Presse Med 54 (2025) 104279

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Quarterly Medical Review - Health technology assessment in France

French reimbursement of health technologies: assessment is at the heart of the procedure

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ARTICLE INFO

Article History:
Available online 9 April 2025

Keywords:
Health technologies assessment
Medicinal products
Medical devices
In vitro diagnostic medical devices
Medical or surgical procedures

ABSTRACT

Background: In France, health technologies can be reimbursed by the national health insurance system. However, not all are eligible, and several steps are required. This article aims at deciphering the various procedures involved.
Methods: We first described the most common steps for reimbursement procedures, from authorisation to health technology assessment, including clinical evaluation and reimbursement decision. We then discussed certain specificities related to the nature of the health technologies (for example, vaccines among drugs, or digital medical devices (DMDs) among medical devices), and to the status of the procedure (derogatory vs. standard).
Findings: France benefits from several procedures aimed at reimbursing health products, and their number is increasing over time. They all share one common step, assessment, which is systematically performed from a clinical perspective and sometimes includes an organisational or an economic viewpoint, by a single actor: the French National Authority for Health (Haute Autorité de santé, HAS).
Conclusion and relevance: HAS evaluations are essential tools for informing healthcare decision-making, and ensuring that patients have access to safe, effective, and affordable treatments. The system will have to face new challenges in the coming years: the European regulation will pool certain procedural steps, there will be more self-directed DMDs on the market and new organizations set up to support innovation as well as scarce human and financial resources. Ultimately, it is all about constantly adapting to meet patients' needs, introducing new health technologies that offer added value and limited risks, while making the best possible use of available resources.

Abbreviations: ANSM, *Agence Nationale de Sécurité du Médicament* (the French national agency for medicines and health products safety); ASA, *Amélioration du service attendu* (Clinical added value for MDs and diagnostic or therapeutic procedures); ASMR, *Amélioration du service médical rendu* (Clinical added value for medicinal products); CEDIAG, *Commission d'évaluation des technologies de santé diagnostiques, pronostiques et prédictives* (Diagnostic, Prognostic and Predictive Health Technologies Evaluation Committee); CEESP, *Commission d'Evaluation Economique et de Santé Publique* (Commission for economic and public health evaluation); CCAM, *Classification commune des actes médicaux* (Common Classification of Medical Procedures); CNAM, *Caisse nationale de l'Assurance Maladie* (French National Health Insurance fund – general scheme); CNEDIMTS, *Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé* (National Committee for the Evaluation of Medical Devices and Health Technologies); CTV, *Commission technique des vaccinations* (Technical Committee for Vaccination); DMD, digital medical device; HAS, *Haute Autorité de santé*, (the French national health authority); HTA, health technology assessment; HTAR, the regulation (EU) 2021/2282 on health technology assessment; HTD, health technology developer; INCa, *Institut National du Cancer* (The French National Cancer Institute); IVD, In vitro diagnostic medical device; LATM, *liste des activités de télésurveillance médicale* (list of reimbursed remote medical monitoring activities); LPPR, *Liste des Produits et Prestations Remboursables* (list of reimbursable products and services); MD, medical device; NABM, *Nomenclature des actes de biologie médicale* (Nomenclature of Medical Biology Procedures); NGAP, *Nomenclature générale des actes professionnels* (General Nomenclature of Professional Acts); PECAN, *Prise en charge anticipée* (digital early access reimbursement for digital medical devices and remote medical monitoring); PECT, *Prise en charge transitoire* (transitional coverage for medical devices); SA, *service attendu* (Clinical benefit for MDs and diagnostic or therapeutic procedures); SMR, *service médical rendu* (Clinical benefit for medicinal products); UNCAM, *Union nationale des caisses d'assurance maladie* (brings together representatives from the general scheme and the agricultural scheme of national health insurance funds)

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https://doi.org/10.1016/j.lpm.2025.104279

1. Introduction

Health technologies comprise a broad spectrum of products, such as (but not limited to) medicinal products (MPs) (from generic drugs to vaccines or advanced therapy medicinal products), medical devices (MDs) and in vitro diagnostic medical devices (IVDs) (aimed for individual or collective use, which may or may not be digital) and medical or surgical procedures (diagnostic or therapeutic). Health technologies may be diagnostic, preventive, therapeutic, or assistive and may or may not require a provision of medical care or procedures, in primary or secondary care.

In France, the national health insurance system allows for the reimbursement of healthcare, including health technologies and public health interventions (using a health technology), provided they are "listed". To be listed, they must follow a procedure involving different steps, conditions and healthcare institutions. This procedure can be divided into two main parts: the regulatory part and the health technology assessment (HTA) part.

The regulatory step of market authorisation is a prerequisite for reimbursement, at least for standard procedures and for some derogatory pathways (see the innovation article [1]). This regulatory step is mainly managed at European level. However, the HTA part is a national responsibility, even if certain elements will soon be pooled across different European nations (see the HTAR article [2]).

The HTA part encompasses reimbursement and pricing decisions. To ensure that these decisions are well-informed, HTA includes evaluation of the clinical and economic benefits, risks, and costs of new and existing medical technologies. This is an essential tool for informing healthcare decision-making, and ensuring that patients have access to safe, effective, and affordable treatments.

As in most countries, France has developed a well-established HTA system, which is overseen by the French National Authority for Health (Haute Autorité de santé, HAS). The HAS is an independent public body that provides scientific expertise to the French government and healthcare system. It provides the Ministries of Health and of Social Security with a clinical assessment as well as a health-economic assessment, on request, to guide their decisions.

One particularity of the French system is that health technologies are not all assessed in the same way, but accordingly to their type (medical devices, vaccines, drugs, procedures...) and following specific regulations, with evaluations based on specific clinical, organisational and health-economic criteria (see the HTA article [3]).

In this context, the objectives of this article are firstly to introduce the general principles of reimbursement procedures in France for medicinal products, medical devices (including digital devices), diagnostic or therapeutic procedures and public health interventions.

Secondly, we will describe the various specific provisions regarding standard procedures, as well as derogatory and experimental pathways.

This will then be followed by a discussion of the challenges facing reimbursement procedures today and in the near future.

