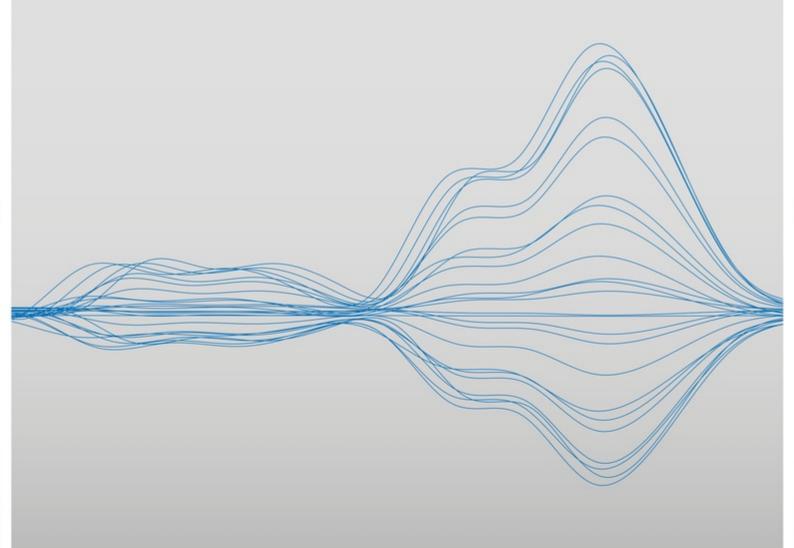
BELGIUM

Telehealth around the world: a global guide





Introduction

The COVID-19 pandemic has caused healthcare systems around the globe to rapidly, and in some cases, radically rethink the delivery of medical care. The global expansion of telehealth services is one way we have seen this transformation occur. This has resulted in significant opportunities in the field, as well as unprecedented regulatory change.

As a quickly evolving area, 'telehealth' can have different meanings in different contexts. In this Global Guide, telehealth refers to the delivery of healthcare services where patients and providers are separated by distance, using information and communications technology for the exchange of information for the diagnosis or treatment of diseases and injuries. We have adapted this definition from the World Health Organisation's definition of telehealth.

Telehealth is not a new concept – healthcare providers, academics and technology developers have been advocating for its use for decades. There are many benefits to the widespread adoption of telehealth, including improved access to healthcare services, risk mitigation, convenience and flexibility, and in many cases, a reduction in overhead costs. However, the use of telehealth is not without its challenges. For example, it is not suited to all forms of healthcare, its implementation and adoption can be time consuming and costly, and additional care must be taken in relation to the transfer of patient health information.

The restrictions of movement in many parts of the world due to COVID-19 has caused governments to recognise the potential of telehealth, and amend laws and regulations seemingly overnight to enable healthcare providers to deploy telehealth solutions. Many governments have adopted telehealth reforms in a matter of weeks, which may otherwise have taken years to be considered and introduced

Although many of these reforms presently have an expiration date (dependent on the duration of the COVID-19 pandemic), there is likely to be continued growth in telehealth due to the advantages of such a service – even after the pandemic. There are enormous opportunities in the telehealth space for businesses already operating in this field, businesses considering expanding into telehealth, and start-ups.

This Global Guide provides an overview of the current state of telehealth regulations worldwide and assists readers to identify the opportunities, challenges and risks, on a country-by-country basis. As the field of telehealth, and the regulations underpinning it, remain highly dynamic and subject to change, this document is intended as a general guide and does not constitute legal advice. Should you wish to discuss any aspects of telehealth with a specialist lawyer, please contact us below.

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Belgium

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Is the use of telehealth permitted?

In Belgium, no specific legal framework exists in relation to telehealth.

However, this could change in the near future as the COVID-19 pandemic has brought attention to the range of possible telehealth applications from which patients and healthcare professionals could benefit. In fact, the Belgian National Council of the Order of Physicians ("NCOP") has already adapted its policy regarding the provision of teleconsultations, which was previously strictly limited. This is explained into more detail below (*see the chapter about telehealth Regulation*).

There is also a lot of attention going towards other aspects of telehealth, like tele-expertise, telemonitoring, tele-assistance and m-health. An example are the test projects that have been carried out by the national institute for sickness and disability insurance (RIZIV/INAMI) with the purpose of creating a framework to reimburse telehealth applications.

