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 name  Authorisation number |  | |
| **In case of SRP**  Product name  Authorisation number  Current 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

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| --- | --- |
| 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  No  If 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/or  Will an Active Substance Master File (ASMF) be used? | Yes  No  Yes  No  If relevant, EU ASMF number: |

1. ONGOING/PLANNED REGULATORY PROCEDURES

|  |  |
| --- | --- |
| Any other regulatory procedure ongoing? | Yes  No  If yes, explain: |
| Any other regulatory procedure foreseen until the intended MRP/SRP submission date? | Yes  No  If 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: | | |
| 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](mailto: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. | |