|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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)  Extension | | Art.10a |
| This is a duplicate of an ongoing or finalised procedure … | | | | | | Yes No | | | |
| Indicate the procedure number of the original dossier: …. | | | | | |  | | | |
| Indicate the number of duplicates: ………………………… | | | | | |  | | | |
| **For generics only**  ***Reference medicinal product authorised for not less than 8 years in the EEA*** | | | | | | | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | | |  | | | |
| First authorisation date (yyyy-mm-dd): ……………...……... | | | | | |  | | | |
| Member State (EEA)/Union: ……..………………………..... | | | | | |  | | | |
| ***Reference medicinal product in the proposed RMS*** | | | | | |  | | | |
| Product name, strength, pharmaceutical form: ……………. | | | | | |  | | | |
| Marketing authorisation holder: ……………………………... | | | | | |  | | | |
| Reference medicinal product is/has been authorised in all proposed CMSs | | | | | | Yes No  N/A | | | |
| For bioequivalence study, name and address of the site: | | | | | |  | | | |
| 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 | | | |
| Applicant´s preferred submission date: ……………………. | | | | | |  | | | |
| Other information *(e.g scientific advice received)*: | | | | | |  | | | |
| I herewith declare that no other Member State has agreed to act as Reference Member State for a Decentralised Procedure for the above mentioned product. | | | | | | | | | |
| Applicant: ……………………………………………………. | | | | |  | | | | |
| Authorised contact person: ………………………………… | | | | |  | | | | |
| Address: ……………………………………………………… | | | | |  | | | | |
| Phone: ……………………………………………………….. | | | | |  | | | | |
| E-mail address: ……………………………………………… | | | | |  | | | | |
| Date: …………..……………………………………………… | | | | |  | | | | |