How is telehealth regulated?

Following the COVID-19 pandemic, there have been some recent developments with regard to teleconsultations.

Firstly, the NCOP has issued a new guidance regarding teleconsultations on 18 June 2022, which can be consulted here. From now on, teleconsultations are explicitly recognized and allowed by the NCOP on a permanent basis. However, this guidance contains several conditions (f.ex.: the doctor's ability to control the patient's identity, the patient's free will, ...) that have to be met in order to proceed with the teleconsultation. Additionally, a therapeutic or care relationship must exist between the person in need of care and the doctor before the teleconsultation. This will have to be proven in accordance with the regulations on electronic evidence of a therapeutic care relationship.

Secondly, on 1 August 2022, a new framework for the reimbursement of teleconsultations has entered into force. Telephone and video consultations will be unlimitedly reimbursed, if they occur (i) with healthcare professionals with whom the patient already has a treatment relationship, (ii) with a specialist on referral from a general practician, or (iii) within medical guard service.

Are there specific fields of healthcare in relation to which telehealth services are currently available, and do they involve the use of proprietary technology or platforms?

There is no specific limit on which services might be provided by way of telehealth applications.

The main difficulty is the reimbursement of telehealth costs. Regarding this issue, we refer to the test projects that RIZIV/INAMI has been carrying out to assess the feasibility of reimbursement frameworks for telehealth applications (as described under the chapters about telehealth availability, costs and anticipated reforms).

Does the public health system include telehealth services, and if so, are such services

free of charge, subsidised or reimbursed? Where the public health system does not include telehealth services, are such services covered by private health insurance?

Since 1 August 2022, digital consultations are financed in the Belgian health system, which means that patients will be reimbursed for the consultations. Doctors can decide which platform they wish to use for the digital consultation and how they collect payment for it.

The number of reimbursed teleconsultations is unlimited. However, certain conditions must be met:

- the teleconsultation must take place with the patient's regular doctor or a specialist recommended by them, or a general medical on-call service;
- it must take place at the patient's request, with the doctor's agreement;
- the doctor must have access to the patient's medical file; and
- the platform or application used must guarantee the security of the information.

Patients only pay a personal contribution of €4 for a video consultation and €2 for a telephone consultation.

Another novelty is the m-health platform (mHealthBELGIUM), which is the result of one of the test projects initatied by RIZIV/INAMI. This platform has been set up in order to grant a "trust stamp" to trusted applications. For each application, the platform stores information regarding its CE marking, data protection, security, data interoperability with other information systems, and also on how the application is financed.

mHealthBELGIUM has been designed as a 3-level validation pyramid. The applications available on the mHealthBELGIUM website will have at least reached level M1 (apps recognised as medical devices) and can gradually climb the hierarchy to level M2 (interoperability and connectivity of the apps with the core services of the eHealth platform) and then level M3 (apps which show a socio-economic added value and which are financed by RIZIV/INAMI, after a positive opinion of their application for reimbursement).

Do specific privacy and/or data protection laws apply to the provision of telehealth services?

No specific rules under data protection Belgian law with regard to telehealth. General rules of the GDPR apply.

How should the cross-border transfer of personal information collected and processed in the course of telehealth services be carried out to ensure compliance with applicable privacy laws?

No specific rules under data protection Belgian law with regard to telehealth. General rules of the GDPR apply.

Are there any currently applicable codes of conduct on the use of telehealth systems and/or security of telehealth data in your jurisdiction?

Currently, there are no general codes of conduct on the use of telehealth systems and/or security of telehealth in Belgium. Telehealth is subject to the general ethical, legal and deontological rules inherent to the practice of medicine. However, the NCOP has issued specific guidelines with regard to teleconsultations, as described under the chapter about telehealth regulation.

Are any specific laws, regulations, or self-regulatory instruments expected to be adopted in the near future?

We do not have knowledge of upcoming regulations. However, we expect that there will be new developments in the coming months as telehealth and its possibilities have been under a lot of attention following the COVID-19 pandemic.

Additionally, RIZIV/INAMI is currently carrying out (or analysing the results of) test projects in the fields of teleconsultations, tele-expertise, telemonitoring, tele-assistance and m-health in order to assess the development of reimbursement frameworks.

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