2. General common steps to all reimbursement procedures

2.1. Market authorisation as a prerequisite for reimbursement

When a health technology developer (HTD) intends to commercialise its technology on the European market, whether national reimbursement is sought or not, it must first obtain the adequate authorisation.

For medicinal products (MPs), including vaccines, this authorisation is delivered by the European Commission subsequently to a positive opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), and following a request by the pharmaceutical company. The CHMP assesses the product's benefit/risk balance, taking into account the demonstration of its efficacy, the foreseeable adverse effects associated to its use and their frequency, the quality of the medicine as well as the quality of the manufacturing processes [4].

For medical devices (MDs), in vitro diagnostic medical devices (IVDs) and digital MDs (DMDs), authorisation to enter the European market corresponds to CE marking [5,6]. This framework defines the essential health and safety requirements with which manufacturers must comply to ensure the safety and reliability of their devices placed on the European market. Depending on the risk class of the MD or IVD, a notified body, which is an independent authorised body, is involved in the CE marking process. Where this is not required, manufacturers, after taking regulatory requirements into account, proceed with self-certification [7].

For diagnostic or therapeutic procedures, there is no regulatory provision for marketing authorisation. The benefit/risk balance is therefore assessed during the HTA process.

However, some derogatory pathways allow marketing and reimbursement of health technologies without European marketing authorisation. These procedures are described in Section 3.2 and more deeply in the article on innovation in this review [1].

2.2. Assessment at the heart of the procedure

Once authorisation has been granted, the HTD may then decide to apply for national reimbursement when the product is a MP or a healthcare product for individual use likely to be reimbursed on an individual basis, such as certain MDs. In France, a dossier must then be submitted to the Ministry of Health and the Ministry of Social Security (the decision-maker, cf 2.3) [8].

With regard to diagnostic or therapeutic procedures, manufacturers or healthcare professionals can propose reimbursement, as can patient associations, however the process is either initiated by the Ministry of Health, National Health Insurance Agency (CNAM), or the HAS; the decision-maker is CNAM (cf 2.3).

For public health interventions, including vaccination strategies, the process is either initiated by the Ministry of Health or the HAS, and may be suggested by other stakeholders. The decision is ultimately governmental (see Fig. 1).

Regardless of the type of health technology, the reimbursement decision and the pricing are based on scientific evidence, assessed by the HAS. The HAS provides a non-binding opinion to the decision maker. However, these opinions are generally followed.

To give its opinion, the HAS conducts HTA in a rigorous and transparent manner with the aim of improving quality and safety of care.

The HAS assessment process is led by three fundamentals:

- Science: The HTA process is based on the best available evidence, using the most relevant assessment methods which ensures that the findings are reliable and valid (see the HTA article of this review for more information [3]).
- Transparency: The HTA process is transparent, which means that all stakeholders have access to the information and can participate in the decision-making process; the opinions of HAS committees are systematically published on its website (www.has-sante.fr).
- Independency: The HAS is an independent body, which means that its recommendations are free from any kind of influence (political, commercial, scientific societies...).

Depending on the type of health technology, different committees will be involved in the opinion-making, after it having been examined by the relevant HAS HTA department (see the HTA article of this review [3]):

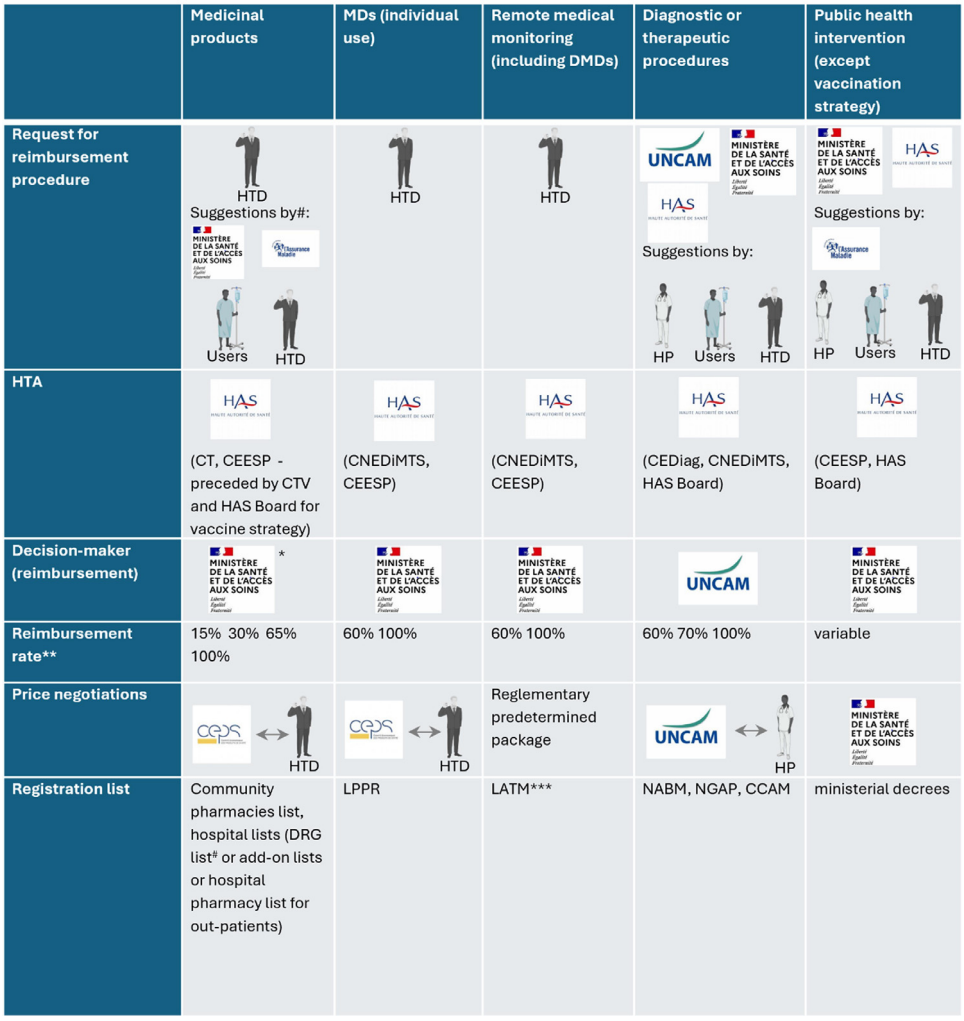

Fig. 1. Actors involved in standard reimbursement procedures in France. For the explanation of the acronyms, please refer to the abbreviations section. # Only for vaccination strategy. Either upon request of the ministry or HAS, or suggestion by the indicated actors ¨ UNCAM (brings together representatives from the general scheme and the agricultural scheme of national health insurance funds) *also decides whether to incorporate the new recommendation into the French vaccination schedule. **UNCAM decides on the rate applicable to each category within the limits set by the regulations [23] ***reimbursement for both DMDs and professional activities, #Diagnosis-related group system.

