eit Health

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White paper

Digital Health Applications (DiGA) in Portugal

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Powered by Lab to Market

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Acknowledgments

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Thanks are also due to the members of a panel composed of five key stakeholders selected for their expertise and understanding of the Portuguese digital health ecosystem and reimbursement mechanisms. Their valuable insights and detailed feedback have significantly shaped the understanding of the need for a Portuguese DiGA framework and its implementation readiness.

Appreciation is expressed to all those who have collaborated on this project, offering their time, expertise, and enthusiasm to ensure its success. Their contributions are greatly appreciated and have been essential in advancing the objectives of this white paper.

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Context

This white paper, prepared by LabToMarket at the request of EIT Health Innostars, presents a comprehensive study on the need and current status of a DiGA framework implementation in Portugal.

About EIT Health

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body. EIT Health is an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of health, demographic change and well-being within the EU, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry seldom turn breakthrough ideas into new transformative products and services. Within the EIT Health network, 120 partner organisations and institutions from academia, business, research and healthcare delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation, and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients.

About LabToMarket

LabToMarket is a strategic consultancy that pushes innovation forward and works as a one-stop-shop that helps researchers, start-ups and clinicians launch their healthcare innovations onto the market. Also, with a vision that promotes a symbiotic relation between health, innovation, and technology, LabToMarket specializes in strategic projects aimed at this goal, having developed programs for both public and private organizations at national and European levels.

Introduction: Setting the Scene

Based on the European context, this white paper aims to lay the groundwork for a comprehensive strategy to support the digitalization of healthcare in Portugal. It is crucial to develop a framework tailored to the Portuguese reality to enable the widespread adoption of digital health solutions within the national healthcare system.

Objectives

In this landscape, EIT Health Innostars can and should play an active and supportive role in guiding member states toward agile and sustainable adoption of reimbursement models of digital health applications.

With these objectives in mind, this white paper serves as a comprehensive resource for stakeholders in the Portuguese health ecosystem, detailing the current state of prescription and reimbursement processes for digital health solutions in Europe. It identifies and analyses challenges and opportunities, offering strategic and actionable steps for national organizations to align with European guidelines and ensure effective integration of digital health applications.

Finally, this study aims to highlight the pivotal role that EIT Health Innostars can play in driving transformative healthcare initiatives and promoting Portugal's readiness in this framework.

Methodology

To achieve these goals, the methodology adopted comprised the following steps:

- Literature review: research on the DiGA and the state-of-the-art throughout Europe, as well as the initiatives promoted by EIT Health Innostars.
- Expert interviews: identification of an expert panel to collect personalized insights into the Portuguese health data ecosystem and benchmark with other countries. This panel includes five experts representing stakeholders in digital health solutions and reimbursement models within the Portugal ecosystem and two international experts:
    1. Representative of a public hospital
    2. Representative of an IT company
    3. Representative of a medical device startup
    4. Representative of an association specialised in value-based healthcare (VBHC)
    5. Profile with expertise in health economics
    6. Profile with expertise in medical device certification
    7. Profile with expertise in implementing DiGA in Germany
- Systematic analysis of interviews: conduct a comprehensive mapping of the Portuguese landscape to assess the need and level of preparedness of implementing a Portuguese DiGA framework.
- Identification of challenges and recommendations: identification of current and future challenges, along with recommendations to overcome and mitigate them and outlining their potential impact.

1 | Background: Understanding the DiGA Fast-Track

Digital health technologies have emerged as powerful tools to enhance healthcare delivery, providing patients with personalised and more accessible solutions. These technologies open a new class of therapeutics – digital therapeutics (DTx), software solutions with evidence-based therapeutic capabilities to prevent, manage, or treat a medical disorder or disease [1].

Their potential to improve health outcomes, streamline healthcare processes, and make health systems more resilient has been widely recognised. However, these digital health solutions' widespread adoption and commercialisation face significant challenges.

Genesis

Today, over 350,000 mobile health applications are available worldwide in the main app stores, and 5 million downloads are recorded daily [2]. However, most are not regulated or certified, making them a risk to be available to patients.

Furthermore, innovators often face difficulties in achieving widespread adoption due to regulatory, reimbursement, procurement or other processes, which are uneasy to navigate and fragmented across Europe. Such barriers delay impactful solutions from reaching patients and citizens [3].

In 2019, Germany addressed this problem for the first time by passing the Digital Healthcare Act, introducing the concept of "apps on prescription," allowing specific digital health applications (DiGA - in German: *Digitale Gesundheitsanwendungen*) to be prescribed by healthcare professionals and reimbursed by statutory health insurers, under the responsibility of its national medicines agency, the Federal Institute for Drugs and Medical Devices (BfArM) [1].

Under this act, a "Fast-Track" was established – a three-month pathway that provides a streamlined regulatory approval process for these technologies.

What is a DiGA?

A DiGA (Digital Health Application) is a CE-marked medical device classified as risk class I, IIa or IIb under the Medical Device Regulation (MDR) or Medical Device Directive (MDD). Its primary function is digital, aiming to recognise, monitor, treat or alleviate diseases and injuries. DiGAs can be used by patients alone or in conjunction with healthcare providers. To be included in the BfArM's DiGA directory, these applications must meet stringent safety, functionality, quality, data protection, data security and interoperability requirements.

