; and
- if the device is invasive/surgically invasive, is implantable or active, or contains a substance which in its own right is considered to be a medicinal substance.

General medical devices and active implantable devices fall within the following categories:

- Class I – low risk;
- Class IIa – medium risk;
- Class IIb – medium risk; and
- Class III – high risk.

In vitro diagnostic (IVD) medical devices in Great Britain are currently categorised differently into four main groups – namely, those which are (there are different classifications under the EU IVDR that applies in Northern Ireland):

- considered as general IVD medical devices;
- within the classifications stated in Annex II List A of the IVDD (which is referred to in UK legislation);
- within the classifications stated in Annex II List B of the IVDD; and
- for “*self-test*” intended to be used by a person at home.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The current UK law governing clinical trials of medicinal products is the Medicines for Human Use (Clinical Trials) Regulations 2004/1031, which transposed the EU Clinical Trials Directive 2001/20/EC into UK law, and has been amended to reflect the UK's departure from the EU. Clinical trials must be conducted in accordance with good clinical practice (GCP), the terms of the approved protocol, clinical trial authorisation and research ethics committee (REC) approval. The EU Clinical Trials Regulation 536/2014, which came into full effect on 31 January 2022, does not apply in Great Britain but, as a result of the Northern Ireland Protocol, certain parts apply in Northern Ireland.

Following a public consultation undertaken by the MHRA in early 2022, new regulations (the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024) were laid before the UK parliament in December 2024 to amend the current UK framework governing clinical trials. The aim is to streamline clinical trial approvals, enable innovation, enhance clinical trial transparency, enable greater risk proportionality, and promote patient and public involvement. The aim is for these changes to come into force by early 2026.

Clinical investigations for medical devices are regulated by the UK Medical Devices Regulations. Requirements relating to clinical investigations under the EU MDR and the EU IVDR apply in Northern Ireland. The amended regulations for medical devices, when introduced by the UK government, will also amend the requirements for clinical investigations.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Before a clinical trial for a medicinal product can commence, a REC must give a favourable opinion, and authorisation must be obtained from the MHRA. A sponsor of a clinical trial must be established in the UK or in a country on an approved country list, which includes EU/EEA countries. Otherwise, the sponsor must have a legal representative.

As of 1 January 2022, applications for all new clinical trials for investigational medicinal products must be prepared, submitted and reviewed via the combined review service – a single application route with co-ordinated review by the MHRA and the REC, leading to a single UK decision on the application. Applications must be submitted via the Integrated Research Application System (IRAS). While this single applica-

tion route is currently available in the UK through various schemes and pilots, it will be enshrined into law when the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024 come into force.

After receipt of a valid application, an assessment will be conducted within 30 days. Following assessment, and ordinarily within 60 days of the submission, the MHRA and the REC will either:

- accept the request;
- accept the request subject to conditions; or
- not accept the request.

The MHRA will focus on the safety and scientific value of the trial, while the REC will focus on the research proposals and review certain documents relating to the trial, including the trial protocol, the informed consent form, the suitability of the personnel, investigator and facilities, and the investigator's brochure.

The MHRA must be notified by the sponsor at least 60 days in advance of the commencement of a clinical investigation involving medical devices. Applications should be submitted via the IRAS. The MHRA will consider the documentation and assess the safety and performance of the device, as well as the design of the investigation. A letter will be sent to the sponsor within 60 days with a decision (providing either an “*objection*” or “*no objection*”). In addition, an opinion of the REC is required.

2.3 Public Availability of the Conduct of a Clinical Trial

Any favourable opinion by a REC is conditional upon the clinical trial being registered on a publicly accessible database.

Since 1 January 2022, the Health Research Authority (HRA) automatically registers clinical trials submitted through IRAS with the International Standard Randomised Controlled Trial Number (ISRCTN) registry.

Information about trials (for both medicinal and devices) being conducted in the UK is made publicly available on the HRA research summaries website and on the UK *“Be Part of Research”* website.

In addition, the advertising code for the pharmaceutical industry published by the Association of the British Pharmaceutical Industry (ABPI) requires companies to disclose details of clinical trials in accordance with international requirements. This is not set out in the equivalent Code applicable to medical devices.

2.4 Restriction on Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials or clinical investigations. However, all advertising and all materials provided or directed to subjects will be reviewed by the REC.

2.5 Use of Data Resulting From Clinical Trials

Data resulting from clinical trials is likely to be considered as special category (sensitive) personal health data for the purposes of the data protection legislation, even if it is in coded/pseudonymised form, and will be afforded greater protection than non-special category personal data. The Data Protection Act 2018 and the UK GDPR provide that pseudonymisation is a security measure that can be used to protect personal data, but it does not mean that the data is beyond the scope of the UK GDPR.

The resulting data can be transferred to a third party or affiliate, provided that any UK GDPR provisions governing such a transfer are complied with.

The Data (Use and Access) Bill was introduced in October 2024, and it proposes to amend the UK GDPR and Data Protection Act 2018 in various ways. In particular, it will allow for patients to provide *“broad consent”* to use of their personal data for scientific research, allowing use of their personal data for broad research purposes. If the Bill receives royal assent, its provisions may come into force by early 2026.

2.6 Databases Containing Personal or Sensitive Data

If a database contains personal or special category (sensitive) personal health data, the UK GDPR would need to be complied with. The key requirements are as follows:

- the data is processed lawfully;
- the data stored is relevant, up to date and limited to what is required;
- sufficient security measures are put in place;
- the data is not stored for longer than is necessary; and
- the relevant individuals have been informed of the use and storage of their data.

The party managing the database would also need to comply with the UK GDPR more widely.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The HMRs define a medicinal product as:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
- any substance or combination of substances that may be used by or administered to human beings with a view to:
 - (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action; or
 - (b) making a medical diagnosis.

The UK Medical Devices Regulations define a medical device as any instrument, apparatus, appliance, software, material or other article, used alone or combined, for humans to:

- diagnose, prevent, monitor, treat or alleviate disease;
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap;
- investigate, replace or modify the anatomy or a physiological process; or
- control conception.

To distinguish between medical devices and medicinal products, it is important to consider:

- the intended purpose of the product, taking into account the way the product is presented; and
- the method by which the principal intended action is achieved.

Where the assessment is not straightforward, or where disagreement arises, the MHRA's Medicines Borderline Section is able to issue determinations. Where a product falls into more than one category, a product will be classified as a medicinal product.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

A medicinal product may only be placed on the UK market if it has been granted a marketing authorisation (MA). Biological medicinal products must meet the same quality, safety and efficacy criteria to obtain an MA as those for non-biological medicinal products. However, since biological medicinal products are especially sensitive to change in starting materials or manufacturing conditions, they are subject to specific requirements, as set out in Annex I to EU Directive 2001/83, as amended by Schedule 8B of the HMRs.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

MA for medicinal products in the UK are valid for an initial period of five years. However, an MA ceases to be valid if the product is not placed on the market within three years of the date of authorisation (known as the “*sunset*” clause).

The renewal application should be submitted to the MHRA six months before expiry. The authorisation may be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the MA will be valid for an unlimited period, unless there are justified grounds relating to pharmacovigilance to proceed with one additional five-year renewal.

The MHRA may revoke, vary or suspend a UK MA in certain situations, including if the MHRA believes that the product is harmful or that the positive therapeutic effects of the product do not outweigh its risks to the health of patients or the public, or that the product's composition is not as described in the application for the MA or the material supplied with it.

With regard to medical devices, a UK Conformity Assessed (UKCA) mark is valid indefinitely, and the underlying conformity assessment does not require renewal unless the specifications of the device change.

The MHRA has the power to issue various notices to manufacturers (eg, prohibition notices) to ban the supply of any goods that are considered unsafe or that do not comply with the UK Medical Devices Regulations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

Medicinal Products

An application for a UK national MA must be made to the MHRA and must include the particulars and research data or justifications for exceptions that are described in the HMRS, which is based on the EU Directive 2001/83. Following Brexit, UK MAs were split into various types, depending on the parts of the UK to which they apply. In particular, applications intended to cover the marketing of a product in Northern Ireland had to comply with the requirements of EU Directive 2001/83 and EU Regulation 726/2004. This led to different types of authorisation in different parts of the UK. However, under the Windsor Framework, from January 2025, applications for a UK-wide product licence can be made to the MHRA under UK law.

Medical Devices

As of 1 January 2021, there is a new route to place a device on the Great Britain market, with an accompanying mark based on the requirements derived from the Medical Device Directives as implemented into UK law: the UKCA. EU CE marking (the acronym for the French *Conformité Européenne* or “European conformity”) will continue to be recognised in Great Britain,

and certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market, up to June 2030, with different dates depending on the device.

