

**TELEMEDICINE
LEGAL FRAMEWORK IN EUROPE & ISRAEL**

July 2021



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*”.

Furthermore, 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.

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

N/A

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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.

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

There is only a draft Amendment to the Act on Healthcare Services, which could regulate the telemedicine on a basic level.

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

- The draft Amendment to the Act on Healthcare Services could legalize the so-called “consulting services“, which could be provided through remote access or in the patient’s own social environment, or in another place of his current location.
- The Board of Czech Pharma - Innovative Industry Association (AIFP), proposed a pilot project for: (i) clinical examination via telemedicine for chronic patients treated in centres; (ii) centric drugs distant prescription and (iii) home delivery available for selected oral drugs. The Czech Regulatory Authority, the State Institute for Drug Control (“SIDC”), accepted the home delivery of centre medicines under strict conditions.
- During pandemic, the SIDC also published rules regarding clinical trials in pandemic, including rules for certain exceptional distant procedures. These exemptions are however valid only until 30.6. 2021 and after that, “standard” rules shall apply.

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

Pursuant to the draft Amendment, the provider will need to have a physical contact point.

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

There are private online project offering online reservations and physicians’ consultancy.

Furthermore, the Society of General Medicine (a professional society) has published recommended diagnostic and therapeutic procedures for general practitioners in the field of telemedicine.

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

N/A



**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 LTD**


• 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
- Special Decrees have been passed due to the Covid-19 Crisis for a specific term

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

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).

Due to the Covid-19, some flexible provisions have been enacted:(i) The Decree n°2020-73 of January 31st, 2020, authorizes teleconsultations with patients potentially infected with the Covid-19 by using any of the technological means and authorizes the reimbursement of teleconsultation of a Covid-19 infected patient or any person at risk until the end of the state of health emergency (February 16th , 2021) (ii)The Decree of July 10th, 2020, authorizes certain acts of telemedicine especially stipulated by the Decree, such as speech therapy, othoptics therapy, chiropodist acts, etc.. (iii) The Decree of December 9th, 2020, authorizes the reimbursement of the authorized telemedicine acts until the end of the state of health emergency (February 16th , 2021).

• **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.
- **Health professionals and psychologists** must have the training and technical skills required for the devices.
- **Exemptions for Teleconsultation:** (i) patients under 16 years old, (ii) emergency situations or (iii) unavailability of the physician: For the reimbursement, the recoured teleconsulting physician should be located within a geographical area. Otherwise, the teleconsultation is possible but will not be reimbursed.
- **The Decree n°2020-73 of January 31st, 2020**, authorizes teleconsultation for Covid infected patients as well as the reimbursement of teleconsultations of the patients.
- The Decree of July 10th, 2020, authorizes certain acts of telemedicine and provides special derogations for teleconsultation.
- The Decree n°2020-227 of October 16th, 2020, extends the Decree of July 10th 2020, until the end of the state of health emergency (February 16th , 2021).
- The Order n°2020-1553 of December 10th, 2020, extends the financial compensation put in place for any teleconsultation or authorized telemedicine act until the end of the state of health emergency (February 16th , 2021).

• **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.

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

It focuses mainly on Teleconsultation however due to the Covid-19 pandemic certain acts of telemedicine especially stipulated by Decree have been introduced in France. There are strictly regulated by the Decree of July 10th 2020 and only are possible until the end of the state of health emergency.

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?**

As a first point, **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.

On the other hand, **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

**Szecskey
Attorneys at
Law****• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?**

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. However, due to the Covid-19 Crissis, a Government Decree on Telemedicine has entered into force in April 30, 2020, (only effective during the State of Danger).

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

- **The Decree** does not go into details.
- **The presence of the patient** is not a condition for the provision and financing of the healthcare services, where the specific service allows it.
- **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?

The telemedicine may only be provided based on the relevant medical licenses.

It is essential to obtain 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.

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 that 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 by the existing regulation, 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 regular performance of oversight and control mechanisms.

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

N/A



ITALIA

Portolano
Cavallo

• IS THE TELEMEDICINE ACCEPTED IN THIS LEGISLATION?

In December 2020, the Italian Ministry of Health enacted New National Guidelines on Telemedicine.

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

- There are no laws in Italy specifically addressing telemedicine.
- Recent Decrees due to the Covid-19 Crisis and National Guidelines pending further regulation.

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

The referred guidelines on Telemedicine include:

- (i) several types of telemedicine services, including tele-visit, tele-monitoring, tele-consultation etc.;
- (ii) description of its organization and the relevant actors involved;
- (iii) detailed operational rules concerning the fee system, prescriptions, booking an appointment with a specialist, etc.

