

Recognising the value of digital health apps: An assessment of five European healthcare systems

16 November 2021

POSITION PAPER

Contents

Preface.....	2
Executive summary.....	3
1. Introduction	4
2. Assessment Criteria and Funding Streams in Five European Countries and Regions.....	5
2.1 Belgium	5
2.2 England.....	6
2.3 France	9
2.4 Germany.....	12
2.5 The Netherlands.....	14
3. Summary	17
4. Next Steps and Recommendations	19
List of abbreviations	20

Figures

Figure 1: mHealthBelgium validation pyramid	5
Figure 2: NICE's digital health evidence framework	9
Figure 3: German fast-track reimbursement process for DiGAs.....	13

Funding and Reimbursement Mechanisms for Digital Health Technologies in Europe

Preface

Europe's health systems are under pressure. Demographic changes, rising incidences of chronic disease, and a shortage of healthcare professionals undermine their ability to deliver care. Digital health technologies (DHTs) have the potential to make healthcare safer, better, and more efficient. Yet levels of their deployment in Europe's healthcare systems remain low.

DHTs include devices (smartphones, tablets, and computers), products (apps, software, and platforms), and advanced technologies (robotics and digital surgery).¹ A common element of DHTs is their ability to generate, store, process and / or transmit data. Connected and interoperable, DHTs can effect positive transformation in Europe's healthcare systems, by helping to deliver:

- **Improved prevention and treatment.** DHTs provide patients and citizens with the information and the tools to monitor, manage, and improve their health and lifestyle;
- **Enhanced access to care.** DHTs move the patient-doctor relationship beyond in-person interaction, through technologies such as remote monitoring, digital health apps, healthcare chatbots, etc.;
- **Safer and more efficient care.** DHTs assist healthcare professionals by delivering timely information and decision support, reducing duplication of services, and unlocking the potential of AI;
- **Better evidence and intelligence.** DHTs make aggregated data available for research, thus giving impulse to precision medicine, public health, and population health management, as well as development and evaluation of new technologies, treatments, and medicines.

It is therefore in the interest of patients, healthcare professionals, and healthcare systems to deploy DHTs as broadly as possible. **An overarching barrier to the deployment of DHTs is the lack of appropriate mechanisms for funding and reimbursement.** In a new set of papers that focus on digital health, we seek to understand and document these barriers in Europe's healthcare systems and propose ways in which these barriers can be mitigated or removed.

MedTech Europe, as the voice of Europe's medical technologies industry (including medical devices and in vitro diagnostic devices), calls on national and regional policymakers and payers to **recognise the value and incentivise the use of DHTs in Europe's healthcare systems** by setting up clear frameworks for reimbursement and funding pathways that will enable their uptake and use in Europe's healthcare systems.

¹ OECD (2019), "Bringing health into the 21st century", in *Health in the 21st Century: Putting Data to Work for Stronger Health Systems*, OECD Publishing, Paris, <https://doi.org/10.1787/e130fcc2-en> (accessed November 2021).

Recognising the value of digital health apps: An assessment of five European healthcare systems

Executive summary

Digital health apps can improve access to and quality of care in Europe's healthcare systems. As such, broad deployment of digital health apps is key to achieving innovation and sustainability in European healthcare. However, the current lack of clear and formally established funding and reimbursement mechanisms hinders their use in Europe, at the expense of patients, healthcare professionals and healthcare systems.

This MedTech Europe position paper provides an overview of funding and reimbursement initiatives for digital health apps that are currently in place in Belgium, England, France, Germany, and the Netherlands. It finds that funding and reimbursement for digital health apps are not uniform across Europe: it identifies common elements and overarching patterns, as well as country- or region-specific differences. **A set of recommendations** are proposed that may guide the further development of these initiatives within and beyond the countries and regions considered at regional, national and/or European levels:

- 1 - Ensure transparency:** Funding for digital health apps should be based on structured, stable, and transparent criteria that are tailored to the needs of the respective healthcare system.
- 2 - Link with funding:** Assessments for digital health apps should be explicitly linked with funding, reimbursement and/or coverage recommendation for health authorities and payers.
- 3 - Consider the value:** Assessments should be appropriate and consider the holistic benefit (e.g., impact on access, quality of life, efficiency of care, health system costs) that these technologies can bring to patients, healthcare professionals, and healthcare systems.
- 4 - Share learnings:** Member States and regions should be incentivised by the EU institutions to analyse and learn from good practices in other countries and regions and seek to identify the conditions that enable faster and widespread uptake of digital apps.
- 5 - Support evidence generation:** The evidence requested should be appropriate to the impact of the app (be it on the basis of real-world evidence, or clinical evidence generated outside of the country of assessment). Where local evidence is required, there should be a shared commitment to evidence generation that extends to sharing the burden of proof of benefits and outcomes, and appropriately compensates the developers of digital health apps. The criteria for evidence should be transparent.
- 6 - Invest in infrastructure and training:** Digital health technologies can enable movement from one care setting to another. This requires investment in infrastructure (where needed), the removal of budget silos, and training of clinicians, patients, and caregivers.

Whilst the initiatives in the five countries and regions examined here are highly welcomed, they should be built upon further to strengthen the uptake of digital health apps and to ensure better access for patients, healthcare professionals and healthcare systems.

1. Introduction

Digital health technologies (DHTs) present an opportunity to make healthcare delivery better, safer, and more efficient.² However, they do not fit easily into existing funding pathways in European countries and regions, which tend to focus on services, medicines, and medical devices. Whilst advances in digitalisation in government and society have fostered interest in DHTs, unlocking funding and reimbursement frameworks for their use has been a slow process. As a result, levels of deployment of DHTs across Europe are low and uneven. This critically undermines European innovation in healthcare.

This paper focuses on current initiatives in five European countries and regions – Belgium, England, France, Germany, and the Netherlands – to provide funding pathways for an important category of DHTs: digital health apps (or health apps). Already widely popular among European patients and citizens, health apps assist patients in preventative care, treatment, and recovery by helping them to improve their lifestyle, treat their medical conditions, or manage recovery after surgery. In recent years, several European countries and regions have started dedicated funding initiatives for health apps, with a view to normalising such funding. This paper takes an in-depth look at these countries and regions' assessments of health apps and related funding initiatives to gauge the efficacy of the respective processes, and to provide a set of recommendations for them and other European countries and regions that might be considering developing similar initiatives.

