

TELEMEDICINE
LEGAL FRAMEWORK IN EUROPE & ISRAEL

June 2023



BELGIUM



Altius Lawyers



- IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

There is no Belgian Act that explicitly regulates “telemedicine” or sets its legal requirements.

- DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

Act of 21 august 2008 on the establishment and organisation of the eHealth platform*.

- WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

*Art. 8/1 states that “**personal data of patients** can only be shared through electronic communications using (i) the official eHealth platform or (ii) services for which the Information Security Committee (“ISC”) has found that they offer equivalent guarantees of information security”.

There are good practices regarding telemedicine published by various institutions, such as the Order of Doctors (body governing the deontological rules for doctors), the Information Security Committee (ISC) due to the Covid-10 Crisis, or the The Belgian National Institute of Sickness and Disability Insurance, such as:

- (i) Consent of the patient as first requirement and after being informed;
- (ii) Continuity of care (exception for urgent interventions);
- (iii) Video or audio communications are not recorded;
- (iv) Documents with personal data can only be exchanged via a system with encryption and a system for authenticating the identity of users;
- (v) Be familiar with the patient’s history and ensure continuity of care;
- (vi) Fixed hourly rate and limitation of number of sessions provider.

- WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

- **Processing of personal data** by using telemedicine should comply with the GDPR, the Belgian Data Protection Act of 30 July 2018 and the Belgian Act on Electronic Communication.
- The patient must be physically and mentally able to use a computer.
- Limitation of the number of sessions per care provider (= quality guarantee).
- Fixed hourly rate for doctors.
- Paying third parties possible or already mandatory.

- IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

- The “Task Force ‘Data & Technology against Corona’” published on the eHealth website (official website for eHealth) an overview of various platforms for consultations without physical contact.
- The national order of Doctors issued a set of deontological rules on the subject (18 June 2022). It repeats a lot of the principles that can be found in the best practices. For example, the doctor should make sure the tool used adequately ensures confidentiality and uses two factor authentication, the session cannot be recorded, the doctor should preferably use the e-health platform tools available and in any case register any relevant details/ information of the consultation in the patient’s (e) medical file.

- IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A

**CZECH
REPUBLIC****Havel &
Partners****HAVEL & PARTNERS**
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- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

No law excludes it. However, there is no Czech Act that explicitly regulates “telemedicine” or sets its legal requirements.

In January 2023, the Government started discussing legislative proposal which defines telemedicine and lays down basic regulatory framework to explicitly enable the provision of telemedicine services.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

If the legislative proposal will be adopted (it is a part of a draft Amendment to the Act on Healthcare Services), telemedicine will be regulated. However, the regulation is expected to be on a general level.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

The draft Amendment to the Act on Healthcare Services defines three categories of telemedicine services:

- Consulting services - healthcare services provided through remote access consisting of assessment of individual treatment procedure or second opinion. Consulting services don't include diagnosing or treating of a patient without any prior physical contact between the patient and the physician.
- Telemedicine services, if their provision consists only of the use of information technology possibly also with the help of remote access, without the participation of the patient - for example, the provision of teleradiology or telepathology (remotely reading of radiological images or biopsy samples).
- Telemonitoring - data on patient's state of health are obtained remotely or with the help of a medical device, and are automatically sent to the healthcare provider.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

In order to ensure the safety and the quality of the communication between the healthcare provider and the patient, the amendment assumes that there will be minimal technical requirements or characteristic of the information technologies used for the provision of telemedicine adopted in form of a ministerial decree.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

There are already private online efforts offering online reservations and physicians' consultancy.

The Society of General Medicine (a professional society) has published recommended diagnostic and therapeutic procedures for general practitioners in the field of telemedicine which are generally accepted as a legalization of telemedicine even without clear legal framework. However, this applies only for the healthcare services provided by general practitioners.

In September 2022, the Agency for Medical Research of the Czech Republic adopted Recommended Practices for Distance medicine which are based on WHO guideline: recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

It is not clear in what timeframe could the legislative proposal become effective. The proposal is yet to be adopted by the Government and introduced in the Parliament for adoption. We assume that the proposal will not be effective sooner than from January 2024.

DENMARK


 Gorrissen
 Federspiel


Gorrissen Federspiel

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes, the conduct of telemedicine is permitted in Denmark, but (as described in further detail below) there is no specific law that regulates telemedicine.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

Danmark's national health authority launched a strategy for dissemination of telemedicine in 2012, and several telehealth projects have been rolled out since (e.g. the large—scale TeleCare North project dealing), with the aim of implementing telehealth solutions for the hospitals in the Danish Regions. Further, the COVID-19 pandemic has boosted on the use of telemedicine solutions. However, there is still no specific Danish law on telemedicine.

Generally speaking, the provision of telemedicine is subject to the same laws and regulations as the provision of regular healthcare services. This means that telemedicine is regulated, i.a., in the Danish Health Act, the Danish Act on authorisation of Healthcare professionals, the Danish Data Protection Act, the Danish Patient Compensation Act, and a number of related executive orders and guidelines.

Further, there is not a specific legal definition for telemedicine under Danish law. However, the Danish Capital Region, which is responsible for the hospitals in the capital region of Denmark, describes telemedicine as 'digitally supported healthcare services provided remotely'. Telemedicine can be provided synchronously (e.g. by telephone or video consultations) or asynchronous (e-mail consultations or wearables logging data).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

N/A

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

As telemedicine is not specifically regulated under Danish law, there are no specific requirements that telemedicine must be provided via a specific media. However, naturally, there are strict requirements as to confidentiality/data protection, observance of the patients' rights, and the healthcare professionals' secrecy.

Also, as Danish healthcare professionals are required to practice their profession with due care and conscientiousness, the healthcare professionals must ensure, i.a., that it is professionally viable and safe that the patient receives treatment or other healthcare services via telemedicine. The healthcare professionals should also consult the patients' health records as relevant.

Naturally, in the provision of telemedicine, the patients' basic rights must also be observed, including the patients' rights to:

- Involvement, information and self-determination, which means that no treatment must be initiated or continued without the patient's informed consent;
- Confidentiality and access to health records; and
- The right to complain and receive compensation.

A healthcare professional practicing medicine in Denmark must also be authorised by the Danish Patient Safety Authority, there are strict requirements as to record keeping, and authorised healthcare professionals are subject to the supervision of and inspections by the Danish Patient Safety Authority.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

A summary of the Danish telemedicine strategy from 2012 can be found here: https://en.digst.dk/media/14145/telemedicine_uk_pdfa_03_11_12.pdf

The Danish company MedCom has been entrusted with the mapping of telemedicine initiatives in Denmark. The interactive telemedicine map can be found here <https://telemedicinsk-landkort.dk/?locale=en>.

A white paper on Denmark as a telehealth nation has been published by the public-private non-profit partnership Healthcare Denmark. The white paper can be found here <https://www.healthcaredenmark.dk/media/r2rptq5a/telehealth-v1.pdf>.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

FINLAND


**Borenium
Attorneys**


- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

There is no Finnish Act that explicitly regulates “telemedicine” or sets its legal requirements.

Telemedicine is not a separate specialist discipline, but refers to general medical treatment at a distance. Thus, telemedicine is accepted and it is subject to general health care legislation. However, legislation on private social and health care is being reformed.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

There is not a uniform and comprehensive Finnish Telemedicine Act.