EU rules will continue to apply in Northern Ireland, and EU CE marking is required. In addition, if the manufacturer chooses to use a UK Notified Body for mandatory third-party conformity assessment for purposes of the Northern Ireland market, the UKNI mark must be applied in addition to the CE mark.

As previously noted, medical devices are given a classification depending on the level of risk associated with their use. Each risk classification also has a separate conformity assessment procedure. If the relevant requirements are met, the Approved Body will issue a UKCA certificate. Only UK-Approved Bodies may conduct conformity assessments in relation to a UKCA mark. They are not able to issue CE certificates other than for the purposes of the “CE UKNI” marking, which is valid in Northern Ireland.

Low-risk Class I medical devices do not need to go through a conformity assessment procedure. For all devices, once the relevant assessment has been completed successfully, the manufacturer may place a UKCA mark on their medical device and put it on the market in Great Britain.

To be placed on the Great Britain or Northern Ireland market, all devices must now be registered with the MHRA, which will only accept the registration of devices from entities based in the UK. Therefore, manufacturers based outside the UK are required to appoint a UK Responsible Person that is established in the UK.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The HMRs state that a person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product, or a medicinal product other than in accordance with the terms of an MA. However, there are exceptions whereby a product can be placed on the market without an MA. The main exception is often called “*named-patient supply*” and applies if the medicinal product is:

- supplied in response to an unsolicited order;
- manufactured and assembled in accordance with the specification of a person who is authorised to prescribe; and
- for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient.

Certain conditions set out in the HMRs must also be met.

When named-patient supply of medicinal products is offered to a co-ordinated patient group, this is referred to as “*compassionate-use scheme*”. However, the legislative provisions of named-patient supply continue to apply.

The Early Access to Medicines Scheme is a voluntary scheme that allows patients to access innovative unlicensed medicines earlier than the current MA procedures permit, but applies only to medicines that target life-threatening or seriously debilitating conditions for which there are no existing satisfactory treatments.

In relation to medical devices, it is also a requirement that all devices placed on the market must have a UKCA or EU CE mark. However, devices that are custom-made for individual patients do

not need a UKCA mark. Custom-made medical devices are defined as devices manufactured specifically in accordance with a duly qualified medical practitioner’s written prescription that gives specific design characteristics, under their responsibility, and is intended for the sole use of a particular patient. The manufacturer of a custom-made medical device must meet the requirements of the UK Medical Devices Regulations that relate to custom-made devices.

The MHRA may also approve exceptional use of a non-compliant device on humanitarian grounds. These devices do not need a UKCA mark. A manufacturer can apply to the MHRA to supply a medical device that does not comply with the law to protect a patient’s health if there is no legitimate alternative available. The same provision may be made for custom-made devices that have not complied with the standard conformity assessment procedure.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

MA holders must operate a pharmacovigilance system to monitor the safety of their product’s life cycle, and to detect any change to their risk-benefit balance for the medicinal product. They must:

- have an appropriately qualified person (QP) responsible for pharmacovigilance located in the EEA (however, where this person does not reside and operate in the UK, there will be a need for a national contact person for pharmacovigilance who resides and operates in the UK);
- maintain a pharmacovigilance master file;
- operate, monitor and update a risk management system for the product;

- record and report all suspected adverse reactions occurring in relation to their products; and
- submit periodic risk-benefit evaluation reports for their products.

The MHRA may grant an MA subject to one or more conditions, including post-marketing obligations such as the requirement to conduct post-authorisation safety and efficacy studies. The MA holder must incorporate any such condition into the risk management system for the product.

Once a medical device has been placed on the UK market, the MHRA requires the manufacturer to monitor and report to it any serious adverse incidents associated with the product. The manufacturer must also take appropriate safety action when required.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices
Requests for information about MAs and pending MAs for medicinal products may be submitted to the MHRA under the Freedom of Information Act 2000 (FOIA).

The MHRA releases very little information in relation to pending applications.

Following the grant or refusal of an MA, the MHRA generally releases detailed information about the application and authorisation, both proactively via disclosures on its website and also in response to third-party information requests. The FOIA provides mechanisms whereby personal data, confidential information and commercially sensitive information may be withheld or redacted from documents requested by third parties, and the MHRA typically allows

MA holders to comment on any proposed redactions prior to their release.

For medical devices, Approved Bodies are private entities. Therefore, access to information provisions that apply to public bodies do not apply. As such, both before and after UKCA marking, the information pertaining to the device remains the property of the manufacturer. Once registered with the MHRA, a manufacturer's details will be added to the Public Access Database for Medical Device Registration. Other information held by the MHRA could be requested under the FOIA, but will only be provided where no exceptions under the FOIA apply.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The UK operates a national accelerated procedure for medicinal products, which took effect in January 2021. Under this route, the MHRA evaluates all high quality UK MA applications and reaches an opinion within 150 days of application validation, with the aim of accelerating market access.

The assessment period is split into two phases. Phase I involves an 80-day period, during which the MHRA will consult with the Commission on Human Medicines (CHM) and/or therapy area experts. Any concerns arising after this initial assessment will be raised in a request for further information letter to the applicant. The applicant has 60 days (a clock-stop period) to address and respond to the concerns (an extension is available in exceptional circumstances only). Phase II begins following MHRA's receipt of the applicant's responses, following which the MHRA will provide an opinion on approvability. If the MHRA

refuses an application upon the advice of CHM, an appeal can be made.

The UK is also part of an access consortium work-sharing procedure. This allows for simultaneous submission to the UK, Australia, Canada, Singapore and/or Switzerland, for an internationally co-ordinated review. The standard procedure takes 180 days (excluding stop-clocks).

In addition, the Innovative Licensing and Access Pathway (ILAP) is an initiative aimed at bringing innovative medicines and medicine-device combinations to the UK market more quickly. It was first launched in January 2021, and was relaunched in January 2025. Successful applicants are awarded an Innovation Passport, which enables developers to work collaboratively with the national health services (NHS), MHRA, and UK Health Technology Assessment (HTA) bodies to bring products to the UK market in a more streamlined and efficient way.

In relation to medical devices, the UK has launched the Innovative Devices Access Pathway (IDAP) pilot that is designed to accelerate the development of innovative medical devices that meet an unmet clinical need in the NHS and support their integration into the UK market. Eight technologies were selected that will receive tailored regulatory and access support.

4.2 Regulatory Reliance

On 1 January 2024, an International Recognition Procedure (IRP) for medicinal products came into force in the UK, which enables the MHRA to consider the expertise of regulatory partners in other countries and utilise pre-existing approvals to speed up authorisation in the UK, including (but not limited to) approvals in the EU. Such partners are referred to as reference regulators (or RR). The product must be classified as a

medicinal product in accordance with the HMRS and the IRP application must relate to the same product for which authorisation has already been granted by an RR. The IRP can be used for multiple types of MA applications, including chemical and biological new active substances, known active substances, generics, hybrids, biosimilars and new fixed combination products.

There are two recognition routes under the IRP: Recognition A (60 day timetable) and Recognition B (110 day timetable), to which different eligibility criteria apply. The main criteria for Recognition A are that the RR approval was granted within the previous two years and manufacturing processes are the same, with evidence of GMP compliance. For Recognition B, possible applicable criteria are more numerous, but the main criterion is that the RR approval has been granted in the previous ten years, subject to exceptional circumstances. While MHRA will conduct a targeted assessment of IRP applications based on the assessment by the RR, it may reject applications on the basis that evidence supplied by the applicant is not sufficiently robust.

For medical devices, as discussed above, EU CE marks are recognised in Great Britain until 30 June 2030 at the latest depending upon the type of device.

The UK Medical Devices Regulations are currently under review and part of the consultation process included considering alternative routes to market. In 2024, the MHRA published a statement of policy intent for international recognition of medical devices, which describes MHRA's intentions for recognition by the UK of international regulators' approvals for medical devices. It is anticipated that comparable regulator countries will be (at least initially) the EU, as well as Australia, Canada and the USA, and various

criteria will need to be fulfilled. The proposed framework would provide a certificate of international recognition that will grant devices access to the Great Britain market. It is anticipated that certain devices, for example custom-made and certain software devices, will be excluded from eligibility.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

A manufacturer licence issued by the MHRA is required in order to manufacture, assemble or import licensed, unlicensed or investigational medicinal products. The process involves the submission of an application and the inspection of the designated manufacturing site by the MHRA to verify compliance with good manufacturing practice (GMP). A manufacturer licence remains in force until it is revoked or surrendered.

