Bird & Bird

Discovering the World of Telemedicine

An International Overview of the Regulatory Legislation

May 2025

Contents

Introduction

Background

Telemedicine has been available to healthcare providers for several years. However, it was not until the arrival of the COVID-19 pandemic in 2020, and the need for social distancing and isolating became paramount, that the field of telemedicine came to the forefront. The pandemic, coupled with the existing burden on the healthcare system forced rapid implementation of telemedicine in day-to-day practice, resulting in the use of technology to provide healthcare becoming essential.

Given the necessity of providing healthcare services at a distance, several countries 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 has left a lasting impact.

Telemedicine is a way to provide healthcare using information technology and telecommunications to overcome distance, involving at least two people, 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 to 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, however:

- Healthcare practitioners must comply with prescribing / dispensing regulations and professional guidelines when providing telehealth services; and
- The availability of telehealth services for some patients can be limited by access to government rebates.

From 1 January 2022, certain telehealth services which had been introduced on a temporary basis in response to the COVID-19 pandemic, became a permanent part of Medicare, Australia's universal healthcare program.

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. However, healthcare practitioners must comply with guidelines developed by the Medical Board of Australia under section 39 of the National Law. We address these guidelines in further detail in response to question 2 below.

The Commonwealth Government's National Digital Health Strategy (2023 – 2028) identifies telehealth and virtual care as key pillars for improving equitable access to health services. The National Digital Health Strategy Delivery Road Map identifies flexible models of care as a priority for policy development, particularly the adoption of digital solutions that enable consumers and healthcare providers to engage emails, messaging, push notifications, telehealth, video conferencing, remote monitoring, home monitoring devices and clinical information sharing.

Electronic prescribing (**E-Prescribing**) was introduced by the Federal Government in 2019 as an alternative to conventional paper-based prescriptions. All States and Territories permit electronic prescriptions through amendments to prescribing regulations in each jurisdiction.

Technologies that enable telemedicine consultations are only regulated to the extent that they meet the definition of a medical device under the *Therapeutic Goods Act 1989* (Cth). In general, communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services, are excluded from regulation under the *Therapeutic Goods (Excluded Goods) Determination 2018*. However, the software may be regulated as a medical device if it also:

- provides a diagnosis or screen for a disease or condition;
- monitors the state or progression of a disease or condition, or the parameters of a person with a disease or condition;
- specifies or recommends a treatment or intervention; or
- provides therapy through the provision of information.

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

Revised guidelines issued in May 2023 by the Medical Board of Australia endorse telemedicine as playing an important role in healthcare in Australia. The guidelines emphasise that health practitioners must follow the "Good Medical Practice: A Code of Conduct for Doctors in Australia" and ensure that the standard of care provided in a telemedicine consultation and as far as possible meets the same standard as provided in an in-person consultation.

Under these guidelines prescribing or providing healthcare for a patient without a real-time direct consultation, whether in-person, via video or telephone, is deemed to not be good practice and is not supported by the Medical Board of Australia.

Guidance issued and last revised in February 2025 by the Royal Australian College of General Practitioners (**RACGP**) provides guidance for general practitioners (**GPs**) in relation to the appropriate use of telephone and video consultations. In particular, the guidelines for GPs recommend that telemedicine services are used where the GP has an established relationship with a patient, as opposed to on-demand services for new patients.

Both of these guidelines place the onus on healthcare professionals to determine if it is appropriate to provide telemedicine services in certain circumstances.

In Australia there has recently been increased media scrutiny of single-issue telehealth providers that supply telemedicine services to patients in certain areas, such as weight-loss or medicinal marijuana. However, at this stage additional restrictions on healthcare practitioners have not been introduced to address these concerns.

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 healthcare professionals.

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 introduced in response to the COVID-19 pandemic to have now largely been permanently retained with some changes (for example, the introduction of a new extended telephone consultation item for patients in rural and remote communities). These items mean that Medicare eligible Australians can access video and phone services for consultations with GPs, medical practitioners, specialists, consultant physicians, nurse practitioners, participating midwives, allied health providers and dental practitioners in the practice of oral and maxillofacial surgery. In most cases the healthcare provider must have had an existing clinical relationship with the patient in order for the patient to be able to access a Medicare rebate.

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. It is noted that this ‘established clinical relationship’ requirement only applies to MBS telemedicine services—the guidelines issued by the Medical Board of Australia allow for a patient to consult a doctor for the first time using telehealth on a privately funded basis.

There are several exemptions to the ‘established clinical relationship’ requirement under the Health Insurance (Section 3C General Medical Services – Telehealth and Telephone Attendances) Determination 2021). Under these exemptions, government funded telemedicine services can be provided (regardless of whether there is an existing clinical relationship) for:

- homeless people;
- urgent after- hours services;
- children under 12 months old;
- patients of Aboriginal Medical Health Services;
- mental health and eating disorder planning and treatment services;

- people living in areas where movement is restricted in response to a COVID-19-related public health order; and
- people living in a natural disaster affected area;

There are additional exemptions for services relating to patients subject to Public Health Orders, specific GP mental health services, nicotine cessation and sexual and reproductive health services. All of these services are available to all patients by telehealth.

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 or, misleading, deceptive or likely to mislead or decieve; 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 $60,000 for individuals and $120,000 for corporations.

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

As noted above, the temporary MBS items introduced in response to the COVID-19 pandemic have largely now been made permanent. Eligible Australians can access reimbursement for telemedicine that fall within the scope of these items.

Medicare funding is also 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 telemedicine 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?*

On 22 April 2024 the Australian government announced an investment of $5 million into further research into how telehealth can be deployed effectively, following the increasing adoption of telehealth services after the COVID-19 pandemic. This funding has targeted six research projects being undertaken in Victoria, New South Wales and the Australian Capital Territory.

The Federal Government Department of Health's 2022-23 Portfolio Budget Statement described the introduction of permanent telemedicine as "th*e most significant structural reform to Medicare since it*

began." This followed an allocation in the 2021-22 Budget of over $114 million to fund telemedicine until the end of 2022.

As part of the Federal Government's 2023-24 Budget, the Federal Government provided $5.9 million to enable access to longer telemedicine consultations with GPs through the MBS from 1 November 2023, with reduced administration for practices. The Federal Government also tripled bulk billing incentives to $3.5 billion to cover common GP consultations including telemedicine. This was the largest increase to the bulk billing incentive in the 40-year history of Medicare.

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Belgium

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

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 for reimbursement of healthcare services, 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 practices[1]. 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?

Video consultations are reimbursed, but telephone consultations are not reimbursed.

Also, specific conditions must be met for telemedicine reimbursement:

1. The general conditions (see question 2) should be complied with.
2. A remote consultation can only occur with the patient's consent and the physician's agreement.
3. The physician must have access to the electronic patient file during the remote consultation and update the data thereof (such as 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).
4. The physician or their staff records the time of the request in the patient's file and makes it available to oversight bodies.
5. Remote consultations occur synchronously through the video connection between the physician and the patient.
6. Specifically for video consultations, communication must occur through a tool with end-to-end encryption, Communication should not be stored on the platform used, and 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.

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.

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 603, 2024 draft edition). On 7 September 2024, the Ministry of Commerce, NHC, and National Medical Products Administration ("**NMPA**") jointly issued a notice announcing the pilot programs for foreign investment in the healthcare **sector**. According to the notice, wholly foreign-owned hospitals can now be established in selected provinces/cities in China. However, iIt 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. The Supervision Rules also explicitly interdicts the generation of prescriptions by automated AI, mandating that such directives emanate solely from the treating physician (while allowing AI to fulfil an auxiliary role in diagnostic support), prioritising physician accountability and patient safety in telemedicine.

