International Comparative Legal Guides

Digital Health 2020

A practical cross-border insight into digital health law

First Edition

Featuring contributions from:

Advokatfirma DLA Piper KB
Astolfi e Associati, Studio Legale
Baker McKenzie
Biopharmalex
Bird & Bird LLP
Cliffe Dekker Hofmeyr
D'Light Law Group
GVA Law Office
Hammad & Al-Mehdar Law Firm
Herbst Kinsky Rechtsanwälte GmbH
Hoet Pelaez Castillo & Duque
Kemp Little LLP
Kyriakides Georgopoulos Law Firm
LEĜA
LexOrbis
Llinks Law Offices
Machado Meyer Advogados
Mason Hayes & Curran
McDermott Will & Emery LLP
OLIVARES
Polsinelli PC
Quinz
Gilat, Bareket & Co., Reinhold Cohn Group
Shook, Hardy & Bacon L.L.P.
The Center for Healthcare Economics and Policy, FTI Consulting
TripleOKLaw LLP Advocates
VISCHER

ICLG.com

ISBN 978-1-83918-027-9
ISSN 2633-7533

Published by
global legal group
59 Tanner Street
London SE1 3PL
United Kingdom
+44 207 367 0720
info@glgroup.co.uk
www.iclg.com

Group Publisher
Rory Smith

Associate Publisher
James Strode

Senior Editors
Suzie Levy
Rachel Williams

Sub Editor
Lucie Jackson

Creative Director
Fraser Allan

Printed by
Ashford Colour Press Ltd.

Cover image
www.istockphoto.com

Strategic Partners

International Comparative Legal Guides

Digital Health 2020

First Edition

Contributing Editor:
William A. Tanenbaum
Polsinelli PC

Expert Chapters

Q&A Chapters

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 European Commission has 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_marketstudy_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, 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 GTelG 2012 in question 2.1); 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 105/2019, (*Ärztegesetz* 1988, ÄrzteG 1988) 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 distance, without direct human contact. The Austrian Medical Association has stated that telemedicine might support the relation 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) in the case of telemedicine, they need to be in full control of the patient's situation, and the tele health 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 104/2019, (*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 100/2018, (*Medizinproduktegesetz*, MPG) implements a large number of European Union directives concerning medical devices, in particular Council Directive 93/42/EEC concerning medical devices. The Medical Device Regulation 2017/745 on medical devices (MDR) will repeal the MPG on May 26, 2020. 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 the 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 (*Gesundheitstelematikgesetz 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.

2.3 What regulatory schemes apply to consumer devices in particular?

The Medical Devices Act and, as of May 2020, 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, 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.

The DSB recently 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 life-style 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?

- **Telehealth**
  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 has to fear 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 telehealth or telemedicine services in general, but a specific regulation has been issued regarding the provision of teleradiology services: the Medical Radiation Protection Regulation (BGBl II Nr 375/2017) 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, (*Gesundheitstelematikverordnung 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.

- **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**
  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).
- **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.

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.

Moreover, digital platforms must take appropriately (high) technical/organisational measures for data security when processing health data (Article 32 GDPR).

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.

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).

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. 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.

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 GTelG 2012 does not apply.

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

Please refer to question 4.3.

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. Nr. 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.

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 (BGBl) 1936/111 as last amended by BGBl I 150/2013 – *Urheberrechtsgesetz* – UrhG), a work is defined as an "original intellectual creation" (Section 1 paragraph 1 UrhG). 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 UrhG, 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 UWG contains in its Sections 26a *et seq.* the Unfair Competition Act ("UWG") 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 (*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 will be protected by copyright law and might eventually also be patentable.

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 in particular 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).

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 presupposes 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?

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 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, practise 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.

Dr. Sonja Hebenstreit is a Partner at Herbst Kinsky Rechtsanwälte GmbH, which she joined in 2005. She specialises in the fields of intellectual and industrial property law, unfair competition, life sciences, data protection as well as antitrust and competition law. Dr. Sonja Hebenstreit is a certified data protection officer.

Education and Career: *Mag. iur.* (Vienna 1997); *Dr. iur.* (Vienna 2001); internships with the European Commission (Brussels 1998) and British Telecommunications Group, Legal Services (Brussels 1999); researcher at the University of Münster (Germany), ITM/Civil Law Department (1999–2000); law practice with Hausmaninger Herbst Attorneys at Law (2000–2005); and Herbst Kinsky Rechtsanwälte GmbH (since 2005). Admitted to the Austrian Bar (Vienna 2003).

Languages: German; English; and French.

Herbst Kinsky Rechtsanwälte GmbH
Dr. Karl Lueger-Platz 5
A-1010 Vienna
Austria

Tel: +43 1 904 2180 161
Fax: +43 1 904 2180 210
Email: sonja.hebenstreit@herbstkinsky.at
URL: www.herbstkinsky.at

The Firm

Since its establishment in 2005, Herbst Kinsky has become one of Austria's leading commercial law firms. 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 markets, corporate and M&A, IP, IT and life sciences, merger control, antitrust and competition, data protection, real estate, dispute resolution and arbitration.

Our Clients

The firm's clients range from large international privately-held and publicly-listed companies, banks, insurance companies and private equity investors to small and mid-size business entities. Clients cut across many different industries, including life sciences, energy, information technology, financial institutions and insurance.

www.herbstkinsky.at

HERBST KINSKY
RECHTSANWÄLTE GMBH

ICLG.com

Current titles in the ICLG series

Alternative Investment Funds
Anti-Money Laundering
Aviation Finance & Leasing
Aviation Law
Business Crime
Cartels & Leniency
Class & Group Actions
Competition Litigation
Construction & Engineering Law
Consumer Protection
Copyright
Corporate Governance
Corporate Immigration
Corporate Investigations
Corporate Recovery & Insolvency
Corporate Tax
Cybersecurity
Data Protection
Derivatives
Digital Business
Digital Health
Drug & Medical Device Litigation
Employment & Labour Law
Enforcement of Foreign Judgments
Environment & Climate Change Law
Family Law
Financial Services Disputes
Fintech
Foreign Direct Investment Regimes
Franchise
Gambling
Insurance & Reinsurance
International Arbitration
Investor-State Arbitration
Lending & Secured Finance
Litigation & Dispute Resolution
Merger Control
Mergers & Acquisitions
Mining Law
Oil & Gas Regulation
Outsourcing
Patents
Pharmaceutical Advertising
Private Client
Private Equity
Product Liability
Project Finance
Public Investment Funds
Public Procurement
Real Estate
Sanctions
Securitisation
Shipping Law
Telecoms, Media & Internet
Trade Marks
Vertical Agreements and Dominant Firms

@ICLG_GLG

The International Comparative Legal Guides are published by:

global legal group