- The Transparency Committee (CT – *Commission de la transparence*) for assessing MPs [9];
- The National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS - *Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé*) for assessing MDs, DMDs, remote monitoring activities, and products other than drugs or MDs designed for individual use [10,11];
- The Economic and Public Health Committee (CEESP - *Commission d'évaluation économique et de santé publique*) for economic assessment of health products and public health intervention assessment [12];
- the Diagnostic, Prognostic and Predictive Health Technologies Evaluation Committee (CEDiag - *Commission d'évaluation des technologies de santé diagnostiques, pronostiques et prédictives*) for assessing all diagnostic, prognostic and predictive health technologies [13];
- the Technical Committee for Vaccination (National Immunisation Technical Advisory Group, CTV – *Commission technique des vaccinations*) which delivers opinions on vaccine recommendations to the HAS Board, which will then issue the HAS formal opinion to the Ministry of Health [14].

For health products, the CT, CNEDiMTS and CEDiag base their appraisal on the available clinical data, while the CEESP delivers an opinion on budget impact and/or efficiency. Of note, for vaccines, CT appraisal follows HAS recommendation which is a multi-criterion-based recommendation (epidemiological data, studies assessing individual and collective benefits and risks, as well as medico-economic analyses…). It should be noted that health economic assessment is required when the HTD claims that its product is innovative and could have a significant impact on expenditure by the French national health insurance system [15]. This criterion includes claims of impact on the organisation of care, professional procedures, or patient care conditions. In addition, it is required when the product's annual sales are equal to or greater than 20 million euros including VAT during the second full year of marketing [16]. For professional procedures, appraisals by the CEDiag and the CNEDiMTS are also based on systematic reviews of clinical data, followed by a final decision by the HAS board. Health economic assessment of diagnostic or therapeutic procedures is carried out by CNAM, not the HAS.

To enable all committees to deliver their opinions, assessments are first carried out by the relevant HAS departments. 2023 standard procedures numbers are presented in Box 1.

Box 1 *Standard procedures in 2023*

In 2023, the HAS issued:
- 339 medicinal product opinions,
- 265 medical device opinions, and 2 opinions on remote medical monitoring activities,
- 87 opinions on diagnostic and therapeutic procedures,
- 22 medico-economic opinions,
- 13 publications related to vaccination,
- 4 publications on public health interventions.

2.3. Reimbursement decision, pricing and reimbursement rates

The decision timeframe is regulated for MPs and MDs for individual use and is set at 180 days [17–19]. For remote medical monitoring activities, under a new reimbursement procedure introduced in 2023, a decision must be communicated to the HTD within 120 days [20] (see Section 3.1). For diagnostic or therapeutic procedures, assessment time by the HAS is set at six months [21]. In addition, the CNAM's pricing period is limited to 180 days for innovative procedures and unlimited for other procedures [22].

The HAS monitors its deadlines and shares them transparently on its website, as well as in its annual reports. For instance, in 2023, it delivered its opinions to ministers on 220 MPs (first product registrations or new therapeutic indications of a registered products) within a median of 103 days (see the article on HTA for more information [3]).

According to the type of procedure, the decision-maker and the negotiator are different. In most cases, Ministers of Health and Social Security oversee the decision-making and the Economic Committee for Health Products (CEPS) oversees price negotiations (Fig. 1).

As mentioned above, HAS opinions contribute to (i) reimbursement decisions; (ii) reimbursement rates for drugs and (iii) price negotiations. To this end, opinions are based on different criteria (see the article on HTA [3]):

- Clinical benefit (called *service médical rendu* "SMR" for drugs and *service attendu* "SA" for MDs and diagnostic or therapeutic procedures),
- Clinical added value (*amélioration du service médical rendu* "ASMR" for drugs and *amélioration du service attendu* "ASA" for MDs and diagnostic or therapeutic procedures),
- For remote medical monitoring activities, the improvement of medical care which is analysed on 3 components: the clinical improvement of patient's health status, the benefit in care organisation and/or the public health interest.

Clinical benefit value (sufficient or insufficient) corresponds to a recommendation for reimbursement or not and, when it is sufficient for drugs, it is incremented to set reimbursement rate (15% if minor, 30% if moderate, 65% if major). For reimbursed MDs, and remote medical monitoring, the rate is 60%. However, some products may be fully reimbursed, for instance when they treat severe chronic illnesses. The reimbursement rates of diagnostic or therapeutic procedures vary between 60% and 70%. Private health insurances can be taken out for full reimbursement. When patients are hospitalised, they do not pay for the health products used or administered.

When reimbursement is not allowed by the ministers in charge of Health and Social Security, the product can still be sold at a price freely set by the HTD to community pharmacies, unless the product is intended solely for in-patients.

After a reimbursement decision, the tariff needs to be set. For health products for individual use, negotiations occur between the HTD and the CEPS. For medicinal products, reimbursement applies to the fixed public price (which includes margins for its distribution). For MDs, commercialisation prices can be freely determined by the HTD. However, the CEPS can negotiate a maximum retail price and does so almost systematically [24]. In some cases, this maximum retail price may be higher than the reimbursement basis. It should be noted that the HTD and the CEPS can agree confidential rebates so that the actual price is lower than the public price (rebates which are paid by the HTD to the national health insurance). The setting of this price primarily considers the added clinical value (cf HAS opinion), where applicable, the results of the medico-economic evaluation (cf. HAS opinion), the prices of products with a similar therapeutic objective, forecast or actual sales volumes, and the foreseeable and actual conditions of the product's use. It may also take into account supply safety for the French market [25–27].