Before the introduction of DiGA, developers of health apps faced significant barriers to reimbursement, often having to negotiate with individual insurance providers. The automatic reimbursement mechanism introduced by the DiGA model removed these barriers, enabling more rapid scaling of digital health solutions.

Objectives and proposals

The main objectives of the DiGA framework aim to create an ecosystem where digital health solutions can thrive, providing tangible benefits to patients, healthcare providers, and the broader health system. Furthermore, other objectives and proposals can be identified:

- Ensure patients access high-quality, safe, and effective digital health solutions that can be prescribed and reimbursed like traditional medications.
- Utilise evidence-based digital therapeutics to complement or replace existing treatments, helping patients achieve better health outcomes.
- Streamline healthcare processes, reduce the burden on medical staff, and improve the sustainability and resilience of health systems through digital technologies.
- Support developers with clear regulatory pathways and guidelines, accelerating the introduction of new digital health solutions into the market.
- Establish uniform regulatory and reimbursement processes to identify clear socio-economic impact, overcome fragmentation and ensure consistent quality and safety across digital health applications.

Stakeholders and benefits

The implementation of DiGA-like models involves a diverse set of stakeholders, each playing a crucial role in the ecosystem:

- Technology developers: startups, researchers and companies developing digital health applications.
- Regulatory bodies: agencies responsible for the review and approval of digital health applications, ensuring they meet safety, quality, and interoperability standards.
- Healthcare providers: doctors and professionals who prescribe and integrate DiGA into patient care, enhancing treatment plans.

- Health insurers: statutory and private health insurers that reimburse approved digital health applications, facilitating patient access without additional costs.
- Patients: the end-users who benefit from digital health solutions, improving their health outcomes.

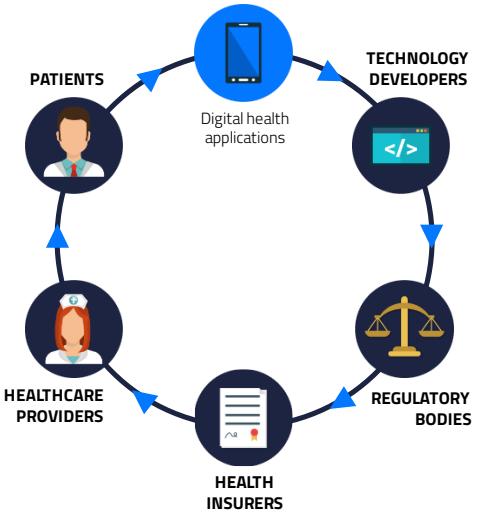

Figure 1 - DiGA stakeholders.

By fostering collaboration and synergy among these stakeholders, DiGA models aim to create a supportive environment that accelerates the adoption of digital health solutions, ensuring that they deliver maximum benefit to all participants in the healthcare ecosystem (Table 1).

Table 1 - DiGA stakeholders benefits.

STAKEHOLDER	BENEFITS
TECHNOLOGY DEVELOPERS	> Develop innovative solutions > Provide market entry pathways
REGULATORY BODIES	> Ensure safety standards > Foster trust
HEALTH INSURERS	> Facilitate access for patients > Promote wider adoption
HEALTHCARE PROVIDERS	> Streamline healthcare processes > Improve patients outcomes
PATIENTS	> Empower health management > Improve health outcomes

2 | Problem Framing: Addressing the Challenges

Since the introduction of DiGA, several EU member states have sought to import a reimbursement model for digital health solutions into their national contexts, each with some variations. These examples provide valuable lessons for other member states, including Portugal, to learn from and adopt in their healthcare systems.

European Landscape

In Europe, there are different maturity levels in the reimbursement process for digital applications. Germany, Belgium and France are currently the leaders, offering the best ecosystem for entering this market. "Fast-followers" include Italy and the Netherlands (Figure 2**Erro! A origem da referência não foi encontrada.**).

Germany

Under the Digital Healthcare Act, there is a directory with all the approved DiGAs. Patients can access a DiGA at no out-of-pocket expense through a prescription or health insurance with proof of diagnosis [4]. Physicians receive additional reimbursement when medical services are needed through an approved and tabulated list of DiGAs [5].

According to Torsten Christann, an expert in DiGA from Digital Oxygen, *"DiGA initially faced a slow adoption curve, but it has grown exponentially. Between September 2020 and September 2023, 374,377 DiGAs were prescribed and used in Germany. Prescription rates have increased significantly over the past three years, rising from 41,000 to 124,000 and 209,000 activated prescriptions, representing growth rates of 202% and 68%, respectively."*

DiGA implementation challenges

- Low adoption due to limited awareness among patients and healthcare professionals (HCPs).
- High non-activation rate of 54% due to barriers in the activation process.
- Lack of remuneration for HCPs for the lengthy prescription process.
- Pricing mechanisms drew criticism from payers, leading to maximum price regulations and arbitration interventions; doctors still perceive DiGA prices as disproportionately high.
- Minimal support from government bodies, payers, or medical associations in promoting the framework.

Table 2 - European landscape of prescription and reimbursement frameworks for digital health applications.

