

Digital Health Reimbursement in France: A HealthTech Charter Fitness Check

The opportunities and challenges facing the
digital health innovation sector in France



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Introduction

Launched in December 2021, the HealthTech Charter serves as a best practice repository of the most empowering policies and measures for digital health innovation across Europe. It's an opportunity to shape the EU into a hub for digital health startups and scale-ups and creates benchmarks to inform policy makers about what innovators need to succeed. Sharing best in-class policies will not only improve individual ecosystems, it will also smoothen the pathway for a digital health startup that is successful in one country to be successful in the whole of Europe, reinforcing the Digital Single Market.

Given that health is a primary competence of individual EU Member States, it is imperative that national and European policies are aligned and harmonised. Allied for Startups is therefore zooming into the Member State level to conduct Fitness Checks of the national healthtech regulatory ecosystem. Having kicked off the series with the Spanish telemedicine environment, we are now delving into reimbursement of digital health applications in France.

Published in 2019, the French Ministry of Health outlined its three-year roadmap to accelerate the national eHealth transition. From health data sharing, e-prescriptions, to increased funding for startups and research, the digitization of France's health system was mapped out along five key pillars. As we come to the end of the final breakthrough year of France's roadmap transition, it's time to take a look at how far we've come.

The French Fitness Check consists of a multi-stakeholder perspective on the digital health reimbursement ecosystem, one of the main topics explored in the HealthTech Charter. It aims to map out the French reimbursement environment and reveal areas for improvement to best empower digital health innovators with the tools to succeed.



The French Reimbursement Ecosystem

A key barrier to the wider adoption of digital therapies and telehealth solutions is the lack of standardised pathways to reimbursement and prescription across European healthcare systems - where publicly-funded health systems are the norm. Digital health entrepreneurs often have to navigate complicated funding pathways at the national, regional, local or even hospital level - and in some cases, reimbursement is not possible at all.

Announced by French President Emmanuel Macron in October 2021, (Trans.) *"We are creating a procedure for immediate market access for [eHealth] innovative products, in the same way as in Germany."* Taking inspiration from the German Digital Healthcare Act (DiGA), which paves a way for digital health applications to be prescribed and reimbursed within the German public health system, France has entered the last stages of formalising telemedicine reimbursement into national legislation.

Telehealth solutions, such as online consultations or telemonitoring, enable medical care to be provided remotely, such as on a mobile phone, watch, or laptop.

According to Benjamin Hardy, CEO of Biloba, an application that connects parents to doctors in less than ten minutes,



"For us, we solve the impossible equation. We do a better consultation at a better user experience, and at a lower cost. So it's better for the patient, it's better for the system, it's better for the GP, but - it's not reimbursed yet."



Under the ETAPES (Expérimentations de Télémédecine pour l'Amélioration des Parcours en Santé) program, kickstarted in 2014, a sandbox was created for the deployment of telemedicine solutions across France. This experimental program reimbursed the remote medical monitoring of five pathologies, notably diabetes, chronic heart failure, chronic renal failure, chronic respiratory failure, and therapeutic implantable cardiac prosthesis.

The sandbox, extended until 2022, aimed to encourage the use of innovative technologies in addition to exploring the advantages telemedicine could bring to the French health system.

The ETAPES program has allowed market-access for remote monitoring activities under France's standard healthcare system - authorising telemedicine startups to be eligible for coverage by the Health Insurance Fund. The medical service of remote monitoring is evaluated by the Haute Autorité de Santé (HAS) according to the clinical benefit or, failing that, the organisational impact. It will soon be possible to apply for reimbursement under the standard system, under the evaluation of a "brand name" (NM) or to be included as a "generic" (LG). Inclusion on the list of remote monitoring activities is valid for a renewable maximum period of 5 years.

Creating sandboxes to test digital health solutions empowers innovators with a conducive and contained space to experiment with innovations outside of the existing regulatory framework and allows regulators to collect important insights before deciding on further regulatory action. According to Brice Van Eeckhout, CEO of Comunicare, a digital platform that aggregates information from the hospital to the patient and collects patient reported outcomes,



"France has been a forerunner by implementing the ETAPES Program, and this is something that should be highlighted. When states providing strong social security want to generate innovation in healthcare, where it directly benefits the patient, they need to enable the reimbursement of these solutions and of the work done by healthcare professionals to make them effective. Although some things could be done to facilitate the system in this experimental program, this is definitely a step in the right direction."