Tariffication of remote medical monitoring activities is set by French regulation [28]. Both HTD and professionals in charge of the surveillance are paid by the national health insurance on a flat-rate basis, with the amount depending on the added value assessment (according to several pre-established flat rates depending on the benefit considered: impact on mortality, morbidity, quality of life, organisational impact) and the number of patients monitored.

As far as diagnostic or therapeutic procedures are concerned, the tariff is discussed directly between CNAM and healthcare professionals' unions. The proposed tariff considers several costs (technical and intellectual work costs) and is also compared to tariffs of other similar procedures. The final reimbursement decision is established by CNAM [21,29].

Ultimately, reimbursement decision is formalised with the registration on a positive list, which depends on the type of health technology and/or the delivery circuit and/or the effector (for a procedure), (Fig. 1).

The reimbursement pathways in the French system generally share common stages, e.g. regulatory prerequisite, HAS assessment, reimbursement decision and price negotiations, although actors may differ according to the type of health technology. The HAS is always responsible for the clinical (and where applicable organisational or economic) assessment, in order to inform the decision.

3. Specific provisions according to the type of health technology and procedure

However, it is worth highlighting certain specificities in reimbursement procedures, which may depend on the product scope or on the type of procedure (standard vs. derogatory, or even experimental).

3.1. Standard reimbursement procedures

3.1.1. Vaccines

Vaccines are a specific type of drug, and their assessment is a two-step process: first, the need to establish national recommendations (the HAS gives an opinion to the Minister of Health, who decides whether or not to include the new recommendation into the French vaccination calendar), then the "usual drug reimbursement process".

The law No. 2017–220, ratified on February 23, 2017 [30], entrusted the HAS with the responsibility of contributing to the development of vaccination policy and providing vaccine recommendations, including in emergency situations at the request of the Minister of Health when necessary.

Currently, vaccines recommended for the general population are covered by reimbursement. However, some vaccines proposed for

targeted use, such as the hepatitis A vaccine for travellers or the varicella vaccine for adolescents, are not reimbursed.

3.1.2. Health products administered in hospitals

When MPs or MDs are mostly administered or used for inpatients, they do not necessarily undergo national price negotiation. However, when they are used in healthcare organisations (public or private hospitals), they are primarily reimbursed through diagnosis related groups (DRGs). Each hospital then negotiates the price with the HTD, directly or through a procurement centre or purchasing group. Some products, however, if sufficiently innovative or if they cannot be covered by the hospital budget, are reimbursed outside of DRGs on the basis of a nationally negotiated price [31].

3.1.3. MPs and MDs for individual use

As far as drugs are concerned, it is important to note that all medicines, whether reimbursed by a community pharmacy or used in hospitals, must be assessed by the HAS. This is not the case for MDs which can be used on/for inpatients, in certain conditions (when they are neither invasive nor risky), even without any assessment.

Furthermore, the registration of a MD (or remote monitoring medical device) on reimbursement lists may either be under the generic description of all or a part of the product in question, or under a brand name. It is up to the HTD (or distributor) to initiate any reimbursement request they wish. In the case of a generic inscription, the HAS will participate in the process of defining and assessing the minimum characteristics necessary to ensure the clinical value of the MDs (by giving an opinion to the ministries) but will not be involved for each registration (directly handled by the ministries). In a similar manner, the CEPS will negotiate the price for all MDs set in the generic description, but once settled, CEPS do not intervene for each product. The CEPS may however, initiate new price negotiations when considered relevant according to legal criteria [26].

Furthermore, to be listed on the reimbursement lists, MDs and DMDs sharing data also have to meet French national requirements regarding interoperability and data safety. Compliance with the criteria is validated by the national agency specialised in this matter (Agence du numérique en santé).

3.1.4. MDs for collective use

MDs related to a diagnostic or therapeutic procedure performed by a healthcare professional are included in the cost of the procedure. When they are used for or during the performance of a diagnostic or therapeutic procedure, MDs used outside of any context of hospitalisation are not subject to individualised pricing; they are valued through the procedure. The latter is included in the joint classification of medical procedures (CCAM).

3.1.5. Public health interventions: example of new-born screening

Newborn screening (NBS) is a national health initiative as defined by Article L. 1411−6 of the French Public Health Code. This programme is conducted free of charge for all newborns before they reach four days of life, after parental consent. NBS in France currently screens 700 000 infants each year for 13 disorders that cause serious developmental and intellectual disabilities, or death, if they are not detected and treated early. Successful NBS for these conditions and follow-up treatment means that babies who might have died or needed specialised long-term care, can now grow into healthy adults.

In France, since 2018, recommendations to include a new disorder in this programme have been given by the French National Authority for Health (HAS) following a health technology assessment. Each disorder is incorporated into the NBS programme as part of a “new initiative” led by the ministry of Health under the “Priority Prevention” Plan. Effective implementation of this new screening requires several preliminary measures:

- Regional newborn screening centres (CRDNs) must identify their equipment needs (i.e. such as dedicated machines for tandem mass spectrometry or PCR) to conduct a budget analysis and meet the demands based on anticipated test volumes.
- The regional agencies of health (ARS) subsequently secure allocations for the upcoming year through the regional intervention fund.
- Regulatory updates are also necessary. A decree is to be published to go into effect on the designated implementation date, amending the Decree of February 22, 2018, which governs the organisation of the NBS Programme, along with its annexes. This amendment shall incorporate the new screening disorder and outline the technical procedures, including the updated screening algorithm.
- Finally, under the National Coordination of the NBS programme held by the CNCDN, the CRDNs roll out this new screening initiative in their respective regions. They ensure that health professionals conducting the tests are properly informed and trained, that families are adequately educated about the screening process, and that the results are comprehensive.
- The websites of the Ministry of Health and National Health Insurance are then updated accordingly.

