

# International **Comparative** Legal Guides



## Digital Health **2021**

A practical cross-border insight into digital health law

### Second Edition

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# International **Comparative** Legal Guides

## Digital Health **2021**

**Second Edition**

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**Haynes and Boone, LLP**

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# Austria

Herbst Kinsky Rechtsanwälte GmbH



Dr. Sonja Hebenstreit

## 1 Digital Health and Health Care IT

### 1.1 What is the general definition of “digital health” in your jurisdiction?

There is no general definition of “digital health” in Austrian law. The Austrian Federal Ministry of Health’s definition (see <https://www.sozialministerium.at/Themen/Gesundheit/eHealth.html>) uses the term “e-health” as the general term, comprising the use of information and communication technologies in health-related products, services (including telemedicine) and processes. The Ministry uses the term “telemedicine” as referring to the provision or support of healthcare services using information and communication technologies, where the patient and the healthcare provider are not present in the same place. This is in line with the definition used by the European Commission who suggested using the term “telehealth” as referring to health-related procedures and “telemedicine” as referring to treating people from a distance (see [https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018\\_provision\\_market-study\\_telemedicine\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_provision_market-study_telemedicine_en.pdf), page 25).

### 1.2 What are the key emerging technologies in this area?

All stakeholders including the public sector acknowledge that data-driven digital healthcare will transform the provision of healthcare services. Key emerging technologies are, in particular, artificial intelligence (hereinafter: AI) applications including machine learning, which can contribute, e.g., to earlier disease detection and more accurate diagnosis.

### 1.3 What are the core legal issues in health care IT?

The main legal issues in healthcare IT are: compliance with data protection (see sections 4 and 5); the technical requirements for telehealth (see *GTdG 2012* in question 2.2); as well as the determination of whether a product qualifies as a medical device (see questions 2.1 and 3.1).

## 2 Regulatory

### 2.1 What are the core health care regulatory schemes?

The Austrian Physicians Act 1998, Federal Law Gazette I 169/1998, as last amended by the Federal Law Gazette I

86/2020, (*Ärztegesetz* 1998, *ÄrzteG* 1998) contains regulations on training and admission as a physician, regulations on the exercise of the profession (e.g. group practices), prohibitions of discrimination and regulations on the organisation of the self-administration of physicians (Medical Association). Section 3 *ÄrzteG* stipulates that medical advice may only be given by licensed physicians. Section 49 paragraph 2 *ÄrzteG* further stipulates that physicians shall practice their profession “personally and directly”. This provision is regarded as not generally prohibiting telemedicine, i.e. the individual diagnosis and treatment from a distance, without direct human contact. The Austrian Medical Association has stated that telemedicine might support the relationship between physician and patient and the treatment process and that digital monitoring and online contact might be helpful for the diagnosis as well as for the therapy, but has emphasised that a clear legal framework is required for telemedicine services. Currently, no such specific legal framework is in place. In any case, physicians are obliged to comprehensively inform the patient and get the patient’s informed consent (likewise), whereas in the case of telemedicine, they need to be in full control of the patient’s situation, and the telehealth treatment must be for the patient’s benefit.

In the context of the referral of patients through online platform operators, the prohibition of commissions according to Section 53 paragraph 2 *ÄrzteG* needs to be observed, according to which the physician may not promise, give, take or have promised to himself or another person any remuneration for the referral of patients to him or through him. According to paragraph 3 *leg cit*, activities prohibited under paragraph 2 are also prohibited for group practices (Section 52a) and other physical and legal persons. This means that the collection of commissions from patients is prohibited not only for doctors but also for other third natural or legal persons.

The Austrian Medicinal Products Act, Federal Law Gazette 185/1983, as last amended by Federal Law Gazette I 23/2020, (*Arzneimittelgesetz*, *AMG*) implements a large number of European Union directives concerning regulations on medicinal products, in particular Directive 2001/83/EC – Community code relating to medicinal products for human use. The *AMG* contains regulations on the authorisation of medicinal products, regulations regarding marketing, advertising and distribution of medicinal products as well as quality assurance requirements.

