

Bird & Bird

Discovering the World of Telemedicine

An International Overview of the
Regulatory Legislation

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Introduction

Background

Telemedicine has been available to healthcare providers for several years. However, it was not until quite recently that the field of telemedicine really took off due to the rise of the COVID-19 pandemic. With the new standard of social distancing and the burden on the healthcare system, the COVID-19 pandemic forced rapid implementation of telemedicine in day-to-day practice, resulting in the use of technology to provide healthcare growing significantly.

Given the necessity of providing healthcare services at a distance, several countries have implemented (temporary) legislation or guidance relaxing regulatory barriers of telemedicine. Although telemedicine might have taken a great leap forward due to the COVID-19 pandemic, this shift in healthcare will leave a lasting impression even after the pandemic has passed.

Telemedicine is a way to provide healthcare using information technology and telecommunications to overcome distance, involving at least two actors, of which at least one is a recognised healthcare provider. Telemedicine refers specifically to remote clinical services.

Europe

According to the European Commission, telemedicine is defined as *“the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients”*.

As a healthcare service, telemedicine should be included in the scope of Articles 56 and 57 of the Treaty on the Functioning of the European Union (TFEU) and as a service, telemedicine should be subject to the general freedom regarding the free movement of services.

Since telemedicine is simultaneously a healthcare service and an information service (i.e., a service normally provided for remuneration, remotely and by electronic means at individual request), the following

European legal framework may apply: Directive 2011/24/EU, concerning the application of patient's rights in cross-border healthcare; Regulation (EU) 2016/679 and Directive 2002/58/EC, concerning data protection; Directive 2000/31/EC and Regulation (EU) 2019/1150, concerning information society services and online intermediation services.

Finally, since healthcare services and the practice of medicine are not entirely harmonised at European level, the provision of telemedicine services may be regulated differently from one member state to another.

For this purpose, we have provided a regulatory overview for the following European countries:

- Belgium
- France
- Germany
- Italy
- The Netherlands
- Poland
- Spain

Non- EU Countries

As telemedicine is characterised by the boundaries encompassing national law, we have also provided a regulatory overview for the following non-EU countries:

- Australia
- China & Hong Kong
- United Kingdom

This overview is intended to summarise the national developments and legal frameworks with regard to telemedicine in order assist our clients in understanding their position. This document does not constitute legal advice, if you require more information, please feel free to reach out to the country contacts in this document.

Australia

1. *What local regulations are in place in respect of telemedicine?*

Telemedicine is not directly regulated in Australia. In late 2020, the Minister for Health and Aged Care Greg Hunt, announced plans to implement a universal telehealth system in Australia. However, this initiative has not yet been progressed.

The Health Practitioner Regulation National Law (National Law), which provides the general regulatory framework for all types of regulated health practitioners, makes no specific reference to telemedicine. Telemedicine is indirectly regulated by limitations on access to government funding at a Federal level and through prescribing and dispensing regulations in each State and Territory.

Electronic prescribing (E-Prescribing) was introduced by the Federal Government through amendments to the National Health (Pharmaceutical Benefits) Regulations 2017 in 2019 as an alternative to conventional paper-based prescriptions. It was identified in

the 2018-2019 Federal budget as a priority to improve efficiency, compliance, safety and data collection and forms a key part of the National Digital Health Strategy, which aims to provide paper-free medication management by 2022. All States and Territories now allow electronic prescriptions through amendments to prescribing regulations in each jurisdiction.

In response to the COVID-19 pandemic, the Australian Government implemented the National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020 (PBS Special Arrangement).

The PBS Special Arrangement temporarily implemented measures to provide easier access to pharmaceutical benefits (government

subsidised medicines) from prescriptions made through telemedicine consultations, including the use of digital images of hard copy prescriptions. The PBS Special Arrangement will be repealed on 30 September 2021, unless extended.

2. *Are healthcare professionals allowed to provide services through Telemedicine?*

Guidelines issued in 2012 by the Medical Board of Australia, emphasised that health practitioners must ensure the “Good Medical Practice: A Code of Conduct for Doctors in Australia” is complied with in relation to any telemedicine service. In July 2020, the Australian Health Practitioner Regulatory Agency (AHPRA) issued updated telehealth guidance in response to the COVID-19 pandemic. The guidance states that any type of health practitioner (including doctors, dentists, pharmacists, physiotherapists, nurses etc) may provide telemedicine services provided it is safe and clinically appropriate. As a result, there is no restriction on the provision of privately funded telemedicine services.

Many healthcare services in Australia are subsidised by the Federal Government, through Medicare Australia. Specific healthcare services which are eligible to receive government subsidies through Medicare are specified in the Medicare Benefits Schedule (MBS). As a result, the inclusion or exclusion of a particular type of healthcare service on the MBS provides a de facto restriction on providers.

3. What types of Telemedicine services are provided (e.g. store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

Temporary MBS items were introduced on 13 March 2021 in response to the COVID-19 pandemic to provide a general exception allowing healthcare professionals to offer telemedicine services where there is an existing clinical relationship with the patient, as well as several other specific exemptions.

An established clinical relationship generally requires the patient to have attended at least one face-to-face consultation at the medical practice in the last 12 months.

From 1 July 2021 specific exemptions made government funded telemedicine services available for homeless people, urgent after-hours services, children under 12 months old, patients of Aboriginal Medical Health Services, services relating to blood borne viruses, sexual and reproductive health, pregnancy counselling and people living in areas where movement is restricted in response to COVID-19. These services can be provided whether or not there is an existing clinical relationship.

These exemptions are due to end on 31 December 2021, unless further extended.

Medicare funded telemedicine services are generally limited to real time video conference consultations. However, under the exemptions discussed above, providers are able to offer telephone consultations in some circumstances, where clinically appropriate.

4. What are the requirements for the advertising of Telemedicine services?

Telemedicine services fall within the definition of a “health service” in the National Law. As such, the advertising of telemedicine services must comply with the advertising requirements set out in section 133 of the National Law. This requires that advertisements for telemedicine services or for a business that provides telemedicine services must not:

- be false, misleading or deceptive or is likely to be misleading or deceptive; or
- offer a gift, discount or other inducement to attract a person to use the service or the business, unless the advertisement also states the terms and conditions of the offer; or
- use testimonials or purported testimonials about the service or business; or
- create an unreasonable expectation of beneficial treatment; or
- directly or indirectly encourage the indiscriminate or unnecessary use of telemedicine services.

Failure to comply with this requirement may result in a fine of up to \$5,000 for individuals and \$10,000 for corporations.

5. Are there local laws regulating reimbursement for services through Telemedicine?

There are no specific laws regulating the funding of telemedicine in Australia.

With the exception of the temporary MBS items introduced in light of the COVID-19 pandemic, currently telehealth services are not generally eligible for Medicare funding. Medicare funding

is available for video consultations by specialist and consulting physicians to patients who live outside of major cities and are at least 15 km from the specialist. Funding is also available for

telehealth consultations with patients in residential care facilities regardless of where they are located.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

As part of the Federal Government's 2021-22 Budget, Minister Hunt announced an allocation of over \$114 million to fund telehealth until the end of 2022.

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Belgium

1. What local regulations are in place in respect of telemedicine?

Two significant changes have occurred since the pandemic. Firstly, the Belgian National Council of the Order of Physicians (NCOP) shifted their stance on teleconsultations, expressly permitting telemedicine and outlining conditions for physicians to engage in teleconsultations, in their opinion of 22 June 2022 titled '*Teleconsultations in today's healthcare landscape - Deontological rules*,'.

Secondly, even though there is no overarching legislative framework in Belgium specifically regulating telemedicine, as of August 2022, Belgium has introduced the concept of telemedicine by the Royal Decree of 26 June 2022 which added a Chapter XI ("Chapter XI - remote healthcare") to the Royal Decree of 14 September 1984 *establishing the nomenclature of medical services for compulsory health insurance and benefits*. This addition introduced 'remote healthcare' services to the health insurance legislation's nomenclature, establishing a framework for reimbursing these services and outlining the prerequisites for their provision.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, HCPs are allowed to provide services through telemedicine per Royal Decree of 14 September 1984.

The decree allows 'remote healthcare' and defines such services as covering remote consultation, tele-expertise, telemonitoring, and teletherapy. Regarding the conditions to perform telemedicine, the NCOP's publication of 18 June 2022 provides some useful guidance and mentions the following:

- There must exist a therapeutic relationship between the patient and the doctor.
- If the therapeutic relationship between the patient and the doctor is established just before the start of the remote consultation, the patient must be thoroughly informed in advance about the consequences of establishing this therapeutic relationship. Moreover, the relationship is terminated at the end of the remote consultation, unless the patient expressly indicates a desire to maintain this therapeutic relationship.
- The patient is informed about the limitations of a remote consultation before using the platform. The patient must be informed on the financial aspects of the e-consultation, including cost and reimbursement.
- The doctor ensures high-quality advice and follow-up: through adequate duration of consultation, by having access to sufficient and relevant patient data, appropriate feedback to patient's doctor holding the actual medical records.
- The doctor must ensure that the services meet the criteria with regard to safeguarding informational privacy. Examples thereof are the prohibition to store the video or audio communication, the prescription of medicines must be electronically generated on Recip-e (i.e., the Belgian electronic platform for electronic prescriptions), etc.

3. What types of Telemedicine services are provided (e.g. store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There is no exact list of which types of telemedicine services can be provided.

Teleconsultations, tele-expertise, telemonitoring, tele-assistance, and m-health, are part of the broader concept of telemedicine and can be seen as 'types' of telemedicine services.

These notions have not been defined further by Belgian law.

According to the NCOP, a teleconsultation is a healthcare service provided remotely by a healthcare provider to a patient. It can take the form of a consultation via phone, email, SMS, or chat, or it can involve a video conversation where the healthcare provider and the patient can speak and see each other from a distance (video consultation).

In general, tele-expertise refers to the remote technology/telecommunication for the purpose of providing medical expertise. Telemonitoring refers to the remote monitoring of a patient's health status or vital signs using technology. Tele-assistance refers to the remote support service to provide assistance or help to patient's using technology. M-health refers to mobile health such as the usage of mobile devices for healthcare purposes (e.g., apps or wearables) which supports the health monitoring, management and communication with healthcare providers).

For the conditions to perform telemedicine, please see our answer to question 2.

4. *What are the requirements for the advertising of Telemedicine services?*

Healthcare providers should comply with the general provisions on advertising applicable to them, notably the rules on (i) unfair and misleading, comparative advertising, as well as on (ii) advertising of the HCP's practice.

In general, healthcare providers are allowed to engage in advertising. However, when they promote their services to the public, they must adhere to the conditions outlined in specific healthcare legislation as well as in the Economic Law Code e.g., for unfair, misleading, and comparative commercial practices¹. It goes without saying that they must uphold the deontological, ethical and professional principles of their profession. The [NCOP's opinion of 23 April 2020](#), emphasizes that among other things, any form of unfair or misleading advertising; comparative fee schedules; and encouraging unnecessary examinations or treatments are not allowed.

Furthermore, the Law of July 14, 1994, on compulsory insurance for medical care and allowances, is also relevant. Article 127 §2 explicitly states that advertising that mentions the *cost-free or reimbursement aspects of medical services*, is strictly prohibited. While this provision does not explicitly address telemedicine, we recommend adhering to the prohibition on advertising cost-free or reimbursement aspects of medical services, which includes telemedicine services.