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 categorised 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) A medical institution (the inviting party) can directly invite another medical institution (the invited party) to provide telemedicine services; (2) The inviting party or third-party institutions may set up a telemedicine services platform and the invited party registers on this platform as an institution.

The internet-based diagnosis and treatment activities must be provided by medical institutions that have obtained a *Medical Institution Practicing License*. In addition, the internet-based diagnosis and treatment 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 a 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.

The Internet hospital is required to 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 offering telemedicine services must secure authorization from the relevant health administrative authority and maintain clinical specialties aligned with the scope of services provided. They are required to employ qualified technical professionals and possess purpose-built medical equipment and infrastructure. For telemedicine delivered directly between institutions or facilitated via a third-party platform, a formal telemedicine cooperation agreement is mandatory.

Medical institutions providing internet-based diagnosis and treatment and Internet hospital services shall ensure that the servers of Internet hospital 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. Medical health related information) is classified as sensitive personal information and must be collected in accordance with the PIPL and 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 October 2020, the NHSA 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.

The National Healthcare Security Administration ("**NHSA**") in a 2023 response further specified that "Internet +" medical services, when equivalent in scope to offline treatments covered by insurance and adhering to the pricing standards of public medical institutions, may be incorporated into the medical insurance payment framework. In scenario of the telemedicine services, patients pay according to the project prices established by the invited party delivering the service. For telemedicine services involving multiple entities - such as the inviting party, the invited party, and technical support providers - or different departments within the same entity, the involved parties independently negotiate and determine their fee distribution arrangements.

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. The State Council's "Healthy China 2030" Planning Outline mandates the standardization and promotion of "Internet + Healthcare" services, encouraging innovation in internet-based healthcare models and the continuous development of integrated national health information services that span the entire life cycle - encompassing prevention, treatment, rehabilitation, and self-health management.

According to the China Internet Network Information Center (CNNIC), as of December 2024, China's internet healthcare user base reached 418 million – a 3.72 million rise from December 2023 – comprising 37.7% of the nation's internet users. In June 2024, the State Council issued the 2024 Key Tasks for Deepening Medical and Healthcare System Reform, prioritizing cohesive development and regulation across medical insurance, healthcare, and pharmaceuticals. The advent of innovative tools like online insurance-backed drug purchases, sophisticated medical models, and AI, alongside a surge in operational

data, is set to hasten the adoption of precise regulatory and implementation directives. This period marks a critical inflection point for securing the enduring sustainability of China's telemedicine ecosystem.

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Finland

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

The Finnish legislation does not provide specific local regulations regarding telemedicine but the existing legislation covering the practice of healthcare in Finland does generally apply also to Telemedicine.

Telemedicine has been recognised in the Finnish Act on the Supervision of Social Welfare and Health Care (741/2023), where the definition of healthcare service specifically includes, among other things, measures taken to determine the patient's state of health, to restore or maintain their health, medical or dental care, or other treatments, that are performed by healthcare professionals as a mobile service, remotely or digitally.

Other relevant legislation that should be taken into account when providing services through Telemedicine includes the applicable EU legislation, the Act on the Status and Rights of Patients (785/1992), the Act on Health Care Professionals (559/1994), the Act on the Electronic Processing of Client Data in Healthcare and Social Welfare (703/2023), and the Act on Strong Electronic Identification and Electronic Trust Services (617/2009).

Further, the Ministry of Social Affairs and Health of Finland has previously outlined in its guidance (3756/2015) that Telemedicine services, i.e. remote healthcare services provided online, are generally comparable to traditional healthcare consultations. The Finnish National Supervisory Authority for Welfare and Health (*Valvira*) gives guidance on their website regarding Telemedicine services.[22] In addition, the Finnish Medical Association (*FMA*), a professional organisation with doctors practising in Finland as members, has provided guidelines regarding the advertising of healthcare services, which may also be applied to Telemedicine.

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

Yes. Similar rules apply to healthcare professionals when offering both healthcare in person and through Telemedicine. Specific statutory requirements as well as guidelines are applied to professionals providing services through Telemedicine.

The Act on the Supervision of Social Welfare and Health Care includes certain provisions regarding the conditions for providing social and healthcare services. The right to provide such services requires that the provider is registered in the national register maintained by *Valvira*. In addition, healthcare professionals must employ generally accepted, empirically justified methods in their professional activities, in accordance with their training, which should be continually supplemented. Each healthcare professional must weigh the benefits of their professional activity to the patient and its possible hazards.

Information given by *Valvira* on their website emphasises that the healthcare professionals providing Telemedicine services are always responsible for the services they provide and for the appropriateness of the provided service. Careful individual evaluation is required to assess which services can be provided through Telemedicine and the client should have the option for an in-person visit or directions to another care facility if needed. The use of Telemedicine services should include reliable identification of the client. The systems used for providing remote services and the methods used for client identification must comply with confidentiality, data protection, and information security regulations.

[2] https://valvira.fi/sosiaali-ja-terveydenhuolto/etapalvelut (in Finnish, accessed on 3 March 2025).

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 Finland, Telemedicine services are provided through various ways by healthcare professionals. On their website *Valvira* has defined Telemedicine services as real-time digital services based on human interaction, where at least one party is located in a different place from another. Part of the care delivered remotely may be based on information and documents transmitted online, e.g., via video or on a smartphone.

Telemedicine services typically include chat-services or video consultations via app or other remote appointment portals. They may also include digital solutions regarding communication between clients or family members (e.g. digital peer support groups), self-monitoring (e.g. symptom diaries), and collecting health and well-being data of clients (e.g. e-forms). Digital tools for providing Telemedicine services for healthcare professionals may also include new types of remote client-provider services such as electronic services and monitoring which have replaced traditional office visits and phone calls, as well as support tools for decision-making, guidance and service delivery.[3]

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

Advertising of healthcare including Telemedicine services is governed by the general provisions of the Finnish Consumer Protection Act (38/1978). In addition, the advertising of healthcare and Telemedicine services is governed by self-regulatory guidelines by professional organisations like the FMA.

Advertising should generally give consumers sufficient information so that they can make informed decisions. Such information shall not be omitted in advertising which, taking into account the factual context, is relevant and which the consumer needs to make a purchasing decision or other decision relating to a consumer good or service, and the omission of which is likely to lead to the consumer making a decision that they would not have made with sufficient information. Any information necessary for consumer health and safety must always be provided.

The Finnish Consumer Ombudsman enforces compliance with consumer protection legislation in Finland and has specifically given guidelines on obligations regarding the presentation of prices and appointment booking for private healthcare services (10/2023). The price of the provided service must be disclosed when the consumer is buying or booking the service via the website. Price means the total price of the service or the basis on which the price is determined, including service fee and other elements constituting the total price that the consumer must pay in order to receive the service of their choice.

The *FMA*'s Marketing guidelines for doctors and medical services[4] apply to doctors, dentists, and healthcare companies subject to the registration within the meaning of the Act on the Supervision of Social Welfare and Health Care. The guidelines are applied regardless of the media used thus including Telemedicine. The advertising must offer clients right and reliable image of the services that healthcare professionals and healthcare companies provide. It must be truthful, appropriate, reliable and in line with good practice, and not intimidating in terms of illness or severity of symptoms. The advertising must also give a genuine representation of the importance of the service provided, and consumers and patients must have available to them the information on the risks involved in medical procedures. In addition, it must be clearly identifiable when a doctor, a medical service provider or a person representing a medical service provider is acting in an expertise role as a doctor or a representative of a medical service provider when advertising through internet or social media in particular.

