ALAN
Acute Leukaemia Advocates Network

Involvement of French Patients in Health Technology Assessment and Reimbursement of Medicines at European and National Levels

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Since 1995, pharmaceutical companies developing new cancer medicines[1] have been required to apply for marketing authorisation from the European Medicines Agency (EMA). This centralized process covers all 27 European Union (EU) countries, as well as Iceland, Liechtenstein, and Norway—collectively referred to as "Europe" or "European countries" in this factsheet, prepared by the Acute Leukemia Advocates Network (ALAN).

The EMA reviews all the clinical trial data to decide whether the benefits of the medicine outweigh its risks. This is called the 'benefit-risk assessment'. Only if the answer is yes, is the medicine granted a marketing authorisation for use across Europe.

1. A European Joint Health Technology Assessment Since 2025

EMA approval alone does not guarantee patient access to a new medicine. For a medicine to be reimbursed through public healthcare systems, it must also undergo a Health Technology Assessment (HTA).

HTA is defined as "*A multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused, and seek to achieve best value*" (EUnetHTA, 2007).

A HTA evaluates whether a treatment offers added benefits over existing options—and whether those benefits justify additional costs. It supports decision-making in the reimbursement process[2] and typically involves two main steps:

- **Assessment**: a scientific review of the evidence (e.g., how strong are the trial results?).
- **Appraisal**: a decision-making phase that looks at context (e.g. is it for a rare disease? Is it affordable?).

Until 2024, each country did both steps on its own (see Figure 1).

European collaboration has extended beyond marketing authorisation to include the HTA assessment phase. This expanded cooperation follows a joint process governed by the European HTA Regulation (HTAR) (see Figure 2).

The goal is to help patients get quicker access to effective medicines by avoiding repetition of work between countries. It also helps ensure greater transparency in decision-making.

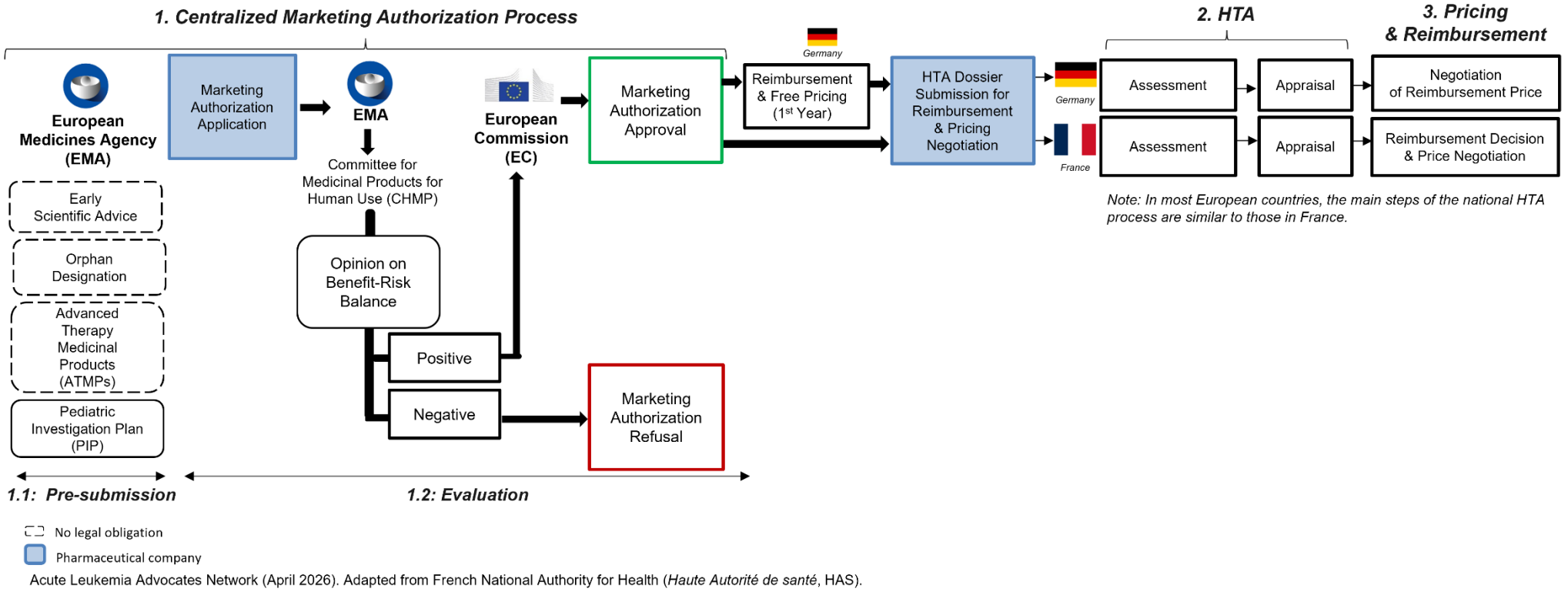
The HTAR currently applies to cancer medicines, including leukemia medicines, and advanced therapy medicinal products (ATMPs). It will expand to rare disease medicines (orphan drugs) in 2028, and to all centrally authorized medicines by 2030. Selected medical devices are also included starting in 2026[3].

[1] In the EU, Iceland, Norway and Liechtenstein, most new and innovative medicines are approved through a centralized procedure: they are reviewed once by the EMA and, if approved, authorized for use in all of these countries. This process is required for medicines that treat serious conditions like cancer, HIV/AIDS, diabetes, and rare diseases, or that use advanced technologies like gene or cell therapy. For other medicines, it's optional, but often chosen.

[2] For more information on what is HTA and how it differs to reimbursement, see our companion factsheet: "Health Technology Assessment and Reimbursement: What is the Difference?"

