HAUTE AUTORITÉ DE SANTÉ

GUIDE

Cooperation between the HAS and users

Arrangements for the involvement of health, social and medico-social care system users and their organisations in the work of the HAS

Validated by the Board on 10 November 2022

Description of the publication

Title	Cooperation between the HAS and users Arrangements for the involvement of health, social and medico-social care system users and their organisations in the work of the HAS
Working method	Development by a working group made up of equal numbers of users and HAS members. Survey of HAS project managers and users having participated in the work of the HAS between 2020 and 2021. Public consultation for a preliminary version of the guide occurred between 5 July and 17 August 2022 (see Appendix 1. Method of production and Participants section).
Objective(s)	To facilitate user involvement in the work of the HAS by updating and clarifying the arrangements for their participation in the institution's work.
Targets concerned	– Healthcare system and social and medico-social care service users: • individuals requiring the intervention of healthcare professionals (e.g. individuals consulting a physician or requiring care for an acute or chronic disease, for the consequences of an accident, for a pregnancy, or for preventive medical follow-up, vaccination, etc.); • individuals supported by a social or medico-social service or institution (e.g. individuals provided with support due to a situation of disability or social vulnerability, institution nursing home residents, children who are subject to child protection measures); • their family/friends and their legal representatives; • members of user organisations and groups. – HAS employees involving users in their work.
Requester	Self-referral – HAS 2019-2024 strategic plan action
Sponsor(s)	French National Authority for Health (HAS)
Project management	Mr Cédric Gesbert and Ms Mathilde Bruneau, project managers – HAS Public Involvement Department (head of department: Ms Joëlle André-Vert)
Literature search	Legal information search on the laws applicable in France regarding the involvement of the individuals concerned. Search for information on practices for the involvement of the individuals concerned in the main institutions in France and internationally. Supported by the bibliographic data from the HAS 2020 guideline entitled "Supporting and encouraging public engagement in social and health care organisations".
Authors	Cooperation guide: Mr Cédric Gesbert and Ms Mathilde Bruneau, project managers, in close collaboration with the working group.
Declaration of interests	The members of the working group communicated their public declarations of interest to the HAS. These can be consulted on the website https://dpi.sante.gouv.fr. They were analysed according to the analysis grid of the HAS guidelines for the declaration of interests and management of conflicts of interest. The interests declared by the members of the working group were deemed to be compatible with their involvement in this work.
Validation	Version dated: 10 november 2022 [French version] – Translation: September 2023
Updating	It is intended that this guide will remain applicable for five years after its publication and will be updated as necessary.
Other formats	Report on the public consultation process concerning the initial version of this guide.

This document can be downloaded from www.has-sante.fr

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Introduction

What is the HAS?

The HAS is an independent scientific public authority that aims to advance quality in the fields of health and social and medico-social care services, for public benefit. It works alongside public authorities to inform policy decisions with healthcare professionals to optimise their practices and working arrangements, for the benefit of individuals by reinforcing their decision-making capacity.

It has three main missions:

- to assess and appraise medicinal products, medical devices and professional practices for reimbursement purposes,
- to recommend best practices for healthcare professionals and develop vaccine and public health guidelines,
- to measure and improve the quality of care delivered in hospitals, clinics, community medicine settings, social and medico-social institutions.

In this context, the HAS is required to carry out scientific assessments with important consequences for all those working in the field of health in the broadest sense, as well as for the people who are the ultimate beneficiaries of these actors' actions. To this end, it regularly collaborates with professionals and users from the health, social and medico-social sectors.

To fulfil its missions, the HAS is organised around:

- a Board with eight members;
- specialised committees and a public involvement council, chaired by a Board member;
- five operational departments.

Its teams are driven by three core values: scientific rigour, independence and transparency.

> Find out more
>
> - About how the HAS is organised and the legal basis of its departments (HAS departments–Applicable legal texts)
> - The missions of the HAS (article L. 161-37 of the French Social Security Code) [in French]

What is the context for the development of this guide?

A longstanding culture promoting user involvement

Keen to build on the practices put in place within France's national health accreditation and assessment agency (ANAES), from which it stems, since it was created in 2004, the HAS has continued to recognise public and patient involvement in its methods and work.

In 2008, it set up a cooperation framework aimed at organising its relations with patient and user organisation (1). This framework laid down the principle of equal treatment of the professionals and users involved in its work, recognising the latter's status as expert participants. This advancement in terms of recognition of the expert status of users in the HAS' work has been fundamentally important.

A need to update the 2008 cooperation framework

Fourteen years after this first publication (1), an update is required to take into account changes in practices and legal and strategic evolutions.

In terms of practices, methodological innovations have been implemented and societal expectations have been expressed, one of the aims being to enable the participation of citizens, under certain conditions, regardless of whether they are members of an organisation. Public and patient involvement has taken a number of forms (participation in specialised committees, working and review groups, completion of questionnaires, individual or group interviews, etc.). Other public institutions have proposed documents relating to the involvement of users or society on their bodies. This is the case for the French National Agency for Medicines and Health Products Safety (ANSM), with its booklet entitled *"À la découverte de l'ANSM"* ["All about the ANSM"] (2), and, previously, for several public research, expert assessment and health and environmental risk assessment organisations, which signed the "*charte de l'ouverture à la société*" ["openness to society charter"](3).

On a legal level, there have been numerous legislative, regulatory and ethical changes. In particular, the health expertise charter introduced a distinction between the status of a stakeholder and that of an expert participating in individual or collective expert assessments (4, 5) (Appendix 3. Role of users in HAS bodies bodies. The French Touraine law (2016) introduced the appointment of an independent ethics officer to the HAS. Other legislative or regulatory changes have also contributed to new rights being granted to user organisations, such as the right to alert (6), have expanded the HAS' scope for action to the social and medico-social care sector (since it took over the missions of the Anesm, the French national agency for the assessment and quality of social and medico-social institutions and services in 2018) or have modified the conditions for public and patient involvement in some of its committees. Finally, with regards to health technology assessment in the European Union, a European regulation of 15 December 2021 (7) requires that the expert assessment of "patients affected by the disease[1]" be collected.

On a strategic level, this update is in line with the HAS' 2019-2024 strategic plan (8), the second pillar of which - "Making public involvement a priority" - is a step towards strengthening the HAS's action in this field (8).

In order to implement this strategy, organisational changes have been made: a public involvement council has been created, as well as a department dedicated to the same subject, which leads a transversal internal group of advisers (one per HAS department (Appendix 5. Momentum concerning pillar 2 of the HAS 2019-2024 strategic plan Momentum concerning pillar 2 of the HAS 2019-2024 strategic plan).

One of the actions of this strategic plan is specifically aimed at updating the 2008 cooperation framework, by extending it to the social and medico-social field and by defining the level of public and patient involvement within the HAS (becoming a partner, collaborating, being consulted, being informed) by type of work, on the basis of feedback from the HAS, the Anesm and experiences in other countries.

1 "*In order to ensure that joint work is of the highest scientific quality and reflects the state of the art, external experts with relevant in-depth specialised expertise should provide input on joint clinical assessments and joint scientific consultations. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts on, for example, the type of health technology concerned or issues related to clinical study design. European Reference Networks could also be used as a source to identify those experts and access relevant knowledge in specific therapeutic areas. Patients, clinical experts and other relevant experts should be selected for their subject matter expertise and act in individual capacity rather than representing any particular organisation, institution or Member State. In order to preserve the scientific integrity of the joint clinical assessments and joint scientific consultations, rules should be developed to ensure the independence and impartiality of patients, clinical experts and other relevant experts involved, and avoid conflicts of interest."* (45)

Who are the public concerned by this guide?

This guide is aimed at health, social and medico-social system users and HAS employees involving users in their work.

Health, social and medico-social system users

It appears difficult to identify a single, meaningful term to describe all the members of society participating in the work of the HAS.

In this guide, to facilitate reading, the term “user” means health, social and medico-social system users, in their capacity as current or past beneficiaries of healthcare or specific support, their families/friends and their representatives, and the organisations or groups who speak on behalf of them. Despite various attempts to enable everyone to identify with this definition, this definition is perfectible, but no better consensus has been found.

Hence, the HAS understands health, social and medico-social system users to include the following:

- individuals requiring the intervention of healthcare professionals (e.g. individuals consulting a physician or requiring care for an acute or chronic disease, for the consequences of an accident, for a pregnancy, or for preventive medical follow-up, vaccination, etc.);
- individuals supported by a social or medico-social service or institution (e.g. people provided with support due to a situation of disability or social vulnerability, nursing home residents children who are subject to child protection measures);
- their family/friends and their legal representatives;
- user representatives, representatives mandated by the Ministry of Health or a regional health agency (ARS) in hospital or public health bodies and elected representatives of persons supported in social and medico-social services and institutions; members of user organisations, whether these are accredited or otherwise and other groups.

As long as they are concerned by the theme of an HAS project, all these individuals are entitled to participate in this work.

Individuals concerned within the HAS

Different individuals within the HAS may be called upon to interact with users:

- project managers, in the context of coordination of their work;
- department heads concerning the organisation of HAS committees and council;
- scientific department and general secretarial service assistants for questions related to logistics and compensation.

What are the objectives of this guide?

The main objective of this guide is to clarify the methods for the involvement of users in the work carried out by the HAS, making a distinction between their participation as an expert or as a stakeholder.

The aim is, firstly, to support users who wish to participate in the work of the HAS by enabling them to better understand the context and practical methods of their participation and, secondly, to help HAS

employees define their expectations and the resources they require to facilitate the involvement of users in their work.

The challenge is to adapt and modernise the mechanisms for including the whole of society in the methods and work of the HAS, and to propose a common framework for all HAS departments, while at the same time respecting the specificities of the institution's different sectors and activities.

This new cooperation guide aims to:

- determine the general principles governing cooperation between the HAS and users;
- harmonise and render transparent the rules for soliciting, selecting and involving individuals from the health, social and medico-social sectors, whether or not they are members of organisations, who are called upon to contribute to the work of the HAS;
- define the methods of involvement, depending on whether user participation is as an expert or as a stakeholder;
- offer support to users to facilitate their involvement in the work of the HAS;
- specify the arrangements for the compensation of user members of committees and working groups;
- propose practical guides aimed at users and HAS employees, appended to this guide.

What are the general principles governing cooperation between the HAS and users?

The 2008 cooperation framework (1) laid down the principle of equal treatment of experts, a status recognised for both professionals and the users involved.

This guide once again confirms this principle **of equality of treatment** of professionals and users participating in the work of the HAS and proposes complying with the following additional essential principles:

- the principle of **health democracy**, based on participative approaches as well as user representation and respect for their rights (9);
- the principle of **effective cooperation** that makes sense for users and HAS members. User involvement in the work of the HAS brings an additional perspective to that of professionals and improves the relevance and efficacy of opinions, decisions, guidelines and mechanisms. In addition, this involvement should be assessed in order to be recognised and continuously improved;
- the principle of **facilitated cooperation**. The HAS must be capable of accessing the resources required to facilitate user involvement. This requires taking into account a phase dedicated to supporting the users participating in the work and adapting its methods to the public invited to participate, in order to not to fall into the trap of token involvement of users.

1. Facilitating user involvement in the HAS

1.1. Recognising users' knowledge

In 2021, the surveys conducted among HAS departments and users demonstrated a high level of public and patient involvement in the work of the HAS and recognition of their specific contribution by project managers (Appendix 2. HAS bodies – Applicable legal texts).

This specific contribution complements the scientific knowledge and experience of professionals: it harnesses the experience-based knowledge of users (10, 11), built up through personal knowledge and experience, and collective knowledge, acquired via the experiences reported within user groups or organisations.

In particular, this experiential or collective knowledge may be based on:

- living with a disease, disability or vulnerability;
- use of a health service or product;
- an organisation or group of individuals concerned;
- partnership with professionals;
- shared group discussions around the healthcare system, etc.

Supported by its experience over many years, the HAS recognises that this public and patient involvement enriches its work and empowers users.

In response to the question "Why involve users in your work?", some project managers highlight the importance of seeking a balance between different sources of knowledge: scientific knowledge, as well as the experience-based knowledge of both professionals and users.