[3] Impact of digital services in health and social care - Publications of the Government's analysis, assessment and research activities 2023:52, https://urn.fi/URN:ISBN:978-952-383-059-2.
[4] Lääkäriliitto: "Lääkäreitä ja lääkärinpalveluja koskevat markkinointiohjeet", latest specification on 15 May 2024.

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

The Social Insurance Institution of Finland (*Kela*) is the primary institution regarding reimbursements for social and healthcare services in Finland in accordance with the Finnish Health Insurance Act (1224/2004). Reimbursements apply to costs arising from services in both public and private sector. This also applies to Telemedicine services, for example, when the service is provided by telephone or via chat or video connection. In order for the Telemedicine service to be reimbursed, the patient must be reliably identified at the time of the contact and the medical records must be properly written. At the moment, the reimbursement rates are generally lower for visits through phone or chat service as well as video service when compared to regular visits.

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

The growing interest for Telemedicine and digitalisation of health services has been present in Finland, and the digitalisation of health services started to increase especially during the corona pandemic. For example, it has been highlighted that Telemedicine services (such as chat-service consultations with a professional) have been one factor in speeding up the access to treatment for patients.

A study of the Finnish Government from 2023[5] has outlined certain understandings of the impact of digital services on social and healthcare. According to the study, digital services and their impact are not well acknowledged in Finnish legislation and areas of improvement still exist regarding e.g., funding of digital services.

The latest Government Programme[6] has outlined digitalisation to strengthen health and social services and the availability of such services as one of the main objectives of the programme. New digital operating models are promoted through the programme and the digital services are planned to be made the primary option for clients for whom it is viable. In addition, the use of Artificial Intelligence (AI) in healthcare and social welfare is also planned to be used in operations such as self-management of health and self-care as well as in service and care provision. The digitalisation will be supported through national legislative measures including changes required by the new EU legislation, such as the European Health Data Space (EHDS) Regulation.

Action for promoting digitalisation of health services and Telemedicine has also been taken through other ways. For instance, the Finnish Ministry of Social Affairs and Health has drafted a strategy for years 2023-2025[7] regarding the digitalisation and information management in healthcare and social welfare. The main purpose of the digitalisation strategy is to support wellbeing services counties as they work to boost the effectiveness of healthcare and social welfare services. Digital services are described as a priority in all areas of wellbeing services counties, for services where it is appropriate or for customers. For example, the workload of social and healthcare staff has been reduced by making better use of information and by introducing advanced technological solutions.

[5] Impact of digital services in health and social care - Publications of the Government's analysis, assessment and research activities 2023:52, https://urn.fi/URN:ISBN:978-952-383-059-2.
[6] A strong and committed Finland: Programme of Prime Minister Petteri Orpo's Government, 20 June 2023. Publications of the Finnish Government 2023:60.
[7] Strategy for digitalisation and information management in healthcare and social welfare. Publications of the Ministry of Social Affairs and Health 2024:1.

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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 French Public Health Code ("**PHC**").

Telemedicine was defined and regulated for the first time by Law no 2009-879 of 21 July 2009 ("loi HPST")[8] that introduced article L. 6316-1 of the PHC, followed by articles R. 6316-1 and seq. of the PHC[9] that define the five different categories of activity covered by telemedicine, along with their implementation conditions.

Although defined and authorized by law, it took several years for telemedicine to be put into practice, after several experimentations were carried out to secure reimbursement by the French health insurance scheme ("*Assurance maladie*").

Teleconsultation, tele-expertise and telemonitoring are now reimbursable, subject to certain conditions set out in the national agreement with the French health insurance scheme.

In 2019, France took a new step in the development of telemedicine with Law no 2019-774 of 24 July 2019[10] that introduced two new concepts: telehealth ("*télésanté*") and telecare ("*télésoin*") with telehealth being the combination of both telemedicine and telecare (see question 3).

The area of telemedicine has experienced spectacular growth due to the COVID-19 pandemic, which has led to a rapid development of the regulation, notably by facilitating the conditions for the practice of telemedicine and by accelerating the adoption of measures for the implementation of telecare.

Finally, the LFSS for 2023[11] of 23 December 2022, introduced a new accreditation system requiring companies providing teleconsultation services to be accredited by the government for their teleconsultations to be reimbursed by the French health insurance scheme. This measure aims to ensure quality and transparency in teleconsultation services. This accreditation procedure is detailed in Decree no. 2024-164 of 29 February 2024[12]. The High authority of Health (*Haute Autorité de Santé* - HAS) published a reference framework[13] of good professional practices relating to the quality and accessibility of teleconsultations and of proposing methods for evaluating teleconsultation companies.

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

In France, healthcare professionals are organised in three categories:

- **Medical professionals:** physicians, midwives, and dental surgeons (articles L. 4111-1 to L. 4163-10 of the PHC);
- **Pharmacists** (articles L. 4211-1 to L. 4252-3 of the PHC);

[8] Law no 2009-879 of 21 July 2009 on hospital reform and patients, health and territories
[9] Decree no 2010-1229 of 19 October 2010 on telemedicine
[10] Law no 2019-774 of 24 July 2019 on the organisation and transformation of the healthcare system
[11] Social security financing law no. 2022-1616 of 2023 of 23 December 2022
[12] Decree no. 2024-164 of 29 February 2024 on teleconsultation companies
[13] Guidelines for good professional practice, applicable to teleconsultation companies - Published on Dec. 22, 2023

- **Paramedical professionals** (nurses, physiotherapists, podiatrists, ergotherapists and psychomotor therapists, orthophonists and orthoptists, medical electroradiology manipulators and medical laboratory technicians, audioprosthetists, opticians, orthoprosthetists and orthotists, epithesists, dieticians), **nurses' aid, childcare assistants, dental assistants and ambulance drivers** (articles L. 4311-1 to L. 4394-5 of the 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 the PHC);
- **Telecare,** for activities performed remotely by a pharmacist or by a paramedical professional (article L. 6316-2 of the 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 ("*Télésanté*") 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 the PHC defines telemedicine as a remote medical practice 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 emergency[14]. 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

Articles R. 6316-2 and seq. of the PHC define the conditions for the practice of telehealth, and specify in particular that any telemedicine or telecare activity must be 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 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 (see question 6). There are also additional conditions exist for the reimbursement of teleconsultation, tele-expertise and telemonitoring by the French health insurance scheme (see question 5).

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 is a form of medical practice like any other, and therefore all the deontological rules that apply to healthcare professional are relevant.

It must be emphasised that, pursuant to article R. 4127-19 of the PHC, "*medicine should not be practiced as a business*". Also, until recently, any direct or indirect advertising of the practice of medicine was prohibited. However, the information and advertising rules applicable to physicians have been amended and softened by Decree no 2020-1662 of 22 December 2020[15], which abolished the general advertising ban and replaced it with a principle of free communication within a specific framework. While physicians are now free to communicate more about their activities, including through a website, they are prohibited, for example, from relying on the testimony of third parties and from making comparisons with other doctors or establishments (article R. 4127-19-1 of the PHC).

[14] Decree no 2021-707 and Order of 3 June 2021 of the Minister of Health, issued after the opinion of the High Health Authority
[15] Decree no 2020-1662 of 22 December 2020 amending the code of ethics of physicians and relating to their professional communication

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

Since 15 September 2018, teleconsultations are reimbursed by the French health insurance scheme[16]. Since 10 February 2019, tele-expertise procedures are also reimbursed[17]. Subsequently, reimbursement of telemonitoring was introduced in 2022 by the LFSS for 2022[18].

