



# LEGAL NEWS

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## TELEMEDICINE WORLDWIDE – LEGAL ASPECTS AND CHALLENGES

### I. INTRODUCTION

With telemedicine/remote treatment, healthcare medical services are provided by means of audiovisual communication technologies over geographical or temporal distances. Telemedicine is diverse and can be provided both in regional rural care or across countries as well as in the specialised care of rare diseases or by specialists that are not available everywhere. Especially after the coronavirus pandemic, telemedicine has increased in importance.

As a relatively new instrument of care, telemedicine requires legal regulation for its use both in the individual countries and in the case of cross-border telemedicine treatment.

In this edition of our international newsletter on the topic of telemedicine, which we have put together along with the partner law firms of Schindhelm Alliance, we provide an overview of the various country regulations for telemedicine.

### II. AUSTRIA

#### 1. IS TELEMEDICINE POSSIBLE IN AUSTRIA; WHAT ARE THE LEGAL BASES FOR THIS?

The legal framework conditions for the provision of telemedical services in Austria can be found in various laws such as the Health Telematics Act (Gesundheitstelematikgesetz), the Hospital and Sanatoriums Act (Krankenanstalten- und Kuranstaltengesetz) or the Medical Devices Act (Medizinproduktegesetz) 2021. The permissibility of the telemedical service provision must be assessed based on the directness principle of § 49(2) ÄrzteG (Ärztegesetz [Physicians Act]). This provision was recently

amended with the Agreement Implementation Act 2024 and the admissibility of telemedicine was expressly anchored under professional law. Relevant criteria for assessing admissibility in individual cases are whether the physician has a sufficient basis for decision-making based on the data transmitted to him/her or the impression of the patient made using audio or video conference systems and can thus control the “risks of telemedical treatment”.

#### 2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?

The admissibility of telemedical treatment always constitutes a decision on a case-by-case basis, taking into account the relevant professional obligations. Despite the lack of physical patient contact, the doctor must obtain sufficient information to make a medical decision for the benefit of the patient. If there are doubts about the basis of the medical decision, the patient must consult the doctor physically. The patient must also be informed of any negative consequences. It must also be taken into account whether the patient is already known to the doctor. Telemedicine treatment of foreign patients will generally be difficult to comply with the rules of medicine due to a lack of knowledge of the medical history and the patient. In compliance with the applicable national regulations, establishing a permanent online practice in which patients describe their symptoms and the doctor creates an individual diagnosis is therefore not permitted.

#### 3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?

According to the Patient Mobility Directive (PatientenmobilitätsRL), the country of origin principle applies in principle to the provision of



telemedical services, i.e. the law of the state in which the doctor is established is applicable. Restrictions under professional law result from the Professional Qualification Directive (BerufsqualifikationsRL), which standardises a destination principle. However, only those rules are covered in this that are “in direct connection with the practice of medical healing and whose non-compliance impairs the patients”. Patient Mobility Directive and Professional Qualification Directive standardise different legal consequences with regard to applicable law. A corresponding choice of law can be made in a treatment contract with the patient and is also recommended.

### III. CZECH REPUBLIC

#### 1. IS TELEMEDICINE POSSIBLE IN THE CZECH REPUBLIC; WHAT ARE THE LEGAL BASES FOR THIS?

In the Czech Republic, many patients are already used to occasionally consult their doctor by phone or email. However, the Czech legal system does not recognise the concept of telemedicine to date and the clear legal basis is missing. The amendment to Act No. 372/2011 Coll. on Healthcare Services and the conditions of its provision, which are currently discussed in the Parliament of the Czech Republic, should change this unclear status and legally define the concept of telemedicine as the provision of healthcare services by means of information and communication technologies and special medical devices. In the amendment, the specific requirements for such a provision of health services should also be newly regulated, in particular with regard to the safety of communication, which is subject to medical confidentiality, and the reliable verification of the identity of the physician and the patient.

#### 2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?

The details are still discussed in the legislative procedure, but it can already be assumed that every health institution (or every doctor) must be in possession of a special licence in order to be able to provide telemedical services. The essential prerequisite for obtaining this approval

will be proof that the applicant meets the increased requirements for the technical equipment in order to ensure confidential communication with the patient. Of course, the quality of the medical service must also be guaranteed at the same level as during a personal visit to the doctor (taking into account the possibilities of remote contact). As was already said, the further conditions and restrictions in the legislative procedure are still being discussed.

#### 3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?

This question is still discussed, but it looks like the applicable law is determined ad hoc in each individual case by agreement of the parties, whereby the patient agrees to the application of Czech law in most cases before the start of the provision of medical services.

