

Update on handling worksharings for variations involving products authorised via MRP/DCP and purely-nationally authorised products (NAPs)

I. Background information

Article 20 of the variations' Regulation 1234/2008, as amended, allows a MAH to submit in one application the same Type IB, the same Type II variation, or the same group of variations corresponding to one of the cases listed in Annex III of the Regulation or agreed with the RMS, the national competent authority (NCA) or the EMA (as appropriate).

The following worksharing procedures including more than one Member State (MS) are possible:

<p>More than one purely-national MA of same MAH <u>in more than one MS</u> (also one purely-national MA of the same MAH in more than one MS)</p> <ul style="list-style-type: none"> One of the MSs will act as reference authority: confirmation by CMDv necessary.
<p>More than one mutually recognised MA of same MAH</p> <ul style="list-style-type: none"> One of the RMSs will act as reference authority: confirmation by CMDv necessary. If the RMS will be the same for all involved MRP/DCP MAs then this RMS will act as reference authority: confirmation by CMDv not necessary.
<p>One or several purely-national MA(s) and one or several mutually recognised MA(s) of same MAH</p> <ul style="list-style-type: none"> One of the RMS or MSs will act as reference authority: confirmation by CMDv necessary.
<p>More than CAP of same MAH</p> <p>One or several purely-national MA(s) and one or several CAP(s) of same MAH</p> <p>One or several mutually recognised MA(s) and one or several CAP(s) of same MAH</p> <p>One or several purely-national MA(s), one or several mutually recognised MA(s) and one or several CAP(s) of same MAH</p> <ul style="list-style-type: none"> EMA will be the reference authority.

II. General handling

- The MAH should propose/choose a NCA to act as the reference authority (RA), except for worksharing of products with the same RMS.
- Before notifying to the CMDv the MAH should contact the chosen NCA and discuss an upcoming worksharing procedure with them by submitting the draft letter of intent (<http://www.hma.eu/163.html>).
- If the NCA agrees to act as RA and confirms in principle that the proposed variation classification(s) and any grouping(s) are acceptable, the CMDv should be notified.
- The MAH should submit the final letter of intent to the chosen RA, copying the CMDv secretariat.
- The final letter of intent submitted at the latest **15 days** in advance of the next CMDv meeting will be discussed at that meeting. A list of CMDv meetings is published on <http://www.hma.eu/153.html>. Pre-submission notifications submitted less than 15 days in advance of the CMDv meeting will be discussed in the second CMDv meeting following submission.
- The CMDv secretariat will include the final letter of intent in the CMDv mailing to allow all involved MSs to check the proposal.
- Discussion will then take place then at the CMDv meeting.
- In the week after the CMDv meeting in which the request was discussed the RA will reply on behalf of the CMDv to the MAH:
 - confirming the CMDv's acceptance of the worksharing or informing on the non-acceptance (copying the CMDv secretariat and the list-v-mrve@eudra.org).
 - providing the worksharing procedure number to the MAH.
- The written confirmation from the RA should be included by the MAH within the variation application.
- Further information on the worksharing procedure can be found in the CMDv/BPG/018 BEST PRACTICE GUIDE for Worksharing (<http://www.hma.eu/163.html>).