

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

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LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine is, in general, permitted in Austria. However, no specific national legal framework is in place in this respect.

The Austrian Physicians Act (*ÄrzteG*) outlines the general conditions and requirements for physicians and stipulates the obligation to exercise the profession 'personally' and 'directly'. This provision is no prohibition of telemedicine per se, however, while the obligation to exercise the profession 'personally' does not pose any problem in general, it is not entirely clear what 'directly' means in the context of telemedicine.

A sufficient basis for decision-making and the need to be able to control potential risks and dangers are considered to be recognised criteria for the permissibility of telemedicine treatments according to legal writing.

Physicians need to be in full control of the patient's situation and the treatment must be for the patient's benefit.

In any case, the line has to be drawn whenever medical treatment requires physical contact between the physician and the patient (otherwise this would be a violation of the principle of directness). Pursuant to a statement of the Austrian Medical Association (*Ärztelkammer*) it is the physician's responsibility to decide when (which) telemedical services are permitted and when they/which are not.

The Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) defines telemedicine as provision or support of health care services where the patient and the physician/healthcare provider (which might, in particular, be a physician, pharmacy, hospital and/or nursing staff) are not present at the same place using information and communication technologies. This corresponds to the definition used by the European Commission (Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society; COM/2008/0689 final).

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

Austrian law does not foresee explicit regulations regarding 'telemedicine' and or 'telehealth' (yet).

Relevant provisions can be found inter alia in the Austrian Physicians Act (*ÄrzteG*), Austrian Dentist Act (*ZahnärzteG*), Austrian Health Telematics Act (*Gesundheitstelematikgesetz*) and the Austrian Health Telematics Regulation (*Gesundheitstelematikverordnung*).

First and foremost, the professional practice of a physician must be in accordance with the *ÄrzteG* which provides various regulations regarding the licensing, organisation, training and exercise of the profession of physicians.

The Health Telematics Act stipulates rules regarding the processing of personal electronic health and genetic data by health care providers; health care providers in this context refer to controllers or processors (as defined in the General Data Protection Regulation (GDPR)) of health data or genetic data in an electronic form for medical treatments, nursing care, invoicing health services, insurance and or exercise of patients' rights on a regularly basis. The Austrian Health Telematics Regulation, in addition, stipulates regulations on encryption and technical implementation of communication.

Moreover, the provisions of Data Protection Act as well as the GDPR have to be complied with in case of providing telemedicine services.

In a particular setting, the provisions of the Hospitals and Sanatoriums Act ('*KAKuG*'), which governs requirements for hospitals and healthcare institutions, and the Health Care and Nursing Act (*Gesundheits und Krankenpflegegesetz*) regulating non-medical health professions, might apply. With regard to the technical requirements, telemedicine is subject to the E-Government Act and the Signature Act, as well as the respective regulations.

Depending on the telehealth care service offered (eg, specific software used), relevant provisions might in certain cases also be found in the Austrian Medicinal Products Act, (*Arzneimittelgesetz*) implementing (parts of) the EU directives concerning regulations on medicinal products and providing for various provisions regarding the authorisation of medicinal products, marketing, advertising and distribution of medicinal products as well as quality assurance. In addition, the Austrian Medical Devices Act (*Medizinproduktegesetz*) implementing (parts of) the EU directives concerning medical devices and the European Union Medical Device Regulation may provide for relevant regulations.

Moreover, the Austrian Medical Radiation Protection Regulation (*Medizinische Strahlenschutzverordnung*) published in 2017, explicitly refers to the provision of teleradiology (in specific cases such as basic and special trauma care as well as in dispersed outpatient primary care facilities of acute hospitals and in order to maintain night, weekend and holiday operations for urgent cases).

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

There are no separate key licensing bodies for telemedicine in Austria.

The general licensing requirements apply for telemedicine providers (eg, licensing requirements imposed under the Austrian Physicians Act or the Hospitals and Sanatoriums Act).

Pursuant to section 3 *ÄrzteG*, medical advice (via telemedicine applications or in person) may only be given by licensed physicians.

4. Was telemedicine authorised during the Covid-19 pandemic?

No specific (special) authorisation for telemedicine has been implemented during the Covid-19 pandemic in Austria.

