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Template for letter of intent for the submission of a worksharing procedure to CMDv.
1. INTRODUCTION

According to Art. 65 of Regulation EU 2019/6 "Work-sharing procedure", where one or more variations requiring assessment identically apply to one or several marketing authorisations which are held by the same marketing authorisation holder and which have been granted by different competent authorities or by the Commission, an identical application shall be submitted to the competent authorities in all relevant Member States and, where a variation to a centrally authorised veterinary medicinal product is included, to the Agency. Worksharing procedures are handled as variations requiring assessment. Further information is available in the Best Practice Guide for variations requiring assessment (CMDv/BPG/XXX).

2. AIM AND SCOPE

2.1 This Best Practice Guide covers worksharing procedures for:

- more than one purely national marketing authorisation of the same holder\(^1\) in more than one Member State (also one marketing authorisation of the same holder purely nationally authorised in more than one Member State)
- more than one mutual recognition/decentralised marketing authorisation of the same holder with more than one Reference Member State (RMS).
- one or several purely national marketing authorisation(s) and one or several mutual recognition/decentralised marketing authorisation(s) of the same holder with more than one responsible Member State/RMS.

All Member States involved in worksharing procedures for purely national marketing authorisations should accept the submission of the application, if the worksharing fulfils the requirements for a worksharing procedure as laid down in Article 65 of Regulation EU 2019/6. It is not possible for a single member state to refuse to participate in such a worksharing.

Since the worksharing procedure involves more than one responsible Member State and/or RMS, the 'Reference Authority' (competent authority assessing the application) shall be agreed by CMDv after taking into consideration the applicant’s request.

This Best Practice Guide does not cover worksharing procedures that involve one or more centralised marketing authorisations. In these cases contact the European Medicines Agency (EMA).

\(^1\) As per Commission Communication 98/C 229/03.
This guidance does not cover the case of changes to several purely-national marketing authorisations and/or mutual recognition/decentralised marketing authorisations which concern only one responsible MS and/or RMS. In this case submitting one application for all marketing authorisations is possible, as described in the BPG for variations requiring assessment (CMDv/BPG/xxxx).

Harmonisation of the complete initial dossier or SPC and product literature is not a prerequisite for a worksharing procedure. It is not necessary for the ‘present’ situation to be identical at the start of the procedure for all marketing authorisations included with the worksharing application. However, the variation application form must reflect the same ‘proposed’ situation applicable to all marketing authorisations included in the worksharing procedure. It is not possible to submit a worksharing application where only some of the data apply to some of the authorisations. In such a case a variation to harmonise the respective marketing authorisation with the other marketing authorisations that are supposed to be included in the worksharing will have to done first for that marketing authorisation only. Alternatively a F.V.b.1.c VRA could be done if the quality part is concerned. Worksharing procedures should result in a harmonised outcome following assessment of any data submitted of the product type (Nat/MR/DC).

The definition of ‘identical’ variations for the mandatory scope of the worksharing according to Article 65(1) is: An identical variation application is characterised by the combination of the title of the change, procedure type and the identical content of this change. Therefore for applications that include identical changes to different marketing authorisations which require assessment worksharing is mandatory. For the purpose of handling the worksharing procedure, the following definition of a marketing authorisation is used: all strengths and pharmaceutical forms of a certain product.

3. REFERENCES AND RELATED DOCUMENTS


4. **PROCEDURE**

4.1 **Choice of Reference Authority**

The applicant should propose a National Competent Authority (NCA) to act as the Reference Authority (RA). However, it should be noted that, after discussion of the proposed application, the CMDv may choose to appoint a different RA if this is considered more appropriate for the marketing authorisations included in the worksharing procedure.

4.2 **Pre-submission notification (letter of intent)**

The MAH should contact the chosen/preferred NCA and discuss an upcoming worksharing procedure with them by submitting a draft letter of
intent. The applicant should use the template published on the CMDv website (Annex of the Best Practice Guide for worksharing).

All the information required in the template must be provided:

a. List of marketing authorisations concerned: product name(s) and respective MR/DC procedure number(s) and/or MA number(s) for purely-nationally authorised products.

b. Description of the change(s) and detailed justification of the proposed classification of those changes according to the EMA/CMDv variations classification guidance. The table with current and proposed situation may be added for clarification.

c. Preferred RA.

d. Justification as to why the MAH believes that a worksharing procedure is applicable.

e. Planned submission date.

f. Confirmation that all marketing authorisations included belong to the same MA holder¹.

g. If applicable, details of submission/approval/rejection of the same variation(s) in any Member State(s).

h. If applicable, details of any marketing authorisations (MR/DC or purely-national) that have been excluded from the proposed worksharing procedure, with reasons. Products may not be excluded if for example the product is not on the market in some MS.

