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Quarterly Medical Review - Health technology assessment in France

The French way of HTA: Between scientific rigor, independence and transparency

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ABSTRACT

Context: The Haute Autorité de Santé (HAS) is an independent body responsible for advising the government on the appropriateness of national funding for healthcare technologies and interventions. To fulfil this role, HAS evaluates their efficacy and safety, especially in comparison to existing alternatives.
Methods: We first described how the HAS is organised to carry out this mission, then outlined the different stages of the evaluation process, highlighting specific features according to the type of health technology being assessed We also reviewed the HAS's activities for 2023.
Results: The HAS relies on international methodological standards to assess health technologies and interventions, on the expertise of healthcare professionals and patient experiences, and input from various stakeholders where appropriate and necessary.
Conclusion: Through this rigorous, independent, and transparent scientific evaluation process, the HAS aims to ensure that patients have access to the best available treatments and care, and, when relevant, to the most efficient options for the French healthcare system, while guaranteeing patient safety.

Abbreviations: AMSTAR, assessing the methodological quality of systematic reviews; 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 procedures); ASMR, "*Amélioration du service médical rendu*" (Clinical added value for medicinal products); ATMP, advanced therapy medicinal product; CAV, clinical added value; CB, clinical benefit; CCDVR, "Cellule de Coordination des Données en Vie Réelle" (Real World Data Coordination Unit); 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); CEPS, "Comité Economique des Produits de Santé"; 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); DEAI, "Direction de l'évaluation et de l'accès à l'innovation" Department of Evaluation and Access to Innovation; DMD, digital medical device; DPI, "Déclaration Publique d'Intérêts" (Public Declaration of interest); EB, expected benefit; ED, early dialogue; EU, European Union; EUnetHTA, European Network for Health Technology Assessment; HAS, "*Haute Autorité de santé* "(the French national health authority); HT, health technology; HTA, health technology assessment; HTD, health technology developer; ICER, incremental cost-effectiveness ratio; INAHTA, the international network of agencies for health technology assessment; JCA, joint clinical assessment; 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; PICO(TS), population, intervention, comparator, outcome (timing, study design); PRISMA, preferred reporting items for systematic reviews and meta-analyses; QUADAS, quality assessment of diagnostic accuracy studies; RoB, risk of bias; SA, "*service attendu*" (Clinical benefit for MDs and procedures); SMR, "*service médical rendu*" (Clinical benefit for medicinal products); UNCAM, "*Union nationale des caisses d'assurance maladie*" (union of representatives from the general scheme and the agricultural scheme of national health insurance funds)

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1. Introduction

The Haute Autorité de Santé (HAS) is the national independent public authority responsible for health, technology and policy assessment in France. Through the Health Technology Assessment (HTA) process, the HAS evaluates different Health technologies (HTs), and other health interventions to determine their efficacy, safety, cost-effectiveness, and potential impact on healthcare and society.

This article aims to describe the HTA process in France and will focus on requests for the assessment of individual health technologies. The HAS remit in the field of HTA is defined by Law and is related to different national health insurance reimbursement lists. The health technologies (HT) assessed by the HAS are: medicinal products, medical devices (MDs) including MDs for individual use (MDs for professional use do not fall under HAS' HTA remit, unless they are associated to a diagnostic and therapeutic procedures and in which case they are assessed as part of the medical procedure) and digital medical devices (DMDs), and diagnostic and therapeutic procedures (new clinical or technical gesture carried out for diagnostic, preventive, therapeutic or rehabilitation purposes by a health professional, in community care or in hospital setting).

In France, the assessment of HT is based on clinical, organisational, and medico-economic analyses. These assessments result in (a publication) of advisory opinions which inform public authorities on the appropriateness of the reimbursement of HT by the community and the setting of their price. Based on the HAS' analysis, the National Union of Health Insurance Funds (UNCAM) sets the reimbursement rates for health products and carries out technical and economic assessments to determine the prices of procedures. The Economic Committee for Health Products (CEPS), an interministerial body under the joint authority of the Ministries of Health and of the Economy, negotiates the public price of health products with the applicant, on the basis of the opinions issued by the HAS, with the exception of digital devices for medical telemonitoring. For the latter, the reimbursement rates (flat rate for both the DMD provider and the medical team responsible for remote monitoring) are established in advance through a decree (see Fig. 1). Moreover, in France, health technologies can receive transitory coverage prior to their evaluation for reimbursement, and sometimes even before their marketing authorisation in the European territory, through what is known as early access authorisations (pre-marketing authorisation, see article on innovation [1])

2. About the HAS

2.1. What is the HAS?

The HAS was established by the Law relative to National Health Security on August 13th, 2004 [2]. The HAS was created to contribute to the maintenance of a healthcare system based on solidarity and to enhance the quality of care provided to patients. The financing of the HAS comes mainly from a subsidy included in the Social Security budget which is voted each year by the French Parliament.

Since its creation, the has been an independent public authority, of a scientific nature, with a legal personality and financial autonomy. This legal status of an independent public authority represents the most advanced form of independence that an administrative authority can have in France, conferring a legal identity distinct from that of the State. This independence is a central value of the HAS, reinforced by a code of ethics and an internal "guide for declarations of interest and management of conflicts of interest" [3] (see article on deontology [4]).

The scope of the HAS is broader than HTA and includes two other key missions: producing guidelines and improving quality of care. Indeed, the HAS develops recommendations for health and social care professionals to optimise and harmonise practices and organisation of care as well as public health guidelines. The HAS also contributes to the framing of vaccine policy in France by elaborating vaccine opinions. Lastly, the HAS is responsible for measuring and improving quality of care delivered in health, medico-social and social care organisations.

The HAS carries out its activity in accordance with three core values: scientific rigour, independence and transparency. It cooperates with all stakeholders serving both individual and collective interests and upholds the values of solidarity and equity in access to care, which are fundamental to the French healthcare system.