There are various either direct or indirect laws and ordinances with an implicit regulation concerning telemedical services, such as, and the most relevant being:

- a) the Act on Private Health Care (152/1990);
- b) the Act on the Electronic Processing of Client Data in Social and Health Care Services (159/2007);
- c) National Health and Welfare decree (2/2015);
- d) the Decree on Private Health Care (744/1990);
- e) the Act on the Status and Rights of Patients (785/1992); and
- f) the Act on Health Care Professionals (559/1994).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- According to the policy of the Ministry of Social Affairs and Health (3756/2015), remote services are comparable to traditional reception visits.
- Healthcare professionals must carefully assess whether the services they provide are suitable for delivery by telemedicine. The applicability of the service must be assessed separately for each patient.
- Telemedicine service providers must have access to suitable premises and equipment (including telecommunications) as well as appropriately qualified staff.
- Pursuant to Section 6 of the Act on the Status and Rights of Patients (785/1992), remote care must take place in agreement with the patient.
- Pursuant to Section 15 of the Act on Health Care Professionals (559/1994,) healthcare professional shall apply generally accepted and empirical methods based on experience and their education.
- Appropriate records of remote appointments should be made in the patient records in the same way as made with traditional appointments (Section 16 of the Act on Health Care Professionals and Section 12 of the Act on the Status and Rights of Patients).

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

The Finnish Medical Association (FMA) has published an ethical code "Telemedicine recommendations" (Available in Finnish at: <https://www.laakariliitto.fi/laakarintietopankki/kuinka-toimin-laakarina/etalaaketieteen-suositus/>).

Pursuant to the Code, generally, the services provided by telemedicine providers must be clinically appropriate and take account of patient safety. Informed patient consent must be obtained.

More specifically:

- Processing of personal data: Processing of personal data by using telemedicine should comply with the GDPR. Further, all telemedicine providers must meet the requirements set out in the Data Protection Act (1050/2018) and the Act on the Electronic Processing of Client Data in Social and Health Care Services (159/2007). For example, telemedicine providers are required to compile and update a self-monitoring plan on their services as set out in the relevant National Health and Welfare decree (2/2015) (thl.fi) (in Finnish).

Systems used to transmit and store patient information must meet the relevant legal requirements on confidentiality as well as data protection and security. Service providers are responsible for ensuring that the

appropriate data protection and security arrangements are in place for the purpose of transferring data and processing personal information.

Practitioners must keep appropriate records and maintain the patient register in accordance with relevant legislation.

The patient's information and documents may be disclosed to another doctor or other healthcare professional only under the conditions laid down by law and with due regard for the principles of confidentiality.

- Strong identification: The patient must be identified using a reliable method. One such method is a "strong electronic identification", as set out in the Act on Strong Electronic Identification and Electronic Signatures (617/2009). It must be possible to verify the method used retrospectively.
- Safety and security: The service producer and the organisation using telemedicine are responsible for the quality and patient safety of the services provided.

When using telemedicine, the physician should ensure that the patient is assisted by adequately trained staff, that the patient has understood the instructions given, and that the patient's follow-up care is secured.

- Licensing: Private sector healthcare providers and independent practitioners must be licensed or registered to provide healthcare services (for example as a doctor, nurse or other healthcare professional) as set out in the Act on Private Health Care (152/1990). All licensed and registered healthcare professionals are also entitled to provide telemedicine services under their existing license. They are not required to apply to amend their license.

Licensing is granted to service providers who meet the criteria set out in the Act on Private Health Care. Where relevant, conditions may be imposed on the license in the interest of patient safety.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

The National Supervisory Authority for Welfare and Health ("Valvira"), which is a national monitoring organisation, gives guidance on questions relating to telemedicine and ensures the safety of marketing and equipment regarding health technology innovations.

Valvira also grants licenses to service providers operating within the remit of two or more Regional State Administrative Agencies, while the Regional State Administrative Agencies grant licenses to service providers operating within the remit of a single agency. (More information available at: <https://www.valvira.fi/web/en/healthcare/private-health-care-licences/telemedicine-services>).

• IS THERE ANY IMPORTANT INFORMATION MISSING?

- No specific regulations have been issued in Finland regarding telemedicine during the COVID-19 pandemic.
- Regulation on technologies for remote healthcare services:

In 2017, the National Institute for Health and Welfare (THL) published a guide for general use of software in social and health care services, which compiles and clarifies procedures and good practices on how general purpose software producers and users can contribute to the privacy and security of customer and patient data processing.

This applies to the general purpose software which, in this context, means that it has not been manufactured specifically to process customer or patient data generated in social and health care in the manner prescribed by the Act on the Electronic Processing of Client Data in Social and Health Care Services (159/2007).

- The Social Insurance Institution of Finland ("Kela") has outlined the services provided as remote occupational health care services to be reimbursed in 2019.

FRANCE



Harlay Avocats



- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes. The term first appeared in 2004 - Law n°2004-810 of August 13th, 2004 relating to health insurance.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- Law n°2009-876 of July 21st, 2009 reforming the hospital and relating to patients, health and territories (The "Bachelot Law").
- Decree n°2010-1229 of October 19th, 2010.
- Law n°2019-774 of July, 24th 2019.
- Articles L.6316-1 and R.6316-1 et seq. of the French Public Health Code.
- Decree n°2021-707 of June 3rd, 2021
- Ministerial Order of June 3rd, 2021

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

Telemedicine is defined as medical procedures carried out remotely, using a device of information and communication technologies.

The Telemedicine regulations cover various medical procedures with specific conditions for each matter:

a) Teleconsultation: it enables consultation to a patient regardless of its location or its specialty:(i) Its coverage by the health insurance is subject to prior knowledge of the patient(ii) For the reimbursement, the patient had to be oriented by its referring physician to a teleconsulting physician who previously had a face-to-face consultation with the patient within the last 12 months.(iii) The physician may issue a prescription electronically with a QR code.

b) Tele-expertise (remote solicitation of medical advice);

c) Medical telemonitoring (remote interpretation of data);

d) Medical teleassistance (remote assistance from another professional during the performance of a medical procedure);

e) Medical response (assistance of urgent medical aid).

The regulatory framework applicable to Telemedicine has been broadened by the adoption of Law n°2019-774 of July 24th, 2019 which introduced the term "Telehealth" ("Télésanté") in the French Public Health Code (the "Code"). The Code now has a Chapter titled Téléhealth (Télésanté) which covers (i) Telemedicine and (ii) Telecare (Télésoins). According to Ministerial Order of June 3rd, 2021, the professionals who can carry out Telecare activities are pharmacists and medical auxiliaries (such as dietitians, physiotherapists and opticians). Decree n°2021-707 of June 3rd, 2021 has been adopted to harmonize the rules regarding Telemedicine and Telecare.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- **Essential conditions for Telemedicine:** (i) Free and informed consent of the patient, (ii) Authentication of professionals and patient's data.
- **Assessment of health professionals:** Only medical professionals, pharmacists or medical auxiliaries can assess and decide whether the recourse to Telehealth (Telemedicine and Telecare) is relevant in a given case.
- **Essential conditions for Telemedicine:** Telemedicine must be carried out under conditions that guarantee the following: (i) the authentication of the health professional involved in Telemedicine activity, (ii) the identification of the patient, (iii) health professionals' access to the patient's medical data necessary for the performance of Telemedicine, (iv) if necessary, training or instruction of the patient to the use of Telemedicine devices.
- **Health professionals and psychologists** must have the training and technical skills required for the devices. If necessary.

