

BEST PRACTICE GUIDE ON BREAK-OUT SESSIONS 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](#)) by Member States during a Mutual Recognition (MRP) or Decentralised (DCP) Procedure, meetings, referred to as Break-out sessions, can be arranged. 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](#). Applicants are allowed to participate in the break-out session to ensure an effective dialogue with Member States on the outstanding issues.

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2. OBJECTIVE OF BREAK-OUT SESSION

The objective of the Break-out session is:

To provide a structured forum for interaction between representatives from the Reference Member State (RMS), all Concerned Member States (CMS), and, if necessary, the applicant, with the objective to achieve consensus through negotiation on points of potential serious risk to public health ([PSRPH](#)) and the Summary of Product Characteristics ([SmPC](#)). This is also an opportunity for Member States to discuss outstanding product leaflet and labelling concerns.

The break-out session is an important liaison facility within the overall MRP and DCP processes to consider Member States viewpoints and clarify any aspects from the applicant that may assist in avoiding the triggering of a CMDh referral procedure. All parties are encouraged to maximise the potential of a break-out session and to participate fully to help achieve consensus.

To facilitate consensus building, the applicant shall be allowed to orally explain outstanding issues if the Member States consider this would be beneficial.

3. PARTICIPANTS

The participants shall include the RMS, who shall chair the discussions, 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.

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The RMS and CMS should be represented by relevant assessors/experts. Full use should be made of video/tele-conferencing facilities in order to facilitate the participation of the different Member States. ~~If the break-out session is to include only representatives of the RMS, CMS and other interested Member States, then Vitero facilities (web meeting/conference) may be used if a face-to-face meeting cannot be arranged within the timeframe of the procedure or is not practicable. Member States and the European Medicines Agency (the Agency) should ensure they have adequate facilities in-house to use these methods of communication. MS should inform the Agency about the need for a videoconference or Vitero meeting at the latest three working days before the meeting.~~

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In the exceptional case a CMS cannot send a representative ~~or cannot participate by teleconference~~, the RMS should be informed by e-mail at least ~~three~~ working day before the meeting. ~~If a CMS is participating by video/tele-conference~~, a contact name and telephone number for the CMS should be provided ~~to the RMS and CMDh Secretariat~~. CMS with remaining ~~PSRPH~~ should endeavour to attend the break-out meeting.

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The applicant 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.

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Other Member States with an interest or concern in the particular product, the active substance or the therapeutic area in question, should attend the meeting as observers. Observers from non-EU countries, Norway, Lichtenstein and Iceland excepted, should sign the Confidentiality Undertaking and obtain explicit agreement from the applicant before attending a break-out session.

4. TIMING

Break-out sessions should be arranged, where possible, to coincide with CMDh meetings.

4.1 New Applications

For mutual recognition procedures, break-out sessions, when required, will normally be arranged around Day 75 (but may take place between Day 73 and Day 80).

For decentralised procedures, break-out sessions, when required, will normally be arranged around Day 195 (Day 75 of the 90-day period), but at the latest by Day 205 (Day 85 of the 90 day period).

MRP

- By Day 50, CMS will inform the RMS and the applicant of their concerns. If possible the CMS should indicate how ~~PSRPH~~ could be resolved (e.g. by ~~Sm~~PC changes).
- By Day 65, the RMS will indicate the expected need for a break-out session circulating a draft agenda, including the length of time for the session, to the CMS and the applicant. Where appropriate, extended break-out sessions will be held to permit sufficient discussion of the issues. The ~~CMDh Secretariat~~ should be informed accordingly in order to guarantee availability of meeting facilities. The ~~CMDh Secretariat~~ will confirm the timetable and meeting room to the RMS by e-mail.
- By Day 70, the CMS should, after reviewing the response from the applicant/RMS, inform the RMS of remaining ~~PSRPH~~.
- The RMS should confirm that a break-out is needed by Day 71. A final agenda should be circulated by Day 71 and should clearly state the remaining ~~PSRPH~~. If the written response from

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the applicant/RMS resolves all outstanding issues, the RMS should in clear terms inform the applicant, CMS and ~~the CMDh secretariat~~ that the break-out session has been cancelled.

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- After the break-out session, the applicant may request meetings with individual Member States with remaining ~~PSRPH~~, keeping the RMS and other CMS fully informed.

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DCP

- By Day 145, CMS will inform the RMS of their remaining concerns. If possible the CMS should indicate how ~~PSRPH~~ could be resolved (e.g. by ~~SmPC~~ changes).

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- By Day 150, if consensus is not reached, the RMS communicates the remaining ~~PSRPH~~ to the applicant.

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- By Day 160, the applicant submits additional clarification, including any revised proposal for the ~~SmPC~~, package leaflet and labelling.

- By Day 180, the RMS will indicate the expected need for a break-out session circulating a draft agenda, including the length of time for the session, to the CMS and the applicant. Where appropriate, extended break-out sessions will be held to permit sufficient discussion of the issues. ~~The CMDh Secretariat should be informed accordingly in order to guarantee availability of meeting facilities. The CMDh Secretariat will confirm the timetable and meeting room to the RMS by e-mail.~~

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- By Day 190, the CMS should, after reviewing the response from the applicant/RMS, inform the RMS of remaining ~~PSRPH~~.

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- The RMS should confirm that a break-out is needed by Day 191. A final agenda should be circulated by Day 191 and should clearly state the remaining ~~PSRPH~~. ~~If the written response from the applicant/RMS resolves all outstanding issues, the RMS should in clear terms inform the applicant, CMS and CMDh Secretariat that the break-out session has been cancelled.~~

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- After the break-out session, the applicant may request meetings with individual member states with remaining ~~PSRPH~~, keeping the RMS and other CMS fully informed.