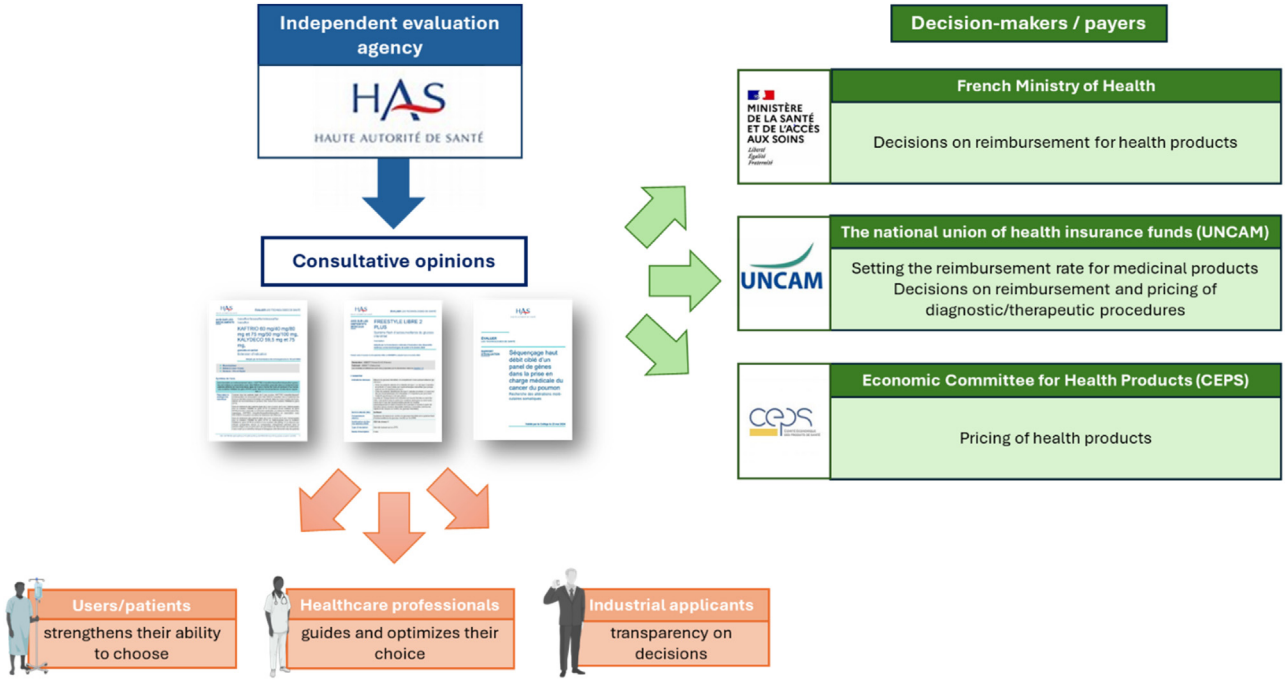

Fig. 1. French reimbursement of health technologies, assessment is at the heart of the process.

Fig. 2. Organisation of the 5 HTA committees of the HAS.

2.2. Organisation

The has a General Director [5] who is involved providing strategic and operational missions. The HAS is organised around a board of eight members including a president (HAS' College) and eight specialised Committees.

The Board is responsible for providing strategic direction, programming, and implementation of its legislatively-assigned scope of action and function. As the decision-making body of the HAS, it is responsible for maintaining high standards and impartiality of its activities and productions.

The President of the Board is appointed by the President of the French Republic, while the other members are appointed by the Ministries in charge of Health and Social Security, by the presidents of the National Assembly, the Senate and the Economic, Social and Environmental Council. These appointments must respect a principle of gender parity except for the President of the Board. Members are chosen based on their expertise and experience in the health and social care sectors. Half of the Board is renewed every three years.

Five HAS' committees are involved in HTA (see Fig. 2). They are responsible for or participating in opinion-making, after instruction by the HAS HTA department. Committees are scientific bodies made up of around thirty members, selected primarily for their scientific expertise in the relevant evaluation field. The members of the committees are recruited through a public call for applications, with the goal of ensuring geographical diversity, variety in professional practice, gender parity, and expertise in the field. Two to three members of each committee are selected from the participants of a patient and healthcare system users' association. Committee members must declare any potential conflicts of interest and meet ethical requirements in order to be recruited. Members are appointed for a term of three years by the Board, with the possibility of renewing their mandate twice.

In 2023, the HAS had 439 employees with diverse profiles, such as medical doctors, allied health professionals, sociologists, pharmacists, epidemiologists, health economists, lawyers, engineers, statisticians, information specialists. 1738 external professional experts and users were solicited. All employees are subject to the obligation of a public declaration of interest (DPI) in order to ensure the transparency and impartiality of HAS' work (see article on deontology [4]).

The HAS is composed of five departments with distinct missions. The department responsible for the HTA is called the Department of Evaluation and Access to Innovation (DEAI) and employs approximately 150 people.

3. HTA process and organisation: a common framework and specificities based on sectors

The evaluation of drugs was already carried out in France before the creation of the HAS. Indeed, it was in 1967 that a decree [6] related to the conditions for reimbursement of medicines to social security beneficiaries laid the foundations for the assessment by stipulating (Article 3) that "only medicines that are effective and that are presumed to provide an improvement in therapy or a saving in the cost of treatment can be included [on the list of medicines reimbursed or covered by social security organisations]".

All the HTA processes follow the same general structure and are comprised of three major phases: submission of a reimbursement request (the HAS may also choose to re-evaluate product on its own initiative if appropriate), assessment, and HAS opinion. Upstream, as part of the HTA process, the HAS also offers support to future applicants in order to foster submission of dossiers in line with HTA requirements.

3.1. Pre-HTA phase: supporting the generation of evidence with high certainty of results for future HTA

In view of the generation of evidence with high certainty of results for future HTA, the HAS can support health technology developers (HTD), or health professional organisations in case of diagnostic and therapeutic procedures while a health technology is still in

development, mainly through two types of consultations: early dialogues (ED) and pre-submission meetings.

- The ED are consultations on the evidence generation plans which are carried out in the early development phase, prior to the onset of the pivotal clinical trial. In addition to being still under development, the health technology (HT) must fulfil two other conditions to be eligible for an ED according to HAS' legal missions: have a new mechanism of action and target an unmet or insufficiently covered medical need.
- The objective of an ED is to provide the HT developers with recommendations and answers to medical and, when applicable, medico-economic questions they have on their draft protocols for pivotal studies (generally phase III trials, or corresponding). External experts (health professionals, methodologists and/or patients) can also be invited to participate, provided they have no conflict of interest in relation to the technology under scrutiny, and respect the confidentiality agreement.
- Besides ED at national level, ED can also be carried out at European level, in which case they are called Joint Scientific Consultations and also involve other HTA bodies, and possibly the European Medicines Agency or the expert panels on medical devices (see HTA in EU article [7]).
- The pre-submission meetings are consultations conducted to prepare a dossier submission to the HAS. These consultations are carried out at a later stage in the development process, specifically when preparing a dossier submission, either for a HTA or a temporary coverage assessment. Unlike the ED, there are no eligibility criteria for this type of consultation. Their objective is to provide the future applicants with insight into the technical and regulatory aspects that are necessary for the constitution or finalisation of their request.

