Telemedicine in Europe

Osborne Clarke

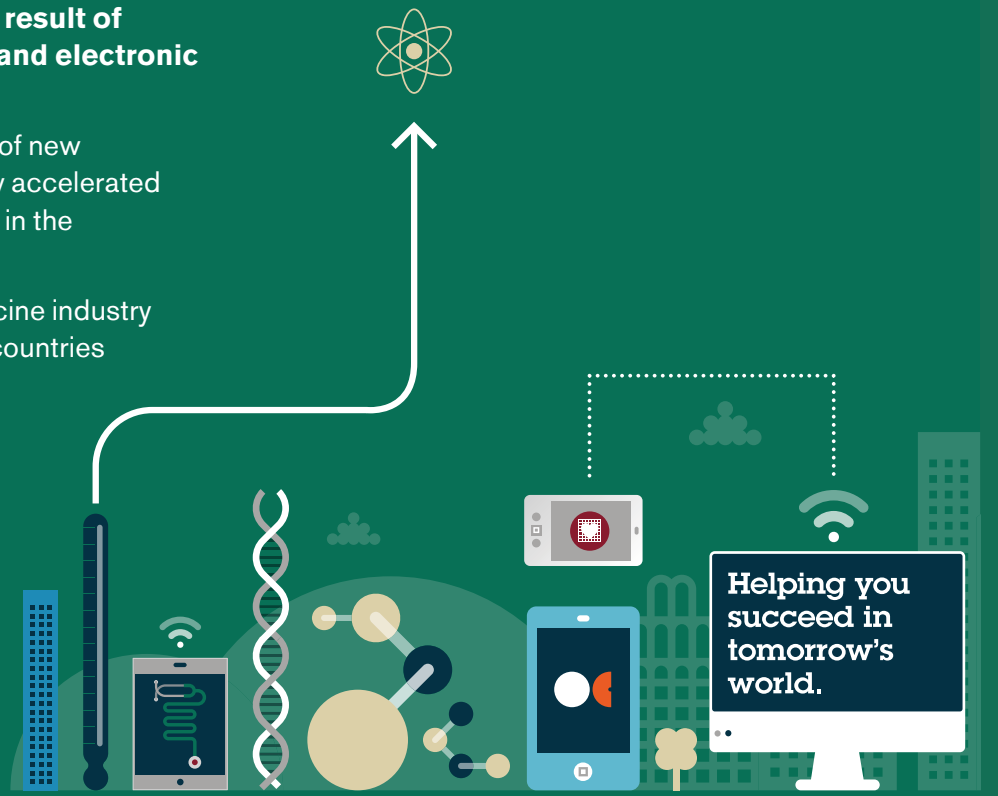
The European telemedicine industry is on the rise as a result of recent legalisation of activities like remote treatment and electronic prescriptions in most countries.

Telehealth became a very popular and important topic in light of new challenges like the global COVID-19 pandemic, which rapidly accelerated the far-reaching developments that were already taking place in the telemedicine market.

As a result, the number of suppliers in the European telemedicine industry is expected to increase in the nearest future since European countries are among the largest healthcare markets in the world.

The following questionnaire provides a brief overview of the national developments and legal frameworks regarding telemedicine in Germany, France, Belgium, Italy, Spain and the UK.

Select a section from the navigation on the left and then choose the country-specific information from the navigation at the bottom.



Belgium | France | Germany | Italy | Spain | UK

Telemedicine in Europe

1. What is telemedicine?

While there is no definition of telemedicine under Belgian law, the Belgian Council of Physicians describes telemedicine as the use of telephone notice, electronic notice and prescription, tele-monitoring (remotely, by videoconference and by medical applications), tele-concertation between professionals and the storage of health data in the cloud. It is considered as an umbrella term encompassing teleconsultation (including tele-expertise, telemonitoring, teleassistance and mHealth). Teleconsultation, on the other hand, is defined as a remote care service between a healthcare provider and a patient. It can take the form of a consultation by phone, e-mail, SMS or chat, or a video consultation during which the healthcare professional and the patient can talk and see each other (video consultation).

Telemedicine in Europe

1. What is telemedicine?

France is one of the exceptions in having a legal definition of telemedicine, which is provided in Article L6316-1 of the French Code of Public Health (**FCPH**):

"Telemedicine is the remote practice of medicine based on information and communication technologies. It aims at having healthcare professionals liaising with each other, together with patients or not."

Telemedicine can be used for:

– diagnosis

– follow-up of patients exposed to risks, either by way of prevention or by way of post-therapy

– requesting medical advice from specialists

– helping in the therapeutic decision-making process

– prescribing health products or medical services

– performing a telemonitoring of patients' care

FCPH further defines five activities of telemedicine:

– Tele-consultation: a healthcare professional's remote medical consultation for a patient.

– Tele-expertise: a healthcare professional remotely requesting medical advice from another professional specialising in other therapeutic areas.

– Medical tele-surveillance: a healthcare professional making remote interpretation on medical data for following up on the treatment of a patient and, as the case may be, making medical decisions regarding such a treatment.

– Medical tele-assistance: a healthcare professional providing remote support to another professional in the performance of a medical act.

– Medical response: a special regime governing hospitals' call centres for managing urgent medical situations.

The FCPH differentiates telemedicine from telecare. Telecare is defined as a *"remote practice of care based on information and communication technologies and connecting patients with one or more pharmacists or medical auxiliaries"*.

Telemedicine in Europe

1. What is telemedicine?

Similar to most countries, there is no definition of telemedicine under German law. However, the German Federal Assembly of Physicians (*"Bundesärztekammer"*) has defined it as follows:

*"**Telemedicine** is a collective term for different concepts of physicians' care that share the principle approach that the medical healthcare services in the fields of diagnostic, therapy and rehabilitation as well as in the field of physician's decision consultation are provided over distance (or at intervals in time) using information and communication technologies."*

Besides, Section 9 sentence 1 of the German Act on Advertising in the Field of Health (*"Heilmittelwerbegesetz"* – **HWG**) contains a legal definition of the term "remote treatment" and defines it as follows:

*"the diagnosis or treatment of diseases, ailments, bodily injury or disease symptoms which is not based on personal observation of the person or animal to be treated (**remote treatment**)".*

Telemedicine in Europe

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1. What is telemedicine?