The Austrian Medical Devices Act, Federal Law Gazette 657/1996, as last amended by Federal Law Gazette I 23/2020, (*Medizinproduktegesetz*, *MPG*) as well as the Medical Device Regulation 2017/745 on medical devices (MDR), whose entering into effect was postponed by the COVID-19 pandemic to May 26, 2021, constitute the major regulatory framework for medical devices. The MDR lays down rules concerning the placing on



the market, making available on the market or putting into service of medical devices for human use and accessories for such devices in the Union. The MDR shall also apply to clinical investigations concerning such medical devices and accessories conducted in the European Union.

## 2.2 What other regulatory schemes apply to digital health and health care IT?

The General Data Protection Regulation, Regulation 2016/679 (GDPR) contains central provisions on data protection. Although the GDPR as a regulation applies uniformly and directly throughout the European Union, a large number of opening clauses allow national deviations by Member States. Providers of digital health and healthcare IT in particular need to take into account the provisions on the lawfulness of the processing of health data pursuant to Article 9 GDPR as well as the obligation to implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk pursuant to Article 32 GDPR.

The Austrian Data Protection Act, Federal Law Gazette I 165/1999, as last amended by Federal Law Gazette I 14/2019, (*Datenschutzgesetz*, DSG) specifies the provisions of the GDPR and, in particular, contains provisions on proceedings before the Austrian data protection authority. For the private sector, the DSG does not provide any provisions for the processing of health data that deviate from the GDPR.

The Austrian Health Telematics Act 2012, Federal Law Gazette I 111/2012 as last amended by Federal Law Gazette I 115/2020, (*Gesundheits-Telematikgesetz* 2012, *GTelG* 2012) contains special regulations for the electronic processing of health data and genetic data (please refer to Article 4 No. 15 and 13 GDPR) by healthcare providers. A healthcare provider in the meaning of health telematics is a professional who, as a controller or processor (in the meaning of Article 4 Nos 7 and 8 GDPR), regularly processes health data or genetic data in electronic form for the following purposes:

- medical treatment or care;
- nursing care;
- invoicing of health services;
- insurance of health risks; or
- exercise of patient rights.

The *GTelG* 2012 also contains detailed regulations on the operation of the Electronic Health Record (*Elektronische Gesundheitsakte*, *ELGA*) by ELGA GmbH, which is owned by the Republic of Austria, the Main Association of Austrian Social Insurance Institutions and the federal provinces or their health funds. In the context of *ELGA*, other e-health services have been introduced as well such as the electronic vaccination card (section 24b *et seq.* *GTelG* 2012) or the electronic medication prescription.

To meet the challenges of the COVID-19 pandemic, (temporary) simplifications to the conditions of transmitting health data (via email and fax) for healthcare providers have been implemented to the *GTelG* as well.

## 2.3 What regulatory schemes apply to consumer devices in particular?

The Medical Devices Act and, as of May 2021, the Medical Devices Regulation (see question 2.1) likewise apply to Consumer Devices.

## 2.4 What are the principal regulatory authorities? What is the scope of their respective jurisdictions?

In connection with *GTelG* 2012 and *GTelV* 2013, Federal Law

Gazette II 506/2013 (*Gesundheits telematikverordnung*) the Federal Minister for Health is competent for notifications and for the operation of the eHealth directory service according to paragraphs 9 and 10 *GTelG* 2012.

In connection with the *ÄrzteG*, the competent authorities are the Austrian Medical Chamber, the respective state governor (“*Landeshauptmann*”) and the Federal Minister for Health.

The Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*, *BASG*) is the central regulatory authority for the medicinal products and medical devices industry. The BASG is responsible, among other things, for the approval of medicinal products, market surveillance and pharmacovigilance, notifications in connection with clinical trials, the control of advertising restrictions and the granting and review of operating licences.