These five countries have focused on three key aspects for assessing digital health apps for reimbursement:³

- 1 - Safety and efficacy assessment**, i.e., levels of medical safety, quality, and reliability. Most European markets already require that health apps considered for reimbursement be CE-marked under the applicable EU medical device (MDR) or in vitro diagnostic device (IVD) directives and regulations. The medical technology industry calls on all European countries and regions that offer funding or reimbursement for health apps to follow this practice. Lifestyle and consumer-related apps should only be reimbursed in exceptional circumstances.
- 2 - Technical and legal assessment**, i.e., levels of compliance with (national and / or European) data security, cybersecurity and privacy conditions, and ability to deliver health data to their health IT systems such as electronic health record systems. The medical technology industry encourages European Member States and regions to require compliance with all applicable laws and regulations regarding information security and data protection, and to define the specifications of how health data should be delivered to provider IT systems.
- 3 - Benefits and outcomes assessment**, i.e., evidence that health apps deliver positive benefits and outcomes, including effects on ease of access, quality of life, and impacts on outcomes from a societal perspective.

² We follow the European Commission's definition of DHTs: "digital health and care refer to tools and services that use information and communication technologies (ICTs) to improve prevention, diagnosis, treatment, monitoring and management of health and lifestyle. Digital health and care have the potential to innovate and improve access to care, quality of care, and to increase the overall efficiency of the health sector." Retrieved at: https://ec.europa.eu/health/ehealth/overview_en (accessed November 2021).

³ See for example the three-part validation pyramid developed by mHealth Belgium in Figure 1: mHealthBelgium validation pyramid below.

This paper focuses specifically on benefits and outcomes. There are other outcomes, besides clinical benefits, that are important for patients, healthcare professionals or health systems, such as patient outcomes, and structural and process outcomes. Collectively, these can be considered the “value” of digital health apps.

2. Assessment Criteria and Funding Streams in Five European Countries and Regions

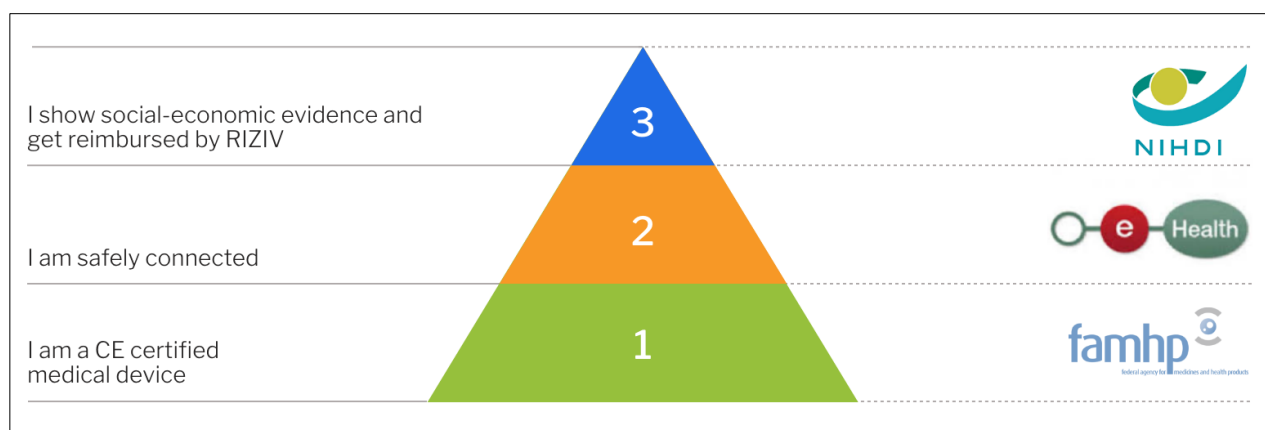
This section sets out the different types of funding frameworks, tools, and processes for health apps that are currently in place in Belgium, England, France, Germany, and the Netherlands. These funding mechanisms for health apps were chosen for consideration because the field of health apps is dynamic and continuously evolving, among other reasons due to accelerated demand for them in the wake of the COVID-19 pandemic.

2.1 Belgium

Provisions for national funding or reimbursement of digital health applications are a recent introduction in Belgium. In February 2020, the National Institute for Health and Disability Insurance (NIHDI), the Belgian authority responsible for healthcare reimbursement, set up a working group to develop reimbursement procedures for DHTs. For health apps, it built on the mHealthBelgium initiative.

mHealthBelgium, founded in 2018, is the Belgian digital platform for all relevant information covering validated apps for patients, healthcare professionals, and healthcare institutions.⁴ Two industry federations, beMedTech (medical technologies) and Agoria (representing companies in the technology sector), drive the implementation and daily management of the platform.⁵ Its scope includes mobile software apps (native app or webapp) that are used by patients to monitor their health (with or without devices), or for telemonitoring services (with medical devices connected to patients).

Figure 1: mHealthBelgium validation pyramid



⁴ <https://mhealthbelgium.be/>

⁵ Information about each organisation can be found on the respective websites, www.bemedtech.be and www.agoria.be/en (accessed November 2021)

The term “validation” refers to meeting specific criteria defined by the Belgian government, visually represented in three levels as the “mHealthBelgium validation pyramid” (Figure 1). Three national authorities are involved in defining the criteria:

- The Federal Agency for Medicine and Health Products (FAMHP), i.e., the competent authority responsible for assessing the safety, quality and efficacy of drugs and health products (level M1 of the validation pyramid);
- The eHealth Platform, i.e., the federal digital health organisation responsible for building the infrastructure for information exchange in healthcare and ensuring that devices are safely connected (level M2 of the validation pyramid);
- The National Institute for Health and Disability Insurance (NIHDI), i.e., the competent authority responsible for reimbursement of healthcare products and services (level M3 of the pyramid).