Moreover, article 31 of the Law of 22 April 2019 (Health Care Quality of Practice Act) stipulates that health care practitioners are allowed to make their practice known to the public, but:

- The information provided to the public must be truthful, objective, relevant, and verifiable and must be scientifically supported.
- This information should not encourage unnecessary examinations or treatments, nor should it aim to solicit patients.
- The information must indicate the specific professional title(s) held by the healthcare practitioner.

There are no specific rules on advertising of certain services, let alone, telemedicine services. The above-mentioned rules entail that in practice, doctors can mention in the context of making their practice known to the public that telemedicine services can be provided, i.e., on their website. But it is not possible to specifically promote telemedicine services.

¹ EU Directive 2006/114/EC on unfair, misleading and comparative advertising; Art. VI. 17 Economic Law Code.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Article 1 of the Royal Decree of 26 June 2022, amending the Royal Decree of 14 September 1984 defines "remote healthcare" to include teleconsultations, telemonitoring, and tele-expertise. In other words, there is no comprehensive catalogue of authorized telemedicine services. Currently, only *teleconsultation* services are reimbursed. These telemedicine services can be utilized by both doctors and patients. Reimbursement is facilitated through the public reimbursement system, as defined in the same Royal Decree.

However, specific conditions must be met for telemedicine reimbursement. Notwithstanding the obligations set out in other pieces of legislation, and the general conditions (see question 2), a remote consultation can only occur with the patient's consent and the physician's agreement, and the physician must have access to the electronic patient file during the remote consultation and update the data thereof. The latter refers to the obligation for the physician to record in the patient's medical file the details of the contact, the reason for the consultation, the advice provided, any modifications to the treatment plan, and the nature of the documents issued.

In a nutshell, reimbursement for telemedicine services is subject to specific conditions.

Moreover, according to article 1, par. 6 of the Royal Decree 26 June 2022, reimbursable consultations include:

a) For video consultations, the following conditions must be met:

- Communication must occur through a tool with end-to-end encryption.
- Communication should not be stored on the platform used.
- If the tool includes other features in addition to video or audio communication, such as document exchange, these must be offered in a way that allows users to comply with applicable legal provisions.

b) Remote consultations can only take place at the request of the patient and with the agreement of the physician. The physician or their staff records the time of the request in the patient's file and makes it available to oversight bodies.

c) Remote consultations occur synchronously through either a telephone call or a video connection between the physician and the patient.

d) The physician has access to the patient's medical records during the remote consultation.

e) The physician has an existing treatment relationship with the patient.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

Notwithstanding the authorization and reimbursement of telemedicine, Belgium currently lacks a dedicated and comprehensive legal framework to facilitate its integration into the healthcare system. The Minister of Health, as outlined in the 2022 policy note, has affirmed the intent to establish a regulatory framework accommodating telemedicine within the Belgian healthcare landscape. Consequently, it is anticipated that key healthcare laws in Belgium, including the Health Care Quality of Practice Act of 22 April 2019 and the Patients' Rights Act of 22 August 2002, will be subject to revisions in the future.

To ensure a robust legal foundation for telemedicine, legal experts recommend that the legislator should introduce a more precise legal definition of telemedicine and provide explicit regulations regarding the translation of general obligations within the realm of telemedicine.

Finally, the NCOP's opinion of 18 July 2022 explicitly states that there should be more attention given to Telemedicine during the education of medicine students: "*Medical professionals involved in education*

must adequately emphasize the use of teleconsultation in the medical curriculum, including both the basic medical training and the specialized master's programs. This emphasis is crucial because many medical trainees feel that teleconsultation receives insufficient attention during their education."

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China

1. What local regulations are in place in respect of telemedicine?

China is one of the early adopters of telemedicine. Throughout the past decades, China has advanced policies and guidance supporting the digitalisation of healthcare services. The “Internet + Healthcare”, i.e., internet-based healthcare service, has become a major national initiative in China.

On 25 April 2018, the State Council published the Opinion to Promote “Internet + Healthcare” (“**Circular 26**”). On the basis of the Opinion, the National Healthcare Commission (“**NHC**”) and the National Administration of Traditional Chinese Medicine (“**SATCM**”) promulgated three administrative rules on 17 July 2018 to specifically govern telemedicine services. The three administrative rules are:

- Administrative Measures for Internet Diagnosis and Treatment (For Trial Implementation);
- Administrative Measures for Internet Hospitals (For Trial Implementation); and
- Specifications for the Administration of Remote Medical Services (For Trial Implementation).

On 15 March 2022, the NHC published the Rules for Supervision of Internet Diagnosis and Treatment (For Trial Implementation) (“**Supervision Rules**”), which put forward more detailed regulatory requirements for medical institutions that provide internet diagnosis and treatment services. The Supervision Rules heighten the quality of internet healthcare to the same level as the traditional in-person healthcare service. It limits the reliance on AI in drug prescription and prohibits profitisation from drug prescriptions or tests. It further requires medical institutions to establish essential infrastructure for network and data security. All entities operating telemedicine services in China shall be aware of the Supervision Rules and ensure compliance with the regulatory requirements.

The State Council on 15 July 2020 issued Opinions and addressed that the permissible scope of internet diagnosis or treatment services shall be further expanded on the preliminary condition of ensuring the safety and quality of services.

For foreign players, the regulations for now are still silent as to their applicability to overseas or Sino-foreign medical institutions. The Chinese government has been encouraging foreign investments in the development of online medical systems (Item 424). It is yet to be seen whether a national standard for telemedicine will address these issues.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes. A licensed medical institution may offer direct hospital-to-patient (“**H2P**”) internet diagnosis and treatment services provided they meet the registration and qualification requirements. Only physicians with more than three years of independent clinical work experience shall be eligible to provide internet diagnosis and treatment services. The physicians and nurses should also be duly licensed and accessible from the National Electronic Registration System for Physicians and Nurses. The physicians and nurses must also authenticate their identity before the consultation to ensure real-person services. Using substitutes, or AI software, will not be allowed for such services.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

The three administrative rules categorized the telemedicine services to be provided in China into three types:

- **Internet-based diagnosis and treatment:** medical institutions, together with their registered physicians, provide follow-up diagnosis and treatment for the patient with common diseases and chronic diseases and provide "Internet +" family doctor contracting service via internet;
- **Internet hospitals:** physical medical institutions can (1) establish an internet hospital via NHC administrative approval to add the internet hospital to its current Medical Institution Practicing License. Or (2) collaborate with a third-party institution, e.g., a tech company, to establish a new internet hospital. The internet hospital formed under (2) must seek a new Medical Institution Practicing License from NHC. The practice scope of an internet hospital shall not exceed the practice scope of the physical medical institutions it affiliated with;
- **Telemedicine services:** (1) host medical institutions can directly invite other medical institutions to provide telemedicine services; (2) host institutions or third-party institutions may set up a telemedicine services platform and use such platform to provide telemedicine services.

The telemedicine services can only be provided after offline medical consultation. Only after a physician confirms that a patient has been clearly diagnosed with certain common diseases or chronic diseases in a face-to-face diagnosis, the physician might provide follow-up consultations via internet for the same diagnosis. If it is diagnosed during a return online visit that the patient's medical conditions have changed and a face-to-face diagnosis by a physician is needed, the telemedicine services must be stopped immediately, and the patient must be redirected to an offline hospital.

Physicians may issue electronic prescriptions for follow-up treatment of common diseases or chronic diseases, and medical institutions and drug distributors may entrust qualified third-party institutions to distribute drugs. In addition, an internet hospital shall also provide patients with the online retrieval function of examination and test results and materials, diagnosis and treatment plans, prescriptions, doctor's advice, and other medical history information.

Medical institutions providing internet-based diagnosis and treatment and internet hospital services shall ensure that the servers of internet hospitals storing medical data are placed within the territory of mainland China, and establish a data access control information system, so as to realise data exchange and sharing with the physical medical institutions.

Additionally, the Supervision Rules requires medical institutions providing internet diagnosis and treatment to implement information security classification protection of level 3 or above for their information systems.

Although there are currently no specific data protection or privacy laws that apply to the provision of Telemedicine services in China, the Personal Information Protection Law (**PIPL**) regulates the processing of personal information generally by stipulating a series of requirements that covers the whole data life cycle. Healthcare professionals and medical institutions should comply with the PIPL when collecting and processing personal information of patients in the course of providing telemedicine services.

For example, healthcare professionals and medical institutions should inform patients of the details of the processing, which includes the categories of personal information to be processed, the purpose and method of the processing, the retention period, the manner and procedure by which the patients may exercise their rights. Where sensitive personal information (e.g., medical health related information) is collected, healthcare professionals and medical institutions are bound by a series of higher requirements, such as additionally informing individuals of the necessity of processing their sensitive personal

information and the impact on them, obtaining their separate consent, and conducting a personal information protection impact assessment prior to the processing.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific laws regulating the advertising of telemedicine services in China and such advertising will be subject to medical advertising regulations and internet advertising measures.

In accordance with the PIPL, where information push or commercial marketing is conducted by means of automated decision making (e.g., profiling), non-personalised options shall be made available, and easily accessible option to opt-out shall be provided to individuals.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Yes. In March 2020, owing to the COVID-19 outbreak, the National Healthcare Security Administration (“NHS”) and the NHC jointly issued the Guiding Opinions on Promoting the “Internet +” Medical Insurance Services during the COVID-19, which provided that the telemedicine follow-up treatment of common diseases or chronic diseases during the COVID-19 shall be included in the reimbursement scope of medical insurance. Circular 26 also pointed out that, to adapt to the development of the “Internet + Healthcare”, the government shall further improve medical insurance reimbursement policies, gradually incorporate telemedicine services into the scope of medical insurance reimbursement and establish an expense-sharing mechanism.

In October 2020, the NHS published the Guiding Opinions on Actively Promoting Medical Insurance Reimbursement for “Internet +” Medical Services, which provided detailed work plans and reimbursement scopes for telemedicine services. Healthcare security administration at the provincial level can determine the diseases and services to be covered by the medical insurance reimbursement scheme. The healthcare security administration of Beijing and Shandong, for example, allow the follow-up online consultation fees and certain refills of prescription drugs to be paid by the healthcare security fund.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

Under the national initiative of “Internet + Healthcare”, the three administrative rules and the Supervision Rules are a manifestation of the Chinese government to promote a more standardised development of telemedicine in the country. With the outbreak of the COVID-19 pandemic, the Chinese government also views telemedicine as a major tool to promote the establishment of a complete national health system and an effective mechanism during public emergencies.

The current rules have not clearly addressed cross-border medical telemedicine collaborations. However, we see a few progresses in policies which are in the benefit of foreign participants. For instance, through the current Catalogue of Industries for Encouraging Foreign Investment (2020 version), the Chinese government has been encouraging foreign investment in, for example, the development of online medical systems (Item 424). China (Beijing) Pilot Free Trade Zone (“FTZ”) issued Work Plans in 2021 to encourage cross-border telemedicine services and promote medical institutions in the FTZ to conduct clinical research on stem cells.