3.2. Derogatory reimbursement procedures

In France, various exceptional reimbursement schemes exist to encourage early access to innovative health technologies or organisations (see the article on innovation [1]). They allow a transitory reimbursement, until uncertainties are sufficiently resolved and until standard reimbursement takes over (e.g. within the framework of standard procedures, although this reimbursement can be reconsidered at any time, see the article on HTA [3]).

These procedures share a common objective, by responding to a patient’s need in advance of the standard pathway, for a presumed innovation, while of course minimising the risks encountered by patients.

However, details of procedures, such as the exact eligibility criteria, the length of the temporary reimbursement period or the price that national health insurance accept to pay during this period, vary according to the perimeters (see the article on innovation for more details [1]).

These pathways comprise of early access for MPs (“*accès précoce*”) [32,33], early fundings (“*Forfait innovation*” [34,35] and “RIHN” [36]) for MDs, IVDs and diagnostic or therapeutic procedures, transitional coverage (“*Prise en charge transitoire*”, PECT) for medical devices [37,38], Digital early access reimbursement (“*Prise en charge anticipée*”, PECAN) for digital medical devices and remote medical monitoring [39,40]), (see Fig. 2).

A common step to all these procedures is the involvement of the HAS to assess some of the eligibility criteria, those revolving around the product’s presumed added value. As per the usual procedures, the HAS gives an opinion to the ministries, and the decision of temporary reimbursement is made by the ministries in charge of Health and Social Security. However, in the case of early access programme (MPs), the HAS supervises the decision, which is one of the few cases in the entire HAS perimeter for which the HAS does so. Consequently, when the HAS decides to grant early access −after the ANSM opinion on the benefit/risk ratio for drugs not yet on the market - reimbursement is automatically granted, based on the price chosen by the HTD. It should be noted that the HTD must then pay rebates to national health insurance scheme, according to a reglementary grid and based primarily on the sales generated by the access (for this specific therapeutic indication).

Other derogatory circuits exist when they primarily target absence of therapeutic solutions for patients. MDs may then be recommended by the HAS and ANSM, when there is no suitable

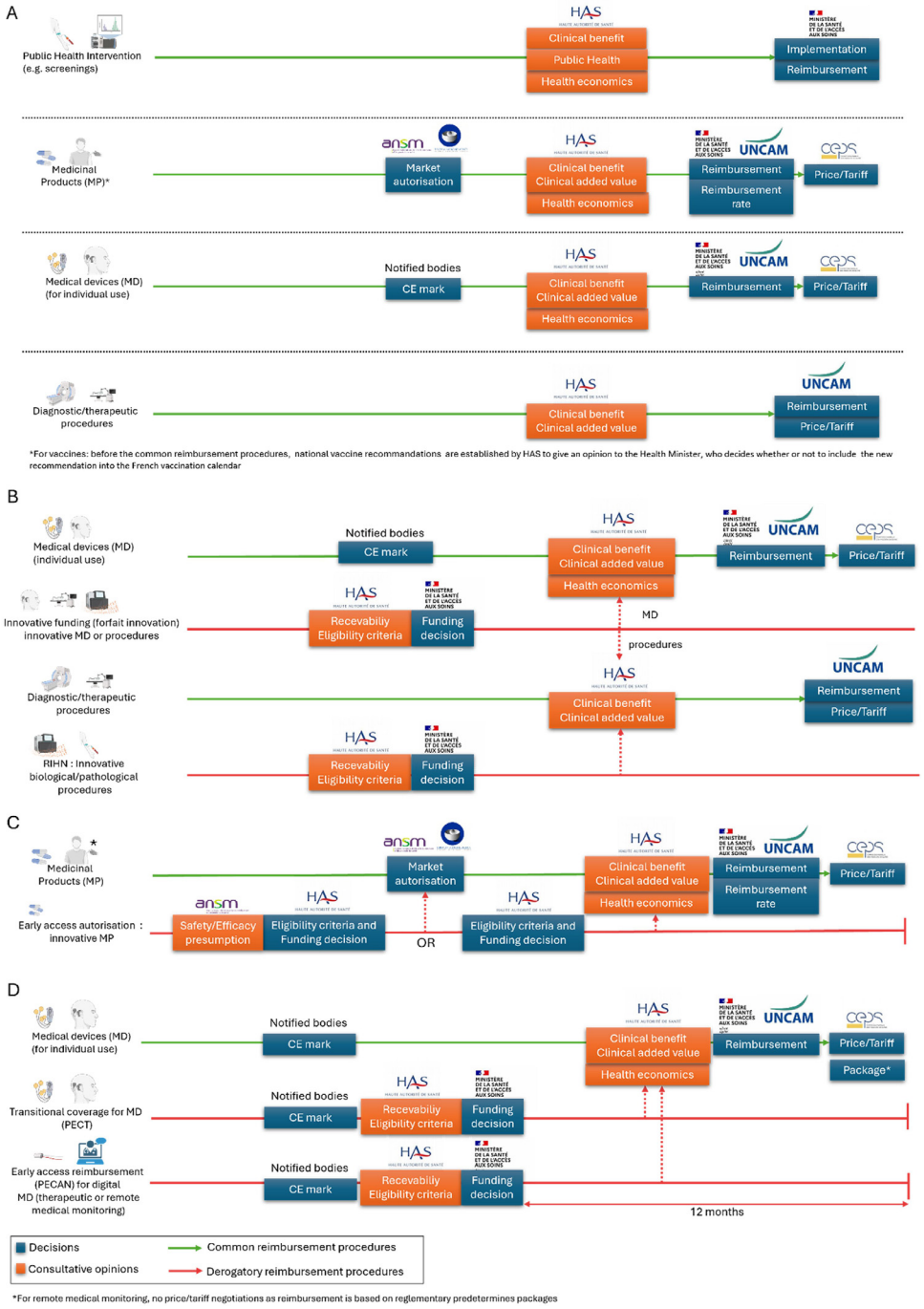

Fig. 2. Standard and derogatory procedures and HAS missions. A) Standard procedures according to the product scope. B) Early funding procedures (*forfait innovation* and RIHN) vs. standard procedure for MDs and diagnostic/therapeutic procedures. C) Early access programme for MPs vs. standard procedure. D) Derogatory pathway for MDs (PECT and PECAN) vs. standard procedures.

alternative, and reimbursed on the decision of the ministries [41]. When drugs have a market authorisation for a therapeutic indication but are commonly used for another medical situation, without any clinical trials in progress, ANSM may decide to give a compassionate framework for this use. For drugs without European or French market authorisation, ANSM may also authorise access (and reimbursement) for designated patients who no longer have other therapeutic options. Where the HTD is conducting clinical trials in the same indication, the HTD must undertake to submit a request to the HAS for an early access programme within a timeframe defined by the ANSM [33,42].