> Why involve users in your work? Survey of project managers
>
> - "For a better quality of the recommendations and guidelines produced, which, ultimately concern the healthcare delivered to users. This enables a balance to be achieved between scientific knowledge, professional knowledge and experience-based knowledge."
> - "To have a point of view or information from the people concerned, who provide information that is sometimes not known or not taken into account by professionals. For better health democracy."
> - "Their involvement is essential at every stage in the production of recommendations and guidelines (scoping, drafting and review) in order to share their experience and expertise acquired within social and medico-social institutions. The various discussions between the project team and the individuals concerned make it possible to hear their feelings, needs, wishes and suggestions in order to improve the relevance, feasibility and acceptability of recommendations and guidelines."
> - "Importance of gathering information about living with a disease, its constraints, the treatment methods used, the difficulties, the wishes of users."

1.2. Clarifying user statuses at the HAS

Just like professionals, users participate in the work of the HAS as experts or as stakeholders. A differentiation between these two statuses is made in the health expertise charter decree [*Charte de l'expertise sanitaire*] that the HAS applies in all its areas of expertise (4).

The status of participants is determined by the HAS in the context of its working methods, which are published (e.g. method for the development of best practice guidelines(12)) or specified at the time of project scoping.

The status under which users are called upon to participate in work must be indicated at the time of the request.

The following sections clarify what it means to be involved as a stakeholder or expert.

1.2.1. Involvement as a stakeholder

Stakeholders are consulted for the interests they defend, particularly through their advocacy.

The health expertise charter defines stakeholders as any "people or groups affected or likely to be affected, directly or indirectly, by the consequences of […] decision(s), especially from organisations and economic or professional players, or who represent the general interests of groups affected by said consequences" (4).

A 2014 decision of the HAS Board sets out the stakeholder consultation procedure (13). The "physical person who represents the stakeholder intervenes to express the interests of the organisation that they represent, and not *intuitu personae*" (13).

> As a stakeholder, the person participating in the work is appointed by their organisation to represent it. The HAS decides which stakeholders it meets or consults, but it does not select the individual that will represent the organisation: that is the sole responsibility of the organisation.

The objective of stakeholder consultation is to gather the opinions of one or more groups on a given theme. In particular, this is the case for user organisations that contribute to health product assessments for reimbursement purposes or that are called upon to be heard by a committee; it is also the case for user organisations that participate in HAS consultation committees (Appendix 4. Health expertise – Applicable legal texts).

Unlike experts, stakeholders are not obliged to communicate public declarations of interest.

Experts and stakeholders consultation must be separated and the same working group cannot be composed of experts and stakeholders (13). The HAS ensures that it consults stakeholders when it considers this to be appropriate.

1.2.2. Involvement as an expert

Experts are consulted for their competences. The objective of expert consultation is to gather individual opinions for group discussion and deliberation. Following the opinion of a user having responded to the public consultation process, deliberation within an expert group enables each participant to compare their points of view, to validate their opinions, to argue their case and to allow themselves the

opportunity to have their “mind changed”. This is the case in expert groups tasked with developing best practice guidelines, for example.

This expertise may be of a professional nature or may be expertise acquired through experience with a specific medical, healthcare or social support situation. Experts are called upon to collaborate with the HAS in a number of its activities.

Health expertise is governed by a specific title in the French Public Health Code (article L. 1452-1). The health expertise charter describes the missions of an expert (4). Hence, an expertise is "a set of activities, in response to a question, aimed at providing a requesting party with an interpretation, an opinion or a recommendation that is as objectively founded as possible, based on available knowledge and evidence, accompanied by professional judgement. As stated in the standard, this definition also applies when the health expertise body and the requesting party are part of the same organisation and when the health expertise body self-refers a question and issues an interpretation, opinion or recommendation on its own initiative.”

It is essential that the expertise be based on (4):

- the completeness of the existing data or current knowledge on the question posed;
- comparison of the different opinions, theories or schools of thought;
- expression of any divergent positions, with supporting evidence.

> Within the HAS
>
> User expertise is recognised as experience or user-based expertise, built up from individual or collective experience (14).

Experts express themselves in their own name (*intuitu personae*) and not on behalf of the organisations, professional societies, organisations or groups to which they belong. It is this that differentiates their involvement from that of stakeholders.

When the HAS calls on experts, it must ensure that they meet the criteria in terms of expertise, experience and independence.

That is why a person participating in the work of the HAS as an expert must disclose their interests, which cover any “interests or activities, past or present, of a patrimonial, professional or family nature, of the expert in relation to the subject of the expertise entrusted to them" (4). The HAS ethics officer[2] is tasked with ruling whether there is any potential conflict of interests, supported by the HAS guidelines for the declaration of interests and management of conflicts of interest (15). The declarations of experts participating in the work of the HAS are published and accessible on the DPI Santé website, managed by the Ministry of Health[3].

1.2.2.1. What is a public declaration of interests (PDI)?

A public declaration of interests (PDI) is a document harmonised by the French law of 29 December 2011 reinforcing the safety of medicines and health products (16).

All actors in the field of public health and the safety of health products and services are concerned, from the moment they are called upon to participate in work in an expert capacity. According to the DPI Santé website, the mechanism meets two main objectives:

2 The ethics officer is currently an independent magistrate who ensures that the public discloses their interests and that measures are taken to prevent or eliminate any conflicts of interest.

3 Public declarations of interest can be consulted via the following link: https://dpi.sante.gouv.fr/dpi-public-webapp/app/home

- "improve the transparency of public actions, by ensuring the publication of the interests of policy-makers and health experts;
- enable the authorities to guarantee the impartiality and objectivity of the persons who participate in health decision-making and expertise, by performing an upstream analysis of declared interests with regard to the cases examined or the functions carried out[4]".

Persons invited to participate as experts in the work of health institutions, including the HAS, must complete, update and publish their PDI, disclosing their interests over the past five years. These public declarations of interest are examined by the HAS ethics officer before the work starts, as provided for in article L. 1451-1 of the French Public Health Code.

> Find out more
> You can consult:
> - the practical guide on "Completing a declaration of interests" (17) [in French];
> - the HAS' ethics page;
> - the Guidelines for the declaration of interests and management of conflicts of interest (15) [in French];
> - the HAS expert's booklet (18) [in French];
> - the "Supporting and encouraging public engagement in social, medico-social and health care organisations "recommendation (14) and in its glossary [in French] (19) on page 16.

1.2.2.2. Institutional vigilance to ensure diversity of expertise and prevent conflicts of interest

The HAS is careful to involve a diversity of experts and this rule applies to both users and professionals. It is defined in the guidelines for the declaration of interests and management of conflicts of interest (15). It is attentive to situations of multiple participation.

An analysis of the interests of any person participating in the work of the HAS in an expert capacity is a prerequisite before any involvement in expert assessment work.

A member whose interests may jeopardise the independence of the work or a question on the agenda of a body will have to **"step down"**, i.e. withdraw and not attend the group discussions and vote so as not to compromise the collegiate decision of a body or undermine the independence of the work.

The HAS deems that it is inappropriate for an expert to sit on several committees. If this were the case, they would have to step down from one of the committees if the same case were to be examined by two separate committees.

The same individual cannot participate as a stakeholder, on behalf of their organisation, and as an expert, in their own name, in the different phases of the same project. If such a situation were to occur, this person would have to withdraw from the work during one of the phases.

4 See page https://dpi.sante.gouv.fr/dpi-public-webapp/app/consultation/accueil [consulted on 30 June 2022]

> Examples:
>
> - the chairperson of a patient organisation participates in a working group on a subject related to a disease: at the review stage, they cannot respond on behalf of their organisation consulted as a stakeholder;
>
> - a member of a user organisation represents their organisation as a stakeholder in an HAS consultation committee (stakeholder committee). If they have also participated in a working group or a specialised committee of the HAS relating to a theme discussed at a consultation committee meeting, they must step down and not participate in the stakeholder debate; conversely, they may prefer to maintain their participation in the stakeholder consultation committee and refuse to participate in the working group.

Occasionally, a limited number of organisations may be involved in the majority of the work open to users over a given period of time. These situations may occur for both users and professionals. The HAS is careful to ensure that this situation does not persist and ensures the diversity of users recruited to participate in its work.

	Expert	Stakeholder
On behalf of whom?	Express themselves in their own name (*intuitu personae*)	Express themselves on behalf of the organisation
On what basis?	Knowledge acquired or built up individually or collectively through personal experience or via experiences reported within a group	Collectively constructed advocacy conveys the organisation's interests This advocacy potentially harnesses collective knowledge
What interests?	Public declaration of interests and analysis of disclosed interests	No public declaration of interests and analysis of disclosed interests
Compensation and expenses	Yes	No
Actions	Help construct an expert assessment within a working group or committee	Convey the organisation's point of view, given its objectives and challenges, via consultation, hearing, questionnaire, etc.
Objective	Produce a scientific work	Provide an opinion to inform work

1.3. Informing users about HAS activities

The HAS provides users with the means to inform themselves about its activities in order to increase their capacity to take action.

1.3.1. HAS news

To keep up to date with HAS news, users can subscribe to the newsletter,[5] consult the website regularly and follow the HAS on social media.

1.3.2. HAS conferences

The HAS holds regular conferences and seminars open to the public and patients. The HAS calendar of events can be consulted online[6].

In addition, users who have agreed to have their details stored by the HAS, in compliance with the European General Data Protection Regulation (GDPR), are kept informed of the dates and ways in which they can participate in the conferences open to them.

1.3.3. User engagement meetings

User engagement meetings are an opportunity for exchange between the HAS and users, focusing primarily on their involvement in the work of the HAS. These meetings are open to all health, social and medico-social care system users.

5 https://www.has-sante.fr/jcms/fc_2876176/fr/abonnement-newsletter
6 https://www.has-sante.fr/jcms/prd1_2989758/fr/agenda-de-la-has

Access the replay
- First user engagement meeting (Sept. 2020)[7] [in French]
- Second user engagement meeting (Oct. 2021)[8] [in French]
- Third user engagement meeting (Nov.2022)[9] [in French]

1.3.4. Occasional meetings or interviews with organisations

The HAS may also be led to organise occasional interviews with a stakeholder organisation. For example, it may invite - particularly at their request - the leaders of an organisation, union or federation of organisations, in order for them to meet, share their viewpoints or understand the reasons for a decision that they contest.

1.4. Adapting to specific situations

1.4.1. Need for adaptation of methods set in advance

Incorporating public and patient involvement in the work of the HAS implies a method and procedures identified in advance by project managers. However, in specific situations, they need to be able to adapt their working methods to ensure the effective and fruitful involvement of users, who are given the opportunity to freely express their views and experiences, and to avoid token participation.

This guide simply sets out milestones to map out the different possibilities and does not lay down any compulsory practices.

Example
In the context of the development of guidelines relative to intellectual development disorders, it seems difficult to hold large group meetings throughout the project bringing together professional experts and people with intellectual developmental disorders themselves. In order to facilitate the involvement of the latter, it is therefore possible to consider forming two separate groups and pooling the results.
Find out more about the working method of the "Supporting people with intellectual development disorders (IDD) - Part 1)" guideline (20) [in French]

1.4.2. Reaching out to excluded populations

The HAS accepts the involvement of anyone who is a user of the health, social or medico-social system. However, some populations are harder to consult than others.

In an age when the majority of communications are electronic and concentrated on the internet and social media, individuals who do not have access to these technologies - either because they live in

7 https://www.has-sante.fr/jcms/p_3148556/fr/rendez-vous-de-l-engagement-des-usagers
8https://www.has-sante.fr/jcms/p_3280334/fr/regarder-en-replay-le-deuxieme-rendez-vous-de-l-engagement-des-usagers-et-personnes-accompagnees
9 https://www.has-sante.fr/jcms/p_3364555/en/3e-rendez-vous-de-l-engagement-des-usagers-des-personnes-accompagnees-et-des-organisations

remote areas without digital services or because they have not mastered their use - have difficulty accessing calls for applications or consultation. HAS employee and organisation networks are therefore essential to “reach out” to and contact these users, cut off from new communication methods.

Particularly vulnerable populations are also difficult to consult for the work carried out by the HAS. This is especially the case for people in situations of social precarity, people in prison, adults under legal protection and minors. For the latter two cases, their voice is often heard through the mediation of relatives or carers, but this cannot replace the direct voice of the people concerned. The HAS is working to adapt the arrangements for user involvement and its communication methods (e.g.: easy read), so that they are suitable for all profiles.

> Example
> The creation of an *ad hoc* working group made up of the parents of children in care or people in vulnerable situations is possible. This encourages people to speak out and react to the proposals of the working group in charge of developing best practice guidelines.

