BEST PRACTICE GUIDE

for

Re-examination of RMS assessment report procedure

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1. **INTRODUCTION**

Re-examination procedures are designed to guarantee applicant’s/marketing authorisation holder’s (MAH) rights. This document describes the procedure and gives guidance for the re-examination of the Reference Member State (RMS) final assessment report in the decentralised procedure in accordance with article 49(5) and the RMS / Reference authority’s (RA) final variation assessment report in accordance with article 66(9).

The document also gives guidance on the timetable for applicant’s/MAH’s involvement and for the assessment by CMDv for decentralised procedures and RMS re-examination for the variation procedures.

2. **SCOPE**

The re-examination procedure described in this procedural advice is applicable to:

- the final assessment report referred to in Article 49(5) which is the final assessment report circulated by the RMS in the decentralised procedure (hereafter referred to as FAR)
- the final variation assessment report referred to in Article 66(9) which is the final variation assessment report circulated by the RMS for veterinary medicinal products authorized under the MR/DC procedure or alternatively, the final variation assessment report circulated by the RA in the case of worksharing variation procedures (hereafter referred to as FVAR)

Whilst the same general principles of this Best Practice Guide will apply to variations requiring assessment purely nationally authorised products (NAPs), applicants are advised to liaise directly with the relevant National Competent Authority (NCA) to discuss the re-examination procedure for NAPs.

3. **LEGAL BASIS FOR THE RE-EXAMINATION PROCEDURE**

3.1 **Decentralised procedures:**

- Article 50(1) of Regulation (EC) No 2019/6 establishes that:
Within 15 days of receipt of the assessment report referred to in Article 49(5), the applicant may provide written notice to the competent authority in the reference Member State requesting a re-examination of the assessment report. In that case, the applicant shall forward to the competent authority in the reference Member State detailed grounds for such a request within 60 days of receipt of that assessment report. The competent authority in the reference Member State shall without delay forward that request and the detailed grounds to the coordination group.

3.2 Variations requiring assessment/Worksharing:

- Article 66 (10) of Regulation (EC) No 2019/6 establishes that:

Within 15 days of receipt of the opinion or the assessment report, the marketing authorisation holder may submit a written request to the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3), or the competent authority in the reference Member State, as applicable, for a re-examination of the opinion or the assessment report. Detailed grounds for requesting a re-examination shall be submitted to the competent authority, the Agency, the competent authority agreed in accordance with Article 65(3) or the competent authority in the reference Member State, as applicable, within 60 days of receipt of the opinion or the assessment report.

4. DESCRIPTION OF THE PROCEDURE

4.1 Applicant's/marketing authorisation holder's request for re-examination

Within 15 calendar days of receipt of the FAR/FVAR which are circulated with the “RMS / RA- Outcome of procedure” email (date of receipt by applicant as documented by Eudralink the applicant/MAH may request a re-examination of the FAR/FVAR using the CMDv template.

In case of the Decentralised procedure the RMS should without delay forward the request to the CMDv.

For variations requiring assessment/worksharing procedures the RMS/RA should without delay forward the request to the CMS.

Where the last day of the 15-day period is a public holiday/Saturday/Sunday, the period will end on the following working day. The days mentioned refers to the public holidays of the RMS.

The applicant’s/MAH’s written request for re-examination must be sent within the stated timeline. In case this deadline is not respected, the request for re-examination will not be accommodated and the FAR/FVAR is considered final.

4.2 Applicant's/marketing authorisation holder's detailed grounds for re-examination

Within 60 calendar days of receipt of the FAR/FVAR the applicant/MAH must submit to the RMS/RA the detailed grounds for the re-examination of the FAR/FVAR using the same CMDv template already populated at day 15 of the re-examination procedure.

For DCP the RMS should without delay forward the detailed grounds to the CMDv.

In case of variation/worksharing procedures the RMS/RA should without delay forward the detailed grounds to the CMS.
Where the last day of the 60-day period is a public holiday/Saturday/Sunday, the period will end on the following working day. The days mentioned refers to the public holidays of the RMS.

The detailed grounds for re-examination of the FAR/FVAR must be sent within the stated timelines. In case these deadlines are not respected, the request for re-examination will not be accommodated and the FAR/FVAR becomes final.

The detailed grounds submitted will determine the scope of the re-examination procedure and may encompass all aspects set out in the FAR/FVAR or only certain aspects of it. In the detailed grounds for re-examination of the FAR/FVAR the applicant/MAH should provide their justification for disagreement(s) with the specific points of the FAR/FVAR that are being challenged.