The definition of telemedicine is contained:

– in the Decree of the Ministry of Health no. 77, dated 23 May 2022 (*"Regulation defining models and standards for the development of territorial assistance in the national health service"*), issued within the reform envisaged by the National Recovery and Resilience Plan (NRRP), that in Exhibit 1, among others defines Telemedicine as *"a modality of providing services and social and healthcare assistance with remote health care relevance, enabled by information technologies and communication, and used by a healthcare professional to provide healthcare services to patients (telemedicine healthcare professional – patients) or consultancy and support services to other healthcare professionals (healthcare professional telemedicine – healthcare professional). Telemedicine represents an innovative approach to practice healthcare, already consolidated in various health sectors, allowing – if included in coordinated healthcare network – the provision of remote health services through the use of digital devices, internet, software and telecommunication networks"*.

– in Article 2.1 of the national guidelines issued by the Ministry of Health and approved by Conferenza Stato-Regioni, agreed between government, regions and the autonomous Provinces of Trento and Bolzano in March 2014, that states: *"Telemedicine means a way of providing healthcare services, through the use of innovative technologies, in particular Information and Communication Technologies (ICT), in situations where the health professional and the patient (or two professionals) are not in the same location. Telemedicine involves the secure transmission of medical information and data in the form of texts, sounds, images or other forms necessary for the prevention, diagnosis, treatment and subsequent monitoring of patients. Telemedicine services must be assimilated to any diagnostic/therapeutic health service.* ***However, performance using telemedicine does not replace traditional healthcare provision in the doctor-patient personal relationship****, but integrates it to improve virtually efficacy, efficiency and appropriateness. Telemedicine must also comply with all the rights and obligations of any medical act. It is noted that the use of Information and Communication Technology tools for the treatment of health information or the online sharing of data and/or health information does not constitute telemedicine services. By way of example, portals of health information, social networks, forums, newsgroups, email or others do not fall within telemedicine."*

Telemedicine in Europe

1. What is telemedicine?

There is no definition of telemedicine under Spanish law. However, the national entity providing healthcare services and benefits in Spain – the National Health System (INSALUD by the Spanish acronym from its former name "National Institute of Health") – abides by the definition of the World Health Organization for telemedicine:

"The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities."

In addition, the same entity published the INSALUD Telemedicine Framework in 1998 defining the term (telemedicine) as follows:

"The use of information and communication technologies (ICTs) as means of providing healthcare services regardless of the location of those who offer the service, the patients who receive it, and the necessary information for providing the healthcare services."

Telemedicine in Europe

1. What is telemedicine?

There is no definition of telemedicine under UK law. However, the NHS has defined it as:

"The use of telecommunication and information technology for the purpose of providing remote health assessments and therapeutic interventions. This could include video or voice messaging services on mobile phones, computers and tablets."

www.datadictionary.nhs.uk/nhs_business_definitions/telemedicine.html

Telemedicine in Europe

Osborne Clarke

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

There is no specific law governing telemedicine in Belgium. Instead, an array of different laws and regulations should be considered:

- A Memorandum of understanding setting out the Belgian e-Health Action Plan 2015-2018 (V2.0) was published in the Belgian official gazette in December 2015, laying down the grounds for the current **mhealthbelgium.be** platform (on which see more under question 6).
- Healthcare practitioners providing telemedicine services are bound by the ethical restrictions and deontological regulations which apply to their profession, including the Code of Deontology enacted by the Council of Physicians (on which see more under question 3). While those rules are not applicable to those who are not registered with the Council (including e.g. private businesses or patients), they have an impact on the roll-out of telemedicine-powered solutions on the Belgian market.
- Certain activities with a digital element are captured by the reimbursement legislation when carried out by healthcare practitioners to provide healthcare to their patients. Such legislation includes for example two royal decrees of 30 June 2017 and 3 December 2017regulating the financial contribution granted to (i) doctors, for the use of telematics and for the electronic management of medical records and (ii) dentists, for the use of telematics and for the electronic management of medical records. These decrees may apply when one of the following electronic techniques is being used: e-prescription, an internet platform for the reimbursement of healthcare, electronic billing, secure patient data sharing and electronic management of healthcare fees.
- Manufacturers of technologies facilitating or enabling the provision of telemedicine services should be mindful of product regulations which may apply to them, including the Belgian product liability act of 25 February 1991, articles 1701/1 et seq. of the Belgian Civil Code which apply to digital content or digital service that constitutes a medical device (e.g. health apps) and can be obtained by a patient without being prescribed or provided by a healthcare practitioner and, more generally, regulation (EU) 2017/745 on medical devices (particularly as regards medical device software).
- Local laws enacted to protect patients and the quality of care are among cornerstones of any telemedicine project launched in Belgium. Those include the patients' rights act of 22 August 2002, the act of 10 May 2015 regulating healthcare professions, the act of 22 April 2019 on the quality of healthcare, and their implementing decrees.

Telemedicine in Europe

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

Telemedicine is governed by the French Code of Public Health (**FCPH**) which was introduced in 2008.

Various implementation decrees have been published detailing the rules applying to telemedicine. Each year, the French Parliament updates the process in the public budget of the French National Health Insurance Programme. The High Health Administration also edits guidelines on telemedicine for the implementation of government medical programs.

In the context of the Covid-19 pandemic, several laws and decrees softened the telemedicine regulations to maximise the Health Insurance coverage of remote medical care costs incurred by Covid-19 patients.

Since then, the most recent changes were introduced by Decree No. 2021-707 of 3 June 2021 and the Order of 3 June 2021, both of which amended the FCPH to define the conditions for implementing and paying for telecare and opening up tele-expertise to healthcare professionals. Further details about the rules governing telemedicine are provided in the following sections.

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

Telemedicine is governed by the following laws:

Since 2018, certain provisions related to telemedicine are included under Section 7 paragraph 4 of the German Professional Code of Conduct for Physicians Practising in Germany (*"Musterberufsordnung für die in Deutschland tätigen Ärzte"* – ***MBO-Ä***) that allowed remote treatment for physicians.

This was followed by the introduction of electronic prescriptions by the Law for more Safety in the Supply of Medicines (*"Gesetz für mehr Sicherheit in der Arzneimittelversorgung"* – ***GSAV***), which the German parliament passed in August 2019.

In January 2020, the Digital Healthcare Act (*"Digitale-Versorgung-Gesetz"* – ***DVG***) came into force. The DVG has three main areas of focus: (i) from 2020 onwards, patients will be able to have digital health apps prescribed by doctors at the expense of the health insurance companies; (ii) they will be able to store their health data in an electronic patient file (**ePA**) and (iii) use telemedical services such as video consultation hours more easily.