### IV. FRANCE

#### 1. IS TELEMEDICINE POSSIBLE IN FRANCE; WHAT ARE THE LEGAL BASES FOR THIS?

Telemedicine has been regulated in France since the law of 21 July 2009, the so-called “HPST” (hospital, patients, health and territories), and represents one of the two components of telehealth in addition to telecare. In 2018, after a gradual trial phase, it was incorporated into the general law of medical practice and its essential role was reaffirmed in the 2022 health plan.

Since 15 September 2018, teleconsultation has been accessible throughout France: Every doctor, regardless of his or her specialisation and area of activity, can now offer his or her patients a remote consultation instead of a face-to-face consultation, for every medical situation that he or she considers suitable.

#### 2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?

Every doctor can carry out a teleconsultation, irrespective of his or her specialisation, area of



activity, or location of activity in the city or in a health care facility.

Each patient, regardless of whether they suffer from an acute or chronic disease, can receive a teleconsultation a priori. However, the decision to use a teleconsultation lies solely with the doctor, who must assess whether remote medical treatment is sensible instead of face-to-face.

However, it should be noted that an upper limit applies to telemedical activities: For this reason, a doctor may not carry out more than 20% of his or her activity volume (teleconsultations and tele-expertise combined) in a calendar year. Failure to comply with this maximum limit for telemedical activities can lead to measures by the health insurance company.

### **3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?**

The same national law will not necessarily apply to all legal systems considered, e.g. the legal systems relating to access to the service market, the contractual obligations towards the patient, the reimbursement of costs, the liability of the service provider, the regulations on the protection of personal health data and the jurisdiction.

In order to determine the applicable law, in particular, a thorough analysis of the contextual elements must be carried out, including the question of whether the patient's home country is an EU member state or not, the nationality of the participating physicians, the country of the state of establishment of the service provider, the shared use of data, etc. EU law allows the determination of the applicable law for telemedical services offered by a European service provider for nationals of another EU member state.

## **V. GERMANY**

### **1. IS TELEMEDICINE POSSIBLE IN GERMANY; WHAT ARE THE LEGAL BASES FOR THIS?**

Telemedicine is not only possible in Germany

in theory, but is already practised in different forms, whereby in addition to the telephone consultation, the most well-known area of telemedicine to date is video consultation between doctor and patient. There is no uniform Telemedicine Act in Germany. However, since 2018, a basic regulation for the consultations and treatments that do not take place in-person has already been found in § 7(4)(3) of the Sample Professional Code (MBO-Ä). According to this, doctors can use communication media not only to support, but also exclusively to advise or treat their patients under special conditions. This regulation was also adopted by most medical associations in Germany into their respective professional regulations. Especially due to the coronavirus pandemic, the video consultation hours practised increased. It was also possible to get a sick leave note by telephone. However, the standard case should continue to be the face-to-face treatment. However, the topic of telemedicine is growing in momentum overall. In the meantime, after the abolition of the telephone sick leave note, this is now possible one again since 7 December 2023. In addition, there should be a contact point for assisted telemedicine in at least 60% of the under-served regions by 2026. In addition, the e-prescription was introduced in January 2024; from the beginning of 2025, the electronic patient file is to be used.

### **2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?**

Telemedicine services should remain an exception. Remote treatments can harbour a particular risk potential due to their shortened form of treatment. They are therefore sometimes subject to high requirements, which must be checked by the doctor in individual cases. This applies in particular to consultation and treatment on the basis of § 7(4)(3) MBO-Ä ((Muster-)Berufsordnung [Sample Professional Code]) or the professional regulations of the



medical associations of the federal states. In each individual case, it is necessary, among other things, to check whether it can be said with certainty that the consultation and treatment of the patient does not require any personal contact between the doctor and patient. The patient must also be informed about the special features of the treatment via the communication medium. In this context, the information also includes instruction on the risks of the telemedicine treatment method and an indication of the possibility of personal treatment. There is also a restriction with regard to the invoicing of the contractual medical services that may be provided by video consultation. These were initially limited to 30% again in each treatment quarter by the National Association of Statutory Health Insurance Physicians and the health insurance companies after the pandemic.

### **3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?**

If no regulation on the choice of law has been made between doctor and patient, the legal system at the usual place of residence of the service provider, i.e. the registered office of the doctor's practice, is decisive in accordance with Art. 4(1)(a) ROM I Regulation. According to Art. 6 Rome I Regulation, mandatory law at the patient's usual place of residence is cumulatively applicable if the patient is a consumer, which is to be assumed regularly. The treatment contract does not constitute a mandatory law to protect the consumer, so that in the case of telemedicine treatment, it can in principle also be governed by another legal system. However, a patient from Germany is nevertheless protected by § 309 No. 7(a) BGB (Bürgerliches Gesetzbuch [German Civil Code]), according to which liability cannot be excluded in the event of injury to life, body or health due to a negligent or intentional breach of duty by the doctor. Individual safeguarding standards of German law in favour of the patient can therefore not be undermined.