[3] Class III implantable medical devices (MDs); Class IIb active device intended to administer and/or remove medicinal product(s) (ARMP) MDs; Class D in-vitro diagnostics (IVD)

Figure 1. Marketing Authorisation and HTA Processes of Cancer Medicines Until 2024



Acute Leukemia Advocates Network (April 2026). Adapted from French National Authority for Health (*Haute Autorité de santé*, HAS).

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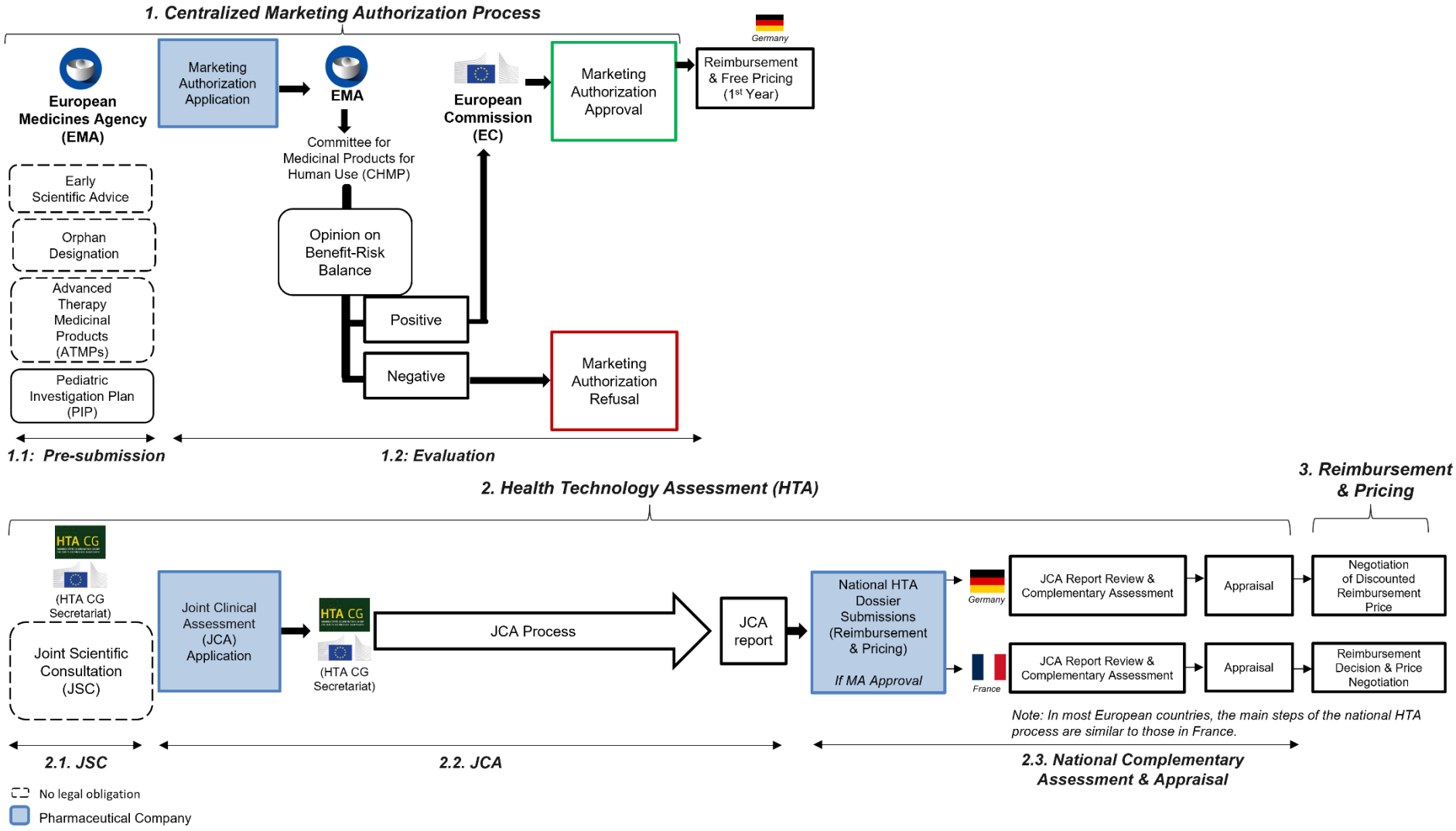
Figure 2. Marketing Authorisation and HTA Processes of Cancer Medicines Since 2025



Acute Leukemia Advocates Network (April 2026). Adapted from French National Authority for Health (*Haute Autorité de santé*, HAS).

For more information on the marketing authorisation process, read our companion factsheet "How Medicines Are Evaluated in Europe?"

2. How Patients Are Involved in European HTA

Since 2025, the HTA Regulation (HTAR) has introduced two key processes at the European level: Joint Scientific Consultation and Joint Clinical Assessment. Their purpose and timeline are presented in Table 1.

Table 1. Objectives and Timeline of European HTA Processes

Process	Purpose	Timeline
Joint Scientific Consultation (JSC)	Provide early advice to help pharmaceutical companies design the right clinical studies	Early input before trials begin.
Joint Clinical Assessment (JCA)	Produce a shared scientific report on how a new medicine works compared to existing treatments	Starts at the time of EMA submission and runs in parallel.

These processes are jointly led by national authorities, the HTA Coordination Group (HTA CG), with support from the European Commission's HTA Secretariat and input from experts (including patients and clinicians) through the HTA Stakeholder Network.

France is represented in the HTA CG by the French National Authority for Health (*Haute Autorité de Santé*, HAS), the independent scientific body responsible for HTA, and the French Ministry of Health.

For more information on European HTA governance and processes, please read our companion factsheet *"*How Medicines are Evaluated in Europe?*"*.