To achieve these aims, the DVG changed a series of articles and introduced new articles into the German Social Code V ("Sozialgesetzbuch V" – SGB V), among others:

– § 33a SGB V: Reimbursement of digital health applications

– § 68a SGB V: Promotion of the development of digital innovations by health insurance companies

– § 68b SGB V: Promotion of innovations in medical care

– §§ 75b, 92a, 92b, §134, 139e, 263a, §§ 303a-303e SGB V

– § 306 ff. SGB V: Telematics infrastructure

– § 341 ff. SGB V: Electronic patient file

– §§ 364-370a SGB V: Telemedical procedures

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2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

Furthermore, the Digital Health Applications Ordinance (*"Digitale-Gesundheitsanwendungen-Verordnung"* – ***DiGAV***), which came into force in April 2020, contains further regulations regarding the approval and reimbursement of digital health applications by the statutory health insurances.

With regard to data protection, the requirements of the General Data Protection Regulation (*"Datenschutz-Grundverordnung"* – **DSGVO**) must be observed. In addition, the Patient Data Protection Act (*"Patientendaten-Schutz-Gesetz"* – ***PDSG***), which came into force in October 2020, regulates the introduction and use of digital services such as electronic prescriptions or electronic patient files and the protection of sensitive health data.

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

There is no specific law on telemedicine in Italy, but it is dealt with in some provisions, the most recent issued in the context of the reform envisaged in the National Recovery and Resilience Plan (NRRP) with regard to the public health sector:

- the "National guidelines" of the Ministry of Health, approved by Conferenza Stato-Regioni on March 2014, that clarify that telemedicine is not a separate medical speciality, but rather a different method of providing health services and that it therefore falls within the application of Legislative Decree n. 502/1992 (Reorganisation of the Health Sector) which applies principally to the public sector;
- the "National indications for the provision of telemedicine services" of the Ministry of Health, approved by Conferenza Stato-Regioni on 17 December 2020, providing indications to be adopted at national level for the provision of some telemedicine services such as televisit, medical teleconsultation, medical and health teleconsulting, tele-assistance by the health professionals and remote reporting;
- the "Directions for the provision of telerehabilitation services by healthcare professionals", of the Ministry of Health, approved by Conferenza Stato-Regioni on 18 November 2021, in which uniform guidance is provided for the entire Italian healthcare system regarding telerehabilitation services;
- the Decree of the Ministry of Health no. 120 of 29 April 2022 ("Approval of the organizational guidelines containing the "Digital Model for the implementation of home care assistance", for the purposes of achievement of EU M6C1-4 Milestone, referred to in the Annex to ECOFIN Council Implementing Decision of 13 July 2021, approving the assessment of the recovery and resilience plan in Italy".), that define a reference model for the implementation of the various telemedicine services in the home setting, through the identification of innovative processes for taking care of the patient at home and the enhancement of multi-professional and multidisciplinary collaboration between different professionals;

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2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

– the Decree of the Ministry of Health no. 77, dated 23 May 2022 (*"Regulation defining **models and standards for the development of territorial assistance in the national health service**"*), which provides for quality, structural, technological and quantitative standards of facilities dedicated to territorial assistance and preventive healthcare, including those regarding telemedicine.

– Telemedicine is also included in the Italian **Code of Medical Ethics**. Paragraph 6 of the annex states: *"The doctor, using telematics systems, cannot replace the medical examination that implies a direct relationship with the patient, with a relationship that is exclusively virtual; he can instead use the telemedicine tools for the remote collection or monitoring activities of biological parameters and clinical surveillance."*

– In 2014, the Italian Federation of Family Doctors adopted a Self-Regulation Code for Telemedicine, which provides for the following areas of activities: teleservice, telemonitoring and telereporting.

Telemedicine in Europe

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

There is no specific law governing telemedicine in Spain, save for Royal Decree 81/2014 that establishes rules to guarantee cross-border healthcare assistance (including telemedicine) to patients and promote cooperation between EU member states. The customary laws that would apply on any form of treatment would accordingly apply to telemedicine, in addition to those laws that become applicable for the use of information and communication technologies (**ICTs**) to provide a particular service.

The Spanish Doctor's Association does cover telemedicine in its Code of Medical Ethics. Sections 3 to 6 of Article 26 of the Code allow telemedicine in the following forms:

– Where the clinical practice of medicine through consultation exclusively by letter, telephone, radio, newspapers or the internet, is contrary to ethical standards. The correct action inevitably involves personal and direct contact between doctor and patient.

– In the case of a second opinion and medical examinations, email or other means of virtual communication and telemedicine are permissible, whenever clear mutual identification and privacy are ensured.

– Patient guidance systems through telemedicine or telephone consultation, are consistent with medical ethics when used solely to aid in decision-making.

Telemedicine in Europe

2. Laws (or other mandatory rules – like professional code of conduct) covering telemedicine

There are not any separate laws or regulations specifically governing telemedicine; the laws and regulations for in-person healthcare services apply in the same way to telemedicine. The Care Quality Commission (**CQC**) is responsible for regulating healthcare institutions and providers in England and requires telemedicine providers to register to perform the regulated activity of *"Transport services, triage and medical advice provided remotely"*, where medical advice is provided remotely, cases need immediate action, attention or triage, and the service is provided by a body established for that purpose. The regulators for the other parts of the UK do not have any additional requirements for telemedical services.

Various regulatory bodies in the UK, including the General Medical Council (**GMC**), have published **guidance** and set out "high level principles" for GMC-registered healthcare professionals to follow when providing telemedicine services.

3. General conditions/restrictions for telemedicine offerings

While telemedicine is not prohibited as a healthcare practice, a number of restrictions in force on the local market should be considered.

Before the coronavirus outbreak, the Belgian Council of Physicians prohibited registered physicians from providing a diagnosis without having a prior physical interaction with the patient, which restricted the use of telemedicine platforms by physicians who wished to comply with this prior requirement. After the COVID-19 pandemic, the Council of Physicians reviewed its position and provided an extensive list of criteria which teleconsultations between a Belgian physician and a patient should fulfil. Those conditions include a number of prior warnings, disclaimers and information requirements, which are set out in an advice of the Council of Physicians of June 2022.

The Code of the Council of Physicians (as updated in December 2022) further provides that teleconsultation with a view to making a diagnosis and proposing a treatment can replace face-to-face consultation in a particular situation if this provides a benefit for the health and safety of the patient and the doctor. It is allowed if the physician:

– knows the patient;

– has access to the medical information concerning her/him (medical file); and

– can guarantee the continuity of care.

