

TOP DIGITAL HEALTH SOLUTIONS

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France, Italy, Germany, Spain, Russia and UK Top digital health solutions

Spain

In brief

The Covid-19 pandemic has accelerated the adoption of digital health solutions by Spanish healthcare providers, both in the public and private sector. The restrictive measures that the Spanish government has taken to fight the spread of the pandemic has boosted the use of digital solutions and remote medical consultations have become standard practice. The experience acquired during the pandemic on digital solutions will probably lead to a permanent change in the way some of the consultations and health assistance takes place.

Top 5 legal issues to have on your radar

1. Medical Device Regulation

If your digital health solution has a medical purpose, you should evaluate whether it may be regulated as a medical device in the EU. Therefore, companies should conduct an assessment to determine whether this is the case and the classification of any potential medical device. Classification as a medical device means that specific validation and approval procedures have to be followed, affecting the product development cycle.

EU medical device regulation is in a state of transition, with Directive 93/42 on medical devices being in the process of being replaced by Regulation 2017/745 on medical devices on 26 May 2021 (the replacement date was recently postponed by one year). During the transitional period, medical devices complying with either of the above provisions may be placed in the market.

During the state of alarm declared to fight the pandemic the Spanish Medicines and Medical Devices Agency (AEMPS) has adopted several measures to guide companies in the process of obtaining approval for medical devices that could help to fight the pandemic. However, these measures do not cover digital solutions.

2. The hurdles in using patient data: data privacy, medical confidentiality and cybersecurity

In the EU, organisations using patient data will need to assess whether they act as processor or controller and comply with corresponding obligations under the GDPR. There can be difficult GDPR questions to address, such as consents, information requirements, security measures, and restrictions on transfers of data. The Spanish Data Protection Authority considers this as one its areas of focus and has issued guidance in recent months, especially pandemic related guidance, insisting on the need to observe and comply with personal data protection obligations (both GDPR and Spanish data protection legislation) when processing health personal data. The Authority has nevertheless clarified that data protection should not be

used as an obstacle to hinder or limit the effectiveness of the measures taken by the authorities, especially health authorities, in the fight against the pandemic.

Among the guidance issued by the Spanish Data Protection Authority, it is worth mentioning the guidelines published for the patients and users of the healthcare system. These guidelines analyse how some general personal data protection obligations should be implemented in this specific area and particularly to the processing of the clinical history. It also provides answers to some frequently asked questions on personal data in the healthcare field and stresses the patients' rights from a personal data protection perspective. Compliance with personal data protection requirements remains a crucial aspect in the approach to patient and health data in Spain.

In addition to this, medical confidentiality should also be taken into consideration, as well as the implementation of the necessary security measures to prevent unauthorized access to health data, particularly protecting such data from the increase of cyberattacks and cybersecurity risks.

3. Registration requirements for regulated activities?

There is no specific telemedicine regulation in Spain and, therefore, it is subject to the general legislation regulating the provision of medical services, which means that remote medical consultation is subject to the same requirements and authorizations as face-to-face medical consultations. Despite of this, the health authorities have been making progress on implementing tele-assistance programs in many of the Spanish regions.

Although digital medical consultations have been growing in Spain during the last years, the Spanish Medical College Organization (Organización Médica Colegial – OMC), which regulates the medical profession in Spain, restricts the situations in which remote consultations may take place. The OMC Code of Practice accepts telemedicine only as accessory or complementary to face-to-face medical consultations. The Code prohibits medical visits based exclusively on remote consultations. The OMC Code of Practice is currently under review. The current draft permits remote consultations with some safeguards.

Despite the restrictive position of the OMC, before the pandemic the regional health services were already actively promoting telehealth as a way of optimizing resources by reducing the need for face-to-face visits. In the fight against Covid-19, telemedicine is being widely used both in the public and private sector and has become the norm for some types of consultations. Some of these are likely to remain in place when the state of alarm ends.

4. Liability

We advise digital health providers to consider and mitigate several potential avenues for liability claims, including:

- Strict liability under the Royal Legislative Decree 1/2007 (General Law for the Protection of Consumers and Users)
- Fault-based liability for negligence, including medical negligence claims
- Contractual liability
- Liability under the medical device legislation

5. Market access and reimbursement

Reimbursement strategies and developing a sustainable business model are becoming increasingly important. Non-healthcare companies in particular need to understand the clinical problems their device seeks to address and whether payers will see value in it.

The healthcare provided in Spain is predominantly public. Therefore, the importance of gaining acceptance by public healthcare authorities also needs to be considered, in particular whether the digital health solution satisfies an unmet and clearly identified need.

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