- **Patient's file:** It is required that professionals record in the patient's file (i) a report on the conducted Telemedicine activity, (ii) the acts and prescriptions realized during Telemedicine, (iii) the identity of the patient and other professionals involved, (iv) the date and time of the Telemedicine activity, (v) where applicable, technical incidents occurred during the Telemedicine activity.
- **Reimbursement/Coverage:** Acts of teleconsultation and tele-expertise are in principle covered by Assurance Maladie (French public health insurance system).

To be eligible to reimbursement, teleconsultation must be part of the "care pathway" (parcours de soins) meaning that the patient must first see his/her registered general practitioner before seeing a specialist. Otherwise, the teleconsultation is possible but will not be reimbursed. Exceptions to this rule include the following cases: (i) patients under 16 years old, (ii) emergency situations or (iii) unavailability of the medical professional, (iv) patients who have not a registered general practitioner.

The patient is required to select a health professional who is located near him/her for teleconsultation.

• **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

- The practitioner must note in the patient's file the report on the performance of the act, the medical acts and prescriptions carried out.
- The physician must store patients data exclusively on servers operated by duly certified hosting providers.
- A Data Protection Impact Assessment may have to be carried out if the processing resulting from the telemedicine activity creates a high risk for the rights and freedoms of individuals.
- Recently, Decree n°2022-1761 of December 30th, 2022 has made medical telemonitoring eligible to coverage by Assurance Maladie. The use of a digital telemonitoring medical device, and the analysis of data and alerts transmitted, will now be reimbursed by the French health insurance system, under certain conditions.

As of July 1, 2023, only diseases that have received a favorable opinion of the French National Authority for Health (HAS) are eligible to the general coverage. These diseases are the following: (i) heart failure, (ii) renal failure, (iii) respiratory failure, (iv) diabetes, (v) cardiac arrhythmia requiring implantable cardiac prostheses. Other diseases may be added to this list upon receiving the HAS' favorable opinion.

Any telemonitoring operator wishing to fall within the scope of this new legislative framework must first declare its activities to the ARS, via a teleprocedure.

• **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

GERMANY



SKW Schwarz



- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes. There are several laws and amendments to current legislation and jurisprudence.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- The German E-Health Act (E-Health-Gesetz) dated 29.12.2015.
- Sec. 87 (2a) sentence 18 in conjunction with Sec. 291g of the German Social Code Book V.
- The German Act for Greater Safety in the Supply of Medicinal Products, dated 15.08.2019.
- Amendment on the professional code of conduct for doctors in May 2018.
- The German Digital Supply Act (Digitale-Versorgungs-Gesetz) dated 29.11.2019 introduced a package of measures.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- A digital structure in the healthcare system** has been provided:
 - Open up telematics infrastructure, applications and devices;
 - Creation of an interoperability directory to improve the communication between different IT systems in health care sector.
- Development of telemedical applications** to enable contract physicians to comprehensively bill for consultation hours online.
- Pharmacists are allowed to dispense prescription-only drugs** previously prescribed by a doctor in an exclusive remote treatment.
- Doctors are allowed to provide exclusive remote-digital treatment.**
- Obliges pharmacies and hospitals to gradually connect to the telematics infrastructure and the electronic prescription system** to be transmitted to pharmacies. This system allows online pharmacies and home delivery of medicaments. Doctors already joined it.
 - **Patients should be able to use digital services** such as the electronic patient file. Its cost will be reimbursed.
 - **Via teleconsultation**, general practitioners in private practice could consult a specialist without the patient having to go to the specialist himself using a common software among doctors.
 - **Simplification of administrative processes** through digitization. Health data will be transmitted pseudonymously to the German National Association of Statutory Health Insurance.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- Exclusive counselling or treatment via communications in individual cases should be previously informed to the patient.
- Pharmacies, hospitals and doctors who do not comply with the obligation to connect to the telematics infrastructure by time limits prescribed by law are threatened with an increased deduction of fees.
- Video Services providers as well as communication service providers that transmit the data for the consiliary evaluation must be certified in accordance with the German Federal Medical Association and must comply with data protection and data security requirements. In the future, only communication service providers approved by "gematik" (company for telematic applications of the health card) will be able to use teleconsultants.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

- Remuneration has been improved for teleconsultation.
- Anyone who wants to offer and charge for telemedical services in the GKV system must be licensed to provide telemedical care: only possible for doctors and medical care centres.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

HUNGARY


 Szecskay
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 Law

 SZECSKAY
 ATTORNEYS AT LAW

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes, telemedicine is permitted by law only in three areas: teleradiology, telediagnosics, teleconsultation.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

There is not a specific law on telemedicine. However, the following health-related laws and government decree provide some regulation on telemedicine:

- Act LVIII of 2020 on transitional rules and epidemic preparedness in connection with the end of an emergence (only effective 90 days after the end of the emergency.) (“**Act LVIII**”);
- In the time on the pandemic crises February 15, 2021 the Government Decree on the telemedicine service no. 57/2021. (II. 10.) had entered into force which regulation is now ineffective. From December 1, 2021 the regulations included in the beforementioned Government Decree implemented in Act CLIV of 1997 on Health Care;
- Decree of Ministry of Health, Social Affairs and Family no. 60/2003 (20.X.) on the minimum professional requirements for the provision of health services;
- Act CLXXXVIII of 2015 on the facial image analysis register and the facial image analysis system;
- Act XLVII of 1997 on the processing and protection of health and related personal data.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

The presence of the patient is not a condition for the provision and financing of the healthcare services, where the specific service allows it. According to the Act LVIII the telemedicine may include the following:

- patient referral in the form of teleconsultation, which is the basis for teleconsultation with a specialist,
- the reception of patient declarations of information, consent and data processing,
- pre-screening in the form of a teleconsultation to assess the need for care and the seriousness of the health condition, based on a personal encounter,
- pre-contact and data collection to make face-to-face care following teleconsultation faster and more efficient,
- diagnosis and therapeutic recommendations by means of teleconsultation, remote monitoring and remote diagnostic tools,
- prescription of medicines,
- follow-up and after-care after a previous face-to-face encounter,
- organisation of teleconsultation,
- issuing referrals,
- psychotherapy, crisis intervention, parental counselling, counselling, supportive psychotherapy,
- physiotherapy by means of teleconsultation,
- breastfeeding counselling,
- care and
- advice and counselling by telephone, online or in other forms.

The healthcare provider must keep proper healthcare documentation, and also establish an institutional protocol for providing telemedicine.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- **Telemedicine may only be provided** based on the relevant medical licenses.

- **The consent of the patient**, as a main rule, does not have to be provided in written form.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

The information for the patients may be provided online as well prior to carrying out the examination of the patient. In the case of invasive procedures, the written consent of the patients is needed.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

We only have information focused on the Government Decree, but lacking the general situation in the only three permitted areas once the Danger State comes to an end.

IRELAND


 Mason Hayes &
 Curran LLP

 MASON
 HAYES &
 CURRAN

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Telemedicine services can be provided Ireland. The Medical Council in Ireland has provided a definition of telemedicine in its Guide to Professional Conduct and Ethics (the “**Guide**”), “Telemedicine describes the delivery of healthcare services through information and communication technologies to promote the health of individuals and their communities. It involves the exchange of information between doctors and patients, or between doctors and professional colleagues, for the diagnosis, treatment and prevention of disease and injuries, and for research, evaluation and continuing education.”

