Et bilde som inneholder skjermbilde, sort

KI-generert innhold kan være feil.**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. 8Art. 18Art. 19(1)Art. 20Art. 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  No  Product 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  No  Is there another Member State(s) where an authorisation is granted for the same product?  Yes  No  If 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: |