Manufacturers of medical devices are not required to obtain a specific authorisation for the manufacture of their products, but are required to register the medical devices with the MHRA in order to place them on the market in Great Britain and (for certain medical devices, including IVD medical devices) Northern Ireland. As previously noted, the MHRA will only register medical devices where the manufacturer or their UK Responsible Person has a registered place of business in the UK.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

A wholesale distribution authorisation (WDA) issued by the MHRA is required in order to:

- sell, supply, offer for sale, procure, hold or export POM, P/OTC, traditional herbal and GSL medicines on a wholesale basis in the UK;
- import QP-certified medicinal products into Great Britain from EEA countries; and
- export medicinal products to EEA and non-EEA countries.

WDA holders located in Northern Ireland can still bring medicinal products into Northern Ireland from Great Britain, provided certain additional conditions are met.

The facility involved in wholesale distribution is subject to inspection by the MHRA before a licence is granted. A WDA remains in force until it is revoked or surrendered.

Distributors of medical devices are not required to obtain an authorisation to engage in wholesale trade.

6.2 Different Classifications Applicable to Pharmaceuticals

See 1.3 Different Categories of Pharmaceuticals and Medical Devices.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The importing and exporting of medicinal products are governed by the HMRs (or EU Directive 2001/83 in relation to Northern Ireland). A Certificate of Pharmaceutical Product may be required. The importing of medical devices is governed by the UK Medical Devices Regulations (or the relevant EU Directive in relation to Northern Ireland). The UK government plans to introduce new regulations for medical devices over the course of 2025 and 2026. These regulations are expected clarify the requirements for economic operators, including importers. There are no specific rules regarding the exporting of medical devices except that a Certificate of Free Sale may be needed depending on the importing country.

HM Revenue and Customs is responsible for border control. The MHRA Enforcement Group is responsible for applying and enforcing the HMRs and the UK Medical Devices Regulations.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Importers of pharmaceuticals and medical devices require an Economic Operator Registration and Identification number, which is entered onto all UK customs declarations. Importers must be a UK-resident business for certain UK customs issues, including the declarations.

The designation of a particular entity as the importer of record for customs purposes will not be conclusive in determining who should hold

any required import authorisations from a regulatory perspective.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Importing medicinal products into the UK from countries outside the EEA for use in the UK or to supply to an EEA country requires a manufacturer's import authorisation granted by the MHRA. Importing QP-certified medicines into Great Britain from the EEA may be performed under a WDA that authorises import.

No authorisation is required to import medical devices, but importers should notify the UK Responsible Person or the Northern Ireland-based Authorised Representative (as described in 3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices), as they are required to provide the MHRA with a list of device importers.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Details of specific tariff duties and measures that apply to particular goods in the UK are contained in the Integrated Tariff of the UK. An importer or exporter is responsible for the correct tariff classification of goods. His Majesty's Revenue and Customs (HMRC) has developed an online trade tariff tool to assist in product classification.

7.5 Trade Blocs and Free Trade Agreements

Under the EU–UK Trade and Co-operation Agreement, and the UK's free trade deal with Norway, Iceland and Liechtenstein, there are no tariffs or quotas on trade in medicinal products and medical devices between the UK and the EU and EEA countries, and mutual recognition of GMP inspections and certificates. The UK has also entered into an economic partner-

ship agreement with Japan, which provides for mutual recognition of conformity assessments for GMP. The UK has entered into free trade agreements and mutual recognition agreements (MRAs) with Australia and New Zealand which provide for no tariffs or quotas on trade in most medicinal products and medical devices as well as mutual recognition of conformity assessment of medical devices and GMP. The UK-USA MRA provides for mutual recognition of conformity assessments for GMP of pharmaceuticals. The UK-Switzerland Trade Agreement provides for mutual recognition of GMP inspections and certifications. The UK-Canada Trade Continuity Agreement includes a protocol relating to mutual recognition of conformity assessments for GMP of pharmaceuticals. The UK-Israel Trade and Partnership Agreement provides for mutual recognition of GMP inspections and certifications. The UK-Singapore Free Trade Agreement provides preferential tariffs and a reduction of non-tariff barriers for medicinal products and medical devices. The UK remains a member of the World Trade Organization.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Statutory controls on pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation. There are currently two schemes for controlling prices of branded medicines purchased by the national health services in the UK: (i) a Voluntary Scheme; and (ii) the Statutory Scheme.

The Voluntary Scheme for Branded Medicines Pricing and Access (VPAG or the “Scheme”) is an agreement, which is non-binding under the

laws of contract, negotiated between DHSC, NHS England and the ABPI. It controls the prices of branded health medicines by:

- limiting the profits made by scheme members from their NHS business;
- controlling the maximum prices which may be charged for medicines within the Scheme;
- establishing a budget cap on the total expenditure by the NHS on branded health service medicines, with member companies making scheme payments to the DHSC as quarterly rebates (calculated as a percentage of eligible net sales) to cover excess expenditure.

New branded health services medicines that contain a new active substance and are supplied by VPAG member companies are subject to free pricing at launch, as are line extensions of such medicines launched within 36 months of licensing of the initial indication in the UK. The prices of such products must be notified to the DHSC prior to launch. The price for all other branded health service medicines supplied by VPAG member companies must be agreed with the DHSC.

If a company is not a member of the VPAG, it is regulated by the parallel Statutory Scheme. The Statutory Scheme is applicable only to branded health service POMs. Since 1 April 2018, it has involved a payment scheme calculated as a percentage of net sales, and from 1 January 2025, the Scheme has differentiated between older and newer medicines in a manner similar to VPAG. The maximum price that may be charged for a branded health service medicine within the Statutory Scheme is that directed by the Secretary of State. The DHSC has stated that it aims for broad commercial parity between the schemes and has in recent years made various

amendments to the Statutory Scheme to bring it in line with changes in the Voluntary Scheme, including harmonising certain exemptions from the requirement to make Statutory Scheme payments, with those applicable in the Voluntary Scheme.

Prices may also be limited as a result of competition, including through tenders. In primary care, the price of some medicinal products may be indirectly controlled by the reimbursement price, as set out in the Drug Tariff (a monthly publication specifying the amounts to be paid to contractors for providing relevant goods and services). These prices are calculated based on sales information provided by pharmacies, manufacturers and wholesalers. Where the Drug Tariff does not list a reimbursement price for a medicine, or where a product is prescribed by brand name, it will be reimbursed at the manufacturer's NHS list price.

Medical devices will only be routinely dispensed in primary care through the NHS if they are included in the Drug Tariff. The DHSC/NHS Business Services Authority (NHSBSA) agrees the reimbursement price of the medical device with the manufacturer at launch, and this is principally determined by comparing the device with similar products on the market and their respective prices. If there are no comparable devices or if the applicant submits evidence to support a different price, the reimbursement price is determined by negotiation between the parties.

8.2 Price Levels of Pharmaceuticals or Medical Devices

There is no formal system of international reference pricing, although the cost of the presentation in other markets is specifically listed as a relevant criterion to which the DHSC should

have regard when agreeing or directing a price under the VPAG or the Statutory Scheme.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

All authorised medicines validly prescribed on an NHS prescription may in principle be reimbursed from public funds, unless expressly excluded.

In primary care, patients receive medicines prescribed by their GPs from community pharmacies. Patients in England must pay a fixed price for NHS prescriptions, unless exempt. Prescription charges have been abolished in Northern Ireland, Scotland and Wales.

Medicinal products used in NHS hospitals are funded by commissioners in accordance with the “*national tariff*”, a set of prices for defined procedures and items of care (currencies) established under the Health and Social Care Act 2012. Hospitals are paid for procedures performed or care provided (including the costs of associated medicines and devices), based on amounts fixed in the national tariff. Certain new and high-cost medicines and medical devices are reimbursed outside the tariff system, and enhanced payments may be made for some patients.

In England, most new medicines (and new indications for existing products) undergo health technology appraisal by the National Institute for Health and Care Excellence (NICE), which issues recommendations on NHS use based on its assessment of clinical effectiveness and cost effectiveness. NHS bodies in England are required by regulations to make funding available so that patients can access treatments recommended by NICE. NICE assesses some medical devices and diagnostic tests through parallel procedures.