Investigations and assessments are typically carried out by the Austrian Agency for Health and Food Safety (*Österreichische Agentur für Gesundheit und Ernährung*, *AGES*) on behalf of the BASG.

The Austrian Data Protection Authority (*Datenschutzbehörde*, *DSB*) is the supervisory authority in Article 4 Section 21 GDPR, for the monitoring of data protection law and the assertion of data subjects’ rights under the GDPR.

## 2.5 What are the key areas of enforcement when it comes to digital health and health care IT?

As far as can be seen, neither the Austrian Medical Chamber nor the *BASG* or the Federal Minister of Health recently took relevant enforcement measures in the regulatory area of digital health and healthcare IT.

In 2018, the *DSB* rendered a major decision regarding the communication between physicians and patients (*DSB* -D213.692/0001-DSB/2018): according to the *DSB*, patients cannot consent to the (unencrypted) transmission of health data (e.g. medical reports) by physicians. The *DSB* reasoned that the choice of the communication method is a technical/organisational measure according to Article 32 GDPR, and that no consent can be provided to insufficient technical/organisational measures.

## 2.6 What regulations apply to Software as a Medical Device and its approval for clinical use?

According to Recital 19 MDR, software qualifies as a medical device, when specifically intended by the manufacturer to be used for one or more medical purposes, while software for general purposes, even when used in a healthcare setting, or software intended for lifestyle and well-being purposes is not a medical device. The qualification of software, as either a device or an accessory, is independent of the software’s location or the type of interconnection between the software and a device. Therefore, as a general rule, software for general purposes, even if used in the healthcare sector, is not a medical device. The manufacturer determines the intended use which is essential for software for general purposes to be differentiated from a medical device.

According to the MDR, manufacturers of medical devices are obliged to carry out a clinical evaluation for all their products – regardless of the risk class – which also includes a post-market clinical follow-up (PMCF). Such clinical evaluation is an essential task of the manufacturer and an integral part of a manufacturer’s quality management system (Article 10 paragraphs 3 and 9f MDR). The clinical evaluation is a systematic and planned

process for the continuous generation, collection, analysis and evaluation of clinical data for a device. Through the clinical evaluation, the manufacturer verifies the safety and performance of his device, including the clinical benefit.

Furthermore, Regulation No. 207/2012 on electronic instructions for use of medical devices must be observed when providing electronic instructions for use.

### 3 Digital Health Technologies

#### 3.1 What are the core issues that apply to the following digital health technologies?

##### ■ Telemedicine/Virtual Care

According to Section 3 *ÄrzteG*, medical advice may only be given by licensed physicians. Furthermore, the physician needs to decide in each individual case of such telehealth consultation if he/she can sufficiently control possible dangers despite the lack of physical contact with the patient and whether he/she has a sufficient information basis for his/her decisions. In case the physician fears that he/she does not have a sufficient basis for his/her medical decision due to lack of physical patient contact, he/she must advise the patient to actually (physically) see a physician.

Austrian law does not contain rules for the provision of telemedicine or virtual care services in general, but a specific regulation has been issued regarding the provision of teleradiology services: the Medical Radiation Protection Regulation, Federal Law Gazette II 375/2017 (*Medizinische Strahlenschutzverordnung*) provides that teleradiology is permitted within the framework of basic and special trauma care as well as in dispersed outpatient primary care facilities of acute hospitals and otherwise only in order to maintain night, weekend and holiday operations for urgent cases.

According to paragraphs 3 and 4 of the *GTelG 2012*, health service providers may transfer health data and genetic data only if:

- the transmission is permitted under Article 9 GDPR;
- the identity of those persons whose health data or genetic data are to be transmitted is proven;
- the identity of the healthcare providers involved in the transmission is proven;
- the roles of the healthcare providers involved in the transmission are demonstrated;
- the confidentiality of the transmitted health data and genetic data is guaranteed; and
- the integrity of the transmitted health data and genetic data is guaranteed.