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- While there is no specific legislation that regulates telemedicine in Ireland, there are various laws, regulations and guidelines that health service providers must adhere to.
- Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare provides that EU citizens have the right to access healthcare in any Member State.
- Section 43 of the Guide relates to telemedicine. Any doctor that provides telemedicine services to patients in Ireland should be registered with the Medical Council.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- Under Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare, a doctor who provides telemedicine services is considered to be providing services in the EU Member State in which they are established. A doctor must comply with the legislation and any regulatory requirements of that Member State. If a doctor based in Ireland is providing telemedicine services in Ireland or in any Member State, they must be registered with the Medical Council in Ireland.
- Under the Guide, doctors who provide telemedicine services to patients within Ireland must:
 - ensure that patients have given their consent to conduct the consultation through telemedicine and consent to any treatment provided;
 - inform the patients’ general practitioner of the consultation;
 - protect the patients’ privacy;
 - explain information policies to users; and
 - comply with data protection principles if they transfer any personal patient information.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- The minimum requirements are to meet the guidelines set out by the Guide
- Health service providers must satisfy themselves that the services provided by telemedicine are safe and suitable for patients. They must also explain to patients that there are aspects of telemedicine that are different to traditional medical practice.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

While the Guide is not legally binding, it sets out the principles of professional practice and conduct that all doctors registered with the Medical Council are expected to follow and comply with. Failure to comply with the Guide may result in a breach of professional duty.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

ISRAEL



Horn & Co.



• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

Yes, telemedicine has been practiced by Israeli healthcare providers since the 1990s, through various technological means and devices.

• DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

General Director Circular No. 6/2019 on Standards for Provision of Telemedicine Services dated June 26, 2019 as guidelines specifically regulating the provision of telemedicine services.

• WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

- **Prior to the Service, the provider shall prepare a dossier with:**
 - (i) A description of the Service its compatibility with technological devices.
 - (ii) Mapping of existing alternatives for the Service through ambulatory treatment or hospitalization, and the pros, cons and risks of the Service.
 - (iii) Digital means involved and the data security safeguards.
 - (iv) Safety rules, specifically with respect to identification of cases where the patient is in need for urgent frontal treatment.
 - (v) Identification of the professional manager in charge of the Service.
- **The Ministry of Health may demand to receive the dossier for review.**
- **The Manager should be a licensed professional** having the same certification as the personnel employed in providing the Service.
- The providers shall undergo **dedicated training in telemedicine.**
- **The healthcare provider shall obtain informed consent** of the patient to be treated prior to commencing the tele-encounter.

• WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

The management of the provider is required to determine whether Services meet appropriate standards of quality and safety and in which cases a frontal treatment would be mandatory.

If the patient is using the service abroad Israel, the treatment shall be conducted by personnel having Israeli certification if such treatment is part of a broader treatment performed in Israel.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

- Enforcement of the Circular is carried out by the Ministry of Health under the general regulations, not specific for remote services.
- The therapist's responsibility in telemedicine services is completely identical to that performing frontal treatment.
- The healthcare provider is required to have in place appropriate data security measures and ensure continuous deployment of oversight and control mechanisms.

• IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A

ITALIA

Portolano
Cavallo

• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

Telemedicine services have been regulated in Italy since 2014, but only with national guidelines issued by the Ministry of Health following the approval of a commission representing the Government and the Italian Regions (*Conferenza Stato-Regioni*). In December 2020, following the Covid emergency, the Ministry of Health enacted New National Guidelines on Telemedicine and, more recently, telemedicine services were provided by mandatory decrees (see below).

• DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

To date, there is no single comprehensive regulation for telemedicine services, but instead various pieces of legislation (such as decrees and guidelines) that concern, in whole or in part, this subject. We mention in particular:

- The Ministry of Health's "National Guidelines for the Provision of Telemedicine Services" dated October 27, 2020;
- The Ministry's of Health's Decree of April 29, 2022 that provides guidelines for a "digital model" for the development of home care;
- The Ministry's of Health's Decree of May 23, 2022 that establishes models and standards for home care assistance;
- The Ministry's of Health's Decree of September 21, 2022 that approves the guidelines for delivering telemedicine services, further specifying the provision of the National Guidelines.

In addition, as the National Health Service ("NHS") in Italy is organized on regional basis, Italian Regions must implement the national regulations in their respective regional healthcare services ("RHS") by issuing specific regional regulations.

• WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

The regulations on telemedicine mentioned above:

- describe several types of telemedicine services, including tele-visit, tele-monitoring, tele-consultation (between doctors), remote medical assistance (involving healthcare professional), telecare etc.; for instance, tele-visits are considered one of the main telemedicine healthcare services that can be provided within the NHS. This is an outpatient activity that a physician may decide to carry out remotely, following careful assessment of the situation;
- describe how it must be organized and the relevant actors involved;
- provide detailed operational rules concerning the fee system, prescriptions, booking of visits, etc.
- provide detailed technical rules concerning the functional and technological standards.

• WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

The above-mentioned regulations provide many detailed rules and prescriptions on the delivery of such services. We mention the following additional aspects:

- Italian Regions must guarantee the supply of tele-visit, tele-consultation, remote medical assistance, tele-care and tele-monitoring services, to assure uniform access to these services all over the country.
- According to the case-law, the place where the medical activity is carried out needs to be authorized only if it is an organized entity aimed at performing medical services, while the place where data are merely collected from a patient and transmitted to a healthcare facility for the purpose to be assessed does not require to be authorized by the competent regional authority if such collection does not qualify as a health activity.
- Software used in the provision of telemedicine services must be certified as medical device in accordance with Regulation (EU) 2017/745 only if it meets the requirements for being classified as medical device under such Regulation.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

From a data protection perspective, the applicable regulations specify that every transfer of data (in the form of videos, images, files, etc.) must be encrypted and in accordance with privacy and security regulations.

• IS THERE ANY IMPORTANT INFORMATION MISSING?

As part of the National Recovery and Resilience Plan adopted by Italy to cope with the economic consequences of the Covid-19 pandemic, the creation of a national telemedicine platform is planned to be launched by the end of 2023, which will serve as a central infrastructure for the uniform delivery of telemedicine services throughout the country.



**Kennedy
Van der
Laan**

Kennedy Van der Laan
The art of capturing the essence

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes. Telemedicine is not regulated by specific laws. Regular healthcare laws would then apply.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

General healthcare laws such as the Medical Treatments Act (WGBO), the Individual Healthcare Professions Act ("Wet BIG") and the Healthcare Quality, Complaints and Disputes Act (Wkkgz). The prescription of medicines at distance is regulated by the Medicines Act ("Geneesmiddelenwet"). Regarding to data-exchange legislation, the Processing of Personal Data in Healthcare (Additional Provisions) Act ("Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg") is applicable. On 1 July 2023 the Electronical data exchange in Healthcare Act will come into force ("Wet elektronische gegevensuitwisseling in de zorg").