However, during the pandemic it was possible to request sick leave remotely (via telephone) as well as to prescribe medication without any personal contact via e-Medikation (*e-Medikation*), an application of the electronic health record (*Elektronische Gesundheitsakte (ELGA)*). In addition, certain conditions for the transmission of health data were (temporarily) relaxed for healthcare providers.

Moreover, telephone health consultations 'corona consultations' for diagnostic clarification of symptoms in suspected Covid-19 cases and consultation regarding further procedures have been introduced nationwide in Austria and a Covid-19-specific symptom check and triaging via app was deployed in Vienna.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario? Or has there been already a change in the regulation in the post-pandemic scenario?

Even prior, but driven primarily by the Covid-19 pandemic, there is considerable movement in the telemedicine/telehealth sector. Physicians, healthcare professionals and lawyers alike are pushing for legal clarifications. It thus appears quite possible that the Austrian regulatory landscape will change in response to these, and potentially other, future developments.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, tediagnosis, telesurgery, among others)?

According to the TeleHealth Commission (*Telegesundheitsdienste-Kommission*), established in 2013 by the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) aiming to develop recommendations for the introduction of specific telemedicine services, the terms 'telehealth' and 'telemedicine' cover a broad spectrum of services provided by health care providers (in particular, physicians, pharmacies, hospitals and nursing staff) for other health care providers or patients, including but not limited to:

- teletherapy (active treatment);
- telemonitoring (monitoring);
- teleconciliations (requesting a second opinion); and
- teleconference (medical advice).

However, there is no conclusive official list of services which can be provided via 'telemedicine/telehealth' in Austria.

Pursuant to a ruling of the Austrian Supreme Court, information on intended medical treatments and regarding clarification of clinical pictures/pathologies and proposed medication via teleconsultation, email or telephone are (in general) allowed. Regarding other forms of telemedicine, the admissibility depends on whether a telemedical treatment is and can be performed *lege artis* (see question 1 above).

Section 302 of the Austrian General Social Security Act (ASVG) expressly refers to telerehabilitation. (Additionally, teleradiology and teletherapy are expressly mentioned in the Austrian Medical Radiation Protection Regulation (*Medizinische Strahlenschutzverordnung*); see question 1 above.

7. Who can use telemedicine services? Please indicate if whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Subject to the above, telemedicine services can be used/provided: (i) physician-physician; and (ii) patient-physician.

8. Please outline the funding model for telemedicine. Is it available in your jurisdiction public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.

Medical advice via phone or videoconference (especially initial consultations and discussion of findings) is, in general, reimbursed by the public health system (ie, the Umbrella Association of Austrian Social Insurance Institutions). The current regulation is in force until the end of 2023. Reimbursement is subject to the following criteria: the telemedical treatment is: (i) medically justifiable; (ii) permitted under applicable physicians professional conduct rules; (iii) equally beneficial as providing the service in person; and (iv) a duty of care is observed. However, there are still uncertainties as the agreement of the Austrian Social Insurance Institutions with the Austrian Medical Association (*Ärztchamber*) states that 'patients [...] will, however, only be treated [...] if they have already been personally treated by the specific physician.' (excluding the case a regular patient is threatened by a medical locum (*Vertretungsarzt*)).

Certain other telehealth services (such as tele-ergotherapy or telepsychotherapy) are also reimbursed by the public health system under certain conditions.

Several private insurance companies offer comprehensive telemedicine/telehealth packages.

During the Covid-19 pandemic, moreover, a free of charge hotline (in Austria) as well as an app (in Vienna) have been offered; see question 4 above.

9. Please indicate whether any insurance requirements applicable to telemedicine services providers.

Austrian law does not foresee explicit regulations regarding telemedicine (yet).

Thus, general insurance obligations of physicians/health service providers apply.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists, alternative health therapies providers, etc).

Austrian law does not foresee explicit regulations regarding telemedicine/telehealth services (yet).

However, the definition of telemedicine implemented in Austria (see question 1) refers to health care providers (in particular, physicians, pharmacies, hospitals and nursing staff).

Also, legal writing confirms the permissibility of providing telehealth services by such healthcare professionals other than physicians under certain conditions.

11. Are there any specific education requirements or trainings that healthcare professionals need to meet or attend to provide telemedicine services?

