

Annex A1

CMD(h) Pandemic Plan

Change of RMS (Section 5.7)

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. There may therefore emerge situations where a change of RMS is needed due to e.g. staff absence in the current RMS.

If the CMD(h) member/the alternate CMD(h)member or the NCA inform the CMD(h) crisis team that they for a defined period are not able to perform their duties as RMS for applications/medicinal products which are prioritised and they haven't succeeded in their attempt to make arrangement with another MS hereof the CMD(h) crisis team takes over the coordination of the prioritised applications.

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).

Change/takeover of RMS can be agreed under the above-mentioned 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.

It is though the obligation of the original RMS, if requested and if possible, to assist either the MS they have made arrangement with or the CMD(h) crisis team with relevant information/material to enable them to coordinate and perform procedure(s) for the prioritised application(s)/medicinal product(s).

The new temporary RMS has first the duty to inform the CMS and the applicant/MAH about the takeover in connection with start of the procedure(s). The CMS can be informed in CTS by making an annotation in the field RMS "application received". The new temporary RMS will perform the procedure(s) using the original RMS allocated main procedure number.

After end of the pandemic period or end of the period agreed between the two parties original RMS respectively new temporary RMS/CMD(h) crisis team the responsibilities for the applications /medicinal products goes back to the original RMS.

This agreement applies only during a pandemic period(WHO phase 6). For all other requests for change of RMS the CMD(h) refers to "CMD(h) procedural advice on changing the reference member state" (current version).