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

The general provisions of the Medical Treatments Act would apply. The Royal Dutch Medical Association ("KNMG") has published a guideline on how these provisions apply to telemedicine. These would include:

- The healthcare professional has informed the patient sufficiently about the procedure for online contact.
- The healthcare professional must ensure that the activities he performs online - such as patient conversations and examinations via video telephony - take place outside other people's observation.
- The healthcare professional has sufficient relevant and reliable patient data at his/her disposal (e.g. a reliable and relevant medical history) to make a medical assessment (e.g. a reliable and relevant medical history) in order to be able to give medically sound individual advice.
- The healthcare professional observes the rules of his profession with regard to the quality and safety of care, as well as the rights of the patient.
- The healthcare professional has sufficiently identified the patient.
- The healthcare professional shall clearly indicate that his or her advice is based on information provided by the patient and any available record data.
- If the healthcare professional is not the patient's general practitioner, he shall inform the patient's own general practitioner of the advice he has given to the patient (unless the patient objects, in which case the healthcare professional strongly advises him to inform his general practitioner himself).

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

See the abovementioned.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

A healthcare professional may only prescribe medication if there is an existing treatment agreement.

This means that the healthcare professional knows the patient, has seen him or her and has a medication history available. In addition, the healthcare professional must have a reliable medical file. This follows from Clause 67 Medicines Act ("Geneesmiddelenwet"). On 11 April 2023 a policy rule ("Beleidsregel voorschrijven via internet") came into force which stipulates that there will be no enforcement of the Minister if the medication is prescribed to a patient who's not known and/or seen by the healthcare professional if the physical consult is not necessary and there is a medical history available. There is legislation pending to lay this down by law.

Furthermore, the healthcare professional must ensure that he uses safe and certified digital applications for telemedicine. The Inspectorate for Health and Youthcare ("IGJ") published a guideline for healthcare professionals on the use of e-health.

(<https://www.igj.nl/publicaties/toetsingskaders/2019/10/18/toetsingskader-inzet-van-e-health-door-zorgaanbieders>)

Lastly, healthcare professionals must comply with legal requirements and standards for the exchange of privacy-sensitive healthcare information.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A



NORWAY

 Advokatfirmaet
 Simonsen Vogt
 Wiig

 simonsen
 vogt wiig

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Yes, Telemedicine is allowed and is regulated by the same laws and regulations as health care services applying for physical visits.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

No, it is governed by multiple laws and regulations. In 2020 the Norwegian government proposed a separate eHealth Act, but the proposal was withdrawn.

Important laws governing telemedicine are: The Norwegian Health Care Act (in Norwegian: helsepersonelloven), the Norwegian Medical Records Act (in Norwegian: pasientjournalloven), the Norwegian Health Register and Processing of Health Data Act (in Norwegian: helseregisterloven), as well as the Norwegian Personal Data Act (in Norwegian: personopplysningsloven).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- The patient does not need to visit a physical clinic before or after using the digital healthcare service, unless the healthcare professional deems this necessary. The digital service provider can provide its services to patients in all regions in Norway.
- The service providers and its employees must comply with the mandatory requirements due to its role as health care professionals, as well as the requirements set out in the GDPR and the Norwegian Personal Data Act.
- Duty of confidentiality. In accordance with the Norwegian Health Care Act section 21, health care personnel are subject to a strict duty of confidentiality that applies in addition to the GDPR requirements.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

In addition to the requirements in Section E, the processing of personal data by using telemedicine should comply with the GDPR, the Norwegian Personal Data Act of and the Norwegian Act on Electronic Communication.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

During the Covid-19 pandemic, physicians were allowed to issue medical certificates (for sick leave) following an online consultation, instead of a physical consultation. From 1 July 2023, this possibility will become a permanent arrangement. According to the adopted bill, the main rule shall still be that medical certificates are issued only after a physical consultation. However, the physician shall be allowed to issue medical certificates following an online consultation if:

- i) the patient is known to the physician,
- ii) the patient's diagnose is known to the physician,
- iii) the physician can evaluate the patient's ability to work without a physical examination, and
- iv) the physician must find it proper according to his/her professional standards to carry out the consultation as an online consultation.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

POLAND


 Wardyński &
 Partners

 WAR PAR
 DYN TNE
 SKI+ RS•

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Telemedicine is allowed in Poland, though there is no specific act setting complex regulations in this regard.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- The Medical Activity Act of 15 April 2011.
- Regulation of the Minister of Health of 12 August 2020 on the organizational standard of teleconsultation within primary health care.
- The Supreme Council of Physicians adopted good practices regarding telemedicine on 24.07.2020

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- Art 3 of the Medical Activity Act of 15 April 2011 has a general provision enabling health services to be provided via IT or communication systems.
- The scope of applying the "Regulation on the organizational standard of teleconsultation within primary healthcare" is limited to publicly funded healthcare services provided under a "primary healthcare" scheme.
- Provisions regulating specific aspects of e-healthcare services are scattered across all relevant healthcare acts (e.g. the Regulation on medical documentation provides for electronic form of storage of patient documentation, the Pharmaceutical Law Act provides for electronic prescriptions etc.).
- Good practices issued by the Supreme Council of Physicians concern the following legal aspects of telemedicine: processing of personal data in connection with online consultation, cross-border online consultations, liability and responsibilities of physician, patient rights.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- Under Medical Activity Act - telemedicine healthcare providers must be entered in a public register of healthcare providers (the same rules apply to non-telemedicine providers).
- The "Regulation on the organizational standard of teleconsultation within primary healthcare" imposes several requirements: e.g. a patient must be informed of the right to meet a doctor in-person; a patient must be verified; confidentiality of consultations must be assured.
- Good practices issued by the Supreme Council of Physicians underlines the importance of the need to comply with GDPR (EU Regulation 2016/679 regarding processing of personal data) with regard to patient personal data.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

In 2023, governmental representatives announced that the Polish government plans to counteract the phenomenon of e-platforms appearing on the Polish market, where patients can obtain a prescription almost automatically in 15 minutes without a doctor's diligent examination of whether issuance is in fact justified. Therefore, telemedicine may be subject to future legal limitations in this regard. A draft regulation regarding controlled substances published in May 2023 provides for the obligation to re-examine a patient prior to controlled substance prescription if the previous in-person examination took place over 12-months ago.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

PORTUGAL


**CRA - Coelho
Ribeiro &
Associados**


• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

Telemedicine is allowed by the Code of Ethics of the Medical Chamber and is foreseen in several rules from the General Directorate for Health and decisions by the Minister of Health.

In October 2016, the Portuguese Government created the Portuguese National Centre of Telehealth (CNTS), which is part of the Shared Services of the Ministry of Health to increase the efficiency of national resources by taking advantage of information and communication technology.

• DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

- Code of Ethics of the Medical Chamber, approved by the Regulation 707/2016, 21 July, published in the Official Gazette, 2nd Series (articles 46.º et seq.)
- Rule n.º 010/2015 from the General Directorate for Health, issued on 15 June 2015
- Rule n.º 005/2015 from the General Directorate for Health, issued on 25 March 2015
- Rule n.º 004/2015 from the General Directorate for Health, issued on 25 March 2015
- Rule n.º 005/2014 from the General Directorate for Health, issued on 8 April 2014
- Decision n.º 5314/2020 from the Health Minister, dated 2020-05-07
- Decision n.º 6280/2018, from the State Secretary for Health, dated 2018-06-28
- Decision n.º 3571/2013, from the State Secretary for Health, dated 2013-03-06

• WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

Teleconsulting must ensure that the physicians are in a position to conduct a clinical interview, allowing them to understand the patient and that both can perceive themselves correctly. Physicians must be able to dialogue with the patient, ask him/her questions, be aware of the symptoms and make a diagnosis.

