20 March 2024

EMA/293212/2017

Administration and Corporate Management Division

Letter of intent for the submission of a work sharing procedure to the European Medicines Agency according to article 20 of Commission Regulation (EC) no 1234/2008

Application details:

This letter of intent for the submission of a <Type IB><Type II><group of variations> following a work sharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008, concerns the following medicinal products:

| **Medicinal product name**  | **Active substance(s) if NAP** | **RMS (if NAP)** | **MRP number (if NAP)**  |
| --- | --- | --- | --- |
| <(invented) name> | <INN/common name>  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

The following variation(s) are intended to be part of the work-sharing procedure:

| **Number as in the classification guideline** | **Title of variation as in the classification guideline**  | **Type of variation**  |
| --- | --- | --- |
| <Number> | <Title of variation as in the classification guideline> | <Type of variation> |
|  |  |  |
|  |  |  |
|  |  |  |

Justification for work sharing:

|  |
| --- |
| *[Include here (or as an Annex 1) a more detailed ‘scope’ description and background of the proposed change(s).* *The justification for work sharing should be provided in a separate paragraph, addressing its suitability and including the applicant’s view on the absence or limited need for assessment of product specific impact.]*<As provided in Annex 1> |

Justification for grouping:

|  |
| --- |
| [*If the work sharing consists of a group of variations, please provide here (or as an Annex 2) a justification for the proposed grouping of variations*]<As provided in Annex 2> |

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|  |

Intended submission date:

Explanation that all MAs concerned belong to the same holder:

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| --- |
| *[Explain here (or in Annex 3) how all MAs concerned are considered to belong to the ‘same marketing authorisation holder’, addressing the relevant elements set out in Commission communication 98/C 229/03*[[1]](#footnote-1)*]*      <As provided in Annex 3>{Conclusion statement}I hereby confirm that the marketing authorisations concerned by the work sharing procedure belong to the same marketing authorisation holder, as per the Commission communication 98/C 229/03 |

<Signature>

<Contact person WS procedure>

<Title>

To submit your request, raise a ticket via [EMA Service Desk](https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=fee01f301bdd39508ad7edf2b24bcba0) via tab “Finance Services”. The type of request to be selected is “Request for high-level procedure or ASMF number” followed by sub-option “Request for high-level procedure number” and then “Workshare procedure number”. This letter of intent should be attached to the request.

If you do not have an EMA Account, you may create one via the [EMA Account Management portal](https://register.ema.europa.eu/identityiq/login.jsf).

1. The same mother company or group of companies or which are licensees or exercise concerted practices concerning the placing on the market of the relevant medicinal product in different Member States [↑](#footnote-ref-1)