In addition, the *GTelG 2012* and the Health Telematics Regulation 2013, Federal Law Gazette II 506/2013, (*Gesundheits telematikverordnung 2013, GTelV 2013*) issued by the Federal Minister of Health on the basis of *GTelG 2012* contain detailed regulations on encryption and technical implementation of communication.

The COVID-19 pandemic has led to a massive increase regarding the use and offer of telemedicine services.

As outlined above (question 2.2), due to the COVID-19 pandemic, (temporary) simplifications to the conditions of transmitting health data (via email and fax) for healthcare providers have been implemented to the *GTelG*.

##### ■ Robotics

According to Section 3 *ÄrzteG*, medical advice may only be given by licensed physicians. Furthermore, robotics

may be subject to MDR when specifically intended by the manufacturer to be used for one or more medical purposes (e.g. robotics for surgical purposes).

##### ■ Wearables

Wearables may be subject to MDR when specifically intended by the manufacturer to be used for one or more medical purposes.

##### ■ Virtual Assistants (e.g. Alexa)

According to Section 3 *ÄrzteG*, medical advice may only be given by licensed physicians. Virtual Assistants in general would not qualify as a medical device. However, natural language processing may be subject to MDR when specifically intended by the manufacturer to be used for one or more medical purposes.

##### ■ Mobile Apps

See question 2.6 (Software as a Medical Device).

##### ■ Software as a Medical Device

See question 2.6.

##### ■ AI-as-a-Service

See question 2.6 (Software as a Medical Device) and section 8 (AI and Machine Learning).

##### ■ IoT and Connected Devices

“Internet of Things” (hereinafter: IoT) and Connected Devices may be subject to MDR when specifically intended by the manufacturer to be used for one or more medical purposes (e.g. blood pressure measurement using cloud recording); furthermore, the GDPR needs to be considered in case personal data is processed.

##### ■ 3D Printing/Bioprinting

Bioprinting raises a wide range of legal and ethical questions. Currently, no *sui generis* regulatory regime governing the entire bioprinting process is in place in Austria. According to the European Commission and the European Medicines Agency, tissue engineered products might fall under the definition of advanced therapy medicinal products (ATMPs). Also, IP and, in particular, patent rights questions might arise.

##### ■ Natural Language Processing

Natural Language Processing generally does not qualify as a medical product (e.g. speech recognition in dictation software). However, Natural Language Processing may be subject to MDR when specifically intended by the manufacturer to be used for one or more medical purposes; furthermore, the GDPR needs to be observed.

#### 3.2 What are the key issues for digital platform providers?

One of the main restrictions on digital platforms for individual healthcare is that medical advice may only be given by licensed physicians (Section 3 *ÄrzteG*; see question 2.1).

Furthermore, online platform operators should keep in mind the prohibition of commissions in Section 53 paragraph 2 *ÄrzteG*, according to which the physician may not promise, give, take or have promised to himself or another person any remuneration for the referral of patients to him or through him. Moreover, these activities are also prohibited for group practices (Section 52a) and other physical and legal persons. This means that the collection of commissions from patients is prohibited not only for doctors, but also for other third (natural or legal) persons.

Digital platforms must take appropriately (high) technical/organisational measures for data security when processing health data (Article 32 GDPR) and the *GTelG 2012* needs to be considered in case personal health data is processed.