3.3. Experimental procedures

In addition to standard and derogatory procedures, experimentation is possible in France and different frameworks allow such experimental designs to gather data or test “in real-life solutions" before making the decision to generalise or not.

3.3.1. The “Article 51" trial of the French social security financing act for 2018

This scheme, introduced in April 2018, aimed to experiment with new healthcare organisations to foster cooperation between regional

and national stakeholders. The aim was to support improvements in the patient care pathway, healthcare system efficiency, and the appropriateness of health product prescriptions, by allowing derogations from certain standard organisational or financial regulations during these trials [43].

3.3.2. Other specific national programmes

Specific programmes may be voted by the parliament.

For example, the ETAPES programme ("*Expérimentations de la Télémédecine pour l'Amélioration des Parcours en Santé*") was an experiment designed to encourage and provide financial support for the national roll-out of remote monitoring projects for patients with diabetes, chronic kidney disease, chronic respiratory disease, chronic heart disease, implantable cardiac prostheses for therapeutic purposes. The programme dedicated to remote monitoring in chronic diseases was launched in 2014 and was ended in 2022, with some adaptations in between remote monitoring trials to improve the care pathway).

The aim of this programme was to help coordinate the stakeholders involved in remote monitoring around the patient to carry out medical remote monitoring, provide a technical solution, or provide therapeutic support for the patient. For each disease concerned, a set of specifications defined the eligible patients as well as the terms and conditions of treatment and reimbursement for healthcare professionals and technical solution providers.

After 8 years of the "ETAPES" programme, generalisation was voted in 2022, and a standard procedure is now operational [44].

Another experimental programme voted by Parliament is "*accès direct*" (direct reimbursement post HAS opinion) scheme for drugs that can be reimbursed for a maximum of 12 months following an opinion from the HAS (price for standard reimbursement needs to be set during those 12 months) at the request of the HTD and decision of the ministers of health and social security, when various eligibility criteria are met (in particular, a minimum level of SMR and ASMR is required). This experiment is scheduled to run for 2 years (until mid-2025), and a report will be submitted to the Parliament to assess the possibility of making the scheme permanent, taking into account the numbers of dossiers, their characteristics, the duration of these temporary reimbursements, the number of patients who have had access to them, the transition to conventional reimbursement and the estimated impact on healthcare expenditure [45].

Others specific programmes are being developed in France to enhance innovation. Set up through calls for projects, these are not reimbursement pathways in the strictest sense of the term but can help develop appropriate evidence and finance part of their development plan to prepare for eventual reimbursement in the end. For several years now, calls have been regularly launched for DMDs and medical devices. A recent call dedicated to preventive technologies has just been launched [46].

3.3.3. Pilot study before launching screening lung cancer (smokers)

Lung cancer is the leading cause of cancer-related deaths in France, claiming over 33,000 lives annually. It is often diagnosed at an advanced stage, resulting in a poor prognosis with a 5-year survival rate of only 20%.

The primary aim of cancer screening is to detect individuals in a seemingly healthy population who are at an elevated risk of developing the disease, allowing for more timely intervention and more effective treatment.

For lung cancer screening, a low-dose chest CT scan—an imaging technique known as computed tomography—is utilised without the need for contrast injection. If any abnormalities are detected, the subsequent diagnostic process usually involves a clinical examination, additional imaging or nuclear medicine tests, and a tumour biopsy.

However, recommending screening of an asymptomatic population with regular low-dose chest CT scans must be weighed against the risks of overdiagnosis and false positives. The latter can lead to unnecessary anxiety, further testing, treatments, and an increased risk of complications. As a result, in February 2022, the HAS advised the National Cancer Institute (INCa) to launch a pilot programme and support further studies to fill the existing knowledge gaps essential to the implementation of a safe and effective organised screening programme.

In July 2024, INCa announced a call for projects to fund research teams dedicated to defining the criteria and parameters for a national screening programme. Evaluations of these proposals are expected within five years [47].

4. Conclusion

In France, most health technologies are eligible for reimbursement, whether the programme directly targets the product (for MPs, for most MDs for individual use) or refers to the diagnostic or therapeutic procedure that relies on the product (for certain IVDs, for MDs for collective use, for example) or a public health programme using the technology.

Reimbursement and pricing are mainly based on HTA, carried out by the HAS, which also serve as valuable clinical guidelines for recommending the best use of existing technologies (see the articles on HTA [3] and good practice [48]).

It is important to note that the legal frameworks evolve in line with the needs of societal and governmental, as well as technological innovation. Reimbursement procedures, including standard and derogatory procedures, have been multiplied and/or modified and/or expanded in the last years (a few examples: 2017: expansion of reimbursed perimeter of hospital MDs, 2021: early access for MPs overhaul, 2022: first dossiers of transitional coverage for MDs, 2023: creation of new reimbursement procedures for remote medical monitoring and dedicated derogatory pathway for digital MDs of which France is one of the pioneering countries [49], 2024: new derogatory pathway for innovative procedures in biology or anatomical pathology…), demonstrating the adaptability of the system.

New challenges lie ahead for the system, which are already calling into question French procedures or will do so in the near future.

The obvious challenge lies in the implementation of European HTA regulation (HTAR), which will apply to certain drugs from January 2025. Value-added assessment and reimbursement decisions will remain at national level, but a common scientific analysis will take place at European level and provide a new basis for HAS opinions (see the article on HTAR [2]). More generally, European collaboration is essential to share best practices and innovations in healthcare technology assessment, ensuring that all countries can benefit from the latest advancements.