To qualify for reimbursement, the app first needs to pass the M1 level (i.e., being CE certified as medical device) and M2 level (i.e., meeting ICT criteria regarding data privacy, authentication, identification as well as therapeutic relationship and informed consent). To pass the M3 level, the app developers submit a dossier showing the clinical and / or socio-economic value: the evidence (whether real-world data or a clinical study) must show that the medical app brings clear value in the care path / process. The funding body then reshapes the financing of the specific care path and sets the criteria and functionality for the app. From that moment, every application that passes level M1 and M2 and meets the criteria for the care path set by NIHDI can do a self-declaration and become M3 granted. This allows healthcare professionals or organisations to use and/or prescribe an M3 medical app, with public funding. Care paths in many therapeutic domains can thus be reshaped, typically in convention format and with bundled payments instead of ‘fee-for-service’ (=payment per medical act), hence removing the classic barrier for DHTs.

While level M1 was launched in January 2019 and level M2 in May 2020, it was not until January 2021 that level M3, the new financing framework for mobile health applications, was completed and launched. mHealth-Belgium encourages app developers to think holistically when defining the value of their app, considering also the wider benefit to society, or savings outside of the healthcare settings in which the cost is generated.

It is important to note that health apps could also be financed by means other than national funding and reimbursement through mHealthBelgium. For instance, hospitals could finance them via their innovation budget; patients or healthcare professionals could finance them out-of-pocket; and health insurance companies could at least partially support the use of the app.

[2.2 England](#)

The key administrative tool for patient-facing health apps is registration in the National Health Service (NHS) Apps Library, which ensures acceptance by providers and commissioners. The NHS App Library is maintained by NHSX, a cross-organisational unit of the British government created in July 2019 to bring

together the Department of Health and Social Care, NHS England, and NHS Improvement working on the digital transformation of the NHS.⁶

The NHS Apps Library collects all health apps that have been assessed against national standards and are proven to be safe and secure. It is therefore advisable that health apps are registered in the NHS Apps library to be accepted by providers and commissioners.⁷ Previously, apps in the NHS Apps Library followed the Digital Assessment Questions. This changed in October 2020 to assessment through the Digital Technology Assessment Criteria.⁸ There is a formalised process for apps to gain acceptance into the app library that (as of October 2020) is at a beta-testing phase.

The assessment criteria are focused on five core areas. Criteria 1-4 form the core assessed standards, criterion 5 being a separate conformity rating and recommendations around usability and accessibility:

- 1 - Clinical safety** to ensure that baseline clinical safety measures are in place and that organisations undertake clinical risk management activities to manage this risk;
- 2 - Data protection** to ensure that data protection and privacy is 'by design' and the rights of individuals are protected;
- 3 - Technical assurance** to ensure that products are secure and stable;
- 4 - Interoperability** to ensure that data is communicated accurately and quickly, safely and securely;
- 5 - Usability and accessibility** to ensure that products are allocated a conformity rating having been benchmarked against good practice. Where there are areas for improvement, recommendations will be made.

As of October 2020, 97 health apps have been registered in the NHS Apps Library. However, registration of health apps in the NHS Apps Library does not mean that funding or reimbursement will necessarily follow. There is no national reimbursement framework for health apps in England and it is left to the Clinical Commissioning Groups (CCGs) and NHS Trusts to negotiate reimbursement with the developers. If an app is listed in the library, it simply demonstrates standards of clinical safety, data protection, technical assurance, interoperability and usability, and accessibility. This way, the developer can work with individual Trusts and Clinical Commissioning Groups on acceptance of the app at local level, with the benefit of accepted standards.

⁶ MTRC Report: *Reimbursement landscape for Health apps in Europe*, July 2020.

⁷ <https://www.nhs.uk/apps-library/> (accessed November 2021)

⁸ <https://www.nhs.uk/key-tools-and-info/designing-and-building-products-and-services/> (accessed November 2021)

Health app developers can also annually submit proposals for the Innovation and Technology Payment mechanism (ITP), if the technology qualifies for the determined inclusion criteria. ITP is an annual competition and there is no guarantee that technologies funded in one year will be funded the next.

Formal evidence standards and review in England

In December 2018, the National Institute for Health and Care Excellence (NICE) published the Evidence Standards Framework for DHTs to ensure that newly developed technologies (including patient facing apps) are clinically effective and offer economic value.⁹ The standards were updated in April 2021. Whilst previous reviews of DHTs (as part of the MedTech Innovation Briefing program) simply summarised data, these new standards are intended to help health app providers and commissioners (CCGs and NHS Trusts) to understand what good levels of evidence for DHTs look like.

Within the NICE assessment framework for DHTs, DHTs are classified by function and stratified into evidence tiers (Figure 2); this classification allows the provider to determine which level of evidence will be required by NICE. Full details of the evidence required for each tier is published by NICE.¹¹ A positive endorsement by NICE is not automatically associated with reimbursement decisions. Nonetheless, evaluation by NICE could be an important independent assessment used to support funding applications via Innovation and Technology Payment or further promotion of technology within NHS, for example, via the MedTech funding mandate.

If a health app can demonstrate system-level improvements or cost savings, it can be subject to evaluation by NICE. During 2020, NICE's Medical Technologies Evaluation Program was updated to include two DHTs in the pilot programme (myCOPD for self-management of chronic obstructive pulmonary disease and Zio XT for detecting cardiac arrhythmias).¹² A positive endorsement from NICE can support the acceptance of the health app by commissioners. NHS England is expected to establish a mechanism to give commissioners and providers the mandate to accept and implement technologies that are recommended by NICE in the

Example: myCOPD App

myCOPD, a health app that assists patients with managing their chronic lung disease, is the only health app reimbursed nationally. Initially, myCOPD obtained reimbursement through the Innovation and Technology Tariff (ITT) mechanism, which was introduced to incentivise the adoption and spread of transformational innovation in the NHS.

As of 2019/20, the ITT was replaced by the Innovation and Technology Payment (ITP) mechanism, which now funds myCOPD. Providers order myCOPD directly from the supplier at no cost and NHS England reimburses the supplier directly.¹⁰

⁹ National Institute for Health and Care Excellence, *Evidence Standards Framework For Digital Health Technologies*, March 2019, accessible at <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf> (access November 2021; **Error! Reference source not found.** is on page 9).