## 4 Data Use

### 4.1 What are the key issues to consider for use of personal data?

The processing of personal data must comply with the GDPR. When processing health data, Article 9 GDPR applies; according to that provision, the processing of health data in connection with healthcare providers is lawful only if (only the most relevant legal grounds have been included in the following):

- the data subject has given explicit consent to the processing of their personal data for one or more specified purposes (Article 9 Section 2 letter a GDPR);
- processing is necessary to protect the vital interests of the data subject or of another natural person where the data subject is physically or legally incapable of giving consent (Article 9 Section 2 letter c GDPR);
- processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems (Article 9 Section 2 letter h GDPR);
- pursuant to a contract with a health professional, when the data is processed by or under the responsibility of a professional subject to the obligation of professional secrecy (Article 9 Section 2 letter h in connection with Section 3 GDPR); and
- processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of healthcare and of medicinal products or medical devices (Article 9 Section 2 letter i GDPR).

### 4.2 How do such considerations change depending on the nature of the entities involved?

In principle, the provisions of the GDPR apply equally to all entities. However, the legal grounds in Article 9 Section 2 letter h only apply to data processing, when the data is processed by or under the responsibility of a professional subject to the obligation of professional secrecy. Therefore, entities not subject to professional secrecy cannot rely on this legal ground.

### 4.3 Which key regulatory requirements apply?

The general regulatory provisions of the GDPR apply, namely the principles of transparency, lawfulness, purpose limitation, data minimisation, proportionality, accuracy, data security and accountability. As in the context of digital health services, large scale processing of sensitive personal data will be involved, the entity providing such services is required to designate a Data Protection Officer in accordance with Article 37 para 1 lit c GDPR. Furthermore, a data protection impact assessment (DPIA) might be required (e.g., according to Article 35 para 3 lit b GDPR) before processing is started.

### 4.4 Do the regulations define the scope of data use?

Yes, please refer to question 4.1. Some legal grounds of Article 9 impose limitations on the purpose of the processing (e.g. preventive or occupational medicine; see question 4.1). Neither the GDPR nor the *DSG* contain regulations defining the scope of data use in the context of digital health.

### 4.5 What are the key contractual considerations?

If the processing is based on explicit consent of the data subject, such valid and fully informed consent needs to be given by the patient/data subject. Furthermore, according to Article 28 GDPR, any data controller must conclude a written data processing agreement with processors, which must contain the minimum contents specified therein. In the event where more than one controller jointly decides on the respective processing, an agreement on joint controllership needs to be concluded between these controllers.

### 4.6 How important is it to secure comprehensive rights to data that is used or collected?

Securing comprehensive rights to the personal data that is used or collected is of utmost importance, not only because of the severe penalties for the unlawful processing of personal data provided for in the GDPR (Article 83 GDPR); it is also vital for a digital health application using personal data to safeguard that such use is lawful as otherwise the application risks being shut down by the data protection authority at any time.

However, the GDPR is only applicable to personal data. Therefore, if no personal data according to Article 6 or Article 9 GDPR is processed, a specific right to process the data is not necessary from a data protection point of view.

## 5 Data Sharing

### 5.1 What are the key issues to consider when sharing personal data?

Sharing health data between healthcare professionals is subject to the *GTelG 2012* (see question 3.1 for the conditions of sharing under the *GTelG 2012*), sharing of data between individuals other than healthcare professionals is solely subject to the GDPR; see question 4.1 for sharing within the EU. For sharing with an individual located outside the EU/EEA, the GDPR provisions on the transfers of personal data to third countries or international organisations apply.

### 5.2 How do such considerations change depending on the nature of the entities involved?

Sharing of data between individuals other than healthcare professionals is solely subject to the GDPR (see question 4.1). In this case the *GTelG 2012* does not apply.

### 5.3 Which key regulatory requirements apply when it comes to sharing data?

Please refer to question 4.3 and 5.1.

## 6 Intellectual Property

### 6.1 What is the scope of patent protection?

Technical inventions which are novel, which, considering the state of the art, are not obvious to a person skilled in the art, and which can be applied in the industry can be subject to patent protection under the Austrian Patent Act, BGBl. No. 259/1970, as last amended by BGBl. I Nr. 37/2018. Only a natural person can qualify as an inventor.

