|  |  |
| --- | --- |
| 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: …………..……………………………………………… |       |