



Proposed Guiding Principles for Reimbursement of Digital Health Products and Solutions

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Legal Notice

This report is presented by the SubGroup on 'Reimbursement'. The group was set up under the formulation of the eHealth Stakeholder Group.

The group comprised experts of a variety of stakeholder organisations. MedTech Europe was in the lead of the Working Group.

The Commission has launched a call for expression of interest to renew the membership of the eHealth Stakeholder Group (<https://ec.europa.eu/digital-single-market/en/news/call-expression-interest-ehealth-stakeholder-group-members>).

The Group mainly contributed to implementing the eHealth Action Plan and to the activities of the eHealth Network.

The opinions and recommendations expressed in this document are those of the Working Groups' members and do not necessarily represent the views of the European Commission.

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Further information

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Executive Summary

Digitalisation has been distinctively reshaping the healthcare sector. However, to achieve the complete modernisation and optimisation of healthcare systems in Europe it is required that digital technologies that facilitate the delivery and organisation of health services and/or provide health benefits are reimbursed and funded appropriately. Reimbursement decisions are a Member State competence and a critical factor in making digitalisation happen across EU healthcare systems.

As digital health products and solutions, this paper considers medical technologies and services which utilise information and communication technologies (ICTs) that can improve prevention, diagnosis, treatment, monitoring, prediction, prognosis and management of health. This paper excludes lifestyle products and services that are not based on evidence and are not CE-marked under medical device legislation.

To facilitate reimbursement of digital health products and solutions, it is suggested that national authorities consider the following principles:

- 1) Specific criteria are needed to make appropriate reimbursement decisions for digital health products and solutions.
- 2) Relevant digital health products and solutions should benefit from either EU or national funds within innovation investment funds.
- 3) European guidelines for relevant and fit-for-purpose evidence generation for digital health products and solutions should be developed.
- 4) The specifics of digital health products and solutions must be considered when developing instruments for assessing and rewarding the value they provide for patients, healthcare actors, health systems' sustainability and society.

The guiding principles below are proposed as a supportive tool for Member States authorities in their efforts to modernise national reimbursement and financing schemes for the purpose of enabling digital transformation in EU healthcare systems.

Background

Many industries in Europe have fully embraced digitalisation, but the healthcare industry needs to keep pace and to take measures to accelerate the shift to a digital ecosystem in Europe. Digital health must support timely access to care along the full care pathway, while also enhancing patient benefits.

About 77 percent of EU health spending is on the delivery of care. Digital tools have the ability to avoid or significantly reduce the increase in spending on care delivery through efficiency gains throughout the patient pathway. One clear example of this is by transitioning patients from the inpatient setting to the lower cost outpatient setting, and continuous remote monitoring. Therefore, digital technologies are redefining healthcare and are an essential component on the way to greater sustainability of European healthcare systems. However, digital health products and solutions are often not routinely funded in Member States as they rarely fit into existing reimbursement and coverage practices (e.g. coding and coverage criteria do not exist). Consequently, valuable transformative innovations are not yet utilised comprehensively by healthcare professionals (HCPs), healthcare providers and patients.

Furthermore, there are additional barriers related to infrastructure, digital health literacy, and the idea of citizens taking an active part in the management of their health. However, these aspects are not addressed within this paper, as they are part of other stakeholder groups' activity within the European Commission's eHealth Action Plan.

Scope of the paper

The scope of this paper covers digital health products and solutions that support the delivery of health services, address the health and social care of individuals, and can be considered for reimbursement by the public sector or sickness funds. This paper **excludes** lifestyle products and services that are not based on evidence and are not CE-marked under medical device legislation. (Detailed definitions related to the digital health terminology in the paper can be found at the end of the document.)

The group has adopted the following collective definition for “**Digital health products and solutions**”: Medical technologies and related services which utilise information and communication technologies (ICTs) across the whole range of functions that affect the health sector, that can improve prevention, diagnosis, treatment, monitoring, prediction, prognosis and management of health and lifestyle.

Key Principles

1) **Specific criteria are needed to make appropriate reimbursement decisions for digital health products and solutions.**

Currently, healthcare systems can integrate innovative digital healthcare solutions into their practices within the scope of pilots or trials. However, these solutions are not widely adopted yet and patients still have limited access to them. Since routine assessment and reimbursement do not exist for digital health products and solutions, healthcare professionals and healthcare institutions are not funded to deliver these kinds of value-added services. This prevents healthcare systems from achieving the full potential of digital healthcare delivery when it comes to improved outcomes, reduced spending of healthcare budgets, and investment in the most economically advantageous solutions for all parties

involved. Digital health products and solutions can support the reform of health systems and their transition to new care models that make their health and social care systems both sustainable and effective.

