
THE REGULATION ON THE ORGANIZATION AND FUNCTIONING OF THE AIFA SCIENTIFIC AND ECONOMIC COMMITTEE (CSE)

DECISION N.89 OF 15/12/25

Approved by the Minister of Health in agreement with the Minister of Economy and Finance and the Minister for Public Administration

A focus by

SCF



CSE organization and Scope

 CSE is composed of **10 members**, appointed by decree of the Minister of Health.



2 Ex officio members:

- AIFA Technical-Scientific Director
- ISS President (or delegate)



8 Non-ex officio members:

- 4 members appointed by Ministry of Health;
- 1 appointed by Ministry of Economy and Finance;
- 3 appointed by Permanent Conference.



Term:

- Non-ex officio members have a **three years term**, renewable consecutively only **once**;
- Members must declare the absence of conflict of interest with the activities of the Committee.

The role of the Chairman

The Chairman is designated in accordance with the article 19, paragraph 4, of Ministerial Decree of 20 September 2004, n. 245, as amended by Ministerial Decree of 8 January 2024, n.3:



Convocation and Agenda

- Convenes the Committee and approves the agenda (jointly with the Technical-Scientific Director);
- Proposes a semi-annual meeting schedule, which is published on the AIFA website, in agreement with the Technical-Scientific Director.



Quorum Verification

- Ensures the proper conduction of Committee by verifying the **quorum** and guaranteeing the orderly progress of proceedings;
- Chairs **discussions and voting procedures** and oversees the **recording of opinions**.



Assignment of Analyses and Minutes

- May assign specific analyses to individual Committee members.

AIFA Offices



Functions of the Offices

AIFA offices play a **key role in supporting the Committee's activities**, ensuring the **quality and timeliness** of the evaluation process.

Preparatory Work

Prepares the **documentation** required for the Committee's evaluations and opinions.

Directorial Oversight

Technical-Scientific Director (or delegate) **supervises the work of the offices.**

Secretariat Support

Within AIFA, a specific unit is designated to perform the **secretariat** functions of the Committee.

The competent AIFA offices transmit all evaluation documents to the Secretariat at last **7 working days before the beginning of the meeting.**

Operating Rules



General Principles



Universal Access

Ensures access to innovative, orphan, and essential medicines within the Essential Levels of Care (LEA).



Economic Sustainability

Operates, including in the issuance of opinions, within a regulatory framework that ensures compliance with pharmaceutical spending limits and alignment with the planned healthcare needs of the population.



Safe and Appropriate Use

Ensures the safe and appropriate use of medicines.



Pricing Policies

Adopts pricing strategies that reward added therapeutic value, taking into account EMA assessments and evaluations from European HTA agencies.

Operating Rules



The Committee operates with **full technical, scientific, and healthcare autonomy** and provides **technical-consultative support to AIFA** for the negotiation of prices for medicines reimbursed by the National Health Service (NHS).

Binding Opinions

- ▲ Definition of supply conditions and prescribing rules.
- ▲ Classification of innovative medicines and assignment of innovation status.
- ▲ Determination of place in therapy and added therapeutic value for reimbursement by the NHS.

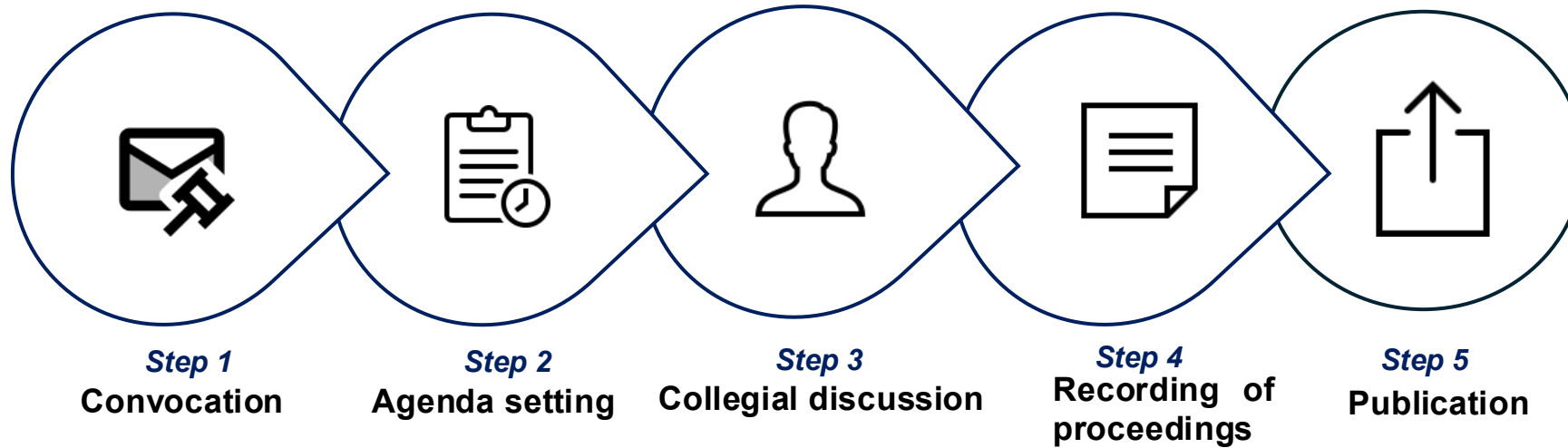
Non-Binding Opinions:

- Evaluate **pricing negotiations** and reimbursement conditions;
- Assess the need for **monitoring medicine use** via registries or therapeutic plans;
- Identify potential **conditional reimbursement mechanisms** and related technical parameters;
- Propose **draft negotiation agreements**, specifying price, supply regime, reimbursement classification, and additional condition;
- Recommend inclusion of medicines in **special national lists** for early or exceptional use;
- Provide opinions on **national joint clinical assessments** and the **Joint Clinical Assessment (JCA)** under EU Regulation n. 2282/2021;
- Submit **pre-marketing classification proposals** for orphan drugs, hospital-only medicines, or drugs of exceptional therapeutic/social relevance;
- Provide technical-scientific evaluations for **marketing authorization, clinical trials and pharmacovigilance**;
- Advise on **technical-scientific matters** or proposals from EMA committees (CHMP, PRAC) when requested;
- Evaluate **therapeutic equivalence** cases upon request.

Organization of the Committee's Work



Workflow Steps:



Meetings:

- The Committee is convened by the Chairman, who communicates the meeting to members at least **7 working days in advance**;
- **Ordinary meetings** are held **monthly**, lasting approximately five days; additional meetings may be convened as needed.

In the absence of the Chairman, the **most senior member appointed by the Ministry of Health** presides over the meeting; in case of equal seniority, the oldest member presides.

Quorum, Hearing and Documentation

Meetings validity and attendance

- The Chairman verifies the **quorum; valid with up to 4 absences;**
- If **non-ex officio members miss three consecutive meetings without justification**, the Chairman reports the matter to the **Board of Directors;**
- Participation of **non-ex officio members** requires **active contribution** to discussions;
- Decision are adopted by majority, votes are public; in the event of a tie, **the Chairman's vote prevails.**

Hearing and Documentation

- The applicant may request a **single hearing** of up to **30 minutes;**
- The **Secretariat prepares the meeting minutes**, including decisions and any minority opinions;
- If the Committee issues a **reasoned denial**, the applicant may submit **up to two counter-statements**, which must be presented within **15 days** of the denial notice (or 5 days of any subsequent confirmation). The Committee reviews counter-statements in the first available session, considering the preparatory work by AIFA Offices;
- Final decisions adopted by Board of Directors, based on the Committee's opinion.

Participation in Committee Meetings



Meeting format:

- Committee meetings are **normally held in person** at AIFA;
- **Remote/hybrid** allowed if: link provided, Chair can verify identities/manage votes, minute-taker perceives events, participants can share documents and vote;
- When these conditions are fulfilled, the **official meeting location** is considered to be that of the **minute-taker**.

Members participating remotely must:

- Report prolonged absences for **quorum**;
- Keep **video and audio active**;
- Ensure **confidential environment**;
- Prioritize **in-person participation** when possible;
- **Audio/video recordings** kept by Secretariat until minutes are approved.

Extraordinary meetings:

- Can be remote;
- At least **1 day's** notice, except in urgent cases;
- Is considered extraordinary if not scheduled in regular calendar;
- Documentation provided as soon as possible or during meeting.



Patient Associations & Scientific Societies

Committee may invite representative Patient Associations or Scientific Societies to hearings on relevant topics. Contribution from these entities are purely informational. Participants are required to submit a public declaration.

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