There are several conditions that must be met in order to be reimbursed by health insurance in France.

1. **For teleconsultations**

(1) Teleconsultation must be part of the "coordinated care plan" ("*parcours de soins*"). Therefore, a teleconsultations= with a specialist must occur after the patient has been referred by his treating physician ("*médecin traitant*").

However, exceptions are provided notably in the following situations:

- The patient is under 16 years old;
- emergency situations;
- the physician is a direct access specialist (gynaecology, ophthalmology, stomatology, oral or maxillofacial surgery, psychiatry or neuropsychiatry and paediatrics);
- the patient does not have a treating physician, or the treating physician is not available within a timeframe compatible with the patient's state of health;
- for prisoners;
- for persons living in institutions for the dependent elderly people or in institutions that house or accompany 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, if necessary, to organise a physical consultation following the teleconsultation.

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 there is no coordinated territorial organisation;
- 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, the French government temporarily waived certain requirements and fully reimbursed teleconsultations to encourage their use, but this exceptional measure ended on 1 October 2022, restoring the standard 70% reimbursement rate, except for specific exemptions.

A Charter[19] of good practice for teleconsultation has also been elaborated by the national health insurance scheme and physicians. The aim of this charter is to inform physicians of the essential recommendations and obligations with regard to the practice of teleconsultation. The good practices described should be followed to benefit from the reimbursement of teleconsultation by the national health insurance scheme.

The LFSS for 2024[20] introduced several measures to better regulate the prescription of medical leaves, with specific measures to ensure that the costs involved are justified. It reinforces the monitoring of the

[16] Amendment no 6 of 10 August 2018 of the national medical convention
[17] Order of 16 August 2018 completing the amendment no 6 of the national medical convention
[18] Article 36 of the LFSS for 2022
[19] Charter of good practices for teleconsultation of the national health insurance scheme
[20] Articles 63 and 65 of the Social security financing law for 2024

medical leaves prescribed by health centres and teleconsultation companies and limits the duration of medical leaves prescribed by teleconsultation to 3 days.

It also restricts the reimbursement of prescriptions issued during teleconsultations and telehealth activities to those that have been discussed through oral video or telephone communication between the prescriber and the patient.

The LFSS for 2025[21] of 28 February 2025 prohibits any online service provider from setting up a platform to provide telemedicine services that prescribe or renew medical leave. In addition, telemedicine services provided by a health professional whose principal place of practice is abroad may not result in the prescription or renewal of a medical leave, regardless of its duration.

2. For telemonitoring

The LFSS for 2022 approved telemonitoring for reimbursement (articles L.162-48 to L.162-57 of the French social security code)[22]. All remote medical monitoring solutions are potentially eligible for registration on the list of reimbursable telemonitoring activities. However, as of 1 July 2023, only pathologies that have received a favorable opinion from the HAS and have been published by order (heart failure, renal failure, respiratory insufficiency, diabetes, oncology, cardiac arrhythmia) are eligible for reimbursement. In the future, other pathologies may be covered and reimbursed following a favorable opinion from the HAS.

Before being generalised (within the above limits), the reimbursement of telemonitoring activities was initiated under the national pilot program ETAPES ("*Experiments in Telemedicine for the Improvement of Health Pathways*") (Articles 51 and 54 of the LFSS for 2018). The telemonitoring experiments covered five pathologies (heart failure, renal failure, respiratory insufficiency, diabetes, implantable cardiac prostheses) and ended on 1 July 2023.

Healthcare professionals who practice remote monitoring must declare their activity to the competent Regional Health Agency (*Agence régionale de santé* - ARS) in order to be reimbursed by the French health insurance scheme, subject to certain conditions:

- The remote medical monitoring activities must be included in the list mentioned in article L. 162-52 of the French social security code;
- They must be provided by a remote medical monitoring operator with a receipt from the ARS;
- The digital device used for the medical monitoring must be provided by the operator to the patient.

In addition, companies operating digital medical devices must comply with the security and interoperability obligations laid down by the Digital Health Agency (*Agence du numérique en santé* - ANS) and obtain a certificate of compliance with the applicable standard (interoperability and security standard).

3. For tele-expertise

Tele-expertise is reimbursed by the French social security scheme for all patients, regardless of their condition. The requesting healthcare professional assesses the relevance of the consultation, and while the patient does not need to be known to the expert consulted, the patient must be informed of the procedure and give prior consent. Tele expertise is not billed to the patient, but is reimbursed directly by the French health insurance scheme to the healthcare professionals involved. Both the requesting professional (currently limited to physicians, midwives, speech therapists and orthoptists) and the consulting physician or midwife receive payment.

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 difficulties in accessing care in certain areas, the lack of medical staff, and the limits encountered by physicians in isolated establishments. It was also seen as a means of saving on health insurance

[21] Article 54 of the Social security financing law for 2025
[22] Article 36 of the LFSS for 2022 was implemented by two decrees of 30 December 2022: i) 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, and ii) Decree No. 2022-1769 of 30 December 2022v providing clarification regarding the content of the declaration of remote medical monitoring activities to the ARS.

costs, 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.

For this reason, France has been encouraging and facilitating the use of telemedicine, through different ways, in particular by implementing a supportive strategy aimed at ensuring confidence in telemedicine (e.g. publication of HAS recommendations). Thus, the HAS has been fully involved in the process of the development of telemedicine and has regularly published guidelines for patients[23] and healthcare professionals[24]. These guides are real "instructions for use" as they describe, for each teleconsultation, tele-expertise and telecare procedure, the conditions required for a safe 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 providing a very clear framework, France has implemented a strong reimbursement scheme that has contributed to the development and expansion of telehealth in France (described above under question 5).

Furthermore, financial has been made available to practitioners willing to equip themselves with the tools and technical solutions necessary for telehealth practice. In particular, through flat-rate annual financial aid granted by the French health insurance scheme for video transmission equipment and related connected medical devices[25], but also through programs put in place by some of the regions of France most affected by limited medical facilities, which offer financial aids to make access to telemedicine easier for the cities and healthcare professionals concerned.

[23] Comment se faire soigner à distance: Téléconsultation et télésoin (HAS, May 2021)
[24] Qualité et sécurité des actes de téléconsultation et de téléexpertise: Guide de bonnes pratiques (HAS, May 2019) Téléconsultation 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)
[25] Order of 16 August 2018 completing the amendment no 6 of the national medical convention

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Germany

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

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

Telemedicinal 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 (*Heilmittelwerbegesetz* – "**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 previously being generally prohibited, in 2018 the MBO-Ä was adapted to allow exclusive telemedicinal consultations or treatments in **individual cases** (i) 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, the consultation, treatment and documentation are carried out, and (ii) under the condition that the patient is sufficiently informed about the particularities of the exclusive consultation and treatment via telecommunication media (see Sec. 7(4) MBO-Ä).

Further important changes were implemented by the Digital Act (*Digital-Gesetz* – *"***DigiG***"*) of 2023, particularly with regard to video consultations. For example, the DigiG introduced Sec. 24(8) Physician's Authorization Ordinance (*Ärzte-Zulassungsverordnung* – "**Ärzte-ZV**"), which enables physicians to conduct video consultations outside of their registered office. Thus, it is now generally permissible for physicians to provide services from their home office. However, this is subject to the condition that the obligations to offer minimum office hours and open office hours at the registered office are fulfilled (see Sec. 19a(1) sentences 2 and 3 Ärzte-ZV). Thus, purely remote practices are currently not admissible. In addition, the DigiG also lifted the legal restriction of the provision of video consultation hours to 30% of the services provided to the respective service provider per quarter in accordance with Sec. 87(2a) sentence 30 SGB V, thereby allowing for a more flexible and frequent provision of telemedicine 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?