Recommendations:

- A dialogue with all stakeholders (e.g. manufacturers, healthcare professionals, patients, and payers) should be conducted during the development and implementation of digital health products and solutions from an early stage;
- A clear and transparent pathway for assessment and coverage decisions is needed at a Member State level (e.g. step by step schemes including clearly defined responsibilities and criteria for obtaining coverage decisions);
- Flexible processes and additional reimbursement criteria should be developed for assessing the value of digital healthcare products and solutions, taking account of the fast-paced nature of digital product innovation;
- Solutions with evidence-based benefits for healthcare delivery and organisations and/or patient outcomes should be distinguished from lifestyle products;

2) Relevant digital health products and solutions should benefit from either EU or national funds within innovation investment funds

At national level, the funding stream should follow the patient through the whole healthcare system to ensure access to innovative medical technologies, and appropriate treatment and care in every healthcare setting. National healthcare systems need to invest in transformation and address budget silos to help ensure that patients – particularly those with chronic conditions – receive timely care, maintain good health, and achieve better and more consistent health outcomes while making total cost of care sustainable.

With this in mind, the next EU Multiannual Financial Framework (MFF 2021-2027) and other EU instruments designed to foster innovation, should allocate dedicated research and

innovation investment budgets for the development and implementation of innovative digital health products and solutions. This will reflect the EU's commitment to implementing the Sustainable Development Goals in the areas of public health, healthcare systems and environment-related health problems, and facilitate Member States in delivering transformative changes and eliminating health inequalities.

Recommendations:

- Create special innovation investment budgets in national or EU budgets to cover financing of the implementation of digital health solutions and services;
- Implement and test new payment mechanisms e.g. a budget which helps overcome barriers between sectors to follow the patient through the whole pathway;
- Consider budgets from the MFF, based on an innovation fund principle, to foster cooperation on answering the call for a competitive digital health market in Europe and to support the development and piloting of relevant projects in healthcare innovation;
- Consider public-private partnerships on digital health products and solutions.

3) European guidelines for relevant and fit-for purpose evidence generation for digital health products and solutions should be developed

To help developers generate meaningful evidence for digital health products and solutions, guidance is necessary on what kind of evidence national authorities expect from them to successfully launch their innovative solutions. Therefore, European guidance should be further shaped (for example as part of the ongoing MDR implementation discussion) and finalised to steer developers on how to invest in the appropriate evidence generation and development processes that would generate the evidence required.

Recommendations:

- The European Commission should actively inform developers and all healthcare actors involved about existing evidence generation frameworks; (e.g. The MAST framework.)
- The European Commission could facilitate a dialogue when developing further guidance for the relevant stakeholders on generating meaningful evidence for digital health products and solutions.

4) The specifics of digital health products and solutions must be considered when developing instruments for assessing and rewarding the value they provide for patients, healthcare professionals, health systems sustainability and society

There is currently an initiative by the European Commission for a framework for cooperation on Health Technology Assessment (HTA), along with other calls for research initiatives, which aim to support the development and implementation of innovative solutions.

Coverage decisions for any digital product, service or solution need to be based on tailor-made and appropriate methodologies that capture the specificities of these technologies. Hence, beyond the investment itself, relevant training, education and a multi-disciplinary approach would be welcome when building these methodologies.

Recommendations:

- Finance continuous professional development (CPD) for the assessment of transformative digital health products and solutions
- Development of dedicated methods for transformative innovations, along with a value-based approach to public procurement of innovative solutions

Conclusion

Digital technologies offer an unprecedented opportunity to deliver the changes needed to steer European healthcare onto a sustainable path while improving patient outcomes. Creating an environment that rewards innovation in digital health is vital. Policymakers must give a signal – to patients, healthcare professionals, providers and companies – that digital technologies are an integral component of Europe’s healthcare future. Central to this will be reimagining aspects of reimbursement and funding systems to ensure a clear and stable route to market for digital innovations.

We do not underestimate the task ahead and know that all members of our Group have an active role to play in championing digital health and adapting to a fast-changing healthcare landscape. The good news is that there are already good examples of modernised reimbursement systems across Europe (see annex). Raising awareness of best practices can help to demonstrate how payers in Europe are already embracing digital tools such as connected devices and telemedicine. By celebrating these success stories, we can help build confidence throughout the system and inspire others to borrow their neighbours’ best ideas.