Both types of consultations are optional, confidential, not binding for either the HAS or the developer/applicant, and free of charge. They are always carried out on request from the HT developer/applicant. The recommendations provided by the HAS during these consultations reflect the state-of-the-art of medical knowledge and national HTA requirements at the time of the consultation. It should be noted that these recommendations do not represent an assessment nor are they an indicator of the future opinion to be issued by a specific HAS' committee or the Board.

Of note, the different early and temporary accesses to innovation that HAS is involved in (see article on innovation [1]) also allow the collection of clinical or medico-economic data required for further conventional coverage to reach a more robust decision.

3.2. Request for assessment

The HTA process in France is usually, except in some specific cases, initiated by an official reimbursement request.

For medicinal products and MDs, the request is generally submitted by the HTD. All requests are treated, on the condition that they are complete. Depending on the request, application fees (of approximately up to €4000) may be required (except for DMDs), which are paid by the HTD to the national health insurance. The assessment is based on the claims made by the HTD and the data they provide. The HTD claims an indication, one or several comparators and one or several clinical added value (*amélioration du service médical rendu* "ASMR" for drugs, *amélioration du service attendu* "ASA" for MDs and the expected benefit for DMDs). The submission dossier is generally based on the results of the clinical studies from the HT under assessment, but the dossier can also contain data not specific to the HT: clinical guidelines, HTA reports from other institutions, direct meta-analyses, indirect comparisons, observational studies, etc.

For diagnostic and therapeutic procedures, and public health interventions, the request can come from several actors (the national health insurance, the ministry of health, manufacturers, health professionals' organisations or patient and users' associations) or from the HAS itself. Depending on the type of the request and who is issuing it, the requests for diagnostic and therapeutic procedures can either be directly accepted (for some requests coming from the national health insurance or the ministry of health, provided that they are complete) or have to follow a selection and prioritisation process before being officially accepted or refused by the HAS board (for all other requests). For diagnostic and therapeutic procedures, the selection and prioritisation process takes place once a year and comprises three phases (see Fig. 3) which follow specific criteria. The

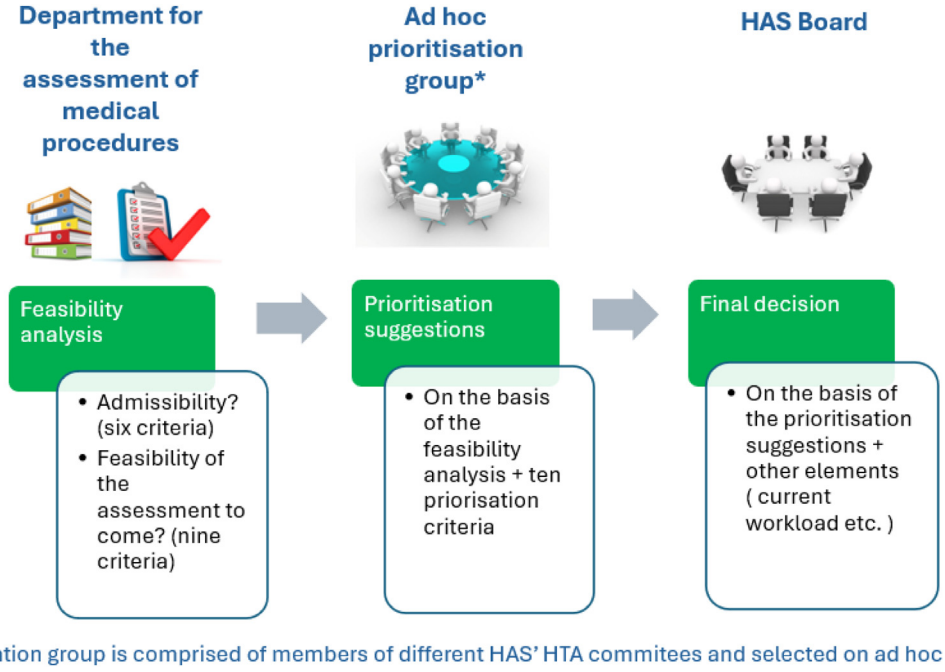

Fig. 3. Selection and prioritisation process for the assessment of diagnostic and therapeutic procedures.

final results of the selection and prioritisation process are published on the HAS' website. The requests for the HTA of diagnostic and therapeutic procedures are currently free of charge.

3.3. Assessment phase: critical analysis of available data

The relevant service of the HAS examines, selects, and critically analyses key data for the HTA. The internal validity of the results of clinical studies, the statistical precision of estimated effects, as well as the external validity of the results are thoroughly assessed.

For medicinal products and MDs, the results of this work are presented in a "preparatory document" which is sent to the corresponding HTA committee before the examination.

For diagnostic and therapeutic procedures, and public health interventions, the HTA is not only based on the dossier submitted by the applicant but relies in fact on a systematic literature review carried out internally. Therefore, the request for assessment is followed by a scoping phase during which the exact scope of the ensuing HTA is defined. First, the scoping phase serves to confirm the HTA domains to be covered by the assessment, i.e. efficacy, safety, organisational aspects, conditions for conducting the procedure if applicable, etc. Moreover, it specifies the assessment questions to be answered by the future HTA (whenever possible in the PICO [8][1] format), and, when applicable, the questions that won't be covered by the assessment. In other words, the major assessment elements such as the comparator and the endpoints (outcomes) of interest are confirmed at this stage. Finally, the methods and means to answer the HTA questions are also defined: e.g. the literature search strategy to be performed in order to retrieve data for the assessment, the literature selection criteria presented in the PICOTS [8] format, the data analysis methods to be applied (descriptive systematic review, meta-analysis, survey, etc.) and which external actors (see chapter 3) to involve in the assessment phase and how.

