

# Telemedicine in Europe



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 sections provide a brief overview of the national developments and legal frameworks regarding telemedicine in Germany, France, Belgium, Italy, Spain, the Netherlands and the UK.

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Belgium



France



Germany



Italy



The Netherlands



Spain



UK

## 1. What is telemedicine?

### 1. What is telemedicine?

There is no definition of telemedicine under Belgian law. The Belgian Physicians' Association describes telemedicine as the use of telephone notice, electronic notice and prescription, telemonitoring (remotely, by video conference and by medical applications), teleconcertation between professionals and the storage of health data in the cloud.



Belgium

## 1. What is telemedicine?

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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:

- Diagnostic.
- Follow-up of patients exposed to risks, either by way of prevention or by way of post-therapy.
- Requesting medical advices 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:

- Teleconsultation: a healthcare professional’s remote medical consultation for a patient.
- Teleexpertise: a healthcare professional remotely requesting medical advice from another professional specialising in other therapeutic areas.
- Medical telesurveillance: 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 teleassistance: 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.

Since July 2019, a new article L6316-2 included in the FCPH defines “telecare” as a “remote practice of care based on information and communication technologies and connecting patients with one or more pharmacists or medical auxiliaries”.

## 1. What is telemedicine?

### 1. What is telemedicine?

Similar to most countries, there is no definition of telemedicine under German law. However, the German Federal Assembly of Physicians 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.”



Germany

## 1. What is telemedicine?

### 1. What is telemedicine?

There is no definition of telemedicine under Italian law. The definition of telemedicine is contained 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.

Article 2.1 ("Definition of Telemedicine") 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."

## 1. What is telemedicine?

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There is no definition of telemedicine under Dutch law. However, in its public communications the Ministry of Healthcare, Wellbeing and Sports uses the following definition of eHealth, which is an umbrella definition also covering telemedicine: "eHealth is the use of modern information and communication technology to support or improve health and healthcare."

In addition, the NEN Guideline (as defined below under question 2) defines telemedicine as:

"A healthcare process or an entire set of healthcare processes which satisfy each of the following two requirements:

- Distance is bridged by using both information technology and telecommunications.
- At least two actors are involved in the healthcare process, of which at least one is a provider of healthcare under the Wet BIG (as defined below under question 2) or acts under the responsibility of such a healthcare provider."

## 1. What is telemedicine?

### 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.”



Spain

## 1. What is telemedicine?

### 1. What is telemedicine?

There is no definition of telemedicine under UK law.

The EU Commission referred to it in 2008 as:

“The provision of healthcare services, through the use of information and communication technologies (**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.”

<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52008DC0689&from=EN>



UK



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

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

There is no specific law governing telemedicine in Belgium. Instead certain elements are covered by different laws as follows:

- The Royal Decree of 30 June 2017 setting the terms and conditions under which the compulsory health and benefits insurance grants a financial contribution to doctors for the use of telematics and for the electronic management of medical records;
- The Royal Decree of 3 December 2017 setting out the terms and conditions under which compulsory health and benefits insurance grants a financial contribution to dentists for the use of telematics and for the electronic management of medical records in 2017.

These decrees provide for a financial contribution for doctors and dental practitioners who use at least one of the following electronic techniques: e-prescription, an internet platform for the reimbursement of healthcare, electronic billing, secure patient data sharing and electronic management of healthcare fees.



Belgium

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

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

Since then, various implementation decrees have been published detailing the rules applying to telemedicine and 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 programmes.

The most recent change was introduced by the law of 24 July 2019, which added the new article L6316-2 into the FCPH providing the legal definition of telecare.

Further details about the rules governing telemedicine are provided in the following sections.



Belgium



France



Germany



Italy



Spain



UK

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

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Telemedicine is governed by the following laws:

Since 2018, certain provisions related to telemedicine are included under § 7 paragraph 4 of the German Medical Association's Professional Code of Conduct ("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.

Furthermore, 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: Digital health applications.
- § 33b SGB V: Promotion of the development of digital innovations by health insurance companies.
- § 68b SGB V: Promotion of innovations in medical care.
- §§ 75b SGB V, 92a, 92b, §134, 139e, 263a, §§ 303a-303e SGB V.