It is important that the RA has a clear overview of the changes proposed by the MAH. Therefore, all changes need to be described by the MAH with as much detail as possible in order for the RA to be in a position to accept the worksharing request and decide upon the suitability of the proposed classification(s).

If the RA already identifies unsuitable classifications at this stage, the RA may request amendments to the letter of intent so that subsequent time delays can be avoided.

The applicants should be aware that after the submission of the documentation package the classification of the variation can change during the validation phase, in exceptional circumstances. The RA will take into account the CMS comments on the procedure. In case of disagreement the RMS will decide.
The pre-submission information should be submitted to the preferred RA with information of the worksharing procedure and a request for agreement two weeks before the CMDv meeting at the latest.

The RA sends the confirmation mail including the WS number to the CMDv (via the CMDv secretariat / list CMDv ) and MAH together with the letter of intent of the MAH as soon as possible for endorsement but no later than the Monday/Tuesday of the week of the CMDv meeting. Confirmations mails sent later will have to be dealt with at the next meeting.

Further confirmation by the CMDv secretariat to the applicant is not necessary, however, the formal agreement of the CMDv with all worksharings applied for will be confirmed and recorded in the report for release. In general, the RA will not confirm the worksharing one more time after the CMDv unless any issues were discovered.

In cases where the preferred RA is unable to agree to act as RA it should inform the MAH as soon as possible. The MAH should afterwards search for another RA/NCA.

The MAH can already submit the worksharing application before formal adoption by the CMDv has taken place, however, the responsibility for agreement remains with the CMDv.

In the rare event that CMDv does not accept the requested RA or the content of the worksharing in its meeting the worksharing application will not be processed even if already submitted. CMDv members may comment on the worksharing request, especially the list of marketing authorisations concerned, description of proposed changes and proposed classifications but the main discussion on the content of the worksharing will take place during the validation phase. In case of any issues with the request, CMDv members are invited to inform the RA by email before (preferably) or at the meeting and, if appropriate, the RA will ask the MAH for an updated letter of intent which will be circulated by the RA for agreement at the next CMDv meeting.

4.3 Numbering

For information on the numbering of worksharing procedures, please refer to CMDv/BPG/xxx for the allocation of the mutual recognition/decentralised procedure application numbers.

4.4 Application package and timelines

A variation or group of variations presented for worksharing should be submitted according to the normal rules applicable for variations requiring assessment (Best Practice Guide for variations requiring assessment (CMDv/BPG/xxx), and should be provided as one submission package covering all variations for all medicinal products. This will include:
• the accepted WS request (LoI accepted by the RA)
• a copy of the confirmation email from the RA
• electronic application form together with separate supportive
documentation and revised product information (if applicable) for
each marketing authorisation concerned.

This will allow the NCA to update the dossier of each marketing authorisation
included in the worksharing procedure with the relevant amended/new
information. The data should clearly indicate which of the variation(s) it is
intended to support.

The MAH shall submit the submission package and any accompanying
identical documentation for the worksharing procedure to all relevant
authorities, i.e. the RA and all Member States where the concerned
marketing authorisations are authorised. The CESP delivery file indicating
the variation procedure number, the dates on which the applications were
sent to the RA and CMS is available in CESP portal. The MAH should inform
the RMS about the submission together with the CESP number. The CESP
submission number is provided by the RMS to the CMS. This way of proceed
also applies for the submission of the responses.

Where the chosen RA is the Competent Authority of a Member State which
has not granted a marketing authorisation for all of the medicinal products
included in the application, the CMDv may on request of the RA ask another
relevant authority to assist the RA in the evaluation of that application.

The RA will validate the application in line with the validation procedure for
variations requiring assessment.

It is foreseen that WS procedures will follow the standard timetable of 60
days. However extended timetables are possible with agreement of all
parties concerned. Reduced timetable are not foreseen unless the changes
required concern urgent safety matters. The procedural timetables are
available in the BPG for variations requiring assessment.
(CMDv/BPG/XXX).

The RA can ask for advice from CMDv or any relevant Working Party
during the procedure.