The scoping is guided by the principle that the HTA questions should not be deduced from or driven by available evidence but should reflect the national policy and public health questions of interest instead. The output of the scoping phase is the scoping document that serves as the HTA protocol in the assessment phase.

Next, a systematic literature search is carried out internally and the literature to be analysed is selected according to the criteria defined in the PICOTS. The medical assessor then extracts and critically analyses the data according to international evidence-based medicine principles (guidelines from the Cochrane collaboration, PRISMA, EUnetHTA etc.) and tools (AMSTAR-2 [9], RoB 2 [10], QUADAS-2 [11] etc.)... Depending on the nature of the selected data, the assessor carries out either a qualitative or a quantitative evidence synthesis (ie, meta-analysis). The results of this work are presented in an assessment report.

The HTA methodology at HAS follows general international evidence-based medicine principles, as well as the specificities of the French regulatory framework, defined in the French Social security code and reflected in the specific reimbursement criteria (see hereinafter). Despite some differences among different HT, the following general assessment principles are common to all:

- The assessments should be based on comparative data demonstrating the superiority of the HT assessed versus the relevant comparator (defined for a given indication, on the basis of the current reference strategy).
- For therapeutic HT, outcomes should be fit for purpose with regards to the disease being treated and the clinical action of the new HT. The results of the clinical studies are analysed with regard to the magnitude of effect, i.e. the patient-centred relevance of the difference in effect obtained compared to the comparator.
- The certainty of results is appreciated through the assessment of the methodological quality of the study design and its results.
- The assessment also takes into account the applicability of the results observed in clinical studies to the population likely to be treated with the HT in question in France.

In that line, direct meta-analyses of well-conducted randomised controlled trials, or randomised controlled trials with appropriate blinding including a clinically-relevant comparator, are the gold standard for the HTA of any HT [12]. The absence of such evidence may be accepted in certain situations, provided they are explained and justified. For example, for MD, it might sometimes be difficult to perform randomised and/or blinded studies [13]. In these situations, other types of studies may be accepted for the evaluation as long as they provide results with a sufficient certainty of results.

These methodological principles as well as the specific assessment criteria (see hereinafter) considered by different HTA committees are presented in the corresponding reference documents [14].

Likewise, the literature search carried out for the assessment focuses on comparative data from publications that are most likely to have high certainty of results, i.e. systematic reviews with or without meta-analysis (including existing HTA reports), or, in case of absence of corresponding synthetic literature, randomised controlled trials as well as prospective diagnostic accuracy studies (in case of diagnostic tests). Other types of studies may also be considered, depending on the nature of the HTA question.

3.4. Appraisal and opinion phase

The different criteria used for the appraisal of different HT in view of their reimbursement and pricing are defined by Law (in the French Social Security code). Regardless of the type of the HT, two categories of criteria are assessed (except for remote medical monitoring activities for which one criterion is assessed):

The first criterion assesses the intrinsic value of a HT relative to existing alternatives, in terms of its benefit (clinical or diagnostic efficacy, disability compensation for MDs safety, place in the corresponding pathway) and impact on public health. This criterion indicates whether a HT should be reimbursed or not. It also determines the reimbursement rate in the case of medicinal products. This criterion is called the "clinical benefit" (with different names in French, depending on the HT: *service médical rendu* "SMR" for drugs and *service attendu* "SA" for MDs and procedures). The specificities of each are detailed in the Table 1).

The second criterion, called « clinical added value" (*amélioration du service médical rendu* "ASMR" for drugs and *amélioration du service attendu* "ASA" for MDs and procedures), assesses the added value of the new HT, in comparison with existing treatment methods or means of diagnosis or disability compensation considered as the current standard of care. There are five possible levels of ASMR or ASA.

The assigned level has an impact on the price of a medicinal product or a medical device, whereas for diagnostic and therapeutic procedures it will have an impact on the delay for setting up the price but not on the price itself. It is to be noted that exceptionally, in case of digital medical devices used for remote monitoring, the HAS assessment criteria does not impact the price negotiation, since the price of this type of devices is set in advance by the Ministry of Health and Social security in the form of a flat fee [15].

[1] P, population (the patients or population(s) in which the intervention under assessment should be used, I, intervention (the intervention under assessment, including setting), C, comparator (the alternative intervention against which the intervention under assessment should be compared), O, outcomes (endpoints of interest), T, time (e.g. minimum follow-up time), S, study design.

Table 1
Assessment criteria for different HT in view of their reimbursement and pricing.

	Clinical benefit (CB) levels and reimbursement rates	Criteria for the assessment of CB	Clinical added value (CAV) levels	Criteria for the assessment of CAV
Medicinal products	High: 65% Moderate: 30% Minor: 15% Absence of CB: no reimbursement	– the efficacy and adverse effects of the medicinal product – its place in the therapeutic strategy, particularly with respect to the other therapies available – the seriousness of the disease targeted by the medicinal product – the preventive, curative or symptomatic nature of the medicinal product – the public health benefit of the medicinal product.	Major (I) Substantial (II) Moderate (III) Minor (IV) Absence of CAV (V) The CAV is used to define the framework for price negotiations.	– the quality of the demonstration, which includes the comparison and the choice of comparator(s), the methodological quality of the study, the appropriateness of the population included for the indication, the relevance of the clinical endpoint and its significance, etc. – the effect size in terms of clinical efficacy, quality of life and safety in view of the robustness of the demonstration; – the clinical relevance of this effect compared to clinically relevant comparators; – the medical need.
MDs and diagnostic -therapeutic procedures	Sufficient Insufficient	– The benefit of the product regarding its therapeutic or diagnostic effect or its effect in compensating for disability, as well as its adverse effects or risks related to its use and its role in the therapeutic strategy considering other available therapies; – Its expected public health benefit, particularly its expected impact on the health of the population, in terms of mortality, morbidity and quality of life, its capacity to meet a therapeutic need regarding the severity of the condition or disability, its impact on the healthcare system and on public health policies or programmes.	Major (I) High (II) Moderate (III) Minor (IV) Absence of CAV (V)	The CAV is granted in relation to the existing therapeutic or diagnostic strategy or strategy for compensation of a disability. It is based on the ability to meet an unmet need and the impact on the healthcare system. Criteria: clinical, quality of life, patient satisfaction, impact on the organisation of care, professional practices or patient care conditions.
DMDs	Expected benefit for the medical service	Expected benefit is positive if it is:Greater than conventional medical monitoring -Equivalent or greater to an already registered telemedicine service	The assessment criteria is characterised according to 3 components: – The clinical improvement in the patient's health state compared with conventional medical monitoring or, where applicable, with a telemedicine service already registered, considering the adverse effects and risks associated with each monitoring method – The significant gain in the organisation of care it enables, in terms of human and material resources, as well as the therapeutic treatments mobilised, without compromising quality of care –The public health benefit, particularly regarding its expected impact on the health of the population in terms of mortality, morbidity and quality of life, and its capacity to meet an unmet therapeutic need, regarding the severity of the condition, and its impact on public health policies and programmes. Regarding the choice of the comparator: If no other DMD is registered on the list, the comparator must be the conventional medical monitoring If one or more DMDs are registered on the list, comparison must be done to every remote medical monitoring activity registered; If not feasible, comparison must be done at least to the last activity registered product	