Germany

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

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There are no specific law governing telemedicine. However, Italy's national Guidelines (mentioned in Section 1) 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 guidelines specify that telemedicine services must be carried out in compliance with the current legislation on personal data protection and in full respect of the professional's obligation to inform patients about the health services received. Telemedicine is 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 and telemonitoring (when the patient undergoes a diagnostic test, in a different place from the surgery of the general practitioner, and the test is delivered to him or her for their interpretation) and telereporting (when the diagnostic test is delivered to a doctor who has the specialist requirements necessary for the required clinical evaluation).

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

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

There is no specific law governing telemedicine in the Netherlands. However the Netherlands Standardisation Institute has set out criteria for healthcare providers and institutions using telemedicine. The Medical Devices Act (“Wet op de medische hulpmiddelen” - **Wmh**) and in relation there to the Medical Devices Decree (“Besluit medisch hulpmiddelen” - **Bmh**). The Wmh and the Bmh are the Dutch implementation of the European Medical Devices Directive 93/42/EEG.

eHealth applications used in the diagnoses or treatment of an illness or a handicap may fall within the scope of the Wmh. The manufacturer of the product will then be monitored by the Dutch Inspectorate for Health and Youth Care (**IGJ**), the authority enforcing the Wmh. If a manufacturer does not meet the legal requirements of the Wmh, this can lead to a fine. This has happened a few times in recent years. However, not every app or other example of eHealth is a medical device. For example, pedometers and other health apps for recreational purposes do not fall within the scope of the Wmh and are therefore not covered by the inspection of the IGJ.

According to the Wmh, software also may be qualified as a medical device. Since 2014, the IGJ enforces the Wmh on manufacturers and developers of software.

- The Healthcare Quality, Complaints and Disputes Act (“Wet kwaliteit, klachten en geschillen zorg” - **Wkkgz**) and the Individual Healthcare Professions Act (“Wet op de beroepen in de individuele gezondheidszorg” - **Wet BIG**).

Healthcare institutions working with eHealth have the responsibility to ensure that eHealth is used safely and the legal framework is set out in the Wkkgz and the Wet BIG.

- The Medical Treatment Contracts Act (“Wet op de geneeskundige behandelingsovereenkomst”) is the legal framework governing the relationship between the provider and receiver of healthcare.
- The Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act (“Wet aanvullende bepalingen verwerking persoonsgegevens in de zorg”).

This act complements the GDPR, addressing personal data protection in the healthcare sector specifically.



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

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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.



Spain

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

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

- There do not appear to be any separate provisions regarding telemedicine. The Care Quality Commission (**CQC**) is responsible for regulating healthcare institutions and providers in England and requires telemedicine providers to register to perform “transport services, triage and medical advice provided remotely.” The regulators for the other parts of the UK do not have any additional requirements for telemedical services.
- For the CQC, telemedicine generally occurs whenever technology is used to provide care services between the doctor and the patient. Doctors providing medical services to UK patients outside of the UK can’t be required to register with and be licensed by the General Medical Council.



### 3. General conditions/restrictions for telemedicine offerings

## 3. General conditions/restrictions for telemedicine offerings

Telemedicine is generally allowed with certain restrictions.

For example, the Belgian Physicians' Association prohibits healthcare providers from providing a diagnosis without having a prior physical interaction with the patient.

Teleconsultation with a view to making a diagnosis and proposing a treatment is only allowed if the doctor:

- Knows the patient;
- Has access to the medical information concerning her/him (medical file);
- Can guarantee the continuity of care.

The medical condition must also allow care to be provided via teleconsultation (Conseil National de l'Ordre des médecins/ Nationale Raad van de Orde van Artsen/ National Council of the Order of Physicians 2019).

Another barrier for healthcare providers comes from the absence of patient reimbursement for healthcare services provided remotely. However, the National Institute for Health and Disability Insurance (**INAMI – RIZIV**) is currently developing a framework for the reimbursement of telemedicine and health apps (see below "Reimbursement").



Belgium



### 3. General conditions/restrictions for telemedicine offerings

## 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 article 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, an 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).

But there are restrictions on the reimbursement of teleconsultation and teleexpertise by the social security administration (see Section 6).

### 3. General conditions/restrictions for telemedicine offerings

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

Since legalisation of remote treatment in 2018, it is also permitted to provide medical advice or treatment exclusively via the means of telemedicine “in individual cases”, even for new patients. However, it must be medically justifiable, the necessary medical care must be guaranteed and the patient must be informed about the particularities of exclusive consultation and treatment via communication media.

Furthermore, the new Digital Healthcare Act (“Digitale-Versorgung-Gesetz” – DVG), which came into force in January 2020, now allows physicians to inform about and advertise telemedicine services on their website. Prior to that, advertising of telemedicine services was restricted (see Section 4).