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France

1. What local regulations are in place in respect of telemedicine?

In France, the area of telemedicine has experienced progressive and exponential development over the years and continues to evolve. Thus, an entire legal framework is dedicated to telehealth under articles L. 6316-1 and seq. and R. 6316-1 and seq. of the Public Health Code (“PHC”).

Telemedicine was defined and regulated for the first time by [Law no 2009-879 of 21 July 2009](#) (“*loi HPST*”) that introduced article L. 6316-1 of PHC, followed by articles R. 6316-1 and seq. of PHC² that define the five different categories of activity covered by telemedicine, along with their implementation conditions.

Although legally defined, telemedicine was not implemented before the [2014 Social Security Financing Law of 23 December 2013](#) provided a first experimental framework of telemedicine for a period of five years, in nine regions before being extended to all of the French territory.

The [2018 Social Security Financing Law of 29 December 2017](#) put an end to the experimentation of telemedicine and made teleconsultation part of the general framework for the reimbursement of medical acts by health insurance (“*Assurance maladie*”). In 2019, tele-expertise, was also made reimbursable by health insurance. The experimental program was renewed for telemonitoring (“*télésurveillance*”) that has now been generalised by the [2022 Social Security financing Law of 23 December 2021](#) and therefore reimbursable by health insurance.

In 2019, France went through a new development step of telemedicine with [Law no 2019-774 of 24 July 2019](#) that introduced two new concepts: telehealth (“*télésanté*”) and telecare (“*télésoin*”) with telehealth being the combination of both telemedicine and telecare (developed under question 3).

Lastly, the area of telemedicine has experienced spectacular growth due to the COVID-19 pandemic, which has resulted in fast development of the regulation, notably by easing the conditions for the practice of telemedicine and by accelerating the adoption of measures for the implementation of telecare.

The [Social Security Financing Law for 2023 \(LFSS\)](#) created a new accreditation system allowing companies performing teleconsultation services to be accredited by the government in order to have their teleconsultations reimbursed by the health insurance system.

Such accreditation aims to ensure that teleconsultation activities meet a certain level of quality and transparency. Indeed, until the LFSS 2023 teleconsultation companies were not subject to a specific regulatory framework and were therefore lacking legal certainty.

This new accreditation regime is provided under [article 53](#) of the LFSS for 2023 and will therefore facilitate the reimbursement system for teleconsultations.

The LFSS for 2023 also specifies that the High authority of Health (*Haute Autorité de Santé* - HAS) will be in charge of publishing a reference framework of good professional practices relating to the quality and accessibility of teleconsultations and of proposing methods for evaluating teleconsultation companies.

² [Decree no 2010-1229 of 19 October 2010](#)

2. Are healthcare professionals allowed to provide services through Telemedicine?

In France, healthcare professionals are organised in three categories under French law:

- **Medical professionals:** physicians, midwives, and dental surgeons (articles L. 4111-1 to L. 4163-10 of PHC);
- **Pharmacists** (articles L. 4211-1 to L. 4252-3 of PHC);
- **Paramedical professionals** (nurses, physiotherapists, podiatrists, ergotherapists and psychomotor therapists, orthophonists and orthoptists, medical electroradiology manipulators and medical laboratory technicians, audioprosthodontists, opticians, orthoprosthodontists and orthotists, epithesists, dieticians), **nurses' aid, childcare assistants, dental assistants and ambulance drivers** (articles L. 4311-1 to L. 4394-3 of PHC).

Telehealth services are divided into two categories based on the healthcare professionals who carry out these activities:

- **Telemedicine**, for activities performed remotely by a medical professional (article L. 6316-1 of PHC);
- **Telecare**, for activities performed remotely by a pharmacist or by a paramedical professional (article L. 6316-2 of PHC)

Thus, according to these legal definitions, only medical professionals, pharmacists and paramedical professionals might provide telehealth services to the exclusion of nurses' aids, childcare assistants, dental assistants and ambulance drivers.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

The term telehealth ("*Télesanté*") was introduced to refer to all healthcare services offered remotely through digital technology such as care, consultation, assistance etc, carried out either between healthcare professionals or between healthcare professionals and their patients. As stated above, it covers **telemedicine** and **telecare**.

Telemedicine

Article L. 6316-1 of PHC defines telemedicine as a remote medical practise using information and communication technologies, that allows a medical professional:

- to establish a diagnostic;
- to ensure, for a patient at risk, a preventive or post-treatment follow-up;
- to request a specialised medical advice;
- to prepare a therapeutic decision;
- to prescribe health products or medical services (and to perform these last);
- to perform a telemonitoring of a patient's condition.

Thus, telemedicine is sub-divided in five different medical activities (Article R. 6316-1 of PHC):

- **Teleconsultation:** when a physician (general practitioner or specialist) offers a consultation remotely through video transmission. The professional can assess the patient's state of health and decide which action must be taken;

- **Tele-expertise:** allows a medical professional to seek the opinion of one or several colleagues remotely by digital means regarding one particular patient;
- **Tele-monitoring** (“*Télésurveillance*”): allows a medical professional to remotely interpret health data necessary for the medical follow-up of a patient. The recording and transmission of data may be automated or carried out by the patient himself or by a health professional;
- **Tele-assistance:** when a physician assists a colleague remotely in carrying out a procedure (either medical or surgical);
- **Medical response:** carried out by the 15-Centres (“*SAMU*” - Urgent Medical Aid Service), it enables a first medical response to be provided remotely and the patient to be guided through the care process.

Telecare

Article L. 6316-2 of PHC defines telecare as a remote practice of care using information and communication technologies and connecting patients with a pharmacist or a paramedical professional.

During the Covid-19 pandemic, telecare was set up progressively for some categories of professional only as a derogation and as an emergency measure, to enable the continuity of care during the health crisis. Recently, it has been made permanent and extended to all pharmacists and paramedical professionals, beyond the period of the state of health emergency³. Telecare is now allowed for all activities remotely exercised by a pharmacist or a paramedical professional to the exclusion of care requiring direct face-to-face contact between the professional and the patient and care requiring specific equipment not available to the patient.

Conditions under which telehealth services are provided

Article R. 6316-2 and seq. provides conditions for the practice of telehealth, and specifies in particular that each telemedicine or telecare activity is carried out under conditions that guarantee:

- The relevance of the use of telemedicine or telecare assessed by the healthcare professional that should refer to the High Authority of Health (“HAS”) guidelines;
- The authentication of the healthcare professionals involved in the procedure or activity;
- The identification of the patient;
- Access by healthcare professionals to the patient’s health data required to perform the procedure or activity;
- When the situation requires it, the training or preparation of the patient for the use of the telemedicine or telecare device;
- The appropriate filing by healthcare professionals in the patient’s medical record (date, report, medical prescriptions).

Besides, the HAS issued guidelines giving further details on the conditions for carrying out telemedicine and telecare in order to guarantee their quality and safety (detailed under question 7).

Moreover, additional conditions exist for the reimbursement of teleconsultation and tele-expertise via health insurance (detailed under question 6).

4. What are the requirements for the advertising of Telemedicine services?

There is no specific law regulating the advertising of telemedicine/ telecare services. However, telemedicine/telecare are a form of medical practice like any other, therefore all the deontological rules of patient care apply.

It must be emphasised that “*medicine should not be practiced as a business*” pursuant to article R. 4127-19 of PHC that also prohibited, until recently, any direct or indirect advertising of healthcare services.

³ Decree no 2021-707 and Order of 3 June 2021 of the Minister of Health, issued after the opinion of the High Health Authority

However, rules applicable to physicians in terms of information and advertising have been amended and softened with [Decree no 2020-1662 of 22 December 2020](#) that removed the ban on advertising and replaced it with a principle of free communication within a specific framework. Indeed, if practitioners can now communicate more about their activity, including through a website, they are prohibited from calling on the testimony of third parties and from making comparisons with other doctors or establishments (article R. 4127-19-1 of PHC).

5. Are there local laws regulating reimbursement for services through Telemedicine?

Since 15 September 2018, teleconsultations have been made reimbursable via health insurance⁴. Since 10 February 2019, tele-expertise procedures are also reimbursed⁵. Reimbursement of telemonitoring was then put in place by the 2022 Social Security Financing Law.⁶

To benefit from health insurance reimbursement in France, several conditions need to be met⁷:

(1) Teleconsultation must be part of the coordinated care plan. Teleconsultations with a specialist must therefore be carried out after referral of the patient by his treating physician.

However, exceptions are provided notably in the following situations:

- patient is under 16 years old;
- emergency situations;
- doctor is a direct access specialist (gynaecology, ophthalmology, stomatology, oral or maxillofacial surgery, psychiatry or neuropsychiatry and paediatrics);
- patient does not have a treating physician, or if their treating physician is not available within a timeframe compatible with their state of health;
- prisoners;
- people living in institutions for dependent elderly people or institutions accommodating or accompanying disabled adults, who are often far from their home.

(2). Besides, teleconsultations must be carried out in the vicinity.

The use of teleconsultation is based on a territorial organisation. The physician conducting the teleconsultation must be located near the patient's home. This proximity makes it possible to ensure regular monitoring of the patient's state of health and organise a physical consultation following the teleconsultation, if necessary.

Exceptions to this rule apply as the proximity is not required in the following situations:

- for teleconsultations with a general practitioner: if the patient does not have a general practitioner, and lives in an area where the access to care is difficult and no territorial organisation is coordinated;
- for teleconsultations with a specialist: if the patient lives in an area where access to care is difficult and no territorial organisation is coordinated.

(3) Teleconsultation must alternate with physical consultations to ensure the best quality and safety of care.

During the COVID-19 crisis, the French government enacted several measures in context of the state of health emergency. First, the requirements above were waived for patients who were COVID-19 positive

⁴ [Amendment no 6 of 10 August 2018 of the national medical convention](#)

⁵ [Order of 16 August 2018 completing the amendment no 6 of the national medical convention](#)

⁶ [Article 24 of 2022 Social Security Financing Law Project](#)

⁷ [Amendment no 6 of 10 August 2018 of the national medical convention completed by Amendment no 8 of 30 September 2020 of the national medical convention](#)

or those that presented symptoms of COVID-19. These patients could go directly to any doctor for teleconsultation and have the related costs reimbursed through health insurance⁸.

Another measure made teleconsultations, and telecare procedures completely reimbursable by health insurance, as opposed to the reimbursement rate of 70% for physical consultations. The full reimbursement scheme for teleconsultations was put in place as an exceptional measure to support the development of teleconsultations during the pandemic. Indeed, teleconsultations were fully covered with no remaining costs for the patient. This exceptional regime was extended several times, before the government ended this procedure on the 1st of October 2022. Indeed, as of the 1st of October 2022, teleconsultations are reimbursed in the same way as physical consultations (70% of the conventional rate), except for a 100% exemption linked to the patient's situation (long-term illness, maternity).

It must be kept in mind that teleconsultations are reimbursed provided they meet the usual conditions for reimbursement: compliance with the coordinated care plan, geographical proximity of the physician, etc.

Furthermore, the Social Security Financing Law for 2022 extended the practice of telemedicine by making it possible for telemonitoring to be reimbursed (articles L.162-48 to L.162-57).