COUNTRY	FRAMEWORK	KEY FEATURES	REIMBURSEMENT MODEL	REIMBURSEMENT ENTITY
GERMANY 2019	DiGA	DTx (Class I, IIa, IIb) Fast-Track pathway, no out-of-pocket expense, provisional and permanent listings in DiGA platform.	> **One-transitional reimbursement:** Initial price is manufacturer's price Negotiated final price after 12 months > Reimbursed by the Statutory Health Insurance (GKV) and free of charge for the patient.	BfArM
BELGIUM 2021	mHealthBelgium	Public-private platform. Three levels of reimbursement eligibility based on social-economic impact.	> Price based on its social-economic impact. > Possibility of temporary reimbursement for 3 years for innovative solutions with evidence. > Reimbursed by the Health Insurance Funds (RIZIV)	FMSAPH, beMedTech, Agoria
FRANCE 2021	PECAN	DTx (Class I, IIa, IIb, II) + telemonitoring solutoins Early reimbursement.	> **One-transitional reimbursement:** Predefined fixed compensations Negotiated final price after 12 months for DTx Predefined prices for telemonitoring solutions	HAS (CNEDiMTS) and ANS

Belgium

In 2021, submitting medical apps became possible under mHealthBelgium [6]. The mHealthBelgium platform was created in 2018 and contains information about all mobile applications that are CE-marked as medical devices. The app's prescription and reimbursement are based on the "3-level validation pyramid" that evaluates the social-economic impact of each product [6], [7].

France

PECAN (*Prise en Charge Anticipée*) initiative was introduced in 2021. Although modelled on the DiGA framework, PECAN distinguishes itself by including telemonitoring solutions despite CE-marked digital medical devices (DMDs). DMDs can receive early reimbursement based on recommendations from the national Health Technology Assessment (HTA) body. Also, PECAN allows early reimbursement by health insurers for one year without conclusive clinical evidence of the effects of the application.

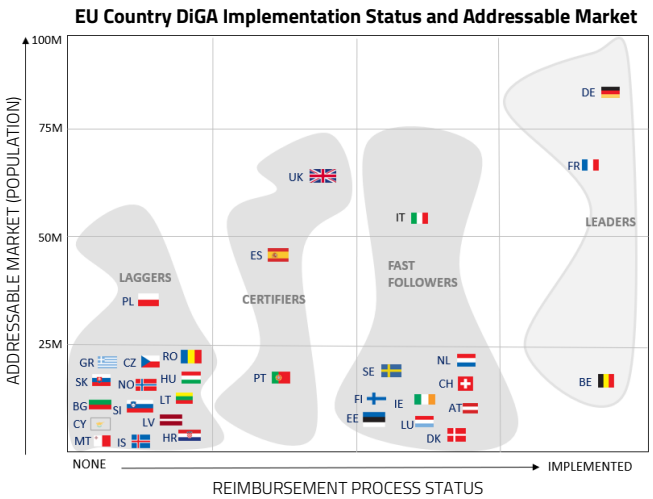

Figure 2 - Implementation status matrix of reimbursement models. From Research2Guidance [12].

During the first year, manufacturers receive a monthly predefined compensation fee per patient. After one year, if the solution shows clinical benefits and is approved by the authorities to be a PECAN, the price can be negotiated for DTx, but remain fixed for telemonitoring solutions.

The PECAN framework introduces two platforms: LATM for health data monitoring devices and LPPR for therapeutic DMDs [8], [9]. Only 3 applications are currently reimbursed and 23 applications have been submitted awaiting validation.

PECAN implementation challenges [10]

- In-depth knowledge of French regulations and processes is required.
- Complex requirements related to compliance with GDPR, interoperability, and security standards.
- Lengthy process with substantial documentation.

Others

ORCHA is an example of a good practice that was developed in the UK in 2015 and currently operates in 12 countries globally. Organisation for the Review of Care and Health Apps (ORCHA) is an infrastructure for delivering safe digital health by establishing quality assurance procedures [11]. It is the first cross-border framework for healthcare providers to evaluate and identify trusted digital health technologies within healthcare and preventive care. For instance, although no dedicated reimbursement provisions for digital health

technologies exist in the Nordic countries, ORCHA has been involved in the development of NordDEC [4].

Current state in Portugal

Compared to the European panorama (Figure 2), Portugal is at the halfway point when it comes to implementing reimbursement processes, being considered a "certifier" - characterised by prioritizing a certification process over a process that allows direct access to the statutory reimbursement system [12].

According to the most recent Startup Portugal Ecosystem Report, by the end of 2023 Portugal was home of 4073 startups, of which 8,45% are from the health sector [13]. According to the European Commission's Digital Skills Indicator 2.0, more than 50% of the population has a basic or higher level of digital literacy [11].

The COVID-19 pandemic accelerated the adoption of digital health solutions in Portugal. More than 80% of NHS public hospitals use some telehealth service, with frequent online tracking and teleconsultation [14].

In order to promote the digitalisation of the health sector and bring innovations closer to healthcare providers, various incentives have emerged:

- PRR (NextGenerationEU): including funds of €300M for Digital Health Transition and modernisation of SNS [15]; €2.5M to develop digital innovation in HealthTech/SmartHealth - DigiHealthPT [16]; and €90M for development of cutting-edge innovations for the health sector - HfPT [17].
- Digital Innovation Hubs: collaborative networks that help SMEs access advanced digital skills, funding opportunities, and resources to test and validate their products [18].
- Test Beds: environments for startups and companies to test their digital health applications in real-world settings [19].
- Technological Free Zones (ZLT): sandbox-like zones that offer regulatory flexibility to experiment with new technologies, including digital health applications [20].