Worksharing procedures will be entered in CTS to maintain the life-cycle
management of each product. The details are provided the BPG for
variations requiring assessment (CMDv/BPG/xxx).
All communication relating to the worksharing procedure should be made
via the Eudra-MRVE mailbox.
4.5 Discussion at CMDv meeting

A systematic discussion of worksharing applications at CMDv meetings is not foreseen. The worksharing applications will be dealt with as normal variations; however, whenever the RA considers that discussion at CMDv could be useful, the RA will propose its inclusion on the agenda.

4.6 Outcome of procedures

The outcome of the procedures will be handled as normal variations as described in the BPG Variation Requiring Assessment (CMDv/BPG/xxx)

4.7 Request for re-examination:

The details are provided in the BPG for re-examination and variations requiring assessment (CMDv/BPG/xxx)

4.8 Disagreement between RA and CMS

In the case of disagreement between the RA and CMS, a breakout meeting can be arranged (according to CMDv/GUI/021 – Guidance for Virtual CMDv product discussions). The occasion and format of the meeting should be determined by the RMS according to the CMDv breakout session protocol and communicated to the CMS, Chair of the CMDv and the CMDv Secretariat. The RA and CMDv Secretariat co-ordinate the arrangements for the breakout meeting. Reference should be made to the breakout meeting protocol for other possibilities of timing within the procedure when disagreement is foreseen.

If no agreement between the CMS and RA about the proposed decision is achieved by the end of the procedure, the review procedure according to Article 54 shall apply. Reference is made to the Standard Operating Procedure for review procedure (CMDv/SOP/xxx). The objecting CMS shall provide without delay a detailed statement of its reasons for objection to the RA, the other CMS and the MAH. The RMS shall refer the points of disagreement without delay to the CMDv. To avoid the review procedure the MAH may withdraw the variation application. The withdrawal should relate to all CMSs and the RA, not just to the objecting MS.
ANNEX

Template for letter of intent for the submission of a worksharing procedure to the CMDv:

4.3.1 <Date>
4.3.1 <Company Reference>

To: The address of the preferred reference authority

Subject: Letter of intent (LoI) for the submission of a worksharing procedure to the CMDv according to Article 65 of Regulation (EU) No 2019/6

Worksharing Applicant details:

Name

Address

Contact person details
(i.e. name, address, email address, phone number).

Application details

This letter of intent (LoI) for the submission of a variation requiring assessment <group of variations> following a worksharing procedure concerns the following medicinal products:

a) List of marketing authorisations concerned:

MR/DC authorised products:

<table>
<thead>
<tr>
<th>Product (trade name)</th>
<th>Active substance</th>
<th>Member State</th>
<th>MA holder name</th>
<th>MRP/DCP no.¹ &amp; MA number</th>
</tr>
</thead>
</table>

¹ Please provide both the MRP/DCP number and the national authorisation to aid identification

EMA/CMDv/204024/2021
Nationally authorised products:

<table>
<thead>
<tr>
<th>Product (trade name)</th>
<th>Active substance</th>
<th>Member State</th>
<th>MA holder name</th>
<th>MA number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

b) Description of the changes

The following variation(s) are intended to be part of the worksharing procedure:

<table>
<thead>
<tr>
<th>Number as in the classification guidance</th>
<th>Title of variation as in the classification guidance</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<Include here a detailed description and background of the changes listed and a justification for the proposed classifications>

<See attachment>*<if grouping is proposed, a justification should be provided>

< The table with current and proposed situation may be added for clarification>

<table>
<thead>
<tr>
<th>Scope</th>
<th>PRESENT(^{6,10})</th>
<th>PROPOSED(^{9,10})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Text</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<See attachment>*

(* If the lists are very long they can be submitted as separate attachments to the Letter of intent)

<If agreed by RA/CMSs the following sentence could be included in the final Letter of intent for complex worksharing procedures: >

<The final variation classifications will be (discussed and) agreed between the RMS and CMSs during the validation period>

c) Preferred Reference Authority

Justification as to why the MAH believes that a worksharing procedure is applicable.

EMA/CMDv/204024/2021
d) **Intended submission date**

e) **Explanation that all MAs concerned belong to the same holder**

f) **If applicable, details of submission/approval/rejection of the same variation(s) in any Member State(s)**

g) **If applicable, details of any MAs (MR/DC or purely-national) that have been excluded from the proposed worksharing procedure, with reasons.**

< This will prevent delays in the consideration of the letter of intent, which can occur when Member States that have the product(s) authorised are unclear why they have not been included in a particular worksharing procedure >

<Signature>