Health professionals who practice remote monitoring will have to declare their activity to the competent Regional Health Agency (*Agence régionale de santé* - ARS) to enable reimbursement by health insurance provided that certain conditions are met:

- remote medical monitoring activities must be included in the list mentioned in article L. 162-52 of the Social Security Code;
- they must be provided by a remote medical monitoring operator with a receipt from the ARS;
- the digital device through which the medical monitoring is carried out must be made available to the insured by the operator

Article 36 of the Social Security Financing law for 2022 was implemented by two decrees of 30 December 2022:

- [Decree no 2022-1767](#) of 30 December 2022 regarding the coverage and reimbursement of remote medical monitoring by the health insurance system, setting out the methods for evaluating devices, registration for reimbursement of remote medical monitoring activities, as well as the conditions for setting costs of treatment. The decree specifies that the new framework will require companies operating digital medical devices to comply with the security and interoperability obligations laid down by the Digital Health Agency (*Agence du numérique en santé* - ANS) and to obtain a certificate of compliance with the applicable standard (interoperability and security standard).
- Moreover, [Decree No. 2022-1769](#) of 30 December 2022 provides clarification regarding the content of the declaration of remote medical monitoring activities to the ARS.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

In France, telemedicine was conceived as a possible solution to major public health issues such as the difficulties of access to care in certain areas, the lack of medical personnel and the limits encountered by isolated establishments physicians. Also seen as a mean to save on health insurance as offering remote services would simplify access to care for people with mobility problems and reduce the costs of unnecessary patient transfers and emergency hospital visits.

Therefore, France has been encouraging and facilitating the use of telemedicine, through different ways and in particular, by conducting a supportive strategy that aimed to guarantee confidence in telemedicine (publication of HAS recommendations, referential of available and compliant digital tools, etc.). Thus, the HAS was fully involved in the process of the development of telemedicine and it regularly

⁸ [Decree n°2020-227 of 9 March 2020](#) repealed on 1 January 2021.

published guidelines for patients⁹ and healthcare professionals¹⁰ which are didactic guides for good practises, quality and safety of telehealth acts. These guides and their summaries are real “instructions for use” as they describe for each teleconsultation, tele-expertise and telecare procedure the conditions required for a secure implementation (planning, premises, video transmission equipment, document management, etc.). The HAS also details the conditions for the success of these procedures at each stage of the medical treatment: information and collection of the patient’s consent, assessment of the relevance of using telemedicine, assessment of the patient’s ability to communicate, technical means, authentication of the professional, identification of the patient, report and organisation, and continuation of the treatment.

In addition to the provision of a very clear framework, a strong reimbursement scheme was implemented in France that contributed to the development and expansion of telehealth in France (described above under question 5).

Furthermore, financial aids were made available for practitioners that are willing to equip themselves with the tools and technical solutions necessary to the telehealth practices. In particular through flat-rate annual financial aid granted by health insurance for video transmission equipment and connected medical devices¹¹, but also through programs put in place by some of the regions of France most affected by limited medical facilities which offers financial aids to make access to telemedicine easier for the towns and health professionals concerned.

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⁹ Comment se faire soigner à distance: Télconsultation et télésoin (HAS, May 2021)

¹⁰ Qualité et sécurité des actes de téléconsultation et de téléexpertise: Guide de bonnes pratiques (HAS, May 2019) Télconsultation et téléexpertise Mise en œuvre (HAS, May 2019)

Qualité et sécurité du télésoin: Critères d'éligibilité (HAS, 3 September 2020)

Qualité et sécurité du télésoin: Bonnes pratiques de mise en oeuvre (HAS, 18 February 2021)

¹¹ Order of 16 August 2018 completing the amendment no 6 of the national medical convention

Germany

1. What local regulations are in place in respect of telemedicine?

There is no explicit legal framework for telemedical services in Germany. Rather, provisions pertaining to telemedicine can be found in various German laws.

Telemedical services are for example regulated in the respective State Professional Ordinances for Physicians (based on the “(Muster-)Berufsordnung-Ärzte” – MBO-Ä), the German Act on Advertising of Medicinal Products (“Heilmittelwerbeengesetz – HWG”) as well as the German Social Code, Book V (“Fünftes Buch Sozialgesetzbuch” – SGB V).

2. Are healthcare professionals allowed to provide services through Telemedicine?

After being generally prohibited, in 2018 the MBO-Ä was adapted to allow exclusive telemedical consultations or treatments in **individual cases** if this is justifiable from a medical point of view and the required medical care is maintained, in particular by the way in which the findings are ascertained, consultation, treatment and documentation are carried out and the patient is also informed about the particularities of the exclusive of consultation and treatment exclusively via communication media.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In principle, all kind of telemedical services can be offered in Germany. However, it must be medically justifiable, the necessary medical care must be guaranteed, and the patient must be informed about the particularities of exclusive consultation and treatment via the specific communications channel (i.e., video/chat/etc.).

The question of whether a telemedical treatment / consultation is suitable must be assessed by the treating physician in each individual case. Should they come to the conclusion that no adequate treatment or consultation can be provided by telemedical services, a regular in-person visit should be recommended instead.

4. What are the requirements for the advertising of Telemedicine services?

The advertisement for such telemedicine services is a hotly debated and litigated topic in Germany. The relevant provision, Sec. 9 HWG, basically prohibits the advertisement for telehealth services unless, according to generally accepted professional standards, personal medical contact with the person to be treated is not required. The question of which telemedical services can be advertised under that restriction is rather open. In October of 2021, the Federal Court of Justice heard a corresponding case, in which the presiding judge of the 1st Civil Senate pointed out that the change to Sec. 9 HWG could extend the possibilities of telemedicine and also more broadly permit such treatments. A reasoned judgement in this case is however not expected until 2022.

In these proceedings, the Court of Appeal of Munich had previously decided with regard to the advertising of telemedicine services that only such specific remote treatments may be advertised to people for whom compliance with recognised professional standards is ensured, i.e., if proper treatment and consultation using communication media is fundamentally possible according to the recognized state of medical knowledge.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Video consultations performed by physicians are only reimbursable if done using a video service provider certified according to Annex 31b to the Federal Collective Agreement for Physicians (Bundesmantelvertrag-Ärzte).

In general, not all German health insurance companies offer reimbursements for telemedicinal services, which thus have to be paid by patients on their own in some cases. However, more and more German health insurance companies conclude agreements with telemedical service providers, thus ensuring such services being reimbursable.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

The Digital Healthcare Act (DVG), which came into force at the beginning of 2020, aims to advance the digitalisation of German healthcare. Among other things, doctors are now able to prescribe digital health apps to their patients in the same way as medicines, at the expense of health insurers. However, such digital health applications (DiGA) of this kind operate in a highly regulated area. Even at the design stage, attention must be paid not only to the basic requirements of medical product law, but also to the protection of particularly sensitive patient data. There are also special features in distribution, especially in advertising and the requirements for smooth reimbursement by health insurers.

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Hong Kong

1. What local regulations are in place in respect of telemedicine?

There is no specific law in Hong Kong governing the service of telemedicine. Certain guidance is provided in the Ethical Guidelines on Practice of Telemedicine ("**Ethical Guidelines**") published by the Medical Council of Hong Kong ("**MCHK**") in December 2019 and the questions and answers published by MCHK in March 2022. The doctors may be liable to disciplinary, but not legal, proceedings if they are in breach of the Ethical Guidelines.

The Ethical Guidelines provide guidance to doctors who wish to engage in telemedicine and sets out some generic principles for doctors who substitute telemedicine for traditional modes of delivery of medical care and/or advice. Doctors shall remain fully responsible for determining the appropriateness of using telemedicine services for their patients. Together with the well-established legal and ethical principles set out in the MCHK Code of Professional Conduct, the Ethical Guidelines stipulate that the doctors practising telemedicine should meet all the prescribed legal requirements and ethical guidelines in the same standard as those conducting in-person consultations.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes. In December 2019, Hospital Authority ("**HA**"), a statutory body managing government hospitals and institutions in Hong Kong, launched HA Go, a one-stop mobile app that offers public healthcare services via telemedicine.

Amidst the COVID-19 outbreak, allied healthcare professionals, such as occupational therapists, physiotherapists and speech therapists, have been using telemedicine service through HA Go to follow-up on treatment or supporting rehabilitation of patients. The HA has also been providing telehealth consultation services through HA Go and other platforms for suitable patients.¹²

Due to the strict social distancing policy in Hong Kong, there is also a rise in demand and popularity of telemedicine service in the private healthcare market. Several network providers, insurance companies and private hospitals have launched their own one-stop private telemedicine platform to facilitate the provisions of regular follow-up consultation and health management services for patients with minor illnesses or chronic conditions.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There is no specific type of medical services under which telehealth consultation may be provided in Hong Kong. For example, generally speaking, the HA would provide telehealth consultation services to follow-up patients who are stable, who do not need clinical examinations, and are physically in Hong Kong.¹³

¹² Press Release, 6 July 2022 [LCQ7: Promoting development of telemedicine \(info.gov.hk\)](https://www.info.gov.hk/lcq7/Promoting%20development%20of%20telemedicine)

¹³ See note 1

There are no specific restrictions on the type of platform that may be used to provide telemedicine services, provided that the technology is suitable for its purpose including system stability and encryption for data protection.

The Ethical Guidelines define “telecommunication system” to include telephone, email, social media (e.g., SMS, WhatsApp, Facebook, internet forum & etc.); and other means of electronic communication between two or more people in different locations, at least one of which is within Hong Kong.

For post-teleconsultation dispensation and delivery of medicine, doctors should be reminded that any dispensation of dangerous drugs to a patient through a third party, such as a courier, may be in breach of the Dangerous Drugs Ordinance (Cap. 134).

Although there are currently no specific data protection or privacy laws that apply to the provision of Telemedicine services in Hong Kong, the Personal Data (Privacy) Ordinance (Cap. 486) (“**PDPO**”) regulates the collection, holding, processing or use of personal data generally based on a set of data protection principles (“**DPP**”). Healthcare professionals should comply with the PDPO and in particular the relevant DPPs when collecting and processing personal data of patients in the course of providing telemedicine services. For example, healthcare professionals should only collect personal data for a lawful purpose directly related to a function or activity of the relevant Telemedicine service, the data collected should be necessary and adequate but not excessive for such purpose, and the means of collection should be lawful and fair. Accordingly, healthcare professionals should provide patients with a “Personal Information Collection Statement” (PICS) when providing telemedicine services setting out, among others, the purpose of collection, the classes of persons to whom the data may be transferred, the consequence if patients fail to provide the data as well as their rights to request access to and correction of their personal data.

Healthcare professionals are also bound by the PDPO to take all practicable steps to ensure that personal data is accurate and is not kept longer than is necessary for the fulfilment of the purpose for which the data is used, and to adopt data security measures in providing telemedicine services. Healthcare professionals should ensure that appropriate data security measures are implemented (e.g., by way of encryption or access control etc.) so that the personal data collected are prevented from unauthorised access.

It should be noted that the MCHK Code of Professional Conduct expressly specifies that Hong Kong registered doctors should have due regard to their responsibilities and liabilities under the PDPO, in particular, patient’s rights of access to and correction of information in the medical record.¹⁴

Healthcare professionals should also be aware that they are bound by common law duty of confidence in respect of patient information collected in the course of providing Telemedicine services and should not disclose patient information obtained in the course of providing Telemedicine services to third parties (e.g., pharmacies or drug dispensaries) without consent from patients.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific law regulating the advertising of telemedicine services in Hong Kong.

