EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Guidance to applicants / marketing authorisation holders on oral explanations at CVMP

1. Introduction and scope

This document is intended to provide practical guidance to companies invited to give oral explanations to the Committee for Medicinal Products for Veterinary Use (CVMP); however, the same principles will usually apply for oral explanations at CVMP Working Parties and other CVMP Advisory Group meetings (irrespective of the type of application / procedure under discussion).

In general, an oral explanation is requested by the CVMP; however, requests for an oral explanation can also be made by applicants/marketing authorisation holders.

In cases where the applicant or marketing authorisation holder requests an opportunity to provide an oral explanation to the CVMP, such requests should be agreed by the CVMP at a meeting prior to the date of the oral explanation (see the question on referrals: *'Will I have the possibility to present my views in front of the CVMP and how is this organised?'*).

2. Preparation for the oral explanation

- In principle, no later than three weeks in advance[1], the European Medicines Agency (EMA) contact point (usually the procedure manager and/or assistant) confirms the date and 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 EMA should usually not exceed 5. Exceptionally, more participants might be acceptable if the company can justify the specific need for all participants, and why 5 would not be enough.
- Where several applicants or marketing authorisation holders are involved in a procedure (e.g. a referral procedure), they are encouraged to group themselves in order to provide a single oral explanation on the issues identified by CVMP or other group concerned. The composition of the group should be sent to EMA no later than 2 weeks in advance of the meeting.

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

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- No later than 2 weeks in advance of the meeting a list of participants including their short curriculum vitae (CV), as well as details of their affiliation, and their role in the oral explanation should be provided to EMA.
- Where a company representative or expert cannot attend the oral explanation in person, the company can exceptionally request (usually no later than 2 weeks in advance of the meeting) only that a particular 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 that participant by telephone. Please note that EMA will not dial into a teleconference system or mobile numbers. It is not possible for anyone else to be connected (for example, just to listen to the oral explanation).
- The company should provide EMA no later than 2 weeks in advance of the meeting with initial written responses to the questions posed including at least those intended to be addressed at the oral explanation. The presentation slides, which will be presented during the oral explanation, should be sent electronically to the Agency and rapporteurs at least 7 working days before the date of the oral explanation. If applicable, any additional technical support required for the presentation during the oral explanation should also be indicated. Presentations are considered as part of responses to questions, and complete responses to all the questions (including the ones that are to be discussed during the oral explanation) should be provided to all CVMP members in writing in accordance with published submission dates.
- Changes to a presentation after submission are generally not foreseen. In the exceptional case of any update of the presentation, an electronic version of the amended presentation should be sent to the EMA contact person by e-mail no later than 1 working day before the oral explanation (Note: even if the company is presenting from their own laptop, an electronic copy of the presentation must be provided to EMA as a formal record).
- 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 a busy meeting agenda or requirement of internal discussion in advance of the oral explanation. Therefore sufficient time should be allowed in planning return flights / journeys. It is also recommended to provide the EMA contact point with a mobile number of one of the participants in case of e.g. any last-minute changes to the timing.
- In case the company considers that there is no need any longer for an oral explanation (e.g. because a point initially considered for discussion has been resolved with the assessment of the written responses), the EMA contact point should be notified as soon as possible. In liaison with the rapporteurs an oral explanation could then be cancelled.

3. Guidance on making a presentation at the EMA

The below guidance is not mandatory and is for information purposes only:

- Presentations should have a white background and all slides should be numbered.
- It is recommended to avoid using the colour red for text as it can be difficult to read from afar.
- For better readability it is recommended that any text is no smaller than 20pt.
- Ideally, slides should not display more than three levels of information per slide.
- For charts, red and green and grey-scale in the same chart should be avoided and font size within charts should not be less than 10pt.

- Light background colours for graphs and charts are recommended. Caution should be taken when figures are taken directly from scientific literature as they may not translate clearly when projected.
- It is recommended not to present more than 10-15 slides (see timeframe outlined below); however, it is possible to add a few “back-up slides” with additional data, which could be used by the company if needed (e.g. to respond to questions raised during the question and answer session after the presentation).

4. Conduct of an oral explanation

- The company should arrive at EMA no later than 30 minutes in advance of the scheduled oral explanation and, after registration, will be asked to wait in the industry lounge. In case of an unexpected delay of arrival, the applicant should inform the EMA contact point as soon as possible.
- The reception will inform the EMA contact point about the arrival of the participants, and the EMA contact point will usually meet the participants briefly in the industry lounge. However, depending on the type of meeting and agenda, this might not always be possible.
- An EMA representative will escort the participants for the oral explanation to the plenary meeting room.
- At plenary, the Chairperson will invite the company’s representatives to briefly introduce themselves and to then give their presentation.
- The overall duration of the oral explanation should be no more than 30 minutes; this time includes the presentation by the company, questions raised by the CVMP/Working Party/other group and the responses from the company to these questions.
  The company presentation should therefore not be longer than 15-20 minutes, and should focus on the relevant scientific evidence submitted and the company’s position in relation to the issues identified by the CVMP/Working Party and notified to the company.
- At the end of the oral explanation, the representatives of the company will be escorted out of the meeting room and the CVMP/Working Party will then engage in discussion on the outcome.

5. Follow-up after an oral explanation

- The company will be provided with verbal or written feedback on the outcome of the oral explanation, indicating e.g. if all the points of the oral explanation have been satisfactorily explained or if there remain any outstanding issues.
- Participants might choose to wait in the industry lounge for direct verbal feedback by the rapporteur(s) / coordinator and/or the EMA procedure manager after the oral explanation. The EMA contact point should be informed about this intention. Such feedback can, however, only be provided during a break or after the end of the meeting, and participants should consider a waiting time, for example by making appropriate travel arrangements.