FRANCE

Alexandre Regniault Partner
alexandre.regniault@simmons-simmons.com
Emmanuel Garnier Managing Associate
Simmons & Simmons LLP, Paris

French authorities face issues in both regulation and reimbursement of digital health products

While the French Government has acknowledged the benefits of digital health, French healthcare authorities are still struggling to grasp how to regulate apps and other digital health products. The issues the authorities face, both on the regulatory side and/or on the pricing and reimbursement side, have led to very few digital related innovations or technologies being granted reimbursement thus far, as Alexandre Regniault and Emmanuel Garnier of Simmons & Simmons LLP explain.

Although France has not yet fully integrated digital health as standard practice, especially with regards to market access and pricing of digital related technologies, the French Government has acknowledged the promising benefits of digital health. Similarly, the French Association of Medical Devices Companies, the French Association of Pharmaceutical Companies and the main associations representing companies in the IT sector, created, a few years ago, the eHealth France Alliance, which aims at fostering eHealth initiatives. The goal of this Alliance is to generate greater commitment to new ideas and reinforce new and current eHealth initiatives.

In France, eHealth has recently been subject to a sector focused development strategy, with the support of both the industry and competent Governmental bodies. This eHealth strategy, launched in October 2016, is articulated around four major goals:

- Developing medicine connected through a 'Big Data' plan. This plan will allow, for example, the development of new remote monitoring applications or interpretation of medical data to assist healthcare professionals in their diagnosis. To this end, the ability to collect substantial amounts of health data through a variety of connected devices such as smartphones, smart watches and apps is key, as it will allow the improvement of health monitoring, prevention and research.
- Fostering co-innovation between health professionals, citizens and economic players through the launch of calls for projects dedicated to eHealth or the development of 'living labs' that allow companies to test their innovations in real life settings in order to conceive, in direct connection with users, the medicine of tomorrow (telemedicine tools, treatment tracking applications, etc).
- Simplifying the administrative burden for patients (by facilitating admission procedures and allowing appointments to be made online) and equipping health democracy with a digital platform to facilitate consultations and the participation of users.
- Strengthening the security of health information systems through a dedicated action plan.

However, despite these strong initiatives, French healthcare authorities are still struggling to grasp how to regulate apps and other digital health products. The issues faced by French healthcare authorities - on the regulatory side and/or the pricing and reimbursement side - have led, so far, to very few digital related innovations or technologies being granted reimbursement on the French market.

Moreover, the regulatory background applicable to digital health has evolved significantly with the EU Regulations on medical devices and in-vitro diagnostic devices published in May 2017.

The Regulations on medical devices and on data protection

Certain statistics assert that one out of every three internet users currently monitors their health or fitness by using an app. Consumers set the trend before healthcare professionals. But now, apps or software are, increasingly, developed specifically for medical purposes. The use of digital innovations can help improve the management of chronic diseases, provide early diagnoses and improve patient-doctor communication, thereby reducing the number of expensive hospital visits. Regarding clinical research, the use of medical apps has the potential to provide higher quality data through continued data gathering, higher patient retention by providing direct feedback and reduced costs by decreasing the amount of study visits.

Nevertheless, developers from the tech industry are sometimes not aware that under European regulations, software will be considered a medical device when, for instance, it records and registers data for medical purposes such as diagnosis, monitoring, prevention, alleviation, or treatment of a medical condition. In such a case, software must comply with regulatory requirements regarding medical devices as set out in the European Medical Device Directive (93/42/EEC) and require a CE mark before it can be sold in the EU.

However, the regulatory requirements regarding medical software will increase under the new Medical Devices Regulation ('MDR') - which has been effective since the end of May 2017 and which enters into application on 26 May 2020 - which provides specific qualification and classification rules in relation to standalone software. The major impact of this rule is that standalone software will be classified based on a purpose and risk assessment and no longer based on purpose alone.

To determine whether a digital product falls under the MDR, it is necessary to conduct a medical and technical assessment of the functionalities of

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the app or digital product and, where applicable, those of its modules and interconnected platforms or hardware.