Following the execution of the ETAPES program, the long-awaited regulation of the reimbursement of remote medical monitoring for five pathologies was supposed to come into effect on 1 July 2022. However, due to the complexity of the legal texts, and an in-depth phase of preparation and consultation, this has been delayed to early 2023.

To ensure patients and entrepreneurs are empowered with continuity of care and services, it is integral to oversee a smooth transition from the ETAPES experimental program to the new upcoming legal framework.

France Digitale Case Study



France Digitale is the largest startup association in Europe, bringing together 1800 startups and 100 investment funds. With 192 startups and 10 specialised funds, e-health is one of the most numerous and active communities in our membership.

The social protection system has a significant influence on the health industry in France, with reimbursement policies conditioning both the demand and the supply sides of the market. More specifically, the French social protection system only reimburses services and treatments that it considers essential and that should be accessible to all patients.

Innovative startup solutions in the fields of biotech, medtech and digital health, however, are still partly not included in this category. France Digitale actively engages with health public administrations to ensure the integration of startups in the public health system and its reimbursement scheme to make more efficient health services accessible to all.

Reimbursement of Teleconsultation

The law defining the 2023 budget of the Sécurité Sociale, the public administration managing the French reimbursement program, is currently being adopted in

Parliament. The reimbursement of teleconsultation services, one of France Digitale's main demands, has finally been integrated into the new reimbursement scheme.

However, this scheme still excludes medical device manufacturers, thus penalising startups like Withings, a producer of smart watches, scales and other monitoring devices. Our Member, France Digitale, has tabled an amendment to modify this criterion to enlarge the teleconsultation reimbursement clause to manufacturers offering teleconsultation services alongside their devices.

Reimbursement of Digital and Connected Medical Devices

The health industry has significant entry barriers due to complex regulations and heavy production costs. To facilitate entrepreneurs' access to this market, France Digitale advocates for a modification of the reimbursement regime to support digital and connected medical devices' producers by extending reimbursements to:

- The compliance costs faced by the device manufacturer
- The costs of the medical team required for the use of the medical device
- The cost of clinical trials required for the clinical evaluation

Reform of the Pricing System for Hospitals

Hospital resources are based at 70% on the T2A system which disincentivizes the use of new services because of the rigidity of its pricing grid and the focus on medical acts rather than on the overall care process. An experimental modification to the T2A system was introduced in the 2018 social security budget's law to counter this effect. With this reform, services contributing to improving the patient journey, the efficiency of the health system, access to care and the relevance of the prescription of treatments could increase in resources allocated to a health establishment. France Digitale calls on institutions to make this reform permanent.

Implementation of a digital transformation package.

The Covid-19 pandemic has proven the necessity to equip caregivers with digital devices to maximise care accessibility. Two support schemes (the "forfait structure" and the "forfait modernisation") have been created to subsidise the adoption and use of digital innovations by medical professionals. France Digitale proposes to redesign and merge these packages to maximize their positive impact on the health system with the following:

- New amount: € 10 000 per practitioner (instead of € 3 600)

- New content: eligibility extended to business SaaS software, online agendas and appointment management systems and ICT tools for care coordination
- New targets: extension to new categories of practitioners (dental surgeons, physio massagers, pedicures and podiatrists, midwives and nurses, in particular)

Adaptation of public procurement criteria to startups.

Enabling the adoption of innovative solutions in public hospitals which are major players in the health sector in France, would be a win-win move for startups and health establishments alike, as it would boost startups' growth and credibility while also increasing the efficiency of the health system. France Digitale is advocating on three specific points:

- Knowledge sharing between startups and hospitals and regional health procurement departments
- Insertion of an innovation clause in public calls for tenders
- Speeding up the scouting and decision-making processes in public procurement. This can be done by defining a single point of contact in each structure and by setting up an indicator evaluating the effectiveness of health establishments' processes.

Digital Therapeutics Alliance Case Study



A non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. The Digital Therapeutics Alliance provides patients, clinicians, payors, and policymakers with the necessary tools to evaluate and utilize DTx products.