The All Wales Medicines Strategy Group (AWMSG) issues guidance in Wales on new technologies immediately following launch. In Scotland, the Scottish Medicines Consortium (SMC) assesses all new medicines and new indications for existing medicines and issues guidance close to the product launch. In Northern Ireland, its Department of Health (NI DoH), considers NICE guidance and reviews it for legal, policy and financial consequences only, before deciding on implementation.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

In theory, NHS prescribers may prescribe any medicine considered clinically appropriate for their patients but, in practice, NHS commissioners control which medicines may be prescribed through local or national formularies, largely determined by the cost-effectiveness of individual products. Treatments recommended by NICE should be included automatically in NHS formularies in England; products not recommended by NICE are generally not funded on a routine basis. An equivalent approach is taken to products recommended by the AWMSG, the SMC and the NI DoH.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Community pharmacists purchase products from manufacturers or wholesalers and are reimbursed by the NHSBSA at the rate specified in the Drug Tariff, or, where no reimbursement price is set in the Drug Tariff, at the manufacturer's list price. When the price paid by the pharmacist is less than that reimbursed by the NHSBSA, the pharmacist makes a margin of profit. The extent of this margin is monitored by the NHSBSA, and claw-backs are imposed to ensure that pharmacy profits do not exceed defined limits.

There is no generic substitution by community pharmacists in the UK, and the Medicines Act 1968 requires the particular product prescribed to be dispensed. However, in general, doctors are encouraged to prescribe products using their international non-proprietary name (INN). Where a product is prescribed by its INN, the pharmacist may dispense any product that meets the specifications/INN described, and is likely to select the lowest-cost product. Generic substitution is standard practice in the hospital context.



Law and Practice

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Arnold & Porter is a 1,000-lawyer firm with a global reach and extensive experience in virtually every area of life sciences law. Arnold & Porter offers renowned regulatory, white-collar defence, product liability and commercial litigation, antitrust, IP and transactional capabilities to clients who include a wide variety of pharmaceuticals, biotech, medical device and diagnostic companies and trade associations, as well as

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The primary legislation governing the authorisation, marketing, sale and supply of pharmaceutical products by the US Food and Drug Administration (FDA) is the Federal Food, Drug, and Cosmetic Act (the “*FD&C Act*”), which has been amended many times throughout the years to reflect increasing FDA mandates for the regulation of pharmaceutical products. The Public Health Service Act (the “*PHS Act*”) is the specific authority used to approve or license biological (including biosimilar) products.

The primary FDA regulations governing drugs and biologics are found in Chapter 21 of the Code of Federal Regulations. Controlled substances, such as opioids, are also scheduled and subject to quotas and distribution controls under the Controlled Substances Act administered by the Drug Enforcement Administration (DEA).

A drug is defined as:

- an article recognised in the US Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, or the National Formulary;
- an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease;
- an article (other than food) intended to affect the structure or any function of the body; and
- an article intended for use as a component of a drug but not as a device (or a component, part or accessory of a device).

A biologic is defined under the PHS Act as “a *virus, therapeutic serum, toxin, antitoxin, vac-*

cine, blood, blood component (or derivative), allergenic product, protein (or analogous product), or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound) applicable to the prevention, treatment or cure of a disease or condition of human beings”. Notably, a protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. Biological products also fall within the drug definition and are generally covered by most of the same laws and regulations; however, differences exist in the regulatory approach.

Medical devices are also regulated by the FDA under the FD&C Act and – although subject to similar intent standards – such products are primarily intended to act via mechanical rather than chemical or biological modes of action. Medical devices are classified by risk and may be:

- exempt from FDA review;
- subject to “510(k)” pre-market notification process if they show substantial equivalence to “predicate” device;
- subject to down-classification via the de novo submission process; or
- eligible for full approval via a pre-market approval (PMA) application.

Although the FDA has traditionally been given significant independence as an agency, and the Commissioner is confirmed by the Senate, the FDA is part of the Department of Health and Human Services (HHS).

The government agencies touching on pricing and reimbursement vary, depending upon the payor programme, and include the Centers for Medicare & Medicaid Services (CMS) (also part of the HHS), the Veterans Health Administration, and state Medicaid agencies. In addition, the

HHS Office of Inspector General oversees laws governing fraud and abuse in the sale of biomedical products and healthcare services. The Federal Trade Commission (FTC), an independent agency, regulates the advertising of non-prescription drugs and non-restricted medical devices.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Agency decisions may be challenged either informally (via guidance-driven processes governing dispute resolution) or via more formal regulatory processes specified under FDA regulations. In addition, a general-purpose vehicle for bringing issues before the agency is the FDA citizen petition, which allows the petitioner to bring a request before the FDA and initiate a public docket in which comments can be lodged. The FDA also maintains ombudsmen in the various centres where products are reviewed, whose role is intended to facilitate the resolution of disputes. Although procedures for dispute resolution vary, depending on the specific statutory provisions at issue and the FDA centre responsible for the category of products, such processes generally follow Administrative Procedure Act (APA) standards for due process and creating an administrative record.

Once administrative processes are exhausted, parties with appropriate standing may challenge FDA decisions in court under the APA. Although administrative processes vary by category, APA legal challenges typically involve a demonstration that an agency action was arbitrary or capricious or otherwise not in accordance with governing law.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Although the default status for drug approvals is technically OTC (ie, non-prescription), most initial drug approvals specify that new drug products are subject to prescription drug controls. Prescription drugs must be labelled as such and are subject to physician prescribing, pharmacy dispensing, and substitution controls under state law.

However, it is possible to seek an initial FDA approval for the sale of a drug product OTC or to seek to “switch” prescription product to OTC status by demonstrating that the condition can be self-diagnosed and treated in accordance with labelling. Moreover, throughout the decades, the FDA has also developed OTC monographs that permit the marketing – without approval – of certain OTC drugs that meet the specific terms (eg, ingredients, dosing, and directions for use) for that class of drug and associated labelling under the relevant monograph. Such drugs remain subject to establishment registration, listing, labelling and current Good Manufacturing Practice (cGMP) requirements. Recent legislation liberalised the processes for amending OTC monographs and this could help reinvigorate OTC product development in the USA.

Additionally, the FDA has issued a final rule that permits OTC drugs with an “*additional condition for non-prescription use*” (ACNU). The purpose of this is to increase options for the development and marketing of safe and effective non-prescription drug products via the use of tools (such as digital apps) that support patient self-diagnosis and treatment.

Medical devices may also be assigned to non-restricted (including OTC) or restricted status, depending on their classification and the FDA’s

determination as to appropriate status under clearance and approval processes.

2. Clinical Trials

2.1 Regulation of Clinical Trials

For drugs and biologics, unless subject to specific exemptions, an investigational new drug (IND) application must be submitted to obtain FDA clearance prior to engaging in clinical research. Such submissions typically include:

- extensive pre-clinical data;
- information on chemistry, manufacturing and controls;
- prior human data; and
- the proposed protocol(s).

The FDA has 30 days either to allow the clinical study to proceed or to impose a clinical hold until outstanding issues are resolved.

Similar rules apply to medical device research and, depending upon the risk posed by the device, a device study may require the submission of an investigational device exemption (IDE) prior to initiating clinical research. Non-significant risk device studies may be conducted with just Institutional Review Board (IRB)/Ethics Committee approval. The FDA maintains an array of good clinical practice regulations governing clinical research, including study sponsor, IRB, and investigator responsibilities.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

As noted in **2.1 Regulation of Clinical Trials**, in addition to obtaining clearance to proceed with clinical research by filing an IND or IDE application (as appropriate), virtually all studies must be reviewed by one or more IRBs prior to initiation.

FDA regulations specify the requirements applicable to the composition and activities of IRBs.

2.3 Public Availability of the Conduct of a Clinical Trial

The US National Institutes of Health maintains a database at clinicaltrials.gov, where most controlled, interventional clinical investigations – other than Phase I clinical investigations – of drugs or biological products subject to FDA regulation must be registered and study results must be posted. Although there is no general requirement to publish clinical trial data in journals, the industry has pledged to seek such publications wherever possible, as a matter of practicality.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Online tools may be used as long as they comply with applicable requirements – for example, privacy, data security, auditability, informed consent and other good clinical practice requirements, as well as establishing lawful status if such tools incorporate certain regulated medical device functionalities. Particular requirements apply to recruiting subjects for clinical studies, whether online or otherwise.

2.5 Use of Data Resulting From Clinical Trials

The personal data resulting from clinical trials is considered protected. However, as long as any transfer of resulting data to a third party or an affiliate is consistent with contractual obligations, informed consent, and privacy protections, transfers are permitted. In certain scenarios, the sponsor and the FDA will have access to such information (including patient-identifiable information) in order to conduct and analyse the data from the study properly and ensure that subjects are protected.

