



Agenzia Italiana del Farmaco

AIFA

European Assessment Office

Rules of Procedure for Meeting with Pharmaceutical Companies in AIFA

Scope

The following Rules of Procedure should be considered every time an Applicant/ Marketing Authorisation Holder (MAH) requires a meeting with AIFA representatives - as CHMP members - for pre-submission meetings, presentation of pipelines, scientific advice etc.

The Applicant/MAH should notify the Italian Medicines Agency in writing that he or she wishes to have a pre-submission meeting, and should provide topics, documentation, and the list of participants who will attend/present at the meeting with Aifa representatives.

The Applicant/MAH is requested to draft the minutes of the meeting to be sent to AIFA for revision; in two weeks' time after the meeting, the final version of the minutes, including AIFA's comments, has to be sent from the Applicant/MAH to AIFA.

Q&A

1. When shall I submit my request for a pre-submission meeting with CHMP Members?

At least two months in advance in order to allow a smooth organisation of the workload.

2. To whom shall I submit my request for a pre-submission meeting with CHMP Members?

Any request for a meeting with Italian CHMP Members should be submitted in English and addressed to the Head of European Assessment office, dott. Paolo Foggi (p.foggi@aifa.gov.it).

3. What shall I include in the request?

Any meeting request with Aifa shall include an agenda (with details of the topic for discussion) and a list of participants who will attend the meeting.

4. When will I receive a confirmation of the meeting date?

When a request for a pre-submission meeting is received, Aifa will propose three possible dates. The Applicant/MAH shall indicate his or her preference within three working days.

5. How many participants/speakers are allowed in the pre-submission meeting?

A maximum of 10 participants is allowed.

6. When shall I submit the final list of participants/speakers for the pre-submission meeting?

The final list of participants, as well as each participant's CV, has to be sent to AIFA within seven working days in advance of the scheduled meeting date.

7. When shall I submit the documentation (briefing package, presentation, slide, LoQs etc.) that I wish to present during the pre-submission meeting?

Any documentation to be used during the meeting has to be sent to AIFA within 15 working days in advance of the scheduled meeting date.

8. To whom shall I submit the documentation and the list of participants for the pre-submission meeting?

To the Head of the European Assessment office, dott. Paolo Foggi (p.foggi@aifa.gov.it). Please always copy the Italian CHMP Members in the correspondence.

9. What is the duration of a pre-submission meeting?

A slot of two hours maximum will be allocated for the meeting.

10. Is it possible to conduct a pre-submission meeting with AIFA via telephone conference during a (Co-)Rapporteur pre-submission meeting?

The pre-submission meeting should be held separately with Rapporteur and Co-Rapporteur in their respective Agencies.

11. Is it possible to conduct a pre-submission meeting with AIFA via telephone conference?

The Applicant/MAH's representatives are requested to come to AIFA in person for the pre-submission meeting.

FACILITIES

Presentations can be shown using DVD, CD-Room, or USB device. There are screens that can be used to project slides. Mobile phones shall be switched off during the meeting.