It should also be stressed that we are not calling for changes to reimbursement systems in isolation. Many of the reforms set out above support broader shifts to which Member States are already committed, including increasing use of community and primary care, as well as home care and self-care. The recommendations we set out above are enablers of the more fundamental reforms under way in health systems across the developed world.

Finally, although we are a diverse group, all health stakeholders, policymakers and authorities have one thing in common: we are all patients or future patients. We know that digital tools have transformed banking, communication and entertainment – and that healthcare still has a distance to travel in its journey to the digital future. Far from being disheartened, we view this as an indication of how much progress awaits us, if we get digital health right.

Definitions

The group has adopted the following collective definitions

- **Digital health products and solutions:** Medical technologies and related services which utilise information and communication technologies (ICTs) across the whole range of functions that affect the health sector, that can improve prevention, diagnosis, treatment, monitoring, prediction, prognosis and management of health.

(Source: Group consensus)

- **Digital health and care:** 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.

(Source: https://ec.europa.eu/health/ehealth/overview_en)

- **Medical technologies** are devices and solutions that diagnose, monitor and treat diseases and conditions that affect us. Whether they are medical devices, imaging equipment, in vitro diagnostic devices or other solutions, they are regulated under the Medical Device Directive (2007/47/EC), which will be replaced by the Medical Device Regulation (2017/745) when it comes into force in 2020.
- **Medical devices:** any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in

combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices: devices for the control or support of conception; products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in the EU Medical Device Regulation.

(Source: Art 2 of the Medical Device Regulation 2017/745)

Annex: Examples

Example 1

Country	Product / Service	Level	Payer
Germany	Functional analyses of Cardiac Resynchronization Therapy (CRT) devices and implantable cardioverter-defibrillators (ICD)	National	Statutory Health Insurance (SHI)

Learning

- doctors need written consent of the patient
- dedicated reimbursement for functional analyses
- doctors can get 116,48 € for following up patients with CRT and ICD four times remotely (in addition they can charge one normal function analyses and three telephone calls)
- on top of this telemedical infrastructure (app or transmitter) is reimbursed (though further work is needed), which is needed for sending data to the doctors

Example 2

Country	Product / Service	Level	Payer
Netherlands	Teleconsults reimbursed since 2018	National	Statutory Health Insurance (SHI)

Learning

- Teleconsults are reimbursed as hospital visits
- this stimulates doctors to treat patients in a @home situation, with or without telemonitoring devices and or symptom based
- this is for all specialism within hospital care

Example 3

Country	Product / Service	Level	Payer
Germany	Video Consultation	National	Statutory Health Insurance (SHI)

Learning

- doctors need written consent of the patient
- service provider needs certification in accordance with national law
- additional reimbursement on top of regular amount for online consultation
- quantitative imitation of video consultations

Example 4

Country	Product / Service	Level	Payer
Switzerland	Remote Monitoring for all cardiac rhythm implants (PM, ICD, CRT, ILR)	National	Statutory Health Insurance (SHI)

Learning

- Guidelines: existing reimbursement for in-house follow-ups in best case
- Limitation of invoices per year

Example 5

Country	Product / Service	Level	Payer
France	Financial compensation for telemedicine in France	National	Statutory Health Insurance (SHI)

Learning

- 2015: introduction of compensation of Teleconsultation and tele-expertise performed by medical doctors by €28 and €14 per consultation respectively.
- 2016: introduction of compensation of teleconsultation and tele-expertise for "long term illness" patients and from home/medico-social care. Medical doctors were compensated per consultation; general practitioners: €26, specialists: €28 and psychiatrists: €43.70.
- Financial compensation for chronic heart failure (CHF), chronic kidney failure (CKF) and chronic respiratory failure (CRF) were later approved as an experiment through package and payment-for-performance schemes. These schemes pay medical doctors €110 for CHF, €73 for CKF and CRF per patient for 6 months.
- Routine financial compensation is currently only provided for one telemedicine service in France.
- The impact of financing still needs to be assessed.
- As of September 15th, 2018, the coverage for teleconsultation was generalized and became effective at the national level.

Example 6

Country	Product / Service	Level	Responsible authority
France	HTA Framework for connected medical devices	National	Haute Autorité de Santé (HAS)

Learning

- Published in 2017, the Guide supports manufacturers seeking reimbursement for connected medical devices
- This guide contains all the information required to build the reimbursement application file, including examples of tables to be provided as well as list of links to search for epidemiological data.
- It aims at addressing the specificities of connected medical devices as well as the organisational aspects linked to these devices.
- The guide contains the information required to build the reimbursement application file for the approval by HAS. This is a first version of a specific guide that will be adapted to the needs identified for the constitution of a dossier