



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support 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 invited to give oral explanations (OE) in front of Committees, Working Parties and Scientific Advisory Groups (irrespective of the type of application / procedure under discussion).

### 2. Preparation for the oral explanation

- In principle, no later than seven working days in advance<sup>1</sup>, the EMA contact point confirms the timeslot of the oral explanation to the company, and also specifies the number of participants allowed to be present. This number may vary, depending on to which group the company is presenting. However, the number of participants allowed to any oral explanation at the EMA should not exceed 10.
- The company provides EMA (no later than 2 days in advance) with a list of their participants, (first name and surname), as well as details of their affiliation, and their role in the OE. The company should also indicate any technical support required for their presentation during the OE (e.g. whether the presentation will be run on a company laptop or from the Agency PC).
- Where several groups of applicants or 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 days in advance of the meeting.
- Where a company representative or expert cannot attend the oral explanation in person, the company can request (no later than 2 days in advance) that this person is connected to the oral explanation via teleconference. In such cases, further to confirmation from EMA, the company should provide an EU landline telephone number to connect the participant by teleconference.

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<sup>1</sup> Derogation from the timelines set in this guideline can be accepted in exceptional cases, when the company is requested to present at short notice by a Committee / Working Party.



Please note that EMA will not dial into a teleconference system or mobile numbers. There is no option for non-listed participants to dial-in to the teleconference.

- A draft of the presentation to be given at the oral explanation should be sent to the EMA contact point and Rapporteurs /Coordinator at the latest 7 working days before the date of the oral explanation.
- An electronic version of the final presentation should be sent to the EMA by e-mail no later than 2 working days before the oral explanation and, in case of any update of the presentation, on the day of the presentation, either by e-mail or on a USB key. (Note: Even if the company is presenting from their own laptop, an electronic copy of the presentation must be provided to the EMA as a formal record).
- EMA will advise whether hard (paper) copies of the presentation are required, and how many. In such cases, the copies should be provided either in advance of the meeting date via courier, or provided directly to the EMA contact point on the day of the oral explanation (no later than two hours in advance of the start of the OE). In case of on-the-day delivery, copies should be brought to the Ground Floor reception area and Reception staff informed of the purpose of the delivery (Oral Explanation at Committee / Working Party, Name of company, and EMA contact name). Presentations cannot be left at Reception but must be handed over to the EMA contact person in the Reception area.
- In making travel arrangements for attendance at the oral explanation, company representatives should be aware that the scheduled starting time for an oral explanation can be delayed, due to busy meeting agendas or requirement of internal discussion in advance of the oral explanation. Therefore sufficient time should be allowed in planning return flights / journeys.

### **3. Conduct of an oral explanation**

- The company should arrive at the EMA no later than 30 minutes in advance of the scheduled oral explanation and will be asked to wait in the Industry lounge.
- An EMA representative will escort the participants for the oral explanation to the meeting room for the oral explanation.
- The Chairman will invite the company's representatives to briefly introduce themselves and to then give their presentation.
- The company presentation should not be any longer than 20 minutes<sup>2</sup> 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. This will be followed by a Questions & Answers session. Normally, the overall duration of the oral explanation and Questions and Answers is up to one hour.
- At the conclusion of the oral explanation, the representatives of the company will be escorted out of the meeting room and the Committee / Working Party will then engage in discussion on the outcome.
- The company will be provided with feedback by the Rapporteur / Coordinator and EMA after the scientific discussion.

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<sup>2</sup> No longer than 30 minutes for Scientific Advisory Group / Ad Hoc Expert group meetings, with overall duration of oral explanation and Questions and Answers normally up to one hour.