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Digital health solution

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

France

In brief

In France, it's a fair bet that there will be a before and after COVID-19 when it comes to remote health services.

COVID-19 is accelerating the adoption of digital health solutions and companies, supported by the French authorities, are innovating at lightning speed to adapt to new needs. For healthcare professionals and patients, digitalization provides for new ways of providing cares and being treated.

The French health authorities emphasize the need to balance innovation and safety and at the same time multiply initiatives to support innovation in digital health. As an example, a "*national counter for innovation and uses in e-Health*" aiming at providing services to innovators to support the emergence of digital health projects, was created few weeks ago in collaboration with the French Ministry of Health.

You will find below our top 5 legal issues to bear in mind when contemplating a project in the digital sector or looking for new business opportunities.

Top 5 legal issues to have on your radar

1. Medical Device Regulation

Before placing a digital health solution on the French market, companies should conduct an assessment to determine whether their products would have a medical purpose and would classify as medical devices.

EU medical device regulation is in a state of transition and comprises the outgoing Directive 93/42 on medical devices (MDD) and the incoming Regulation 2017/745 on medical devices (MDR). The MDR will only fully replace its predecessor, the MDD, on 26 May 2021 (in order to allow manufacturers to focus on COVID-19 responses, the application date has been postponed for one year). During the transition period, devices can be placed on the market under the current MDD, or the new MDR, and the two regimes operate in parallel.

The French Health Authority published several guidelines and Q&A in order to help and explain to the manufacturers and distributors of medical devices the medical devices regulations (e.g. clinical studies, compatibility of medical devices, guidance to determine whether the products are medical devices or not etc.).

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

Contemplating a digital health project goes with data privacy implications, medical confidentiality and cybersecurity issues.

In France, compliance with GDPR is only one part of the jigsaw puzzle when using patient data.

Indeed, under French law, companies also need to comply with the French Data Protection Act and the French Public Health Code provisions. Such provisions not only protect doctor-patient confidentiality but also add a centrepiece to the puzzle. Indeed, Article L. 1111-8 of the French Public Health Code requires that "*any entity hosting personal health data collected in the course of prevention, diagnosis, care or social and medico-social monitoring activities, on behalf of the natural or legal persons at the root of the production or collection of such data or on behalf of the patient him/herself*" be certified for such activity. This French specific certification requirement is a long and heavy process aiming at ensuring a high level of protection for patients' data collected in France.

3. Registration requirements for regulated activities?

In France, telemedicine is an activity defined and regulated by the French Public Health Code. It does not require a specific registration or authorization *per se* but is allowed under specific conditions to be complied with, such as: patient consent, healthcare professional authentication and specific reports to be made in patient files. Moreover, out of the five medical acts qualifying as telemedicine[1], only two of them, remote medical consultations and tele-expertise are reimbursed under strict conditions.

Due to the current context, the conditions for the reimbursement of remote medical consultations for COVID-19 infected patients, long duration diseases patients, patients over 70 years of age and pregnant women have been relaxed for a limited period. Freelance midwives, speech therapists, occupational therapists, psychomotor therapists and masseur-physiotherapists are also, by way of derogation, authorized to conduct remote consultations. Will the large increase in the use of telemedicine observed in France during the COVID-19 context change mentalities, particularly those of healthcare professionals and patients who, for some of them, were reluctant to use such ways of providing cares and being treated? Will it encourage the French Government who might adopt some of these temporary measures on a permanent basis?

4. Liability

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

- strict liability under the Civil Code (article 1245 et seq.) which implements the EU Product Liability Directive;
- fault-based liability for negligence, including medical negligence claims;
- contractual liability, depending on the contracts entered into;
- potential criminal liability, depending on the circumstances and the applicable laws and regulations; and
- exposure to liability under the MDD and MDR.

5. Market access and reimbursement

In France, applications for reimbursement of a digital health solution qualifying as medical device can only be filed once the product at stake is duly CE marked.

One of the challenges for the French health authorities in evaluation digital health solutions for reimbursement is to conciliate between evaluation requirements and the pace of development in order to promote the rapid introduction of these innovative medical devices.

In view of the acceleration of the adoption of digital health solutions, the French authorities have produced a guide intended to help companies that manufacture or operate digital health solutions to anticipate the clinical requirements required by the CNEDiMTS (the Medical Device and Health Technology Evaluation Committee is the committee which evaluates medical devices) to determine the interest of such a medical device to be supported by national solidarity.

During the COVID-19 crisis, the French health authorities have also implemented a temporary prioritization process for pricing and reimbursement assessment procedures for medical devices and digital health technologies that have no equivalent in the treatment of serious diseases or where there is no alternatives and for which an application for a first registration for reimbursement or a reimbursement for a new indication is filed (this includes COVID-19 products). Once again, we wonder if the effectiveness and usefulness of these measures will influence the French authorities to adopt this temporary process on an ongoing basis.

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[1] (1) Remote medical consultations (between a healthcare professional and a patient), (2) tele-expertise (enabling a healthcare professional to seek the opinion of one or more healthcare professionals remotely), (3) medical tele-surveillance (enabling a healthcare professional to remotely analyze patient data), (4) medical tele-assistance (enabling a healthcare professional to remotely assist another healthcare professional to perform a medical treatment) and (5) medical response that is provided within the framework of medical regulation (emergency medical services by phone).

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