Teleconsulting must also ensure that the physician make the corresponding records and protect confidentiality.

The Medical Chamber's position is that teleconsulting should only take place, in the vast majority of cases, when sufficient knowledge already exists about the patient, which presupposes a "face to face" medical consultation beforehand.

There are some clinical consultations which, due to its differentiation, could be made through teleconsulting provided that the necessary technical requirements are met, and be made by highly differentiated physicians in reference clinical centres of certain medical specialty, such as imaging, dermatology, orthopaedic, neurosurgery, etc.

• WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

Within the scope of the National Health Service institutions, the patient must approve the teleconsulting, being mandatory to obtain his/her express and informed consent, in writing, which should be attached to the corresponding medical record. Teleconsulting can be either programmed or urgent. Certain electronic records are mandatory when performing a teleconsulting.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

Due to the COVID-19 pandemic, the Minister of Health issued an order to the governing bodies of the health and care providers part of the National Health Service to ensure that as long as the epidemiological situation is not contained, health care provision is made resorting to non-face to face means, including tele screening, teleconsulting, and telemonitoring programmes, except as clinically or technically impossible or inadvisable.

• IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A

RUSSIA

Lidings Law
Offices

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Changes into the healthcare law have been enacted in 2018 to make telemedicine legal and promote its implementation.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- Federal Law dd. 21.11.2011 No. 323-FZ "On the basics of public health protection in the Russian Federation"; Federal Law dd. 27.07.2006 No. 149-FZ "On Information, Information Technologies and the Protection of Information"; Federal Law dd. 27.07.2006 No. 152-FZ "On Personal Data".
- Order of the Ministry of Health of the Russian Federation dd. 30.11.2017 No. 965n to organize and provide medical care using telemedicine; Decree of the Government of the Russian Federation dd. 09.02.2022 No. 140 "On the Unified State Information System in the Healthcare"; "GOST 34244-2017. Interstate Standard. Telemedicine systems. General requirements for basic safety and essential performance to stationary telemedicine consultative and diagnostic centers".
- Due to the Covid19 Crisis, a bill has been proposed for providing medical care remotely in emergency situations to conduct primary examinations, make final diagnoses and prescribe treatment remotely. As of July 2021, this bill is still under consideration.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- **Telemedicine technology has two formats:**
 - a) doctor-to-doctor communication: health workers contact with each other and solve healthcare issues;
 - b) patient-to-doctor communication.
- **The regulatory environment of telemedicine** can be divided into two statutory blocks: legislation on healthcare and legislation on personal data protection.
- **The patient-to-doctor communication** is aimed at prevention, collection, analysis of patient's anamnesis data, evaluation of the effectiveness of treatment and diagnostic measures, medical monitoring of the patient's health, as well as making a decision on the need for in-person physician visit.
- **Telemedicine can apply only to** a secondary, supportive "visit" of the patient, not the initial diagnosis. The certain exceptions are provided for the medical organizations of the private healthcare system - participants of the experimental legal regime in the field of digital innovation in accordance with the program of the experimental legal regime in the field of digital innovation, approved in accordance with the Federal Law dd. 31.07.2020 No. 258-FZ "On experimental legal regimes in the field of digital innovation in the Russian Federation".
- **Services can be provided only** via a special state-run IT system.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- Services can be provided only on the basis of the "ground" medical license.
- Remote consultation excludes making a diagnosis. Patient's examination, as well as final diagnosis establishing, can be held only within in-person physician visit. The applicability of the first two bullets can be changed or excluded for the medical organizations of the private healthcare system - participants of the experimental legal regime in the field of digital innovation in accordance with the program of the experimental legal regime in the field of digital innovation, approved in accordance with the Federal Law dd. 31.07.2020 No. 258-FZ "On experimental legal regimes in the field of digital innovation in the Russian Federation".
- Telemedicine services can be provided only by health care professionals registered with the federal register of medical workers of the USISHC (Unique State Information system in the health care).
- A doctor shall have an advanced electronic signature and use licensed software and equipment, counting on a license for the relevant types of medical activities, in order to practice telemedicine.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

- New healthcare startups and Apps are developing telemedicine. The certain criteria which helps to define what software is recognized as a medical device are developed. Distance selling of OTC-medicines has been launched, while distance selling of RX-medicines, currently, is going through a legal experiment. Remote monitoring of the patient's health is in focus of the telemedicine development: there are certain information systems called "personal medical assistant" which helps to collect and transfer data from medical Apps to medical organizations (Order of the Ministry of Health of the Russian Federation dd. 01.03.2023 No. 91n). There are also examples of the registration of a digital medical drug (digital inhaler), which consists of eModule + HCP dashboard + cloud platform + mobile app + medical drug. Patient support programs are becoming very popular as an approach to provide patients with telemedicine.
- Russian legislation treats any information about patients' health as "special" personal data.
- Telehealth operators and all parties involved in data exchange must maintain a high level of security, using cryptographic information protection tools and facilities, which might be subject to licensing.

• IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A

SLOVAKIA



Havel & Partners



- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Currently, telemedicine is only partially regulated in Slovakia.

This means that the regulation of telemedicine in Slovakia is effective only during the duration of the state of crisis in Slovakia, namely the state of emergency due to the war in Ukraine (law was primarily adopted as a reaction to the COVID-19 pandemic).

Apart from this partial regulation, there is no complex regulation of telemedicine in Slovakia, although there are long-term plans, as stated in the Strategic Framework for Healthcare 2014-2030, to enshrine it.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

Act no. 576/2004 Coll. on Health Care, as amended (Transitional provisions).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

Transitional provisions of the Act on Health Care provides that for the duration of the state of crisis:

- a general practitioner or a specialised doctor shall be entitled, after verifying the identity of the person and the insurance relationship with his/her competent health insurance undertaking, to provide the person with a consultation by electronic communication; and
- the provision of the consultation by electronic communication must be entered by the doctor in the person's medical records.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

There stated legislation does not provide minimum requirements apart from thoses stated in the previous column.

Please note, telemedicine, as the term, is not recognized by the Slovak legislation.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

In Slovakia, there are already existing possibilites such e-recipes which are issued by healthcare providers electronically and by them patients are allowed to pick up theirs prescribed medicine at the pharmacy.

However, the complex legislation is still missing.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

Apparently, there is no other rule in the current legislation leaving room for any act within the scope of telemedicine.

SPAIN



Lener
Asesores
Legales y
Económicos,
S.L.P.

lener

- IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

N/A

- DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

There is no specific law on Telemedicine, but with the approval of the new Medical Code of Ethics (2023), a step forward has been taken to address this aspect. The Spanish Association for Standardisation has also approved a norm that sets out the minimum requirements and recommendations for the provision of teleconsulting services.

- WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

- Following the **Guidelines of the Standing Committee of European Doctors** ("CPME"), for the telemedicine it is required:
 - (i) Safe doctor-patient identification in telemedical consultation.
 - (ii) The modality of the contracted service must be clearly indicated.
 - (iii) face-to-face consults are preferable, with the telemedicine limited to situations where the doctor cannot be physically for de necessary time.
- **A direct telemedical consultation** should normally only take place if the doctor has a professional relationship with the patient, in a follow up treatment and the doctor has sufficient knowledge of the problem in qu
- **The prescription of medications** may be either on paper or electronically in accordance with Royal Decree 1718/2010 of 17 December on medical prescriptions and dispensation orders. Eprescription is possible but there are limitations: deontological codes do not allow prescriptions that are done in an online diagnosis, but it is possible for renewal of precription, or in follow up basis after a previous diagnosis made in a physical consult.
- **The virtual medical consultation** in the emergency room allows a triage prior to the hospital service. However, in practice, the public health system has barely implemented them. It is only often in the private insurance system
- The scheduled medical consultation, in primary and specialized care, without the need for an in-person patient, allows for activities such as:
 - monitoring of complex chronic patients,
 - communication of test results,
 - management of sick leave (in primary care),
 - review of medical records, etc.
 - Prescription of medicines, through the electronic prescription system.

- WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

- According to the new Code of Ethics (2023), the use of telematic means is in accordance with the Medical Code of Ethics as long as the identity of those involved is unequivocal, ensuring confidentiality and using means of communication that guarantee the maximum security available.
- **The use of telemedicine and all non-face-to-face modalities** of care are governed by the ethical deontological precepts of the Code regarding the doctor-patient relationship, the protection of patients' rights and safety of the patient, as well as the respect and autonomy of health professionals.
- The telemedicine means by which the consultation was made, as well as the medical treatment prescribed and the recommendations given, **should be recorded in the medical record**.
- **When the doctor uses telemedicine**, his or her interventions must be governed by scientific professionalism, truthfulness and prudence.
- **Prescription medicines cannot be sold online**, it is not possible to have home delivery from the pharmacy after having bought it. No third parties allowed to sell them either.
- **The doctor who disseminates professional content in telematic or similar media** must explicitly mention the should explicitly mention the sponsorships received received and possible conflicts of interest.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

When a doctor makes use of a telemedicine communication system, he or she shall be liable for his or her actions and for the direct and indirect damage that may result from them.

The clinical records must be collected and recorded for at least 5 years.

It is ethically acceptable, in the case of second opinions and medical reviews, the use of e-mail or other non-face-to-face means of communication and telemedicine, provided that mutual identification is clear and privacy is ensured.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

SWEDEN


 Advokatfirman
 Delphi

Delphi

- IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

This means that the regulation of telemedicine in Slovakia is effective only during the duration of the state of crisis in Slovakia, namely the state of emergency due to the war in Ukraine (law was primarily adopted as a reaction to the COVID-19 pandemic).

- DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

- Governed by several laws and regulations (not unified).
- The central legislation is the Swedish Healthcare Act (Sw. Hälso- och sjukvårdslagen (2017:30)).

- WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

A healthcare provider has the legal obligation to register its business with the Swedish Health and Social Care Inspectorate at the latest one month before the start of the operations.

Digital healthcare services can be provided using several different means such as written communication, video calls or telephone calls. The patient does not need to visit a physical clinic before or after using the digital healthcare service, unless the healthcare professional deems this necessary. The provider will rather have access to the patient's medical history and follow-up and coordination with other actors is possible. However, patients should be referred to physical care providers when necessary.

The patient does not need to visit a physical clinic before or after using the digital healthcare service, unless the healthcare professional deems this necessary. The provider will rather have access to the patient's medical history and follow-up and coordination with other actors is possible. Also, the digital service provider can provide its services to patients in all regions in Sweden.

Swedish Association of Local Authorities and Regions (Sw. SKR), issued recommendations in June 2019 in order to lower compensation for digital primary care.

The compensation model for digital healthcare services has temporarily changed during the Covid-19 in order to be boosted.

- WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

- **A healthcare provider has the legal obligation** to register its business with the Swedish Health and Social Care Inspectorate at the latest one month before the start of the operations.
- **A healthcare provider must comply with data protection rules**, mostly the Patient Data Act

- IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

- Healthcare in Sweden is largely tax-funded, even when the service is from a private provider.
- The reimbursement system for primary care differs from regions.
- A digital healthcare provider usually enters into an agreement with a physical clinic that has entered into a reimbursement agreement with a region.
- If a patient from another region uses the digital healthcare service, the region in which the patient resides will compensate the region which has entered into a reimbursement agreement as if it were a "subcontractor".

- IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A

SWITZERLAND

Walder
Wyss Ltd.

walderwyss

- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

N/A

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

- There is not a uniform and comprehensive Swiss Telemedicine Act.
- There are various either direct or indirect laws and ordinances both at a federal and cantonal level with an implicit regulation concerning telemedical services.
- Swiss Federal Act on Electronic Patients' Files (2017).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

Telemedicine centres are regulated by Cantonal law and controlled by Cantonal authorities. All Swiss residents may lawfully contact a telemedicine centres.

The Swiss Federal Act on Electronic Patient's Files recognized the right to have an electronic patient's file: (i) requires prior informed consent of the patient (ii) Patients have access to their own electronic patient's file (iii) Medical personnel only have access if they have certification or belong to a certified healthcare organization and the patient has granted access.

Regarding prescriptions, the Federal Act on Medicines Products and Medical Devices states that a medicinal product may only be prescribed if the state of health of the consumer or patient is known (not uniformly regulated).

Telemedicine as first point of contact in case of illness is a mandatory healthcare insurance-plan option.

Swiss residents may choose it from different healthcare plans within the mandatory healthcare insurance system).

Doctors can be employed or free-lance; responsible vis-à-vis the Canton for the orderly medical practice, other doctors may be employed under the supervision of the responsible head-physician(s).

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- **Telemedical Treatments** requires (i) professional duty of care (ii) Swiss data protection regulations (iii) Professional secrecy (iv) the principle of the documentation of the medical history (v) the remuneration of telemedical are subject to (vi) a time limit.
- Telemedicine is neither explicitly allowed nor prohibited, so a telemedical treatment must be the appropriate method in the specific situation based on an assessment by case.
- **Health data** are sensitive personal data and therefore requires that every patient agrees to the data processing and to the transfer of the data to third parties.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

- Telemedicine doctors may also prescribe pharmaceuticals and send the prescription directly to a pharmacy of choice by the patient or to a tele-pharmacy.
- Walder Wyss advises the leading telemedicine centre, which also operates outside Switzerland.
- No specific regulations have been issued in Switzerland regarding telemedicine during the COVID-19 pandemic.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

They sent an email and a complete portfolio.

TURKEY



Gun + Partners



- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Telemedicine activities are regulated under the Regulation on Remote Provision of Healthcare Services which was entered into force in 2022.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

Governed by the Regulation on Remote Provision of Healthcare Services (2022).

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

Within the scope of remote healthcare activities, physicians may remotely conduct examination and consultation, issue prescription, follow-up parameters such as blood sugar and blood pressure, provide services supporting a healthy life and psychosocial health, conduct invasive and surgical operations upon receiving approval from the Ministry, protect people's health during endemic and epidemic outbreaks, monitor the health status of elderly and high-risk groups and people requesting monitoring of their health data via wearable technologies.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- **Obtaining Authorization Certificate:** The healthcare centres that would like to provide remote healthcare services will need to obtain authorization by applying to the General Directorate of Healthcare Services with the required documents.
- **Protection of Patient Data:** When providing remote healthcare services the physician must inform the patient of his/her expertise, the scope of the service, the differences between remote and applied healthcare services and data protection-related matters. The healthcare centres will be responsible for protecting patient privacy and health data within this framework. Accordingly, the healthcare centres must store and send the transactions and activities regarding remote healthcare services to the Ministry's database.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

The Regulation on Remote Provision of Healthcare Services also allows healthcare centres authorized for international healthcare tourism to provide remote healthcare services internationally.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A

UKRANIA Asters



- **IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

Regulations on telemedicine were approved in 2015. In 2017, they were reinforced at the level of law into the Basics of Ukrainian Legislation on Healthcare. Another law was passed for the use of telemedicine in rural areas.

