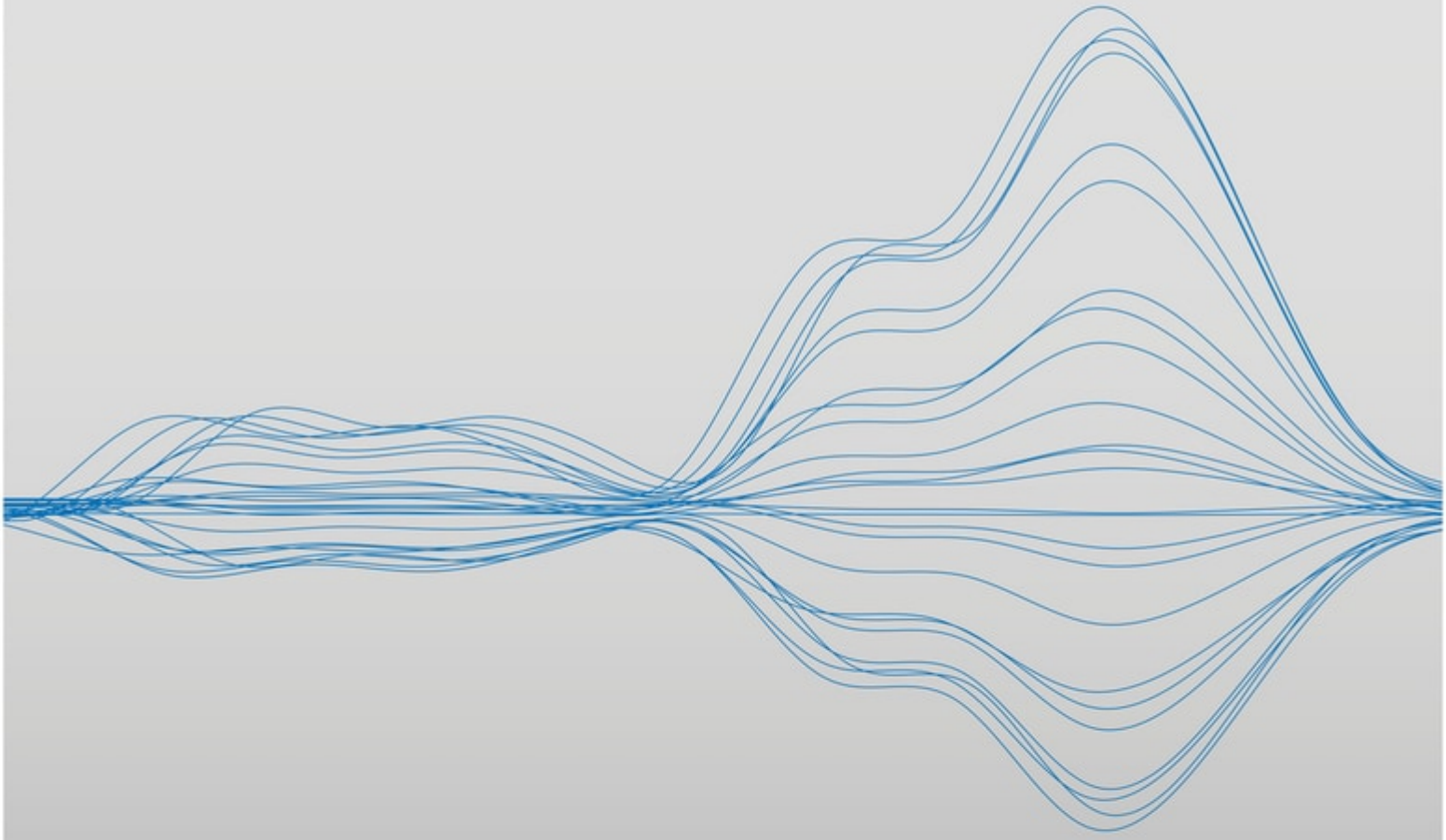
SLOVENIA

Telehealth around the world: a global guide



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Introduction

The COVID-19 pandemic has caused healthcare systems around the globe to rapidly, and in some cases, radically rethink the delivery of medical care. The global expansion of telehealth services is one way we have seen this transformation occur. This has resulted in significant opportunities in the field, as well as unprecedented regulatory change.

As a quickly evolving area, 'telehealth' can have different meanings in different contexts. In this Global Guide, telehealth refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries. We have adapted this definition from the World Health Organisation's definition of telehealth.

Telehealth is not a new concept – healthcare providers, academics and technology developers have been advocating for its use for decades. There are many benefits to the widespread adoption of telehealth, including improved access to healthcare services, risk mitigation, convenience and flexibility, and in many cases, a reduction in overhead costs. However, the use of telehealth is not without its challenges. For example, it is not suited to all forms of healthcare, its implementation and adoption can be time consuming and costly, and additional care must be taken in relation to the transfer of patient health information.