Prescription and reimbursement mechanisms

Infarmed is the National Competent Authority for regulating medicines and medical devices in Portugal. The Health Technology Assessment (HTA) process helps decide which technologies the National Health Service (SNS) should use and fund, based on quality, safety, effectiveness, and efficiency. SiNATS, a system within Infarmed, sets these criteria and makes funding decisions for health technologies, including medical devices [21].

No national reimbursement framework has yet been implemented for digital solutions. The existing processes vary between the public and private sectors.

Public sector

The solution must be prescribed by an SNS doctor so that the patient can be reimbursed. This co-payment can be total or partial.

To date, only two solutions are subsidised: a free mobile app developed by SPMS (Shared Services of the Ministry of Health) to monitor vital signs and symptoms (Telemonit SNS 24). [22]; the FreeStyle Libre glucose meter, co-payed at 85% through medical prescription [23].

Since 2024, the Social Prescription has also been launched, which aims to reimburse activities that promote well-being and mental health (e.g. physical exercise, dancing, painting, etc.). The doctor prescribes, and the activity is reimbursed and provided in conjunction with municipalities, inter-municipal communities or third-sector organisations [24].

Private sector

Healthtech companies and startups develop digital solutions that users can access directly, recommended by doctors, or accessed through reimbursement models. Payment can be made out-of-pocket by users, based on a protocol with public or private entities (free for the user), or by the user with subsequent reimbursement requests to private entities, such as insurers.

Addressing the challenges in Portugal

Considering the current landscape of prescription and reimbursement processes for digital health solutions in Portugal, along with insights gathered from interviews with six national and international experts, five major challenge areas are anticipated to implement a national reimbursement model (or a DiGA-like model).

1. **Resistance to change the culture of care delivery and lack of focus on rewarding patient outcomes**

   The current culture within Portugal's healthcare system is reported as the primary barrier to integrating new technologies. *"Portugal needs to face a different mentality and culture organization in how we deliver care,"* explains Filipe Costa, expert in Health Economics and VBHC.

> *The current health systems do not serve the present and the future. A cultural shift is needed towards Value-Based Healthcare (VBHC).*
>
> ***— Ana Rita Londral***

- Innovation is still seen as a cost rather than an investment, mainly because hospitals often fail to track patients' health outcomes and not measuring the value of implemented innovations.
- Reimbursement is still a cost-based rather than a value-based model. Payers and providers are not aligned since insurers focus on reducing costs rather than increasing the quality of care. The priority is paying for procedures and volume over value. "*When using new technologies, we are increasing the costs to deliver better outcomes, so it is mandatory to increase the outcomes deeply*, " says Filipe Costa, explaining how reimbursement must reflect the correct use of technology in the value chain.

> *People are worried about the reimbursement of technologies when they should be worried about the reimbursement of good outcomes with the help of technology.*
>
> ***— Filipe Costa***

2. Fragmented ecosystem and need for straight collaboration between all the stakeholders.

As was seen during the DiGA adoption in Germany, collaboration and communication between all the players is essential for widespread adoption. In this regard, some challenges are expected in Portugal:

- The Portuguese healthcare system is fragmented. Stakeholders such as insurers and public and private hospitals often compete rather than collaborate. This lack of collaboration leads to an unbalanced system that hampers the integration of digital health solutions.
- Although several funds are available, they are spread thinly across various stakeholders, resulting in fragmented initiatives with many entities struggling to secure financing for survival.

3. Concerns in digital literacy in health and lack of technological skills among healthcare professionals.

Although Portugal is considered a country with good digital literacy, ranking 12th in the EU27 [11], there are still concerns regarding digital literacy when applied to health.

- Low adoption of mobile health applications. Although more than 65% of population use health services digitally as electronic prescriptions, only 20% report to use applications to monitor their health and well-being [25].
- Healthcare professionals lack the skills to use and integrate digital health solutions, hindering widespread adoption and implementation.
- The lack of expertise is strongly linked to the outdated educational model of healthcare professionals and administrators, which does not instruct the use of digital solutions.
- Fear surrounding the use of data in healthcare due to privacy and security concerns. It is expected that the implementation of the EHDS framework will overcome this issue[1].

4. Complex regulatory landscape and lack of a framework to support innovators navigating it.

Navigating the regulatory environment is inherently complex, and the lack of coherence among Member States' frameworks further complicates this process for innovators and developers.

- The lack of a Portuguese (and European) framework for prescription and reimbursement of digital tools forces startups and companies to comply with different regulatory requirements based on the target market. *"Additionally, integrating with each country's healthcare system, payment methods, and standardized laws requires extra effort in certification and technology development. These processes demand significant investment from startups and companies,"* as noted by José Paulo Carvalho, CEO of startup HopeCare.
- No consensus on technical quality standards or clinical requirements. This means developers looking to expand into multiple European markets

[1] Find out more about this topic by reading the EIT Health White Paper "European Health Data Space in Portugal" published in 2024.

must often modify their solutions or invest in additional clinical evidence.