Beyond this European challenge, and its national implications, France will have to address other issues, such as the balance between derogatory and standard access (with some drugs not moving from the transitory to common reimbursement, due to the level of uncertainty and therefore to the complexity of price negotiations), the role of medico-economic assessment in reimbursement decisions, particularly in a context of budget constraints, the development of methods for measuring organisational impacts, the funding model of MDs used by professionals, particularly when they are digital and built on artificial intelligence models, the development of multidimensional technologies that will challenge the current structure of reimbursement lists, and the continued involvement of patients in the decision-making process, which is crucial to ensure that they are well informed about new technologies and treatments, and to ensure that their needs and concerns are taken into account.

Above all, the greatest challenge will be to continue adapting to meet patients' needs while making the best possible use of resources.

Declaration of competing interest

The authors have no competing interests relevant to this paper to disclose.

CRediT authorship contribution statement

Cédric Carbonneil: Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Corinne Collignon:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Hubert Galmiche:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Andrea Lasserre:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Charlotte Masia:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Floriane Pelon:** Writing – review & editing, Writing – original draft, Validation, Supervision, Project administration, Methodology, Formal analysis, Data curation, Conceptualization.

Acknowledgements

The authors would like to express their gratitude to Julie Bonamour, Carine Busin, Pierre Cochat, Lionel Collet, Bénédicte Colnet, Judith Fernandez, Eunice Low, Nadia Naour, Aurélie Pacull, Estelle Piotto, Michel Vaneau for their thorough review and insightful comments as well as Sylvie Lascols for helping to format the article.

References

[1] Serain C, Chevret S, Chambon Y, Hernando V, Lucet F, Seksik S, et al. French evaluation of innovative health technologies: early access and fundings. Presse Med 2025;54:104284. doi: 10.1016/j.lpm.2025.104284.
[2] Fernandez J, de Boissieu P, Galbraith M. Health Technology Assessment in Europe: a comparison of organizations and introduction to the European regulation. Presse Med 2025;54:104282. doi: 10.1016/j.lpm.2025.104282.
[3] Baba J, Guerrier N, Guzina I, Hernando V, Ressencourt V, Spasojevic I, et al. The French way of HTA: between scientific rigour, independence and transparency. Presse Med 2025;54:104281. doi: 10.1016/j.lpm.2025.104281.
[4] ANSM. Autorisation de mise sur le marché pour les médicaments [En ligne] 2021. Disponible: https://ansm.sante.fr/page/autorisation-de-mise-sur-le-marche-pour-les-medicaments [cité le 6 octobre 2024]
[5] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance). Offic J Eur Union 2017 L 117/1-175 http://data.europa.eu/eli/reg/2017/745/oj.
[6] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance). Offic J Eur Union 2017 L 117/76-332 http://data.europa.eu/eli/reg/2017/746/oj.
[7] ANSM. Mise sur le marché des dispositifs médicaux et des dispositifs médicaux de diagnostic in vitro [En ligne] 2021. Disponible: https://ansm.sante.fr/page/mise-sur-le-marche-des-dispositifs-medicaux-et-des-dispositifs-medicaux-de-diagnostic-in-vitro [cité le 6 octobre 2024]
[8] Ministère de la santé. La fixation des prix et du taux de remboursement [En ligne] 2024. Disponible: https://sante.gouv.fr/soins-et-maladies/medicaments/le-circuit-du-medicament/article/la-fixation-des-prix-et-du-taux-de-remboursement [cité le 6 octobre 2024]
[9] HAS. Transparency Committee [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/c_1729421/en/transparency-committee [cité le 6 octobre 2024]
[10] HAS. National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS*) [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/c_2036238/en/national-committee-for-the-evaluation-of-medical-devices-and-health-technologies-cnedimts [cité le 6 octobre 2024]
[11] HAS. Pathway of medical devices in France [En ligne] 2021. Disponible: https://www.has-sante.fr/upload/docs/application/pdf/2022-01/guide_pathway_of_-medical_devices_in_france.pdf [cité le 6 octobre 2024]
[12] HAS. Economic and public health evaluation committee [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/c_2036304/en/economic-and-public-health-evaluation-committee [cité le 6 octobre 2024]
[13] HAS. Diagnostic, prognostic and predictive health technologies evaluation committee (CEDiag) [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/p_3495474/en/diagnostic-prognostic-and-predictive-health-technologies-evaluation-committee-cediag [cité le 6 octobre 2024]
[14] HAS. Technical committee for vaccinations [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/c_2758065/en/vaccine-committee [cité le 6 octobre 2024]
[15] Article R161-71-3 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000037008543 [cité le 6 octobre 2024]
[16] HAS. Décision n°2022.0212/DC/SED/SEM du 23 juin 2022 du collège de la Haute Autorité de santé relative à l'impact significatif sur les dépenses de l'assurance maladie déclenchant l'évaluation médico-économique des produits de santé revendiquant une ASMR ou une ASA de niveaux I, II ou III [En ligne] 2022. Disponible: https://www.has-sante.fr/jcms/p_3358899/fr/decision-n2022-0212/dc/sed/sem-du-23-juin-2022-du-college-de-la-haute-autorite-de-sante-relative-a-l-impact-significatif-sur-les-depenses-de-l-assurance-maladie-declenchant-l-evaluation-medico-economique-des-produits-de-sante-revendiquant-une-asmr-ou-une-asa-de-niveaux-i-ii-ou-iii [cité le 6 octobre 2024]
[17] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. Offic J Eur Union 1989;L 40 /8-11 http://data.europa.eu/eli/dir/1989/105/oj.
[18] Article R165-8 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000021020326 [cité le 6 octobre 2024]
[19] Article R163-9 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000043912065 [cité le 6 octobre 2024]
[20] Article R162-79 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000046879972 [cité le 6 octobre 2024]
[21] Article L162-1-7 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000046812411 [cité le 6 octobre 2024]
[22] Article L162-1-8 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041396907 [cité le 6 octobre 2024]
[23] Article R160-5 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000043188289 [cité le 6 octobre 2024]
[24] CEPS. Rapport d'activité 2022 [En ligne] 2024. Disponible: https://solidarites-sante.gouv.fr/IMG/pdf/ra_ceps_2022.pdf [cité le 6 octobre 2024]
[25] Article L162-16-4 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000044628577 [cité le 6 octobre 2024]
[26] Article L165-2 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041396987 [cité le 6 octobre 2024]
[27] Article L165-3 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041397109 [cité le 6 octobre 2024]
[28] Arrêté du 16 mai 2023 fixant le montant forfaitaire de l'activité de télésurveillance médicale prise en charge par l'assurance maladie prévu aux II et III de l'article R. 162-95 du code de la sécurité sociale, ainsi que les modulations applicables à ces tarifs et la périodicité de leur révision [En ligne]. Disponible: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000047571442 [cité le 6 octobre 2024]
[29] Article R162-52 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000043413482 [cité le 6 octobre 2024]
[30] Loi n° 2017-220 du 23 février 2017 ratifiant l'ordonnance n° 2016-966 du 15 juillet 2016 portant simplification de procédures mises en œuvre par l'Agence nationale de sécurité du médicament et des produits de santé et comportant diverses dispositions relatives aux produits de santé [En ligne]. Disponible: https://www.legifrance.gouv.fr/jorf/article_jo/JORFARTI000034078427
[31] Ministère de la santé. La liste en sus [En ligne] 2024. Disponible: https://sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/autorisation-de-mise-sur-le-marche/la-liste-en-sus [cité le 6 octobre 2024]
[32] HAS. Accès précoce à un médicament [En ligne] 2021. Disponible: https://www.has-sante.fr/jcms/r_1500918/fr/acces-precoce-a-un-medicament [cité le 6 octobre 2024]
[33] Ministère de la santé. Autorisation d'accès précoce, autorisation d'accès compassionnel et cadre de prescription compassionnelle [En ligne] 2024. Disponible: https://sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/autorisation-de-mise-sur-le-marche/article/autorisation-d-acces-precoce-autorisation-d-acces-compassionnel-et-cadre-de [cité le 6 octobre 2024]
[34] HAS. Forfait innovation [En ligne] 2020. Disponible: https://www.has-sante.fr/jcms/c_2035788/fr/forfait-innovation [cité le 6 octobre 2024]
[35] Ministère de la santé. Le forfait innovation [En ligne] 2024. Disponible: https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/forfait-innovation [cité le 6 octobre 2024]
[36] Ministère de la santé. RIHN 2.0: un soutien renouvelé à l'innovation pour les actes de biologie médicale et d'anatomopathologie [En ligne] 2024. Disponible: https://