The same applies to people with disabilities, who benefit from specific measures to facilitate their involvement, including the reimbursement of expenses for accompanying persons.

A user participating in the work of the HAS and in a specific situation may ask to be supported by a person to help them. They may contact the public involvement department, which will refer them to the most appropriate person to provide this assistance.[10]

Where the attendance of a person requires that they be accompanied by a third party, the latter may be subject to the same ethical rules as other experts, if they are to attend the working sessions. Their travel and accommodation costs may be reimbursed.

> Find out more
> - Facilitating your attendance at the HAS and, in particular, the response to the question “Are the travel expenses of individuals accompanying people with disabilities covered?”(21) [in French]
> - The involvement of persons concerned in the development of best practice guidelines for the social and medico-social care sector (22) [in French]

1.5. Compensating experts and reimbursing their expenses

1.5.1. Principle

The HAS compensates the experts it selects on the basis of the missions assigned to them. Any expert participating in an HAS activity that is eligible for compensation is entitled to a sum that depends on the amount of time worked and the body in which they participate.

This compensation is aimed at both user experts and professional experts, participating in a committee (23) or working group, or in individual or collective interviews (24). The fee is 90 euros before tax.

Stakeholders participating in the work of the HAS are not eligible for compensation.

10 Contact us using the form accessible via the HAS website: https://www.has-sante.fr/jcms/p_3148563/fr/contact or by telephone via the HAS switchboard.

Participation	
Compensation paid	**No compensation paid**
Committees	Involvement as a stakeholder
Expert working group	Review group
Individual interviews in the context of an expert assessment (e.g. early meetings)	Organisation committee or interventions for symposia, online conferences
Group interviews (e.g. focus group)	Anonymous individual or collective interviews
Panels	

1.5.2. Exceptions and adaptations

The principle stated may be adapted. Any expert may refuse this compensation.

In addition, the HAS can study potential solutions on a case-by-case basis, at the request of user experts, to ensure that compensation does not become a source of difficulty, particularly when the users are in receipt of social welfare benefits (risk of losing their benefits). Users may submit their request to the HAS human resources department, through the project manager or the assistant who is their contact within the HAS.

However, because of its legal status, the HAS cannot compensate a legal entity.[11] Therefore, it is not possible for the HAS to pay to an organisation compensation due to an expert who is a member of said organisation.

1.5.3. Reimbursement of expenses

Stakeholders are not eligible for reimbursement of expenses.

For experts, the HAS undertakes to cover the costs without advance payment, in accordance with the rules specified at the time an invitation to a meeting is sent:

- travel expenses (air, train, etc.);
- necessary accommodation expenses.

In addition, the following may be reimbursed with supporting documents:

- a mileage allowance for the use of personal vehicles, subject to conditions;
- costs relating to the journey from the expert's home to the departure railway station or airport;
- any car parking expenses;
- toll expenses;
- public transport expenses (RER, bus, metro);
- taxi expenses, in the absence of public transport, and in the Paris area only before 7 a.m. and after 8 p.m. or in the event of a strike. People who have reported a medical condition or disability that makes it necessary to use a taxi outside these times may be reimbursed.

11 The payment of an expense can only be made to creditors themselves or to their legal or contractual representative (article 36 of French decree No. 2012-1246 dated 7 November 2012 relative to budget management and public accounting).

It should be noted that for people with disabilities who need to be accompanied, the transport and accommodation expenses of their travel companion are also covered, if this person is among those invited to the meeting.

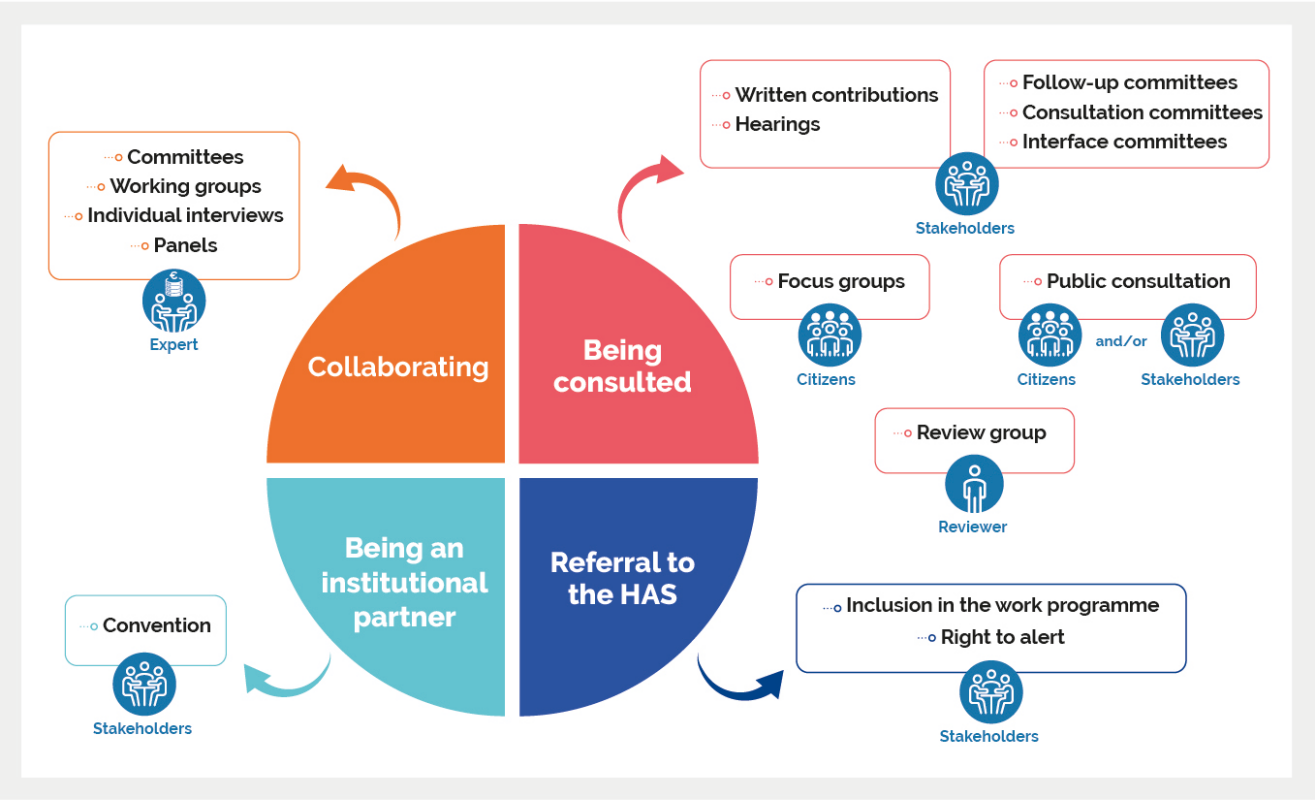
The document entitled “Facilitate your participation in the work of the of the HAS” (25) includes an FAQ section to answer questions that may be asked by user experts and stakeholders wishing to participate in the work of the HAS.

2. Getting involved in the work of the HAS

2.1. Numerous methods of cooperation depending on the HAS' activities

A variety of different methods of public and patient involvement are possible.

Diversity of methods of participation to the work of the HAS



HAS
HAUTE AUTORITÉ DE SANTÉ

November 2022

These methods depend on several factors:

- the regulations to which the HAS is subject;
- the institution's expectations in the context of a project or a decision-making body;
- and, obviously, the availability and preferences of users for a given method or another type of involvement.

Depending on the organiser, meetings can be on-site or take the form of a video conference.

Users are not required to have any specific training to participate in the work of the HAS.

Before applying: they can obtain information from project managers or the public involvement department or their organisation, so that they can decide whether or not to apply to take part in the work of the HAS.

Once their application has been accepted: some subjects may be technical and users, like any expert, must be able to be supported by the HAS personnel involved in the project in order to obtain information, be referred to validated sources of information and prepare for their participation as well as possible. Project managers schedule time for discussion with users in order to explain the method and the project schedule and to answer their questions before their participation.

The HAS publishes training guides or tools aimed at users to facilitate their involvement (Appendix 6. Key figures for the involvement of users and people requiring assistance in the activities of the HAS since 2019) and may put in place specific training for users, related to its activities.

Before a user gets involved in the work of the HAS, at the initiative of the HAS team, time for discussion relative to the project timetable and an estimate of the time dedicated to it should be scheduled. Users should not hesitate to contact project managers for any questions related to a specific project, or to contact the public involvement department[12] for more general questions.

> Find out more
> - Consult Appendix 5. Momentum concerning pillar 2 of the HAS 2019-2024 strategic plan relating to the drive to encourage public and patient involvement in HAS missions
> - See the replay of the First user engagement meeting in 2020 [in French]

2.2. Collaborating as a member of a committee or working group

2.2.1. How to apply

Members of HAS specialised committees are generally recruited every three years. In addition, working groups are regularly formed, with the themes on which the HAS works being determined every year by the work programme published at the start of the calendar year and updated in July each year.

Users can apply to participate in ongoing work related to their user expertise in a variety of ways:

- by responding to requests from their organisation, contacted by the HAS to identify users who have developed expertise in a given area;
- by responding to calls for applications published on the HAS website[13] (26) to participate in working groups or become a committee member; these calls for applications are sent to user organisations and professional organisations and are published on social media and in the HAS newsletter;
- using the HAS contact form;[14] applications are examined, forwarded to the department in charge of the work or to the expert department and a response is given.

In addition, in compliance with the General Data Protection Regulation (GDPR), the HAS asks individuals who participate in its work or events for their permission to keep their personal details for a period of five years in order to constitute a pool of people to be contacted.

CVs and application letters may be sent by post or email.

12 Contact us using the form accessible via the HAS website: https://www.has-sante.fr/jcms/p_3148563/fr/contact

13 See the section: calls for applications – https://www.has-sante.fr/jcms/r_1482317/fr/devenez-expert-et-appels-a-contribution

14 Contact us using the form accessible via the HAS website: https://www.has-sante.fr/jcms/p_3148563/fr/contact or by telephone via the HAS switchboard.

Find out more
- Practical guide on "How to apply" (27) [in French]
- Contributing to the work of the HAS (26) [in French]
- HAS work programme (28) [in French]

2.2.2. Becoming a member of a committee

Members of committees serve as experts. They are called upon to adopt a position in a very diverse range of situations (prevention, screening, care, treatment, support, information and organisation of a pathway and its improvement, quality assessment in institutions). User experts also contribute their knowledge based on their individual and collective experiences (see Recognising users' knowledge).

For some HAS committees, it is specifically scheduled that users should be members of organisations accredited in accordance with article L. 1114.1 of the French Public Health Code.[15] Where this is the case, the call for applications shall specify it.

An organisation may ask one of its members to apply for a committee because of their knowledge and experience in this committee's field. However, such members will intervene *intuitu personae* and not as a representative of the organisation having suggested that they submit an application.

2.2.3. Becoming a member of a working group or a panel

Calls for applications published on the HAS website are common to both users and professionals. The projected timetable and objectives of the project, as well as the expertise and experience expected, are included. The call for applications also specifies the compensation arrangements.

The HAS can also contact users directly or through the relevant organisations, which are well placed to know the users who have acquired knowledge and experience on the subject of the working group.

The role of a user member of a working group or panel is to bring a user perspective to the reflection process on the theme of the working group (a more targeted expertise compared to participation in a committee). They take part in the discussions and deliberations of the group or panel, like the other members.

Participation as an expert is on an *intuitu personae* basis. This commits experts in a personal capacity and in this context they do not represent their organisation.

If users require further information before submitting an application, they can contact the department that issued the call for applications or the public involvement department.[16]

15 These are the healthcare institution certification committee, the technical vaccination committee, the economic and public health evaluation committee (article R. 161-71-1 of the French Social Security Code), the transparency committee (article R. 163-15 of the French Social Security Code) and the national committee for medical device and health technology assessment (article R. 165-18 of the French Social Security Code).

16 Use the contact form: https://www.has-sante.fr/jcms/p_3148563/fr/contact

2.2.4. Useful expertise

The expertise deemed useful varies depending on the subjects being handled by working groups or committees.

It may concern knowledge related to:

- a disease or a specific social or medico-social situation;
- access to care or the overall care pathway of people in a specific situation;
- the medicinal product or medical device circuit;
- digital health care;
- the impact of public health policies, etc.