In addition to specifying the two criteria mentioned above, the HAS' HTA opinions also help to determine the conditions of good use of a HT and its place in the corresponding pathway of care.

For digital medical devices used for remote medical telemonitoring, the assessment criteria is the "expected benefit (EB) for medical service" [16]. It is characterised by 3 components: 1) the clinical improvement in the patient's health state compared with conventional medical monitoring or, where applicable, with a registered telemedicine service, considering the adverse effects and risks associated with each monitoring method; 2) the significant gain in the organisation of care it enables, in terms of human and material resources, as well as the mobilised therapeutic treatments, without compromising quality of care and 3) the public health benefit

The advisory opinions are issued by the different HAS' HTA Committees or, in case of diagnostic and therapeutic procedures, and public health interventions, by the HAS Board (after a first examination by an HTA Committee). For medicinal products and MD, all members of a Committee are called upon to vote, giving their opinion on the concerned technology or intervention concerned. For diagnostic and therapeutic procedures, and public health interventions, the Board examines the HTA report in light of the Committees' comments in a first meeting. At the second meeting, the Board assesses and votes the different criteria in view of reimbursement (see here above) which are then included in the Advisory opinion to be published together with the final version of the assessment report (taking into account Committee and Board comments) on the HAS' website. The applicant as well as all actors having contributed to the external consultations are notified of the publication.

The composition of the various HTA Committees of the HAS is described in Fig. 2. Health products can be assessed by four Committees : the Transparency Committee *(CT – Commission de la Transparence*), Committee for the Evaluation of Medical Devices and Health Technologies (*CNEDiMTS - Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé*), the Economic and Public Health Committee (*CEESP - Commission d'évaluation économique et de santé publique*) and the Diagnostic, Prognostic and Predictive Health Technologies Evaluation Committee (*CEDiag - Commission d'évaluation des technologies de santé diagnostiques, pronostiques et prédictives*). Vaccines can be assessed by three different Committees: the Technical Committee for Vaccination *(CTV - Commission technique des vaccinations)*, the CT, and the CEESP. The HTA reports of diagnostic and therapeutic procedures can be examined by three Committees: either CEDiag or CNEDIMTS, or, exceptionally, the Health Care Management Committee, which is another HAS Committee mainly in charge of recommending best practices, relevant care, care pathways and indicators (it is not an HTA Committee as such).

As part of its work programme, the CEESP is also required to give opinions to the Board on public health recommendations. The evaluation of public health actions and programmes is based on a population-based approach that assesses the benefit-risk ratio, as well as the cost-effectiveness ratio, of the various possible interventions at the population level. The aim is to gather the arguments needed to judge whether it is appropriate to introduce these actions or programmes, to modify existing programmes and to specify the involved procedures. This assessment and its conclusions take the form of a public health recommendation designed to inform public decision-making. These recommendations are therefore addressed to the public authorities.

Of note, the Diagnostic, Prognostic and Predictive Health Technologies Evaluation Committee currently does not issue Advisory Opinions but prepares HAS' Board's deliberations on the assessment of diagnostic, prognostic or predictive diagnostic and therapeutic procedures. It can also provide its expertise to other HAS Committees for the assessment of other types of diagnostic, prognostic or predictive HT, e.g. to the CT (for the assessment of medicinal products requiring a companion test, a radiopharmaceutical or a contrast agent used in radiology procedures), to the CNEDiMTS (for the assessment of diagnostic, prognostic and predictive medical devices for individual use) or to the CEESP (for the assessment of tests integrated into screening strategies).

Committee agendas are published in advance on the HAS website. In the interest of transparency, the contents of the debates, conclusions and votes are recorded, transcribed and published on the HAS website. The meeting minutes are published on the HAS' website.

3.5. Contradictory phase and publication of the opinion

For most HT (except diagnostic and therapeutic procedures), once the dossier has been examined by the Committee, the concerned HAS service produces a draft opinion containing the Committee's assessment conclusions, mostly based on the assessment criteria. This document is then adopted by the Committee members at the next meeting. Once adopted, the opinion is sent to the applicant (and to national professional councils for the requests of registration on the list of remote medical monitoring activities – "*Liste des activités de télésurveillance médicale", LATM*), who can comment on the decision during a contradictory phase. The applicants can request that the Committees reconsider their decisions after the provisional opinion is issued. They can send written observations and/or ask for a hearing. However, they cannot present new data to the Committees. Experts chosen by the applicants may participate in the hearing. After having considered the written observations and/or having heard the applicants, the Committees then decide with a vote if they maintain or change their original opinion. After the contradictory phase, the final opinion is forwarded to the applicant as well as to the public decision-makers, and is published on the HAS website. The associations that participated are notified of the publication of the decision.

3.6. Post-HTA

Following the HTA, uncertainties may remain regarding the clinical benefit of the health product, its role in the therapeutic, diagnostic, or disability compensation effect in the therapeutic strategy and in light of alternatives, as well as the short- or long-term consequences of its introduction to the public. As a result, the HAS may request the conduct of post-registration studies from the applicant [17].

