Notice to the Applicant:
Procedure for pre-submission meeting – veterinary medicines

The objective of pre-submission meetings at the Federal Agency of Medicines and Health Products (FAMHP) is to give guidance on the preparation of an application for marketing authorization (MA), registration or variation.
Such meetings contribute to the efficient handling of the upcoming application from the submission until the finalization of the procedure.

A request for pre-submission meeting could be asked for procedures related to veterinary medicines.

A pre-submission meeting is highly recommended:

- for the marketing authorization application via centralized procedure when Belgium acts as Rapporteur and Co-Rapporteur , even if such a meeting is already organized by the EMA.
- for the application for marketing authorization , for line-extensions , for repeat-use, for variations of for work sharing when Belgium acts as RMS via the DCP or MRP,

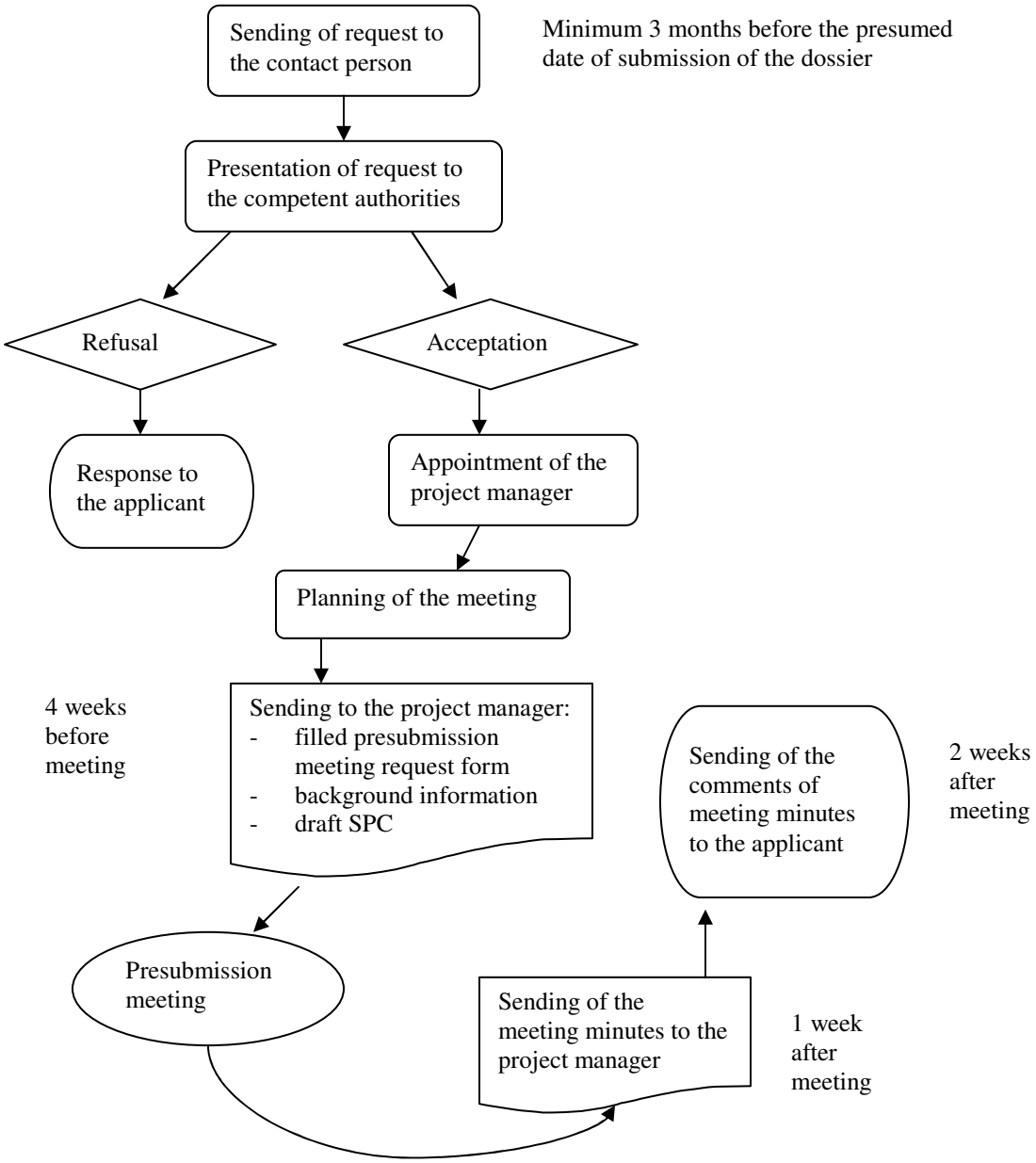
The pre-submission meeting addresses product-specific legal, regulatory, scientific and administrative issues.

The pre-submission meeting request form provides an overview of the most relevant topics. The applicant is advised to consider each topic during the preparation of the meeting. Other topics not listed in the form may be added.
Only the topics addressed by the applicant will be discussed during the meeting.
All requests for pre-submission meeting, the pre-submission meeting request form and other documents have to be sent to the specific mail-box: infovet@afmps-fagg.be

The following flowchart shows the process and delays for pre-submission meetings in function of requests within the framework of the DCP, MRP and national procedures.

In the centralized procedure, the process is determined by the EMA.

The organization of a pre-submission meeting can also be considered within the framework of the national procedure if the request falls out of scope of the national Scientific –Technical Advice (STA).
Please also consult the advice of FAMHP for clinical trials and marketing authorizations according to the procedures and the detailed guidance for National STA requests on the website.


Sending of request to the contact person
Minimum 3 months before the presumed date of submission of the dossier
Presentation of request to the competent authorities
Refusal
Acceptation
Response to the applicant
Appointment of the project manager
Planning of the meeting
4 weeks before meeting
Sending to the project manager:
- filled presubmission meeting request form
- background information
- draft SPC
Sending of the comments of meeting minutes to the applicant
2 weeks after meeting
Presubmission meeting
Sending of the meeting minutes to the project manager
1 week after meeting

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