Under the Code, physicians should asses independently whether teleconsultation is advisable. They should be aware of the limits of this type of service and should be mindful of any signs that would justify referring a patient immediately to a face-to-face consultation. Suitable equipment should be used to that effect, presenting sufficient guarantees of technical and functional quality, security and confidentiality. The Belgian reimbursement legislation has recently evolved in a similar way (see more below under question 6).

Telemedicine in Europe

3. General conditions/restrictions for telemedicine offerings

Telemedicine is allowed in France and governed by FCPH Art. L6316-1 and R6316-1 et seq. Telemedicine services can only be provided by healthcare professionals or healthcare organisations such as hospitals. The FCPH states that telemedicine acts:

– can only be performed with the informed consent of patients;

– must ensure the identification of the involved healthcare professionals and patients;

– must ensure the professional's access to the personal medical data of the patients which are necessary for his or her treatment;

– must organize, where necessary, appropriate training of patients for their use of the telemedicine tools;

– must be appropriately recorded by each of the involved healthcare professionals (date, report, medical prescriptions).

The fees for telecare activities may not be higher than those charged by healthcare professionals in their face-to-face interactions with patients.

And pursuant to the Good Practices for Teleconsultation of the French Health Insurance administration, healthcare professionals' teleconsultations and tele-expertise are capped to 20% of their total activity.

Telemedicine in Europe

3. General conditions/restrictions for telemedicine offerings

Telemedicine services are generally allowed if they are used **in addition** to personal contact.

Since the legalisation of remote treatments in 2018, the provision of medical advice or treatment **exclusively** via the means of telemedicine is also permitted "in individual cases", even for new patients. However, it must be (i) medically justifiable, (ii) the necessary medical care must be guaranteed and (iii) the patient must be informed about the particularities of consultation and treatment exclusively via communication media.

Furthermore, the new Section 9 of the German Act on Advertising in the Field of Health (*"Heilmittelwerbegesetz"* – ***HWG***), which came into force in December 2019, now allows physicians to inform about and advertise telemedicine services on their website under certain conditions if, according to *"generally accepted professional standards, personal medical contact with the person to be treated is not required"* (Section 9 sentence 2 HWG). Prior to that, advertising of telemedicine services was generally inadmissible (regarding the advertising of remote medical treatment see Section 4).

Annex 31b to the Federal Master Agreement for Physicians (*"Bundesmantelvertrag-Ärzte"* – ***BMV-Ä***) contains general requirements for the technical procedures for video consultations, for example, provisions on information technology security as well as requirements for the video service provider and the physician.

Telemedicine in Europe

3. General conditions/restrictions for telemedicine offerings

The National Guidelines issued in 2014, as amended by the National indications for the provision of telemedicine services of December 2020, provide, among others, a classification of the telemedicine areas of activities and a model of organisation of telemedicine services. They also list the specific requirements that, in addition to those provided for by Decree 502/1992, both public or private facilities must satisfy in order to provide telemedicine services and, in particular, provide that healthcare professionals in private sector must (i) be registered in the Register of Doctors and (ii) comply with the standards of the telemedicine services defined by the Region where they operate, also taking into account the standards defined at national level. Standard of telemedicine services have been recently updated by Decree no. 77/2022 with specific regard to the public health sector.

Among the conditions/restrictions for telemedicine services:

– the patient must be deemed suitable to receive telemedicine services. Telemedicine is not recommended for patients with acute pathologies or exacerbations of chronic pathologies in progress;

– the patient must express its written consent to receive healthcare services through telemedicine and the personal data processing must take place in compliance with the provisions of the GDPR;

– the digital tools used must allow proper communication between the healthcare professional and the patient and in case of use of medical device these need to be compliant with the regulatory provisions in force.

Telemedicine in Europe

3. General conditions/restrictions for telemedicine offerings

Telemedicine is generally allowed in Spain.

There are no expressly stated limitations or restrictions applicable to telemedicine under Spanish law. However, it should be noted that the decentralised healthcare services are transferred to the 17 autonomous communities of Spain ("AACC"). Therefore, each AACC healthcare authority has the autonomy to plan, change and upgrade their healthcare infrastructures, including the types of services they offer (i.e. telemedicine).

Also, please note that the Code of Medical Ethics of the General Council of Medical Associations of Spain considers the practice of medicine exclusively by means of internet unethical. Therefore, it would be recommended to conduct patient-doctor first consultation in person, and restrict telemedicine to the follow-up treatment and minor health issues.

Telemedicine in Europe

3. General conditions/restrictions for telemedicine offerings

Telemedicine is generally allowed in the UK and is currently regulated in the same way as in-person healthcare services. Consequently, healthcare professionals will be subject to the same legislation, licensing and registration obligations as well as the professional codes of conduct applicable to the medical services they provide whether in-person or remote.

UK data privacy regulations, including the UK GDPR, the Data Protection Act 2018 and the Privacy and Electronic Communications Regulations (**PECR**), will be applicable to the provision of telemedicine services given that patient's personal data will likely be provided.

The Medical Device Regulations 2002 may also be applicable in relation to the software used in telemedicine which may be considered a medical device. These regulations set out certain requirements that need to be met for any medical devices (including registration with the MHRA and specific product markings). It is worth noting that the regulations applicable to medical devices are currently under review following the outcomes of a consultation by the Medicines and Healthcare products Regulatory Authority (**MHRA**) on the future of medical device regulations. As at the date of publication of this Insight, the UK government is aiming for core aspects of the future regime for medical devices to apply from 1 July 2025. In addition, post Brexit arrangements have extended the period during which CE marked medical devices can be placed on the Great Britain market. Separate requirements apply to Northern Ireland.

Telemedicine in Europe

4. Advertising telemedicine offerings

All telemedicine offerings should be advertised in compliance with the general B2C and B2B advertising regulations set out in the Belgium Code of Economy. Further:

– If a telemedicine service is reimbursed by NIHDI, it should be noted that Belgian law prohibits advertising which mentions that social security fully or partially reimburses the cost of a healthcare services.

– If a telemedicine technology qualifies as medical device software, the advertising rules applicable to medical devices must be complied with (including, as applicable, relevant provisions of the medicines act of 25 March 1964, the medical devices act of 20 December 2020, regulation (EU) 2017/745 on medical devices, and if the economic operator of the device is a member of beMedTech, the beMedTech Code of deontology).