#### 3. General conditions/restrictions for telemedicine offerings



Germany

### 3. General conditions/restrictions for telemedicine offerings

The national Guidelines, mentioned in Section 1, among others, provide 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.

#### 3. General conditions/restrictions for telemedicine offerings



Italy

### 3. General conditions/restrictions for telemedicine offerings

The use of telemedicine is generally allowed. In principle there is no differentiation in Dutch legislation between healthcare with or without the use of telemedicine. All laws and regulations applicable to healthcare also apply to healthcare using telemedicine.

#### 3. General conditions/restrictions for telemedicine offerings

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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.



Spain

### 3. General conditions/restrictions for telemedicine offerings

### 3. General conditions/restrictions for telemedicine offerings

Telemedicine is generally allowed in the UK. The E-Commerce Directive 2000/31/EC will apply to telemedicine services as they are likely to be caught by the definition of “Information Society Services”, being “any service normally provided for remuneration at a distance, by means of electronic equipment for the processing and storage of data, at the individual request of a recipient of the service.” Article 8 of the directive requires member states to control whether healthcare professionals are respecting their professional rules when offering these services.

Consumer rights legislation is also relevant. Directive 2011/83/EC on consumer rights (Consumer Rights Directive) applies where an individual purchases an app relating to health/lifestyle/wellbeing. Any data being transferred is also likely to be considered personal data.

Post Brexit, the E-Commerce Directive will continue to apply to the UK for the duration of the transition period.



UK

#### 4. Advertising telemedicine offerings

## 4. Advertising telemedicine offerings

Although there is no law specifically covering telemedicine in Belgium, applicable laws and deontological codes have installed various mechanisms that require the a priori control of communications related to medical products/services:

- Advertising is permitted for medical products/medical devices, but Article 9 of the Act on Medicinal Products sets out several prohibitions and restrictions regarding the advertising of medicinal products and implantable medical devices to the general public.
- Ethical rules governing the practice of healthcare professionals allow advertising if (i) its purpose is to communicate the medical activity to the public and (ii) it does not fall under any of the ethical restrictions.



Belgium

## 4. Advertising telemedicine offerings

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 medical code of ethics.

### 4. Advertising telemedicine offerings



## 4. Advertising telemedicine offerings

In the past, the German Law on Advertisement of Medicinal Products (“Heilmittelwerbegesetz” - **HWG**) prohibited the advertising of telemedicine services.

In January 2020, the new Digital Healthcare Act (“Digitale-Versorgung-Gesetz” – **DVG**) came into force and changed Article 9 HWG. The article now states that the prohibition of advertising for the recognition or treatment of diseases shall not apply to advertising for “remote treatment which is carried out using communications media if personal medical contact with the person to be treated is not required according to generally recognised professional standards”.

### 4. Advertising telemedicine offerings



Germany

## 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.

### 4. Advertising telemedicine offerings



Italy

#### 4. Advertising telemedicine offerings

## 4. Advertising telemedicine offerings

There are no specific laws or regulations governing advertising of telemedicine.

The advertising for telemedicine or eHealth is allowed, if the advertising is in compliance with the current legal framework for misleading advertising, (prescribed) medicines and medical treatments, including laws, regulations and self-regulatory codes of conduct specific to healthcare.

In general, unfair commercial practices are illegal in the Netherlands. As a high-level overview, commercial practices targeting or reaching consumers are considered unfair if they are not in compliance with professional diligence and are suited to materially influence the economic behaviour of consumers. Unfairness also occurs where a person engages in a misleading commercial practice which is suited to cause the consumer or other market participant to take a transactional decision which they would not have taken otherwise.

It can also be considered misleading to conceal facts that are significant for the consumer's transactional decision and if the concealment is suitable for influencing the decision. It is therefore an unfair commercial practice to hide material information, or to provide it in an unclear, unintelligible, ambiguous or untimely manner.

In addition, advertising of telemedicine may be covered by more specific rules and restrictions contained in the advertising laws, regulations and codes of conduct:

- The Code of conduct for Medical self-care Devices ("Code reclame voor Medische zelfzorg Hulpmiddelen" - **CMH**) generally prohibits advertising of devices which are incompatible with the standards of the Wmh.

Continues on next page

## 4. Advertising telemedicine offerings

Within the scope of the CMH it is generally permitted to advertise for the (additional) self-care of conditions that (i) can be diagnosed by the user himself, (ii) have already been diagnosed by a doctor or (iii) have been diagnosed by a doctor and were treated by other means.