The inventor can either file a patent himself or transfer his right to a third party. The patent owner has the exclusive right to manufacture, put into circulation, offer for sale and use the patented invention for the duration of the patent, namely up to 20 years. A “prolongation” of the patent protection can only be achieved by virtue of a Supplementary Protection Certificate, a *sui generis* intellectual property right available for specific medicines and plant protection products.

Software programs as such cannot be subject to patent protection.

## 6.2 What is the scope of copyright protection?

Under Austrian law (the Austrian Federal Law on Copyright in Works of Literature and Art and on Neighbouring Rights, Federal Law Gazette I 1936/111 as last amended by Federal Law Gazette I 105/2018 – *Urheberrechtsgesetz, UrbG*), a work is defined as an “original intellectual creation” (Section 1 paragraph 1 *UrbG*). The author has the exclusive right to use his or her work in the way defined by the law (in particular reproduction right, distribution right, rental and lending right, broadcasting right, right of public performance and of communication to the public of a performance, making available right). Protection starts in the very moment of creation, which means that no registration with any authority is required for protection under the Copyright Act. According to Section 1 paragraph 1 *UrbG*, works can be original intellectual creations in the area of literature (including computer programs), musical arts, visual arts and cinematography. In principle, only creations of human beings are regarded as works and protected by copyright and the legislator has so far not provided for specific rules for “computer generated works”. According to current doctrine, computer-generated works might still be subject to copyright protection and the programmer as the author in case the programmer, although not directly involved in the creation of the work, has created the creative framework for it by programming the appropriate autonomy.

The Copyright Act further grants exclusive rights to performers (such as singers, dancers and actors) as well as phonogram producers, photographers, broadcasters and the producers of a database (*sui generis* right).

## 6.3 What is the scope of trade secret protection?

The Unfair Competition Act, Federal Gazette I 448/1984, as last amended by Federal Gazette I 104/2019 (*Bundesgesetz gegen unlauteren Wettbewerb, UWG*) contains in its Sections 26a *et seq.* civil law and civil procedural law rules for the protection of trade secrets. According to the legal definition in Section 26b *UWG*, information that is:

- secret, namely not known or readily accessible by persons that normally deal with the respective information;
- of commercial value because of its secrecy; and
- subject to reasonable measures to be kept secret, qualifies as a trade secret.

It must be proven that *reasonable measures* have been taken; these may include specific IT security measures and the restricted accessibility of secret information (e.g. only accessible to particularly trustworthy employees).

A variety of information may be regarded as a trade secret, for example, inventions and designs (if not protected as a patent or design) as well as not otherwise protected information such as production processes, customer information, business models or the like.

The owner of a trade secret is particularly entitled to claims of forbearance, removal, and damages against anyone who unlawfully acquires, uses or discloses his trade secrets.

Section 26h *UWG* contains specific rules to ensure the protection of trade secrets in civil proceedings.

## 6.4 What are the typical results on academic technology transfer rules?

Universities may claim any service invention made by one of its employees within three months of notification of the invention (see Section 106 paragraph 2 University Act, Federal Gazette I 120/2002, as last amended by Federal Gazette I 3/2019, (*Universitätsgesetz, UG*) in connection with the Patent Act’s rules on service inventions); the employee is generally entitled to a special remuneration if the university makes use of that right. If the university does not claim the invention, the general rule applies, namely, the inventor is entitled to the invention. Regarding the commercialisation of technology developed by its researchers, Austrian universities pursue different strategies – from outlicensing to transferring IP and increasingly, additionally acquiring shares in its spin-out companies.

## 6.5 What is the scope of intellectual property protection for Software as a Medical Device?

There are no specific rules for Software as a Medical Device from an intellectual property protection point of view, i.e. the software as such will be protected by copyright law; whether patent protection can be sought needs to be assessed individually.