– If advertising for telemedicine offerings is intended directly and specifically to make (telemedicine) healthcare providers known or to provide information on the nature of their (telemedicine) practice, the advertisement will be considered as professional information. Dissemination pf professional information is tolerated in Belgium but subject to a number of conditions set out in the Belgian act of 22 April 2019 on the quality of healthcare.

Telemedicine in Europe

4. Advertising telemedicine offerings

(i) Advertising by healthcare professionals themselves

Although there is no specific prohibition on telemedicine advertising, ethical rules governing the practice of physicians prevent them from promoting telemedicine. Telemedicine is governed by the Ethical Code for Physicians, which provides that "medicine must not be practiced as a trade." (art. R4127-19 FCPH)

The Ethical Code for Physicians also prohibits the latter (art. R4127-20 FCPH) from authorizing the use their names or the reference to their professional activity to commercial entities for their own businesses.

Physicians are only authorized by their Ethical Code to communicate to the public by any means, including websites, information on their practice to unable patients to freely choice their practitioners (art.R4127-19-1 FCPH).

(ii) Advertising by teleconsultation platforms

On the basis of the above-mentioned provisions of the Ethical Code for Physicians, courts can sanction the practice of medicine as a business as well as unethical advertising by the providers of teleconsultation platforms (for instance: Paris judgment of 6 November 2020 No. RG 20/54799).

4. Advertising telemedicine offerings

In the past, Section 9 of the German Act on Advertising in the Field of Health (*"Heilmittelwerbegesetz"* – ***HWG***) generally prohibited the advertising of remote medical treatment (*"Fernbehandlung"*). In December 2019, a new exceptional rule in Section 9 sentence 2 HWG was added and loosened this general advertising ban.

According to the new Section 9 sentence 2 HWG, advertising for remote treatment is permissible if *"according to generally accepted professional standards, personal contact with the person to be treated is not necessary."*

A definition of what is to be understood as "generally recognized professional standards" or from which these can be derived is not given in the law itself. To date, there has only been one decision of the German Federal Court of Justice (*"Bundesgerichtshof"* – ***BGH***) regarding Section 9 sentence 2 HWG (BGH ruling of December 9, 2021 – I ZR 146/20 – *"Werbung für Fernbehandlung"*).

In this rather restrictive ruling, the BGH ruled on how Section 9 sentence 2 HWG is to be interpreted and defines the term "general professional standard" with reference to the corresponding term pursuant to Section 630a para. 2 German Civil Code (*"Bürgerliches Gesetzbuch"* – ***BGB***) and the principles developed in this regard concerning the obligations to be fulfilled by the physician under a medical treatment contract.

A professional standard provides information about the treatment in a specific field of medicine that can be expected of a conscientious and attentive physician in this field from a professional point of view at the time of treatment. It represents the respective state of scientific knowledge and medical experience that is required to achieve the medical treatment goal and has proven itself in practice.

According to this court ruling, the guidelines of medical societies as well as the guidelines of the German Federal Joint Committee (*"Gemeinsamer Bundesausschuss"* – ***GBA***) in accordance with Section 92, 136 of Book V of the German Social Code (*"Sozialgesetzbuch – Fünftes Buch"* – ***SGB V***) can offer proof of the required standards. Since such telemedical standards will only establish over time, a dynamic development and adaptation of standards can be assumed.

Ultimately, under the current legal situation in Germany, the admissibility of advertising for remote treatment is an ongoing, constantly evolving process and is therefore still subject to legal uncertainties at this point in time. The development in further case law remains to be seen.

Telemedicine in Europe

4. Advertising telemedicine offerings

Advertising is allowed as it is for other healthcare services, although all forms of advertising or health communication by doctors and health facilities must comply with articles 55, 56 and 57 of the Code of Medical Ethics.

Telemedicine in Europe

4. Advertising telemedicine offerings

The advertising of telemedicine services is generally allowed under Law 34/1988 on general advertising and Royal Decree 1/2007 for the protection of consumers and users. This legislation does not provide any additional obligation or restriction on the advertising of telemedicine different from those that apply to other sectors.

Telemedicine in Europe

4. Advertising telemedicine offerings

There are no specific laws in the UK regarding telemedicine advertising. However, there are rules which apply to the marketing communications for medicines, medical devices, treatments and health-related products, including **Section 12** of the Advertising Standards Authority's (**ASA**) CAP Code. Compliance with these rules is regulated by health regulators such as the MHRA.

The ASA published advice on the advertising of UK medical devices stating that any *"medicinal or medical claims and indications may be made for an appropriately certified medical device"* but advertisers must ensure that medical devices are either CE Marked (the original EU system) or UKCA Marked. A medicinal or medical claim is *"a claim that a product or its constituent(s) can be used with a view to making a medical diagnosis or can treat or prevent disease, including an injury, ailment or adverse condition, whether of body or mind, in human beings"*.

Advertisers must ensure that they hold robust evidence for their medical claims – a CE/UKCA certification itself is not enough to constitute evidence.

Telemedicine in Europe

5. Prescription and delivery of drugs

As regards drug prescriptions, physicians and other specialists registered to practice in Belgium are required to use electronic prescriptions since 1 January 2020. Paper prescriptions are only permitted in cases where there is no electronic option (e.g. on house calls). Patients will receive a hard copy from the doctor, printed, and containing a barcode; the code is then scanned by the pharmacist and the prescription is then archived. In case of teleconsultation, drug prescriptions are created electronically on Recip-e and can be viewed by the patient via her/his Personal Health Viewer. The unique number of the electronic prescription does not contain any personal data and can be transmitted to the patient (or the person requiring care).

In terms of drug delivery, the decree of 21 January 2009 regulating pharmacies provides that pharmacists cannot deliver drugs for human and veterinary use (as well as some other healthcare products) outside the pharmacy. The same decree only authorises the internet sale of non-prescription drugs for human use under strict conditions.

Telemedicine in Europe

5. Prescription and delivery of drugs

After a teleconsultation, the healthcare professionals can draw up a prescription (e.g drugs, additional examinations), which will be sent to the patient in paper form by post, or through secured digitalized means guaranteeing the confidentiality of the exchanges. The care prescribed following the teleconsultation is paid for under the usual conditions.