In 2022, recognizing the importance of telemedicine for improving the access to health services that was critically affected by the Russia-Ukraine war, the Ministry of Health of Ukraine (MOH) introduced temporary telemedicine regulations for the period of martial law (ongoing as of the date of this update) and six months after it.

- **DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?**

The key telemedicine regulation is the Order of the MOH No. 681 dated 19 October 2015 "On Approval of Regulations for Use of Telemedicine in Healthcare" ("**2015 Telemedicine Regulation**"). For the period of martial law and six months after it, the 2015 Telemedicine Regulation is replaced with the Order of the MOH No. 1695 dated 17 September 2022 "On Approval of the Procedure for the Provision of Healthcare Using Telemedicine and Rehabilitation Care Using Telerehabilitation for the Period of Martial Law in Ukraine or Its Separate Regions" ("**Martial Law Telemedicine Regulation**").

On a more general level, telemedicine is regulated by the following laws:

- Article 35(6) of the Basics of Ukrainian Legislation on Healthcare No. 2801-XII dated 19 November 1992 (as amended on 14 November 2017); and
- Law of Ukraine "On Increase of Availability and Quality of Medical Care in Rural Areas" No. 2206-VIII dated 14 November 2017.

- **WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?**

- **Telemedicine is permitted** for all levels of healthcare system (primary, secondary, tertiary levels), both for public and private healthcare providers;
- **It may extend to different stages of care**, including diagnostics, consultations, treatment, rehabilitation;
- **Forms of telemedicine** include telemedical consulting, telemedical multi-disciplinary case discussion, telemetry, home consulting and remote medical interventions.
- **Informed consent of the patient** is required for the use of telemedicine.

- **WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?**

- **Telemedicine may be implemented** by healthcare providers based on their general medical license (in Ukraine medical licensing works on per institution basis).
- **There are certain requirements** (including in terms data protection) **to platforms** that may be used by healthcare providers for telemedicine services, subject to data security expertise by a government authority

In 2022, MOH significantly relaxed these requirements, permitting the usage of foreign telemedicine platforms and engagement of foreign health professionals into provision of telemedicine services to patients in Ukraine. Compliance with confidentiality and medical secrecy standards remains a must for telemedicine services.

- **IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?**

Telemedicine is not yet sufficiently spread in Ukraine due to lack of resources, though significant progress has been made. COVID-19 pandemic, followed by the Russian invasion of Ukraine, have intensified the uptake of telemedicine solutions. It has been acknowledged that the existing outdated regulatory framework is a barrier to the sustainable adoption and scale-up of telemedicine services. To address that, MOH has developed the Strategy for Development of Telemedicine in Ukraine, which is pending approval by the Government. In addition, MOH has proposed telemedicine-focused amendments to the Basics of Ukrainian Legislation on Healthcare. As of the date of this update, they have not yet been approved by Parliament.

- **IS THERE ANY IMPORTANT INFORMATION MISSING?**

N/A


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• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

Telemedicine is not explicitly addressed in UK legislation but it is a long-established practice in the UK although it did not become widely used until the Covid-19 pandemic necessitated remote consultations. It is now actively encouraged by the UK's National Health Service (NHS), with plans for digital healthcare programmes being pursued by all 4 countries within the UK.

• DOES A SPECIFIC LAW REGULATE THE TELEMEDICINE? IF SO, WHICH LAW?

- There is no UK legislation that specifically addresses telemedicine other than the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014** which states that medical advice provided remotely is a regulated activity. As a result, telemedicine is regulated in the same way as other healthcare services. This include registration by service providers with the Care Quality Commission (**CQC**) in England, and equivalent body in other regions of the UK, and, for pharmacies supplying medicine online (or by telephone), registration with the General Pharmaceutical Council (**GPC**), which regulates pharmacists.
- As a result of the lack of legislation, the bodies responsible for the regulation of healthcare professionals in the UK have worked together to publish guidance on the conduct of remote consultations. These bodies include the General Medical Council (**GMC**), which regulates doctors, and the GPC. The guidance is called "**Remote prescribing high level principles**". In addition to this high level guidance, both the GMC and GPC have issued more detailed guidance aimed at their particular professions.
- Further, the NHS issued updated guidance in 2021, "**A Guide to Good Practice for Digital and Data-Driven Health Technologies**", setting out principles that the NHS will apply to the assessment of telecare or telemedicine innovations. Compliance with all regulations on data protection is an important aspect of the guidance as are clinical safety and cybersecurity.

• WHAT ARE THE MAIN CHARACTERISTICS OF SUCH REGULATION, IF ANY?

- The general aim of the CQC in its regulation of telemedicine is to ensure that the traditional standards on quality and safety that apply to healthcare providers in face-to-face consultations apply to remote consultations as well.
- The guidance "**Remote prescribing high level principles**" issued by the GMC, GPC and others sets out 10 key principles which cover points such as:
 - making patient safety the first priority;
 - identifying and protecting vulnerable patients;
 - ensuring that the patient understands how the remote consultation will work;
 - explaining to the patient that drugs can only be prescribed when safe to do so; and
 - obtaining informed consent.
- The GMC's supplemental guidance for doctors concerns matters such as considering whether a remote consultation is appropriate, having adequate knowledge of the patient's health and specifying when a physical examination is necessary. In overview, the GPC's supplemental guidance for pharmacies operating at a distance has 5 broad principles aimed at ensuring that the arrangements, including staff, premises and equipment used, safeguard the health, safety and wellbeing of patients and the public.
- As already mentioned the NHS's "**A Guide to Good Practice**" makes clear that all digital or data-driven healthcare technology should comply with all applicable regulations on data protection, clinical safety and cybersecurity.

• WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

The minimum requirements are effectively to meet the principles and other requirements set out in the guidance issued by the CQC, GMC and/or GPC as well as the regulations applicable to healthcare providers generally and regulations on GDPR, ecommerce and distance selling that apply to all industry sectors.

• IS THERE ANY OTHER RELEVANT INFORMATION TO HIGHLIGHT?

- The NHS has drawn up plans for “Technology Enabled Care Services” (**TECS**) with guidance on the resources available for TECS for those who commission health services. The aim is to create a commissioning environment that encourages the use of innovative technologies, including for telemedicine, so as to improve the treatment of long term patients, to help meet demand and to make treatment and care services more cost-effective.
- UK patients can only receive treatment from a doctor registered with the GMC. A doctor based outside the UK therefore needs to be registered and cannot advertise to patients in the UK using the title “doctor”, including over the internet, unless registered.
- Since Brexit came into effect, online pharmacies are no longer required to display the EU Distance Selling Logo, save for those in Northern Ireland (for which they must register with the Medicines & Healthcare products Regulatory Agency (MHRA) and comply with the Electronic Commerce (EC Directive) Regulations 2002). The GPC has a voluntary logo and the MHRA is considering whether to introduce a mandatory UK logo.

• IS THERE ANY IMPORTANT INFORMATION MISSING?

N/A