|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Requested MS to act as RMS: .......................... | | | |  | | | | |
| Intended number of CMSs (if known): ……….... | | | |  | | | | |
| Active Substance(s): ……………………………. | | | |  | | | | |
| ATC Code: …………………………………..….. | | | |  | | | | |
| Proposed Product Name | | Pharmaceutical Form(s) | | | | | Strength(s) | |
|  | |  | | | | |  | |
|  | |  | | | | |  | |
|  | |  | | | | |  | |
| Proposed indication(s): | | | | |  | | | |
| Legal basis of application: | | | | | | | | |
| Art.8(3)  Art.10b | Art.10(1)  Art.10c | | Art.10(3)  Art. 16a | | | Art.10(4) | | Art.10a |
| In case of extension application, indicate the procedure number of the existing authorisation ……..……………….. | | | | |  | | | |
| An application for the same medicinal product is submitted/the same medicinal product is already authorised in a separate procedure[[1]](#footnote-1) ……………………… | | | | | Yes No | | | |
| Indicate the procedure number of the original dossier: …. | | | | |  | | | |
| Duplicate/multiple applications will be submitted ……..…. | | | | | Yes No | | | |
| Indicate the number of duplicates: …………………………. | | | | |  | | | |
| **For applications under Art. 10(1), Art. 10(3) and Art. 10(4)**  ***Reference medicinal product (RefMP) authorised for not less than 8 years in the EEA*** | | | | | | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | |  | | | |
| First authorisation date (yyyy-mm-dd): ……………...……... | | | | |  | | | |
| In case of CAP RefMP, notification date (yyyy-mm-dd):,,,,, | | | | |  | | | |
| Member State (EEA)/Union: ……..………………………..... | | | | |  | | | |
| ***RefMP in the proposed RMS*** | | | | |  | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | |  | | | |

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| Use of European Reference Product (ERP)[[2]](#footnote-2) in RMS or any of the CMSs …………………………………………………… | |  |
| In case of national RefMP, is the product information harmonised?........................................................................... | |  |
| For bioequivalence study, name and address of the site:…  Bioequivalence study number  For Art 10(3), indicate difference(s) compared to the reference medicinal product………………………………….. | |  |
| The new product will be marketed in the proposed RMS: … | | Yes No |
| Name(s) and address(es) of the manufacturer(s) of active substance: | | Has a Ph.Eur. Certificate of suitability (CEP) been issued for the active substance and/or will an Active Substance Master File (ASMF) be used? |
|  | | CEP ASMF  N/A  If ASMF, will ASMF worksharing be used? Yes No EU ASMF number, if already allocated: |
|  | | CEP ASMF  N/A  If ASMF, will ASMF worksharing be used? Yes No EU ASMF number, if already allocated: |
|  | | CEP ASMF  N/A  If ASMF, will ASMF worksharing be used? Yes No EU ASMF number, if already allocated: |
| Name(s) and address(es) of the manufacturer(s) of the finished product……………………………………………… | |  |
| Does the manufacturer of the finished product have an EU GMP certificate?................................................................... | | Yes No |
| Applicant´s preferred submission date (month/year): | |  |
| Other information *(e.g scope of any scientific advice received and from which MS)*: | |  |
| I herewith declare that no other Member State has agreed to act as RMS in a DCP for the above mentioned product and no request to act as RMS in a DCP for the above mentioned product is pending in another Member State. | | |
| The applicant accepts that the EEA National Competent Authorities may share information about this slot request amongst themselves for the purposes of resource planning and coordination. | | |
| Applicant: ……………………………………………………. |  | |
| Authorised contact person: ………………………………… |  | |
| Address: ……………………………………………………… |  | |
| Phone: ……………………………………………………….. |  | |
| E-mail address: ……………………………………………… |  | |
| Date: …………..……………………………………………… |  | |

1. with same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies or which are “licensees”, in accordance with the European Commission’s communication (98/C 229/03). [↑](#footnote-ref-1)
2. When the reference medicinal product has never been authorised in a Member State, a reference product nationally authorised in another Member State should be identified. [↑](#footnote-ref-2)