France is still running experimental programs for the electronic circulation of medical prescriptions in a secure and efficient way, from the prescribers to the patients and to the pharmacists delivering the prescribed pharmaceutical products, and ultimately to the social security administration for coverage of the related costs through the National Health Insurance Program. For this purpose, an Ordonnance of 18 November 2020 enhances the digitalization of medical prescriptions, which should be part of the widespread practice by the end of 2024 (Article L4071-1 of the FCPH). The development of e-prescriptions will be gradual, starting with an experimental period for each type of prescription.

Telemedicine in Europe

5. Prescription and delivery of drugs

Electronic prescriptions ("**e-prescriptions**") were first introduced by the Law for more Safety in the Supply of Medicines (*"Gesetz für mehr Sicherheit in der Arzneimittelversorgung"* – ***GSAV***).

According to Section 360 para. 3 SGB V, e-prescriptions shall be made available nationwide and for all patients who are covered by public health insurance the offer of electronic prescriptions shall even become mandatory for prescription drugs.

The nationwide rollout of e-prescriptions in medical facilities will be carried out according to a regionally and temporally staggered procedure: The first phase of the gradual e-prescription rollout started in pilot practices and hospitals in the regions of Westphalia-Lippe and Schleswig-Holstein in September 2022.

Provided that at least 25 percent of prescriptions are issued electronically in these pilot test regions, the rollout is planned to be expanded successively to further regions in Germany.

In the meantime, the rollout was paused due to necessary adjustments to the process required by data protection law. The next steps of the phased rollout will be determined by the German National Agency for Digital Medicine ("**gematik**") in a timely manner.

Independently from the regionally supported mandatory e-prescription rollout, the e-prescription can already be used voluntarily in medical facilities nationwide. From September 1, 2022 on, pharmacies throughout Germany will be able to redeem e-prescriptions and bill them with health insurances.

The Patient Data Protection Act (*Patientendaten-Schutz-Gesetz"* – ***PDSG***), which came into force in October 2020, regulates the use of e-prescriptions. The e-prescription is created and signed digitally only, but the prescription code can be redeemed on the smartphone as well as by printout at any online pharmacy or regular pharmacy of the patient's choice. In order to receive and redeem prescriptions electronically, patients need the gematik's e-prescription app called "Das E-Rezept". Besides, the redemption of electronic prescriptions via the electronic health card ("*Elektronische Gesundheitskarte"* – ***eGK***) shall be possible from mid 2023 on.

However, for the time being, the e-prescription is not intended to completely replace the hard copy prescription which is still available on request. The supply of medicines to patients is thus ensured in all cases.

Telemedicine in Europe

5. Prescription and delivery of drugs

In the public sector, the prescriptions are mainly electronic (hard copy prescriptions are still issued for certain kinds of drugs), while the private sector still uses hard copy prescriptions. However, even if the prescription is issued electronically, it must still be printed out to present to the pharmacy.

Under Italian law, prescribed medicines can only be sold and supplied by stationary pharmacies to which the patient has to provide the prescription (i.e. the printed copy of the electronic prescription or the hard copy of the prescription depending on certain circumstances).

Legislative decree n. 17/2014 – that implemented in Italy EU Directive 2011/62/EU amending EU Directive 2001/83/CE – allowed authorised pharmacies to sell non-prescription medicinal products at a distance through a website.

Telemedicine in Europe

5. Prescription and delivery of drugs

Royal Decree 1718/2010 on medical prescription and dispensing orders sets out that prescriptions may be issued physically or electronically, either in the public or private sector, and that electronic prescriptions are legally valid as traditional hard copy prescriptions.

According to Spanish law, prescribed medicines can only be sold and supplied by stationary pharmacies.

Despite the fact that patients may have access to prescriptions online, they cannot buy drugs that are subject to prescription online, as the Spanish legislator has considered that such distance selling (without the particular assessment of a pharmacist) could pose a threat to the public health. Therefore, the full treatment of patients cannot be conducted electronically.

In case of electronic prescriptions, only pharmacies connected to the electronic prescription system may supply the prescribed medicines, once the patient has been identified. Only legally authorised pharmacies can sell non-prescription drugs through a website.

These websites must meet the requirements established in the Royal Decree 870/2013 regulating distance selling of non-prescription drugs to the public.

Telemedicine in Europe

Osborne Clarke

5. Prescription and delivery of drugs

The electronic prescription service (**EPS**) allows prescribing contractors (e.g. a GP) to send NHS prescriptions electronically to a dispenser (e.g. a pharmacy) of the patient's choice who will then dispense to the patient. Patients are able to either collect their medication from their chosen dispenser or opt for it to be delivered to them via dispensers. The National Health Service (**NHS**) is responsible for authorising prescribing contractors to use the Electronic Prescription Service.

When providing telemedicine services, healthcare professionals should consider whether remote consultations and prescriptions are appropriate for the patient. The GMC has issued **guidance** and set out high level principles on the provision of remote prescriptions which include (without limitation):

1. prioritising patient safety and ensuring there are adequate patient safeguards in place, including appropriate identity and verification checks;
2. identifying vulnerable patients and taking appropriate steps to protect them;
3. only prescribing medication if it is safe to do so (note that it is not considered safe if i) the doctor does not have sufficient information about the patient's health or if remote care is unsuitable to meet their needs, and/or ii) relevant information is not shared with other healthcare providers involved in the patient's care); and
4. ensuring that there is appropriate aftercare and support for ongoing monitoring or treatment of the patient.

The General Pharmaceutical Council (**GPhC**) has also set out the categories of medicine that pharmacies based in England, Scotland and Wales can and cannot not supply without specific assurances and safeguards in place.

Telemedicine in Europe

Osborne Clarke

6. Public or private reimbursement for telemedicine services

Public reimbursement by NIHDI

Prior to the COVID-19 pandemic, an important barrier to the development of telemedicine in Belgium was the absence of patient reimbursement for healthcare services provided remotely. Since 1 August 2022, a new legal framework has been put in place for the reimbursement of remote medical consultations.

This framework replaces the system created in Belgium at the start of the COVID-19 crisis. Under the new rules, the number of telephone and video consultations that is reimbursed by the National Institute for Health and Disability Insurance (NIHDI) is not limited. However, remote consultations must take place with:

– a physician with whom the patient already has a therapeutic relationship,

– a specialised physician ("specialist") to whom the patient has been referred by another physician, or

– general medical on-call service.

In 2018, a national mobile health platform (mhealthbelgium.be) was set up with a recognition system for mobile health applications (mhealth apps). To appear on the website, a mhealth app must comply with certain criteria following a step-by-step pyramidsystem. Depending on the number of criteria that have been fulfilled, the app will be granted a level 1 to level 3 recognition:

– Level 1 (M1): Legal and regulatory compliance: mhealth app complies with applicable legislation (CE-marking, medical devices laws and regulations and the GDPR).