2.6 Databases Containing Personal or Sensitive Data

A database containing personal or sensitive data may be subject both to contractual and statutory protections obliging maintenance of data security and privacy.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

Such determinations are typically made by assessing the primary mode of action of the product and whether it works by chemical, biological, mechanical or other means. If the product combines chemical, biological and/or mechanical modalities, a Request for Designation may be submitted to determine how the FDA believes the product should be regulated, under definitional and pathway provisions.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Drug products are approved via New Drug Applications (NDAs). Additional indications, dosage forms, etc, may be added via NDA supplements. Biological products are approved in a virtually identical process via Biologics Licence Applications (BLAs). The standard for approval is “*substantial evidence*” of safety and effectiveness (technically, “*safety, purity and potency*” for biologics), resulting from at least one – and typically several – adequate and well-controlled clinical studies. The typical drug or biologic review process takes ten months after initial acceptance for filing (a 60-day period); however, a priority review of six months is given to certain drugs and biologics intended to treat serious or life-threatening conditions.

Substantial user fees – USD4,310,002 in fiscal year 2025 for an NDA or BLA containing clinical data – are required to facilitate a review of applications.

3.3 Period of Validity for Marketing Authorisation for Pharmaceuticals or Medical Devices

There is no mandatory re-authorisation process for approved products. However, the FD&C Act and FDA regulations include processes for the withdrawal or revocation of an approval based upon a significant safety or effectiveness issue or non-compliance with approval requirements. These processes can be expedited in certain scenarios, such as an applicant’s failure to confirm the efficacy of an accelerated approval product in a post-market study, or where there is an imminent hazard. In general, a marketing authorisation may not be revoked merely because the product has not been placed on the market – although a failure to market an orphan drug could result in a loss of orphan exclusivity.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceuticals and Medical Devices

As noted in 3.2 Granting a Marketing Authorisation for Biologic Medicinal Products, the pathways for approval of drugs consist of:

- the submission of an NDA (including a 505(b)(2) NDA relying on data for which the applicant does not have a right of reference); and
- the Abbreviated New Drug Application (ANDA) for generic products, which demonstrates equivalence to a reference listed drug.

A biologic is licensed via the submission of a BLA; however, that process is largely the equivalent of an NDA submission. A biosimilar application demonstrates that, based on the totality

of the evidence, the biosimilar is either “*highly similar*” to – or interchangeable with – a reference biologic.

The FDA is authorised to require paediatric studies of drugs or biologics when other approaches are insufficient to ensure that the products are safe and effective for use in children. The agency may also issue a written request for paediatric research and, if the sponsor fulfils the data request, it may obtain six months of paediatric exclusivity.

As noted, changes to an existing marketing authorisation may be obtained through supplements or amendments to existing applications. As regards medical devices, the submission of additional 510(k) submissions can result in the clearance of significant changes to previously cleared device products. A PMA may also be supplemented or amended. In many cases, the transfer of a clearance or approval without manufacturing site or significant product changes requires only fairly simple notifications to the FDA.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The FDA maintains regulations permitting expanded access to investigational products. Such expanded access to INDs and IDEs may relate to an individual patient (often called “*compassionate use*”) or may allow broader use by patients not eligible for controlled clinical trials, depending upon the seriousness of the disease and the availability of alternative treatments. Sponsors of such INDs may not charge patients for the investigational drug without specific authorisation from the FDA permitting cost recovery only.

In addition, the 201 “*Right to Try*” Act permits certain eligible terminally ill patients to have broad access to eligible investigational drugs in certain circumstances when manufacturers are willing to supply. To date, most companies have shown a reluctance to permit their products to be used via this pathway in lieu of the more traditional IND pathway.

There is also a very limited Humanitarian Device Exemption (HDE) pathway for approval of a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects – or is manifested in – not more than 8,000 individuals in the USA per year.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Virtually every drug, biological or device product is subject to ongoing requirements relating to establishment registration, product listing, compliance with cGMPs/quality systems, track-and-trace requirements, and safety reporting/adverse-event reporting regulations. In certain cases, the FDA may require closer, ongoing oversight of a drug or biologic under a risk evaluation and mitigation strategy (REMS) or may mandate post-market studies or trials.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceuticals and Medical Devices

While the FDA does release approval letters and – after review for redaction of confidential and trade-secret information – summary review and approval documents, it does not currently publish “*complete response letters*” that reject an application under review. Available information on approved products may be obtained via the FDA’s Drugs@FDA website. Often, exten-

sive information about pending applications is released in the form of briefing papers and presentations used at FDA Advisory Committee meetings. The FDA does not reveal the existence of pending INDs or IDEs unless the sponsor has publicly acknowledged the filings.

Third parties may submit requests for information under the Freedom of Information Act (FOIA); however, there are a variety of exceptions from disclosure, as well as a major FDA backlog of requests. Most importantly, the FDA has an obligation under the FOIA to refrain from publication of trade secrets or confidential commercial or financial information. Sponsors/applicants are afforded an opportunity to review potential releases of information and request confidential treatment under those FOIA exceptions.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

There is an array of expedited programmes for the registration of medicines and medical devices. These programmes include:

- fast track designation for drug and biological products for serious conditions where said products demonstrate the potential to address an unmet medical need;
- designation as a breakthrough therapy in the case of drugs for serious conditions where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint over available therapies, or in the case of the breakthrough devices programme that applies to designated devices that provide for more effective treatment or diagnosis of life-

threatening or irreversibly debilitating human disease or conditions, among other criteria;

- accelerated approval for products that treat a serious condition, provide a meaningful advantage over available therapies, and demonstrate a significant impact on a surrogate endpoint that is reasonable likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality – although the clinical effectiveness of such products must be confirmed in post-market studies; and
- priority review for drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness (or if the FDA is presented with a priority review voucher).

Each of the above-mentioned programmes provides various benefits that may accelerate approval, ranging from additional agency input to rapid review.

4.2 Regulatory Reliance

If a company has already obtained authorisations (whether product-related or establishment-related) from internationally recognised jurisdictions, the FDA does not expedite the issuance of its own authorisations. However, there are frequent interactions between the FDA and other jurisdictions – in particular, Canada, the UK, and the EU – concerning issues such as establishment inspection priorities and product safety.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

In general, manufacturing plants are not subject to a separate authorisation from the related product approvals – although they must be registered with the FDA (and the products produced at the facility must be listed as associated with the establishment). Moreover, in most cases, the FDA will review extensive manufacturing information in the product application and conduct a pre-approval inspection of the facility before approving a drug or device. Such establishments are also subject to both routine (typically every two years) and for-cause (eg, in response to a product defect and recall) inspections.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

In general, wholesale activities are subject to licensure requirements at the state level and registration as distributors at the federal level. The requirements and length of such licences vary by state.

The FDA may inspect any facility holding drugs for shipments – although state inspection activities and fees vary greatly. Significant additional requirements administered by the DEA and states apply to wholesale trade in controlled substances.

The authorisation to trade in pharmaceuticals varies greatly by state; however, most pharma-

ceutical distributors must hold a state licence. Such requirements often do not apply to entities that are not physically handling drug products.

6.2 Different Classifications Applicable to Pharmaceuticals

Drugs may be either prescription – ie, as defined under state law, generally subject to prescription by a designated healthcare practitioner and dispensing by a licensed pharmacist – or OTC (permitting sale without intervention by a healthcare practitioner or pharmacist). Certain products (eg, pseudoephedrine) must be kept behind the pharmacy counter, owing to specific statutory requirements. The FDA has issued a proposal that could expand direct OTC availability of drug products – for example, through the use of mobile apps, as well as via kiosks in pharmacies that permit education and diagnostic screening.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

The FD&C Act and general import and export administration laws govern the import/export of pharmaceuticals and medical devices. Typically, imported medicines and medical devices must be subject to an approval or clearance (if applicable) in the USA. Only the original manufacturer of a drug may re-import a drug product back into the USA, subject to limited programmes – aimed at demonstrating how the importation of certain drugs can be accomplished in an attempt to reduce prices – that may or may not proceed in the coming years. The importation of even

an identical drug produced at a facility that is not inspected in the course of the US approval would be considered unlawful. Limited exceptions are permitted for individuals to engage in personal, physical importation of foreign products for their own use, if based upon a prescription from a healthcare professional and a lack of alternatives in the USA.