However, any advertisement relating to use of medicine, surgical appliance and treatment of a list of diseases is prohibited, as provided in Schedule 1 of the Undesirable Medical Advertisements Ordinance (Cap. 231). Also, practice promotion is not permitted under the MCHK Code of Professional Conduct.¹⁵

From a PDPO perspective, health professionals must not use personal data (e.g., patients' personal data) or provide personal data to another person for use in direct marketing unless it has obtained the data subject’s consent.¹⁶ Consent is defined to include “an indication of no objection to the use or provision”¹⁷

¹⁴ Article 1.1.5, [Code of Professional Conduct \(English version\) \(mchk.org.hk\)](https://www.mchk.org.hk)

¹⁵ Article 5.2.2, [Code of Professional Conduct \(English version\) \(mchk.org.hk\)](https://www.mchk.org.hk)

¹⁶ Sections 35E and 35K, Personal Data (Privacy) Ordinance, Cap.486, Law of Hong Kong

¹⁷ Sections 35A, Personal Data (Privacy) Ordinance, Cap.486, Law of Hong Kong

of personal data for such purposes (e.g. checking the tick box indicating “I do not object to the use of my personal data for direct marketing of XXX”). Therefore, if health professionals are to use patients’ personal data to conduct direct marketing of the Telemedicine services, they should obtain requisite consent from the patients.

5. Are there local laws regulating reimbursement for services through Telemedicine?

There is no specific law regarding the funding or reimbursement of telemedicine services.

Under the MCHK Code of Professional Conduct, doctors are not allowed to offer to, or accept from, any person or organization any financial or other inducement for referral of patients for consultation, investigation, or treatment.¹⁸

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

Owing to the COVID-19 outbreak, Hong Kong Government has been encouraging more private hospitals, medical groups, healthcare professionals, etc., to provide free telemedicine services to members of the public (including COVID-19 patients).¹⁹

For long-term development, HA in its Strategic Plan 2022-2027 formulated strategies for developing smart hospitals and smart care, and one of the goals is to build up telemedicine and telecare as an adjunct to existing public healthcare service.²⁰

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¹⁸ Article 14, [Code of Professional Conduct \(English version\) \(mchk.org.hk\)](https://mchk.org.hk)

¹⁹ See note 1

²⁰ [Hospital Authority Strategic Plan 2022-2027 Overview \(ha.org.hk\)](https://ha.org.hk)

Italy

1. What local regulations are in place in respect of telemedicine?

Telemedicine is not expressly regulated by Italian law. However, the Italian Ministry of Health ("**MOH**") and the Italian National Institute of Health ("**ISS**") adopted guidelines providing principles and rules related to Telemedicine services.

Specifically:

- On March 17th, 2014, the **MOH** adopted [national guidelines on telemedicine](#)²¹ (hereinafter the "**Guidelines**"). The document provides several principles and rules applicable to telemedicine;
- On April 13th, 2020, the ISS published the Interim provisions on telemedicine healthcare services during COVID-19 health emergency²². The document provides support for the realisation of services in telemedicine during a COVID-19 emergency, offering indications, identifying operational problems and proposing solutions supported by evidence, but also easily dispensable in practice.
- On October 10th, 2020, the ISS published interim guidance on telemedicine health services for Pediatrics during and beyond COVID-19 pandemic²³. The document provides the scientific indications to support the implementation of telemedicine health services for pediatric patients, both in early childhood and in developmental age, and during the different phases of the COVID-19 pandemic.

On October 27th, 2020, the MOH issued the National Indication for the providing of telemedicine services²⁴ ("**National Indication**"). The document provides practical indications related to the management and delivery of health services through telemedicine.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, in principle, healthcare professionals may provide services via telemedicine. Anyway, the provision of healthcare services by telemedicine, shall be done in accordance with the relevant health laws and regulations, ethics code, order²⁵ and bioethics guidelines²⁶, Guideline and National Indication (in this sense, reads answer provided under section 3 below). Healthcare professionals providing services by telemedicine are fully liable for their professional activities²⁷.

²¹ See: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf.

²² See: https://www.iss.it/rapporti-covid-19/-/asset_publisher/btw1J82wtYzH/content/rapporto-iss-covid-19-n.-12-2020-indicazioni-ad-interim-per-servizi-assistenziali-di-telemedicina-durante-l-emergenza-sanitaria-covid-19.-versione-del-13-aprile-2020

²³ See: https://www.iss.it/rapporti-covid-19/-/asset_publisher/btw1J82wtYzH/content/rapporto-iss-covid-19-n.-60-2020-indicazioni-ad-interim-per-servizi-sanitari-di-telemedicina-in-pediatria-durante-e-oltre-la-pandemia-covid-19.-versione-del-10-ottobre-2020

²⁴ The National Indication was approved by the permanent conference for relations between the state, the regions and the autonomous provinces of Trento and Bolzano on December 17th 2020, see: <http://www.statoregioni.it/media/3221/p-3-csr-rep-n-215-17dic2020.pdf>

²⁵ In this sense, please note that Biologists – according to the relevant ethic code and order - could not visit patients by telemedicine. However, as consequence of Covid-19, the Order of Biologists, decree n. N. 103 dated November 5th, 2020, authorised biologists to use telemedicine in order to provide their service online "[...]provided that the professional adopts all the technical precautions necessary to ascertain the identity of the patient and their major age (and, if of minors, the consent of the parents or of the operators of parental responsibility), as well as the tools necessary to guide the patient in the detection of the measures, preferring for this purpose the use of video links".

²⁶ Pursuant to Section 3, p. 10, National Indication.

²⁷ Pursuant to Section 3, p. 10, National Indication.

Moreover, it should be noted that according to the National Indication, telemedicine may be useful in case of health emergency, monitoring of those diseases significant for the NHS governance; accessibility to diagnostic services and continuity of care; monitoring of patients remotely. Telemedicine may be used also for medical certification whether: (i) the patient medical contact, albeit via video call, can be valid, truthful; (ii) the anamnestic information can be acquired directly from the applicant; (iii) the data are collected are certain and objective, immediately transmitted; (iv) the certificate can be released immediately and in a certified way.

3. *What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?*

Telemedicine services may be provided by tele-examination²⁸, teleconsultation²⁹, health-medical teleconsultation (or tele-cooperation³⁰), tele-healthcare³¹, tele-reporting^{32,33}.

- **Tele-examination** is a medical act in which the doctor interacts remotely in real time with the patient, even with the support of care-giver. During the tele-examination it is possible to prescribe medicinal products and health treatments. For this purpose, it is necessary that the doctor can see and interact with the patient at a distance (through a telecommunications infrastructure). Such examination can take place in real time or it can be deferred. However, according to the National Indication, considering also the Doctors Ethic Code, tele-examination shall not be intended as the unique approach to manage the doctor/patient relation. Tele-examination, pursuant to the National Indication, shall be intended as a way to manage patients whose diagnosis has already been formulated during a physical consultation.

In this sense, tele-examination can be provided in the case of patients that do not require a physical examination (traditionally consisting of inspection, palpitation, percussion and listening) and when at least one of the following conditions are met:

- i the patient needs the service in the context of an individualised pathway/diagnostic therapeutic pathway;
- ii the patient is placed on a follow-up pathway concerning known disease;
- iii the patient suffering from a known disease needs a check or monitoring, confirmation, adjustment or change of the therapy in progress (e.g., renewal or modification of the therapeutic plan);
- iv the patient needs anamnestic evaluation for the prescription of diagnostic tests, or staging of a known or suspected pathology;
- v the patient needs the doctor to verify the results of the tests carried out, which can be followed by the prescription of any further information, or a therapy.

²⁸ Pursuant to Section 2.3.1, paragraph 3, of the Guideline.

²⁹ Pursuant to Section 2.3.1, paragraph 4, of the Guideline.

³⁰ Pursuant to Section 2.3.1, paragraph 5, of the Guideline and National Indication, page 7, section "Teleconsulenza medico-sanitaria".

³¹ Pursuant to National Indication, page 7, section "Teleassistenza da parte di professioni sanitarie (Infermiere/fisioterapista/logopedista etc)".

³² Pursuant to National Indication, page 7, section "Telerefertazione".

³³ Please note that, according to the National Indication, the e-triage should not be included in the telemedicine services. National Indication, p. 8, reads as follow "the triage or telephone consultation carried out by doctors or health professionals to patients in order to indicate the most appropriate diagnostic/therapeutic pathway and the need to perform the visit quickly in presence or remotely or the possibility of postponing it to a later time by assigning a new appointment, is not part of the activities ascribable to telemedicine"

- **Teleconsultation**, is a medical act in which the healthcare professional interacts remotely with one or more doctors to discuss, also via video call, the clinical situation concerning a specific patient, based primarily on the sharing of all clinical data, reports, images, audio-video.

The sharing of documents takes place electronically. Teleconsultation between healthcare professionals can also take place in an asynchronous manner. When the patient is virtually present, the teleconsultation takes place in real time and is configured as a multidisciplinary tele-examination.

The purpose of teleconsultation is to share the approaches by healthcare professionals involved in a specific case. It is also a way to provide a second specialistic opinion regarding the concerned specific case. The teleconsultation will be included in the final report.

- **Health/medical teleconsultation** is a consultation among healthcare professionals (not necessarily doctors). It is provided by two or more healthcare professionals having different responsibilities regarding a specific case. It concerns the request of support, from a healthcare professional to another healthcare professional, during the execution of health activities.
- **Tele-healthcare** concerns healthcare professional's interaction (e.g., nurses/physiotherapist etc.), where each healthcare professional provides the relevant virtual assistance to the patient. The purpose of remote assistance is to facilitate the correct performance of assistance activities, which can be carried out at home.
- **Tele-reporting** is a report issued by a doctor who has requested a clinical or instrumental examination. The tele-report is transmitted through digital and telecommunication systems, formalised with a qualified electronic or digital signature of the relevant responsible doctor.

Moreover, regarding tele-reporting the relevant national scientific body issued a guideline³⁴. According to the applicable guidelines, in case of a final report issued by a radiologist following a teleconsultation with another radiologist, the written opinion of the consultant radiologist, in order to be legally valid, shall be signed by the consultant radiologist his/herself in a legible manner via a qualified electronic or digital signature.

Please finally also note that – during the teleconsultation – the radiological medical act is guaranteed by the radiologist present at the execution of the examination. In such moment, the medical professional shall inform the patient regarding the teleconsultation, shall have the patient consent both to do so and to transmit the diagnostic image.

In order to provide Telemedicine services:

- **Patient shall be adequately informed and shall consciously accept, before telemedicine services are provided:**
 - the type of service (i.e., what the service consists of, what its objective is, what are the advantages that the patient may have and any possible risks);
 - the method used to manage and maintain the information and who will have access to the patient's personal and clinical data;
 - the facilities and professionals involved and relevant duties and responsibilities;
 - the identification and relevant details of the owner/s of the processing of personal data and of at least one person in charge (responsible person) if identified, indicating how to know the updated list of responsible people and relevant contacts;
 - the patients' rights regarding their data³⁵.
- **The following infrastructure requirements shall be guaranteed:**
 - connection infrastructure always available between doctors and patients
 - web portal accessible to doctors in order to manage their patients

³⁴ Guideline regarding the radiological medical report issued by the Italian Society of Radiology (SIRM).