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4.2 Variations

Break-out sessions may be necessary in some cases, for Type II variations being processed according to a 60-day or an extended 90-day assessment time scale, for example when adding a new indication. [Note: these timings refer to the completion of the assessment report and correspond to overall time scales of 90 and 120 days respectively, for completion of the procedure (excluding clock-off times)].

In exceptional circumstances, a break-out session may be held for variations concerning urgent safety issues which are being processed according to an expedited (30-day) overall time scale. In this case the break-out session should be held during the clock-stop period to allow the Pharmacovigilance Working Party (PhVWP) to discuss issues arising, as needed.

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The exact timing of a break-out session will be dependent upon the individual situation for an application, but the following possibilities exist for the 60-day or 90-day process (depicted below as 60/90):

- At Day 30/50, in rare cases for difficult emerging situations identified by the RMS ahead of circulation of the preliminary variation assessment report (PVAR) at Day 40/70.
- During clock-off period, after receipt of supplementary information from the company and before circulation of the finalised variation assessment report (FVAR) at Day 60/90.
- At Day 75/105, ahead of CMS notifying acceptance/non-acceptance of FVAR decision (at Day 85/115). In this instance, the RMS should restart the clock (Day 60/90) by circulating the FVAR at an appropriate time point in relation to the next CMDh meeting.

Action by RMS and CMS

The RMS will liaise with the CMS and applicant as appropriate to determine the need for a break-out session and agree its timing. The RMS will schedule the break-out session for a given application. The CMDh Secretariat should be informed accordingly in order to guarantee availability of meeting facilities. The Agency will confirm the timetable and meeting room (if appropriate) to the RMS by email.

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The actions taken by the RMS and CMS in the lead-up to the break-out session are illustrated by the following example for a Type II variation in which the CMS maintains a discordant position after release of the FVAR. (Note: Timings for break-out sessions at other times envisaged above follow a similar structure as per the example below). These steps should be taken as soon as possible, however the timings shown below are suggested maximum timelines that allow the RMS to arrange the break-out session at around Day 75/105 to coincide with the next CMDh meeting:

Day 60/90 RMS circulates FVAR to CMS and applicant with draft decision.

By Day 68/98 CMS inform the RMS of the need for a break-out session and provide a list of outstanding issues.

By Day 69/99 RMS schedules the break-out session with the CMDh Secretariat. RMS informs the applicant of the break-out session and forwards a draft agenda and a list of outstanding issues to be addressed. RMS may request the applicant to be prepared to address these.

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By Day 72/102 *Break-out session confirmed:* RMS circulates the final agenda to CMS and applicant.

Or

Break-out session cancelled: CMS inform the RMS if the break-out session is no longer needed e.g. if the outstanding issues have been resolved. In this case, the RMS will inform the CMS, CMDh Secretariat and applicant that the break-out session has been cancelled.

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Day 75/105 The break-out session takes place.

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5. REQUIREMENTS FOR APPLICANTS

- New Applications: - For **MRP**, applicants will receive the CMS points by Day 50, at the latest. Applicants will provide their responses to RMS and CMS, by Day 60. For **DCP**, applicants will receive the CMS points by Day 150 at the latest. Applicants will provide their responses to RMS and CMS, by Day 160.
- Variations: - The RMS will liaise with the applicant in advance of the break-out session to advise on particular outstanding issues and whether attendance is required at the meeting and the need to come prepared to address the issues.

Applicants should arrive at the Agency premises no earlier than half an hour before the break-out session, checking in at the reception. Applicants should check out at the Agency reception before leaving the premises.

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Applicants attending the Agency for break-out sessions should be aware that they may not be required to participate in the full session, but may be asked to agree amendments to SmPCs or to answer questions from Member States. It is, therefore, beneficial if applicants are present at the Agency. Applicants should ensure that their representatives are authorised to make decisions on amendments to SmPCs being proposed by Member States

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6. MEETING STRUCTURE

Face-to-face meetings should be conducted by the RMS in three parts as follows,

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- A discussion, aimed at resolving remaining issues between Member States. The RMS should then identify remaining PSRPH to be discussed with the applicant.
- The applicant will be asked to join the meeting to respond to outstanding issues if Member States consider this will be beneficial. 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 room the Member States should continue their discussions on the outstanding issues, with the objective to reach consensus where possible.

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7. POST MEETING ACTIONS

- Immediately after the meeting, the outcome of the discussions with Member States should be stated orally to the applicant by the RMS.
- The RMS will give an oral report on the break-out session to the CMDh plenary meeting.

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- Brief summary minutes of the break-out meeting should be prepared by the RMS as soon as possible (within 2 working days) after the meeting. The minutes should focus on the main issues for discussion and the outcome of the discussion. Detailed comment is not required. A template for the minutes is included as an appendix to this BPG on break-out sessions. The minutes should be copied to the Chairperson of the CMDh, the ~~CMDh Secretariat~~, CMS and the applicant.
- Within 2 working days of receipt of the minutes of the break-out session, the applicant should submit amended ~~SmPC~~, ~~package~~ leaflet and labelling, as appropriate, and any complementary information, to the RMS and CMS in accordance with agreements made during the meeting.

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Outcomes of all break-out sessions will be monitored by CMDh.

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Appendix 1

MINUTES OF BREAK OUT SESSION

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

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Best Practice Guide link
<http://heads.medagencies.org/mrfg/docs/bpg/breakfin.pdf>¶

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

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