For example, the CT and CNEDiMTS can request the collection of additional data necessary for the subsequent reassessment of the therapeutic value of the drug or the clinical benefit of the MD. During the initial assessment, the CT or CNEDiMTS formulates a research question which can be about patient characteristics, conditions of use, efficacy, or safety, along with a timeline for reassessment. The HT developer is then responsible for conducting study(ies) that generate evidence with the appropriate certainty of results, whether through real-world data or new clinical trials. The DEAI supports the HT developer/applicant by reviewing post-registration study protocols to ensure alignment of study designs with the CT's or CNEDiMTS' data requirements. This support can involve the real-world data unit (*"Cellule de Coordination des Données en Vie Réelle", CCDVR*) of the DEAI.

3.7. Special cases

3.7.1. Products that require an economic evaluation

When a health product meets certain eligibility criteria, it must undergo a medico-economic evaluation. The eligibility criteria are as follows:

- For medicinal products: when the HTD claims a high clinical added value score (ASMR I to III) and the concerned product is an advanced therapy medicinal product (ATMP), or the forecast pre-tax sales for the 2nd year of marketing in the indication are

greater than or equal to 20 million euros per year, or the company claims to have an impact on the organisation of care, professional practices or patient care conditions.
- For medical devices: when the HTD claims a high clinical added value score (ASA I to III) and when the forecast pre-tax sales for the 2nd year of marketing in the indication are greater than or equal to 20 million euros per year in the case of a registration procedure, or when the pre-tax sales recorded during the 12 months preceding the application for renewal of registration in the indication are greater than 20 million euros per year.

Under specific conditions, an economic evaluation is not requested when the medicinal product is not protected by a patent or a supplementary protection certificate, the request concerns a paediatric extension of indication for which the adult indication is already covered by national solidarity, the request concerns an extension of indication which will result in an increase in the population reached by the product of <5% over 2 years (medicinal products only).

CEESP economic appraisals conclude on the degree of confidence in the submitted economic analysis, considering the applicant's methodological choices. They are forwarded to the Economic Committee of healthcare products (CEPS - *Comité économique des produits de santé*), with the aim of contributing to the negotiation of the price of the concerned products.

The CEESP issues its opinion based on two possible analyses: the cost-effectiveness of the product, that may follow methodological guidelines of the HAS [18] for economic evaluations, assessed by the incremental cost-effectiveness ratio (ICER) of the product compared to relevant comparator(s), and/or the budget impact of the product, that may follow methodological guidelines of the HAS for budget impact assessments, to assess the consequences for the budget of a given funder of the introduction and market dissemination of a healthcare product. The CEESP is tasked with issuing an opinion based on the critical analysis of the cost-effectiveness and budget impact analyses submitted by the applicant. It does not redo the medico-economic analysis but provides a judgment on the methodological quality of the dossier. This opinion will be used by other public authorities (e.g., the CEPS) to account for the potential societal benefits of a healthcare strategy or a healthcare product.

3.7.2. Vaccines

Marketing authorisation is insufficient to meet the criteria for vaccines to be reimbursed by national health insurance, they must primarily be recommended for use in France. The assessment of vaccines and vaccination strategies is conducted by the CTV and the relevant departments of the DEAI, then by the board of the HAS. Vaccine evaluation adheres to international standards, similar to other health technologies. The CTV elaborates vaccination opinions and specifies vaccination strategies relevant to France. Such opinions may concern the entire French population or a sub-group such as individuals in a specified age-range, individuals with certain comorbidities, or professionals at risk of either contracting or transmitting a disease.

Users of the healthcare service are represented on the CTV through the presence of a voting member. Civil society input, including the opinions of learned societies and other organisations, is considered through public consultations on proposed vaccination guidelines.

As vaccines fall within the category of medicinal products, vaccines must also be assessed by the CT, after a favorable vaccination recommendation has been made by the CTV.

In the case of a favourable vaccination opinion by the CTV, approved by the Board of the HAS, and a positive opinion by the CT (sufficient SMR), the level of reimbursement is decided by the "*Union nationale des caisses d'assurance maladie"/UNCAM* (union of representatives from the general scheme and the agricultural scheme of national health insurance funds).

In the case of a negative vaccination opinion by the CTV, the CT endorses this opinion and consequently grants an insufficient SMR (SMRi). In this case, the vaccine is unlikely to be reimbursed by social security, but health professionals are still at liberty to suggest the vaccine to patients on an individual basis provided that the vaccine conforms to the indications mentioned in its marketing authorisation. Vaccines may therefore be evaluated by three different Committees: the CTV, the CT, and the CEESP, as applicable.

3.8. Key figures of the HAS

In 2023, the HAS issued 339 CT opinions, 265 medical device opinions, 87 opinions on diagnostic and therapeutic procedures, 22 medico-economic opinions, 13 publications related to vaccination and 4 on public health interventions. Regarding the opinions for a registration on the LATM, only 2 opinions were published, knowing that 4 files were received for this new reimbursement list just opened in 2023. The evolution of the levels of added value assessed over the last 10 years are illustrated in Fig. 4.

Depending on the HT, the evaluation deadlines can be regulated. For medicinal product and MDs, the transparency directive [19] indicates that the procedure for reimbursement (including the evaluation phase by the HAS and the price negotiation by the CEPS and the HTD) must be completed in 180 days (see innovation article for derogatory procedure deadlines). For DMD used for remote medical telemonitoring, HAS assessment must be completed in 90 days (70 days if the DMD has obtained a temporary coverage)**Error! Bookmark not defined.**. For diagnostic and therapeutic procedures, the duration is regulated for specific requests only (from the UNCAM and the Ministry) and not for the whole process but only for the assessment phase and is of 180 days since 2024.

In 2023, the average evaluation duration was 103 days for medicinal products (all procedures, such as early access, included), 76.5 days for MDs (early access requests not included) and 396 days for diagnostic and therapeutic procedures (all types of requests combined).

In terms of consultations before the HTA phase, in 2023, the has organised 6 ED for medicines (4 national ED and 2 international ED), 20 national ED for medical devices and 8 national ED for diagnostic and therapeutic procedures. The has organised 12 pre-submission meetings as part of a future medico-economic evaluation, 30 pre-submission meetings for MDs and 3 for diagnostic and therapeutic procedures. Concerning derogatory access instructions for medicines, the HAS organised 42 pre-submission meetings with the HTD.

