Pre-submission request for a national application or for Ireland to act as RMS in a DC/MR/SR procedure for Veterinary Medicinal Products

1. Applicant details

Name:

Address:

Authorised contact person:

Email address:

Phone:

1. Application details

|  |  |
| --- | --- |
| Type of application | [ ]  DCP[ ]  MRP[ ]  SRP[ ]  National |
| Type of veterinary medicinal product | [ ]  Chemical (other than biological)[ ]  Biological (other than immunological)[ ]  Immunological[ ]  Homeopathic (acc. to Art. 85(2) of Reg. (EU) 2019/6)[ ]  Other (please specify):       |
| Intended CMS |       |

1. Procedure type

|  |
| --- |
| **In case of National** |
| Proposed product name(s) | Pharmaceutical form(s) | Strength(s) |
|       |       |       |
|       |       |       |
|       |       |       |
| **In case of MRP**Product nameAuthorisation number |            |
| **In case of SRP**Product nameAuthorisation numberCurrent EU procedure number |                 |
| **In case of DCP** |
| Proposed product name(s) | Pharmaceutical form(s) | Strength(s) |
|       |       |       |
|       |       |       |
|       |       |       |
| **For all applications** |
| This is a **duplicate** of an ongoing or finalised procedure | [ ]  Yes[ ]  No |
| Original procedure finalised | [ ]  Yes [ ]  No |
| Complete the procedure number of the original dossier |       |
| List the number of duplicates |       |

1. PRODUCT DETAILS

|  |  |
| --- | --- |
| Active substance(s)  |       |
| ATCvet code |       |
| Target species (as written in the proposed SPC) |       |
| Indication(s) (as written in the proposed SPC) |       |

1. Legal basis

|  |  |  |  |
| --- | --- | --- | --- |
| [ ]  Art. 8 (Full dossier) | [ ]  Art. 18 (Generic) | [ ]  Art. 19 (Hybrid) | [ ]  Art. 20 (Combination product) |
| [ ]  Art. 21 (Informed consent) | [ ]  Art. 22 (Well-established use) | [ ]  Art. 23 (Limited markets) | [ ]  Art. 25 (Exceptional circumstances) |
| This application concerns a change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species to an existing marketing authorisation. | [ ]  Yes [ ]  No |
| Identify the existing product(s) to which the change relates  |       |
| Indicate the nature of the change(s) that result in this being considered a change of active substance(s), strength, pharmaceutical form, route of administration or food producing target species to an existing marketing authorisation | [ ]  Qualitative change in active substance[ ]  Change in bioavailability [ ]  Change of pharmacokinetics [ ]  Change/addition of food-producing target species [ ]  Change/addition of new administration route [ ]  Change/addition of new pharmaceutical form [ ]  Change/addition of a new strength/potency Comments:       |

1. REFERENCE MEDICINAL PRODUCT

|  |
| --- |
| **For generics and hybrids only** |
| **Reference medicinal product authorised for not less than 8 years in the EEA** |
| Product name, strength, pharmaceutical form |       |
| Target species |       |
| Marketing authorisation holder |       |
| Date of first authorisation |       |
| Member State (EEA/Community) |       |
| **Reference medicinal product in the proposed RMS** |
| Product name, strength, pharmaceutical form |       |
| Marketing authorisation holder |       |
| Marketing authorisation number |       |
| Reference medicinal product has been authorised in all proposed CMSs | [ ]  Yes [ ]  NoIf no, please list those CMSs where the reference medicinal product has not been authorised:     [ ]  N/A |
| Demonstration of bioequivalence | [ ]  Bioavailability studies [ ]  Exemption[ ]  N/A |
| Location of and reference product used in any bioequivalence study(-ies) conducted |       |
| Difference in the composition compared to the reference medicinal product (e.g. preservative, colouring matter, other excipients) |       |
| Other relevant information |       |

1. ACTIVE SUBSTANCE INFORMATION

|  |  |
| --- | --- |
| Name(s) and address(es) of the manufacturer(s) of the active substance(s) |       |
| Has a Ph. Eur. certificate of suitability (CEP) been issued for the active substance?and/orWill an Active Substance Master File (ASMF) be used?  | [ ]  Yes [ ]  No[ ]  Yes [ ]  NoIf relevant, EU ASMF number:       |

1. ONGOING/PLANNED REGULATORY PROCEDURES

|  |  |
| --- | --- |
| Any other regulatory procedure ongoing? | [ ]  Yes[ ]  NoIf yes, explain:       |
| Any other regulatory procedure foreseen until the intended MRP/SRP submission date?  | [ ]  Yes[ ]  NoIf yes, explain:       |

1. Declaration

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| I hereby declare that no other Member State has agreed to act as RMS for the above-mentioned product: Yes [ ]  No [ ]

|  |  |
| --- | --- |
| Signature:       | Date:       |
|  |  |
| Print name:        | Title/position:       |

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| I hereby confirm that the dossier in support of the application complies with the current legislation/EU guidance | [ ]  Yes [ ]  No |

1. Form submission

|  |  |
| --- | --- |
| Applicant’s preferred submission date |       |
| Please submit this form electronically to vetinfo@hpra.ie. Note that in performing their role as RMS, the HPRA may on occasion make use of the services of other agencies/external experts. |