Request for MRP/RUP for Medicinal Products for Human Use

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Requested MS to act as RMS:** | | | | | | | | | | |
| **Anticipated submission date:** | | | | | | | | | | |
| **Product name(s)/**  **pharmaceutical form(s)/**  **strength(s)**  One line per application if multiple applications | | | | **MRP/DCP no.**  **(if available):** | | | | **Indicate RMS MA/identification number(s) for original dossier(s):** | | |
| **Active substance(s):** | | | | | **ATC Code:** | | | | | |
| First wave(MRP): | | | | | Yes  No | | | | | |
| Repeat use(RUP): | | | | | Yes  No | | | | | |
| If repeat use, date of finalisation of last MRP: | | | | |  | | | | | |
| Extension for a previously completed MRP: | | | | | Yes  No | | | | | |
| **Is the product a duplicate:**  Yes  No  If yes, please state the name of the original product/mother license: | | | | | | | | | | |
| **Indicate the CMS (if known):** | | | | | | | | | | |
| **Legal basis of medicinal product(s) approved:** | | | | | | | | | | |
| Art.8(3) | Art.10(1) | Art.10(3) | Art.10(4) | | | Art.10a | Art.10b | | Art. 10c | Art. 16a |
| **Reference medicinal product is/has been authorised in all proposed CMS (abridged applications only)?**  Yes  No  If no, please state the CMS(s) where a European Reference product will be used: | | | | | | | | | | |
| **Has a Ph.Eur. certificate of suitability (CEP) been issued for the active substance?**  Yes  No  And/or  **Will an Active Substance Master File (ASMF) be used?**  Yes  No.  **If yes, indicate the version of the ASMF to be submitted in the updated dossier(s):** | | | | | | | | | | |
| **Common Renewal Date (CRD):** | | | | | **For bioequivalence study(-ies), when performed/CRO/ used reference medicinal product:**    **The study(-ies) meet(s) the current guidelines**:  Yes  No  If no explain in Appendix 1\* | | | | | |
| **I hereby confirm that the dossier complies with the current legislation/EU guideline:**  Yes  No | | | | | | | | | | |
| **Is there any other regulatory procedure ongoing:**  Yes  No  If yes explain in Appendix 1\*  **Is there any other regulatory procedure foreseen until the intended MRP/RUP submission date or potentially during the MRP/RUP:**  Yes  No  If yes explain in Appendix 1\* | | | | | | | | | | |
| **The MAHs authorised contact person for this request. Indicate company, name, phone and E-mail address:**  Company:  Authorised contact person:  Phone:  E-mail: | | | | | | | | | | |
| **Other information if relevant:** | | | | | | | | | | |
| **Marketing authorisation number of the reference medicinal product (abridged applications only)?** | | | | | | | | | | |

**\*The Appendix 1 has to be submitted to the RMS together with the request.**