With regard to experts, it is important to be part of a collaborative approach, which requires:

- communicating in a way that everyone can understand, in a spirit of respect, openness and listening;
- being flexible;
- presenting one's case using factual statements based on personal knowledge or experience, supported, where appropriate, by collective experience related to the subject concerned.

This expertise can be acquired within the framework of associative activities or training courses, delivered by organisations or universities, relating in particular to health democracy, partnerships between users and professionals, patient education, etc.

Finally, the involvement of users in a committee or working group requires:

- being able to position oneself within a group, the ability to be step back and be objective about one's own experiences and to put them into perspective;
- an investment in terms of upstream preparation time and meeting time, and a long-term commitment, which is more difficult to sustain than a one-off involvement.

The required level of availability varies significantly depending on the situations:

- a one-day meeting every two weeks for some committees, every two or three months for others; the individuals selected are appointed for a period of three years in general;
- one to ten meetings, of one day or two hours for the working groups, over a period of between three and 18 months, depending on the project.

> Find out more
> - HAS's expert booklet (18) and Contributing to the work of the HAS (26)[17] (professionals and users) [in French]
> - Don't hesitate to call to talk to the person indicated on the call for applications

2.2.5. Knowing the selection criteria for examination of applications

For expert assessment work, applications are examined by the departments responsible for the committees, working groups or projects depending on the qualities highlighted by the applicants.

17 https://www.has-sante.fr/jcms/r_1482317/fr/contribuer-aux-travaux-de-la-has

Applicants selected for expert assessment work can only be appointed after their declaration of interests has been examined and validated by the ethics officer.

For experts, the aim of selecting candidates is to encourage a diversity of perspectives, opinions and expertise.[18]

A prerequisite for any participation as an expert: examination of potential conflicts of interest

HAS project managers indicate that, first and foremost, they consider the conflicts of interests criterion.

Characteristics specific to applicants

Project managers take into consideration the experience, acquired expertise and motivation of the applicant. Individual experience as well as collective experience related to participation in an organisation or a user group are often sought.

The HAS is not entitled to require that a user who is a member of an organisation be mandated by the latter, since this is an expert task carried out in an individual capacity.

Some organisations appreciate being informed by applicants that they are applying to take part in an HAS committee or working group. For example, some organisations require their members to have the approval of their organisation before applying to participate in an HAS expert assessment. This depends on the statutes or internal rules of the organisations. However, if they deem it useful, applicants may enclose a letter of recommendation from their organisation with their application.

Criteria designed to ensure a diversity of profiles in working groups and committees

In the constitution of working groups or committees, the HAS is committed to promoting and valuing diversity. Hence, objective conditions relating to the constitution of a group of experts or a body are used, when analysing applications. Consideration is given to gender balance, diversity in terms of place of residence, socioeconomic criteria, age, size of the organisation of which the applicant is a member if applicable, etc.

Once their application has been accepted and their participation confirmed, users can, firstly, be supported by members of the HAS to obtain information and be referred to validated sources of information and, secondly, like any expert, have access to the HAS' documentary and bibliographical resources to inform their understanding of a context or to form an opinion.

> The HAS can set up specific training for users and has published guides aimed at users to facilitate their participation (Appendix 6. Key figures for the involvement of users and people requiring assistance in the activities of the HAS since 2019).

18 In the context of user representation, in a decision of 26 April 2018, the Council of State specifies that "it follows from the provisions of Article L. 1114-6 of the French Public Health Code cited in point 1 that the *Union nationale des organisations agréées d'usagers du système de santé* [French national union of accredited healthcare system user organisations] is authorised to represent users in dealings with the public authorities, although this authorisation does not deprive the approved organisations of the rights conferred on them by virtue of Article L. 1114-1 of the same code, in particular that of putting forward candidates to represent health system users." Note: a survey carried out in 2022 among HAS project managers revealed that those who had published calls for applications to include users in their working groups were rarely in a position to make a choice because the responses to the calls for applications made did not result in enough applicants, in relation to the number of places open to users, for a genuine selection process to be put in place.

2.3. Being consulted

2.3.1. Stakeholder hearings

For some of the HAS's work, the contribution of healthcare professionals, users or stakeholders representing them may be sought in the form of a hearing before a working group or committee. Individuals being heard as a stakeholder must be aware of their organisation's interests linked to the industry players and professionals involved in the research and must be able to disclose them during the hearing process.

The purpose of the hearing is to collect the points of view of interested parties, to obtain information and feedback on the advantages and disadvantages perceived by users for a medicinal product, a medical device, a health technology, a care or support strategy or for a pathway, in particular through the experience of users: it takes into consideration the user experience of living with a disease or a particular social situation.

Any patient organisation can be consulted, whether accredited or not. In some cases, a group not constituted as an organisation may also be consulted. An organisation or group directly concerned by the forthcoming decision (and interested in acting) may ask to be heard, but the decision to consult this stakeholder remains with the HAS committee or working group.

2.3.2. Within a stakeholder committee

The HAS has set up permanent committees for dialogue with the stakeholders with whom it collaborates within the scope of some of its missions.

The purpose of these committees is to lay the foundations of the relationship, to exchange views on assessment procedures and their evolution, to clarify the arrangements for discussions between stakeholders and the institution and, if applicable, to ensure the follow-up of shared strategic directions or to perform a retrospective analysis of the work progress.

In the context of specific themes, interface committees are made up of HAS members and stakeholders of the same nature (e.g. pharmaceutical companies).

When dealing with transverse issues, consultation committees are composed of HAS members and a variety of different types of stakeholders (federations of public or private health or social and medico-social services or institutions, multi-professional organisations, professional societies, organisations or groups of people concerned, etc.). These committees may include the participation of user or people requiring assistance organisations as stakeholders only.

In a stakeholder committee, stakeholder user organisations and groups express their collective interest and are represented by their chairpersons or any person appointed to represent them.

A list of stakeholder committees can be found in Appendix 7. List of stakeholder committees

2.3.3. Written contribution for health products assessments for reimbursement purposes

An organisation may contribute to the assessment of a medicinal product or medical device for reimbursement purposes or public funding cover.

It can transmit information that it deems useful to the HAS assessment committees (transparency committee, national committee for medical device assessment and economic and public health evaluation committee).[19]

Any patient or user organisation, whether accredited or not, can submit a contribution using the dedicated questionnaire. Only one contribution per organisation is accepted.

Contributions by individual patients or carers are not accepted. Individuals wishing to provide information for a particular assessment are invited to approach/engage with patient and user organisations.

The contributions involve medicinal products and medical devices for which an assessment is scheduled for inclusion in the list of reimbursed medicinal products[20] or early access medicinal products.[21]

For medical devices, only devices registered under a “brand name” are concerned, i.e. products that are innovative or that may have an impact on public health spending.

> Find out more
>
> Two guides and a training document aimed at organisations have been developed:
>
> - Contribution of patients’ and users’ organisations to the assessment of medical devices (29)
> - Early access to medicinal products (30) [in French]
> - Understanding health technology assessment: training document for patient and user organisations (31) [in French]
>
> For the list of health products currently undergoing assessment:
>
> - Medicinal products, consult the page “Contributing to the assessment of medicinal products for their future reimbursement or an early access authorisation” (32) [in French]
> - Medical devices, consult the page “Contributing to the assessment of medical devices” (33) [in French]

2.3.4. Individual interviews

An individual or qualitative interview is a open or structured survey technique that gives access to information from the experiences, thoughts and/or perceptions of each interviewee.

The objectives are usually to gather the experience and motivation of a target population and to understand its behaviours. This is to identify interesting phenomena, explore a theme, and raise new questions.

19 For more information, consult the page: https://www.has-sante.fr/jcms/c_2666630/fr/contribuer-a-l-evaluation-des-medicaments-et-des-dispositifs

20 Article R. 161-71 of the French Social Security Code specifies: “The *Haute Autorité de santé* [French National Authority for Health] may invite patient and health system user organisations to contribute to the assessment of medicinal products and the products or services mentioned in articles L. 165-1 and L. 165-11. To this end, it shall inform the organisations, in particular via its website, of the purpose and scope of the assessment for which a contribution may be submitted. The procedures for collecting contributions are defined by the competent specialised committee at the HAS.”

21 Article R. 5121 -69-1 of the French Public Health Code specifies: “In addition, the HAS and, if applicable, the French National Agency for Medicines and Health Products Safety (ANSM) may invite the holder of the operating rights or its representative, any patient or healthcare system user organisation or any other stakeholder to be heard during the assessment process or to submit their written contributions and, on this occasion, transmit to them the draft therapeutic use protocol proposed by the holder of the operating rights or its representative.”

Any user can be approached for an individual interview, whether or not they are a member of an organisation. It is the people steering the project who determine the profile of the people they are looking for and who are responsible for contacting the people they will talk to.

As a general rule, the user profiles sought concern direct experience with a specific medical or social situation, or even indirect experience (e.g. carer, volunteer working with a specific population, etc.). A diversity of respondents and perspectives is systematically sought.

2.3.5. Group interviews (focus group)

A focus group is a qualitative semi-structured group interview technique designed to gather in-depth information in a short period of time. It is not intended to resolve differences of opinion or reach a consensus.

The objectives are multiple:

- to gather the perceptions, concerns, needs and expectations of one or more of the populations concerned without aiming to validate any one hypothesis rather than another;
- to encourage free and open communication, albeit guided by pre-defined questions around the themes of the project;
- to identify the main opinions of the participants, points of convergence and divergence within the group or between groups (e.g. by cross-referencing information from a patient group and a professional group);
- to provide information for the development of additional quantitative surveys or questionnaires or to guide a document search or clarify the scoping phase of a subject;
- to pre-test an informative tool in order to optimise it.

The group put together needs to be homogeneous. Participants (between 6 and 12) are selected via a call for volunteers on the HAS website or through an external provider. In the latter case, the names of the group members may not be made known to the HAS.

In addition to these tried and tested focus group techniques, discussions with groups of patients or people requiring assistance can take place, particularly when it is a question of reaching groups of people in vulnerable situations or who are excluded from the health system, in order to better understand their expectations.

> Find out more
>
> - Public and patient involvement in the context of the development of best practice guidelines in the social and medico-social care sector (22)

2.3.6. Written opinion concerning the intermediate version of a document

The HAS regularly asks reviewers, users and professionals or stakeholders to give an opinion on the intermediate version of a document, in particular to assess its clarity and acceptability (e.g., recommendations, guides, questionnaires, etc.).

Review groups are made up of people who respond on their own behalf, in order to review documents before their final validation by the HAS. Reviewers are invited to apply via the HAS website or through their organisations. The latter can be solicited directly by the HAS in order to propose users who will participate in the review. No compensation is paid for this participation.

Applications are analysed by the project manager responsible for coordinating the project.

As regards users, if there are too many applications, which is rare, the selection is made mainly by seeking a maximum diversity of reviewers, whether social, geographical or in terms of experience, in view of the situation being assessed. The opinion of people with no expertise in the subject matter may be sought, especially when the target population is a general population and not a specific one.

Users are then invited to comment and suggest corrections based on documents drafted by a working group or project team within the HAS.

The review group gives a formal opinion on the content and form of the initial version of the documents created. Members give an advisory opinion in their individual capacity.

The comments of the review group and their possible ratings are then analysed and discussed by the HAS working group or project team, which drafts the final version of the recommendations or guidelines, before submission to the HAS validation bodies.

Sometimes, the HAS wants to obtain the opinion of stakeholders. In this case, it approaches the chairs of user organisations, professional societies, or other bodies, in order to obtain the potential comments of these interested parties.

2.3.7. Public consultation

Public consultation is a process during which, on the basis of a draft working document (or the statement and indication of a technology to be assessed), the HAS solicits, collects and analyses the opinions and comments of a public from which it does not select the participants (34).

The aim is to collect opinions and comments on a draft version of recommendations or assessments that will make it possible to:

- identify new elements to be taken into account, in particular data relating to practices or experiences, additional areas for assessment;
- measure the clarity and acceptability of the text;
- identify the obstacles and levers for the implementation of practices;
- analyse and, if necessary, adjust the text issued for consultation or the decision.

The HAS defines the public whose opinion it wishes to collect in advance (individual or institution/organisation interested in or concerned by the theme, in the immediate or longer-term future). When the number of expected responses may be high, the target audience for the public consultation may be limited to organisations (patient or user organisations, health or medico-social institutions, etc.) in order to collect a collective opinion per organisation. The principle of public consultation is that any individual or organisation meeting the criteria defined during the scoping phase of the project can participate, with no restrictions on participation. In this respect, it differs from review groups where participants are proposed to the HAS and then selected.

