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 [ ]  NoIf 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 [ ]  NoAnd/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 [ ]  NoIf 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 [ ]  NoIf 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:**      |
| **For NCA use:*****To allow individual information***      |

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