National Applications Pre-submission Request Form for Veterinary Medicinal Products

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| --- | --- | --- | --- | --- | --- |
| **Active substance(s):** | | | | | |
| **ATC code:** | | | | | |
| **Target species (as written in the proposed SPC):** | | | | | |
| **Indication(s) (as written in the proposed SPC):** | | | | | |
| **Proposed product name(s):** | | **Pharmaceutical form(s):** | | **Strength(s):** | |
|  | |  | |  | |
|  | |  | |  | |
|  | |  | |  | |
| **Legal basis of application:** | | | | | |
| Art. 12(3) | Art. 13c | | Art. 13(3) | |  |
| Art. 13a | Art. 13d | | Art. 13(4) | |
| Art. 13b | Art. 13(1) | | Extension | |
|  | | | | | |
| This is a duplicate of an ongoing or finalised procedure: | | | Yes  No | | |
| Complete the procedure number of the original dossier: | | |  | | |
| List the number of duplicates: | | |  | | |
|  | | | | | |
| **For generics only** | | | | | |
| **Reference medicinal product authorised for not less than 6/10 years in the EEA** | | | | | |
| Product name, strength, pharmaceutical form: | | |  | | |
| Marketing authorisation holder: | | |  | | |
| Date of first authorisation: | | |  | | |
| Member State (EEA/Community): | | |  | | |
|  | | | | | |
| **Reference medicinal product in Ireland** | | | | | |
| Product name, strength, pharmaceutical form: | | |  | | |
| Marketing authorisation holder: | | |  | | |
| Marketing authorisation number: | | |  | | |
| 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 | | |
| Applicant’s preferred submission date: | | | | | |
| Other relevant information: | | | | | |
| I hereby declare that an application for the same veterinary medicinal product has not been granted or is not pending in another Member State. Yes  No | | | | | |
| **Applicant:** | | | | | |
| **Authorised contact person:** | | | | | |
| **Address:** | | | | | |
| **Telephone:** | | | | | |
| **Fax:** | | | | | |
| **E-mail:** | | | | | |

Please submit this form electronically to: [vetinfo@hpra.ie](mailto:vetinfo@hpra.ie)

Note that in performing their assessment, the HPRA may on occasion make use of the services of other agencies/external experts.