> There is no notified body in Portugal, forcing developers to initiate certification processes in other countries, often resulting in longer response times.

> Startups and SMEs often have limited financial and human resources, making it challenging to hire qualified resources for regulatory compliance activities (QMS, clinical trials, etc.).

To enter and compete in foreign markets, like Germany or France, we have to follow their rules and standards, which can be different and more stringent than those in Portugal and requires funding that most of the startups do not have.
— José Paulo Carvalho

5. Insufficient digital infrastructure and challenges in ensuring interoperability between existing IT systems

Portugal is a country where public administration processes are already digitalised, and so is the national health system (SNS). However, there are still challenges that impact the implementation of digital health applications.

> Interoperability is the main challenge since each healthcare units have different IT systems and they are often incompatible. *"Regarding the definition of national interoperability standards, Portugal has not significantly advanced over the last years. This has clearly delayed the digital transformation in healthcare and will likely impact the adoption of digital health applications,"* explains Anne Geubelle, CEO of Prologica.

> Lack of data standardisation and access to high-quality data sources. Patient-generated health data are often stored in unstructured formats, hindering their effective use and integration.

> Limited infrastructure within hospitals that needs better broadband connectivity and data security to enable the common use and integration of digital health applications.

3 | Solution Overview: Charting the Path Forward

The following actions are grouped by areas of operation, mirroring the previous section's structure. Each recommendation is assessed for its potential impact and includes possible partners for implementation. These recommendations result from a multi-stakeholder perspective, reflecting unique insights into the challenges across various national health data ecosystem sectors.

1. Foster a Value-Based Healthcare culture to measure the impact of digital health applications

To successfully integrate digital health applications, Portugal must foster a VBHC culture that emphasizes measuring the impact of these technologies.

> Develop a framework tailored to digital health applications to assess and monitor the value of digital innovations to patients and the healthcare system and demonstrate it to payers and decision-makers. *"This framework must be different from the existing ones used for medicines and medical equipment,"* highlights Ana Rita Londral, expert in VBHC.

> Pilot projects in target groups and contexts before their nationwide rollout are essential for identifying potential issues and assessing digital solutions' effectiveness (clinical, economic, social, and environmental). As declared by Ana Rita Londral, *"Portugal has the potential to serve as a testbed for cultural change within the healthcare system."* Since 2024, the healthcare systems have implemented Local Health Units (ULS), new entities that integrate hospitals and health centers under a single management. These ULS create an optimal scenario for carrying out pilots [13].

> Develop "fast-tracks" for currently certified companies to develop value studies in real health contexts in conjunction with Infarmed and insurance companies.

> Establishing a dedicated change management team within hospitals could help lead this digital transformation, addressing resistance and cultivating a culture of innovation across the healthcare sector.

The ULS system [in Portugal] creates the perfect scenario to implement such pilots to identify potential issues and assess the effectiveness of digital solutions.
— Mafalda Carvalho

Potential partners: Coordinated by SPMS, ACSS (Central Administration of the Health System), and working closely with healthcare providers, insurance companies and primary care centres. Organisations with expertise in VBHC, such as universities or research centres, could also contribute.

2. Foster collaboration and co-creation initiatives among healthcare stakeholders.

To overcome the ecosystem's fragmentation, it is important to invest in joint projects and clarify the added value that collaboration between all the players can bring to adopting digital health applications, enabling further markets.

> Promote innovation procurement and value-based procurement. These mechanisms prefer cutting-edge technologies that allow hospitals to gain competitive edge, promoting opportunities for innovators. Additionally, value-based procurement promotes more flexible legislation and collaboration between clinicians and procurement professionals to focus on patient outcomes and satisfaction rather than only relying on costs. *"These approaches play a crucial role to initiate acceptance and adoption of digital health applications in health systems. Both guarantee healthcare providers' readiness to tap technologies, stimulate start-ups, and ensure that the primary concern lies in value besides scale,"* explains Anne Guebelle.

> Create co-creation incentives for regulatory bodies, industry stakeholders, and healthcare providers in order to reward projects and solutions that meet actual needs while simultaneously ensuring practical and feasible solutions and compliance.

> *Innovation procurement promotes development and new healthcare delivery methods by stimulating market demand and start-up opportunities to introduce their technologies.*
> ***— Anne Geubelle***

Potential partners: The Ministry of Health, SPMS and ACSS could coordinate the allocation of funds through initiatives. These organisations could collaborate with institutions such as ANI, responsible for divulgating and developing national and European initiatives in this area. Lastly, the policymakers could contribute to and make legislation on mechanisms such as innovation procurement more flexible.

3. Promote digital literacy in health and rethink the current educational model integrating digital skills in management and health-related schools.

To ensure a natural adoption by all stakeholders (from citizens to healthcare professionals and payers), investing in training and digital literacy in healthcare is crucial.

> Enhance digital literacy in health for both patients and healthcare professionals. Adopt accessible language, teach how data is used to build confidence and encourage the adoption of digital health applications.

> Establish dedicated help desks to support all stakeholders. Help patients with app usage, doctors with prescription processes, or developers with regulatory guidance. This comprehensive support will facilitate smoother adoption and compliance of digital health applications.