2.1. Joint Scientific Consultations (JSCs)

The JSCs of the HTA CG share a similar approach with the EMA's scientific advice (*scientific advice*), but their objectives differ. EMA scientific advice guides pharmaceutical companies on the design of their clinical trials before initiation, with a view to obtaining a marketing authorisation. It primarily assesses the medicine's safety and efficacy. The JSCs, on the other hand, help pharmaceutical companies improve the design of their clinical trials before initiation, in order to generate the necessary evidence for future JCAs.

The contribution of patients, clinicians, and other relevant experts is a fundamental component of JSCs, as defined in the HTAR. They do so as individual experts. Patient contribution is not based on scientific or technical expertise but on their knowledge and lived experience of the disease, knowledge of existing treatments, and understanding of patient expectations regarding therapeutic innovations.

Patient organisations may also be invited through the HTA Stakeholder Network, which includes groups representing patients, healthcare professionals, and scientific societies.

Per the HTAR, the involvement of patients and clinicians in JSCs is mandatory— unlike EMA's scientific advice, where patient participation is optional. In practice, however, constraints (such as availability or conflicts of interest) may exceptionally limit participation, though measures are implemented to avoid such situations. All experts, whether patients or clinicians, must declare any conflicts of interest.

2.1.1 How Patients are Selected for a JSC

The HTA Secretariat is responsible for identifying experts (patient and clinician) and compiling a list of experts who have fulfilled the public declaration of interest requirements.

To build this list, the HTA Secretariat may request suggestions from:

- The HTA Stakeholder Network
- European Reference Networks (ERNs)
- The Orphanet portal for rare diseases and orphan drugs
- National contact points designated under Article 83(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council
- The EMA's pool of patient experts

If no suitable expert is identified through these channels, the HTA Secretariat may also consult:

- Other databases beyond those previously mentioned,
- Members of the HTA Coordination Group (HTA CG) and its subgroups,
- International and European organisations and agencies.

Any shared information must comply with the General Data Protection Regulation (GDPR)—for example, the expert must have given explicit consent for their details to be shared.

Final selection is made by the JSC Subgroup (the dedicated group within the HTA CG for joint scientific consultations). All selected experts must sign a confidentiality agreement.

The HTA Secretariat then relies on the Brussels Centre for Collaboration in Health (BCCH) to manage contractual and logistical arrangements with the experts.

2.1.2 What Patients Do in a JSC

Expert patients and clinicians:

- Receive the draft briefing package submitted by the company,
- Provide written or oral contributions (interviews) using a structured template (see Table 2).
- Review key documents, such as the list of issues and the outcome document,
- Are invited to participate in a discussion meeting with the JSC subgroup of the HTA CG and the pharmaceutical company (see Figure 3).

In addition to individual contributions, patient organisations may be consulted to provide broader perspectives on the disease or therapeutic options.

Table 2. Structured Form for JSC Patient Input

Section Number	Section Title	Description
1	Scope and objectives	Explains the purpose of the questionnaire.
2	How to complete this questionnaire	Provides guidance on how to fill it out.
3	Background information of the individual patient	Collects basic details about you as the contributing patient
4	Input by patient contributors (or representatives, proxies, carers, etc.)	Your experience with the disease
4.1	Impact of the disease/condition	How the condition affects your daily life and that of carers
4.2	Experience with currently available therapies/health technologies	How current treatments work (or don't work)
4.3	Expectations for new therapies/health technologies	What you hope a new treatment could improve or change;
4.4	Clinical development plan	Your thoughts on the proposed study design
4.5	Additional information	Any other points you would like to raise
4.6	Summary and key messages	A short summary of your most important points

The template described in Table 2 is valid until April 2026, after which the JSC subgroup will update it.

Clinicians use a different format than patients to provide their input. They use the PICO framework (Population, Intervention, Comparators, Outcomes) when advising on study design during JSCs (see Table 3).

Table 3. PICO Framework

Elements	Meaning
P – Population	Who is the treatment for?
I – Intervention	How does it work?
C – Comparators	What is it being compared to?
O – Outcomes	What outcomes matter most to patients?

All contributions to JSCs are submitted via the HTA IT Platform, which is managed by the HTA Secretariat,

For further details on the procedural requirements for JSCs on medicinal products, refer to Implementing Regulation 2024/3169 and the applicable Procedural Guidance for JSCs on Medicinal Products.