Thus, for re-examination procedures, only scientific data previously used during the procedure to support the application are admissible at the re-examination stage. No new data can be submitted nor considered. It is not acceptable to include, for example, results from new studies not previously submitted or results from ongoing studies with a later data cut-off than the data provided to the RMS and CMS at the time of submission. On the other hand, new presentation, elaboration or clarification of previously provided data can be acceptable, provided that it is not based on new underlying factual information.

For decentralised applications, due to the involvement of the CMDv, the applicant is strongly advised to contact the RMS as early as possible to discuss the most appropriate dates for submission of the detailed grounds for re-examination of the FAR, within the legal timeframe, to accommodate, as far as possible, the scheduled CMDv meeting dates.

4.3 Assessment of the applicant’s/marketing authorisation holder’s detailed grounds for re-examination

4.3.1 Timetable

Within 60 calendar days of receipt of the detailed grounds for the re-examination of the FAR/FVAR, the CMDv or the RMS/RA will re-examine the FAR/FVAR. The timelines described below are presented for guidance only and may be modified on a case-by-case basis, depending on, amongst other factors, the date of receipt of the detailed grounds for re-examination in relation to the scheduled CMDv meeting dates. In any case, the total time for assessment can never exceed 60 calendar days (i.e. there is no possibility of a clock-stop).

Decentralised procedure:

<table>
<thead>
<tr>
<th>Within 15 days of receipt of final RMS assessment report</th>
<th>The applicant may notify the RMS in writing of their intention to request a re-examination of the RMS final assessment report. The RMS forwards this request to the CMS and enters the date of the receipt in the CTS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 60 days of receipt of final RMS assessment report</td>
<td>The applicant submits, to the RMS only, the detailed grounds for the re-examination of the RMS final assessment report.</td>
</tr>
</tbody>
</table>
### Variations requiring assessment/Worksharing:

<table>
<thead>
<tr>
<th>Within 15 days of receipt of final RMS/RA assessment report</th>
<th>The MAH may notify the RMS/RA in writing of their intention to request a re-examination of the variation assessment report. The RMS/RA forwards this request to the CMS and enters the date of the receipt in the CTS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 60 days of receipt of final RMS/RA assessment report</td>
<td>The MAH submits, to the RMS/RA, the detailed grounds for the re-examination of the RMS/RA variation assessment report to the RMS only. The RMS/RA will without delay forward that request and the detailed grounds to the CMSs.</td>
</tr>
<tr>
<td>Day 0</td>
<td>Re-examination procedure starts the next calendar day following receipt of detailed grounds.</td>
</tr>
<tr>
<td>Day 20</td>
<td>RMS/RA re-examination of variation assessment report and draft list of questions sent to the CMS</td>
</tr>
<tr>
<td>Day 30</td>
<td>Comments from the CMSs</td>
</tr>
<tr>
<td>Day 40</td>
<td>Updated RMS/RA re-examination assessment report and latest version of the SPC/PL</td>
</tr>
<tr>
<td>Day 50</td>
<td>Comments from CMSs</td>
</tr>
<tr>
<td>Day 60</td>
<td>Final re-examination assessment report and end of procedure</td>
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</tbody>
</table>
The reasons for the conclusions reached in the re-examination procedure will be annexed to the assessment report.

All the email correspondence will be sent to the CMDv and list V-MRNA/V-MRVE mailbox.

4.3.2 Oral explanation at CMDv meeting

The applicant/MAH has the right to present their point of view to the CMDv through an oral explanation. In light of the short timelines of the re-examination procedure, any request for an oral explanation should be submitted as early as possible in the procedure. The applicants/MAHs are reminded that they are only allowed to provide clarification of the aspects relating to the scope of the re-examination (those elements of the initial opinion that have been contested by the applicant/MAH in their detailed grounds for re-examination) and that no new information (as compared to the information available during the DCP or variation procedures) can be included in the context of the oral explanation in the re-examination procedure.

4.4 Finalisation of the re-examination procedure

All Member States in the decentralised procedure and member states concerned in the variation/worksharing procedure shall use their best endeavours to reach agreement on the particulars that have been raised by the applicant/MAH to resolve the matter in due course.

When the Member States reach an agreement within the 60-day Re-examination procedure, the RMS shall record the agreement and close the procedure. The Re-examination assessment report will be appended to the FAR/FVAR for the ongoing Decentralised/variation/worksharing procedures.

In case the Member States fail to reach an agreement during the Re-examination procedure, the RMS shall record the disagreement and close the procedure. The initial RMS FAR/FVAR will remain unchanged and represents the final position of the Re-examination procedure.