

BEST PRACTICE GUIDE ON BREAK-OUT SESSIONS/HEARINGS FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

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1. INTRODUCTION

In order to facilitate discussion of *potential serious risk to public health* (ref. Commission Guideline on definition of a potential risk to public health 2006/C 133/05) during a Mutual Recognition (MRP) or Decentralised (DCP) Procedure, a meeting can be arranged between Member States, and if necessary the applicant. These meetings are not routinely required for every procedure and will take place when considered necessary and useful by the Member States involved, taking into account an applicant's request for a meeting.

The objective of the discussion is to provide a structured forum for interaction between the Reference Member State (RMS), all Concerned Member States (CMS), and, if necessary, the applicant, in order to achieve consensus through negotiation on points of potential serious risk to public health (PSRPH).

This is an important liaison facility within the overall MRP and DCP processes to consider Member States viewpoints and clarify any aspects from the applicant, particularly when the RMS is of the opinion that the application is not approvable or where discussion will help reach agreement among MS and avoid the triggering of a CMDh referral procedure by a CMS. All involved parties are encouraged to maximise the potential of such a meeting and to participate fully to help achieve consensus.

2. FORMAT OF MEETING

Hearings, in cases where the RMS regards the application as non-approvable or where the RMS considers that a discussion with the CMDh on a procedure would be beneficial, will be included in the CMDh agenda and held in the plenary meeting.

Break-out sessions, involving the RMS, CMS and, if necessary, the applicant should be arranged to be held by teleconference, and should take place in advance of a CMDh plenary meeting so that further discussion can take place between MS at the plenary meeting, if necessary.

3. PARTICIPANTS

The participants in a break-out session teleconference shall include the RMS and should include representatives from all CMS involved in the procedure, in particular the Member State(s) with outstanding PSRPH, representatives from other Member States with a specific interest in the discussion, and if necessary, representatives from the applicant.

For a Hearing, the discussion will take place in the plenary CMDh meeting and all Member States will participate. The applicant may be invited to participate in the discussion.

4. TIMING

Break-out sessions should be arranged, where possible, in advance of a CMDh meeting unless the RMS considers the discussion should take place in the CMDh plenary meeting. This is the case when 1) the RMS has raised a potential serious risk to public health and the application would be refused without any possibility

for the applicant to make their case in a CMDh referral procedure, or 2) the RMS is positive, but considers that it is beneficial for the issues to be discussed at the CMDh plenary meeting.

For mutual recognition procedures, the discussion will normally be arranged around Day 75 of the procedure.

For decentralised procedures, the discussion will normally be arranged around Day 195 of the procedure, but could be earlier if necessary.

A break-out session or hearing may be necessary in some cases for Type II variations, for example when adding a new indication. The exact timing of the meeting will be dependent upon the individual situation for an application.

In all cases, if a hearing is to be arranged in the plenary meeting, the RMS should inform the CMDh secretariat at least 5 working days before the start of the meeting so that it can be included on the CMDh agenda. Where the applicant is to attend the plenary meeting, they should be represented by not more than five persons in total; a list of the names of proposed attendees representing the applicant should be sent to the RMS and the CMDh Secretariat on the Wednesday before the plenary CMDh meeting.

Break-out sessions via teleconference are arranged by the RMS, who should send out an invitation to CMS, and if necessary, the applicant, indicating which topics will be discussed.

5. MEETING STRUCTURE

Meetings, both teleconferences and hearings, will be chaired by the RMS and will usually be conducted in three parts as follows:

- There should be an initial discussion aimed at resolving remaining issues between Member States. The RMS should then identify the remaining PSRPH to be discussed with the applicant.
- The applicant will then be asked to join the meeting to respond to outstanding issues if Member States consider this will be beneficial. (Note: the technical practicality of this when the meeting is via teleconference may need to be considered by the RMS). The RMS should start by introducing the representatives of the Member States to the applicant and invite the applicant to do likewise. The RMS should then summarise the remaining PSRPH to the applicant and explain the status of the discussion. Limited time is available and the applicant must give focused presentations. An agreed approach to the questioning of the applicant should be defined by the Member States before inviting the applicant to participate. Upon completion of the questions and discussion, the applicant should be informed that they will be notified by the RMS about the outcome, including any remaining PSRPH.
- Following the departure of the applicant from the meeting, Member States should continue their discussions on the outstanding issues, with the objective to reach consensus where possible.

6. POST MEETING ACTIONS

Immediately after the meeting, the outcome of the discussion with Member States should be stated orally to the applicant by the RMS.

Where the break-out session was held by teleconference, the RMS will prepare brief summary minutes, which will be tabled at the next CMDh plenary meeting. The RMS will give an oral report at the CMDh meeting. A template for the minutes is included as an appendix.

Where the hearing was held in the CMDh plenary meeting, the outcome of the discussion will be included in the CMDh minutes.

Appendix 1

MINUTES OF BREAK OUT SESSION

Product name Procedure number(s) Active substance Date and place of meeting RMS	
CMS involved in the procedure	
Attendees from Member States	
Attendees from Applicant	

Issues for discussion
Discussion between RMS and CMS
Discussion with Applicant/Presentation
Summary and Conclusions
Further Action