In principle, all kind of telemedicinal services can be offered in Germany. However, as outlined above (cf. Q2), 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 telemedicinal 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 telemedicinal services, a regular in-person visit should be recommended instead.

Providing telemedicine services in a cross-border context is also generally permissible. In fact, as some European jurisdictions give more freedom to provide remote treatments than Germany, the offers of cross-border telemedicine services are increasing.

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

The advertisement for telemedicine services is a hotly debated and litigated topic in Germany. The relevant provision, Sec. 9 HWG, generally prohibits the advertisement for telemedicine services unless, according to generally accepted professional standards, personal medical contact with the person to be treated is not required.

In a landmark decision of 2021, the Federal Court of Justice (*Bundesgerichtshof* - "**BGH**") clarified that the permissibility of *providing* remote treatments must be distinguished from the permissibility of *advertising* them [26]. While the conduct of the remote treatment might be subject to the local professional laws of the physician´s place of practice, the permissibility of advertising must be assessed based on generally accepted medical standards in Germany as rooted in Sec. 630a (2) BGB, which defines the standard of care expected in medical treatment which is not necessarily congruent with the requirements of professional law. This leads to the – rather awkward – situation that not every permissible telemedicine service can also be advertised in Germany.

Following this precedent, several German courts have further defined the scope of these professional standards. The Higher Regional Courts of Munich (in 2023)[27] and Cologne (in 2022)[28] ruled that advertising for telemedical treatments of erectile dysfunction, hair loss, and premature ejaculation is unlawful if there is no personal doctor-patient contact. The courts found that in these cases, a physical examination is generally required and that therefore, advertising for remote treatments that only require answering an online questionnaire in order obtain a prescription for such medical conditions did not comply with the accepted German standards and is therefore inadmissible. The Higher Regional Court of Hamburg (in 2023)[29] found that offering follow-up prescriptions via telemedicine without prior in-person treatment does not comply with professional standards. Moreover, the Higher Regional Court of Karlsruhe (in 2022)[30] prohibited the general advertisement for remote treatment, finding that any limitations must be clearly communicated in the advertisement. Importantly, it also clarified that the burden of proof for compliance with the accepted professional standards rests with the advertiser.

Hence, the courts have taken a rather strict approach to the advertising of remote treatments. However, the Regional Court of Hamburg (in 2023)[31] clarified that the advertising of remote services relating to contraceptives – even though being subject to prescription – is permissible. The restrictions on advertising remote treatments pursuant to Sec. 9 HWG only apply to the diagnosis and treatment of medical conditions, not the areas of care and prevention. Pregnancy and infertility cannot be considered a disease.

In summary, while advertising for telemedicine is possible, due to the constantly evolving jurisprudence, telemedicine providers should carefully asses legal compliance on a case-by-case basis before advertising any telemedicine services.

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

The regulations for the remuneration of telemedicine services for statutory health insurance patients are set out in Annexes 31-31c of the Federal Collective Agreement for Physicians (*Bundesmantelvertrag*-Ärzte – "**BMV-Ä**"). Annex 31 defines the requirements and framework conditions for the provision and remuneration of telemedicine services. According to Annex 31b, video consultations performed by

[26] Federal Court of Justice, judgment of 9 December. 2021 (I ZR 146/20 MMR 2022, 672).
[27] Higher Regional Court Munich, judgment of 27 April .2023 (29 U 7344/21).
[28] Higher Regional Court Cologne, judgment of 10 June. 2010 (6 U 204/21).
[29] Higher Regional Court Hamburg, judgment of 15 August 2023 (5 U 93/22).
[30] Higher Regional Court Karlsruhe, judgment of 22December 2022 (4 U 262/22).
[31] Regional Court Hamburg, order of 02 January 2023 (406 HKO 114/22).

physicians are only reimbursable if done using a certified video service provider. Moreover, Annex 31c sets out the specific requirements for ensuring the quality of care of telemedicine services, which must be met in order to be reimbursed. Thus, the BMV-Ä lays down the framework conditions for reimbursable telemedical services, whereas the specific amount is determined on basis the uniform fee schedule, i.e., equally to in-person consultations/treatments (*Einheitliche Bewertungsmaßstab* – "**EBM**").

In general, telemedical services are increasingly reimbursed by German health insurance companies. In the statutory health insurance system (GKV), many telemedicine services are covered in the EBM or in special contracts between insurers and providers. However, for privately insured patients, reimbursement depends on the individual insurance policy, as the German fee schedule for physicians (*Gebührenordnung-Ärzte* – "**GOÄ**") does not yet include specific billing codes for telemedicine services.

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

The expansion of reimbursement options by the DigiG and the increased openness to telemedicine services in the broader public are promoting the digitalization of healthcare, encouraging healthcare providers to adopt digital tools. The German legislator further strengthened investment opportunities in the area of digital health services for public institutions. According to Sec. 68a et. seq. SGB V, statutory insurance funds and associations of statutory health insurance are entitled to promote digital innovations by (partially) covering costs. In addition, there are also fiscal incentives such as funding programs under the supervision of the Federal Ministry of Health (*Bundesministerium für Gesundheit* – "**BMG**") for healthcare providers to implement digital technologies and integrate telemedicine into their practices.

Also the Digital Healthcare Act (*Digitale-Versorgungs-Gesetz* – "**DVG**"), which came into force at the beginning of 2020, aims to advance the digitalisation of German healthcare. Among other things, physicians are now able to prescribe digital health apps to their patients in the same way as medicinal products and regular medical devices, at the expense of health insurers. However, such digital health applications (*Digitale Gesundheitsanwendung* – "**DiGA**") operate in a highly regulated area. Already at the design stage, attention must be paid not only to the basic requirements of medical device law, but also to the protection of particularly sensitive patient data. There are also special requirements for the distribution, especially with regard to 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. MCHK was established to exercise regulatory and disciplinary powers for doctors while nurses and allied healthcare professions in Hong Kong are subject to other councils including The Nursing Council of Hong Kong and the Supplementary Medical Professions Council. 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. No specific guidelines on telemedicine have been issued for nurses and allied healthcare professions in Hong Kong but they should continue to observe their respective code of professional conduct when providing services through telemedicine.

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

Yes. Telemedicine service is widely used in both the public and private healthcare systems.

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 provides, amongst others, telehealth consultation services for suitable patients.

A rise in demand and popularity of telemedicine service in the private healthcare market was also observed. Private hospitals and medical groups, as well as insurance companies, have launched and continue to operate 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. The HA, for example, provide telehealth consultation services to follow-up patients with stable condition and, do not require physical examination during consultations, and are physically in Hong Kong[32].

[32] FAQs, HA Go Website.

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 whom 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) and the Pharmacy and Poisons Ordinance (Cap. 138).

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.[33]

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.[34]

Private healthcare institutions and medical groups should also comply with the Trade Descriptions Ordinance (Cap. 362) by ensuring that any trade descriptions given with respect to their telemedicine services are true and not misleading.