As to the remuneration system, the Guidelines specify that the fee for a telemedicine service shall be equivalent to the fee for the same service when provided in the traditional way within the Basic Level of Assistance (“LEA”), including any cost-sharing. Specific indications are also provided for the fee system as it regards two specific types of services: televisits and teleconsultation (that may occur between healthcare providers during a visit). Unlike televisits, a teleconsultation does not involve a fee nor patient cost-sharing, and does not require a specific NHS prescription, since it is considered an integral part of the service delivered to patients.

The list of the essential healthcare services specified in the LEA to be granted to all Italian patients includes certain telemedicine services. Private entities shall meet for it the same requirements for conventional health providers.

The Italian regions must implement the Guidelines in their respective regional healthcare services (“RHS”) and the place where the medical activities is carried out need to be authorized only if it is an organized entity aimed at performing medical services.

No authorization is required when the medical activity is carried out by single professionals without a health facility open to public. Only if the health activity requires authorization, it will necessary for telemedicine as well.

Televisits 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, when the conditions set out in the Guidelines are met (e.g. patient with a known pathology who does not need a complete physical examination).

Digital tools needed for the implementation of the services remotely: certain technological tools are required to enable the physician and the patient to communicate safely and effectively and thereby ensure that remote services are provided effectively (e.g. computers, tablets, or smartphones).

E-prescription was introduced in 2011, and since the Covid19 Crisis it doesn't require a paper memorandum to be shown to the pharmacist: On March 25, 2020, the Ministry of Economy and Finance issued a new decree on “Extension of the dematerialization of prescriptions and therapeutic plans and alternative methods to the paper memorandum of the e-prescription”, amending the previous Ministerial Decree of November 2, 2011. Such Ministerial Decree extended the scope of use of the e-prescription, providing the dematerialization of prescriptions for (i) medicines with AIFA therapeutic plan, (ii) medicines distributed through methods other than the conventional regime with the NHS, and (iii) medicines with restrictive prescriptions.

Moreover, on December 30, 2020, the Ministry of Economy and Finance adopted a decree that provided the possibility for doctors to issue e-prescriptions for drugs not reimbursed by the NHS.

• WHAT ARE THE MINIMUM REQUIREMENTS OF SUCH REGULATION?

- The place where data are 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.
- Decree enacted on 25 March 2020 (pending of further regulation) will make it possible to have a complete digital process from the tele-visit to the issuing of the e-prescription and its transmission to the patient (or directly to the pharmacy for the delivery of the relevant medicine to the patient's home).

- **The place where the medical activities is carried** out need to be authorized only if it is an organized entity aimed at performing medical services.
- **Prescription drugs** cannot be sold online, only in the pharmacy. Pharmacist may organize the post-delivery.

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

A stronger development of these services throughout Italy has taken place due to the COVID-19 emergency.

- The place where data are 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, since no medical activity is carried out.
- It is essential for every transfer of data (in the form of videos, images, files, etc.) to be encrypted and in accordance with privacy and security regulations.

The Guidelines also envisage that (i) the physician shall be supported by a technical coordination centre responsible for the management of telemedicine activities that will offer assistance and a help desk for patients and physicians, and that (ii) a training program shall be implemented to train subjects involved (i.e., patients, caregivers, healthcare professionals) in using the technologies employed.

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

Short information about the services developed within the Covid-19 crisis.



**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) and the Individual Healthcare Professions Act ("Wet BIG"). The prescription of medicines at distance is regulated by the Medicines Act ("Geneesmiddelenwet").

- **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").

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.igi.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?**

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?**

The lack of interaction between health care professionals within the same municipality in Norway has made it difficult to communicate and retrieve correct and updated information from a patient's medical records. The Norwegian eHealth directorate is currently in the process of introducing a system with one joint medical record ("Akson") for each patient within the same municipality. The intention is also to ease interaction with health personnel/hospitals etc. in the rest of the country.

The reimbursement system was adjusted in order to meet certain of the new challenges/questions arising in connection Covid-19, e.g. reimbursement for work in relation to Johnson & Johnson vaccination.

- **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”.
- Order of the Ministry of Health of the Russian Federation dd. 30.11.2017 No. 965n to organize and provide medical care using telemedicine.
- 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.**
- **Services can be provided only** via a special state-run IT system.

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

Telemedicine services can be provided only on the basis of the “ground” medical license, and 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).

It must be taken into account that remote consultation excludes making a diagnosis. Patient’s examination, as well as final diagnosis establishing, can be held only within in-person physician visit.

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 start-ups and Apps are developing 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?**

No there is not.

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

Neither current laws nor projects for future legislation on telemedicine.

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

N/A

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

Telemedicine is not recognized in the legislation and therefore it is not subject to reimbursement from the healthcare system.

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

N/A

- **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.



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

We find in the Spanish legislation several legal and deontological rules indirectly related to telemedicine services.

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

Notwithstanding the abovementioned, there is not a specific direct law on Telemedicine 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 at hand.