4. External consultations to inform evaluation

The HTA method employed by the HAS relies on the complementarity between, on one hand, the assessment of the certainty of results of clinical and economic evidence, and, on the other hand, the opinions of different actors (notably health care professionals and patients) engaged in the evaluation process. That is why the assessment phase, and, when applicable, the scoping phase, often include external consultations.

During individual expert consultations, healthcare professionals usually address questions related to the interpretation of the medical relevance of the data analysed and their transposability to the French practice, whereas patients may provide their living experience of the disease, the health technology or the public health intervention under assessment.

The experts involved may be external to the HAS or "internal", i.e. a member of a HAS' HTA Committee. All experts who wish to contribute to the HAS' work must comply with its deontological rules to

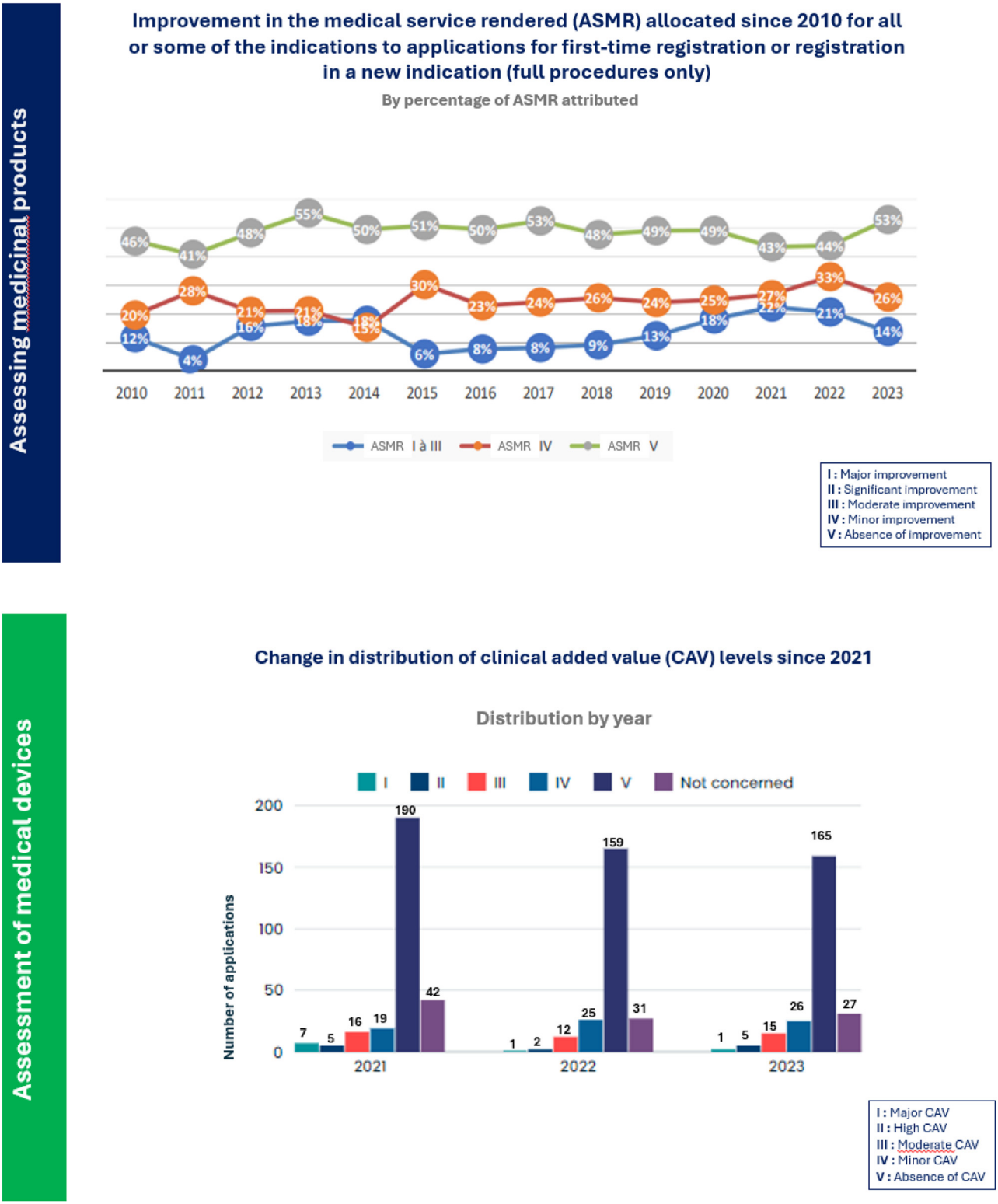

Fig. 4. Key figures of the HAS.

guarantee its independence and impartiality [3,20] (see article on deontology [4]).

Another way to involve health care professionals or patients in the different phases of the HTA process is through stakeholder consultation. Unlike the individual expert consultation where participants express their personal opinions, stakeholder consultation aims at gathering collective feedback from different parties (national councils of healthcare professionals, patient associations) concerned by the ongoing assessment. Stakeholder consultations follow a specific procedure developed for this purpose [21].

In practice, for example the list of drugs and medical devices currently under assessment is available on the HAS website. Patient and healthcare system user associations can contribute to the assessment by completing a downloadable questionnaire. Their contribution is

presented to the corresponding Committee and published together with the corresponding Opinion once finalised. For diagnostic and therapeutic procedures, different stakeholders can review and comment the draft assessment report. Their feedback is included in the final version of the assessment report.

5. Perspectives

5.1. Forthcoming challenges at European level

The Regulation (EU) 2021/2282 of 15 December 2021 [22] on health technology assessment will apply as of the 12th of January 2025. This means that all EU member states will cooperate to produce joint clinical assessments (JCA) of certain health technologies. The number of products eligible for a JCA will increase progressively. The first health technologies to be subject to JCA as of the 12th of January 2025 will be new cancer medicines, advanced therapy medicinal products (ATMP) and some medical devices (MD) i.e. selected high-risk MD and class D in vitro diagnostic MD for which the relevant expert panels have provided a scientific opinion/ view. Then, orphan medicines will require a JCA as from the 13th of January 2028 before it becomes compulsory from the 13th of January 2030 for all the other new medicines authorised through a centralised procedure. The expected benefits of the HTA regulation are numerous: reduction of duplicated national efforts for agencies and industry, production of high quality and timely scientific reports, improved transparency for patients, improved and accelerated access to technologies with added value, more efficient clinical evidence generation and submission, sustainable cooperation framework in the field of HTA. The HAS will apply the European regulation on HTA while preserving its fundamental values of scientific rigor, transparency and independence.