At DTA, we focus on DTx which deliver to patients evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage, or prevent a disease or disorder. They are used independently or in concert with medications, devices, or other therapies to optimise patient care and health outcomes. They are part of the SaMD (Software as a Medical Device) category. The term is defined by the International Medical Device Regulators Forum (IMDRF) as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

In France, there is currently no specific pathway for the reimbursement of DTx. The new PECA (Prise En Charge Anticipée de dispositifs médicaux numériques) decree terms will be published in Q1 2023 so we are all waiting to see what it is going to look like.

What we know is that it was based on the DiGA system and there will also be a reimbursement for remote patient monitoring digital health products.

As of now, manufacturers have used the following experimental pathways:

- Article 51: Limited duration experimental program for innovative products. Conditions of eligibility include product innovation, feasibility, ease of distribution, and price to quality ratio.
- Innovation Package for Medical Devices (forfait innovation): Temporary funding system to facilitate early patient access to innovative technologies. Conditions of eligibility include product innovation and relevant clinical and health economic studies.
- ETAPES (Expérimentations de Télémédecine pour l'Amélioration des Parcours en Santé = Experimentation of Telemedicine to Ameliorate the Health Care Paths): only for Remote Patient Monitoring digital health tools. Only five health conditions are covered by this experimental pathway: cardiac deficiency, renal deficiency, respiratory deficiency, diabetes and implantable cardiac prosthesis. This program will be incorporated in the common law, as part of the new PECA decree.

Techtomed Case Study



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In France, as in the rest of Europe, we are gradually seeing the Digital Health ecosystem being organised with the desire to regulate and access the market for digital solutions.

The ETAPES programme paved the way for the reimbursement of remote medical monitoring. This experimental system, which was due to end in May 2022, has been extended until December 2023 and is in the process of being brought under common law. This new law, awaited by many players in the sector, is taking shape. On 30 December 2022, the first decrees governing the practice were adopted. As regards the amounts of reimbursement, another decree is expected at the beginning of 2023.

In France, there is currently no specific pathway for the reimbursement of DTx.

The new PECA (Prise En Charge Anticipée de dispositifs médicaux numériques) decree terms will be published in November 2022 so we are all waiting to see what it is going to look like.

Concerning other digital solutions not related to remote medical monitoring, the market access pathway exists today (the pathway for digital DM called LPPR, Liste des Produits et Prestation Remboursables). However, France is waiting for the decree on early reimbursement (PECA), which would allow a fast-track of the market access process, with proof of commitment to clinical studies with future data. Other questions also remain unanswered, notably for foreign startups who wonder about the acceptability by the French authorities of their clinical file validated in their country of origin.



Conclusion

Digital technologies are key to unlocking better global health outcomes. Entrepreneurs should be empowered with the right tools to scale their solutions across borders, so that in turn they can provide patient-centric solutions. - This rests in creating a startup friendly inclusive regulatory landscape.

Healthtech innovation in France has experienced an unprecedented push forward, but there is still work to be done. As smaller actors with access to often less resources, it is crucial to consider startup perspectives in policy and government. Shaping regulation with smaller actors in mind will not only improve the French innovation ecosystem, but also drive Europe into a hub for digital health scale-ups.

In terms of digital health reimbursement, empowering healthtech innovators in France rests in creating a clear and inclusive regulatory pathway for reimbursement - for telemedicine operators and beyond. The ETAPES program provided a sandbox for public procurement in telehealth solutions: empowering patients with reimbursable telemedicine, creating a pathway for telehealth entrepreneurs to be reimbursed for their innovations, and feeding regulators with the necessary data on why creating a dedicated framework for telehealth reimbursement would benefit the French healthcare system. We look forward to seeing a smooth transition of the ETAPES program into national legislation.

Although telehealth reimbursement is a large step forward, we urge policy makers to consider the breadth of digital health reimbursement beyond telemedicine, so that more healthtech technologies can be offered a pathway for reimbursement and more patients can reap the benefits of what digital health has to offer.

Interested to share your perspective in digital health or introduce a best practice in the HealthTech Charter for policy makers to understand what we need more of across Europe? Reach out to us at laura@alliedforstartups.org we're keen to learn from you!





Get in touch with us

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