Austrian law does not provide for specific requirements for trainings in order to provide telemedicine/telehealth services.

In addition to compliance with the general requirements for exercising the health care profession, the strict provisions of applicable data protection laws regarding telemedicine/telehealth need to be stressed; in this regard, training may be useful or even mandatory (eg, in case a Data Protection Officer is required) under certain conditions.

12. Is there any registration requirement applicable to physicians that provide telemedicine services?

Austrian law does not provide for specific registration requirements in order to provide telemedicine services.

Private certifications for physicians, as well as companies offering telemedicine services, have already been established in Austria (such as TELEMED Austria; an association certifying that the telemedical quality criteria of the Austrian professional society (*Österreichischer Fachverband*) are met).

However, besides the general registration requirements for physicians (physicians have to be registered with the list of physicians of the Austrian Medical Association (*Ärztelkammer*)) no additional registration is required regarding the provisions of telemedicine.

13. Please indicate whether special licences or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.

Austrian law does not provide for specific license or authorisation requirements in order to provide telemedicine/telehealth services.

Regarding the provision of medical advice, please see question 3 above.

REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES

14. Are there specific requirements applicable to the telemedicine platform?

In connection with the provision of telemedicine via platforms, particular attention must be paid to whether data protection (see question 20) and statutory confidentiality obligations can be complied with.

In case a platform is solely connecting patients and physicians, Section 52 paragraph 2 of the Austrian Physicians Act needs to be complied with, pursuant to which physicians may not be promised remuneration for referring patients to or from the physician (ie, collection of commissions for patient referrals is forbidden).

This also applies to group practices (*Gruppenpraxen*) and other legal or natural persons.

15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?

No specific requirements regarding the electronic equipment or internet speed are stated under Austrian law.

However, the Austrian Health Telematics Act, as well as the applicable Data Protection laws, foresee strict requirements, especially regarding data storage, processing and transmission, which need to be complied with by telemedicine/telehealth services providers. Platforms and service providers have to take the respective (high) technical and organisational measures for data security.

Certain duties of care in this context can also be assumed on the part of the physician as a professional (section 1299 Austrian Civil Code) to ensure that the internet transmission is suitable for the performance of the medical treatment. For example, if internet speed does not allow for a consultation, it would likely have to be changed to in-person. However, this is rather an outflow from the general duties and not an independent regulation.

Regarding data protection, please see question 21.

16. Does the legislation provide for specific rules concerning patients' medical records?

Several obligations apply regarding the documentation of treatments and medical assessments and the keeping of medical records.

In Austria, the electronic health record (ELGA) has been introduced gradually over the past few years by the Austrian state (ie, the Umbrella Association of Austrian Social Insurance Institutions). ELGA is an information system that enables location- and time-independent retrieval of relevant health data. The Austrian Health Telematics Act foresees detailed provisions in this regard.

Moreover, in general, strict secrecy provisions apply regarding health/medical information noted in the medical records.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

In general, no specific legal requirements regarding the location requirement for the provision of telemedicine apply within Austria.

However, pursuant to Section 45 paragraph 4 Austrian Physician Act, physicians in private practice in Austria are prohibited from practising their profession without a specific place of practice (*Verbot der Wanderpraxis*). Specific provisions are foreseen for physicians who are solely providing services which do not require a place of practice (such as draft reports, physicians specialised on schools/employees; *Wohnsitzärzte*).

Provision of telemedicine by telework, outside the usual workplace, be it mobile (eg, during an emergency), or at a specific location (eg, on a conference) is not per se prohibited. However, physicians in private practice are required to also provide telemedicine services from their place

of practice (pursuant to prevailing legal writing). In cases where physicians in private practice perform services that can only be rendered outside the place of practice because the patient cannot be forced to visit the place of practice (eg, in case of sport events or home visits) provision of telemedicine outside the place of practice is possible (such as telemedical travel accompaniment of sick persons) pursuant to Austrian legal writing.

Salaried physicians have a place of employment. This, in general, does not prevent them from working remotely; however, it must be assessed on a case-by-case basis (among others on the basis of the contractual relationship with the employer) from where telemedicine services can be offered.

With respect to any provision of cross-border telemedicine services, especially regarding services rendered for patients (being consumers), the law governing the contract as well as the laws of the country of the patients residence might be applicable (favourability principle; *Günstigkeitprinzip*).