> Provide training programs on regulatory processes. *"This could include materials tailored to the needs of all stakeholders, from startup founders to healthcare professionals and health authorities,"* suggests Sandra Balseiro, expert on medical device certification.

> Create an education model integrating digital skills that promotes a universal language across schools (e.g., management, medical, nursing, pharmaceutical, engineering). This will create a generation with a culture of using digital tools and measuring their impact on clinical practice.

> *In Portugal, integrating technology is a mandatory approach that needs to start in medical schools.*
> ***— Filipe Costa***

Potential partners: DGS (Directorate-General for Health), SPMS, Infarmed, local administrations and the several schools themselves should work together to create and disseminate educational materials and update educational courses.

4. Create a transparent and accessible regulatory framework that aligns with all stakeholder's values.

Creating a balanced ecosystem among payers, providers, and suppliers is essential to integrate stakeholders effectively. A transparent model incorporating data and enhancing all stakeholders' relationships is crucial. *"Without this additional layer of transparency, the focus will remain on cost reduction rather than value-based care"*, explains Filipe Costa, expert in Health Economics and VBHC.

- Develop a framework that ensures transparency and collaboration among all stakeholders by providing clear insights into each stakeholder's contribution to the healthcare value chain. This will help prevent barriers to use, such as prescriptions by doctors or reimbursement by payers.
- Align reimbursement models with value-based outcomes by establishing meaningful KPIs. To this end, the number of prescriptions must be measured, as well as the actual impact of these solutions. It is also crucial to evaluate if technology integration truly enhances the care pathway. If it does, the technology should be adopted as part of standard practice; if not, it remains merely an innovation without added value. This approach ensures that technology is not just implemented but effectively contributes to improving healthcare outcomes.

Potential partners: The involvement of all stakeholders without exception is fundamental so that their interests are ensured and implemented. However, ACSS, SPMS and Infarmed could take the lead, as they are influential and experienced organisations in this area.

5. Invest in digital infrastructure and expertise and enhance interoperability across health systems.

It is well known that modernising the infrastructure within hospitals and healthcare system requires funding and high-level decision-making. However, some measures can be implemented that facilitate the integration of digital health applications.

- Invest in training and hiring data and IT specialists dedicated to implementing good practices across health data-generating units and ensure that healthcare facilities can manage and share data effectively.
- Foster a culture of data standardisation and interoperability. Healthcare providers generate vast amounts of health data, often unstructured. By ensuring that data generated within healthcare providers follows standardized norms will allow seamless sharing across IT systems and developers' use to train algorithms and support clinical decision-making models. *"Additionally, the output of these solutions have to be fully integrated with the patients flows and easily accessible by healthcare professionals to really be used as a clinical support decision tool,"* highlights Anne Geubelle.

Potential partners: The organisations involved in implementing the EHDS will play a significant role in these measures. In particular the policymakers, who are aware of European regulations. The SPMS would be a key organisation to coordinate.

Does Portugal need to implement a national reimbursement model?

YES. From the conducted interviews, the necessity for Portugal to implement a national reimbursement model for digital health applications was consensual. The healthcare systems need to integrate digital innovation to improve the equity and accessibility of services to the entire population and improve the efficiency of interventions. Also, establishing such a model is crucial for making Portugal an attractive market, incentivizing Portuguese companies and SMEs to stay in the country to develop and test technologies that enhance the national healthcare system. Additionally, it would attract foreign companies to bring their innovations to Portugal. Supporting SMEs fosters diversified innovation, addressing a broader range of needs and preventing market dominance by large corporations. This approach ensures a balanced and competitive environment, encouraging continuous advancement in digital health solutions.

BUT, being a small country, it may not justify replicating Germany's DiGA model exactly or creating a brand new framework from scratch. Instead, Portugal can benefit from alternative quality frameworks and pan-European collaboration and from sharing the assessment work with other EU Member States. This approach allows Portugal to leverage existing frameworks while tailoring them to the national context.

To successfully implement a reimbursement system in Portugal, it is important to invest in an iterative process that includes:

- Stakeholder engagement, to promote awareness and adoption among all players from the outset.
- Defining a quality framework, promoting a VBHC culture. An ORCHA-like model could be an excellent example of a framework that could be integrated into the NHS.
- Define roles and responsibilities, mainly regarding the entities involved in digital health assessment.

> *Effective stakeholder engagement (policymakers, healthcare providers, payers, industry stakeholders, and patient advocacy groups) is paramount for driving awareness, acceptance, and adoption of DTx across the healthcare continuum.*
>
> ***— Torsten Christann***

4 | Call to Action: Mobilising for Change

Sections 2 and 3 provided a better insight into the challenges in using digital health applications and possible recommendations that could turn these barriers into opportunities driving the successful implementation and adoption of a DiGA-like model for Portugal.

