

Annex A8

CMD(h) Pandemic Plan

Communication and Implementation of Safety Information

A joint working group of CMD(h) and PhVWP usually meets every second month, to discuss issues of common interest.

Communication between CMD(h) and PhVWP is to be facilitated by two (2) appointed delegates from each group. One of the delegates is usually from the member state holding the presidency. In the event of staff absences during a pandemic the CMD(h) crisis team should be informed of the unavailability of the facilitators and the team should assume this responsibility for any urgent issues.

During the crisis period safety issues should be prioritised according to their potential public health impact on European patients. Consideration should be given as to whether any proposed product information updates can be held over to the end of the crisis or whether they need to be implemented immediately or in a short time-frame. Any pharmacovigilance issues related to medicinal products that would be used to treat or relieve the pandemic disease would take priority.

Product related safety issues which result in a recommendation to amend product information (SPC and PL) before the end of the crisis should still be handled in a harmonised way. There may however be a necessity for a temporary RMS to be appointed in some cases (see separate annex on changing RMS during the pandemic). Consideration should also be given to setting an implementation timetable that can practically be achieved during the crisis period taking into account the level of absence at NCAs and the affected companies.

This agreement applies only during a pandemic period (WHO phase 6). During the 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. For other new recommendations for safety warning updates the latest version of the 'PhVWP and CMD(h) Best Practice Guidance on Communication and Implementation of Safety Information' should be followed.