The CMH further requires that an advertising message may not conflict with the information in the enclosed user manual and the information set out on the packaging.

- The Dutch Code for the Advertising of Medicinal Products to the General Public (“Code voor de Publieksreclame voor Geneesmiddelen”) prohibits public advertising of prescription medicines in the Netherlands.
- In addition, the Dutch Media Act (“Mediawet”) prohibits advertising of medical treatments for linear and on-demand media services.

### 4. Advertising telemedicine offerings

## 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.

### 4. Advertising telemedicine offerings



Spain

## 4. Advertising telemedicine offerings

There are no specific laws in the UK regarding telemedicine advertising.

### 4. Advertising telemedicine offerings



UK

## 5. Prescription and delivery of drugs

Physicians and other specialists 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 will be archived.

According to Belgian Royal Decree of 21 January 2009 which relates to pharmacists, pharmacists cannot deliver drugs for human and veterinary use, medical devices or raw materials outside the pharmacy. The same Royal Decree only authorises the internet sale of non-prescription medicinal products for human use and medical devices under strict conditions.

### 5. Prescription and delivery of drugs



Belgium

## 5. Prescription and delivery of drugs

Subject to certain conditions, medical prescriptions can be electronically transferred and the prescribed medicines shipped by online pharmacies.

France is still running experimentation programs for the electronic circulation of medical prescriptions in a secure and efficient way, from the prescriber 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 Programme.

### 5. Prescription and delivery of drugs



## 5. Prescription and delivery of drugs

The electronic prescriptions (**e-prescriptions**) were introduced by the Law for more Safety in the Supply of Medicines ("Gesetz für mehr Sicherheit in der Arzneimittelversorgung" - **GSAV**), passed by the German Parliament in August 2019.

The leading organisations in the healthcare sector shall create the necessary technical and administrative foundations for the use of e-prescriptions by June 2020. However, there is not yet a fixed date for the widespread application of digital regulations regarding the e-prescription and until then e-prescriptions are only allowed within the scope of several pilot projects.

In the future, when the physician prescribes medications during a video consultation, the patient will receive an e-prescription, which can be redeemed in an online pharmacy or regular pharmacy of his choice. However, the e-prescription is not intended to completely replace the hard copy prescription which is available on request.

The e-prescription will enable further new digital applications from medication reminders to medication plans with built-in interaction checks. This makes it easy to check whether all the medicines are compatible with each other.

### 5. Prescription and delivery of drugs



Germany

## 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.

## 5. Prescription and delivery of drugs

Article 67 of the Dutch Medicines Act (“Geneesmiddelenwet”) generally prohibits prescribing medicines via internet to someone who has never personally met the prescriber, or who does not know the prescriber or whose prescriber does not have access to the person’s medication history.

Accordingly, a doctor may only prescribe prescription drugs via internet if:

- The doctor and the user have a doctor-patient relationship;
- The doctor knows the user’s medication history;
- The doctor has a reliable medical file from the user.

Also a doctor operating online is not allowed to prescribe drugs on the basis of a questionnaire that the user has completed.

Chapters 6 and 7 of the Medicines Act Regulations (“Regeling Geneesmiddelenwet”) set out the legal requirements for distance selling of drugs.

In general, only those who are allowed to prescribe drugs on the basis of the Dutch Medicines Act, as described above, are allowed to sell them online, provided that the other requirements of the Medicines Act Regulations are met. Non-prescription medication may also be sold by registered pharmacies.

## 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.

## 5. Prescription and delivery of drugs

The National Health Service (**NHS**) is responsible for authorising prescribing contractors to use the Electronic Prescription Service. This responsibility is included in paragraph 39A of Schedule 6 of the GMS Contract Regulations.

Babylon GP at Hand clinicians can prescribe medication in line with NHS guidelines. Electronic prescription services can also be used through telephone appointments through most GP.

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 include a number of specific conditions subject to which distance-selling pharmacies are permitted to operate:

- They do not offer to provide essential services face-to-face to patients;
- The premises may not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

- The pharmacy procedures for the premises must secure the uninterrupted provision of essential services during core and supplementary opening hours to persons anywhere in England who request those services;
- The pharmacy procedures must also secure the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the contractor or their staff and
- The contractor cannot restrict service provision to certain areas of England or to certain categories of patients.

With GP at Hand, the patient can either pick up the medication from a stationary local pharmacy, or prescriptions can be delivered electronically direct to the patient using Echo, Well+ and Lloyds Pharmacy.

