HAUTE AUTORITÉ DE SANTÉ

ASSESS HEALTH TECHNOLOGIES

SCOPING DOCUMENT

Digital medical devices for professional use

Validated by the HAS Board on 31 August 2022

Referral date: 17 May 2021 **Requester**: French Social Security Department (DSS)

Department(s) concerned: Lead department: Digital Health Mission (MNS);
Associated department: Professional Procedures Assessment Department (SEAP)

Person(s) responsible for the project: Simon Renner (MNS project manager), Aude Rochereau (MNS project manager), Corinne Collignon (MNS project manager), Melissa Dali (SEAP project manager), Cédric Carbonneil (SEAP project manager)

Presentation and scope

Request

The French Social Security department (DSS) consulted the HAS to "*set up a working group on medical procedure-related digital solutions in order to draw up an inventory of existing and/or innovative digital solutions, to define their purpose (diagnosis, prevention, decision support, treatment aid, etc.), as well as safety, quality and use criteria, and their specific evaluation characteristics, and to consider the introduction of a quality standard*".

Context

Digital technology is an integral part of the healthcare system. The technologies used are extremely heterogeneous in terms of their functionalities, their nature and their potential applications.

However, although numerous digital solutions are used in routine care, their utility or relevance in relation to the existing arsenal is not always really established or even questioned.[1] In particular, this is the case for digital solutions for professional use, which do not fall within the existing evaluation frameworks for public funding cover. Consequently, **healthcare professionals often use digital medical devices (DMDs) as part of a medical procedure without being fully informed about their performance or limitations or, conversely, are reluctant to use them**. In fact, while the marketing authorisation regulations make manufacturers responsible for the performance of the medical device they market, healthcare professionals also have responsibilities when they use them.

[1] Haute Autorité de santé. Numérique : quelle (R) évolution ? Rapport d'analyse prospective 2019. Saint-Denis La Plaine: HAS; 2019.

Consideration of these different responsibilities when using a medical device that makes use of artificial intelligence should soon be the subject of a European legal framework.[2]

Hence, it is necessary to reflect on the specificities of the assessment of DMDs for professional use and, beyond that, on possible assessment approaches to inform the choices of healthcare professionals and decision-making bodies responsible for purchasing equipment. The characteristics of the digital technology market - i.e. the multitude of technologies and their diversity already mentioned, but also their disruptive nature and the speed with which they evolve - will need to be taken into account so as not to slow down useful innovation. It should be noted that these reflection processes are also taking place in other countries and have led to solutions tailored to particular health systems in some cases.

Challenges

Build a framework of trust dedicated to DMDs for professional use, in order to promote the incorporation of those that are useful and innovative into the healthcare system.

Targets

- Healthcare professionals using DMDs for professional use
- Public decision-makers: French Ministry for Health and Prevention, French National Health Insurance
- Decision-making bodies responsible for purchasing equipment in healthcare facilities
- Manufacturers and software developers

Objectives

Based on the broad objectives formalised in the referral, this project aims to propose tools for professionals/structures and recommendations on the mechanism to be set up.

The objective is to:

- support healthcare professionals and organisations in the selection of DMDs by proposing the most appropriate scaled decision support approaches, without acting as a brake on innovation (e.g. decision support guides for user professionals and/or methodological guides for assessors in specialised centres, professional boards and/or assessments on request for certain DMDs and/or more systematic assessments in the event of an identified risk, etc.);

- **propose a mechanism for the assessment of the DMDs concerned to the Ministry of Health and Prevention** via this scoping document (see definition of the theme).

Definition of theme / issues to be considered

DMDs for professional use include a very diverse range of tools with heterogeneous functionalities: administrative management and support, telemedicine software, decision support software, etc. Hence, it is necessary to define the scope of response to the referral.

This project will focus on digital technologies:

[2] https://digital-strategy.ec.europa.eu/fr/policies/european-approach-artificial-intelligence

- with a medical purpose and the status of medical device;
- related to a medical procedure;
- and that are not eligible for a national assessment process.

The following will not fall within the scope of the project:

- Digital solutions that are not included in the medical device category;
- Digital medical devices **for individual use (i.e. those used by patients themselves)** already included in an assessment process via the List of products and services qualifying for reimbursement (LPPR) or the list of remote monitoring activities;
- Digital medical devices **that have been or are already the subject of work at the HAS**, such as software to aid the prescribing or dispensing of medicinal products, for which it has developed a certification procedure and standards, or telemedicine (in particular, teleconsultation and telecare), which is the subject of standards and good practice guidelines.

The scope will therefore focus on DMDs designed to aid screening, diagnosis, medical decision-making or therapeutic decision-making (excluding prescribing aid/dispensing aid software), with DMDs potentially combining several functionalities.

Implementation procedures

- ☒ HAS
- ☐ Label
- ☐ Partnership

This project may lead to the setting up of pilot programmes or partnerships to implement pre-identified scenarios.

Envisaged working method and practical actions for conduct of the project

The method implemented will consist of:

- Analysis of the scientific literature in order to identify the different types of existing DMDs, the metrological performance assessments of these DMDs and, finally, to describe the position of regulators and international health technology assessment agencies;
- Stakeholder consultation;
- If applicable, a call for public contributions.

List of envisaged stakeholders:

Medical profession representatives - national professional councils (CNPs):[3] the French Federation of Medical Specialities (FSM) will be consulted to identify the CNPs of interest for this work.

Institutional stakeholders: French National Agency for the Safety of Medicines and Health Products (ANSM), Social Security department (DSS), Ministerial Delegation for Digital Health (DNS), National Health Insurance fund for salaried workers (CNAM), National Agency for the Assessment of Health

[3] Order of 20 August 2019 listing the national professional councils that may conclude agreements with the State in application of article D. 4021-1-1 of the French Public Health Code

and Medico-Social System Performance (ANAP), French Institute for Artificial Intelligence Research in the field of health.

Manufacturers of DMDs for professional use and software developers, via their professional and union organisations.

User representatives: France Assos Santé, HAS User Involvement Council.

International counterparts and INAHTA members.

Qualitative composition of groups

The method does not schedule the immediate creation of a working group, but a call for contributions may be made at the beginning of the project. In all cases, stakeholder interviews will be conducted in advance and the project will be put together with the involvement of stakeholders.

Scheduled outputs

At least the following will be produced:

- **A summary document** including: an inventory of DMDs for professional use, an analysis of the literature, the positions of stakeholders and their methodologies for the selection of these tools and **a risk matrix for existing or emerging DMDs for professional use**, with a view to production of an assessment matrix if necessary.

- **A decision support guide for the selection of DMDs for professional use** that will guide users and buyers by helping them identify the key questions to consider or ask concerning the DMD (development, validation of the tool and associated performance, integration in pathways, economic model, maintenance questions, fate of data, etc.).

Depending on the needs identified in terms of evolution of the assessment of this type of technology:

- The HAS may issue **proposals to the public authorities**;

- And a number of practical actions and additional output forms could be implemented, in particular **methodological guides/assessment standards** for this type of DMD, aimed at professionals or user centres and any players wishing to perform their own assessments, etc.

Provisional schedule for outputs

Q4-2022/Q1-2023