Note that a developing potential exception to these rules is the FDA's decision to authorise Florida's drug importation programme from Canada for a period of two years pursuant to a 2020 final rule establishing this pathway, with the goal of lowering drug prices in the USA. Additional steps must be implemented before such importation occurs, and the products at issue have yet to be disclosed. Moreover, the success of this pathway is highly uncertain, given that Health Canada has made clear in a [statement](#) that it will take *"all necessary action to safeguard the drug supply and ensure Canadians have access to the prescription drugs they need"*, arguing that *"bulk importation will not provide an effective solution to the problem of high drug prices in the US[A]"*.

At the border, the primary regulators are the FDA (administering the FD&C Act for potential violations) and US Customs and Border Protection (administering the broad array of US laws governing customs matters). Other agencies – for example, the Department of Commerce and the Department of Agriculture – may have responsibilities as well, depending on the nature of the imported article.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

Importers of record may be designated by the manufacturer or distributor and they have specific responsibilities. A US importer of record (ie, the owner, purchaser, or licensed customs

broker designated by the owner, purchaser or consignee) files entry documents for the goods with the port director at the goods' port of entry. It is the importer of record's responsibility to arrange for the examination and release of the goods. Initial importers may also be responsible for meeting registration and listing requirements. US Customs and Border Protection requires the importer of record to file an importation bond that is typically equal to at least three times the invoice value of the goods.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In order to be lawfully imported, a drug or medical device must be either:

- cleared or approved (and the product properly listed in association with a registered establishment); or
- the subject of an active IND or IDE.

Exceptions are made for importation of a very limited amount of a product for personal use. The FDA will also work with potential importers in certain situations (eg, compassionate use or short supply) to expedite the satisfaction of regulatory requirements.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Upon entry into the USA, declarations and information must utilise the Customs Harmonised Tariff Schedule codes according to the Harmonized Tariff Schedule of the US (HTSUS) and FDA product codes. Such declarations are subject to specific regulations issued by US Customs and Border Protection and the FDA. A failure to classify a product properly may result in an improper payment of customs duties and, consequently, associated penalties.

7.5 Trade Blocs and Free Trade Agreements

The USA is a member of the WTO and has free trade agreements in effect with 20 countries. Some are bilateral agreements, but others are multilateral in nature. The USA is also party to Trade and Investment Framework Agreements that provide frameworks for governments to discuss and resolve trade and investment issues at an early stage, as well as bilateral investment treaties that help protect private investment, develop market-oriented policies in partner countries, and promote US exports. Additionally, the FDA is party to various Memoranda of Understanding and mutual recognition agreements aimed at facilitating global discussions and risk assessments with regard to, for example, inspections.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Until recently, the USA had little in the way of pricing limitations on pharmaceutical products and medical devices. Therefore, in most cases, the manufacturer of a product sets the initial price and adjusts prices (including rebates and other price concessions) over time in response to market conditions. However, in a major shift, the Inflation Reduction Act 2022 (IRA) incorporated provisions to lower prescription drug costs for those covered by Medicare and reduce drug spending by the federal government. Among others, the IRA includes the following provisions.

- The federal government is in its second round of negotiating pricing for certain drugs chosen for inclusion in the programme. Such negotiations establish “*maximum fair price*”

for certain drugs covered under Medicare Part B and Part D with the highest total spending (excluding specific categories of drug). Under this Drug Price Negotiation Programme, the number of drugs subject to price negotiation included ten Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. The drugs are chosen from the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. A prohibitive excise tax will be levied on drug companies that do not comply with the negotiation process.

- Drug companies are now required to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries.
- Out-of-pocket spending is capped for Medicare Part D enrollees and other Part D benefit design changes.
- Monthly cost sharing for insulin is now limited to USD35 for people with Medicare.

Various aspects of the IRA have been quite controversial, including provisions that disadvantage certain orphan drugs, as well as small molecules relative to biologics. The IRA drug-pricing provisions are currently being challenged in multiple lawsuits under a wide variety of theories.

There are also other federal laws that cap pharmaceutical prices for certain purchasers or require minimum rebate levels in the following ways.

- Subject to ongoing litigation concerning the scope and terms of the programme, manufacturers sell their outpatient drugs to “*covered entities*” (typically, certain clinics and

hospitals believed to serve safety-net functions) at or below a statutorily set ceiling price under the 340B Drug Pricing Programme.

- Manufacturers must sell brand name drugs to four federal agencies (the Department of Veterans' Affairs, the Department of Defence, the Public Health Service, and the Coast Guard) at or below "*federal ceiling price*" determined by a statutory formula.
- Manufacturers must pay a rebate set by a statutory formula on each unit of their outpatient drugs paid for by the Medicaid programme. This is not literally "*price control*" programme because it only controls the rebate paid to Medicaid after the drug has been dispensed or administered. As such, the price that Medicaid pays upfront to the dispensing pharmacy or to a physician's office or clinic that administers a drug is not affected by the Medicaid rebate programme.

8.2 Price Levels of Pharmaceuticals or Medical Devices

In the USA, companies typically set their prices based on a wide range of factors, and the price level of a pharmaceutical product or medical device does not depend on the prices for the same product in other countries. Although reference-pricing schemes have previously been proposed in the USA, the provisions of the IRA described in 8.1 **Price Control for Pharmaceuticals and Medical Devices** are currently the primary vehicle for industry/government price negotiations under US law.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The largest healthcare programme in the USA today is the Medicare programme, which provides healthcare coverage for people who are 65 and older, are disabled (for two years or more),

or have end-stage renal disease. Medicare accounts for roughly 20% of US health spending. Most pharmaceutical products are eligible for some form of Medicare coverage, either through:

- Part B (Medicare's traditional outpatient benefit, which covers a small but important set of drugs, including physician-administered drugs);
- Part D (the Medicare drug benefit, which has provided broad coverage for pharmacy-dispensed oral drugs since 2006); or
- Part A (Medicare's inpatient benefit, which covers drugs provided as part of covered inpatient hospital stays and in certain other inpatient settings).

The second-largest healthcare programme today – accounting for roughly 17% of US health spending – is the Medicaid programme, which is a joint federal–state programme providing coverage for certain low-income individuals (with the specific eligibility criteria varying by state). Medicaid is run chiefly by states, with federal government oversight, and state Medicaid programmes generally provide broad coverage for prescription drugs. Medicaid programmes have sometimes imposed on high-cost drugs coverage restrictions that arguably conflict with Medicaid's statutory obligations.

At present, it is likely that there will be significant cuts to the Medicare and Medicaid programmes under the second Trump Administration.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The process and evidence that US payors use to make decisions about pharmaceuticals and medical device coverage varies widely by payor

(and is not always entirely transparent). These variations can include:

- the criteria considered appropriate for evaluation (eg, whether a product's cost or cost-effectiveness is taken into account in coverage decisions);
- the scientific rigour of the evidence considered and the weight placed on the types of evidence considered;
- the decision-making body and the processes for making coverage decisions; and
- the legal standards that apply to the coverage decision-making process and the resulting package of covered products and services.

Many organisations are engaged in developing value-assessment tools of various sorts and the CMS has experimented with outcome-based models. Essentially, these tools are designed to help payors, healthcare providers, and patients assess outcomes of competing pharmaceuticals on a systematic basis and thereby reach conclusions about their value in a more systematic and rigorous way than is currently usual. The future of such programmes is uncertain under the Trump Administration.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Pharmacists are paid for dispensing prescriptions by the patient's insurer (assuming the

patient is insured and the product is covered) and the patient. The circumstances in which pharmacists may dispense a substitute for the prescribed product without obtaining the prescriber's authorisation are governed by state law. State laws on this issue can vary but, in general, they permit pharmacists to substitute a product approved by the FDA as a generic equivalent for the prescribed product (unless the prescription specifically states "*dispense as written*" or a similar phrase indicating no substitution).

There has also been a recent regulatory focus and extensive litigation relating to pharmacy compounding of approved weight loss drugs in the USA, which was permitted in bulk only when such products were in shortage.

During the past several years, the standards for permitting pharmacists to substitute "*biosimilar*" product for a prescribed biological product have been a topic of considerable debate. The provisions of these laws vary but often only permit biosimilar pharmacy-level substitution if:

- the substituted product has been designated as "*interchangeable*" with the prescribed biological product by the FDA;
- the prescriber and the patient are both notified of the substitution; and
- the pharmacist maintains records of the substitution.

Trends and Developments

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Ropes & Gray LLP is home to one of the world's pre-eminent life sciences groups, with a global platform for innovators at every stage of the development life cycle. The firm's collaborative approach – spanning more than 25 practice areas and touching all offices around the world – offers one of the largest and most experienced industry-specific teams, comprising more than

300 lawyers, subject-matter experts and technical advisers who deliver sophisticated transactional, regulatory, IP, and litigation and enforcement strategies to position industry innovators and investors for success. The Ropes & Gray team is sought after to lead clients in navigating the complex legal landscape in which the life sciences industry operates.