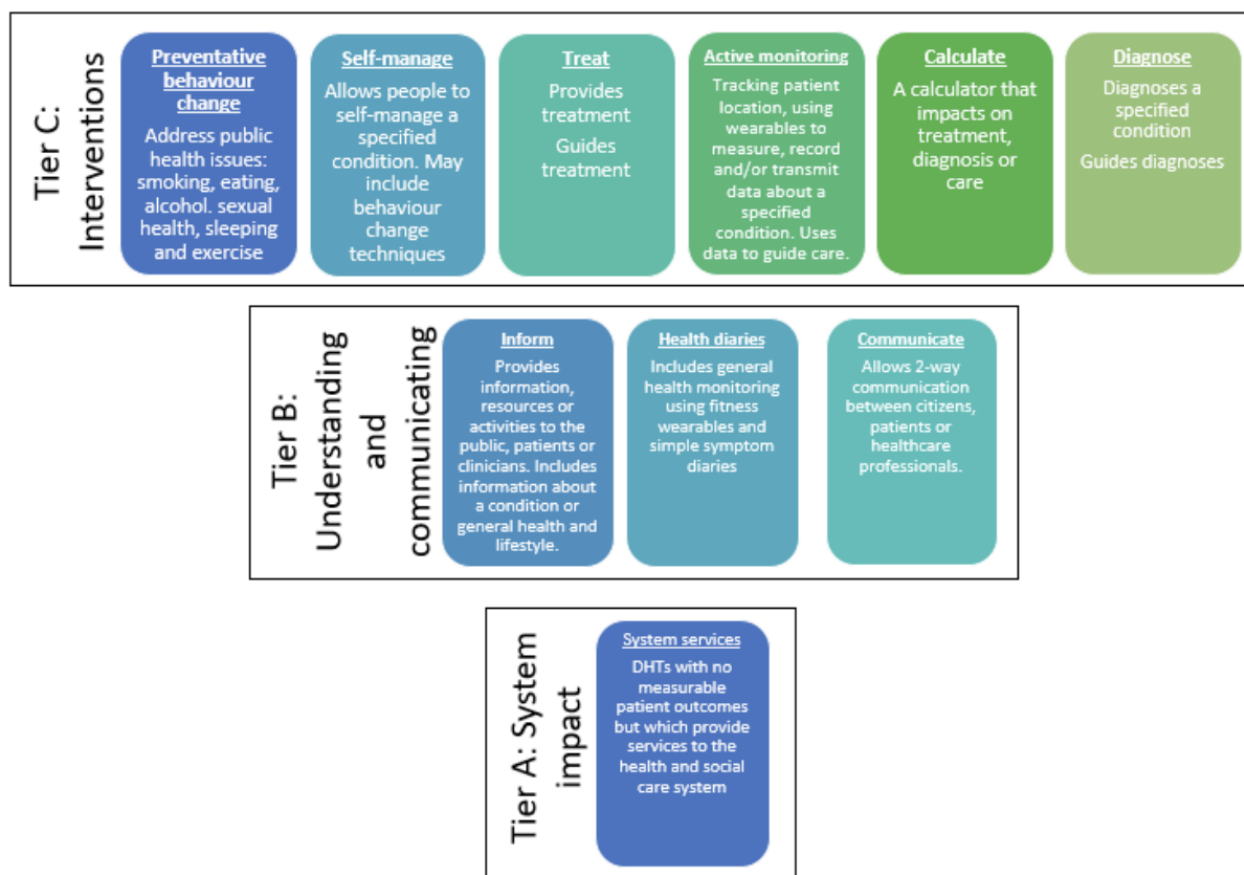
¹⁰ Information about the ITP can be accessed at <https://www.england.nhs.uk/aac/what-we-do/what-innovations-do-we-support/innovation-and-technology-payment/> (accessed November 2021). For the current mechanism go to https://wessexahsn.org.uk/img/projects/Implementation%20Toolkit_myCOPD.pdf (accessed November 2021).

¹¹ <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf> (accessed November 2021)

¹² <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-evaluation-programme> (accessed November 2021)

Medical Technologies Evaluation Program or Diagnostic Guidance and are included in the MedTech Funding Mandate by NHS England. However, a final decision on this is currently delayed.¹³

Figure 2: NICE's digital health evidence framework



2.3 France

In France, the authority for the reimbursement of medical devices is the Haute Autorité de Santé (HAS, French National Authority for Health). Connected medical devices (CMDs) have recently been added to the scope of HAS' list of products and services that qualify for reimbursement (LPPR, Liste des Produits et Prestations Remboursables). In the past, two separate submission guides were available: a general one for any type of medical device, and another CMD-specific document produced by the HAS in 2018 related to the specific features of CMDs. As medical device connectivity is today considered in many reimbursement dossiers submitted to the Medical Device and Health Technology Evaluation Committee (CNEDiMTS), a submission guide (updated in September 2020) now includes specific questions inherent to CMDs, thus providing a single document to support reimbursement submissions in which specific CMD requirements are highlighted.¹⁴ The process of enlisting a health app in the LPPR is therefore similar to the pathway for

¹³ <https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/the-medtech-funding-mandate/> (accessed November 2021)

¹⁴ "LPPR: Dossier submission to the Medical Device and Health Technology Evaluation Committee (CNEDiMTS)": https://www.has-sante.fr/jcms/c_2964238/en/guide-to-the-specific-features-of-clinical-evaluation-of-connected-medical-device-cmd-in-viewof-its-application-for-reimbursement (accessed November 2021)

implantable devices, invasive non-implantable devices, and medical aids, which require a very good level of evidence.

Given the available evidence, the CNEDiMTS assesses the following¹⁵:

- Actual clinical benefit
- Clinical added value
- Intended role in the therapeutic strategy for a given disease
- Indications and usage (treatment duration, frequency, proper use)
- Target population (estimated number of patients affected by the therapeutic indications).

In addition, the severity of the disease, efficacy, adverse effects, intended role in the therapeutic strategy in comparison to other available therapies, as well as public health benefits are all taken into account. If the actual clinical benefit is sufficient, a favourable opinion for registration on the LPPR is given. Clinical added value is further assessed considering comparative efficacy and safety data versus alternative solutions. There are five levels of clinical added value which will impact the reimbursement tariff: I major, II important, III moderate, IV minor, V no improvement.