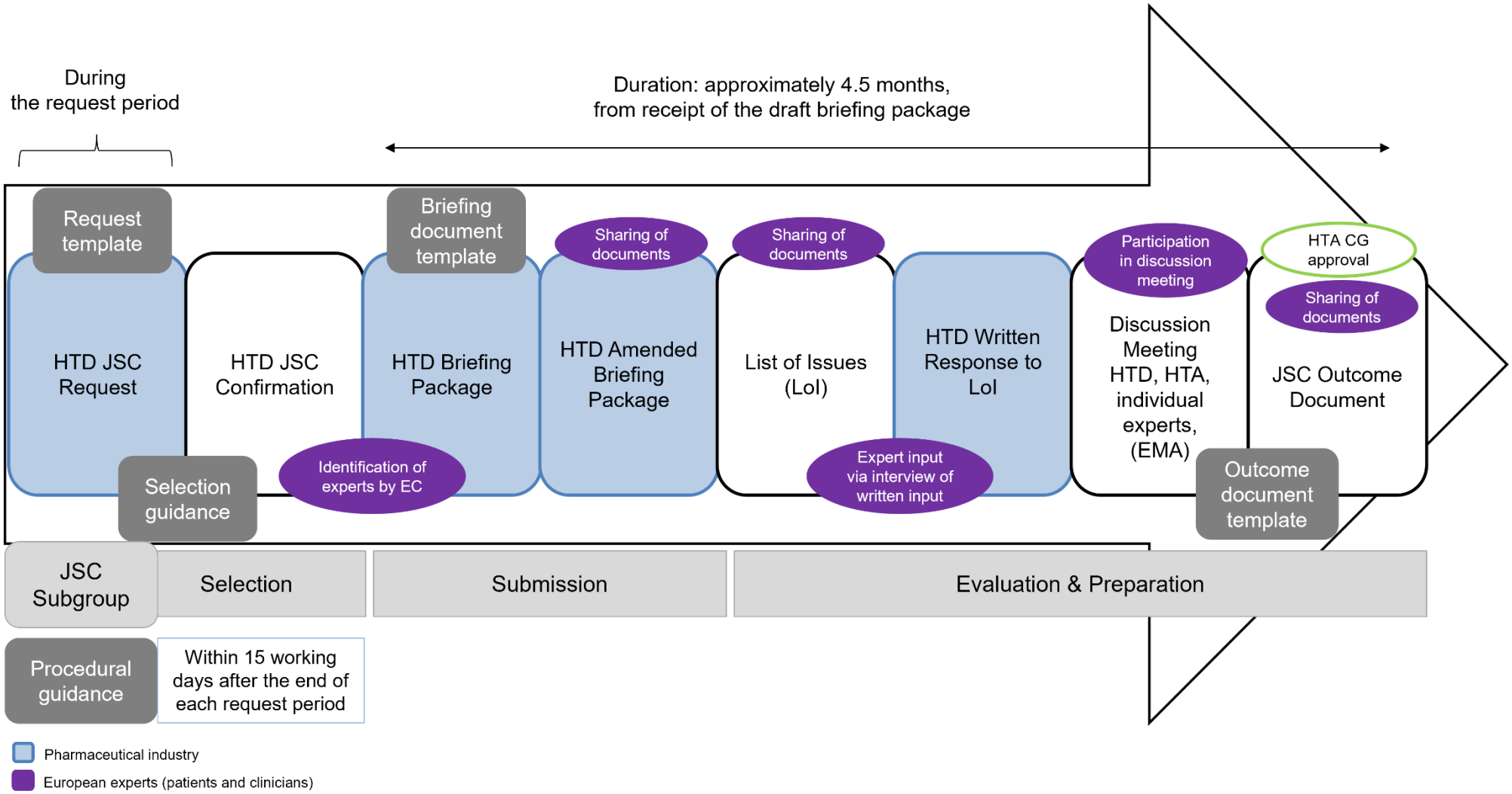
If you cannot find the answers to your questions, you may also contact SANTE-HTA-JSC@ec.europa.eu.

2.2. Joint Clinical Assessments (JCAs)

A JCA report is a shared scientific report drafted by two European HTA bodies (referred to as assessor and co-assessor). It is the outcome of the assessment phase, during which the new medicine is compared to existing treatments. Each country will subsequently use this report to inform its appraisal phase, which involves deciding on the medicine's funding (reimbursement, access conditions, etc.).

The JCA process begins when a company notifies the HTA Secretariat of the medicine's claimed indication (i.e., the proposed therapeutic use) at the same time it submits a marketing authorisation application (MAA) to the EMA. At this stage, no clinical trial data are submitted.

Figure 3. Involvement of European Patients in Joint Scientific Consultations (JSCs)



Acute Leukemia Advocates Network (April 2026). Adapted from HTA CG "Health technology assessment: Webinar for patients and clinical experts". February 6, 2026.

The assessor and co-assessor develop an initial draft assessment scope using the PICO framework. It is also called draft PICO proposal, it is shared with all European countries via a PICO survey to gather national needs and priorities.

To ensure patient perspectives are reflected, patient experts may be invited to contribute, either directly by the HTA Secretariat or indirectly through national HTA agencies (see Table 3 & Figure 4).

2.2.1. How Patients are Selected for a JCA

French patients may contribute to a JCA in two ways:

- As individual experts with European-wide experience, selected by the HTA Secretariat (see Section 2.1.1).
- As national experts, consulted by the HAS, the French HTA body.

While participation at the national level is optional, it is mandatory at the European level. In practice, constraints (such as availability or conflicts of interest) may exceptionally limit this participation, though measures are implemented to avoid such situations.

To speed up recruitment, the HAS has created a pool of expert patients, called the 'JCA-PICO Pool'. Below is the process for registering in this pool:

- A patient organisation nominates a candidate.
- The candidate fills out the CANDIDATUS form on the HAS's website.
- The HAS checks their CV and profile.
- If approved, the person fills out a public declaration of interest form.
- The HAS adds them to the JCA-PICO pool and contacts them when needed.

The declaration of interests must be completed for each patient selected, depending on the medicine being evaluated, and updated annually. The declaration is reviewed by the HAS Ethics Officer (*Déontologue*). If the Ethics Officer provides a favourable opinion regarding the patient's participation, the patient signs a confidentiality agreement.

2.2.2. What Patients Do in a JCA

As individual experts with European-wide experience, selected by the HTA Secretariat

The HTA Secretariat may invite European-level experts (patients and clinicians) to provide input on the draft PICO proposal. This step is optional.