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. E-prescription 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 prescription, 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 the following:

- 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?**

- **There are no specific duties for online providers**, they have the same responsibilities according to the College of Doctors.
- **A doctor cannot prescribe a medication** without physically seeing the patient: the Code of Medical Ethics expressly prohibits the exclusive use of telephone or video conferencing in medical care as contact with the patient is unavoidable.
- **If the prescription is made electronically** through the corresponding platform, the patient's electronic ID certificate is required or, if not available, the patient's ID plus the Physician's electronic certificate.
- **In order to use the electronic prescription system**, it is necessary to comply with the requirements and obtain the authorization of the General Council of Physicians by subscribing to the commitments and acquiring the system's temporary approval.
- **Health drugs cannot be sold online**, it is not possible to have home delivery from the pharmacy after having bought it. No third parties.

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

Doctors using telemedicine shall be liable for the defective use of telemedicine techniques, whether due to a lack of skill on the part of the doctor or due to improper use.

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

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

N/A

SWEDEN


 Advokatfirman
 Delphi



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

Yes, digital healthcare services are regulated under the same laws as healthcare services that include physical visits.

- **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?**

Telemedicine is allowed on a Cantonal basis, where it is permitted or not opposed. It is remarkable to point out that telemedicine is not a separate specialist discipline, but refers to general medical treatment at a distance.

- **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?**

It is not a practice fully regulated in Turkey.

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

- Telemedicine is not introduced in Turkish Law yet.
- The Turkish MoH had taken initial steps to incorporate online systems (SAGLIKNET and E-Nabiz).

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

- **The Medical Deontology By-law and Ethical Principles for Physicians** prohibits remote examination, diagnosis and treatment of patients.
- **Recent steps to store health data of patients** in order for the patients or third parties authorized HCPs by them to access their health data. These systems allow the patients or their HCPs to have direct information about their own health status, and in the light of this information, they may participate in decisions concerning their health, their diagnosis.
- **The Private Hospitals Regulation** allows a exception for their HCPs to provide teleconsultation service without violating the prohibitions regarding remote examination, diagnosis and treatment.
- **Private hospitals may provide teleconsultation** with respect to immunization, disease prevention, early diagnosis, family planning, nutrition and healthy eating habits and health education.

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

N/A

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

Private hospitals started to provide telemedicine services to book online appointments for examination. HCPs may discuss with their patients via online platforms and if physical examination or medical analysis/tests are deemed necessary.

- **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 to for the use of telemedicine in rural areas.

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

Oder of the Ministry of Health of Ukraine No. 681 dated 19 October 2015 "On Approval of Regulations for Use of Telemedicine in Healthcare";

- Article 35(6) of the Basics of Ukrainian Legislation on Healthcare No. 2801-XII dated 19 November 1992 (as amended);
- 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);
- **It may extend to different stages of care**, including diagnostics, consultations and treatment;
- **Healthcare providers need** to run a separate set of internal reporting forms in connection with telemedicine services;
- **Public healthcare providers** are exceptionally permitted to charge patients for telemedicine services provided to patients at home;
- **The National Board of Health and Welfare** has issued four principles for the performance 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).
- **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.

- **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.

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

*It is said that specific laws have been enacted on Telemedicine. However, there is lack of information on its development.


 Clyde & Co
 LLP

CLYDE&CO

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

Yes, but in the form of guidance issued by the General Medical Council (the GMC, which regulates doctors).

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

- There are no specific laws or regulations for remote consultations with patients.
- The supply of medicines by online/telephone pharmacies is also subject to regulation.

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

The National Health Service has various telemedicine long term projects, such as a national advice telephone line and website, and as a result of the coronavirus has sent a letter to all doctors' practices encouraging remote consultations.

Teleconsultation is focused mainly in primary care, and it is reimbursed on a capitalised basis. There is a current plan to improve it: (i) to ensure at least 25% of appointments are available for online booking with a quality framework development, and (ii) all patients will have the right to online consultations by April 2020 and video consultation by 2021 (iii) non mandatory prices published for a not face to face activity.

Electronic prescriptions are a developed mechanism: Registration of online pharmacies are allowed, but they must be registered and comply with the e-commerce directive, and so they can provide electronically. Every interaction pharmacist - patient is registered, and the pharmacists can check the patient's treatment. The patient can return to the pharmacy to pick up their treatment without having to go through the Primary Care consultation.

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

- **The GMC's guidance** has 10 high level key-general ethical guidance to doctors.
- The regulator: it is a criminal offense to provide health without specific certification for online providers.
- Reimbursement of the regime of consultation has not concluded but the aim to have a full reimbursement.

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

Before coronavirus less than 1% of consultations were remote.

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

The regulation on the supply of medicines by online/telephone pharmacies is mentioned but they don't develop it.