Provision of medical advice in Austria is solely permissible for physicians licenced in Austria. Specific provisions apply to physicians of other EU/EEA (European Economic Area) member states or Switzerland providing medical advice cross-border in Austria (Austrian Physicians Act).

Additionally, special requirements might apply to the cross-border transfer (collection and processing) of health data (ie, personal information), including the GDPR and the corresponding national implementation Acts as well as the findings from the *Schrems II* judgment.

18. Does the healthcare professional need to obtain patient's consent to engage in a telehealth?

In general, physicians are obliged to comprehensively inform the patient and obtain the patients informed consent.

Austrian law, however, does not request any specific (additional/separate) consent declarations regarding telehealth.

Please note that depending on the service offered the general provisions regarding consent requirements for data transfer/processing might apply.

In this regard, it should be noted that (based on case law) a patient in Austria cannot consent to the unencrypted transmission of his or her health data via email.

19. Is there any other important requirement that should be highlighted?

Austrian law foresees certain restrictions regarding advertisement and public communications of physicians. These restrictions might also have to be observed regarding advertising of telemedicine services.

DATA PRIVACY ASPECTS

20. Are there data privacy issues should be considered for the exploitation of such market? If your answer is positive, please provide a short description.

Since health data generally qualify as a special category of personal data within the meaning of Art 9(1) GDPR (ie, sensitive data), strict data protection provisions apply in the telemedicine context.

Primarily, the processing of health data is governed by the GDPR, whereas the Austrian Data Protection Act (*Datenschutzgesetz*) specifies and supplements some provisions of the GDPR and contains procedural rules concerning the Austrian Data Protection Authority. Moreover, specific data protection provisions are included in various laws regulating medical professions (eg. the Austrian Physician Act (*Ärztegesetz*) and Pharmacy Act (*Apothekengesetz*)) or medical institutions (eg, the Hospitals and Sanatoriums Act (*Kranken- und Kuranstaltengesetz*)). In particular, these laws contain statutory bases for the lawful processing of health data within the meaning of Art 9(2)(h) and (i) GDPR. Otherwise, the processing of health data may be based on the patient's freely given, specific, informed and explicit consent under Art 9(2)(a) GDPR.

The above-mentioned laws are supplemented by specific rules concerning the confidential and secure processing and transfer of electronic health and genetic data:

- Austrian Health Telematics Act (*Gesundheitstelematikgesetz*); and
- Austrian Health Telematics Regulation (*Gesundheitstelematikverordnung*).

These laws govern, inter alia, the secure communication of electronic health data between patients, physicians, hospitals and other health care services and, therefore, are of particular relevance for telehealth applications.

21. Does the applicable regulation provide for criteria and requirements for the security systems to protect the patient's information?

Besides the general provisions of the GDPR and the Austrian Data Protection Act (*Datenschutzgesetz*), detailed data security regulations for health service providers are implemented in the Austrian Health Telematics Act and the Austrian Health Telematics Regulation.

The Austrian Health Telematics Act stipulates specific requirements for the transfer of electronic health and genetic data, obligating health service providers to inter alia: (i) verify the identity of data recipients; (ii) maintain data confidentiality (by using secure networks, data encryption and other specified measures against unauthorised access); and (iii) safeguard data integrity (eg, by using electronic signatures and seals). In addition, health service providers are required to document all information security measures in a comprehensive IT security concept.

The Austrian Health Telematics Act also includes provisions establishing and regulating key governmental e-health services like the eHealth Register Service (eHVD) and the Electronic Health Record.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

With respect to international data transfers, Austrian law defers to the provisions of the GDPR. Hence, data transfers within the EU are not subject to any additional requirements, while transfers to third countries have to comply with the special provisions of Chapter V, GDPR. Accordingly, data transfers to third countries may be permissible, particularly where the recipient country is covered by an adequacy decision of the EU Commission under Article 45 GDPR

(*Angemessenheitsbeschlusses*), confirming that the recipient country offers an adequate level of data protection. Absent such a decision, data transfers to third countries may be permissible where appropriate safeguards within the meaning of Article 46 GDPR are implemented (eg, standard contractual clauses), and enforceable rights and effective remedies are available to data subjects.