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Opportunities and Complexities Shaping the US Life Sciences Landscape

The US life sciences industry experienced a dynamic year in 2024. As the public markets gained traction, IPO activity and venture investment saw a resurgence, signalling renewed investor confidence and reflecting sustained interest in biotech innovation. However, the M&A market presented a mixed picture, with overall deal values declining but deal volumes remaining robust. Licensing deals, particularly those involving biologics, later-stage assets, glucagon-like peptide-1 (GLP-1)-targeted therapies and glucose-dependent insulinotropic polypeptide (GIP)-targeted therapies, continued to play a crucial role in shaping the industry landscape. This article delves into the key trends in the sector in 2024 and offers insights into what lies ahead for 2025, given driving trends and the new administration.

Market trends

The public financing markets gained modest traction in 2024, allowing for a steady resurgence for the life sciences industry. The US biotech stock average, as measured by the S&P XBI, was generally volatile during the course of 2024 but ended the year modestly higher than it began. IPO activity also saw a significant uptick, with USD3.8 billion raised by 19 companies going public in 2024 (compared to USD2.7 billion from 13 IPOs in 2023), according to [JP Morgan](#).

The largest IPO occurred early in the year, setting high expectations, when CG Oncology raised USD380 million in January. Later in the year, there were signals of continued investor confidence when Bicara Therapeutics, Zena BioPharma, and MBX Biosciences collectively raised more than USD700 million during a single day in September. According to [Stifel](#), bio-

tech and healthcare IPOs accounted for 23% of total US IPO proceeds in 2024, indicating a renewed interest by investors in the sector. However, many of these companies experienced significant declines in their share price following the IPO. Similarly, follow-on offerings began strong in 2024, but tapered off as the year progressed. While the strong start to 2024 was not sustained throughout the year, the authors still view the public follow-on market as trending upwards, with [annualised follow-on value](#) reaching USD52 billion in 2024, compared to USD36 billion in 2023 and a historic peak of USD86 billion in 2020. [Commentators](#) expect this positive trend to continue into 2025, but certainly not to the extent of the peak levels seen during the COVID-19 boom.

Venture equity investment in the life sciences sector experienced a significant surge in 2024. According to [Stifel](#), annualised venture equity deals in the sector totalled more than USD50 billion – a significant increase from USD33 billion in 2023. [Notable deals](#) included Xaira Therapeutics raising more than USD1 billion in April in a Series A round, reflecting sustained interest in AI for drug discovery, and Mirador Therapeutics securing USD400 million in a Series A round for precision medicine. Overall, 2024 was the third-most active year for biotech fundraising in history, based on aggregate deal value. Series A and Series B venture financing in biotech companies also saw a substantial increase in 2024, but with a notable focus on certain “hot” assets, as well as a flight away from certain other asset classes (including expensive-to-develop cell therapy treatments).

In 2025, [analysts](#) expect an overall increase in venture capital volume, with the trend towards larger funding rounds and the continued incursion of tech venture capitalists into healthcare,

particularly in areas such as AI in healthcare delivery – suggesting a positive outlook for biotech venture equity deals in the coming year.

Deal-making trends

M&A centres on smaller-value deals and early-stage assets

The M&A market in 2024 was relatively flat, with an overall deal value of USD82 billion – significantly down from USD178 billion in 2023, according to [Stifel](#). The year saw no transactions for the acquisition of a biotech or pharma company that exceeded USD5 billion and, while companies remained active in the M&A market, the values of the deals were notably lower than in past years. The [largest biotech deal](#) by upfront payment was the acquisition of Alpine Immune Sciences, Inc by Vertex Pharmaceuticals in April for USD4.9 billion, and the [highest-value deal in the pharma industry as a whole](#) was Novo Holdings' acquisition of Catalent and some of its manufacturing facilities for USD16.7 billion in December. These transactions are modest compared to, for example, Pfizer's USD43 billion acquisition of Seagen in 2023.

Despite the drop in individual deal values, deal volume remained healthy. According to [Stifel](#), there were still six acquisitions of public biotech or pharma companies for USD1 billion or more, which is relatively high – albeit down from a record-breaking ten of such acquisitions in 2023. Overall, 2024 had the sixth-highest total number of M&A deals over USD1 billion since 1995, with 15 public and private target acquisitions occurring during the year.

One explanation for this trend towards smaller deal sizes is that acquisitions in 2024 tended to involve more early-stage assets compared to acquisitions in 2023; earlier-stage assets come with higher risk and thus attract smaller

sums. According to [Stifel](#), in 2024, only 20% of acquisitions involved Phase III or approved assets (down from 40% in 2023). It is important to note that – while a higher proportion of acquisitions involved earlier-stage assets – large pharmaceutical companies continued to spend more on later-stage assets overall than on early-stage assets, with Stifel reporting that USD49 billion and USD43 billion were spent on Phase III and Phase II assets respectively, compared to USD28 billion and USD21 billion for Phase I and pre-clinical assets respectively. This reflects the greater cost of purchasing later-stage assets, given their higher likelihood of success.

Looking ahead to 2025, [commentators](#) expect that changes associated with the new administration (including potential Federal Reserve rate cuts) bode well for deal-making activity, and a less hostile antitrust environment paints a positive picture for M&A specifically. [Other factors](#) that could spur M&A activity in the coming year include large pharma companies' impending patent cliffs for certain blockbuster drugs, which could incentivise such companies to fill gaps in their pipelines by pursuing M&A opportunities. The JP Morgan Healthcare Conference set an optimistic tone at the start of 2025, with USD18 billion in acquisitions announced on the first day of the conference, including J&J's USD14.6 billion takeover of Intra-Cellular Therapies. Although M&A did not rebound as strongly as expected in 2024, there is a sense that 2025 will be an active year for M&A, with potential increases in both deal value and deal volume.

Licensing driven by lower upfront economics and focus on pipeline development

Licensing deal volume and upfront payments remained steady in 2024. According to [JP Morgan](#), while the number of licensing deals in 2024 remained lower than its peak during the COV-

ID-19 pandemic, the total number rose slightly to 148 compared to 145 in 2023 – indicating that deal flow was relatively flat. However, in contrast with M&A deal values, the overall value of licensing deals improved, with deal value increasing from USD174 billion to USD183 billion. Notably, 28 licensing deals in 2024 involved upfront payments of USD100 million or more, compared to 20 such deals in the previous year. In 2024, upfront deal value stabilised at approximately 7% of overall deal value (similar to 2023), continuing the trend of lower upfront economics seen since the peak of 13% in 2019. [Analysts](#) note that deal option payments and milestone payments have also helped bolster deal sizes, as such payments distribute the financial risk through development and commercialisation.

Licensing deals relating to biologics, later-stage assets, GLP-1-targeted therapies and GIP-targeted therapies have notably impacted licensing deal values in 2024. According to [JP Morgan](#), biologics led the way in licensing deal values, followed by small molecules. Advanced modalities (including cell and gene therapies), which are generally more expensive to develop, lagged behind. From 2023 to the third quarter of 2024, USD4.9 billion in total announced upfront cash and equity was directed towards biologics licensing deals, with USD3.1 billion directed to small molecule licensing deals. In contrast, the figures for more advanced modalities were much lower, in the multimillions. In terms of asset stage, large pharma companies' focus on in-licensing late-stage assets has increased the value of programmes nearing approval, with notably higher median upfront cash and equity payments for Phase II and Phase III deals in 2024 compared to 2023. Finally, recent advances in GLP-1-receptor (GLP-1R)-targeted therapies and GIP-receptor-targeted therapies have driven collaborative activity in 2024, with a focus on

disease areas including obesity, diabetes, and other indications beyond metabolic diseases. In 2024, deals focusing on GLP-1-, GLP-1R-, and GIP-targeted therapies had a total announced potential deal value of USD8 billion, whereas deals focusing on obesity and diabetes totalled USD6.4 billion in announced potential deal value (according to [JP Morgan](#)).

While licensing volume and upfront payments have remained steady in recent years, the impending patent cliff for large pharma companies is expected to incentivise companies to fill gaps in their pipelines, contributing to a promising outlook for licensing and collaborations in 2025. For instance, major drugs such as Johnson & Johnson/Bayer's blood thinner Xarelto, Boehringer Ingelheim/Eli Lilly's Jardiance, and AstraZeneca's Farxiga will [lose regulatory exclusivity](#) this year. Other significant [patents set to expire](#) in the next few years include BMS's Eliquis and Opdivo, Merck's Keytruda, and Amgen's Prolia and Xgeva, exposing these companies to substantial generic and biosimilar competition. [Commentators](#) believe that an increased focus on external innovation and strategic partnerships will be crucial for companies seeking to maintain their competitive edge and ensure future growth.