– Level 2 (M2): Interoperability: the mhealth app meets all imposed criteria regarding authentication, security and the use of Belgium's ecosystem of e-health services by means of standardised tests.

– Level 3 (M3): Partial or full reimbursement: the social-economic added value is being or has been demonstrated before NIHDI.

As at March 2023, there are currently 36 apps listed on the platform: 23 apps with a M1 recognition, 12 with M2 recognition and 1 with M3 recognition (i.e. in the process of proving its social-economic value and therefore only temporarily financed by NIHDI).

Private reimbursement

Since 2020, private healthcare insurers such as Partenamut & Partena Ziekenfondsen officially recognise mHealthBelgium and refund certain apps on the portal. For telemedicine services or technologies that are not covered by public funds or the mHealthBelgium pyramid system, patients can either discuss potential options with their healthcare providers and enter into an agreement on a case-by-case basis or benefit from a reimbursement through private social security providers.

Telemedicine in Europe

6. Public or private reimbursement for telemedicine services

The French Government and Parliament have been encouraging the development of telemedicine, and the reimbursement of telemedicine acts (as defined under Section 1 above) by the Social Security Administration through the National Health Insurance Programme has developed over the past ten years.

Teleconsultation can be is reimbursed by the French health insurance system at the same rate as face-to-face consultations, provided that the following requirements are met :

– teleconsultation must be carried out by secure video transmission;

– with some exceptions, it must be part of the coordinated care pathway;

– the healthcare professional must be located in the same territory as the patient;

– it must respect the quality of care (e.g regular monitoring of the patient, alternating between face-to-face consultations and teleconsultations depending on the patient's need and the professional's assessment);

– a report must be recorded in the medical patient file.

As a derogation due to the Covid-19 pandemic, teleconsultation procedures are today 100% covered by the National Health Insurance Programme (until **30 September 2022**, if not extended later on). In situations where the telemedicine acts would not be fully covered by a Social Security reimbursement through the National Health Insurance Programme, the private sector insurance providers should cover the part of the costs generated by the telemedicine act which is not covered by the Social Security Administration (fully or partly, depending on the private insurance policies subscribed to by patients).

Telemedicine in Europe

6. Public or private reimbursement for telemedicine services

In the past, only some telemedicine services were reimbursed by health insurance providers in Germany, significantly more so by the private health insurance providers than by the statutory health insurance providers. However, both numbers are increasing. Due to regulatory changes regarding telemedicine, the conditions for the reimbursement of telemedicine services have changed accordingly, for example:

– Video consultations are now not only reimbursed by the private health insurance providers but also by the statutory health insurance providers.

  However, whilst during the COVID-19 pandemic physicians and psychotherapists were able to offer and bill video consultations unlimitedly for patients with statutory health insurance, the number of cases have now again been limited to 30 percent of their medical services since April 2022.

– Patients now get reimbursed for the costs of digital health applications (*"Digitale Gesundheitsanwendungen"* – ***DiGA***) by the private and the statutory health insurance providers as well. For patients with statutory health insurance, the prerequisite is that the health app has been listed in the DiGA-directory (*"DiGA-Verzeichnis"*) according to Section 139e Book V of the German Social Code (*"Sozialgesetzbuch – Fünftes Buch"* – ***SGB V***).

In case the insurance providers do not reimburse the costs, patients have to pay for telemedicine services themselves.

Telemedicine in Europe

6. Public or private reimbursement for telemedicine services

The National Guidelines issued in 2014 (art. 5.6) expressly provide that, as for all the other medical activities, telemedicine tools can be charged to the National Health Service (NHS). In order to benefit from the public reimbursement, a proper agreement must exist between the NHS and the Services Provider Centre.

The National indications for the provision of telemedicine services of December 2020 contains some provision on the remuneration and tariff system, prescription, booking and reporting for the public sector.

Both the public and private sector cover telemedicine services. In particular, as noted in the IVASS (Institute for Insurance Supervision) report dated September 2021, private health insurance covers many telemedicine services.

6. Public or private reimbursement for telemedicine services

Both public and private sector cover telemedicine services.

Public reimbursement for telemedicine services is not covered in Spanish legislation, except for cross-border healthcare assistance pursuant to Royal Decree 81/2014. Said regulation sets out the general principles for the reimbursement of cross-border healthcare services expenses. In addition, the Royal Decree also states that the relevant public healthcare administration will reimburse the corresponding expenses.

Private healthcare insurance may reimburse some telemedicine services.

Telemedicine in Europe

6. Public or private reimbursement for telemedicine services

If it is provided within the National Health Service (**NHS**), telemedicine will be free at the point of delivery, and funded by UK taxpayers' National Insurance contributions. Many private health insurers include telemedicine as standard, for example Vitality Health.

7. Cross border offerings of telemedicine services

There is little information about the cross-border provision of telemedicine that involves the participation of Belgian healthcare providers and patients. However, a research paper on Cross-border telemedicine (*"Observatoire social européen"*) states that:

- most telemedicine projects in Belgium are pilot projects or initiatives set up as a way to support health professionals (telemonitoring services or providing telecardiology);
- the cross-border provision of healthcare almost exclusively takes place in the form of tele-expertise;
- the telemedicine services are provided on a commercial basis, in an academic setting or with a humanitarian perspective (between Belgium and developing countries);
- cross-border telemedicine for Belgian patients is a rather rare phenomenon, the services are more often provided to patients or health professionals in another country (mostly outside the European Union).

Reimbursement: in accordance with the Directive 2011/24/EU, the Member State where a patient has healthcare cover has to reimburse the costs of cross-border healthcare if the healthcare in question is among the benefits to which the insured person is entitled in his Member State of affiliation but the Member State of affiliation may impose on an insured person seeking reimbursement of the costs of cross-border healthcare the same conditions, eligibility criteria and regulatory and administrative formalities as it would impose if this healthcare were provided in its territory.

7. Cross border offerings of telemedicine services

In accordance with the EU treaty and the principle of free movement of services within the EU, it is considered that a doctor licensed to practice outside of France, but within the EU, could provide a teleconsultation to a French patient located in France.

However, the related cost would not be covered by the French Health Insurance Programme.