**23. Is there any registration of databases requirement that companies must observe?
Are there requirements regarding the recording of data in the patient's medical records?**

Austrian law does not provide for specific registration of database requirements of companies. However, the Austrian Health Telematics Act (includes provisions establishing and regulating key governmental e-health services like the eHealth Register Service (eHVD)). The eHVD is a directory of all health service providers operating and registered in Austria, including their roles and identification. It is operated by the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) and the relevant data are entered and exported by the responsible registration bodies (such as the Austrian Medical Association (*Ärztammer*)).

With respect to private certificates please see question 12 above and regarding recording of data in the patient's medical records please see question 16.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and institutions involved in telemedicine practices.

Austrian law does not foresee specific liability schemes for telemedicine practices. Austrian tort law stipulates in general that those damages have to be compensated which have been caused culpably and unlawfully (*schuldhaft und rechtswidrig*). In connection with treatment by physicians, in particular, information (ie, compliance with information obligations – the patient must be in the position to provide informed consent) plays a major role in compensation for damages. Austrian law foresees compensation for pain besides compensation for actual/material damages.

In general, no punitive damages are foreseen under Austrian law in this context.

Physicians must observe a high standard of care (according to section 49 para 1 Austria Physicians Act) in exercising their profession (expert liability in accordance with section 1299 Austrian Civil Code (ABGB)). Failure to comply with these standards may trigger liability. In addition, special liability provisions are provided for in the event that confidentiality provisions are breached.

Specific liability insurances are required for physicians (hospitals and group practices) under Austrian law.

Who exactly is held liable (especially for the system used) depends on whether the physician is a salaried physician or a physician in private practice. In the first case, the contractual relationship is established between the hospital/the employer and the patient, and the hospital/employer, in general, is liable (the physician at most is additionally liable *ex delicto*).

In case of certain telehealth application, the provisions of the Austrian Product Liability Act (*Produkthaftungsgesetz*) might be applicable under certain circumstances.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

In 2021, a report, '*Telemedizin in Österreich*',¹ was issued on behalf of Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK) that examines the use and acceptance of telemedicine in Austria based on studies conducted in 2020.

Pursuant to one of the studies published in the report (conducted between March and June 2020), out of 426 persons who had contact with a physician during the period in question, 25 per cent of respondents had contact with physicians via telephone, four per cent of contacts were made by email, and three per cent used chat or video services. Ninety per cent were satisfied with the telemedicine service.

Another study (conducted between April to June 2020) said that out of 606 physicians 61 per cent consider telemedicine a perfect solution during the Covid-19 pandemic; 57 per cent agreed that this is also the case after the crisis.

Patient acceptance of telephone care was rated as very high or high by 84 per cent of physicians. This figure was somewhat lower for digital care, for example, via email, chat or video telephony. Here, 58 per cent of respondents said they rated patient acceptance of this form of care as very high or high.

With regard to the potential of telemedicine in Austria, system maintenance in times of crisis and patient care from a distance were mentioned most frequently, with slightly more than two-thirds of respondents agreeing in each case. The greatest challenges for telemedicine in practice were seen in the affinity of older patients for technology, legal challenges and data protection.

A survey of Austrian physical therapists, occupational therapists and speech therapists found that the Covid-19 pandemic had changed attitudes toward telemedicine applications. Interest in teletherapy increased significantly among 75 per cent of respondents.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

One of the emerging topics is the use of artificial intelligence and machine learning in medical treatments/diagnoses.

Moreover, pilot projects have been implemented in Austria regarding the use of telemedicine in emergency cases (ie, medical advice by emergency physicians in non-critical emergency cases).

In order to keep up with this rapidly evolving sector and to reduce uncertainties (due to the lack of explicit legal regulations (see above)), we would like to see the Austrian legislator establish a clear legal framework.

¹ Document (in German) available at: www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiwwd27-u39AhUpIlsKHVFvCIUQFNoECAwQAQ&url=https%3A%2F%2Fwww.sozialministerium.at%2Fdam%2Fjcr%3A2a1d797f-c234-4760-85ad-042956ada6cb%2FTelemedizin_Landschaft_Bericht_final.pdf&usg=AOvVaw2hxQOXk2nbb4w93ogKui1x&csid=1679433812004930.