5.2. Integration of environmental impact in HTA evaluation

The harmful effects of climate change on population health are undeniable. At the same time, activities within the healthcare system, while crucial, exert considerable pressure on the environment. They contribute to global warming, accounting for over 8% of greenhouse gas emissions in France. The has established a roadmap [23] to structure internal reflections and identify actions to better consider health-environment issues within the framework of its various missions and work. Regarding HTA, the has committed to enhancing existing criteria that take environmental aspects into account in the evaluation methods of health products (for example: more detailed evaluation of the packaging of medical devices) and to engaging in discussions about h*ow the environmental impact of health technologies can be incorporated into medico-economic assessments conducted by the HAS*. In this same dynamic, the HAS is also part of the Environmental Sustainability Learning Group of the International Network of Agencies for Health Technology Assessment (INAHTA).

6. Conclusion

Despite some differences among different HT, the following general assessment principles are common to all: the assessments should be based on comparative data demonstrating the superiority of the HT assessed versus the relevant comparator (defined for a given indication, on the basis of the current standard of care). The assessments should be based on the best available clinical evidence, using the most relevant assessment methods which ensures that the findings are reliable and valid. The scientific opinions issued are of paramount importance as they directly impact all reimbursement decisions, as well as reimbursement rates and price negotiations for some health technologies. This is why the HAS carries out its evaluation missions in accordance with its three core values: scientific rigor, independence, and transparency. The HAS also plays a crucial role in implementing healthcare democracy. This is why it involves different actors, especially patients or their representatives, in its work by various means.

The stakes of HTA are high (e.g. the European regulation), hence the HAS strives to maintain a high level of quality in the work it carries out.

Conflict of interest

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

CRediT authorship contribution statement

Joachim Baba: Writing – review & editing, Writing – original draft. **Nathan Guerrier:** Writing – review & editing, Writing – original draft. **Irena Guzina:** Writing – review & editing, Writing – original draft. **Vanessa Hernando:** Writing – review & editing, Writing – original draft. **Vassilia Ressencourt:** Writing – review & editing, Writing – original draft. **Ivana Spasojevic:** Writing – review & editing, Writing – original draft. **Dominic Thorrington:** Writing – review & editing, Writing – original draft. **Charlotte Masia:** Writing – review & editing, Validation, Supervision, Project administration, Conceptualization.

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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; 2025:104284. doi: 10.1016/j.lpm.2025.104284.
[2] Loi n 2004-810 du 13 aout 2004 relative a l'assurance maladie [cited 2025 May 6]. Available from: https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000625158.
[3] HAS. Déclarations d'intérêts et gestion des conflits d'intérêts. Guide de déontologie [En ligne] 2023 Disponible: https://www.has-sante.fr/upload/docs/application/pdf/guide_dpi.pdf.
[4] Lyonnet M, Gelli R, Galmiche H. Taking ethics into account: the point of view of the HAS. Presse Med 2025:104283. doi: 10.1016/j.lpm.2025.104283.
[5] Loi n 2017-55 du 20 janvier 2017 portant statut general des autorites administratives independantes et des autorites publiques independantes [cited 2025 May 6]. Available from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000033897475.
[6] Decret n 67-441 du 5 juin 1967 relatif aux conditions de remboursement des medicaments aux assures sociaux [cited 2025 May 6]. Available from: https://www.legifrance.gouv.fr/loda/id/JORFTEXT000000870187
[7] Fernandez J, de Boissieu P, Galbraith M. Health technology assessment in Europe: a comparison of organizations and introduction to the European regulation. Presse Med 2025:104282. doi: 10.1016/j.lpm.2025.104282.
[8] Richardson WS, Wilson MC, Nishikawa J, Hayward RS. The well-built clinical question: a key to evidence-based decisions. ACP J Club 1995;123(3):A12–3.
[9] Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ 2017;358:j4008. doi: 10.1136/bmj.j4008.
[10] Sterne JA, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019;366:l4898. doi: 10.1136/bmj.l4898.
[11] Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, et al. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med 2011;155(8):529–36. doi: 10.7326/0003-4819-155-8-201110180-00009.

[12] HAS. Methodology for the clinical development of medical devices [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2021-09/guide_methodology_for_the_clinical_development_of_md.pdf
[13] HAS. Transparency Committee doctrine [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2019-07/doctrine_de_la_-commission_de_la_transparence_-_version_anglaise.pdf
[14] HAS. Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2019-11/assessment_-principles_established_by_cnedimts.pdf
[15] 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 [cited 2025 May 6]. Available from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000047571442
[16] Décret n 2022-1767 du 30 décembre 2022 relatif à la prise en charge et au remboursement des activités de télésurveillance médicale [cited 2025 May 6]. Available from: https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000046849110
[17] Fernandez J, Babin C, Thomassin C, Pelon F, Kelley S, Cochat P, et al. Can requests for real-world evidence by the French HTA body be planned? An exhaustive retrospective case-control study of medicinal products appraisals from 2016 to 2021. Int J Technol Assess Health Care 2024;40(1):e33. doi: 10.1017/s0266462324000291.
[18] HAS. Choices in methods for economic evaluation – HAS [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2020-11/methodological_guidance_2020_-choices_in_methods_for_economic_evaluation.pdf
[19] 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.
[20] Gesbert C, André-Vert J, Guerrier M, Galbraith M, Devaud C, Dupont JK, et al. The contribution of French patient and consumer groups to health technology assessments over a 2-year period: an observational retrospective study. Int J Technol Assess Health Care 2021;37:e48. doi: 10.1017/s0266462321000180.
[21] HAS. Décision n 2014.0115/DC/MJ du 28 mai 2014 du collège de la Haute Autorité de santé portant adoption de la procédure de consultation des parties prenantes [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2014-09/c_2014_0115_adoption_procedure_parties_prenantes.pdf
[22] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance). Offic J Eur Union 2021 L 458/1-32 http://data.europa.eu/eli/reg/2021/2282/oj.
[23] HAS. Environmental health roadmap [cited 2025 May 6]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2024-07/environmental_health_roadmap_-_has.pdf