<Date>

<Reference>

<The address of the preferred reference authority>

**Subject: Letter of intent for the submission of a worksharing procedure to the CMDh according to Article 20 of Commission Regulation (EC) No 1234/2008**

**Worksharing Applicant details:**

|  |  |  |
| --- | --- | --- |
| Name  | **:** |  |
|  |  |  |
| **Address** | **:** |       |
|  |  |  |
| **Contact person details** (i.e. name, address, e-mail address, phone number) | **:** |       |

**Application details**:

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

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

The following medicinal products included in the worksharing procedure are authorised via national procedure:

|  |  |  |  |
| --- | --- | --- | --- |
| **Medicinal product** | **Active substance(s)** | **National MA number** | **Member State** |
| <(invented)Name in MS > | <INN/common name> |  |  |
| <(invented)Name in MS > | <INN/common name> |  |  |
| <(invented)Name in MS > | <INN/common name> |  |  |
| <(invented)Name in MS> | <INN/common name>  |  |  |
| <(invented)Name in MS> | <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> |
| <Number> | <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 worksharing | **:** | *[Include here (or as an Annex 1) a more detailed ‘scope’ description and background of the proposed change(s).* *The justification for worksharing 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 worksharing consists of a group of variations, please provide here (or as an Annex 2) a justification for the proposed grouping of the variations]*     <As provided in Annex 2> |

|  |  |  |
| --- | --- | --- |
| Intended submission date | **:** |       |

|  |  |  |
| --- | --- | --- |
| Preferred reference authority | **:** | *[List here reference authorities (more than 1) in preferred order.**Explanation of the choice of the preferred reference authority in case the preferred reference authority has not granted a marketing authorisation for all concerned marketing authorisations]*      |

|  |  |  |
| --- | --- | --- |
| Explanation that all MAs concerned belong to the same holder | **:** | *[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 worksharing procedure belong to the same marketing authorisation holder, as per the Commission communication 98/C 229/03 |

<Signature>

<Contact person WS procedure>

<Title>

Please send this letter electronically to the preferred reference authority ([*List of CMDh contact points*](https://www.hma.eu/69.html) for requests to act as reference authority in a variation worksharing procedure).

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)