Experimental programme for telemonitoring - ETAPES

In addition to the centralised pathway of LPPR listing, some health apps can also be reimbursed via the experimental programme for telemonitoring in France “ETAPES” (Expérimentation de Télémédecine pour l’Amélioration des Parcours en Santé). ETAPES is a temporary programme initially launched in 2014 in nine regions which was later expanded nationally. It is not dedicated to health apps but has been a good pathway to obtain funding for telemonitoring apps that met the specific requirements in one of the five clinical fields covered by the programme: heart failure, kidney failure, respiratory failure, diabetes, and implantable cardiac devices. The funding provided through ETAPES includes three components:

- 1 - Payment for the physician performing telemonitoring;
- 2 - Payment for the healthcare professional providing the therapeutic support to the patient;
- 3 - Payment to the provider of a technical solution for telemonitoring (e.g., a connected medical device, health app, digital platform, or a combination of those).

¹⁵ https://www.has-sante.fr/jcms/c_2035654/fr/methods-and-criteria-for-assessing-medical-devices (accessed November 2021)

¹⁶ More information can be found at https://www.has-sante.fr/jcms/c_2964253/fr/moovcare-poumon and in the French Official Journal (<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000042165410> (both websites accessed November 2021)).

Example: Moovcare App

In August 2020, Moovcare, an app for the telemonitoring of recovered lung cancer patients, became the first reimbursed health app in France after the following steps: positive clinical assessment by CNEDiMTS, pricing decision by the Economic Committee for Health Products (CEPS), and the reimbursement decision published in the Official Journal of French Republic. A specific sub-section, “Web application and software intended for remote monitoring”, was created in the LPPR title 1 dedicated to medical aids for home care. The reimbursement is EUR 500 including tax, every three months. Only a specialist (oncologist, pulmonologist, or surgeon) can determine if the patient is eligible and prescribe the application. Prescription is for six months, with options for renewal.¹⁶

Thus, if a health app can be used as part of the telemonitoring solution in the fields of heart failure, kidney failure, respiratory failure, or diabetes, the developer of the app could register its solution for the ETAPES experiment and obtain reimbursement for providing a telemonitoring solution. An exception to this are telemonitoring solutions connected to implantable cardiac devices, which have previously been granted reimbursement through the LPPR and do not get extra payment within ETAPES.

The ETAPES programme is set to end December 2021, and a final assessment report is planned. Meanwhile, under the impact of the Covid-19 epidemic, the French Ministry of Health announced that telemonitoring would be reimbursed through general legislation.¹⁷ New funding mechanisms are under discussion.

Coverage with evidence development schemes

If clinical evidence to justify inclusion in the LPPR is not sufficient, then non-DHT specific coverage with evidence development programmes (e.g., Hospital Clinical Research Program PHRC, Health Economic Research Program PRME) could be an alternative to obtain reimbursement while developing evidence. After annual national and regional calls for proposals, lump sums are delivered to cover a limited period. This is funded by an agency dedicated to public interest. There are different examples of projects focusing on the use of health apps, which have been funded in past years.¹⁸

In addition, health apps could become part of the experiment according to the Article 51 Social Security Financing Act.¹⁹ This programme aims to improve cooperation between healthcare stakeholders and to reduce silos between different parts of the healthcare system through innovative funding or innovation in the organisation of healthcare. The projects eligible for funding via Article 51 should improve access to healthcare, the efficiency of the system, relevance of prescription, and patient pathway. To submit a project, each sponsor should provide a brief description with a letter of intent on an ad hoc platform which, depending on the territorial scope of the project, will be national or regional. The experimental projects are selected on their innovative, efficient, and reproducible character. The improvement of the service provided to the population, the balance of the financing plan, the impact on organisations, the relevance of the chosen evaluation methods and the operational feasibility are also taken into account. Several selected projects have involved the use of health apps, including recently for gestational diabetes.

At the end of 2020, the French government launched G_NIUS I, the *Guichet National de l'Innovation et des Usages en e-Santé* ("national portal for eHealth innovation").²⁰ Supported by the Ministerial eHealth Delegation and other relevant agencies including HAS, G_NIUS is a sectoral web service that directs digital

¹⁷ https://www.legifrance.gouv.fr/download/pdf?id=Lm5sclzrlW_aejqDtuXntxJZvxKXBoNLUNa3sUly-c= (accessed November 2021). The new legislation will be the new Social Security Financing Act 2022 (LFSS for Loi de Financement de la Sécurité Sociale).

¹⁸ <https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/recherche-et-innovation/l-innovation-et-la-recherche-clinique/appels-a-projets/article/les-projets-retenus> (accessed November 2021)

¹⁹ <https://solidarites-sante.gouv.fr/systeme-de-sante-et-medico-social/parcours-des-patients-et-des-usagers/article-51-lfss-2018-innovations-organisationnelles-pour-la-transformation-du/article-51> (accessed November 2021)

²⁰ <https://gni.us.esante.gouv.fr/en> (accessed November 2021)

health innovators to content and experts within the public authorities. It also explains various sources of financing for e-health at French and European levels, in French and English.²¹

In October 2021, the government launched a strategy to accelerate digital health including an intent to simplify market access for digital health solutions.²² In the same month, President Macron announced his intent to implement a “fast track” reimbursement mechanism modelled on the DiGA mechanism in Germany (see next chapter).²³ Details may be included in the upcoming Social Security Financing Bill for 2022.²⁴

2.4 Germany

The 2019 Digital Healthcare Act (Digitale-Versorgung-Gesetz or DVG) provided for the reimbursement of various DHTs, including health apps and web-based applications. It defined the pathway for the statutory introduction of health apps as medical devices and the process for manufacturers to apply for reimbursement.

The regulation uses the term “Digitale Gesundheitsanwendung” (DiGA) to define health apps and web-based applications (class I and IIa MDR/IVDR) that are part of standard care and are reimbursed by the statutory health insurance funds. The manufacturer applies to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) to become eligible for reimbursement. This constitutes a new reimbursement pathway for those specific health apps. DiGAs are required to indicate positive medical benefits (including the improvement of health, the reduction of the duration of a disease, extension of life and improvement in quality of life) as well as improvements in structures and processes that are relevant for the patient. The BfArM guidance lists specifically the areas of:

1. Coordination of treatment procedures
2. Alignment of treatment with guidelines and recognised standards
3. Adherence
4. Facilitating access to care
5. Patient safety
6. Health literacy
7. Patient autonomy
8. Coping with illness-related difficulties in everyday life
9. Reduction of therapy-related efforts and strains for patients and their relatives.