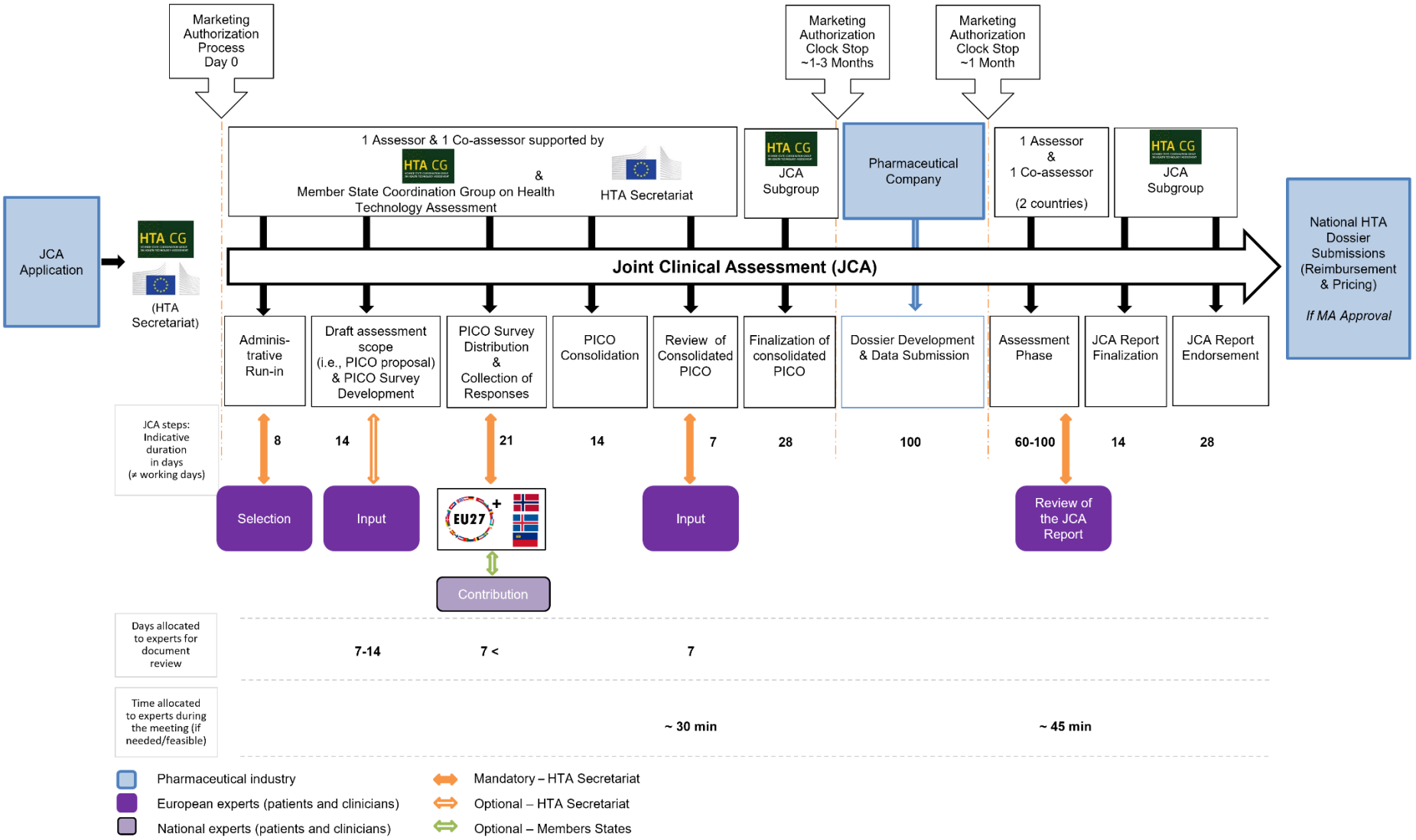
Once the assessing and co-assessing countries have reviewed and consolidated the comments on the proposed PICO(s) [4], the HTA Secretariat shares the consolidated version of the PICO with European experts, allowing them to provide further input. This step is mandatory.

After finalization, the consolidated PICO is sent to the manufacturer, which must then submit a dossier containing the data and evidence addressing the PICO requirements.

Based on the data provided by the manufacturer, the assessing and co-assessing countries conduct their evaluation in light of the consolidated PICO and draft a JCA report. European experts (patients and clinicians) are then invited to review the draft JCA report before its validation, in accordance with Article 15 of the JCA Implementing Regulation (see Table 3 & Figure 4).

[4] Each country can submit one or more PICOs that reflect its national needs. These remain in the JCA process unless the country later chooses to remove them. If several PICOs are similar, they may be merged to simplify the process — but only if the relevant countries agree.

Figure 4. Involvement of European Patients in Joint Clinical Assessment (JCA)



MA : Marketing authorization; HTA CG : Member State Coordination Group on Health Technology Assessment; PICO : Patient, Intervention, Comparators, Outcomes

Acute Leukemia Advocates Network (April 2026). Adapted from French National Authority for Health (*Haute Autorité de santé*, HAS). And HTA CG .

As national experts, consulted by the HAS

As the PICO survey is circulated to Member States for their input, they have the opportunity to engage national patient experts to contribute to their response to the proposed PICO(s). France is one of the few of Member States —such as Cyprus and Germany —that engage experts to comment on the PICO proposal, as this step is optional.

As soon as the selected patient expert has signed the confidentiality agreement, the SEU of the HAS provides them with the available information (i.e., the indication and, if the consultation timeline allows, the proposed PICO(s)), so that they can submit their comments using the PICO criteria.

Due to the tight deadlines for submitting PICO contributions and recruiting experts (21 days), the median number of effective working days available to expert patient was 13 days in 2025 (minimum: 3 days; maximum: 25 days).

All JCA contributions are submitted via the HTA IT Platform.

2.2.3. Information and Questions

For more information on the selection and role of patient and clinician experts in JCAs, visit the HTA Secretariat website and its dedicated FAQ page. You can also refer to the procedural requirements for JCAs, including Implementing Regulation 2024/1381 and the applicable Procedural Guidance for JCAs on Medicinal Products.

If you cannot find answers to your questions, you may contact: SANTE-HTA-JCA@ec.europa.eu.

For technical issues related to the HTA IT Platform, send your inquiries to: SANTE-HTA-IT-SUPPORT@ec.europa.eu.