[33] Article 1.1.5, Code of Professional Conduct (English version) (mchk.org.hk)
[34] Article 5.2.2, Code of Professional Conduct (English version) (mchk.org.hk)

From a PDPO perspective, healthcare 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.[35] Consent is defined to include "an indication of no objection to the use or provision"[36] 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 healthcare 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.[37]

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

No. There are currently no incentives promoting telemedicine or digitaalisation of health services. 19For long-term development, as part of its Strategic Plan 2022-2027 HA continues to formulate strategies for developing smart hospitals and smart care, with one of the goals being to build up telemedicine and telecare as an adjunct to existing public healthcare service.[38]

[35] Sections 35E and 35K, Personal Data (Privacy) Ordinance, Cap.486, Law of Hong Kong
[36] Sections 35A, Personal Data (Privacy) Ordinance, Cap.486, Law of Hong Kong
[37] Article 14, Code of Professional Conduct (English version) (mchk.org.hk)
[38] Hospital Authority Strategic Plan 2022-2027 Overview (ha.org.hk)

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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 17, 2014, the MOH adopted national guidelines on telemedicine[39] (hereinafter the "**Guidelines**"). The document provides several principles and rules applicable to telemedicine;
- On April 13, 2020, the ISS published the Interim provisions on telemedicine healthcare services during COVID-19 health emergency[40]. 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 10, 2020, the ISS published interim guidance on telemedicine health services for Pediatrics during and beyond COVID-19 pandemic[41]. The document provides 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 December 17, 2020, the Conference State-Regions adopted the document issued by the MOH.
- On October 27, 2020, concerning "National Indication for the providing of telemedicine services"[42] ("**National Indication**"). The document provides practical indications related to the management and delivery of health services through telemedicine.
- On November 18, 2021, the Conference State-Regions issued guidance on the actual implementation of the National Indications.
- In 2022, followed a few decrees from the Italian Ministry of Health concerning guidelines covering certain specific aspects of telemedicine (e.g. service level, criteria for healthcare home assistance, presentation of telemedicine service at regional level etc).

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

[39] See: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2129_allegato.pdf

[40] 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

[41] 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

[42] 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

regulations, ethics code, order[43]and bioethics guidelines[44], 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 activities[45].

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-examination[46], teleconsultation[47], health-medical teleconsultation (or tele- cooperation[48]), tele-healthcare[49], tele-reporting[5051].

- **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;

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[43] 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)*".

[44] Pursuant to Section 3, p. 10, National Indication.

[45] Pursuant to Section 3, p. 10, National Indication.

[46] Pursuant to Section 2.3.1, paragraph 3, of the Guideline.

[47] Pursuant to Section 2.3.1, paragraph 4, of the Guideline.

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

[49] Pursuant to National Indication, page 7, section "*Teleassistenza da parte di professioni sanitarie (Infermiere/fisioterapista/ logopedista etc)*"

[50] Pursuant to National Indication, page 7, section "*Telerefertazione*".

[51] 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*"

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.

- **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 guideline[52]. 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;

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

- the patients' rights regarding their data[53].

- 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
  - 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 performed[54].

- **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.

[53] Pursuant to Section 2, p. 10, National Indication.

[54] 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 responsibility[55].

- 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);
- 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

[55] Pursuant to Section 8 of the Guideline

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 presence[56].

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 assistance[57].

Innovative start-up regime may be applied.

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[56] National Indication, p. 9.
[57] 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 are various laws and regulations that are relevant to the use of telemedicine. For example, the Dutch laws 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*) are of relevance. 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 between physician and patient, 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*) which was last updated in 2024. This guideline also includes provisions from the former, now revoked, KNMG guideline 'Online physician-patient contact' (*KNMG-richtlijn Online arts-patiënt*)[58]. According to the 'Dealing with medical data' 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[59]. 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;
- 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;

[58] Herzien: richtlijn Omgaan met medische gegevens | KNMG. (13 Feb 2020).
[59] KNMG Guideline for dealing with medical data 2024, p. 58.

- 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 medical advice they have given to this patient.[60]

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 further 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.[61]

For the duration of the COVID-19 crisis, the Dutch inspectorate for Health and Youth Care (*Inspectie Gezondheidszorg en Jeugd (IGJ)*) permitted physicians to prescribe medication via the internet. 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 the general practitioner as soon as possible afterwards. [62]

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.[63]

In April 2024, the KNMG and its partners[64] presented new conditions to the IGJ and the Ministry of Health, Welfare and Sport (*Ministerie van Volksgezondheid, Welzijn en Sport (VWS)*) to ensure the continued safe practice of online prescribing without prior physical consultations. The proposal sets out two cumulative conditions: the physician must have access to the patient's medication records and must be affiliated with an organization or collaborative network that provides easily accessible physical locations for physical or psychosocial examinations.[65] However, the proposal has not (yet) led to the submission of a legislative proposal to amend the Dutch Medicines Act.

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 it fits in the above-mentioned regulatory framework. Various forms of telemedicine can thus be offered, using different communication channels.

[60] KNMG Guideline for dealing with medical data 2024, p. 59-60.
[61] *Kamerstukken II* 2005/06, 29359, nr. 81.
[62] Regeling Online medicijnen voorschrijven na videoconsult vervalt per 1 juni | KNMG.
[63] Government Gazette 11 April 2023, no. 10521, explanatory note p. 2.
[64] The involved partners were: The Royal Dutch Dental Association (KNMT), yhe Dutch Association of Physician Assistants (NAPA), and Nurses and carers Netherlands (V&VN). Furthermore, the Dutch Association of Mental Health and Addiction Care (De Nederlandse GGZ), Royal Dutch Society for the Advancement of Pharmacy (KNMP), The Royal Dutch Organisation of Obstetricians (KNOV), Dutch Federation of University Medical Centres (NFU), Netherlands Association of Hospitals (NVZ), Independent Clinics the Netherlands (ZKN), ActiZ, Association of Dutch Healthcare Insurers (ZN), and the Patient Federation (Patiëntenfederatie) were also involved in reviewing the proposal.
[65] 'KNMG en partners ontwikkelen nieuwe voorwaarden voor digitaal voorschrijven', KNMG, 23 April 2024.

For instance, online prescribing may be conducted through video calls with audio, audio-only connections, or text-based messaging (including chat messages or email correspondence).[66] Some (additional) conditions may apply to different communication channels.

Following 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.[67]

The use of other communication services, such as email, WhatsApp, and social media, is also addressed in the KNMG Guideline. Physicians must ensure that the recipient of any transmitted medical information is authorized to receive it and that the communication channel provides adequate confidentiality. For example, standard email systems are generally not secure enough to protect medical data. The NEN standard NTA 7516, published in 2019, provides clear guidance on how to securely use email in healthcare. This standard also applies to WhatsApp and other messaging services. The KNMG Guideline advises physicians to assess the security of the communication service first, including its privacy and data protection measures, independent of the patient's consent to use electronic communication. If anonymity cannot be ensured, particularly when sending sensitive content like images, alternative communication methods should be considered. Additionally, physicians must be cautious when using social media, ensuring patient privacy.[68] The KNMG provides specific guidance on physicians' use of social media.[69]

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*)) and the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*).

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.

The Code of Conduct lays down rules for pharmaceutical advertising, based on the Dutch Medicines Act (*Geneesmiddelenwet*) and Directive 2001/83/EC on the Community code relating to medicinal products for human use. "Advertising" refers to any form of public or systematic, direct or indirect, of medicinal products and related services, including offering or solicitation of goods or services authorisation holders and healthcare professionals.[70]

For sake of completeness, advertising for telemedicine services cannot include advertising for prescription medicines, as this is generally forbidden under Dutch law.