³⁵ Pursuant to Section 2, p. 10, National Indication.

- web page accessible to healthcare professionals both from computer, tablet, smartphone
- easy access for patients (i.e. easy login method) with adequate identity verification and possibility to connect with the digital tools common available (i.e. computer, tablet, smartphone)
- compliance with the GDPR for the processing of personal data
- certification of the relevant hardware and/or software, as a medical device where required, adequate for the type of telemedicine service to be performed³⁶.

- **Telemedicine services report.**

- At the end of the tele-examination or other telemedicine services, the doctor or other health care professional – where applicable by reason of the service provided – shall conclude with a report indicating also (i) the presence of any assistant, caregiver or other healthcare provider; (ii) the quality of connection infrastructure and the adequacy of it in accordance with the service provided; (iii) valid digital signature.
- The report, in compliance with the privacy and cyber security laws and regulations, shall be available to the patient by his/her preferred technology solution and shared with other healthcare professional if requested by the patient.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific laws regulating the advertising of telemedicine services.

It derives that rules normally applicable to the promotion of subjects/companies providing healthcare services shall apply also to telemedicine. To be more specific, according to the provisions contained under Law Decree n. 223/2006 (converted in Law n.

248/2006, the so called “Legge Bersani”), both professionals and companies providing healthcare services can promote their activity online and offline, provided such promotion complies with the following principles:

1) According to what is provided under Law n. 145/2018 (so called “Budget Law 2019”), the advertising shall have an informative purpose (meaning should not have promotional and/or suggestive purposes) and can contain the only following information (see Article 2 of Law Decree n. 223/2006):

- (i) title and professional specialisations;
- (ii) characteristics of the services offered;
- (iii) fees and total costs of the services in accordance with transparency and truthfulness criteria.

In addition to that, the promotional message shall respect “[.] *the patient’s free and conscious determination, to protect public health, the dignity of the person and his right to correct health information*”.

2) According to the provisions contained under both the legislative decree n. 206/2005 (so called “Consumer Code”, see, in particular, Article 21 thereof) and the relevant ethical code, they should not provide misleading and/or untrue information (otherwise the relevant conduct may be regarded as a misleading commercial practice), and/or information that is incorrect and/or violates professional secrets and/or that may be ambiguous or denigratory.

³⁶ Pursuant to Section “Prestazioni sanitaria a distanza: elementi e standard necessari”, p. 12, National Indication.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Yes, according to the Guidelines and National Indication services provided in telemedicine can be reimbursed by the NHS.

In order to do so, specifically pursuant to section 3.2 of the Guideline, the following aspects shall be considered:

(i) organisational model

Telemedicine organisation model should be: Users/Provider/ Services Centre ("**Telemedicine Business Model**").

In the Telemedicine Business Model,

- the User, is the individuals using a telemedicine service, and for this purpose sending health information and/or receiving relevant results. User can be: the patient / caregiver (tele-examination; teleconsultation); the doctor in the absence of the patient (teleconsultation); the doctor or another health care professional (tele-examination, tele-cooperation).
- the Provider, is who provides healthcare services through a telecommunications network (or infrastructure). A Provider may be:
 - Entities belonging to the Italian National Healthcare System (NHS) [9], authorised or accredited, either public or private;
 - Healthcare professionals belonging to the NHS (i.e., general practitioners, paediatricians, medical specialists). The Provider receives health information from the User and returns the results of the service.
- the Service Centre has the responsibility for the management and maintenance of the information system, including transmission and storage of relevant information. Please note that Provider can also act as Service Centre.

(ii) relevant authorisations

Specifically, Providers should hold: (i) all authorisations normally required for the performance of health and socio-health activities in a traditional manner (see Article 8-ter of Italian Legislative Decree n. 502/92); (ii) regional accreditation where the Provider facility is based (see Article 8-quarter of Italian Legislative Decree n. 502/92) and in case telemedicine services intended to be reimbursed by the NHS, the Provider should also conclude contractual arrangements with the relevant regions (see Article 8-quinques of Italian Legislative Decree n. 502/92); (iii) any other additional authorisations which may be required in relation to the IT tools to be used for the provision of the concerned healthcare services.

(iii) By contrast to companies, an individual doctor providing health services by using telemedicine does not need of any prior authorisation being the registration of doctor before the relevant professional order sufficient in order to provide healthcare services in telemedicine). In the case that a doctor is also interested to have such services reimbursed by the NHS, they should conclude an agreement with the NHS that covers the ethical aspects, processing of personal data with electronic tools, professional responsibility³⁷.

- Ethical aspects: ensuring that the doctor-patient relationship can be developed and improved also through telemedicine (by way of example, dedicating the necessary time in order to adequately inform the patient, beyond the informed consent);

³⁷ Pursuant to Section 8 of the Guideline

- Processing of personal data: personal and health data necessary for the provision of telemedicine services falls within the processing of sensitive data carried out by electronic means. Such data shall be processed pursuant to Italian Legislative Decree 196/2003 and subsequent amendments and additions.
- Professional responsibility: for this purpose may be also significant an adequate information on treatments, informed consent of patients, rights of the client over their personal data.

Moreover, for all the services provided in telemedicine, will be applied the remuneration/professional fee system already in force for the provision of the same services in presence³⁸.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

There are several national incentives that may be applicable. By way of example, among others,

- The Italia National Recovery and Resilience plan (“**PNRR**”) – approved by the European Commission the 22nd of June 2021 - provides as goals innovation, digitalisation and health.

Regarding the health sector, the PNRR provides as goals: (i) proximity networks, structures and telemedicine for territorial health care (ii) innovation, research and digitalisation of the national health service. Specifically, in the light of the issues emerged during the health emergency, telemedicine appears as a way to overcome the fragmentation and lack of healthcare services homogeneity provided in the whole national territory and to support patient homecare. 40% of the Italian population is affected by chronic diseases. Telemedicine may be a way to manage and support the patients directly from home.

The PNRR has a duration of six years, from 2021 to 2026, and a total size of 672.5 billion euros (of which 312.5 grants).

- According to Law n. 178/2020 (“Budget Law”), regions allocate 0.5 % of EUR32 million in order to incentivise purchase - by public and private health facilities accredited with the NHS - of devices and IT applications that enable remote reporting, consultation between specialists and remote home assistance³⁹.

Innovative start-up regime may be applied.

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³⁸ National Indication, p. 9.

³⁹ In this sense reads paragraphs 444 and 442, article 1, Budget Law 2021.

The Netherlands

1. What local regulations are in place in respect of telemedicine?

In the Netherlands there is no explicit legal framework for the use of telemedicine. However, there are various laws and regulations that are relevant to the use of telemedicine. For example, the Dutch legislative framework on medical devices (the Medical Device Act (*Wet medische hulpmiddelen*), Medical Devices Regulations (*Regeling medische hulpmiddelen*) and Medical Devices Decree (*Besluit medische hulpmiddelen*)), legislation regarding data protection (GDPR) and the Dutch Medicines Act (*Geneesmiddelenwet*). Also, the Dutch Individual Health Care Professions Act (*Wet op de beroepen in de individuele gezondheidszorg*) specifies reserved actions that only certain groups of medical professionals may perform.

Other relevant regulations:

- The Healthcare Quality, Complaints and Disputes Act (*Wet kwaliteit, klachten en geschillen zorg*). This act describes standards for the provision of good quality care. The care provider must meet these standards for every healthcare request and situation.
- The Medical Treatment Contracts Act (*Wet op de geneeskundige behandelingsovereenkomst*). This act provides rules about the treatment contract between the physician and the patient (including the establishment and termination of the contract, informed consent, confidentiality, rights of minors and proper provision of care).
- The Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act (*Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg*). This act contains safeguards for clients in electronic data interchange.
- The Policy Rule Prescribing via the Internet (*Beleidsregel voorschrijven via internet*). This policy rule will be discussed in the section below.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, healthcare professionals may provide services via telemedicine, provided they meet the conditions.

The Royal Dutch Medical Association (KNMG) has published various guidelines that are relevant to telemedicine, e.g., the KNMG Guideline 'Dealing with medical data' (*KNMG-richtlijn Omgaan met medische gegevens*). This guideline also includes some provisions from the former KNMG guideline 'Online physician-patient contact' (*KNMG-richtlijn Online arts-patiënt*)⁴⁰. According to this guideline, a physician may only decide to have online contact with a patient without an existing relationship if the quality of care is sufficiently guaranteed, the risk of adverse effects is sufficiently limited and if the care provided is of benefit to the patient. The responsibility for the decision to maintain online contact with the patient and the responsibility for the medical treatment lies with the physician. The physician can be held accountable for this.⁴¹ This guideline provides terms and conditions for online consultation with medical advice:

- The physician has sufficiently informed the patient about the procedure for online contact;
- The physician must ensure that the services they provide online (such as patient consultations and examinations via video conferencing) take place outside the observation of others;

⁴⁰ Herzien: KNMG-richtlijn Omgaan met medische gegevens | KNMG. (13 Feb 2020).

⁴¹ KNMG Guideline for dealing with medical data 2022, p. 56.

- The physician has sufficient relevant and reliable data from the patient to be able to give a medically sound individual advice;
- The physician adheres to the rules that apply in their field of expertise for the quality and safety of care and the rights of the patient;
- The physician has sufficiently established the identity of the patient;
- The physician clearly indicates that their advice is based on the information provided by the patient and any available records;
- If the physician is not the patient's (general) practitioner, they will inform the patient's own general practitioner about the advice they have given to the patient.⁴²

The prescription of medicines is subject to the Dutch Medicines Act. The prescription of medicines following online contact between the prescriber and the patient is subject to rules and conditions. Pursuant to article 67 Dutch Medicines Act, it is prohibited to prescribe medicines via the internet to persons whom the prescriber has never met in person, or whom the prescriber does not know, or whose medication history the prescriber does not have at his disposal. This does not include communication via the internet between a physician and a patient based on an existing physician-patient relationship. According to parliamentary papers, the internet must be regarded as an addition to the existing means of communication and can have a clear added value.⁴³

The KNMG Guideline 'Dealing with medical data' stipulates the following conditions for prescribing medication pursuant to article 67 Dutch Medicines act in addition to the conditions already stated for online consultations with medical advice:

- The prescribing physician must have met the patient;
- The prescribing physician must know the patient;
- The prescribing physician must have the patient's medication history;
- There is sufficient reliable and relevant information available to exclude any contraindications to the intended medication and to decide to prescribe the medication on that basis;
- Based on the available information and in view of the medication to be used, there is no reason to perform a (supplementary) physical or other examination;
- The physician sufficiently informs the patient about the use of the prescribed medication and any possible side-effects thereof.⁴⁴

For the duration of the COVID-19 crisis, the Dutch inspectorate for Health and Youth (*Inspectie Gezondheidszorg en Jeugd (IGJ)*) care permitted physicians to prescribe medication online. On 1 June 2022, this temporary exception to article 67 Dutch Medicines Act was reversed. During the COVID-19 crisis online prescription was possible if the prescriber was able to see the patient's current medication history (including allergies) and the prescriber informed the patient's primary care provider and/or GP as soon as possible afterwards.⁴⁵

As of 12 April 2023, a new policy rule for the online prescription of medication has come into force: The Policy Rule Prescribing via the Internet. This policy rule introduces a tolerance policy for the online prescription of medication without the prescriber ever meeting the patient in person beforehand. Under this policy rule, no enforcement action will be taken against violation of article 67 Dutch Medicines Act if conducting a physical consultation or examination is not necessary to determine whether and, if so, which medication should be prescribed, and the prescriber has access to the current medical history of the patient available and consults this accordingly. This policy rule is only an interim stage prior to the adoption of an amendment of the Dutch Medicines Act. The Dutch government intends to eventually replace the strict prohibition of article 67 Dutch Medicines Act with a more nuanced provision.⁴⁶

⁴² KNMG Guideline for dealing with medical data 2022, p. 57-58.