3. How French Patients are Involved in HTA and Reimbursement at National Level

After a JCA is completed for a new medicine, the pharmaceutical company must apply for national reimbursement in each country. Each country then decides:

- Whether the medicine should be reimbursed
- Which patients should have access
- Under what conditions (e.g. hospital use only)
- At what price

In France, two commissions are responsible for advising public authorities on whether a medicine should be reimbursed, for whom and under what conditions. They also provide an economic opinion (*avis*) to inform price negotiations, which are led by the Economic Committee for Health Products (*Comité Economique des Produits de Santé*, CEPS).These commissions are supported by specialised departments within the HAS:

- **Transparency Commission** (*Commission de la Transparence,* CT) – evaluates the medical benefit (*service médical rendu*, SMR) and the added medical benefit (*amélioration du service médical rendu*, ASMR) of the medicine, with support from the Medicines Evaluation Unit (*Service Evaluation des Médicaments, SEM*).
- **Economic and Public Health Evaluation Commission** (*Commission d'Evaluation Economique et de Santé Publique,* CEESP) – reviews economic value (cost-effectiveness) with the support from the Economic and Public Health Evaluation Unit (*Service Evaluation Economique et de Santé Publique,* SEESP).

Patient involvement in medicine evaluation at the HAS occurs in two ways:

- As patient expert within one of these two commissions,
- As patient organisation, through written contributions or consultations.

3.1. What the CT does in Health Technology Assessment

3.1.1. Appraisal for the Purpose of Reimbursement

The CT helps decide whether a new medicine should be reimbursed in France—and if so, under what conditions.

Until the end of 2024, the Medicines Evaluation Unit (SEM) assessed all new medicines, and the CT was responsible for the final appraisal, also referred as 'opinion' (*avis*).

Since 2025, the assessment of oncology medicines and innovative therapies (Advanced Therapy Medicinal Products, ATMPs) has been conducted at the European level through the JCA process. The CT continues to issue its opinion, using the JCA report as its scientific basis as well as relying on the SEM's expertise. It cannot request data already submitted during the JCA, but it may request additional information. Pharmaceutical companies, for their part, are prohibited from resubmitting at the national level any data previously submitted at the European level.

This division of responsibilities will extend to rare disease medicines (orphan drugs) in 2028, and to all medicines authorised by the EMA by 2030. Selected medical devices have also been included since 2026[5].

The CT is responsible for three key decisions

- **Target population**: Identification of the patients who may use the medicine. If its use is limited to specific patients, this is referred to as an "indication restriction" (*restriction d'indication*).
- **Medical benefit** (*Service Médical Rendu, SMR*): Assessment of the medicine's overall medical benefit, based on five criteria:
    - Severity of the disease,
    - Clinical efficacy and safety of the product,
    - Therapeutic objective, role in the therapeutic strategy,
    - Impact on public health.

  On the basis of these criteria, the SMR is classified into four levels, which determine the reimbursement rate: Important (65%), Moderate (30%), Weak (15%), and Insufficient (not reimbursed).
- **Improvement of the medical benefit** (*Amélioration du Service Médical Rendu, ASMR*). Measurement of the added value compared to existing treatments, the ASMR serves as the basis for price negotiations with the Economic Committee for Health Products (CEPS) and is rated from I to V:
    - I (major improvement) à IV (minor improvement): Price higher than that of comparators.
    - V (no improvement): Price aligned with that of comparators.

[5] Class III implantable medical devices (MDs); Class IIb active device intended to administer and/or remove medicinal product(s) (ARMP) MDs; Class D in-vitro diagnostics (IVD)

CT Decision Criteria

The CT bases its decisions on:

- The severity of the condition,
- The clinical efficacy and safety of the medicine,
- How the medicine fits into existing treatment options
- Where applicable, the public health benefit (*intérêt de santé publique*, ISP).

Under the European HTA Regulation (HTAR), the CT must

- Attach the JCA report to its HTA report.
- Explain how the JCA was used in its appraisal.
- Send its final HTA report to the HTA Secretariat within 30 days.

The CT may reassess a medicine if new evidence becomes available.

3.1.2. Assessment and Appraisal for the Purpose of Early Access

The French early access scheme (*accès précoce*) allows specific patients to benefit from promising treatments before marketing authorisation or final reimbursement is obtained.

Since this scheme is not covered by the HTAR, its assessment remains a national process and is conducted by the SEM. The CT then issues an appraisal/opinion based on the SEM's conclusions. The final authorisation is granted by the HAS Board (*Collège de la HAS*).

For medicines that have not yet obtained a marketing authorisation, the French National Agency for Medicines and Health Products Safety (*Agence Nationale de Sécurité du Médicament et des Produits de Santé*, ANSM**)** first verifies whether the available clinical data demonstrate the presumed benefit (*bénéfice présumé*) outweighs the risks. For medicines that have already been granted marketing authorisation by the EMA, this first criterion is automatically considered met.

To grant early access, the CT assesses whether the medicine meets another four criteria:

- The medicine must be intended to treat serious, rare or disabling diseases.
- There is no suitable treatment options available.
- The implementation of the treatment cannot be deferred.
- The medicinal product is presumed to be innovative, particularly with regards to possible clinically relevant comparators.

3.2. The Role of the Economic and Public Health Evaluation Commission (CEESP)

The CEESP assesses whether a new medicine offers an acceptable cost-effectiveness ratio for the publicly funded French healthcare system. It intervenes when the manufacturer claims:

- A moderate to major ASMR (levels I to III), and
- A "significant impact" on national health insurance expenditures.

The notion of significant impact applies in the following cases:

- The product is an advanced therapy medicinal product (ATMP), or
- The forecasted revenue in the second year of marketing is expected to exceed €20 million per year, or
- The manufacturer claims an impact on healthcare organisation, professional practices, or patient care conditions.

In these situations, the CEESP reviews the economic studies provided by the manufacturer, such as cost-effectiveness analyses, and issues an opinion. This opinion is then used by the Economic Committee for Health Products (CEPS) to guide price negotiations.