7. Cross border offerings of telemedicine services

The use of telemedicine services offered by physicians located outside Germany, but within the European Union (**EU**), is unrestricted. According to the principle of free choice of physician (*"Freie Arztwahl"*) that applies in Germany, patients in Germany are basically free to choose the physicians treating them.

Besides, according to the EU Treaty and the principle of free movement of services within the EU, a licensed physician based in Germany can also offer telemedicine services to a patient located elsewhere in the EU.

Cases of cross-border healthcare within the EU are regulated in the European Patients' Rights Directive 2011/24/EU ("Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare"):

– According to Article 4 para. 1 No. 1 of the Directive 2011/24/EU, cross-border healthcare shall be provided in accordance with (a) the legislation of the member state of treatment, (b) standards and guidelines on quality and safety laid down by the member state of treatment and (c) Union legislation on safety standards.

'Member state of treatment' in cross-border healthcare means the member state on whose territory healthcare is actually provided to the patient. In the case of telemedicine, healthcare is considered to be provided in the member state where the healthcare provider is established (Article 3 para. 1 lit. d) Directive 2011/24/EU).

– Article 7 of the Directive 2011/24/EU contains the basic regulation on reimbursement according to which the costs incurred by an insured person in connection with cross-border healthcare are to be reimbursed provided that the healthcare service in question is among the healthcare services to which the insured person is entitled in the member state in which he is insured.

According to Article 7 para. 7 of the Directive 2011/24/EU, the legislator may provide for the same prerequisites, eligibility criteria and formalities as in the case of a domestic claim.

– Article 11 of the Directive 2011/24/EU governs the recognition of individual prescriptions issued in another member state.

7. Cross border offerings of telemedicine services

The National Guidelines dated 2014 expressly provide that cross-border telemedicine (when doctor and patient are in two different countries), falls within the scope of EU legislation and that the European Commission intends to support the local authorities and stakeholders by clarifying how EU legislation can affect telemedicine.

European countries have established a system for mutual recognition of national medical licenses and crossborder medical care. In particular, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, requires that cross-border healthcare has to be provided in accordance with the legislation of the Member State (MS) of treatment. In the case of telemedicine, it expressly defines the MS of treatment as that of the service provider's MS of establishment. Italy has implemented this directive by Legislative Decree no. 38 of 4 March 2014.

The Commission (see "Commission Staff working documents on the applicability of the exiting EU legal framework to telemedicine services", dated 6 December 2012) has also clarified that to provide cross-border telemedicine services, the doctor is not required to change location. Therefore the authorisation of the patient's MS is not required. Authorisation is only required where the doctor wants to operate in another MS than the one of his/her habitual residence, then the doctor may need to request authorisation.

In light of the above, an Italian doctor based in Italy who provides telemedicine services to a patient in another country, shall be subject to the Italian legislation. Similarly, a German doctor based in Italy, whose licence has been recognised, could offer telemedicine services to a patient abroad subject to Italian legislation.

7. Cross border offerings of telemedicine services

The Spanish Royal Decree 81/2014 on patients' rights in cross-border healthcare includes a legal provision on telemedicine within the definition of "Member State of treatment". According to the referred provision, *"in the case of telemedicine, healthcare shall be deemed to be provided in the Member State where the provider is established"*. Therefore, the licensing and registration requirements of the country where the provider has its registered office would apply.

In regards to the reimbursement to Spanish patients for cross-border healthcare services, it will depend on the specific scenario (e.g. if the healthcare assistance is programmed or not, for example in case of a medical emergency). The restrictions envisaged in the Spanish Royal Decree on patients' rights in cross-border healthcare shall apply in Spain for any reimbursement scenario, among others: (i) previous authorisation shall be required in certain cases; (ii) reimbursement shall be granted in accordance with services and amounts stipulated in the common portfolio of services of the Spanish National Health System; and (iii) a subsequent evaluation by a GP (General Practitioner) may be required by the Spanish National Healthcare System.

There are currently two possible scenarios for cross-border healthcare assistance both for Spanish patients abroad and for foreign patients in Spain (i.e. restricted to the territory of the European Union and also in Iceland, Liechtenstein, Norway and Switzerland – which is the territorial scope for the European Health Insurance Card):

– Non-programmed assistance (e.g. medical emergency):

- National Healthcare System: in this case patients might not have to pay for the services if the citizens of the host country do not have to pay for such services in turn (please note that European Health Insurance Card may be required when being assisted for this possibility to be feasible), bearing the Healthcare System of the country of origin of the patient the costs.
- Private medical practice: patients may have to pay in advance, and then request the reimbursement if such service is available for patients in the National Healthcare System of their country of origin. Reimbursement made in this case shall be done according to the costs set by each country as bearable by the National Healthcare System.

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7. Cross border offerings of telemedicine services

– Programmed assistance –there are two possible scenarios in this case:

- The National Healthcare System of the patient directly assumes the costs before the medical treatment is provided: this is possible only for treatments and assistance provided by public healthcare services, and not for those provided by private practices or clinics. Note that this scenario in Spain requires the previous authorisation of the Spanish National Healthcare System for those treatments envisaged in Annex II of the Spanish Royal Decree on patients' rights in cross-border healthcare.
- Patients pay in advance for the services, and then request the reimbursement in their country of origin: this option is available for both public and private healthcare services, if such service is available for patients in their country of origin (note that previous authorisation may be required). Please note that the reimbursement in this case shall be made in accordance with the costs set by each country as bearable by the National Healthcare System of the patient.

7. Cross border offerings of telemedicine services

Under the UK Medical Act, doctors treating patients in the UK must be registered with the GMC and hold a licence to practice. However, the GMC cannot force doctors outside the UK to register with it.

In accordance with **guidance** provided by the GMC, UK based healthcare professionals looking to offer remote services to patients overseas need to check whether they are required to register with regulatory bodies in the country where they are based (the UK); where the patient is based; and where any medicines they prescribe are to be dispensed.

UK healthcare professionals will need to comply with UK and applicable overseas legal requirements in relation to the telemedicine services and prescriptions. The GMC have issued **guidance** on considerations for overseas prescriptions, including:

a) how UK or local healthcare professionals will monitor the patient's condition;

b) any legal restrictions on prescribing or supplying particular medicines;

c) whether the UK healthcare professional has adequate indemnity or insurance to cover their practice in all relevant countries;

d) any differences in a product's licensing, licensed names, indications, recommended doses or accepted clinical use in the local country; and

e) whether the UK healthcare professional needs to be registered with multiple regulatory bodies.

Telemedicine in Europe

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