Figure 3 on page 13 outlines the process for fast-track reimbursement for DiGAs.²⁵

²¹ <https://gnius.esante.gouv.fr/en/financing> (accessed November 2021)

²² <https://gnius.esante.gouv.fr/sites/default/files/2021-10/sasn.pdf> (accessed November 2021); the media release is available here [here](#) (accessed November 2021).

²³ <https://www.healthcareitnews.com/news/emea/france-enable-rapid-market-access-digital-therapeutics> (accessed November 2021)

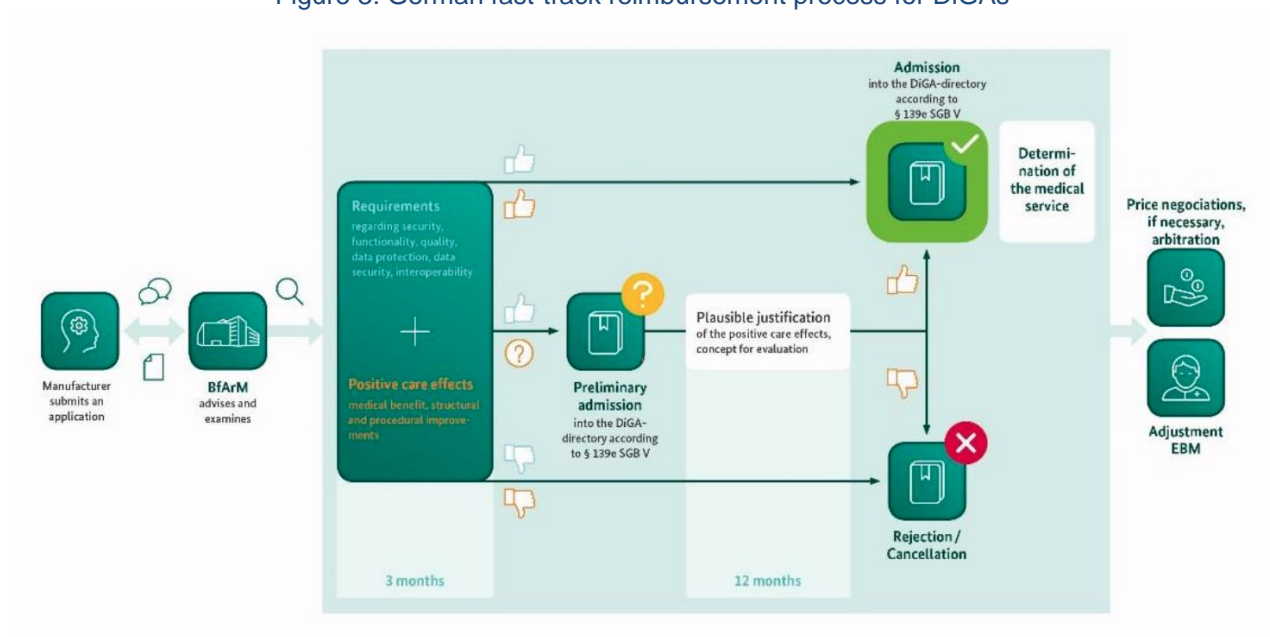
²⁴ <https://www.economie.gouv.fr/presentation-projet-loi-financement-securite-sociale-2022> (accessed November 2021)

²⁵ The BfArM website contains detailed information about the DiGA fast track reimbursement process in German and English. https://www.bfarm.de/EN/Medical-devices/Tasks/Digital-Health-Applications/_node.html (accessed November 2021). Figure 3 is reprinted from the DiGA Guide (page 8), available on the same website.

DiGAs are required to indicate positive medical benefits (including the improvement of health, the reduction of the duration of a disease, extension of life and improvement in quality of life) as well as improvements in structures and processes that are relevant for the patient. The BfArM guidance lists specifically the areas of:

10. Coordination of treatment procedures
11. Alignment of treatment with guidelines and recognised standards
12. Adherence
13. Facilitating access to care
14. Patient safety
15. Health literacy
16. Patient autonomy
17. Coping with illness-related difficulties in everyday life
18. Reduction of therapy-related efforts and strains for patients and their relatives.

Figure 3: German fast-track reimbursement process for DiGAs



BfArM makes a coverage decision within three months after receiving the application. If criteria for inclusion are met, the health app is included in the Directory²⁶ (permanently listed) and can be prescribed and reimbursed by statutory health insurances (SHI).

Before submitting an application, manufacturers must decide whether to apply for temporary / provisional or definitive / permanent inclusion in the list. If the manufacturer cannot immediately prove the benefit, but the

²⁶ <https://diga.bfarm.de/de/verzeichnis> (accessed November 2021)

method seems promising and has the potential to prove the associated benefits, a testing trial for 12 months with a temporary listing in the Directory can be activated on application from the manufacturer (Fast-Track procedure). If the evidence after 12 months is still not sufficient, the manufacturer can prolong the trial period for a maximum of additional 12 months.

If the health app is added to the Directory, the manufacturer sets the price for the first 12 months. After that period, the manufacturer negotiates the reimbursement tariff with the federal association of statutory health insurance funds (GKV SV). Only apps that are prescribed by the physician / specialist, psychotherapist (outpatient sector) or directly approved by the SHI are subject to reimbursement. Private health insurances which cover only 10% of the population are not subject to this regulation but case by case decisions can be made. In general, the regulation requires comparative studies carried out in Germany or in the rarest of cases in a system with a comparable healthcare setting to demonstrate the benefits of proposed health apps.

One year after the first listed DiGA in October 2020, more than 20 applications have successfully completed the BfArM's assessment procedure and are published in the directory. Three quarters of the manufacturers have opted for the temporary listing. Most study designs are based on randomised controlled trials (RCTs) with a focus on medical benefits.