[66] KNMG Guideline for dealing with medical data 2024, p. 61.
[67] KNMG Guideline for dealing with medical data2024, p.57
[68] KNMG Guideline for dealing with medical data2024, p.57
[69] KNMG Guideline for physicians and social media 2020.
[70] Article 3.1(h) Code of Conduct for Pharmaceutical Advertising (Gedragscode Geneesmiddelenreclame).

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

The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit (NZa)*) has published an update of their digital care costing guide very recently (*Wegwijzer bekostiging digitale zorg 2025*).[71] This guide is not solely about telemedicine, but also focuses on digital care in general, including 'e-care' such as e-diagnosis, 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. It remains required that the care complies with "the state of science and practice". The Dutch Healthcare Insurance Act describes which medical aids (such as eHealth technology) qualify for reimbursement from the basic health insurance package.[72]

Based on the guide, the general rule is that if existing, already insured care is offered in a digital form, that care remains insured care if the composition and effectiveness does not essentially change from the original care. This includes digital consultations with general practitioners or physicians at the hospital and telemonitoring for COPD, heart failure, and high-risk pregnancies. The added value of the digital application compared to traditional care delivery must be assessed to confirm insurance.[73]

Also, the Association of Dutch Healthcare Insurers (*Zorgverzekeraars Nederland*) and the Dutch patients' federation (*Patiëntenfederatie Nederland*) have been promoting telemedicine and advocating a right to digital healthcare for years. They want patients to have a choice between going to see a physician at the hospital or receiving digital healthcare at home.[74]

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 or a medical specialist. By making the regulations more flexible, the government is making it easier for general practitioners to assess a patient's situation. In addition, speech therapists and medical specialists now have more opportunities to provide therapy and care online.[75]

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. [76]

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 Act regulates how the exchange of data should take place. With this Act, an obligation is imposed on healthcare providers to exchange data electronically.[77]

[71] Wegwijzer bekostiging digitale zorg 2025.
[72] Wegwijzer bekostiging digitale zorg 2025, p. 7.
[73] Wegwijzer bekostiging digitale zorg 2025, p. 7.
[74] Ambities Zorginkoop digitalisering en gegevensuitwisseling 2025 | ZN.nl; Generieke adviezen over Zorg op Afstand 2024 | Patientenfederatie.nl; Naar hybride zorg 2023 | Patientenfederatie.nl.
[75] Stimuleren gebruik e-health | E-health (digitale zorg) | Rijksoverheid.nl.
[76] Waar kan ik een persoonlijke gezondheidsomgeving (PGO) voor gebruiken? | Rijksoverheid.nl.
[77] *Kamerstukken II* 2021, 35 824, nr. 3, p. 3.

Since the COVID-19 pandemic, telemedicine has been included in a government stimulus package designed to promote innovation in healthcare, particularly with the belief that digital care can enhance both efficiency and cost-effectiveness. Following the E-Health at Home Inventive Scheme (*Stimuleringsregeling E-Health Thuis (SET)*), the Dutch government launched the Technology in Support and Care Inventive Scheme (*Stimuleringsregeling Technologie in Ondersteuning en Zorg (STOZ)*) in May 2024.[78] This scheme provides subsidies, subject to specific conditions, for treatments via e-health platforms, digital consultations, telemonitoring, and other related services.[79]

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[78] Stimuleringsregeling E-Health Thuis (SET) | Rov.nl; STOZ: Voorwaarden en beoordelingscriteria | Rvo.nl
[79] STOZ: Overzicht van digitale en hybride processen | Rvo.nl.

Poland

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

Several acts set out admissibility criteria and/or organisational standards for telemedicine:

1. The Act of 15 April 2011 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 the following to be issued without the need for a personal examination of the patient:

- prescriptions for the continuation of treatment, and/or
- orders to continue the supply of medical devices,

where is justified by the patient's health condition as reflected in 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 in 2015) on the professions of physician and dentist ("APPD"), which allows these professions to provide services through IT systems or communication systems. The principles of medical ethics as set out in the Code of Medical Ethics (the doctors' association self-regulation, "CME") also permit the provision of telemedicine services.

5. The Act of 25 June 1999 (as amended) on cash benefits from social insurance in the event of illness and maternity apply to the rules concerning the issuance of e-sick leave certificates.

6. 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.

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 medical advice cannot be provided without a physical examination of the patient.

Separate and more restrictive regulations apply with respect to the delivery of mental health e-services and e-prescriptions of psychotropic medications. According to the Mental Health Act of 19 August 1994, a doctor can issue 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 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, in accordance with the patient's clinical condition. The Ministry of Health has issued a number of regulations that substantially modify

how narcotic and psychotropic medicines are prescribed, restrict the possibility of purchasing certain types of medication only after a personal consultation with a doctor (Regulation of the Minister of Health of 12 July 2023 amending the Regulation on narcotic drugs, psychotropic substances, category 1 precursors and preparations containing these drugs or substances), or exclude the possibility of issuing e-prescriptions for opioids, morphine, fentanyl and other narcotic substances, including hemp (Regulation of the Minister of Health of 29 October 2024 amending the Regulation on narcotic drugs, psychotropic substances, category 1 precursors and preparations containing these drugs or substances).

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

With some exceptions, healthcare professionals can provide services through telemedicine, including issuing prescriptions.

According to Art. 42 of the APPD, a health assessment can be carried out by a physician after examining the patient in person or examining the patient via ICT or communication systems, and after analysing the person's available medical records. Without examining the patient (whether in person or during an e-visit), the doctor is only allowed to issue a prescription necessary for the continuation of treatment.

With the support of telemedicine, it is possible to provide almost the full range of medical services. The few limitations include medical services in the field of psychiatry and concerning narcotic and psychotropic substances. Under Art. 11 of the Mental Health Act, a doctor may only issue a diagnosis of the health status of a person with a mental disorder, issue an opinion, or refer the patient to another doctor, psychologist, or medical facility based on a prior personal examination of that person. A prescription for narcotic or psychotropic drugs may be issued by a physician during an in-person or remote visit if the following conditions are met: the prescription is part of the continuity of treatment, the last examination took place within the last three months, and the patient agrees to make their prescription history available to the physician. Patients can make their prescription history available to the doctor in three ways: through their Internet Patient Account (in Polish: *Internetowe Konto Pacjenta, "*IKP"), "myIKP" (in Polish: *mojeIKP*) mobile phone application, or using a code received via text messaging on their mobile phone during their visit.

Since 1 January 2025, the CME has undergone an important amendment, covering new ethical principles related to the use of telemedicine and artificial intelligence by doctors.

Regarding telemedicine, the new rules emphasise that, if a doctor provides medical services remotely, they must maintain the same standards of care that apply to in-person visits. An obligation to inform patients about the limitations of teleconsultations has also been imposed, which is intended to ensure transparency and accountability in the remote treatment process.

The increased role of AI in everyday medical practice (including telemedicine) has also been recognised, and new regulations adopted allowing doctors to use AI tools (e.g., AI assistants, chatbots, AI prediagnostic apps), provided that the algorithms used are properly certified and approved for medical use. Importantly, doctors must ensure that the patient gives informed consent to the use of artificial intelligence in the diagnostic or therapeutic process. What is particularly worth emphasising is that, even with the use of AI tools, the doctor still has the decisive role in the treatment and diagnostic process.