# 7 Commercial Agreements

## 7.1 What considerations apply to collaborative improvements?

If not otherwise regulated, collaborative improvements belong to the respective inventors of such improvement, whereas the ownership of the basis technology will not change following such improvements. The ownership, and eventually licences regarding the use of such collaborative improvements, is therefore usually regulated precisely and meticulously in the respective agreements containing the regularities for the collaboration.

## 7.2 What considerations apply in agreements between health care and non-health care companies?

Besides regulatory considerations (see question 2.1), the general principles apply, namely Austrian law’s (federal) rules on commercial contracts, providing regulations on the general principles and specific contract types.

The general principles of contracts as well as a large number of specific contracts are regulated in the Civil Code (*Allgemeines Bürgerliches Gesetzbuch*) and in the Commercial Code (*Unternehmensgesetzbuch*).

# 8 AI and Machine Learning

## 8.1 What is the role of machine learning in digital health?

Many digital health devices use machine learning (such as, e.g.,



in the field of radiology, and generally in diagnosing). Machine learning is substantial for developing smart digital health solutions and is said to have the potential to substantially transform healthcare both for patients and medical professionals.

## 8.2 How is training data licensed?

The protection and licensing of training data does not differ from any other protection of information, creations and data. If the training data were created in a specific way by a human being (e.g., texts for speech recognition) they may be subject to copyright protection (see question 6.2). In addition, training data may also be subject to trade secrecy protection (see question 6.3). For using such data, a licence agreement needs to be concluded with the respective right holder.

## 8.3 Who owns the intellectual property rights to algorithms that are improved by machine learning without active human involvement in the software development?

Software may in principle be protected by copyright (see question 6.2). However, copyright protection requires an “intellectual creation” which, according to Austrian law, can only originate from the thoughts of a human being. Assuming that the improvement could have only been achieved because the programmer has “instructed” the algorithms correspondingly, it could be argued that the programmer is the author of the work (the improvement, which is furthermore depending on the basis work). In case the improvement was indeed created without active human involvement it does not qualify for copyright protection.

## 8.4 What commercial considerations apply to licensing data for use in machine learning?

For the provision of data for use in machine learning, the licensor is often commercially interested not only in remuneration but will often have an interest in technical cooperation under which the licensor acquires rights to the results of the machine learning. Therefore, the provision of data for use in machine learning is often based on a broad cooperation.

# 9 Liability

## 9.1 What theories of liability apply to adverse outcomes in digital health?

No specific liability schemes for adverse outcomes in digital health exist under Austrian law. Austrian tort law generally stipulates that the tortfeasor is obliged to compensate for those damages which he or she has culpably and unlawfully caused. In addition to material damages, the injured party is also entitled to receive compensation for pain and suffering in case of injuries to the body and/or health. Punitive damages are not paid in Austria. Unlawfulness in the context of the provision of health services typically results from the violation of contractual obligations (e.g. duties of care, non-valid consent to the treatment because of incorrect or insufficient information). The liability for personal injury cannot be excluded and/or limited by contract.

The Austrian Product Liability Act, Federal Law Gazette 99/1988, last amended by Federal Law Gazette I 98/2001, (*Produkthaftungsgesetz*, PHG) transposes in particular Directive 1999/34/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. If a defect in a product kills a person, causes bodily injury or damage to health, or damages a physical object other than the product, the manufacturer, distributor and the importer shall be liable for damages under Section 1 PHG. Liability is subject to the product being defective and therefore not offering the safety that can be expected under consideration of all circumstances (Section 5 paragraph 1 PHG). However, liability shall be excluded if the manufacturer, distributor or importer proves that: (i) the defect is due to a legal provision or official order with which the product had to comply; (ii) the characteristics of the product are in accordance with the state of the art in science and technology at the time when the person making the claim put it into circulation; or (iii) where the person claimed has manufactured only one basic material or part of a product, the defect was caused by the design of the product into which the basic material or part has been incorporated or by the instructions of the manufacturer of that product.