In practice, the draft version of a recommendation or assessment is posted on the HAS website for six to eight weeks during the external review phase. This version is accompanied by an electronic form via which anyone wishing to participate in the public consultation can submit their opinions or comments. This form, adapted on a case-by-case basis depending on the project, includes comment areas and may include open and/or closed questions.

The HAS may opt to delegate this consultation process to an external service provider.

This method and the public hearing method enable a public debate to be organised.

> Find out more
> - Method for the organisation of public hearings (35) [in French]
> - Public consultation method (36) [in French]

2.3.8. Practice surveys and calls for contributions

The HAS calls for contributions are intended to provide content on issues that are little or not addressed in the literature.

These are qualitative online surveys to gather the views of users and professionals or to find out about their practices relative to a specific subject.

Therefore, the aim of these surveys is not to obtain figures applicable to all institutions, but to provide elements for a better understanding of practices.

2.3.9. User tests

A user test consists of observing and interviewing the target users of a product, particularly written documents or digital tools, in order to understand their real needs and identify any difficulties in their usage that may arise.

The objectives of user tests are, for example:

- for a digital tool: to observe the behaviour of visitors to a website or a digital application, to get feedback on how sites or applications are used, to find out how visitors interact with a site based on one or more defined scenarios via a panel of testers, to validate whether a concept is easy to understand, to assess browsing experience quality, to detect any anomalies that need to be corrected and to collect suggestions from testers in order to improve the product;
- for a written document: to obtain information on the readers' understanding, the acceptability of the text or illustrations, any missing elements required to complete the information delivered, etc.

2.3.10. Vox pop

This communication practice consists in conducting a very brief interview of targeted people, consisting of one or two questions, usually in the street, in order to collect spontaneous opinions which will be used to improve a message of communication.

Anyone may be concerned by a vox pop, depending on the communication topics.

2.4. Referral to the HAS

Only organisations can submit a referral to the HAS to request work in two ways: requests to include work in its work programme or in application of the right of alert.

2.4.1. Request for inclusion in the work programme

Each year, the HAS determines it work programme based on public health priorities. To this end, it maintains a dialogue with the Ministry of Health, the French National Health Insurance, healthcare

professionals and patient and health system user organisations (health, social and medico-social fields).

Organisations representing users of the health system or social and medico-social services and institutions, as well as national professional boards or professional societies of which they are members, may propose work themes to the HAS in the fields in which they are involved, as provided for in the HAS Board's internal regulations (37).

Requests for inclusion may concern the drafting of:

- recommendations on the validity and conditions of reimbursement for a set of treatments or categories of products or services and, where applicable, the associated care protocols; this type of request, which falls within the scope of periodic assessment of the expected clinical benefit of health products, procedures or services and of their actual clinical benefit, may only be formulated by patient and user organisations that are nationally accredited to represent users in hospital or public health bodies (article R. 161-71 of the French Social Security coded);
- best practice guidelines or recommendations for healthcare professionals or professionals in the social and medico-social sector;
- any other topic relating to the quality and safety of care or social support, falling within the remit of the HAS.

The HAS is not in a position to handle all the requests submitted to it. In its yearly work programme, requests from the public authorities and the French National Health Insurance also need to be processed within set time-frames.

The work programme for the year is published on the HAS website at the start of the year and updated in July (28). The procedures for referral by organisations are also specified on the site.

> Find out more
>
> Each year, in the spring, the HAS publishes on its website the opening date for applications for inclusion (38) and the application form for inclusion in the work programme by patient and user organisations. The closure of applications is generally at the start of summer.
>
> Organisations may request the support of the public involvement department[22] if necessary.

2.4.2. Exercising the right to alert

The right to alert, defined by Article L. 161-37 of the French Social Security Code, allows accredited patient and health system user organisations to refer to the HAS “any fact with a significant impact on health, requiring the HAS to use its powers as defined in this chapter”. Only organisations accredited in accordance with article L. 1114-1 of the French Public Health Code may exercise this whistleblowing right.

If the right to alert case is admissible, it is investigated by the HAS services. This stage does not prejudge the outcome of the referral, particularly when it concerns an area that does not fall within the scope of the HAS’ expertise.

22 To contact this department: https://www.has-sante.fr/jcms/p_3148563/fr/contact

After examining the request, the HAS Board rules on the admissibility and competence of the HAS to deal with the right to alert case. It specifies the action taken and, where appropriate, whether a hearing of the organisation or any other interested party is envisaged.

In the event that the HAS is not competent to investigate the right to alert case referred to it, it may refer the organisation to the institutions or bodies that it considers competent.

The HAS undertakes to investigate right to alert cases within two months and publishes its decisions on its website (39).

2.5. Being an institutional partner

Being an institutional partner implies the signature of an agreement between the HAS and another legal entity.

Cooperation agreements exist between the HAS and certain institutions in order to promote the development of exchanges on methods, the sharing of experience and the joint production of certain works. These exchanges are subject to an agreement or convention which are available on the HAS website (40). The tasks of each of the parties are then fixed in advance before the agreements or conventions are signed. The partnership is built around joint concerns with the aim of pooling the results of a project and shared communication.

The HAS may also sign partnership agreements with certain non-commercial organisations (professional societies, user organisations) in order to carry out a joint project falling within the scope of the HAS' missions.

> Examples
>
> - Survey of women having undergone mastectomy following cancer, conducted in partnership with the INCa (French National Cancer Institute) and the Seintinelles organisation
> - Drafting of the document given to the families of a newborn concerning neonatal screening tests, carried out in partnership with the French National centre for the coordination of neonatal screening

3. Participating in the HAS' quality mechanisms in health, social and medico-social institutions

The HAS pilots several quality assessment mechanisms in health, social and medico-social services and institutions, in which users may participate. For example, they can give their individual opinions following a hospitalisation, or a collective opinion in the case of a healthcare institution certification process or the assessment of social and medico-social institutions.

3.1. Collection of experience and satisfaction data

Since 2016, the HAS has run the e-Satis survey, a continuous national survey to measure hospitalised patient satisfaction and experience. The questionnaires are adapted to the type of stay (either more than 48 hours in medical, surgical and obstetrical departments, or outpatient surgery (AC), or during follow-up and rehabilitation care (SSR)). They aim to collect the patient's point of view during the important stages in the care pathway: admission, inpatient care, and discharge. Other questionnaires are being developed for hospitalisation in the home or in psychiatric units.

In practice, two weeks after discharge, patients who have agreed to provide their e-mail address to the healthcare institution receive an e-mail containing a unique, individual and secure link enabling them to log onto the online e-Satis questionnaire. They have up to 10 weeks to complete the questionnaire after receiving the link. Each healthcare institution has access to its detailed results, enabling it to assess its strengths and weaknesses. The results are also accessible to the public evaluated by a score out of 100, on **QualiScope,** the public information service on the level of quality and safety of care measured by the HAS in all public and private hospitals in France.

The e-Satis questionnaires were developed by working groups composed of equal numbers of professionals and users as experts. The working groups are also involved in the follow-up and any revisions made to the questionnaires.

This process has been defined in accordance with the General Data Protection Regulation (GDPR).

> Find out more
>
> Educational video
>
> Leaflet: Quality of care – We value your opinion (41) [in French]
>
> QualiScope can be used to compare quality results between several public and private hospitals (42) [in French]

3.2. Participation in healthcare institution certification

In place for more than 20 years in France, certification is a compulsory independent assessment procedure for the quality and safety of care in public and private healthcare institutions. It is conducted every four years by professionals (peers) appointed by the HAS (surveyors).

User representatives, from accredited organisations, have been involved in the healthcare institution certification mechanism since 2005. This expertise, acquired through the exercise of a user representation mandate in a healthcare institution, is necessary to participate in the HAS' certification work.

At the HAS, in the context of development of the new certification campaign (2020-2021), a specific working group has been set up to develop practical guides to enable user representatives to be involved throughout the process, from preparation to follow-up of certification (43).

Thus, user representatives have a genuine role to play in the preparation of certification within institutions and during surveyor visits.

Finally, users participate in the preparation of certification decisions within the HAS committee in charge of certification, which includes three users with significant experience as user representatives within a healthcare institution.

> Find out more
> - User representatives in the quality of care certification process (44) [in French]
> - Quality of care certification: webinar dedicated to user representatives – 7 Dec. 2020, HAS webinar in partnership with France Assos Santé (45) [in French]
> - User representatives and certification: taking action for the quality of care – FAS/HAS webinar – May 2022 (46) [in French]

3.3. Participation in assessment of the quality of social and medico-social services and institutions

In 2022, the HAS published the first national guideline for the assessment of quality in social and medico-social service and institutions (ESSMS), along with the manual specifying the application conditions. This guideline, focusing on the people requiring assistance, aims to promote a continuous quality improvement process for the benefit of people requiring assistance.

At the HAS, in the context of the development of the assessment system, people requiring assistance and their representatives participated in the various working groups.

In the context of the assessment of social and medico-social institutions, people requiring assistance are also involved, firstly, in the context of the assessment outlined in Chapter 1 using the tracing method and, secondly, during a meeting between the assessor and social council members, the procedure for which is set out in practical guide 6 "Guide to interviewing Social Council members" on p. 194 of the manual (47).

Finally, they participate in the monitoring of the implementation of the mechanism within the HAS' social and medico-social committee, which includes four people requiring assistances as users of the social or medico-social system.

> Find out more
> - About the Social and medico-social committee (CSMS) (48) [in French]
> - Understanding the new mechanism for the assessment of quality in social and medico-social services and institutions (ESSMS) (49) [in French]

4. Recognising and valuing public and patient engagement

Various actions can be used to recognise and value user involvement at the HAS. The following proposals do not constitute an exhaustive list.

4.1. Citing the individuals concerned

A fair way of acknowledging the work carried out by users is to name them in the documents resulting from the work in which they participated. Moreover, transparency is one of the HAS' three core values. Hence, the institution is keen that all the work it carries out, along with the methods used, should be made public. Similarly, the people who have contributed to a decision or work process should be named, with some exceptions, and their affiliation clearly stated when they are involved as stakeholders.

However, for users and persons concerned, this principle of transparency may conflict with the principle of privacy or medical confidentiality. In fact, membership of a group or organisation can, at least indirectly, reveal information about the individual or a relative that is private. For example, if a health system user is a member of a transplant patient organisation, this may indicate that they have received a transplant. A balance must therefore be struck between transparency, which implies giving the names and affiliations of the participants in the work and respecting the wishes of the users and individuals concerned not to make public their state of health or that of one of their relatives. The HAS therefore reflected on the best way of naming users and persons concerned who participate in its work and its Public involvement council has issued an opinion (50). In particular, the Council indicated that a generic term should be used that respects the privacy of individuals, not linking the name of the person with their situation. For example, the terms "patient", "person with a disability" or "vulnerable person" should not appear next to the name of the individual participating in the work of the HAS; the terms used to name the individuals participating in the work of the HAS should also be adapted to the context of this work.

In view of the different positions and the requirements of the European General Data Protection Regulation (GDPR), the HAS proposes to name users by their first and last names and to add the words "health system user" or "social or medico-social system user". When a user participates in the work of the HAS as an expert, i.e. in an individual capacity, the name of the organisation or group to which they belong will not be mentioned alongside their name.

If a user feels that there is a significant risk of disclosure of their health status or condition, they may ask not to be named in the document in which they participate.

In the context of work where stakeholders, user organisations, professional societies, professional organisations and groups have been consulted or have proposed the participation of one or more users, they are cited at the end of the documents produced.

> In practice:
>
> - "Participants" section of all HAS documents
>
> The following professional bodies and patient and user organisations were consulted to propose experts invited individually to take part in working/review groups:
>
> - organisation x; organisation y, professional society x, etc.

- “Working group” section:
    - Ms Sophie Dupont, health system user
    - Mr Claude Durand, social or medico-social system user

4.2. Facilitating validation of acquired experience (VAE)

Some users may wish to have their experience acquired within HAS bodies or working groups validated. In practice, the validation of this experience within the HAS does not depend on the HAS but on certifying bodies. It is the latter who decide on a case-by-case basis whether to accept this experience for certification of acquired experience. he HAS is able to issue a certificate confirming the users' participation in one or more of the HAS work processes or a letter of recommendation to access a qualifying training programme.