The restrictions of movement in many parts of the world due to COVID-19 has caused governments to recognise the potential of telehealth, and amend laws and regulations seemingly overnight to enable healthcare providers to deploy telehealth solutions. Many governments have adopted telehealth reforms in a matter of weeks, which may otherwise have taken years to be considered and introduced.

Although many of these reforms presently have an expiration date (dependent on the duration of the COVID-19 pandemic), there is likely to be continued growth in telehealth due to the advantages of such a service – even after the pandemic. There are enormous opportunities in the telehealth space for businesses already operating in this field, businesses considering expanding into telehealth, and start-ups.

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis. As the field of telehealth, and the regulations underpinning it, remain highly dynamic and subject to change, this document is intended as a general guide and does not constitute legal advice.
Should you wish to discuss any aspects of telehealth with a specialist lawyer, please contact us below.

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Slovenia

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Is the use of telehealth permitted?

Yes, the use of telehealth in Slovenia is permitted. Broadly speaking, Slovenian law explicitly recognises and allows two types of telehealth services, namely:

i. "Telemedicine" (in Slovene: *telemedicina*) which isdefined as provision of healthcare services through the use of information and communications technology where the health professional and the patient (or two health professionals) are not in the same location, according to Article 3 (3) of the Slovenian Health Services Act (*Zakon o zdravstveni dejavnosti* – "ZZDej") ("Telemedicine "); and
ii. "Telepharmacy" (in Slovene: *telefarmacija*) which is defined as means of remote counseling through modern telecommunication technologies within the context of pharmaceutical activities, according to Article 4 (1) no 18 of the Slovenian Pharmacy Practice Act (*Zakon o lekarniški dejavnosti* – "ZLD-1") ("Telepharmacy").

How is telehealth regulated?

First and foremost it shall be noted that a comprehensive legal framework regulating telehealth in Slovenia has not yet been adopted.

Telehealth is, however, partially regulated by several legal acts.

Telemedicine

For instance, Article 3 (3) ZZDej sets out that Telemedice services shall be carried out according to the rules of medical doctrine. Furthermore, apart from the data protection aspects (discussed in detail below), the said Article also transposes the relevant parts of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 by stipulating that in the case of Telemedicine, healthcare shall be deemed to be provided in the country in which the healthcare provider providing the Telemedicine is established.

Additionally, when determining the legal framework pertainig to Telemedicine, the Slovenian Patients' Rights Act (*Zakon o pacientovih pravicah* – "ZPacP") shall be considered. In particular, a potential challenge for the provision of Telemedicine services represents Article 20 (2) ZPacP which stipulates that it is a patient's right to have the doctor provide explanations / relevant information in a direct fashion.

Telepharmacy

According to Article 6 (1) no 6 ZLD-1, Telepharmacy is recognized as a regulated pharmacy activity.

Moreover, Article 19 (2) no 16 of the Slovenian Regulation on the Conditions for Conducting Pharmacy Activities (*Pravilnik o pogojih za izvajanje lekarniške dejavnosti*) and Article 8 (3) no 13 of the Slovenian Regulation on the Provision of Pharmacy Services in a Hospital Pharmacy (*Pravilnik o izvajanju storitev lekarniške dejavnosti v bolnišnini lekarni*) set forth the requirements regarding recordkeeping pertaining to Telepharmacy activities.

Other aspects

A further legal act regulating the realm of telehealth in Slovenia is the Slovenian Healthcare Databases Act (*Zakon o zbirkah podatkov s podroja zdravstvenega varstva* – "**ZZPPZ**"). ZZPPZ sets forth different requirements in relation to health data processing and the Slovenian web portal "eZdravje", described below.

Are there specific fields of healthcare in relation to which telehealth services are currently available, and do they involve the use of proprietary technology or platforms?

A harmonized health information system (eVEM/eZdravje) at national level. The eVEM/eZdravje system provides various health information services within Slovenian public health system and consists of:

- online prescription service"eRecept" (*ePrescription*);
- online doctor´s appointment booking portal: "eNaroanje" (*eBooking*);
- the "ePosvet" option (*eCounseling*) which is electronic communication between healthcare workers, family medicine physicians, and doctor specialists for the purpose of sharing opinions on clinical questions;
- Online Central Patient Data Register (in Slovene: *Centralni register podatkov o pacientih*) with regard to patients that temporarily and permanently reside in Slovenia, pursuant to Article 14.b ZZPPZ. The purpose of the Central Patient Data Register is to enable electronic exchange of health data between healthcare providers, with the goal of making patient data easily accessible to all who treat them;
- patient-facing zVEM platform which serves as the access point to the above functions (available also as a mobile application);
- healthcare providers-facing zVEMPlus platform for collection of data;
- Telekap (*Telestroke*), a video conferencing system and a web-based diagnostic support application that operates through audio-video conferencing for patient examinations and is used in 12 hospitals throughout Slovenia. The users of the Telekap information solution are specialist doctors, physicians, and other healthcare professionals;
- numerous COVID-19-related functions including, but not limited, platforms for vaccination appointment scheduling and digital COVID-19 certificates; and
- several other platforms that enable communication between different entities pertaining to radiological data, injury-related information (for the purposes of police investigations), and the like.