## **VI. ITALY**

### **1. IS TELEMEDICINE POSSIBLE IN ITALY; WHAT ARE THE LEGAL BASES FOR THIS?**

Telemedicine is permitted in Italy and can be used for secondary prevention, diagnostics, rehabilitation and monitoring purposes.

The legal basis for this is provided by regulations issued by the individual regions or autonomous provinces. The linee guida nazionali (national guidelines) issued by the Ministry of Health dated 2 November 2022 is directed at these regions or autonomous provinces and is intended to ensure homogeneity at the national level and efficiency in the area of telemedicine. The linee guida nazionali dated 2 November 2022 therefore establishes the functional and technological minimum requirements for the use of telemedicine and determines which training and competences must be available for the medical personnel involved. Furthermore, the guidelines determine which constitution and capabilities the patient must have in order to be suitable for the use of telemedicine.

### **2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?**

The patient must have sufficient digital knowledge and technical equipment and must be able to use the telemedical services according to their clinical situation. The treating physician is responsible for assessing this. The healthcare professional must master the technical aspects, the special care requirements and the data protection aspects of telemedicine and receive appropriate training. The guidelines differentiate between five forms in which telemedicine may be provided: Televisita (real-time connection between patient and physician), Teleconsulto (remote connection between physicians), Teleconsulenza (remote connection between physician and nursing staff), Teleassistenza (remote communication between patient and healthcare professions such as physiotherapists, speech therapists) and Telemonitoraggio (digital transmission of clinical parameters using sensors). Different



legal requirements apply depending on the form of provision.

### **3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?**

In this case, there are no separate and specific Italian regulations; rather, the directives already cited refer generally to the “regulatory instruments” issued at EU level.

## **VII. SLOVAKIA**

### **1. IS TELEMEDICINE POSSIBLE IN SLOVAKIA; WHAT ARE THE LEGAL BASES FOR THIS?**

Unfortunately, there is still no legal regulation for telemedicine as such in Slovakia, and there is currently no proposal in the legislative procedure that would change this situation. The Act No. 576/2004 Coll. on Healthcare and National and International Ethical Medical Standards is applied to support the provision of remote medical services. However, Slovakia will have to wait for a comprehensive legal regulation of telemedicine.

### **2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?**

When providing health services remotely, it must be ensured that medical confidentiality is maintained and that a suitable communication channel is used for this purpose. However, no further details will be provided. When using “telemedicine”, the state of health of the patient and the possible type of his or her illness must also be taken into account. In the absence of legal definitions, however, there are no further specifications in this area either.

### **3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?**

The application of the applicable law is generally agreed between the physician and the patient before the services are provided and the patient signs a declaration of consent in this regard.

## **VIII. TURKEY**

### **1. IS TELEMEDICINE POSSIBLE IN TURKEY; WHAT ARE THE LEGAL BASES FOR THIS?**

The Regulation on the remote provision of healthcare services was announced in Turkey on 10/02/2022 and came into force on the same day.

With the entry into force of this Regulation, the remote provision of healthcare services in Turkey is fundamentally permitted if the conditions of the Regulation are met. In addition, the prohibitions and restrictions on the provision of telemedical services were also regulated in a separate paragraph in the relevant regulation. Prior to the entry into force of the Regulation, according to the interpretation of the relevant legal provisions, the provision of healthcare services in Turkey was not permitted.

### **2. WHAT ARE THE CONDITIONS AND RESTRICTIONS FOR THE PROVISION OF TELEMEDICINE SERVICES?**

Approval from the Ministry of Health is required for the provision of telemedical services. For this purpose, the information system, that is to be used for the provision of telemedical services, must be developed by the Ministry or authorised external developers in accordance with minimum standards set by the Ministry and registered in the Ministry's system. The permissible telemedical services are defined and include medical examinations, medical consultations, interventional and surgical services as well as monitoring and measurement of health data, as far as possible remotely. Otherwise, the recommendation must be made to see a doctor. Electronic prescriptions and sick leave notes can also be issued. Before providing telemedical services, the patient must be informed in detail and the protection of personal data must be guaranteed.

### **3. WHAT LAW IS APPLICABLE IN THE CASE OF CROSS-BORDER TELEMEDICINE?**

If one assumes that a doctor from abroad can provide telemedical services, the applicable law is as follows: According to Turkish law, the



legal relationship between the patient and the doctor is an order. Orders are contractual obligations. Article 24 of Law No. 5718 on International Private and Procedural Law applies to the law applicable to contractual obligations. According to Article 24, the applicable law can be agreed for the provision of health services. In other words, if a choice of law is made in the treatment contract, the law agreed in this way applies. If a choice of law has not been made, the law of the country in which the debtor who provides the characteristic service has his or her habitual residence shall apply. In the treatment contract, the characteristic service is the treatment, so that the law of the state in which the treating physician has his or her habitual residence would have to be applied.

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