Example

A woman who is a member of a committee wants to validate her acquired experience in order to obtain a state diploma in social engineering.

She contacts the HAS so that the skills used within the committee in terms of expertise and advice, design and development or assessment can be transmitted to the organisation validating her acquired experience.

4.3. Involving users in the promotion of HAS work

Users and people requiring assistance can be involved in the dissemination of the work through their network and may participate, alongside the members of the HAS, in promoting the work in which they are involved. Their testimonies relating to their participation are very useful in terms of valuing their involvement and encouraging further involvement. Finally, the promotion of the HAS’ work involving several different perspectives - professional and users experts, HAS members - highlights the drive to encourage user involvement and successful collaboration between experts, professionals and users.

In practice:

- Following publication of the HAS’ work, users who have participated in the work can disseminate it within their own organisations or networks, contribute to a communication at a conference or a publication in a journal, participate in a press conference, etc.
- Practical guide “Participating in the work of the HAS as an expert: what communication is possible? ” (51) [in French]

5. Evaluating public and patient involvement at the HAS

Although the involvement of users and people requiring assistance in the work of the HAS is not intended to be systematically evaluated, its evaluation must nevertheless be regularly envisaged, both to ensure that its benefits are effective and to optimise this involvement.

Different arrangements may be put in place. For example:

- an evaluation during or at the end of the work; project managers can ask all the experts involved in the project to evaluate their perception of the progress of the work and the quality of the discussions within the group. The objective is then to explore solutions to improve the expert participation is appropriate;
- an annual institutional evaluation, a period of time after participation in the work, provides a broad picture of user involvement and the overall time per year spent by users on HAS work and their perception of their involvement in the work of the HAS. This type of evaluation is carried out by the public involvement department;
- an evaluation in the context of a specific study, in particular following an experimental phase; this type of study, whether retrospective or prospective, may lead to publication (52).

> The public involvement department can also be contacted[23] in the event of difficulties encountered by an expert user or a people requiring assistance in order to remove obstacles or answer questions and to identify levers for action, in conjunction with the department concerned.

[23] To contact this department: https://www.has-sante.fr/jcms/p_3148563/fr/contact

6. Review and updating of the guide

Involvement practices are likely to evolve as society changes. Therefore, this guide is not set in stone and should not be an obstacle to greater public and patient involvement in the work of the HAS. Innovations in this field are anticipated in order to maintain the momentum for user involvement; all those concerned by this guide are invited to contribute.

In addition, since regulations are constantly changing, the arrangements for public and patient involvement may have to evolve.

An evaluation of this guide - and its revision if necessary - will take place at the latest five years after its publication.

Table of appendices

Appendix 1. Method of production

– **Project scoping**:
  - discussions with the members of the public involvement council during the scoping phase of the updating project to identify expectations and specify the scope of the future cooperation guide (meetings on 22 October 2019 and 7 January 2020);
  - submission of the scoping document to the HAS Board for its opinion on 8 January 2020;
  - project launch delayed due to the Covid health crisis in 2020-2021.

– **Presentation at the first user engagement meeting** on 29 September 2020 of the various public and patient involvement methods implemented at the HAS and the results of the satisfaction survey of users having participated in the work of the HAS in 2019, followed by an exchange with the webinar participants.[24]

– **Bibliographic review**:
  - analysis of legislative and regulatory texts performed by the HAS legal department;
  - benchmark of public and patient involvement practices in various agencies in France and internationally on the basis of public data accessible on the agencies' websites (ANSES, ANSM, SPF, ABM, EFS, IRSN, INCa, NICE, KCE, INESSS, CADTH, SBU, EUNEHTA, etc.);
  - HAS publications related to public and patient involvement (Appendix 6).

– **Setting up of a mixed working group (HAS/users)** in October 2021, tasked with drafting the new cooperation guide:
  - call for applications published on the HAS website;
  - relaying of the call for applications by the social media;
  - relaying of the call for applications by France Assos Santé and by the 390 users having participated in the work of the HAS in 2021 (from 148 different organisations);
  - targeted communication of the call for applications aimed at organisations present in the elderly sector;
  - the call for applications resulted in 34 applications, including from members of a variety of organisations, such as AFSEP, Spondyl(o)action, Renaloo, CSF, AD PEP 45, Aides, On est là !, Organisation française du syndrome de Rett, Organisation française pour la recherche sur l'hidrosadénite, Respire à cœur, FFAIR, Blabl-Aphasie, AFM, HANDEo, France Rein, Organisation des sclérodermiques de France, Jusqu'à la mort accompagner la vie, Repairs ! 94, ADEPAPE, AFA Crohn, RCH France, Psy'activ, Apsyade, UNAFAM, Familles rurales, Coopération patients, Vivre sans thyroïde, Alliance maladies rares, Résist and Prévention suicide.

– **HAS Board working meeting** presented the situations identified during the work that could be the subject of practice changes within the HAS (17 March 2022).

– **Presentation of the working group's conclusions** for discussion at the public involvement council on 5 April 2022.

24 *Haute Autorité de santé*. User engagement meeting. 29 September 2020. https://www.has-sante.fr/jcms/p_3148556/fr/rendez-vous-de-l-engagement-des-usagers [consulted on 29 November 2021]

- **Public consultation process open to organisations and user groups** (53) and internal review to gather comments on the initial version of the updated cooperation guide (5 July-17 August 2022).

- **Finalising of the guide** by the working group and the HAS project team (October 2022).

- **Presentation of the finalised guide** for discussion at the public involvement council on 11 October 2022.

- **Deliberation of the Board** and communication actions (October to December 2022).

Appendix 2. HAS bodies – Applicable legal texts

I. Regulated committees

▪ Committee for the assessment and improvement of the quality of social and medico-social services and institutions

– Article R. 312-207 of the French Code for social action and families (CASF)

The Committee for the assessment and improvement of the quality of social and medico-social services and institutions is composed of twenty-five full members with voting rights, appointed by decision of the HAS Board, including four members chosen from among the members of an organisation of users of a social or medico-social institution or service mentioned in Article L. 312-1[25] and two substitute members called upon to replace the full member(s) appointed under the same conditions.

– Internal regulations of the Committee for the assessment and improvement of the quality of social and medico-social services and institutions

▪ National committee for medical device and health technology assessment

– Article R. 165-18 of the French Social Security Code

The National committee for medical device and health technology assessment is composed of twenty-two full members with voting rights, including two members chosen from among the members of an organisation of patients and health system users mentioned in article L. 1114-1 of the French Public Health Code (CSP)[26] and a substitute member who can be called upon to replace them under the same conditions.

– HAS Board Decision No. 2022.0168/DC/SJ of 25 May 2022 adopting the internal regulations of the national committee for medical device and health technology assessment

▪ Transparency committee

– Article R. 163-15 of the French Social Security Code

The transparency committee is composed of twenty-two full members with voting rights, including two members chosen from among the members of an organisation of patients and health system users mentioned in article L. 1114-1 of the French Public Health Code (CSP) and a substitute member who can be called upon to replace them under the same conditions.

25 Article L. 312-1 of the CASF draws up a list of the 16 categories of social and medico-social institutions concerned.

26 Article L. 1114-1 of the CSP "I. – Organisations, which are regularly declared, with an activity in the field of the quality of health and patient care can be the subject of accreditation by the competent administrative authority on either a regional or national level. Accreditation is granted following the approval of a national committee comprising representatives of the State, including a member of the administrative court and a member of the court of appeal, either in active service or honorary, a member of the French parliament and a senator and their substitutes, as well as persons qualified by their expertise or experience in the associative field. Accreditation is subject, in particular, to the organisation's effective and public activity in defending the rights of patients and health system users, as well as to the training and information activities it carries out, the transparency of its management, its representativeness and its independence. The conditions for accreditation and withdrawal of accreditation, as well as the composition and operation of the national committee shall be determined by Council of State decree. Only accredited organisations represent health system users in hospital or public health bodies. II. – User representatives in the bodies mentioned in I shall undergo basic training delivered by the user representative organisations accredited under the terms of the same I.

This training shall comply with a set of specifications. The specifications as well as the list of organisations delivering the training are decreed by the Minister of Health.

This training entitles the user representative to an allowance paid by the organisation providing the training A decree determines the arrangements according to which a public subsidy is allocated to the organisation for this purpose. An order of the Minister of Health sets the amount of this allowance."

– HAS Board Decision No. 2022.0168/DC/SJ of 25 May 2022 adopting the internal regulations of the transparency committee

▪ Economic and public health evaluation committee

– Article R. 161 161-71 of the French Social Security Code

The economic and public health evaluation committee is composed of twenty-two full members with voting rights, including two members chosen from among the members of an organisation of patients and health system users mentioned in article L. 1114-1 of the French Public Health Code (CSP) and a substitute member who can be called upon to replace them under the same conditions.

– HAS Board Decision No. 2022.0168/DC/SJ of 25 May 2022 adopting the internal regulations of the economic and public health evaluation committee

II. Non-regulated committees

▪ Technical vaccination committee

– HAS Board Decision No. 2022.0189/DC/SEESP of 23 July 2020 adopting the internal regulations of the technical vaccination committee

The internal regulations stipulate that the committee is composed of twenty-eight members with voting rights, including two members chosen from among the members of an organisation of patients and health system users mentioned in article L. 1114-1 of the French Public Health Code (CSP).

▪ Guidelines impact committee

– HAS Board Decision No. 2021.0208/DC/DCIEU of 26 August 2021 adopting the internal regulations of the guidelines impact committee

The internal regulations stipulate that the committee is composed of twenty-two members with voting rights, including four members chosen as user representatives, recruited for their experience in the health, social or medico-social sector.

▪ Guidelines, relevance, pathways and indicators committee

– HAS Board Decision No. 2022.0290DC/SJ of 8 September 2022 amending the internal regulations of the guidelines, relevance, pathways and indicators committee

The internal regulations stipulate that the committee is composed of twenty-one members, including two members chosen as members of an organisation of health system users.

▪ Healthcare institution certification committee

– HAS Board Decision No. 2020.0199/DC/SCES of 17 September 2020 adopting the healthcare institution certification committee

The healthcare institution certification committee is composed of twenty-one members with voting rights, including at least two permanent committee members chosen from among the members of an organisation of patients and health system users mentioned in article L. 11141 of the French Public Health Code (CSP).

III. Board

- HAS Board Decision No. 2022.00182/DC/SJ of 16 June 2022 amending the internal regulations of the Board. French Official Journal, 19 October 2022 (243)

Point 1.2.2: "The College decides on its work programme each year following a procedure conducted in consultation with the Ministry of Solidarity and Health and the French national health insurance fund. Requests for inclusion in the work programme received from institutions and bodies qualified to consult the HAS, in accordance with article R. 161-71 of the CSS concerning the periodic assessment of the expected clinical benefit of health products, procedures or services.

At the exclusive request of the Minister for Health, referrals may be included outside the annual review of the work programme, and their inclusion may lead the Board to modify its initial work schedule.

Organisations representing users of the health system or social and medico-social services and institutions, as well as national professional boards or professional societies of which they are members, may propose work themes to the HAS.

If the Board refuses to include work in its work programme, it shall inform the applicant of the reasons for this refusal."

Point 1.6: "The Board may consult any qualified individual or expert that it deems useful. Following the presentation of the report, any hearings of experts and debates, the Board deliberates."

IV. Public involvement council

- HAS Board Decision No. 2018.0237/DC/DG of 12 December 2018 creating the Public involvement council
- HAS Board Decision No. 2019.0042/DC/DG of 27 February 2019 amending Decision No. 2018.0237/DC/DG of 12 December 2018 creating the Public involvement council

The Public involvement council is composed of nineteen members appointed by decision of the HAS Board, including nine members chosen to represent patients, persons receiving care, the public and citizens, with experience within the health, social or medico-social systems, whether or not involved in an organisation.

Appendix 3. Role of users in HAS bodies

Find out more about HAS bodies

Consult the expert guide (18) or the Organisational structure of the HAS page

Appendix 4. Health expertise – Applicable legal texts

On a European level

- 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
- EUnetHTA: Guidance for the interaction with patient representative, healthcare professional and other experts

On a national level: health expertise charter

- French decree No. 2013-413 of 21 May 2013 approving the health expertise charter provided for in article L. 1452-2 of the French Public Health Code

Procedure implemented within the HAS

- HAS Board Decision No. 2014.0115/DC/MJ of 28 May 2014 adopting the stakeholder consultation procedure
- Ethics charter adopted by the HAS board on 19 November 2008
- Guidelines for the declaration of interests and management of conflicts of interest amended by decision of the HAS Board on 15 March 2017. These guidelines are in the process of being revised. A new version is set to be published during the first half of 2023

Appendix 5. Momentum concerning pillar 2 of the HAS 2019-2024 strategic plan

Since 2019, the momentum to encourage public and patient involvement in the HAS been organised around a body, a department, and a group of cross-functional resource persons.