Other driving trends

Surge in in-licensing from Chinese biotech companies

Cross-border licensing transactions involving molecules invented in China became increasingly popular in 2024 – a significant [31%](#) of the molecules in-licensed by large pharma companies were sourced from China, up from 29% in 2023. Moving forwards into 2025, the availability of relatively inexpensive China-developed drug candidates is expected to boost licensing between biotech companies in China and biopharma

companies in the USA, according to [Stifel](#). While this collaboration may drive increased research and development in the biotech sector, these trends also could negatively impact US biotech companies developing comparable molecules, as it may drive down the economics that licensees are willing to pay for such US assets.

Continued influence of AI in drug discovery and innovation

The ongoing trend for integrating AI into drug development activities is expected to continue in 2025. Nearly 60% of biotech and pharma executives surveyed by [Deloitte](#) said they plan to increase investments in generative AI. However, although AI carries exciting potential, industry leaders caution against mistaking this hype for AI's ability to immediately impact clinical trials in the shorter term. A [Jefferies](#) report notes that there is a long road to realising AI's full potential in biotech. Even now, not all biotech and pharma executives are optimistic that AI will significantly transform R&D productivity – voicing concerns particularly about data quality, significant data gaps, and still-murky regulatory waters, according to [Stifel](#) and [LaBiotech](#).

Despite these reservations, 2024 saw the growth of a new AI-driven trend, which signalled strong enthusiasm from both life sciences and technology companies in deepening AI's integration in biotech. “Techbio” refers to the trend of tech giants such as Google, Microsoft and NVIDIA “taking more space” in the biotech sector, both through direct initiatives and strategic partnerships, [according to Andrea Bortalato](#), vice-president of drug discovery at SandboxAQ. By way of example, Amgen and NVIDIA [announced](#) a collaboration early on in 2024 for the use of NVIDIA's DGX SuperPOD platform to build AI models trained to analyse one of the world's largest human datasets in order to produce “a

human diversity atlas for drug target and disease-specific biomarker discovery” and to “help develop AI-driven precision medicine models, potentially enabling individualised therapies for patients with serious diseases”. NVIDIA took the stage again at the 2025 JP Morgan Healthcare Conference, [announcing additional partnerships](#), including:

- with IQVIA to build custom AI models to speed up research and clinical development;
- with Illumina to enhance genomic analysis for drug discovery;
- with Mayo Clinic to develop advanced digital pathology models using NVIDIA's Deep GPU (Graphics Processing Units) Xceleration (DGX) systems; and
- with Arc Institute to develop advanced AI models that can understand and analyse biological data such as DNA, RNA, and proteins.

These collaborations between tech and biotech suggest that excitement in the space is likely to continue throughout 2025.

Continued consumerisation of obesity-related drugs

2024 kicked off with pharma companies Novo Nordisk and Eli Lilly spiking list prices for their blockbuster diabetes drugs and, throughout 2024, the market for GLP-1s remained hot. There were 24 obesity drug R&D and licensing deals signed in 2024, [with a value totalling USD6.4 billion](#), and many companies of all sizes announced GLP-1 development programmes. Although significant gaps remain in affordability and access, this increasing competition may drive down prices of drugs such as Ozempic, Wegovy, Mounjaro and Zepbound. However, the companies behind these popular drugs are [not keen to allow](#) this to happen and many commentators have [voiced their concern](#) throughout

2024 as to whether these companies would be able to meet the high demand for their drugs, particularly if the United States Food and Drug Administration chooses to restrict mass compounding.

Due to manufacturing and supply constraints, Novo Nordisk and Eli Lilly faced challenges meeting the overwhelming demand for GLP-1 drugs during commercial roll-out. [FiercePharma](#) reports that contract development and manufacturing organisations have been crucial for meeting near-term demand by providing immediate production solutions (particularly for the final fill-and-finish step of the manufacturing process), while both companies invest in building out their production lines for the long term, including Novo Holdings' acquisition of Catalent in late 2024. This high demand is not expected to wane in 2025; 36% of respondents to a Jefferies' poll said that obesity-related drugs will have the biggest impact in biotech and pharma this year. Although the commercial success of this class of drugs is expected to continue in 2025, one thing to keep an eye on is the [selection](#) of Ozempic and Wegovy for Inflation Reduction Act (IRA) Medicare price negotiations in 2027, along with 13 additional drugs. This announcement triggered a fall in Novo Nordisk's share price, but the future of the IRA under the new Trump administration remains to be seen.

Effects of new Trump administration

Antitrust and the FTC

Two Trump nominees have signalled a new and biotech-friendly era for antitrust under the second Trump administration. Trump has chosen Andrew Ferguson to take the place of Lina Khan as chair of the Federal Trade Commission (FTC) and Ferguson's leadership is likely to result in a lighter antitrust enforcement environment than during Khan's term, according to a [Stifel](#) report.

President Trump has also chosen Gail Slater to head up the Department of Justice's antitrust division, which

[The New York Times](#) notes may mark a potential redirection away from the Biden administration's vigorous enforcement of antitrust laws that has resulted in significant merger blockages. According to [BioPharma Dive](#), commentators in the industry expect these leadership changes to be good signs for increased biotech M&A activity.

HHS, tax cuts and the Biosecure Act

Significant uncertainty remains as to how the different personalities in the Trump administration will affect health and drug policy, and how that will reverberate through the life sciences industry. On one side of the coin, President Trump has chosen prominent tech CEO Elon Musk (an advocate of high innovation and low regulation) to lead the new Department of Government Efficiency (DOGE). Musk's leadership could trend towards decreased oversight. On the other side of the coin, President Trump has picked Robert F Kennedy Jr to head up the United States Department of Health and Human Services (HHS). [Endpoints News](#) highlights the stark distinction between DOGE's objectives and Kennedy's perspective on biotech and pharma. Kennedy is well-known for anti-vaccine views and has a skeptical view of the biotech and pharma industry, viewing it as under-regulated and corrupt. According to a [Stifel](#) report, upon the announcement of his nomination, the XBI dropped from 104 to less than 92 – reflecting widespread concern in the biotech sector that Kennedy's term will negatively impact public health infrastructure and policy. Further, shares in vaccine producers such as Pfizer, Moderna, BioNTech, and Novavax also [declined](#) after the announcement of Kennedy's appointment.

While there are concerns in the industry regarding the volatile personalities in the Trump administration, [economists predict](#) that a bump for the market could come in the form of significant tax reductions enacted by the Republican majority in Congress. Tax cuts such as the ones President Trump has supported would give big pharma companies massive tax breaks, according to [Public Citizen](#). That said, the boost to the industry that these tax breaks could provide may be [tempered](#) by proposed tariffs on countries including Canada, Mexico and China. [BioPharmaDive](#), reports that Trump's "America First" approach to international relations could give the Biosecure Act – a national security bill that would have the effect of limiting US companies' freedom to contract with certain named Chinese service providers – a better chance of passage, which could create hardships for US companies that are dependent on these Chinese companies.

Given all of these various and conflicting factors, the only certainty may be uncertainty. As Priya Chandran (leader of the Boston Consulting Group's biopharmaceuticals team) expressed to [Endpoints News](#) at the JP Morgan Healthcare Conference in January, nobody "*is in any position to predict exactly*" what the ultimate impact on the life sciences sector will be.

Conclusion

The life sciences industry navigated a complex landscape in 2024, marked by a resurgence in public markets, robust venture investment, and a mixed M&A environment. Licensing deals – particularly those involving biologics, later-stage assets, GLP-1-targeted therapies and GIP-targeted therapies – played a pivotal role in maintaining industry momentum. That complexity seems likely to multiply in 2025, as commentators note that several key factors are poised to shape the sector's trajectory.

The impending patent cliff for a number of blockbuster drugs is expected to drive increased licensing and M&A activity as companies seek to fill gaps in their pipelines. Advances in AI and the growing consumerisation of obesity-related drugs will likely continue to influence innovation and market dynamics. The increasing importance of Chinese-manufactured molecules and collaborations between US and Chinese biotech firms may also play a significant role in shaping the industry's future. Finally, the new administration's policies on antitrust, healthcare, and international relations will introduce opportunities and uncertainties alike.

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