

GUIDANCE ON ORAL EXPLANATIONS TO CMDh
Annex to CMDh SOP
Disagreement in Procedures – Referral to CMDh

Doc. Ref.: CMDh/104/2006/Rev2
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Reference: *Article 29(3) of Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code and relating to medicinal products for human use.*

1. BACKGROUND

When one or more of the Member States involved in a particular Decentralised Procedure (DCP) or Mutual Recognition Procedure (MRP) cannot approve the draft assessment report in DCP or assessment report in MRP, the SPC, labelling and PL in 90 days from receipt of the relevant documents according to Article 28(4) of the above mentioned Directive, the points of disagreement shall be referred to the CMDh. Standard Operating Procedure for a referral to CMDh is published on <http://www.hma.eu/26.html>. Within this procedure Member States shall use their best endeavours to reach agreement on the action to be taken and they shall allow the applicant to make his point of view known orally or in writing.

The presented guidance should contribute to efficiency of oral explanations provided by the applicants to the CMDh.

2. ADVICE ON AN ORAL EXPLANATION

In the case of disagreement in a particular procedure a list of questions (LoQ) is agreed by the CMDh and sent on Day 10 of the procedure to the Applicant by the CMDh secretariat, including the following:

- List of questions
- Request to send a written response document which addresses each question from the list, at latest by day 25
- Advice to discuss with the RMS the need for an oral explanation in addition to the written response document for all or specific questions
- Request to inform the CMDh secretariat and the RMS contact, within two weeks following the receipt of the LoQ, about the applicant's wish to present its point of view orally at the CMDh meeting.

3. PREPARATION FOR AN ORAL EXPLANATION

If an oral explanation is agreed, the CMDh secretariat will confirm to the applicant, one week prior to the meeting, the time slot assigned for the oral explanation, after consultation with the RMS.

The applicant should not be represented by more than five persons in total; a list of the names of proposed attendees representing the applicant, as well as details of their affiliation and their role in the oral explanation should be sent to the RMS and the CMDh secretariat by Wednesday before the CMDh meeting. The applicant should indicate the technical support required for their presentation during the oral explanation (e.g. overhead projector, own computer, slide projector). It is recommended, whenever possible, to make a computer assisted presentation.

At the request of the applicant and upon agreement of the CMDh a teleconference may be arranged by the EMA.

The applicant should provide the RMS, CMDh members and CMDh secretariat with the presentation in electronic version at the latest by Friday before the oral explanation (not later than 3 p.m. GMT).

On the day of the oral explanation, the applicant should arrive at the EMA premises no earlier than one hour before the time scheduled for the oral explanation and provide the CMDh secretariat with 60 paper copies of the handouts and the final electronic version of the presentation.

4. ORAL EXPLANATION

Oral explanation takes place in the scheduled CMDh meeting according to the timetable.

Before the arrival of the applicant the RMS should summarise:

- Outcome of the review of the response document submitted by the applicant, including advice from CHMP, HMPC, their working parties or HMPWG, if relevant
- Comments on the new SPC, PL and labelling or commitments proposed by the applicant, if relevant
- Remaining issues of concern.

The RMS should ask the MSs which have raised potential serious risk to public, if the remaining concerns are addressed. A short presentation of the concerns can be made by any of the MSs and it is recommended to make the presentation available to all CMD (h) Members before the meeting. An agreed approach to the questioning of the applicant should be defined by the CMDh members before inviting the applicant to participate.

The oral explanation should be prepared by the applicant taking into account that the actual presentation should:

- Be maximum 20 minutes
- Focus on responses to the most relevant questions from the LoQ followed by a conclusive statement
- If appropriate, describe the impact on the SPC and PL and/or commitments proposed by the applicant.

The actual presentation may be followed by questions and answers session. The overall duration of an oral explanation including questions and answers session should be maximum 40 minutes, taking into account the number of questions and the subject concerned.

After the applicant has left the room, the CMDh members should continue their discussions on the outstanding issues, with the objective to reach agreement on the action to be taken. In principle, final agreement on the outcome of the procedure is aimed to be reached within the CMDh meeting. In the case no agreement could be reached at the CMDh meeting, the full 60 days as foreseen in the legislation should be used to get an agreement on the subject between RMS, CMSs and the applicant.

After the oral explanation and subsequent discussion, the RMS informs the applicant about the outcome of the discussion and of any remaining issues.