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/orWill 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

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