## 6. Public or private reimbursement for telemedicine services

Belgian law does not yet provide for a general reimbursement of telemedicine services for patients, however we see the following developments:

- i. The Belgian Federal Government (in cooperation with FAMHP, beMedTech, Agoria, RIZIV/INAMI) has set up a platform ([mhealthbelgium.be](https://mhealthbelgium.be)) where detailed information about mhealth applications can be found. In order to be recognized and published on the website, a mhealth app must comply with certain criteria (validation pyramid). Depending on the number of criteria that are fulfilled, the app will be granted a level 1 to level 3 recognition:
  - Level 1 (M1): Legal 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 local e-health services by means of standardised tests.

- Level 3 (M3): Reimbursement: the social-economic added value has been demonstrated (The RIZIV/INAMI is currently developing a framework for the reimbursement of telemedicine/health apps).

An app always enters at the lower level, M1, and can climb in hierarchy via M2 to the top level, M3. At the moment there are 14 apps with a M1 recognition, but none of them are reimbursed by the RIZIV/INAMI.

- ii. Since 2020, private healthcare insurers Partenamut & Partena Ziekenfondsen are the first to officially recognise mHealthBelgium and refund all apps on the portal.

In all other cases, patients can either discuss it with their healthcare providers and enter into an agreement on a case-by-case basis or benefit from a reimbursement through a private social security provider.

The Royal Decrees of 30 June 2017 and of 3 December 2017 (see above) provide for a telematics premium for health care providers who make use of electronic tools developed by the government with the help of the private sector (eg recip-e, MyCareNet).

### 6. Public or private reimbursement for telemedicine services



Belgium

## 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 Program has developed over the past ten years.

To benefit from the Health Insurance Program in France, the patient having a teleconsultation must be initially directed by his/her usual treating doctor if the teleconsultation is not conducted by him/her (the usual treating doctor being mandatorily a doctor practicing in France and registered in this capacity at the social security administration).

With the COVID-19 crisis, the French government enacted a special decree, effective as from March 10 until April 30, 2020 (if not extended later on), pursuant to which the requirement above was waived:

Patients who are COVID-19 positive or people presenting the COVID-19 symptoms can skip the first step (i.e. having their usual treating doctor routing the teleconsultation), go directly to any doctor for teleconsultation and have the related costs reimbursed through the French Health Insurance Program.

In situations where the telemedicine acts would not be fully covered by a Social Security reimbursement through the National Health Insurance Program, 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).

### 6. Public or private reimbursement for telemedicine services

## 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 public 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 consultation hours are now not only reimbursed by the private health insurance providers, but also by the public health insurance providers;
- Patients now get reimbursed for the costs of digital health apps by the private and the public health insurance providers as well.

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

### 6. Public or private reimbursement for telemedicine services



Germany



## 6. Public or private reimbursement for telemedicine services

The Italian Guidelines on Telemedicine (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.

Both the public and private sector cover telemedicine services. In particular, as noted in the IVASS (Institute for Insurance Supervision) report on the new health policies on digital health insurance dated October 2016, private health insurance covers many telemedicine services.

6. Public or private reimbursement  
for telemedicine services



Italy

## 6. Public or private reimbursement for telemedicine services

Although not specifically directed at telemedicine, the Dutch Healthcare authority (**NZa**) has published the Directive on the reimbursement of the costs of eHealth 2019 (“Wegwijzer bekostiging e-health 2019” - **the Wegwijzer**) covering, among others, some telemedicine services.

In general, the Wegwijzer provides that if previously insured healthcare is provided in an eHealth form, such healthcare will still be treated as insured healthcare if the composition and effectiveness do not substantially change. The reverse also applies - healthcare that was not insured in the original form will also not be insured if it is offered in the form of eHealth.

In addition, generally eHealth solutions complimentary to a primary healthcare service are not eligible for reimbursement as opposed to eHealth solutions which are the primary healthcare service.

Therefore, if telemedicine falls within the scope of insured healthcare, it will be covered by private health insurance.

The healthcare (and health insurance) market in the Netherlands is a “regulated” market, meaning that free competition is combined with the government’s regulation of general interest objectives. The NZa monitors the accessibility and affordability of healthcare. In addition, the IGJ supervises its quality.

## 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.

### 6. Public or private reimbursement for telemedicine services



Spain

## 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.

GPatHand is a free NHS funded service. There are no additional legal requirements for the telemedical industry in the UK.

