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Human Medicines Division

Guidance to applicants /Marketing Authorisation Holders (MAHs) on oral explanations at EMA

1. Introduction and Scope

This document is intended to provide practical guidance to companies on oral explanations/discussion meetings before Committees, Working Parties, Scientific Advisory Groups (SAGs) and Ad Hoc Expert Groups (AHEGs) (irrespective of the type of application / procedure under discussion).

2. Preparation for the oral explanation

- In principle, no later than 7 working days in advance¹, the EMA contact point confirms the timeslot to the company to attend the oral explanation in front of Committees, Working Parties, SAGs and AHEGs. The number of participants allowed to any oral explanation at the EMA should not exceed 12.
- The company provides EMA, no later than 2 working days in advance (if applicable), with a list of their participants (first name, surname, email address and contact phone number), as well as details of their affiliation, and their role during the oral explanation.
- Participants will be allowed to join the plenary meeting at the start of the oral explanation.
- Where several groups of applicants/MAHs are involved in a procedure (e.g. a referral procedure), they are encouraged to further group themselves in order to provide a single oral explanation on the issues identified by the Committee concerned. The composition of the group should be sent to the EMA no later than 2 working days in advance of the meeting if applicable.
- Please note that EMA will not admit to the meeting any non-listed participants.
- An electronic version of the final presentation should be sent to the EMA by e-mail (or uploaded via the IRIS portal where applicable) no later than 2 working days (if applicable) before the oral explanation.

¹ Derogation from the timelines set in this guidance are specific to some Working Parties or can be accepted in exceptional cases, when the company is requested to present at short notice by a Committee / Working Party.



- In preparation of attendance at the oral explanation, company's representatives should be aware that the scheduled starting time for an oral explanation can be slightly anticipated or delayed, depending on the running of the meeting and internal preparatory discussion in advance of the oral explanation. Therefore, sufficient time should be allowed for attending the oral explanation.

3. Conduct of an oral explanation

- An EMA representative will check the participants' names before admitting them to the plenary meeting for the oral explanation.
- The Chairperson will invite the company's representatives to briefly introduce themselves and to then give their presentation.
- An EMA representative will display and navigate the company's presentation².
- The company presentation should not be any longer than 20 minutes³ and should focus on the relevant scientific evidence submitted and company's position in relation to the issues identified by the Committee and notified to the company (it is recommended not to plan more than 2 or 3 speakers for a 20-min presentation). This will be followed by a Questions & Answers session. Normally, the overall duration of the oral explanation (presentation and Q&A session) is up to one hour.
- At the conclusion of the oral explanation, the representatives of the company will leave the plenary meeting and the Committee / Working Party / SAG / AHEG will then engage in further discussions.
- The company will be provided with feedback by the Rapporteur / Coordinator and EMA after the scientific discussion.

² In some Working Parties / SAGs / AHEGs meetings, the conduct of an oral explanation may be different.

³ No longer than 30 minutes for SAGs / AHEGs meetings, with overall duration of oral explanation and Questions & Answers session normally up to one hour.