In particular, as a European organisation dedicated to the health innovation sector, EIT Health can play a proactive role in this regard. Considering an effort/impact ratio, there are two critical areas where EIT Health's involvement can make a significant difference:

1. Establish a Health Innovation Agency

EIT Health should rely on its network and partners and support the creation of a Health Innovation Agency in Portugal. This agency or taskforce would bring together key stakeholders, including startups, SMEs, insurance companies, healthcare providers, regulators, academia and patient associations, to foster collaboration and promote co-creation processes that address critical issues of the Portuguese ecosystem. Objective examples that could be on the agenda of this agency:

- Foster the implementation of the good practices based on the work of the European Taskforce for Harmonised Evaluations of Digital Medical Devices, contributing to greater regulatory standardisation and easy navigation between member-states. Invest in creating a "Super-DiGA," which establishes a common framework covering 80% of regulatory requirements, with the remaining 20% adaptable to each market's specific processes, such as local laws, prescription and payment mechanisms. This approach will make it easier for innovations to be adopted across different countries.
- Developing a national reimbursement framework focused on VBHC, supported by a comprehensive database of digital health applications and their documented outcomes.
- Study the viability of creating a national notified body.

2. Promote Funding and Training Programs

EIT Health could promote programs and incentives to support the funding and training startups and SMEs navigating the regulatory landscape. This could include, for example, organising roadshows across countries that are leaders in reimbursement models, such as Germany, France, and Belgium, to learn from their best practices.

> *There is an advantage in Portugal: we are no longer first-movers, so we can learn from the experience of others who have started this process.*
>
> ***— Ana Rita Londral***

Conclusion

This white paper highlights the pressing need for Portugal to develop a national reimbursement model for digital health applications tailored to the country's unique healthcare landscape. Drawing on the successes and lessons from European models, particularly Germany's DiGA, the study outlines strategic recommendations and actionable steps to foster a outcome-based culture, improve digital literacy, streamline regulatory frameworks, enhance digital infrastructure, and encourage stakeholder collaboration.

By implementing these measures, Portugal can stimulate innovation, improve healthcare outcomes, and become a more attractive market for digital health solutions. The involvement of key entities like EIT Health Innostars, SPMS, ACSS and Infarmed is crucial in driving these initiatives, ensuring the successful integration of digital health applications within the national healthcare system. The findings and recommendations aim to guide stakeholders towards a cohesive, efficient, and patient-centred healthcare ecosystem in Portugal.

Outputs

As key outputs of this white paper:

- Overview of European and Portuguese status and challenges in the implementation of reimbursement models.
- Strategic and specific recommendations to implement a reimbursement model of digital health applications in Portugal.
- A potential role for EIT Health Innostars in driving the implementation of these measures.

With these findings, every reader is empowered to become an active player in transforming Portugal's healthcare system into a leading digital health ecosystem. Be part of this movement!

Statement of EIT Health Innostars

The successful implementation of Digital Medical Devices (DMDs) relies on more than just reimbursement. Efficient prescription processes and the proficiency of medical professionals and patients are also crucial. Different countries have varying solutions, as seen with France and Germany's assessments of the same technology. This disparity risks fragmented market access for DMDs, which can hinder digital health innovation in Europe. Key recommendations include raising political awareness, improving digital skills, building national digital health infrastructures, and using EU funds. A pan-European scheme for the centralized evaluation and approval of DMDs, similar to the process for pharmaceuticals, could facilitate integration. EIT Health is playing a crucial role in this effort, coordinating the European Taskforce for Harmonising Evaluation of DMDs and developing common standards for all countries, as demonstrated by its active programs and initiatives.

— Ferenc Pongracz

Deputy Managing Director at EIT Health Innostars

EIT Health InnoStars Portugal is actively seeking engagement of all relevant stakeholders to develop a national strategy for implementing a DiGA-like system in Portugal. We provide an ideal platform to raise political awareness of digital health and enhance the digital skills of healthcare professionals and patients, a task that requires collaboration between national and European actors. Local policymakers must take proactive steps to develop a national digital health infrastructure, make health data accessible for research, build networks for validating and piloting solutions, and define implementation processes, leveraging EU funding for these initiatives. EIT Health InnoStars Portugal can co-coordinate and support national efforts to design and harmonize with other European reimbursement strategies, facilitating the validation and market entry of new digital therapeutics.

— Marta Passadouro

Ecosystem Lead of Portugal at EIT Health Innostars

References

[1] Federal Institute of Drugs and Medical Devices, "Digital Health Applications (DiGA)," Federal Institute of Drugs and Medical Devices. Accessed: May 27, 2024. [Online]. Available: https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/Interesting-facts/_artikel.html

[2] mobihealthnews, "Digital health apps balloon to more than 350,000 available on the market, according to IQVIA report." Accessed: May 27, 2024. [Online]. Available: https://www.mobihealthnews.com/news/digital-health-apps-balloon-more-350000-available-market-according-iqvia-report

[3] EIT Health, "Report on EIT Health Innostars Roundtable: 'The fundamentals of the Portuguese DiGA model,'" 2022.