Public involvement council

The public involvement council is a permanent group offering support and resources to clarify the institution's work. It is designed as a place for reflection and discussion bringing together various types of expertise, in order to promote the involvement of patients and persons supported within the health, medico-social and social system (54).

The public involvement council was created by decision 2018.0237/DC/DG of 12 December 2018 (54). The missions set are as follows:

- accompany, support and assess all the HAS' actions to encourage health engagement;
- contribute to consideration of the ethical issues that may arise in the context of HAS assessment or guideline work;
- contribute to progress through its work, in terms of health engagement in the French health system, including within the HAS;
- initiate, with the collaboration of the relevant scientific and institutional bodies, a health engagement observatory;
- provide an opinion on the subjects that the Board deems useful for the preparation of its deliberations, in particular concerning requests for inclusion in the work programme and the whistleblowing right formulated by organisations of patients, people requiring assistance or users;
- inform the Board in the event of any difficulties encountered in the implementation of HAS actions aimed at encouraging health engagement.

It is made up of eighteen members, including nine health, social or medico-social system users, and a chairperson, who is a member of the HAS Board (55), along with three vice-chairs, forming the bureau (56).

In accordance with the principle of adaptation, a review of this initiative will be organised in the course of 2024 to inform the HAS' reflection process and decide whether this trial format should continue or evolve.

> Find out more
> Consult the public involvement council's activity reports

Public involvement department (SEU)

The public involvement department was created in 2019 by decision 2019.0030/DP/SG in order to coordinate and oversee public and patient involvement in the HAS' different missions.

Its missions are to:

- define the context for collaboration between the HAS and society;
- provide methodological support to HAS teams and test new forms of public and patient involvement;

- coordinate the user information policy in the context of the work programme;
- lead the drafting of documents to aid shared decision-making;
- organise institutional relations with user organisations;
- investigate whistleblowing cases submitted by user organisations;
- respond to individual user requests, working in collaboration with the departments concerned.

It is available to users and HAS members who encounter any difficulties in their relations during the course of work and aims to facilitate exchanges with other departments, in a form of arbitration if necessary.

> Contact the public involvement department[27]

User involvement advisers

User involvement advisers are employees within each HAS department mobilised as contact persons who their colleagues may contact for any questions concerning user involvement in the work of their respective departments. They meet every two months.

They are required to work in a transversal manner with the other members of this group and with the HAS public involvement department.

Their mission:

- to support HAS professionals in charge of projects when user involvement is sought;
- to be a resource to help identify organisations and/or groups in the fields concerned and to consult the public involvement department in order to facilitate the search for concerned users;
- to pool their experience and involvement of users and people requiring assistance and share appropriate methods, if applicable;
- to contribute to consideration of the adaptations that need to be made in order to encourage greater involvement of users and their organisations within the HAS.

[27] To contact this department: https://www.has-sante.fr/jcms/p_3148563/fr/contact

Appendix 6. Key figures for the involvement of users and people requiring assistance in the activities of the HAS since 2019

Each year since 2019, the HAS has been recording public and patient involvement in its departments, committees and councils. At the same time, it conducts an annual survey of contributors in order to collect feedback on their experience and their satisfaction.

In 2021, these user surveys were supplemented by a survey of HAS employees, aimed at better describing the ways in which users are involved in their work and at gathering feedback on their perceptions of this collaboration with users.

Without seeking to be exhaustive, the following data are intended to illustrate what public and patient involvement in the work of the HAS represents.

Involvement that relies on numerous people from a very broad range of organisations

In 2021, 324 different users participated in the work of the HAS, corresponding to 434 contributions; there were 236 in 2019 and 185 in 2020, a year when the Covid-19 pandemic had resulted in changes to the organisation of working groups within the HAS.

The persons having contributed applied using several possible methods: via their organisation (64%), via a call for applications (15%), by direct consultation following a previous project (7%), via professionals (6%), not specified (8%).

They were mostly members of user organisations: 148 organisations, unions or federations of different unions have at least one member who participated in the HAS' work in 2021.

The survey conducted among users having participated in work in 2020 or 2021 (75 respondents/375 participants) shows that 89% of them have organisation involvement; 39% of them also have a user representative mandate or have been elected to a social council.

Involvement in numerous HAS activities, with a high level of engagement

Public and patient involvement is a reality in all of the departments of the HAS.

The survey conducted among HAS project managers in 2021 reveals that 92% of the 66 respondents engaged users to participate in their work, and that this was systematic for 59% of them. 94% agree that public and patient involvement enriches the work of the HAS.

This participation can be for variable periods of time and according to various arrangements (table 1).

Thirty-three users are committee or council members, appointed for a period of between three and five years (Appendix 3), and 28 represented their organisation in the context of stakeholder committees (Appendix 4).

However, most participations are of a shorter duration (e.g. a one-year working group to develop a patient experience questionnaire or a best practice guideline), or even on an ad hoc basis (e.g. review of a scientific document for a professional practice assessment or for an information document for users).

Some types of involvement, such as written contributions for health product assessment, are steadily increasing and now exceed participations in the drafting of guidelines (Table 2).

Table 1. Number of user contributions in 2021, according to participation type

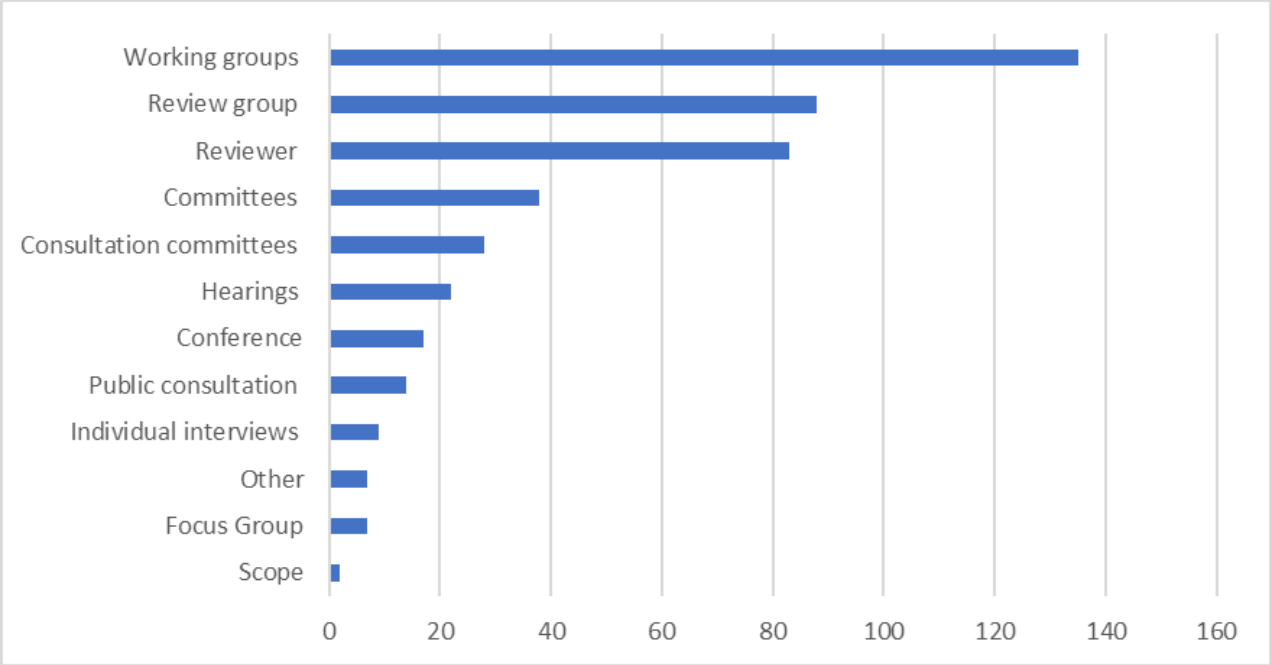
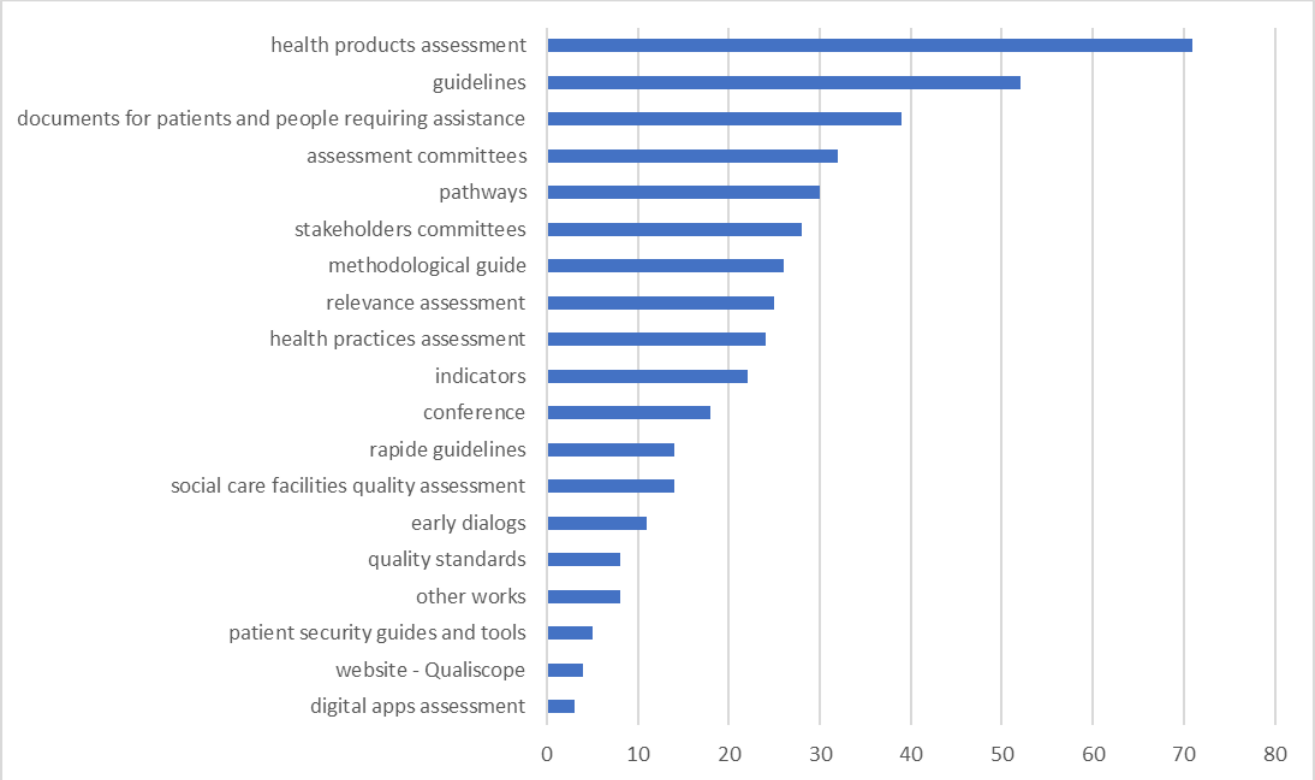


Table 2. Number of participations in 2021 according to the HAS' missions and activities



Users' ease of conveying their point of view

A survey conducted in January 2022 gathered the views of 75 respondents out of 375 users who participated in work in 2020 and 2021.

92% felt that they knew what was expected of them, and 60% felt that they did not need specific training to participate in the work.

82% of them felt comfortable conveying their point of view and participating in discussions.

Project managers and the public involvement department are available to users requiring specific information or support.

