

Annex A9

CMD(h) Pandemic Plan

Referrals to CMD(h) (Section 6.5)

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. Some of these procedures or other procedures pending at the time of an outbreak of a pandemic situation might result in disagreements among CMSs and be referred to CMD(h) according to Article 29(1) of the Directive 2001/83/EC as amended.

A CMD(h) referral for a 'routine' product may be *suspended* when there is a phase 6 situation and one of the Member States declare that a pandemic has occurred in their country which affects the running of procedures. This should be done by the CMD(h) member/the alternate CMD(h)member or the NCA who informs the CMD(h) crisis team that they for a defined period are not able to perform their duties as RMS or CMS for applications.

If the product is prioritised according to section 6.1 and the referral concerns a safety issue, the CMD(h) referral should continue and the CMD(h) crisis team takes over the coordination of the prioritised application referral if the RMS itself is unable to fulfil its duties..

Where a referral proceeds, the timelines in section 5.6 should be agreed and the discussion should be performed by e-mail and telecon preferably by Vitero. This applies also for the oral hearing of the applicant.

Furthermore, should the exceptional situation arise that a CMD(h)member/NCA cannot be reached through MS's normal channels then the CMD(h) crisis team has the power to take over the coordination for the urgent prioritised application(s).

The procedure in the previous paragraph can be agreed (pandemic situation) without first having an agreement with the applicant/MAH. The agreement can be made by e-mail correspondence or other media and does not require a formal written signature between the current RMS and the new MS/CMD(h) crisis team.