[4] EIT Health Ireland-UK, "Digital health on prescription: Is Ireland ready?," 2023. [Online]. Available: https://eithealth.eu/wp-content/uploads/2023/02/Whitepaper-EIT-Health-Ireland-UK-Health-Apps-On-Prescription-1.pdf

[5] KV Hessen, "DiGA zulasten der GKV verordnen." Accessed: Jun. 12, 2024. [Online]. Available: https://www.kvhessen.de/abrechnung-ebm/diga-abrechnen

[6] Medical Device Network, "As of January 2021, medical apps can now be submitted for reimbursement in Belgium for the first time." Accessed: May 28, 2024. [Online]. Available: https://www.medicaldevice-network.com/analyst-comment/mhealthbelgium/

[7] mHealthBelgium, "mHealthBelgium." Accessed: May 28, 2024. [Online]. Available: https://mhealthbelgium.be/

[8] M. Bucksch, "PECAN & DMD – Guide to DiGA in France." Accessed: May 28, 2024. [Online]. Available: https://quickbirdmedical.com/en/pecan-france-diga-dmd/

[9] Medical Device Network, "France's pioneering approach to digital medical devices reimbursement," Features. Accessed: May 28, 2024. [Online]. Available: https://www.medicaldevice-network.com/features/frances-pioneering-approach-to-digital-medical-devices-reimbursement/?cf-view&cf-closed

[10] J. Stevovic, "DTx: the PECAN French reimbursement scheme is approved." Accessed: Jun. 04, 2024. [Online]. Available: https://blog.chino.io/dtx-pecan-reimbursement-scheme/

[11] R. Vuorikari, N. Jerzak, Z. Karpinski, A. Pokropek, J. Tudek, and Joint Research Centre (European Commission), "Measuring digital skills across the EU ," 2022. doi: 10.2760/897803.

[12] V. Chawla, "Where is the money in digital health? The roadmap to digital health app reimbursement in Europe," Research 2 Guidance. Accessed: Jun. 04, 2024. [Online]. Available: https://research2guidance.com/where-is-the-money-in-digital-health-the-roadmap-to-digital-health-app-reimbursement-in-europe/

[13] Portugal.Gov.PT, "Nova organização dos cuidados de saúde: conheça a grande reforma do SNS para 2024." Accessed: Jun. 04, 2024. [Online]. Available: https://www.portugal.gov.pt/pt/gc23/comunicacao/noticia?i=nova-organizacao-dos-cuidados-de-saude-conheca-a-grande-reforma-do-sns-para-2024

[14] International Trade Administration, "Portugal - Country Commercial Guide ," International Trade Administration. Accessed: Jan. 23, 2023. [Online]. Available: https://www.trade.gov/country-commercial-guides/portugal-medical-equipment-and-devices

[15] Mais Transparência, "Projeto PRR - Transição Digital na Saúde." Accessed: Jun. 04, 2024. [Online]. Available: https://transparencia.gov.pt/pt/fundos-europeus/prr/beneficiarios-projetos/projeto/C01-i06/

[16] Mais Transparência, "Projeto PRR - DigiHealthPT." Accessed: Jun. 04, 2024. [Online]. Available: https://transparencia.gov.pt/pt/fundos-europeus/prr/beneficiarios-projetos/projeto/03/C16-i03/2022.P763/

[17] NOVA FCT, "HfPT - Health from Portugal." Accessed: Jun. 04, 2024. [Online]. Available: https://www.fct.unl.pt/investigacao/projetos-financiados/hfpt-health-portugal

[18] IAPMEI, "Rede de Polos de Inovação Digital." Accessed: Jun. 04, 2024. [Online]. Available:

https://www.iapmei.pt/PRODUTOS-E-SERVICOS/Empreendedorismo-Inovacao/Inovacao-e-Competitividade/Programas-e-iniciativas/Rede-de-Polos-de-Inovacao-Digital.aspx

[19] Portugal Digital, "Testbeds." Accessed: Jun. 04, 2024. [Online]. Available: https://portugaldigital.gov.pt/acelerar-a-transicao-digital-em-portugal/testar-e-incorporar-nova-tecnologia/testbeds/

[20] ANI, "Zonas Livres Tecnológicas." Accessed: Jun. 04, 2024. [Online]. Available: https://www.ani.pt/pt/valorizacao-do-conhecimento/interface/zonas-livres-tecnol%C3%B3gicas/

[21] Infarmed, "Avaliação de tecnologias de saúde." Accessed: Jun. 04, 2024. [Online]. Available: https://www.infarmed.pt/web/infarmed/entidades/medicamentos-uso-humano/avaliacao-tecnologias-de-saude

[22] SNS24, "App Telemonit SNS 24." Accessed: Jan. 31, 2023. [Online]. Available: https://www.sns24.gov.pt/guia/app-telemonit-sns-24/#o-que-e-a-telemonit-sns-24

[23] M. Carriço, "Estado vai comparticipar medidor de glicose sem picada no dedo a 15 mil diabéticos," Observador. Accessed: Jun. 04, 2024. [Online]. Available: https://observador.pt/2017/11/13/estado-vai-comparticipar-medidor-de-glicose-sem-picada-no-dedo-a-15-mil-diabeticos/

[24] A. Campos and D. Rocha, "Prescrição social. 'Já foram beneficiadas mais de 800 pessoas e referenciadas mais de 1500,'" Público. Accessed: Jun. 04, 2024. [Online]. Available: https://www.publico.pt/2024/04/08/sociedade/entrevista/ja-beneficiadas-800-pessoas-referenciadas-1500-2086211

[25] Roche, "Mais de 65% dos portugueses usa serviços de saúde digitais." Accessed: Jun. 04, 2024. [Online]. Available: https://www.corporate.roche.pt/atualidade/mais-de-65--dos-portugueses-usa-servicos-de-saude-digitais

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