**Planned submission of a national procedure,**

**medicinal products for human/ veterinary use**

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| **Information about the applicant** |
| Applicant:        |
| Address:       |
| Phone:       | E-mail address:       |

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| **Information about the medicinal product** |
| Proposed Product Name:       |
| Pharmaceutical Form(s):       | Strength(s):       |
| Active substance:       | ATC Code:       |
| Name(s) and address(es) of the manufactures 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  |

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| **Information about the marketing authorisation** |  |
| **Legal basis of the application:****[ ]** Art. 8(3) [ ]  Art. 10(1) [ ]  Art. 10(3) [ ]  Art. 10(4) [ ]  Art. 10a [ ]  Art. 10b [ ]  Art. 10c [ ]  Art. 16a **[ ]** Art. 8 **[ ]** Art. 18 **[ ]** Art. 19(1) **[ ]** Art. 20 **[ ]** Art. 21 **[ ]** Art. 22  **[ ]** Art. 23 [ ]  Art. 25  |
| **Is the application a line extension (human) or an application for a variation requiring assessment that is classified as change of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species (veterinary):** **[ ]  Yes [ ]  No**Product name and MA-no. of existing marketing authorisation:       | If yes, please specify:[ ]  Change or addition of a new pharmaceutical form[ ]  Addition of a new strength[ ]  Addition of a new route of administration[ ]  Other, please specify:       |
| Is this a duplicate of the existing marketing authorisation: [ ]  Yes [ ]  NoProduct name and MA no. of existing marketing authorisation:       |
| *If the application is a line extension/variation requiring assessment as described above:*Is there another Member State(s) where an application for the same product is pending [ ]  Yes [ ]  NoIs there another Member State(s) where an authorisation is granted for the same product? [ ]  Yes [ ]  NoIf yes, please specify which MS:       |
| ***For generics only: Please specify information about a reference medicinal product authorised for not less than 6/10 years in EEA*** |
| Product name, strength, pharmaceutical form:       |
| Marketing authorisation holder:       |
| First authorisation date (yyyy-mm-dd):        |
| Member state (EEA/Community):       |
| Reference medicinal product in NO:       |
| Product name, strength, pharmaceutical form:       |
| Marketing authorisation holder:       |

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| **Other information** |
| Applicant’s estimated submission date:       |
| Please sign below if it is acceptable to you to receive our Validation letter, Assessment Report(s) and Clock stop letter by e-mail and which e-mail address to use for this purpose.  |
| Signature: | E-mail address:       |