3.3. Members of Patient Organisations and Healthcare System User Groups in the CT and CEESP

3.3.1. The Composition of CT and CEESP Commissions

Both commissions include independent experts, who are appointed for a three-year term (renewable twice):

- 22 voting members, including:
  - 20 scientific or medical experts (CT) or public health or evaluation experts (CEESP)
  - 2 members of accredited patient organisations and healthcare system user groups.
- 7 alternate members, including 1 alternate member who is a member of an accredited patient organisation and healthcare system user group.
- 6 non-voting members, representing:
  - The Social Security Directorate (*Direction de la sécurité sociale,* DSS*)*
  - The Directorate-General for Health (*Direction générale de la santé*, DGS)
  - The Directorate-General for Healthcare Provision (*Direction générale de l'offre de soins*, DGOS)
  - The National Health Insurance Fund (*Caisse nationale de l'assurance maladie*, CNAM)
  - The Agricultural Social Security Fund (*Mutualité sociale agricole*, MSA).
  - The French National Agency for Medicines and Health Products Safety (ANSM – in the CT only)
  - The National Union of Health Insurance Funds (*Union nationale des caisses d'assurance maladie*, UNCAM – in the CEESP only).

All voting members have an equal vote, and members of accredited patient organisations or healthcare system user groups can significantly influence decisions, particularly in cases where votes are closely divided.

3.3.2. Selection Process for Patient and Healthcare User Representatives

The HAS opens calls for applications to renew its members. To apply, patient experts must:

- Be a member of an accredited patient organisation,
- Provide a motivation letter, a CV, and a public declaration of interests.
- A selection committee (including an ethics officer) reviews the applications. Final approval is granted by the HAS Board.

3.4. Patient Input into the Evaluation of Medicines at National Level

3.4.1. Patient Involvement in Early Dialogues ("*rencontres précoces*")

The HAS offers early dialogue (*rencontres précoces*) with pharmaceutical companies for innovative products in clinical development. At the request of companies, these meetings provide recommendations on clinical development and specify the data required for reimbursement evaluations. Early dialogue serves a similar purpose to JSCs

In this context, the HAS may invite patients to one-hour interviews to gather their experience living with the disease, identify unmet needs not addressed by current treatments, understand the endpoints and outcomes that matter most to them, and explore their hopes or concerns regarding the medicine and future treatments.

The HAS does not organize early dialogue for a medicine that has already undergone (or is undergoing) a JSC. Conversely, the HAS does not participate in a JSC if it has already conducted early dialogues for the same medicine.

3.4.2. Patient Involvement in Early Access & Reimbursement Process

One Patient Organisation Contribution, Two Commissions

When a new medicine is under review, patient organisations have the opportunity to submit a written contribution to the HAS's Patient and Public Involvement Unit (*Service Engagement des Usagers*, SEU). This document is then shared with the SEM and the CT and, if relevant, with the CEESP. Members of both commissions review the contribution, and members of patient organisations and healthcare system user groups in the CT or CEESP may present or reference it during meetings.

See Figure 5 for an overview of how patient contributions are integrated in the French HTA process for reimbursement purpose.

How to stay informed about medicines under review

Patient organisations can stay informed by:

- Signing up for email alerts (see instructions in the footnote)[6]
- Following the HAS Twitter/X account
- Checking the weekly updates on its website, which lists medicines under evaluation and submission deadlines.

Who can submit input

Only patient organisations—not individual patients—may submit written contributions. Patient organisations do not need to be officially accredited to send a contribution.

[6] *https://www.has-sante.fr/jcms/fc_2875371/fr/abonnement-alerte-email*, then select « Qualité des soins et de l'accompagnement > Droits des usagers > Information et droits des usagers > médicaments ». Choose « fréquence quotidienne » to be promptly informed of any new evaluation.

What the written contribution involves

The SEU provides a standard template questionnaire covering:

- How the disease affects daily life of patients and caregivers
- Experiences with existing treatments
- Expectations and concerns about the new medicine

The standard deadline for submitting input is 45 days, though shorter timelines may apply.

Presentation of Contributions in CT and CEESP Meetings

In the context of early access evaluations (*accès précoce*), patient organisations may request to present their contribution during a CT meeting. However, the CT retains full discretion to accept or decline this request.

