The term "pre- submission meeting" refers to a meeting held between a Pharmaceutical Company and the Spanish Medicines Agency (AEMPS) in advance of the submission of a marketing authorisation application (MAA) and provided that the product development is complete and the whole data package available.

This document sets out the national requirements for such meetings similarly to those established by the European Medicines Agency (EMA), and affects only those Centralised procedures where the AEMPS has been designated as Rapporteur or Co-Rapporteur for the evaluation.

This document is not intended for meetings that may be requested within other procedures such as national, decentralised or mutual recognition procedures, or those related to methodological or regulatory aspects of products in early stages of development. The latter would imply the Applicant following the information available on the AEMPS website on the application for scientific advice.

Purpose/scope of the meeting

MAA pre-submission meetings are aimed at providing the evaluation team with information about the upcoming MAA. If necessary, assessors may comment on practical aspects highlighting those issues which may be particularly relevant. Such meetings are not expected to be a pre-assessment of data supporting a marketing-authorisation application.
MAA pre-submission meetings should be requested before submitting an initial application or in case of relevant variations implying significant changes in the marketing authorisation conditions of an authorized product, line extensions, etc…

Procedures & timeline for MAA pre-submission meetings

These meetings will be organized by the AEMPS upon the request of a Pharmaceutical Company. The request (Application form) can be sent directly to the following mailbox: centralised@aemps.es

Payment of fees is not required for this type of meetings.

They will preferably be a *face-to-face* meeting that will take place at the AEMPS´ premises (Calle Campezo nº 1, Madrid). The AEMPS will provide with the necessary logistic framework including if needed, the possibility of join additional participants such as other Regulatory European Agencies (EMA or other National Agencies) or AEMPS/Applicant´s external experts via teleconference.

Pre-submission meetings for MAA usually take place 3-6 months before submission, so that the meeting can be set-up at a mutually agreed date taking into account availability of AEMPS/Applicant's participants and meeting rooms.

The estimated duration of the meeting will be one hour and may reach a maximum of one hour and a half. The Applicant should introduce the attendees and make a brief presentation followed by a discussion on the most relevant aspects.

Applicant's representatives should not exceed 6 participants. The Applicant should notify in advance the names of participants and their position within the Company.

Meeting background information should be provided to the AEMPS at the latest 2 weeks before the agreed meeting date. It is advisable to send the documents in an electronic format, via a Secure Message Transfer Application (Eudralink), to centralised@aemps.es

Detailed meeting minutes should be prepared by the Applicant and provided to the AEMPS in an electronic format to the above-mentioned mailbox, within 2 weeks after the meeting. Evaluation team members will subsequently review the minutes within 2 weeks and will send their comments. The final (amended) minutes will be agreed with the Applicant and (Co)-Rapporteur and EMA should receive a copy.

Comments, opinions or recommendations given by the AEMPS in these meetings are not binding. The final recommendation will be given once the whole dossier documentation is assessed in depth at the time of the MAA submission.