

Annex A4

CMD(h) Pandemic Plan

Best Practice Guide on Break-Out Sessions for Mutual Recognition and Decentralised Procedures

During a pandemic period (WHO phase 6) work will be undertaken for the CMD(h) priority functions detailed in Section 6 of the CMD(h) Pandemic Plan and within the framework of Section 9.

In order to facilitate discussions on points of potential serious risk to public health (PSRPH) of prioritised applications in Mutual Recognition (MRP) and Decentralised Procedures (DCP) for both new applications and variation applications, there will be a need to make full use of Break-Out Sessions (BoS).

The following revisions to the normal procedure for Break-Out Sessions should be implemented during a pandemic period (WHO phase 6):

Communication tools for Break-Out Session

In the event that normal CMD(h) activities are restricted and there are no regular CMD(h) meetings, it will not be possible to hold Break-Out Sessions at the EMEA with RMS, CMS and the Applicant. Therefore, in order to facilitate discussions between all interested parties, it will be necessary to make full use of other communication channels including, video/teleconferencing or Vitero facilities. Member States and the EMEA should ensure that they have adequate facilities in-house to use these methods of communication.

Participants at Break-Out Sessions

Every effort should be made for the RMS, all CMS, other interested MS and if necessary representatives from the Applicant to join in discussions at the Break-Out Session. The RMS and CMS should be represented by relevant assessors/experts or in their absence by the CMD(h) member and/or the alternate CMD(h) member. In the exceptional circumstances that the RMS assessors/experts or CMD(h) member cannot be involved in the BoS or cannot be contacted through the Member States normal communication channels, then the CMD(h) Crisis Team should take over the management/coordination of the Break-Out Session and chair the discussions.

Timing of Break-Out Session

Break Out Sessions should follow the normal timelines described in the BPG for the relevant new or variation application procedure, except where a Member State (RMS or CMS) or the Applicant identify an urgent need to seek early discussion on an issue in order to clarify any outstanding concerns or to achieve consensus through negotiation on points of PSRPH and/or the Summary of Product Characteristics and other product particulars.