In terms of next steps, the German authorities are considering introducing similar mechanisms for digital care applications (to assist citizens in care facilities), or to expand the scope of DiGAs to higher class digital applications (DiGAs class IIb and III). The scope may further be widened to non-patient facing digital health solutions (e.g., clinical decision support tools) or to include apps used at the hospital level to reduce costs and drive patient outcomes. The DiGA process has already attracted attention outside Germany, and may trigger discussions both at EU and Member State levels.

[2.5 The Netherlands](#)

Currently, there is no top-down framework developed by the Dutch government to assess the application and adoption of health apps. The government monitors closely the development and adoption of health apps, while leaving the valuation decision largely to the market. The most common route for market adoption of the health apps is through the individual insurance companies that assess the use of the digital technology based on the needs of their ecosystem's stakeholders. This consist of patients, care providers, the authorities that monitor and evaluate the quality of care provided, and others. The key pathway for a health app in the Netherlands is to obtain coverage by individual health insurance companies. The key focus for insurance companies is on improving care processes, patient outcomes, and reducing the cost of care. Typically, the engagement is started with one insurance company and one or several providers.²⁷ The Dutch government supports the development of a framework for assessing the quality and reliability of health and wellness apps by the European Committee for Standardization CEN. The impact on reimbursement is unclear.²⁸

²⁷ <https://www.zorgvoornoveren.nl/financiering/zorgverzekeraarsroute> (accessed November 2021)

²⁸ The initiative is driven by the Dutch standards body NEN. <https://www.nen.nl/en/health-and-wellness-apps> (accessed November 2021)

In addition to the need for health apps, the reimbursement model also considers the settings in which the apps will be used, such as community / home care settings or within specialist care settings. According to the guidance from the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa), DHTs that are connected to hospital specialist care typically fall under the reimbursement via Diagnosis Related Group (DRG).²⁹ By contrast, devices intended for use in community or home settings are reimbursed by the individual decisions of insurance companies.³⁰

Other stakeholders that play a role in the health apps adoption by contributing to the creation of safe platforms for information and data exchange are Nictiz and NeLL:

- **Nictiz** is the Dutch competence centre for national electronic exchange of health and care information. They are financed by the Dutch Ministry of Health and play a central and facilitating role in the development of information standards and health informatics building blocks. These are required for safe, reliable, and harmonious medical information exchange in all healthcare settings. The activities of Nictiz include the targeted development and management of information standards at the request of and in partnership with the stakeholders in healthcare. Nictiz advises these parties on all aspects of information exchange and identifies (future) national and international developments.³¹
- **The National eHealth Living Lab (NeLL)** is an independent scientific network that collaborates with different partners (the Dutch Ministry of Health, various med-tech manufacturers, and academic institutions) with the goal to advance the potential of self-management and self-care for Dutch citizens and to provide care professionals with tools for using digital health within existing care processes. NeLL was established to assess apps (according to NeLL criteria) and to develop a repository of apps that are efficient, effective, and easy to use. As of December 2020, NeLL has contributed up to sixty (60) e-health applications, two that have acquired the 'NeLL compatible' mark.³²

Currently, there is no national reimbursement framework for health apps in community or home care settings; it is up to individual health insurance companies to decide if, and how, they will provide health apps to their enrollees. Usually, the health insurance company, provider, and manufacturer conduct a 6-12-month pilot project to demonstrate the clinical or system efficacy and cost savings. System efficiencies and economic impact are of the highest interest to the insurance companies. Once a pilot project proves the value of the technology, the technology can be disseminated further within the existing insurer. Often other insurance companies will also learn from this experience and discuss the use of this technology with other care providers and/or patients (depending on the need and the infrastructure). Apart from the coverage by individual insurance companies, health apps can enter coverage with evidence schemes, including the "small

²⁹ <https://www.nza.nl/zorgsectoren/medisch-specialistische-zorg/registreren-en-declareren-van-behandelingen> (accessed November 2021)

³⁰ <https://www.nza.nl/documenten/vragen-en-antwoorden/hoekan-ik-farmaceutische-telezorg-declareren-en-wat-is-het-tarief> (accessed November 2021)

³¹ <https://www.nictiz.nl> (accessed November 2021).

³² <https://nell.eu/projecten> (accessed November 2021)

scale experiment” programme and potentially, a subsidy scheme for promising care (low probability, as it mainly focuses on expensive technologies).³³

As of 2021, there is an additional possibility for financing digital health opportunities known as “facultative indicator”. This means that healthcare insurance companies and healthcare providers are enabled to make agreement on new initiatives that are challenging to be covered by the regular DRG³⁴.

³³ <https://www.nza.nl/zorgsectoren/geestelijke-gezondheidszorg-ggz-en-forensische-zorg-fz/zorginnovatie-aanvragen> (accessed November 2021)

³⁴ https://puc.overheid.nl/nza/doc/PUC_655318_22/1/ (accessed November 2021).

3. Summary

The funding initiatives around health apps in Belgium, England, France, Germany, and the Netherlands are important steps towards the digital transformation of healthcare. Whilst the national and regional approaches considered share some key elements, they also differ in important ways, reflecting the diversity and specificity of Europe's healthcare systems and relative funding and reimbursement mechanisms.

Table 1 below provides a high-level comparison of these initiatives. A set of criteria were selected, such as the availability of a top-down reimbursement framework (defined specifically from a health system perspective) and the presence of a common national framework to document digital apps approved for reimbursement and market adoption.