⁴³ *Kamerstukken II* 2005/06, 29359, nr. 81.

⁴⁴ KNMG Guideline for dealing with medical data 2022, p. 58-59.

⁴⁵ Regeling Online medicijnen voorschrijven na videoconsult vervalt per 1 juni | KNMG.

⁴⁶ Government Gazette 11 April 2023, [no. 10521](#), explanatory note p. 2.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In principle, healthcare can be offered in any form, as long as the above-mentioned regulatory framework is met. Various forms of telemedicine can thus be offered, using different communication channels. Some (additional) conditions may apply to different communication channels.

With the emergence of the COVID-19 pandemic, the use of video conferencing has increased. The KNMG Guideline 'Dealing with medical data' gives some advice on the use of video conferencing. It indicates that it is always preferable to use the most secure and certified application, for example one that has been specially developed for healthcare. If the physician is not sure whether the application they want to use is sufficiently secure, they must inform the patient in advance that the communication may not be sufficiently secure and the patient should give their consent to its use. However, in the Guideline it is explicitly stipulated that the patient's consent is not a licence for not complying with security obligations. The legal requirements and standards for the exchange of privacy-sensitive healthcare information must always be complied with. It is also advised in the Guideline to delete chat history after each conversation.⁴⁷

4. What are the requirements for the advertising of Telemedicine services?

In the Netherlands, there are no specific laws regulating the advertising of telemedicine services. However, article 6:194 Dutch Civil Code prohibits misleading advertising in general. Some self-regulatory codes also apply, such as the Dutch Advertising Code (*Nederlandse Reclame Code*). The Dutch Advertising Code contains rules which all advertising must comply with and stipulates that advertising may not be misleading or contrary to the truth. The Dutch Advertising Code also contains some more subjective standards, for example that advertising may not be gratuitously offensive or contrary to good taste and decency.

As a part of the Dutch Advertising Code, there is also a special advertising code for medical devices and a special advertising code for medical self-care devices.

However, advertising for telemedicine services cannot include advertising for prescription medicines, as this is generally forbidden under Dutch law.

5. Are there local laws regulating reimbursement for services through Telemedicine?

The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit (NZa)*) has published a digital care costing guide (*Wegwijzer bekostiging digitale zorg 2023*). This guide is not specifically about telemedicine but focuses on digital care in general, including 'e-care' such as e-diagnosis, e-consultations, monitoring and e-prevention intervention in the event of an individual of high risk.

In the guide it is explained that digital care can only be reimbursed if it meets the so-called package criteria as follows from the Dutch Healthcare Insurance Act (*Zorgverzekeringswet*) and the Dutch Long-Term Care Act (*Wet langdurige zorg*). The most important criteria are that the treatment must be safe and proven effective. The Dutch Healthcare Insurance Act describes which medical aids (such as eHealth technology) qualify for reimbursement from the basic health insurance package.⁴⁸

⁴⁷ KNMG Guideline for dealing with medical data 2021, p. 52.

⁴⁸ *Wegwijzer bekostiging digitale zorg 2023*, p. 8.

Based on the guide, the general rule is that if existing, already insured care is offered in an eHealth form, that care remains insured care if the composition and effectiveness does not essentially change from the original care.⁴⁹

Also, the Association of Dutch Healthcare Insurers (*Zorgverzekeraars Nederland*) and the Dutch patients' federation (*Patiëntenfederatie Nederland*) have recently taken the stand promoting telemedicine and advocating a right to digital healthcare. They want patients to have a choice between going to see a physician at the hospital or receiving digital healthcare at home.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

In the Netherlands, several important initiatives are launched by the government to facilitate and strengthen eHealth.

In 2021, the Dutch Healthcare Authority (NZa) increased funding for e-Health. This means that the costs of telehealth – for example an online consultation by video conferencing – can be reimbursed in the same way as face-to-face healthcare services provided by a general practitioner (GP) or a medical specialist. By making the regulations more flexible, the government is making it easier for GPs to assess a patient's situation. In addition, speech therapists and medical specialists now have more opportunities to provide therapy and care online.⁵⁰

The Dutch government is investing in a digital personal health environment, where people can access their health data online in one place to make people more involved in their own health. Personal health environments are currently free for users and are paid for by the government.⁵¹

On 1 July 2023, the Electronic Data Exchange in Healthcare Act (*Wet elektronische gegevensuitwisseling in de zorg*) entered into force. This Act aims to achieve full interoperability when it comes to electronic data exchange between healthcare providers on the basis of unambiguous language and technical requirements. This Act does not create a new obligation to exchange data. If there is a legal ground for the exchange of data in existing legislation, this new Act regulates how the exchange of data should take place. With this Act, an obligation is imposed on healthcare providers to exchange data electronically.⁵²

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⁴⁹ Wegwijzer bekostiging digitale zorg 2023, p. 8.

⁵⁰ Stimuleren gebruik e-health | E-health (digitale zorg) | Rijksoverheid.nl.

⁵¹ Waar kan ik een persoonlijke gezondheidsomgeving (PGO) voor gebruiken? | Rijksoverheid.nl

⁵² Kamerstukken II 2021, 35 824, nr. 3, p. 3.

Poland

1. What local regulations are in place in respect of telemedicine?

There are several acts which set out admissibility criteria and/or organisational standards for telemedicine:

1. The Act of 15 April 11 on medical activity which stipulates that health care services may be provided through IT systems or communication systems.

2. The Act of 27 August 2004 on health care services financed from public funds (as amended) which, as of January 2015, allows, without the need to conduct a personal examination of a patient, the issuing of:

- a prescription for the continuation of treatment and/or
- orders for the supply of medical devices as a continuation of the supply of medical devices, if it is justified by the patient's health condition that is reflected in the medical records.

3. The amendment of the Act on the information system in health care and certain other acts (introduced in December 2015), which allows patients to be examined via IT systems and/or communication systems.

4. The Act of 5 December 1996 (as amended) on the professions of physician and dentist, which allows them to provide services through IT systems or communication systems. The principles of medical ethics as set out in the Code of Medical Ethics (doctors' association self-regulation) also permit the provision of telemedicine services.

5. The Ordinance of the Minister of Health of 31 October 2019 amending the ordinance on guaranteed benefits in the field of primary health care, which introduced the provision of medical advice at a distance using IT systems or communication systems into the scope of financed health care services.

6. The provision of healthcare services via ICT or communication systems involves the processing of personal data, including sensitive health data in the meaning of the GDPR.

There are also numerous Regulations of the Minister of Health, including the Ordinance of the Minister of Health of 12 August 2020 on the organisational standard of tele-advising in primary healthcare (effective from 15 March 2021), which sets out the circumstances in which the provision of medical advice is not allowed without a physical examination of a patient.

Separate and more restrictive regulations apply with respect to delivery of mental health e-services and e-prescription of psychotropic medications. According to the Mental Health Act, a medical decision on the state of health of a person with a mental disorder, an opinion or a referral to another doctor or psychologist or a treatment entity may be issued by a doctor only based on a prior personal examination of that person.

In accordance with the Regulation of the Minister of Health of 11 October 2022 amending the regulation on guaranteed services in the field of psychiatric care and addiction treatment, in the case of psychiatric or psychological services, the diagnostic process cannot be carried out exclusively using ICT systems. Remote visits are provided only to patients continuing treatment, in accordance with an agreed therapeutic plan or plan of therapy and recovery plan, according to the patient's clinical condition. In August 2023, new regulations came into force concerning substantial modification in prescribing such medicines.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, the healthcare professionals can provide services through telemedicine.

According to the Act of 5 December 1996 (as amended in 2015) on the professions of physician and dentist, a doctor may, without examining the patient in person, issue a prescription required for the continuation of treatment and an order for the supply of medical devices as a continuation of the supply of medical devices, if the issuance of these documents is justified by the patient's state of health reflected in the medical records.

The Ordinance of the Minister of Health of 12 August 2020 on the organisational standard of tele-advising in primary healthcare lists circumstances in which the provision of services through telemedicine is not allowed, i.e.:

- when a patient visits a GP, nurse, or midwife for the first time
- when a patient has a chronic disease, and their condition has worsened, or the symptoms changed
- when there is a suspicion of cancer
- if in other cases, the patient or their legal custodian does not consent to the services being provided remotely
- when it concerns a child under 6 years of age (although telemedicine is allowed when the services concern follow-up advice during treatment, determined as a result of a personal examination of the patient, which can be given without a physical examination).

Providing services through telemedicine is allowed in the following cases:

- for issuing a prescription for continued treatment,
- for issuing a referral for test or examination and discussing the results of such,
- for issuing sick leave.

In addition, remote contact with a doctor is required whenever there is a suspicion of coronavirus infection.

All e-documents (prescription, sick leave, referral for tests, order for medical devices) are issued and sent electronically. A patient can have access to the individual documents via an Internet Patient Account (IKP).

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There are no specific rules on the types of telemedicine services that are allowed. In general, telemedicine can be provided by GPs, nurses or midwives in the form of telephone advice, videocall, audio chat, text chat or (in exceptional cases) by email.

When giving advice virtually, the doctor may also use and supervise a diagnostic test that is performed by a patient at home with a telemedicine device constituting a medical device (e.g., blood glucose or ECG measurement, implantable loop recorder (ILR), blood pressure monitor, spirometer, cardiotocograph, pulse oximeter, otoscope).

A telemedical device is a medical device which has medical certification of class IIa or higher and is registered for home use by a patient, including implantable devices with a data transmission function.

Data from such devices are transmitted securely to a doctor in the form of reports, which are then discussed with the patient during a remote visit.

Medical centres are obliged to provide information on the possibilities and organisational standards of the telemedicine. The information should include the following data:

- a list of services that are provided only if there is a direct visit,
- a system through which doctors provide teleservices,
- how to schedule teleservice,
- the method that the medical centre uses to establish contact with the patient to provide teleservices and the manner in which they are provided,
- the possibility of a direct visit taking place when it is necessary.

It seems therefore that new types of telemedicine could be successively introduced in Poland.

4. What are the requirements for the advertising of Telemedicine services?

Advertising of any healthcare services is restricted in Poland. In general, medical centres and doctors are only allowed to indirectly advertise their healthcare services, by providing information on their activities, sponsoring conferences etc.