6. Public or private reimbursement  
for telemedicine services



UK

## 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 teleexpertise;
- 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.

Based on this approach and the absence of patient reimbursement for telemedicine services in Belgium, Belgian patients will not be reimbursed for cross-border telemedicine services (except Teleradiology services).

## 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 Program. To benefit from the Health Insurance Program in France, the patient having a teleconsultation must be:

- Initially directed by his/her usual doctor if the teleconsultation is not conducted by him/her (the usual doctor must be practicing in France and registered in this capacity at the social security administration), and
- Known by the doctor conducting the teleconsultation (the doctor must have conducted at least one face-to-face consultation with the patient in the last past twelve months).

## 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 doctor that applies in Germany, patients are basically free to choose the doctors treating them.

However, the services from abroad are usually not reimbursed by the German health insurance providers. Public health insurance providers would generally only cover the costs of services provided by German physicians who are participating in statutory health care system.

Conversely, according to the EU Treaty and the principle of free movement of services within the EU, a licensed physician located in Germany can offer telemedicine services to a patient based the EU. However, it is likely that the service is not reimbursed by the insurance and the patient would have to pay the German doctor directly for the teleconsultation.



## 7. Cross border offerings of telemedicine services

The Guidelines 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 cross-border 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.

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

In principle, every patient in the Netherlands may take advantage of telemedicine services in other countries and every patient from another country may take advantage of telemedicine services in the Netherlands. There is no Dutch legislation prohibiting or preventing this. However, not all types of telemedicine services are reimbursed, depending on the type of service, the country in which the service is provided and the patients' healthcare insurance policy.

i. Patients insured by a Dutch healthcare insurer.

Every person living or working in the Netherlands, must take out an insurance policy at a Dutch healthcare insurance company. According to the Dutch Health Insurance Act ("Zorgverzekeringswet"), Dutch patients are entitled to worldwide coverage for telemedicine services if the service would be reimbursed by the Dutch healthcare insurer should the service have been provided in the Netherlands.

As explained in Section 6, eHealth services are covered by the healthcare insurer if: (i) the original form of healthcare is insured; and (ii) the composition and effectiveness of the eHealth service does not substantially change compared to the original form.

However, certain limitations apply to the reimbursement for telemedicine services provided abroad:

- Prior consent for receiving telemedicine services abroad may be required if: (i) consent is mandatory based on the terms of the healthcare policy; or (ii) the telemedicine service is received in a country outside the EU, that does not have a bilateral agreement with the Netherlands. The healthcare provider may refuse the request if, on the basis of care-related criteria laid down in professional standards, the telemedicine service does not outweigh the insured person's need for care.

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## 7. Cross border offerings of telemedicine services

- According to the Dutch Healthcare Insurance Decree (“Besluit zorgverzekering”), the amount of reimbursement is limited to the amount that is reasonable under Dutch market conditions. Furthermore, certain additional provisions or discounts may apply, depending on the type of healthcare insurance. If the costs for telemedicine services abroad are higher than the reimbursement in the Netherlands, the patient must pay part of the costs himself.
- Patients insured in the Netherlands must pay a compulsory excess of minimum EUR 385 every year, before healthcare costs are eligible for reimbursement.
- ii. Patients from other countries using telemedicine services in the Netherlands.

Patients who do not have Dutch healthcare insurance, are entitled to receive telemedicine services in the Netherlands. Dutch healthcare providers are prohibited from making any distinction based on the origin of patients. How these services

are reimbursed, depends on the patient’s insurance and the applicable rules in the country of origin. A patient cannot claim reimbursement of a scheduled telemedicine service in the Netherlands without Dutch healthcare insurance.

A patient without a Dutch healthcare insurance must pay for the telemedicine services in the Netherlands himself, unless:

- There is an arrangement between the telemedicine service provider and the patient’s healthcare insurer abroad, or
- The patient is entitled to social security in the Netherlands without residing or working in the Netherlands, according to the EU Regulation on the coordination of social security systems (e.g. Dutch pensioners or benefit recipients residing abroad).

## 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 General Practitioner (**GP**) 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):

- i. 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.



## 7. Cross border offerings of telemedicine services

- 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.
- ii. 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 license to practise.

However, the GMC cannot force doctors outside the UK to register with it – and under European law, cross-border prescribing within the European Economic Area (**EEA**) is allowed, meaning that doctors anywhere in the EEA could theoretically legally offer consultations or prescribing to patients in the UK.

The law in this area is developing and may change in light of Brexit.

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