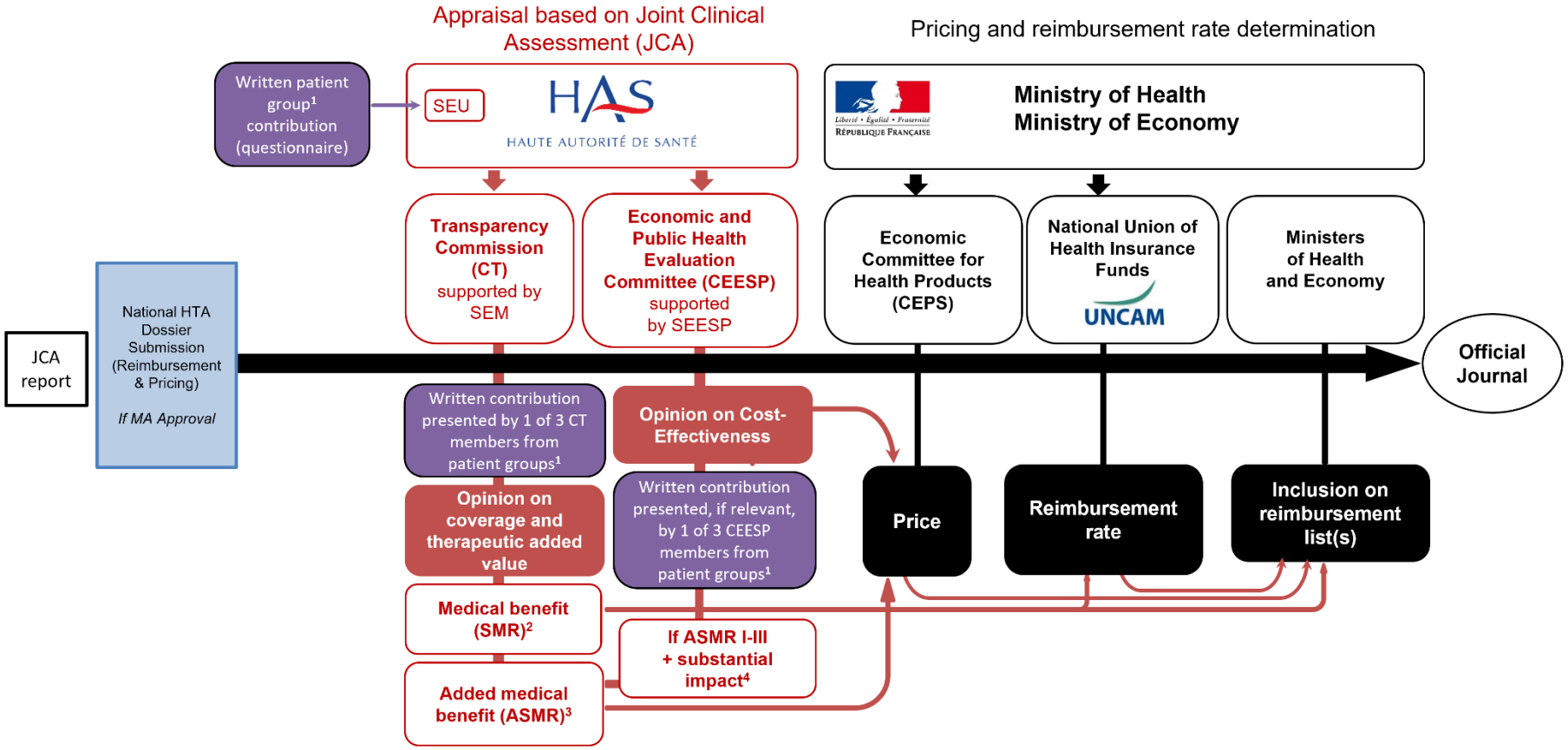
If the request is declined, one of the three members of the CT who are members of patient organisations or healthcare system user groups presents an oral summary of the written contribution, typically using 4–5 slides in 5 minutes. These slides cover the main topics of the questionnaire:

- The impact of the disease on patients and carergivers,
- The advantages and disadvantages of existing treatments,
- The advantages and disadvantages of the medicine under evaluation (if the organisation has experience with the medicine),
- Expectations and concerns about the medicine under evaluation, such as expected improvements in quality of life (if the organisation has no experience with the medicine).

They also include the organisation's perspective on three of the four key criteria required for granting early access:

- The medicine must be intended to treat serious, rare or disabling diseases
- There is no suitable treatment options available
- The medicinal product is presumed to be innovative, particularly with regard to a possible clinically relevant comparator
- For reimbursement evaluations, patient organisations cannot present their contribution directly during the CT meeting. In such cases, one of the three CT members who are members of patient organisations or healthcare system user groups presents the key points on their behalf, following the same format as for early access (with the exception of the early access-specific criteria).
- If the CEESP is also involved in reviewing the medicine for reimbursement, one of its three members who is a member of a patient organisation or healthcare system user group may present the same contribution during the Commission's discussions.

Figure 5. Involvement of French Patients in National Complementary Assessment and Appraisal



Patient involvement/contribution

SEU: Patient and Public Involvement Unit (Service Engagement des Usagers) ; SEM: Medicines Evaluation Unit (Service Evaluation des Médicaments) ; CT: Transparency Commission (Commission de la Transparence ; CEESP: Economic and Public Health Evaluation Commission (Commission d'Evaluation Economique et de Santé Publique) ; SEESP: Economic and Public Health Evaluation Unit (Service Evaluation Economique et de Santé Publique); UNCAM: National Union of Health Insurance Funds (Union Nationale des Caisses d'Assurance Maladie); CEPS : Economic Committee for Health Products (Comité économique des produits de santé)

1 The HAS's official terminology for referring to patient associations is "patient organisations and healthcare system user groups"

2 SMR answers the question « Does this medicine bring enough benefit for it to be covered by the national health insurance?"

3 ASMR answers the question « Does this medicine offer any improvement over existing treatments"

4 « Substantial impact » : The product is an advanced therapy medicinal product (ATMP), or The forecasted revenue in the second year of marketing is expected to exceed €20 million per year, or The manufacturer claims an impact on healthcare organisation, professional practices, or patient care conditions.

Acute Leukemia Advocates Network (April 2026). Chart adapted from the Haute Autorité de santé (HAS).

3.5. After CT and CEESP Opinions: Pricing & Reimbursement

Once the CT and CEESP give their opinions, two key steps follow:

- the French National Union of Health Insurance Funds (UNCAM) sets the reimbursement rate
- the Economic Committee for Health Products (CEPS) negotiates the price with the pharmaceutical company

The final decision on reimbursement rests with the Ministry of Health. As for pricing, while the ministry provides formal validation, it is the CEPS that leads negotiations and proposes the final price. The price is determined based on:

- The ASMR score
- Prices of similar medicines in France (clinically relevant comparators)
- Prices in other European countries

Finally, the CT's opinion and the contributions from patient organisations and healthcare system user groups are published on the HAS website.

It is important to note that patient groups are not invited to comment on the CT's draft opinion before finalization. Their input is limited to the upstream phase, prior to the development of the draft recommendation.

However, patients can express their disagreement with the outcomes of a medicine evaluation. Any written communication raising questions or concerns always receives a response and may lead to in-person meetings. These exchanges are managed by the SEU.

Want to Learn More?

Please read our companion factsheets:

- Health Technology Assessment and Reimbursement: What is the Difference?
- How Medicines Are Evaluated in Europe?
- Involvement of German Patients in Health Technology Assessment and Reimbursement of Medicines at European and National Levels

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