sante.gouv.fr/systeme-de-sante/innovation-et-recherche/rihn [cité le 6 octobre 2024]
[37] HAS. Dispositifs médicaux: la prise en charge transitoire [En ligne] 2023. Disponible: https://www.has-sante.fr/jcms/p_3269665/fr/dispositifs-medicaux-la-prise-en-charge-transitoire [cité le 6 octobre 2024]
[38] Ministère de la santé. Prise en charge transitoire de certains produits et prestations [En ligne] 2021. Disponible: https://sante.gouv.fr/soins-et-maladies/autres-produits-de-sante/dispositifs-medicaux/article/prise-en-charge-transitoire-de-certains-produits-et-prestations [cité le 6 octobre 2024]
[39] HAS. Dispositifs médicaux numériques: la prise en charge anticipée [En ligne] 2024. Disponible: https://www.has-sante.fr/jcms/p_3376633/fr/dispositifs-medicaux-numeriques-la-prise-en-charge-anticipee [cité le 6 octobre 2024]
[40] Ministère de la santé. Prise en charge anticipée numérique (PECAN) [En ligne] 2024. Disponible: https://gnius.esante.gouv.fr/fr/financements/fiches-remboursement/prise-en-charge-anticipee-numerique-pecan [cité le 6 octobre 2024]
[41] Article L162-17-1-2 - Code de la sécurité sociale [En ligne]. Disponible: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000041397304 [cité le 6 octobre 2024]
[42] ANSM. Accès compassionnel [En ligne] 2024. Disponible: https://ansm.sante.fr/vos-demarches/industriel/acces-compassionnel [cité le 6 octobre 2024]
[43] Ministère de la santé. Expérimenter et innover pour mieux soigner [En ligne] 2024. Disponible: https://sante.gouv.fr/systeme-de-sante/parcours-des-patients-et-des-usagers/article-51-lfss-2018-innovations-organisationnelles-pour-la-transformation-du/article-51 [cité le 6 octobre 2024]
[44] Ministère de la santé. Prise en charge en droit commun de la télésurveillance [En ligne] 2023. Disponible: https://sante.gouv.fr/IMG/pdf/animation_stand_telesurveillance_.pdf [cité le 6 octobre 2024]
[45] Ministère de la santé. Dispositif d'accès direct pour certains produits de santé [En ligne] 2023. Disponible: https://sante.gouv.fr/soins-et-maladies/medicaments/professionnels-de-sante/autorisation-de-mise-sur-le-marche/article/dispositif-d-acces-direct-pour-certains-produits-de-sante [cité le 6 octobre 2024]
[46] Bpifrance. Challenge prévention: démontrer la valeur des innovations en vie réelle [En ligne] 2024. Disponible: https://www.bpifrance.fr/nos-appels-a-projets-concours/challenge-prevention-demontrer-la-valeur-des-innovations-en-vie-reelle [cité le 6 octobre 2024]
[47] INCa. Appel à candidatures 2024 Dépistage des cancers du poumon - Programme pilote [En ligne] 2024. Disponible: https://www.e-cancer.fr/Institut-national-du-cancer/Appels-a-projets/Appels-a-projets-en-cours/DEPKPOUMON24 [cité le 6 octobre 2024]
[48] Blanchard S, Lindecker-Cournil V, Mussetta B, Nahmias F, Carbonneil C. French HTA and appropriateness of care: beyond reimbursement. Presse Med 2025;54:10428010. doi: 1016/j.lpm.2025.104280.
[49] Tarricone R, Petracca F, Weller HM. Towards harmonizing assessment and reimbursement of digital medical devices in the EU through mutual learning. NPJ Digit Med 2024;7:268. doi: 10.1038/s41746-024-01263-w.