Irrespective of the above changes in the law, the provisions of the Regulation of the Minister of Health of 12 August 2020 on the organisational standard of tele-advising in primary healthcare still apply. The Regulation lists circumstances in which the provision of services through telemedicine is not allowed:

- 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 their symptoms have changed;
- when there is a suspicion of cancer;
- when, in other cases, the patient or their legal custodian does not consent to the services being provided remotely;
- when the treatment concerns a child under six 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 a test or examination and discussing the results;
- 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 a 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 the patient takes 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 medically certified as class IIa or higher and registered for home use by patients. This includes 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 telemedicine. That information should include the following:

- a list of services that are provided only if there is a direct visit,
- the 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 the services are provided,
- the possibility of a direct visit taking place when this 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?

The advertising of 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.

Under Art. 14(1) of the Act of April 15, 2011, on medical activities, an entity performing medical activities may make information public on the scope and types of health services it provides. The content and form of this information cannot be considered advertising. Under Art. 2, paragraph 1, point 5 of the Act on Medical Activities, a medical practitioner practising as part of a medical practice is also considered to be a medical practitioner carrying out medical activities. It follows from the above that the prohibition of advertising provided for in Art. 14 of the Act also applies to doctors and dentists running a medical practice.

However, attention should be paid to other legal aspects related to the rules of informing about the practice of the profession of a doctor or dentist, and to the prohibition of advertising such activities.

At the end of 2024, the restriction on the freedom of advertising and information on the provision of medical services was removed from the Code of Medical Ethics by deleting Article 63, which prohibited doctors and dentists from advertising and consenting to the use of their name or image for commercial purposes.

The new regulations in the CME allow doctors to promote their services, but only if this is done ethically. Instead of a strict prohibition on advertising, as was the case in the previous version of the Code, doctors can now communicate their services in a transparent, reliable and professional manner. It is important that the promotion of medical services does not undermine public trust in the medical profession and does not use the authority of a doctor to advertise products not directly related to the practice of medicine.

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 relevant provisions of law, i.e., ordinances of the President of the National Health Fund.

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 as well as in outpatient specialised care, drug and chemotherapy programmes, long-term care, palliative care and hospices.

For patients using telemedicine, it is also important that it is now also possible for them to obtain an e-prescription for reimbursable medication through virtual medical/health facilities. This is subject to the telemedicine services being provided by the healthcare provider that keeps the person's medical records.

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

The government has launched numerous important initiatives to increase the digitalisation of health services.

The Minister of Health has established an e-Health Centre, a unit funded from the national budget. The digital e-health ecosystem for citizens includes: the Internet Patient Account (IKP), mojeIKP ('myIKP') and Covid scanner applications, e-services: e-prescriptions, e-referrals, e-registration for vaccinations, central e-registration, the 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, 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.

Medical/health facilities can obtain various types of funding (grants, subsidies, etc.) for implementing modern technologies. Funding can be provided for different areas, e.g., for modernising solutions for telephone/online medical registration, or for IT solutions for medical facilities, including those related to the management and analysis of health data, the protection of patient data, cybersecurity, etc.

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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. However, Article 4.7 of Act 44/2003, 21 November, on the Organisation of Health Professions, 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, healthcare professionals 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.

In this regard, the Spanish Code of Medical Ethics introduced in 2022 a specific chapter related to telemedicine, due to the development that this medical variant has undergone in the last decade. The Spanish Code of Medical Ethics has no legal value, but it is binding on all medical practitioners in Spain and imposes due diligence obligations that must be followed in their professional practice, so the provisions on telemedicine contained therein should be observed.

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

Yes, the use of telematic means or other non-face-to-face communication systems to assist in professional decision-making is in accordance with Spanish medical ethics.

The previous version of the Spanish Code of Medical Ethics (2011) considered telemedicine as an auxiliary system, establishing that healthcare professionals were allowed to provide services through telemedicine as long as the provision of these services was justified on public health grounds, in the interest of the patient, or for reasons of health emergency (as was the case in the situation caused by COVID-19[80]).

However, the most recent version of the Spanish Code of Medical Ethics (2022) does not make this consideration and provides a specific chapter regulating the use of telemedicine services.

In accordance, medical practitioners when providing services through telemedicine must:

- Ensure that the identification of those involved is unequivocal and confidentiality is guaranteed.
- Use communication channels that guarantee the maximum available security.
- Record in the medical record the telemedicine means by which the consultation was made, as well as the medical treatment prescribed, and any recommendations given.
- Take extreme care to protect patient security and confidentiality, paying particular attention to the privacy settings of the media used.

[80]The Spanish Council of Medical Associations (*Consejo General de Colegios Medicos 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. This Report stressed the complementary nature of telemedicine with face-to-face doctor patient care, the importance of respecting 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. This Report also established 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.

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 healthcare services that can be provided through telematic means or other non-face-to-face communication systems. However, whenever a medical practitioner uses telemedicine, their interventions must be scientifically based, professional, truthful and prudent, and must always be in accordance with the content of the Spanish Code of Ethics and, in particular, with the considerations set out in section 2 above.

The previous version of the Spanish Code of Medical Ethics (2011) 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).[81]

However, the most recent version of the Spanish Code of Medical Ethics (2022), although it introduces a specific chapter on telemedicine, has opted for excluding these initial recommendations and does not provide a specific list of healthcare services that can be provided through telemedicine. Therefore, it can be understood that it is up to the medical practitioner to determine whether the use of telematic means is technically and scientifically appropriate in each case.

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, limited to those services and activities for which they have authorisation.

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 specific regulation providing for the reimbursement of services provided through telemedicine.

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

With respect to the digitalisation of healthcare services, Spain has published a Digital Health Strategy for the period 2021-2026. This Strategy foresees different work plans related to the development of the Spanish National Health System, and a report on its implementation has been published in December 2024[82].

The whole Strategy is oriented towards the digitalisation of healthcare services, but, in particular, the Plan for the Digital Transformation of Primary Care contains working groups especially related to the field of

[81] Article 26 of Spanish Code of Medical Ethics (2011).
[82] General Secretariat for Digital Health, "*Monitoring of the Digital Health Strategy (2021-2026)*", December 2024.

telemedicine. This plan includes, among others, programs related to the development of the digital health record and the telemonitoring of patients.

The total budget foreseen for this Plan amounts to EUR 230 million, of which EUR 154 million were still available in December 2024. In particular, the budget execution of the working group related to the telemonitoring of patients presents one of the lowest percentages of budget execution, with only 8,4% of the available budget executed as of December 2024, leaving the remaining 91,6% available for execution in the two years remaining for the implementation of the Digital Health Strategy.

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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 August 2021 the CQC published guidance "*How CQC monitors, inspects and regulates providers of online primary care"* to clarify the regulatory requirements for telemedicine providers. Primary online care services are defined as delivering regulated health care services by an online means. This transmitting information by text, sound, images or other digital forms to deliver care and treatment to patients and any follow up. The CQC states that its approach to monitoring and inspecting telemedicine providers is similar to how they regulate face-to-face medical services, 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. In addition to the High Level Principles, the General Medical Council (which regulates doctors), General Pharmaceutical Council (which regulates pharmacists) and Health and Care Professionals Council (which regulates a range of care professions, including physiotherapists occupational therapists and paramedics) have published specific guidance on how regulatory requirements must be met when providing telehealth services.

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 or through a "collection and delivery arrangement" (e.g. automated dispensing or click and collect arrangements). 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*".[83]

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.[84]

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[83] https://www.gov.uk/government/speeches/building-the-best-health-system-in-the-world.
[84] https://www.gov.uk/government/publications/trend-deck-2021-technology.

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