Apart from that, there are also several private sector telehealth services available on the Slovenian market.

Does the public health system include telehealth services, and if so, are such services free of charge, subsidised or reimbursed? Where the public health system does not include telehealth services, are such services covered by private health insurance?

Generally speaking, the services provided in the context of the eVEM/eZdravje platform and services linked thereto are provided free of charge.

Private health insurers, on the other hand, may cover the costs of telehealth services, especially by way of providing their own telehealth services.

Do specific privacy and/or data protection laws apply to the provision of telehealth services?

Yes, as long as the telehealth services include processing of personal data, the Slovenian / EU data protection regime would need to be complied with.

Primarily, the General Data Protection Regulation ("**GDPR**") needs to be taken into account. Besides GDPR, the following legal acts are relevant:

- the Slovenian Personal Data Protection Act (*Zakon o varstvu osebnih podatkov* – "ZVOP-2");
- ZZDej; and
- ZLD-1.

The above legal acts provide basic and general protection of personal data in the health sector, but do not provide any specific regulations for the provision of telehealth service in Slovenia.

This notwithstanding, it shall be pointed out that Article 3 (3) ZZDej stipulates that health documentation in the field of Telemedicine shall be transmitted/processed in accordance with stricter rules that apply to a specific type of personal data – the so-called "sensitive personal data" (in Slovene: *obutljivi osebni podatki*). Therefore, in relation to the transmission of sensitive personal data or health documentation in the field of Telemedicine, special principles stemming from, among others, Article 9 GDPR shall be adhered to.

How should the cross-border transfer of personal information collected and processed in the course of telehealth services be carried out to ensure compliance with applicable privacy laws?

It shall be noted that GDPR plays a crucial role regarding the transfer of data (including telehealth Data) in EU Member States, however, Slovenian legislation sets out few rules that regulate the subject matter at hand at the side of and without prejudice to GDPR.

1. ZVOP-2 sets out special provisions pertaining to transfer of data in the context of the public sector. Special procedural rules which need to be adhered to are stipulated in Articles 39 et seq. ZVOP-2.
2. ZPacP which constitutes/*lex specialis* in the context at hand sets out various provisions in regard to personal data protection. According to Article 45 (8) in conjunction with Article 45 (4) and (5) ZPacP, the patient has a right to determine to whom, when and what information about their health condition may or may not be communicated by a doctor or another person authorised by the doctor. Furthermore, Article 44 (7) in conjunction with Article 44 (4) ZPacP stipulates that any use and other processing of the patient's medical and other personal data outside medical treatment procedures shall be permitted only with the patient's consent or the consent of persons entitled thereto if the patient is incapacitated (e.g., parents or customary care-givers, pursuant to Articles 35 et seq. ZPacP). After the patient's death, their immediate family members may give their consent, unless the patient has disallowed this in writing. Such consent, moreover, is not required when the data is transmitted to another healthcare provider due to the needs of treatment, pursuant to Article 44 (7) in conjunction with Article 44 (6) no 4 ZPacP.
3. Finally, according to the Article 14.c of Slovenian Healthcare Databases Act, if a health provider is situated outside the European Union (a foreign health provider), the data processing is permitted only on the basis of a patient's consent.

Are there any currently applicable codes of conduct on the use of telehealth systems and/or security of telehealth data in your jurisdiction?

According to publicly available information, there are no official guidelines adopted by Slovenian authorities exclusively for telehealth services. Therefore, general guidelines on privacy and code of ethics for health workers adopted by Slovenian authorities and guidelines of European Union authorities (such as European guidelines on confidentiality and privacy for health workers) shall apply.

Are any specific laws, regulations, or self-regulatory instruments expected to be adopted in the near future?

According to the Ministry of Health, the national strategy on the field of telehealth will be considered and prepared together with the strategy for digitalisation of health system in the following year. Currently, there are no special legal acts in the public discussion or in a legislative procedure.

Article 1(6) of the Slovenian Resolution on National Plan of Health Care 2008-2013 "Satisfied users and performers of medical services" had explicitly mentioned telehealth, telecare, Telepharmacy and other information technologies as one of the goals of the period at hand. However, the lack of legislation by 2020 shows that these goals were not reached.

The current document, Resolution on the National Health Care Plan 2016-2025, on the other hand, does not specifically address Telemedicine in great detail. Therefore, it can be assumed that the competent Slovenian authorities and legislator will not enact any new acts on the subject matter in the near future.

Regardless, the current COVID-19 pandemic and its effect on health services could potentially affect the dynamics of legislation activities in this realm.

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