## 9.2 What cross-border considerations are there?

In case of any cross-border provision of digital health services, the respectively applicable law and the applicability of regulatory requirements have to be determined.

In case it is intended that foreign doctors provide telemedical treatment to Austrian patients, these require an Austrian professional licence if their activity does not fall under Section 37 *ÄrzteG* (freedom to provide services). According to Section 37 *ÄrzteG*, nationals of EU or EEA Member States or Switzerland who lawfully exercise the medical profession in another EU/EEA Member State or Switzerland may, from their foreign professional domicile or place of employment, practice medicine in Austria only if the medical activity is temporary and occasional, which must be assessed on a case-by-case basis, in particular on the basis of the duration, frequency, regular return and continuity of the activity.

Further considerations refer to the law applicable in a cross-border scenario: the provision of health services is typically based on a contract concluded by a natural person for a purpose which can be regarded as being outside his trade or profession (the patient) with another person acting in the exercise of his trade or profession (the medical professional). According to Article 6 Regulation 593/2008 on the law applicable to contractual obligations (Rome I) the contract as well as the contractual liability derived therefrom shall therefore be governed by the law of the country where the consumer has his habitual residence, provided that the professional: (i) pursues his commercial or professional activities in the country where the consumer has his habitual residence; or (ii) by any means, directs such activities to that country or to several countries including that country. Cross-border healthcare providers therefore typically have to comply with the laws of a large number of countries in which they offer their services.

For claims arising from product liability under the PHG, pursuant to Article 5 Regulation 864/2007 on the law applicable to non-contractual obligations (Rome II), the law applicable shall be: (i) the law of the country in which the person sustaining the damage had his or her habitual residence when the damage

occurred, if the product was marketed in that country; or, failing that; (ii) the law of the country in which the product was acquired, if the product was marketed in that country; or, failing that (iii) the law of the country in which the damage occurred, if the product was marketed in that country. As a result, providers of medical devices must therefore also comply with a large number of legal systems in the area of product liability.

## 10 General

### 10.1 What are the key issues in Cloud-based services for digital health?

Like for healthcare IT in general (see question 1.3) the main legal issues for cloud-based services for digital health are the compliance with data protection (see sections 4 and 5), the technical requirements for telehealth (see *GTelG 2012* in question 2.1) as well as determining whether a product qualifies as a medical device (see questions 2.1 and 3.1).

### 10.2 What are the key issues that non-health care companies should consider before entering today's digital health care market?

The intended business model and the actual product or service that shall be offered needs to be carefully examined from a legal perspective, in particular from a regulatory (e.g., the Physicians Act and limitations of telemedicine, Medical Devices Regulation) and from a data protection point of view. Furthermore, if such is relevant depending on the business model, it should be assessed whether reimbursement of the services in question by the sick funds is at all possible.

### 10.3 What are the key issues that venture capital and private equity firms should consider before investing in digital health care ventures?

A comprehensive regulatory (including data protection) due diligence is advisable in order to safeguard that the business the digital healthcare venture intends to undertake or already undertakes complies with all applicable legal requirements.

### 10.4 What are the key barrier(s) holding back widespread clinical adoption of digital health solutions?

One key barrier is Section 3 *ÄrzteG* according to which medical advice may only be given by licensed physicians. Furthermore, the funding and/or (non-)reimbursement of digital health solutions by the state sick funds is a major issue and might be a barrier to the widespread use of digital health solutions.

### 10.5 How critical is it for a digital health solution to obtain formal endorsement from physician certification bodies (e.g., American College of Radiology, etc.) as a driver of clinical adoption?

From a formal point of view, under Austrian law, the formal endorsement of digital health solutions from physician certification bodies might not be of specific relevance. However, such an endorsement might put political pressure on the relevant decision-makers and therefore encourage them to take legal initiatives. Within a possible legislative process, these bodies are typically consulted.



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