Online advertising is allowed both for direct and indirect communications about provided healthcare services. For instance, it is possible to inform patients on the advantages of the telemedicine, such as convenient forms of contact, the possibility of obtaining medical services from any place, saving time, safety, 24/7 availability or short waiting times. However, advertising is only allowed if it does not contradict other rules for practising the profession, in particular the dignity and prestige of the profession, as well as professional secrecy and reliability towards clients and other professionals. As an example, an advertisement would contradict those rules if it were too aggressive, too intense, or misled potential patients as to the therapies offered.

5. Are there local laws regulating reimbursement for services through Telemedicine?

Yes, the Ordinance of the Minister of Health of 31 October 2019 amending the ordinance on guaranteed benefits in the field of primary health care introduced medical advice provided at a distance using IT systems or communication systems into the scope of financed health care services. Financing is subject to certain conditions set out in the respective provisions of law, i.e., ordinances of the President of the National Health Fund.

There are several national legal acts and regulations of the Minister of Health, as well as communications of the National Health Fund which confirm that telemedicine is a publicly funded and guaranteed service. This means that telehealth costs can be reimbursed in the same way as face-to-face healthcare services provided by a general practitioner (GP) or a medical specialist. This includes telemedicine in primary care, but also in outpatient specialised care, in drug and chemotherapy programmes, in long-term care, palliative care and hospices.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

There are numerous important initiatives that have been launched by the government to increase digitalisation of health services.

The Minister of Health has established the e-Health Centre, which is a unit funded from the national budget. The digital e-health ecosystem for citizens includes: Internet Patient Account (IKP), mojeIKP ('mójIKP') and Covid scanner applications, e-services: e-prescription, e-referral, e-registration for vaccinations, central e-registration, EU Covid Certificate, and Electronic Medical Records. Through this digital personal health environment, patients and doctors can access health data online.

The Polish government is investing in a digital personal health environment. This is also the aim of the Polish National Recovery Plan approved by the European Commission. There are several different projects co-financed by the government. The projects are designed for different stakeholders. Support is provided for both public and non-public health services, including improvements to the infrastructure and technology used to improve and develop digital services, as well as prevention, early detection and research.

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Spain

1. What local regulations are in place in respect of telemedicine?

In Spain, there are no specific regulations on telemedicine, with only a few mentions and recommendations on its use, such as those listed in the Spanish Code of Medical Ethics⁵³

Among the few mentions of telemedicine made by the Spanish regulation is Article 4.7 of Act 44/2003, 21 November, on the Organisation of Health Professions, which establishes that “*the health professions shall be practised with full technical and scientific autonomy, with no limitations other than those established by law and by the other principles and values contained in the legal and ethical code*”. In other words, doctors may opt for telemedicine if they consider it technically and scientifically appropriate, but always in due compliance with the principles and limitations contained in the Spanish Code of Medical Ethics.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes, as long as the provision of these services is justified on public health grounds, in the interest of the patient (for example, when the patient is in a remote location where there is no access to medical services) or for reasons of health emergency (as is the case in the current situation caused by COVID-19⁵⁴).

Please note that, under the Spanish Code of Medical Ethics, it is advisable that the patient is under the face-to-face control of their doctor⁵⁵, who will be the interlocutor between the tele-doctor (who will focus on telemonitoring, teleconsultation and second opinion services⁵⁶) and the final decision-maker in the care process.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

In Spain, there is no specific list of care services that can be provided virtually. However, in practice it is recommended that such services be limited to (i) the provision of a second opinion after the one given by a doctor physically; (ii) occasional medical reviews; (iii) the provision of advice to other professionals in making certain decisions; and (iv) telematic home monitoring of chronic diseases or pathologies (through wireless sensors, for example).⁵⁷

⁵³Article 26 of the [Spanish Medical Ethics Code](#).

⁵⁴ In this point, the Spanish Council of Medical Associations (*Consejo General de Colegios Médicos de España*) published on 10 June 2020 a [Guidance Report](#) with different considerations on the appropriateness of the application of telemedicine in the situation originated by COVID 19. In any case, this Report stresses the complementary nature of telemedicine to face-to-face doctor-patient care and sets out the importance of respect the principles listed in the Spanish Medical Ethics Code, the defence of patient rights and patient safety as well as the respect for the health professionals. Finally, this Report also establishes that the use of telematic means is in accordance with Spanish Code of Medical Ethics provided that there is an express consent of the patient, which shall be recorded in the clinical history.

⁵⁵ It is important to mention that the Global Medical Association (AMM) - of which Spain is associate - published the [Declaration on the Ethics of Telemedicine](#), which setting out a series of principles and recommendations on telemedicine. In the absence of a unified European or national legal framework, this is one of the indicative reference frameworks available for the purpose of listing the principles applicable to telemedicine.

⁵⁶ MONTEAGUDO, L. SERRANO, C. HERNÁNDEZ SALVADOR, La telemedicina: ¿ciencia o ficción?, Anales Sis San Navarra vol.28 no.3 Pamplona sep./dic. 2005

⁵⁷ Article 26 of Spanish Code of Medical Ethics.

In any case, it is necessary that, for the provision of such services, the health professional's mutual/insurance company is identified, and the patient's privacy is ensured (Article 26 of the Spanish Code of Medical Ethics).

In addition, it should be noted that it is not allowed to prescribe medicines virtually without having previously carried out a clinical examination of the patient physically, as well as granting a diagnosis, except for certain specialities such as dermatology or ophthalmology or the monitoring of chronic or monitored pathologies.⁵⁸

4. What are the requirements for the advertising of Telemedicine services?

In Spain, only healthcare centres and establishments authorised to provide healthcare services are authorised to advertise these healthcare services (Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of healthcare centres, services and establishments⁵⁹).

In addition, prior to advertising these services, these centres and establishments shall obtain prior authorisation from the competent health body of the Autonomous Community where their registered office is located.

5. Are there local laws regulating reimbursement for services through Telemedicine?

No, there is no regulation providing for reimbursement of services provided through telemedicine.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

No, currently, no incentives (economic or fiscal) are provided to promote telemedicine in Spain.

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⁵⁸ Report on telemedicine issued by Fundación 2000 on September 2012.

⁵⁹ Article 6 of Royal Decree 1277/2003, of 10 October, which establishes the general bases for the authorisation of healthcare centres, services and establishments.

United Kingdom

1. What local regulations are in place in respect of telemedicine?

There are no specific laws which regulate telemedicine in the UK. Rather, telemedicine is regulated through binding standards, codes of conduct and guidelines issued by regulatory authorities. Regulation of health care services, including telemedicine, occurs at two distinct levels—health care providers and individual health care professionals.

The Care Quality Commission (**CQC**) licenses and regulates health care providers under the *Health and Social Care Act 2008* in England, including hospitals, dental practices, GP practices and aged care facilities. Equivalent bodies regulate health care providers in each of the devolved nations of the UK (the Care Inspectorate in Scotland, the Care Inspectorate Wales in Wales, and the Regulation and Quality Improvement Authority in Northern Ireland). For present purposes, we focus on the position in England.

The CQC assesses health care providers to ensure the minimum standard of care set out in the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* is met and conducts periodic inspections to ensure compliance. In March 2017 the CQC published “*Clarification of regulatory methodology: PMS digital healthcare providers*” to clarify the regulatory requirements for telemedicine providers. The CQC states that it regulates telemedicine providers according to the same assessment framework applied to conventional health care providers, by focusing on whether the services offered are safe, effective, caring, responsive to people’s needs and well-

led. In 2019 many of the regulatory authorities and several bodies representing health care professionals agreed a set of *High level principles for good practice in remote consultations and prescribing (High Level Principles)*. Although these principles do not amount to clinical or regulatory guidance, they outline an overarching approach to telemedicine and direct health care professionals to specific regulatory guidance from regulatory authorities, where available. The High Level Principles stress the need for health care professionals to be aware of the limitations of telehealth, particularly in relation to remote prescribing and notes that UK based health care professionals offering services overseas must be aware of local regulatory requirements and comply with them in addition to UK requirements.

All providers of regulated health care services in England must register with the CQC. Before granting registration, the CQC must be satisfied the services offered by the provider meet the requirements of the *Health and Social Care Act 2008*. The CQC also undertakes enforcement action including inspection of health care provider sites in order to ensure ongoing compliance with the registration requirements.

In addition to the CQC registration, individual health care professionals are regulated by regulatory authorities (**Councils**) for each of 10 practice areas. These Councils are responsible for setting registration requirements, practice standards and codes of conduct for health care professionals in each practice area, as well investigating complaints and taking enforcement action.

2. Are healthcare professionals allowed to provide services through Telemedicine?

Yes. There are very few restrictions on the types of telemedicine services permitted in the UK. Health care professionals may offer any service within their scope of practice, provided they comply with the registration requirements for their practice area, any specific telemedicine guidance issued by the regulatory authority and operate through a service provider registered with the CQC.

Pharmacy services are a notable exception and are subject to a number of restrictions when providing online or delivery pharmacy services. From July 2015 until January 2021 all pharmacies in the

UK offering medicines online were required to apply to the UK Medicine and Healthcare products Regulatory Agency (**MHRA**) for registration as a distance selling pharmacy. Once registered, the pharmacy must display the EU Distance Selling Logo on all parts of the website where medicines are offered for sale. From 1 January 2021 this requirement was removed (except in Northern Ireland); however, the MHRA is considering introducing an equivalent UK Distance Selling Logo in future.

Under the UK *Human Medicines Regulations 2012* pharmacy and prescription only medicines may only be sold or supplied at the premises of a registered pharmacy and under the direct supervision of a pharmacist. As a result, where a delivery service is offered, the General Pharmaceutical Council states the handover of the product to the delivery agent must occur at registered pharmacy premises under the supervision of a pharmacist.

3. What types of Telemedicine services are provided (e.g., store-and-forward; remote monitoring; real-time interactive services) and under which conditions is it possible to provide services in Telemedicine mode?

There are no specific restrictions on the type of platform that may be used to provide telemedicine services, provided that health care professionals: offer services within their scope of practice; comply with the registration requirements for their practice area and any specific telemedicine guidance issued by the regulatory authority; and operate as or through a service provider registered with the CQC.

4. What are the requirements for the advertising of Telemedicine services?

There are no specific requirements for the advertising of telemedicine services *per se* in the UK and such advertising will be subject to general advertising regulations and guidance.

5. Are there local laws regulating reimbursement for services through Telemedicine?

There are no specific rules regarding the funding or reimbursement of telemedicine services. A wide range of telemedicine services are fully government funded and offered at no cost to patients by the NHS, supported by dedicated IT infrastructure provided by NHS Digital. These include GP, pharmaceutical, psychology and some dental services. Additional privately funded services are offered by a range of commercial providers.

6. Are there any incentives (also fiscal benefits) promoting telemedicine or the digitalisation of health services?

While telemedicine is already prominent in the UK health care sector, there is currently a significant drive in the UK to further promote and innovate telemedicine and digital health generally. The UK government has expressed its intention to drive innovation, including “*embracing telemedicine like never before*”.⁶⁰

Telemedicine, smartphone apps and wearable sensors are all examples of technologies likely to be routinely used in the

healthcare sector in the years to come. Progress towards this has accelerated during the COVID-19 pandemic, with 99% of England’s GP practices now activating remote consultation platforms.⁶¹

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⁶⁰ <https://www.gov.uk/government/speeches/building-the-best-health-system-in-the-world>.

⁶¹ <https://www.gov.uk/government/publications/trend-deck-2021-technology>.

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