In this respect, where no claim is made regarding the suitability of a network or mobile device for medical purposes, medical device regulations should normally not apply. However, a significant area of uncertainty has arisen in defining the boundary between general wellness and diagnosis or treatment of a disease or health condition, which is linked to the issue of distinguishing between mobile medical software and mobile wellness software. The impact on quality of life or health outcomes may significantly improve through preventive and self-monitoring activities. Some eHealth apps, such as health and fitness apps, intended to support general consumer wellness, could arguably, if integrated for example in a diagnosis and treatment regimen, be classified as a medical device.

Further, the EU General Data Protection Regulation ('GDPR') will apply from 25 May 2018 and will have a major impact on digital health programs, and especially digital health products that collect personal data from patients. EU Member States will however remain free to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

In France, ASIP Santé, supervised by the Ministry of Health, is the French digital health agency responsible for assisting the development of eHealth services. In France, personal health-related data can only be hosted by an accredited health data host, and such accreditation must be issued by ASIP Santé.

Pricing and reimbursement mechanisms in France

In France, despite the willingness of the Government and national authorities to promote access for patients to digital health technologies and innovations and healthcare professionals, national authorities (especially the French National Authority for Health, 'HAS' and the Economic Committee for Health Products, 'CEPS') are not yet fully ready to implement a dedicated pathway for the reimbursement of mHealth products. The national authorities are, generally, not yet convinced of the usefulness of connected apps or mHealth devices. Even though it is up to medical device companies to demonstrate the added value of their device/technology for the patient applying for reimbursement of their products, the authorities' perception remains key in allowing greater and faster access of said digital technologies to the market.

Health technology assessment ('HTA') authorities in France published however, in October 2016, guidelines applicable to mHealth and eHealth innovations and technologies, which is general - yet useful - guidance in this respect.

In addition, the procedures for applying for reimbursement are lengthy and could be an obstacle to market access for some products, whose life span is more often longer than for non-digital medical devices. This is particularly challenging for SMEs since the funding of innovations is key to their survival.

Gaining market access presents several challenges for manufacturers, that have to provide clinical evidence that the device/technology will improve the patient's life. The conducting of medical and clinical analysis to help convince national authorities in charge of reimbursement decisions of the cost-effectiveness of the digital product and the determination of the requirements under which the digital product/app could be linked to an eHealth system, are time consuming and expensive processes. In addition, dealing with national health authorities, such as the French national authority in charge reimbursement for medical devices (the National Commission for Evaluation of Medical Devices and Health Technologies or 'CNEDiMTS,' which is part of HAS), which are not yet accustomed to performing technical assessments of digital products, is currently an issue.

In terms of clinical data, many digital products that demonstrate significant results in clinical investigations fail to do so in real world settings. One of the reasons for this is that the success of digital innovations is linked to a greater extent to patient engagement than medicines, for example. Patient engagement is likely to be higher in clinical investigations, in contrast to real world settings, given the absence of tools for ensuring that patient engagement is kept at a similar level to that found in a clinical investigation. In addition, there is no tailor made tool available to French HTA authorities when assessing a digital health innovation submitted to their review for reimbursement. Although a step forward was made last year in France with the first authorisation for reimbursement awarded to a digital medical device (an app used as part of a telemedicine service for diabetic patients to help them monitor their insulin dosage), the CNEDiMTS limited reimbursement to use of the app for type 1 diabetic patients - to whom specific training on the use of the medical device should be delivered - excluding type 2 diabetic patients because insufficient data was available.

It is obvious that current guidelines and assessment criteria are not appropriate for the assessment of digital health products, thus constituting an obstacle to reimbursement via the social security system. In this respect, HTA reform in France is high on the agenda but policymakers are avoiding an open debate that could lead to an overhaul of the reimbursement system.

It is also interesting to point out that the European Commission on 31 January 2018 published a draft regulation on HTA to address concerns regarding the degree of variation with which HTAs are conducted and applied across Europe. The proposal aims at enhancing cooperation and coordination among Member States in measuring the value of innovative drugs and medical devices, through a number of policy tools to build on previous EU initiatives (e.g. EUNetHTA) and assist Member States in achieving a 'smooth functioning of the internal market, sustainable health systems and an ambitious research and innovation agenda.'

With specific regard to registries of real world data, the proposal provides an opportunity to link the EU legislative framework for HTA to that of the EU Digital Single Market and the EU research agenda. This is just the start of a very long process, but perhaps a first step in providing the right incentives to unleash the potential of digital health for improving health systems across Europe.