RULES OF PROCEDURE FOR THE REQUESTS OF MEETINGS BETWEEN PHARMACEUTICAL COMPANIES AND THE AGENCY'S POST MARKETING SURVEILLANCE'S DIVISION OFFICES

The following Rules of Procedure should be considered every time an Applicant/ Marketing Authorisation Holder (MAH) requires a meeting with representatives of Post marketing Surveillance Division, for example for pre-submission meetings for procedures where Italy acts as PRAC Rapporteur/Co-Rapporteur, or to discuss safety related issues on authorised medicinal products. These Rules of Procedure is aligned with the AIFA's Standard Operating Procedure 351 "Rules on meetings with pharmaceutical companies"

The Applicant/MAH should notify in writing the request to organise a meeting, providing proposed topics, documentation, and a list of participants who will attend/present at the meeting with the Agency's representatives.
As per Agency's procedures, the Applicant/MAH will be requested to draft the minutes of the meeting and send it to AIFA for revision/integrations, in accordance to the agreed timelines; the final meeting minutes will be agreed in two weeks after the meeting.

Q&A

1. When shall I submit my request for a meeting with staff of Post marketing Surveillance Division?
At least one month in advance, in order to allow a proper organisation.

2. To whom shall I submit my request for a meeting with Post marketing Surveillance Division's offices?
The request for a meeting should be submitted in Italian, in case of national procedures, or in English in case of EMA procedures, by certified email (protocollo@pec.aifa.gov.it). It should be addressed to the chief(s) of the interested Office(s).

3. Which documentation shall I include to the request?
Beyond the cover letter with the reasons for the meeting request, the submitted documentation should include a proposed agenda (with details of the proposed topics for discussion), a preliminary list of the company's participants who will attend the meeting and any other useful documentation.

4. How it will be identified the meeting date?
When a request for a meeting is received, AIFA will propose three possible dates. The Applicant/MAH shall indicate their preferences within three working days.

5. How many company's participants/speakers are allowed in the meeting?
A maximum of 10 participants from the company is allowed.

6. When shall I submit the final list of participants/speakers for the meeting?
The final list of participants, as well as each participant's CV, has to be sent to AIFA within 7 working days before the scheduled meeting date.

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

Any documentation to be used during the meeting has to be sent by email to the Agency's appointed contact point within 15 working days (30 working days in case of EMA procedures) in advance of the scheduled meeting date.

8. How shall I submit the documentation and the list of participants at the meeting?
By certified email (protocollo@pec.aifa.gov.it) and, if appropriate or required, by direct email to the Agency's appointed contact point.

9. What is the duration of a meeting?
A slot of 2 hours maximum will be allocated for the meeting.

10. Is it possible to conduct a meeting with AIFA through remote connection?
Preferably, the meeting should be held face to face at AIFA premises; however, a teleconference meeting could be arranged to accommodate specific requests.

FACILITIES
Presentations can be shown using PC, DVD, or USB device. Internet connection is provided by AIFA. Any further technical support should be requested at the time of confirmation of the meeting date.

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