Table 1: Overview of the country systems

	Belgium	England	France	Germany	Netherlands
National-level reimbursement framework for low-risk health apps	Yes mHealthBelgium	No Individual Trusts/CCGs can cover apps	Yes Apps follow the assessment pathway similar to the one for devices.	Yes Apps (class I and IIa) are included in the BfArM directory.	No Individual insurance companies can cover apps, and jointly can purchase them
App catalogue	mhealth Belgium applications	NHS Apps Library	[no catalogue]	DiGA Verzeichnis	[no catalogue]
Role of Health Technology Assessment body in assessing digital health solution	NIHDI's assess apps for reimbursement supported by the national HTA body KCE	Digital Health Technology Framework developed by NICE, the English HTA body	HAS, the HTA body, developed guidance for assessing connected medical devices	BfArM (not the HTA body) will evaluate the benefits	Currently, not evaluated within HTA framework
Trend and anticipated development	Financing of several new care paths allowing medical apps to be expected in 2021-2022	Better alignment for the application of NICE DHT framework and the new Digital Technology Assessment Criteria (DTAC) for NHS Apps Library	Expansion and refinement of the LPPR list for digital health apps	The new framework will be further implemented, expanded, and may change the market	The system will most likely remain stable

This is the state of play in the five countries and regions considered as of November 2021:

- In **Belgium**, the mHealthBelgium initiative lists on its website all the health apps that are undergoing the three-level validation process. Level 3 is reserved for apps that have delivered evidence of their effectiveness and are therefore eligible for financing by the country's public payers ("mutualities"). So far, one health app only has reached level 3.
- In **England**, the NHS runs the NHS Apps Library³⁵ of medical health apps, but there is no path to reimbursement, and it is up to local CCGs and NHS Trusts to reimburse health app developers. The only health app recognised for national reimbursement is reimbursed through the NHS's ITP scheme.
- In **France**, the LPPR listing provides a centralised reimbursement pathway but no catalogue of apps. In addition, some health apps can be reimbursed via ETAPES, the experimental programme for telemonitoring in France. Only one health app listed in the LPPR is currently reimbursed.
- In **Germany**, the DVG provides an integrated process for assessment and validation for reimbursement by the country's public payers. Apps that have passed this process are listed in the DiGA directory run by the federal health ministry's BfArM agency.
- In the **Netherlands**, there is no national reimbursement framework for health apps or catalogue of health apps available. Instead, the country's private insurance companies decide individually which apps they will reimburse; they can also collectively purchase health apps for their members.

In sum, among the five countries and regions, **only Belgium, France and Germany** currently have national reimbursement frameworks in place for health apps. England has one nationally reimbursed app. The Netherlands has none.

This brief comparison of the different healthcare systems is not exhaustive and should be considered a living document due to the dynamic nature of digital health apps and the supporting infrastructure around it. While these funding initiatives are new and developing, it should be noted that **at this time there is no health app that has been assessed and approved for funding in more than one country**. The market for digital health apps remains fragmented, and the barriers for operation in more than one country appear significant.

³⁵ <https://www.nhs.uk/apps-library/> (accessed November 2021)

4. Next Steps and Recommendations

DHTs have the potential to make European healthcare truly sustainable. In particular, digital health apps provide patients with the assistance they need in preventative care, treatment and recovery, by helping them manage and treat their medical conditions, or assist them in surgery management. Yet levels of deployment of digital health apps and, more generally, DHTs, in Europe's healthcare systems remain low.

As this paper shows, funding and reimbursement mechanisms for digital health apps are not uniform across Europe. This critically undermines the ability of European countries to capitalise on the benefits that digital health apps provide for patients, healthcare professionals and healthcare systems. Whilst the initiatives in the five countries and regions taken into account are highly welcomed, they should be built upon further.

MedTech Europe, as the voice of Europe's medical technologies industry (including medical devices and in vitro diagnostic devices), recommends the following actions to be considered at regional, national and/or European levels:

- 1 - Ensure transparency:** Funding for digital health apps should be based on structured, stable, and transparent criteria that are tailored to the needs of the respective healthcare system.
- 2 - Link with funding:** Assessments for digital health apps should be explicitly linked with funding, reimbursement and/or coverage recommendation for health authorities and payers.
- 3 - Consider the value:** Assessments should be appropriate and consider the holistic benefit (e.g., impact on access, quality of life, efficiency of care, health system costs) that these technologies can bring to patients, healthcare professionals, and healthcare systems.
- 4 - Share learnings:** Member States and regions should be incentivised by the EU institutions to analyse and learn from good practices in other countries and regions and seek to identify the conditions that enable faster and widespread uptake of digital apps.
- 5 - Support evidence generation:** The evidence requested should be appropriate to the impact of the app (be it on the basis of real-world evidence, or clinical evidence generated outside of the country of assessment). Where local evidence is required, there should be a shared commitment to evidence generation that extends to sharing the burden of proof of benefits and outcomes, and appropriately compensates the developers of digital health apps. The criteria for evidence should be transparent.
- 6 - Invest in infrastructure and training:** Digital health technologies can enable movement from one care setting to another. This requires investment in infrastructure (where needed), the removal of budget silos, and training of clinicians, patients, and caregivers.

MedTech Europe calls on national and regional policymakers and payers to recognise the value and incentivise the use of DHTs, by putting in place the framework conditions for clear funding pathways that will enable these solutions to be implemented more widely in Europe.

List of abbreviations

BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte, Federal Institute for Drugs and Medical Devices (DE)
CCG	Clinical Commissioning Group (England)
CMD	Connected Medical Device
CNEDiMTS	Medical Device and Health Technology Evaluation Committee (FR)
DHTs	Digital Health Technologies
DiGA	Digitale Gesundheitsanwendung, Digital Health Application (DE)
DRG	Diagnosis Related Group
DVG	Digital Health Law, Digitale-Versorgung-Gesetz (DE)
ETAPES	Expérimentation de Télémedecine pour l'Amélioration des Parcours en Santé (FR)
FAMHP	Federal Agency for Medicine and Health Products (BE)
GKV SV	Federal association of statutory health insurance funds, Gesetzliche Krankenkassen Spitzenverband (DE)
G_NIUS I	Guichet National de l'Innovation et des Usages en e-Santé (national portal for eHealth innovation) (FR)
HAS	Haute Autorité de Santé, French National Authority for Health (FR)
HCP	Healthcare professional
HTA	Health Technology Assessment
ITP	Innovation and Technology Payment Mechanism (England)
ITT	Innovation and Technology Tariff (England)
IVDR	In Vitro Diagnostics Regulation
LPPR	Liste des Produits et Prestations Remboursables, List of reimbursable products and services (FR)
MDR	Medical Device Regulation
MS	Member States [of the European Union]
NeLL	National eHealth Living Lab (NL)
NHS	National Health Service (England)
NICE	National Institute for Health and Care Excellence (England)
NIHDI	National Institute for Health and Disability Insurance (BE)
NZa	Nederlandse Zorgautoriteit (NL)
SHI	Statutory health insurances, Gesetzliche Krankenkassen (DE)