Appendix 7. List of stakeholder committees

Committee name	Basis
Consultation committee for the quality and safety of care (CCQSS)	Decision creating the committee of 23 November 2016
Social and medico-social consultation committee (CCSMS)	Decision creating the committee of 27 June 2018
Psychiatric and mental health care committee	List of member organisations, September 2018 (since 2013)
Risk committee between different specialties	Specifications for organisations approved for the accreditation of physicians and medical teams
Interface committee – Medicinal products	Internal regulations, March 2016
Interface committee – Medical devices	Internal regulations, March 2016
Interface committee – Monitoring of the "Increasing public and patient involvement in health technology assessment" roadmap	Roadmap, July 2021

Appendix 8. List of HAS opinions and guidelines made available to users or their organisations fortheir participation in the HAS' work or quality mechanisms

Making user involvement in the health, social and medico-social system a reality

- Supporting and encouraging user involvement (14)
- Opinion of the public involvement council:
  - Improving public and patient involvement in user committees and social councils (57)
  - Covid-19 – User involvement in feedback (58)
  - Covid-19 – Opinion of the public involvement council (59)

Participating in the work of the HAS

- Participating in public consultation (2 pages) (34)
- Participating in a recommendation/guideline in the social or medico-social field (link to come) (47)[28]
- Participating in the assessment of a medicinal product or a medical device
  - For reimbursement in the common law framework (29)
  - For early access authorisation (30)
- Participating in the assessment of a medical device (33)

Participating in the HAS' quality mechanisms

- Participating in the collection of hospitalised patient experience and satisfaction data
  - e-Satis: measurement of hospitalised patient satisfaction and experience (60)
- Participating in quality processes
  - Tracer patients in a healthcare institution (61)
  - Tracer patients in the community medicine setting (62)
- Participating in healthcare institution certification
  - As a tracer patient (63)
  - As a user representative during the certification visit (44)
  - Understanding quality of care certification (64)
  - Certification manual (65)
  - Practical guides aimed at user representatives (43)
- Participating in the analysis of a care-related adverse event (66)
  - Care-related adverse event: the care team would like to hear your story (67)

- Participating in the assessment of social and medico-social services and institutions (47)
  - As person requiring assistance being traced (68)
  - As an elected social council member (69)
  - Understanding the new method for assessment of social and medico-social service and institutions (49)

28 HAS. Methodological guide in the process of being validated – available autumn 2022

Appendix 9. Glossary

The aim of this glossary is to provide a precise definition of the terms used in order to ensure a good understanding of the document as a whole.

Accreditation of patient and health system user organisations

Mechanism provided for by the French law of 4 March 2002, subsequently amended by several laws; its updated version can be consulted in article L. 1114-1 of the French Public Health Code.[29] This accreditation allows organisations to represent users in hospital and public health bodies and to participate in the health policy development (70). Only organisations that meet several specific criteria can apply for accreditation: effective and public activity for at least three years, training and informative activities, representativeness, independence and transparency of management (71).

Accreditation can be granted for representation at regional or national level. At regional level, regional health agencies are responsible for organising and implementing the accreditation system. This allows organisations to be active in local hospital or public health bodies and to participate in Regional health and autonomy conferences (CRSA), which give an opinion on the regional health programme. On a national level, accreditation is issued by the Ministry of Health and allows organisations to participate in the bodies of national institutions, such as the *Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales* (ONIAM - National Office for compensation of medical accidents, iatrogenic conditions and hospital-acquired infections) or the regulated bodies of the HAS which specify it.

The maximum accreditation duration is five years. The list of accredited organisations is publicised by the Ministry of Health (72).

In certain conditions, the HAS is obliged to request the participation of users who are members of accredited organisations[30].

Carer

Person providing assistance to an individual in a situation of dependence and/or disability who is a member of their family or a friend or has been chosen by the person (73).

Collaboration

Participation in the development of a common work (75).

Cooperation

The act of participating (with one or more people) in a common work or action. Help, agreement between members of a group towards a common goal (74).

Citizen

Person acting in their capacity as a member of civic society (73).

Expert

A person who speaks on their own behalf and who is chosen because of their expertise in the field of the work undertaken by the HAS. A user can be considered to be an expert on the basis of their capacity to provide objective experience based on their own experiences and to summarise collective

29 For an updated version of this article, consult the Légifrance website: https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000038314868/

30 Supplemented by a list of regulatory texts requiring accreditation.

experiences. The status/quality of expert may raise doubts for users about their legitimacy compared to professional experts. However, a distinction must be made between user expertise, based on personal and collective experience in relation to a specific medical or social situation, and expertise based on professional training and experience.

Friends/family

Means any person accompanying a patient, regardless of the nature of the relationship between them (73). This definition is extended to persons close to or assisting persons supported by a social or medico-social service.

Legal entity

In French law, a legal entity is a group with legal personality (definition by the National Institute of Statistics and Economic Studies).

Organisation

A non-profit group of persons with similar interests or goals (*Académie française* dictionary). A list of "French law 1901" organisations declared by the prefecture can be consulted via the French Official journal website.[31]

Person requiring assistance

In the social or medico-social sector, the preferred term for the beneficiaries of a social or medico-social service. The latter do not always recognise themselves in the term "user".

Person concerned

Persons designated as "users" or "persons concerned" are people with direct or indirect experience of the disease or the clinical or social situation related to this work (patient, sick person, person with a disability or in a vulnerable situation, family, close friends, peer helpers, voluntary organisations, etc.) (14).

Patient

"Person directly concerned by a preventive, diagnostic or therapeutic act which falls within the scope of their relationship with a healthcare professional. This term excludes their friends or family." (73) This person may be ill or otherwise (e.g. pregnant women, persons requiring a screening procedure, vaccination, a method of contraception requiring prescription, etc.).

Partnership

For the World Health Organisation, a partnership can be defined as a collaborative relationship between two or more parties based on trust, equality and mutual understanding, for the achievement of a jointly agreed goal. Partnerships involve risks as well as benefits, making shared accountability critical (14).

Stakeholder

Group of people, directly or indirectly impacted by the decisions taken, who speak on behalf of that group (4). They may be:

- from the organisation sector;
- economic actors;
- professional actors (industry, learned societies, etc.);
- representatives of the general interest of groups concerned by the consequences of the work.

31 Home page where a search may be launched: https://www.journal-officiel.gouv.fr/pages/accueil/

Représentant des usagers (user representative)

Depending on the health or medico-social field, the arrangements for user representation are different (14).

- Health field: the members of an organisation accredited under the terms of article L. 1114-1 of the French Public Health Code may be designated as user representatives (RU) by the regional health agency (ARS) of their region, upon application, or by the Ministry of Solidarity and Health on a national level. “At each decision-making level of the health system, user representatives play a dual role: to observe this system from the perspective of the user or the persons concerned and to make this specific point of view heard.” (76)
    - In practice, it is not necessary to be a “user representative” within the meaning of Article L. 1114-1 of the French Public Health Code in order to participate in an HAS committee or working group, unless the regulations require it.
- Medico-social field: in social or medico-social institutions or services, people are elected by their peers to represent them and speak for them in the body known as the “social council”.

Society

Community of individuals organised around shared institutions (73).

User

Any person concerned by the use of the health system for themselves or for someone close to them (73). This definition is extended to people supported by a social or medico-social service. However, the latter do not always recognise themselves in the term “user” and the term “person concerned” or “people requiring assistance person requiring assistance” may be preferred.

Participants

The persons referred to below as users are people who have direct or indirect experience of an illness or social situation requiring support from a social or medico-social service or institution (patient, sick person, person with a disability or in a vulnerable situation, family, close friends, peer helpers, voluntary organisations, etc.).

Participants in the working group were invited to apply through a call for applications on the HAS website, relayed by several user organisations, in particular France Assos Santé, and through social media. They contributed as experts invited as individuals to take part in the working group.

Working group

Gérard Abraham, health system user

Mamédi Diarra, social system user

Marianick Lambert, health system user

Marika Lefki, medico-social system user

Lise Molimard, health system user

Annie Morin, health system user

Gérard Nguyen, health system user

Fabienne Ragain-Gire, health system user

Thomas Sannié, health system user

Joëlle André-Vert, department head, HAS

Mathilde Bruneau, project manager, HAS

Marjolaine Barbiot, legal specialist, HAS

Margaret Galbraith, project manager, HAS

Floriane Gasto, legal specialist, HAS

Cédric Gesbert, project manager, HAS

Ligier Florence, project manager, HAS

Alexandre Pitard, project manager, HAS

Caroline Tranche, project manager, HAS

Public consultation

ANHET.F (organisation for patients with familial hypercholesterolaemia and lipoprotein a)

ANTICOAG-PASS-S2D Sang dessus dessous, organisation for patients on anticoagulant therapy

APRRES Cerdagne (organisation for respiratory prevention and rehabilitation and health education)

Organisation De l'Air (organisation for lung cancer patients)

Organisation française des hémophiles (French organisation for haemophiliacs)

Organisation Laurette Fugain (organisation for leukaemia patients)

Organisation nationale des malades du cancer de la prostate (national organisation for prostate cancer patients)

Organisation pour la lutte contre les maladies inflammatoires du foie et des voies biliaires (organisation for patients with inflammatory liver and bile duct diseases)

Organisation pour la recherche sur les tumeurs du rein (organisation for kidney cancer research)

Organisation SAEF : Soutien, aidance et écoute des familles (organisation to support, help and listen to families)

Cancer aide info réseau entrepreneurs 13 (cancer support and information network)

Collectif Handi Actif France (collective for active people with disabilities)

ELLyE (Ensemble leucémie lymphome espoir) (leukaemia and lymphoma organisation)

Fédération ALTER « Lien, trauma et résilience » (post-traumatic stress disorder federation)

Fédération CAIRE (cancer information and support federation)

Fibromyalgies.fr Ne jamais renoncer (fibromyalgia organisation)

France Rein Centre-Val de Loire (kidney diseases organisation)

UNAPEI Auvergne-Rhône-Alpes (organisation defending the interests of people with mental disabilities)

UNAF Union nationale des organisations familiales (national union of family organisations)

VIVRE AVEC son cancer (cancer organisations)

Sandrine Alliaume, health system user

Catherine Barett, health system user

Yves Béliard, health system user

Natacha Benard, health system user

Valérie Benotti, medico-social system user

Michel Beristain, health system user

Charlotte Bondu, health system user and medico-social system user

Dominique Bonetti, social and health system user

Nathan Bourges, health, social and medico-social system user

Gérard Bourgy, health system user

Nicolas Brun, health system user

Annie Cateigne, health and medico-social system user

Jacques Cerda, health system user

Dominique Chauvet, health system user

Pierre-Antoine Corret, health system user

Marie-Madeleine Dautel-Colombani, health system user

Jacques Dedieu, health system user

Bruno Delferrière, health system user

Jacques Desplan, health system user

Françoise Desvaux, health system user

Déborah Fabre, health system user

Jean-François Faloviez, health system user

Christine Gavaudan, social system user

Chantal Genty, health system user

Gilles Godard, health system user

Marie Gouyou-Beauchamps, health system user

Isabelle Martrès Olivier, health system user

Raja Laghouane, medico-social system user

Jean-Pierre Lassaigne, health system user

André Le Tutour, health system user

Christian Le Fahler, medico-social system user

Marc Lejeune, health system user

Sophie Ler, medico-social system user

Francine Laigle, health system user

Didier Lucas, health system user

Francis Fittante, not indicated

Roland Muntz, social system user

Jean-Luc Plavis, health system user

Jean-Louis Radet, health system user

Lionel Ribes, health system user

Michel Sabouret, health system user

Martine Sene Bourgeois, health system user

Amélie Taroudjit, health system user

Claire Valette, health system user

Lydie Vieillame, health system user

Anonymous, medico-social system user

Anonymous, health system user

Internal consultation via user involvement advisers

Laurence Chazalette, project manager, best practice guidelines department

Cécile Lagarde, project department, guidelines department

Candice Legris, assistant head of department, department of quality and safety of care assessment and tools

Bertrand Mussetta, project manager, department for the assessment of medicinal products

Emmanuel Nouyrigat, project manager, best practice guidelines department

Anne-Françoise Pauchet-Traversat, project manager, best practice guidelines department

Hélène Robert-Rouillac, project manager, digital healthcare mission

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Abbreviations and acronyms

HAS	*Haute Autorité de santé* (French National Authority for Health)
ARS	*Agence régionale de santé* (regional health agency)
RU	*Représentant des usagers* (user representative)
CRSA	*Conférences régionales de la santé et de l'autonomie* (Regional health and autonomy conferences)
ONIAM	*Office national d'indemnisation des accidents médicaux, des affections iatrogènes et des infections nosocomiales* (national office for compensation of medical accidents, iatrogenic conditions and hospital-acquired infections)
…	…

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