Application for a Registration Certificate for Veterinary Medicinal Product for Pets under Article 5(6) of Regulation 2019/6

This form is to be used only in respect of products, which meet the criteria set out in Article 5(6) of Regulation 2019/6.

For general guidance on products eligible for registration and on completing this form, please refer to the HPRA ‘*Guide to Registration of Veterinary Medicinal Products for pets that qualify for registration under Article 5(6) of Regulation 2019/6’* (available on the [HPRA website](http://www.hpra.ie)). Specific documents detailed below must accompany this form.

Please refer to the HPRA *‘Guide for Electronic Submissions – Veterinary Medicines’* for details on how to submit this form.

1. Application details

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| --- | --- |
|  | Name of applicant  Name of company  Address  Country  LOC-ID  Telephone  Email |
|  | Name and email address for person to communicate with during the procedure: |
|  | Location (including LOC-ID) and contact details of the qualified person responsible for pharmacovigilance: |
|  | Reference number of the pharmacovigilance system master file relating to the product: |
|  | Product name: |
|  | Active substance name(s): |
|  | Full qualitative and quantitative composition of the product: |
|  | Pack size(s): |
|  | Product specification: |
|  | Pharmaceutical form: |
|  | Route(s) of administration: |
|  | Target species: |
|  | Proposed route of sale and supply: |
|  | Indication(s) for use: |
|  | Warnings or precautions: |
|  | **Documents to accompany this application:**  Fee form and proof of payment  Name and address of each manufacturing siteinvolved in the manufacture/packaging/importation of the product (including LOC-ID for each site)  GMP certificate (or EudraGMP reference) for each site involved in the manufacture/packaging/importation of the product in electronic format  Copies (in electronic format) of any registrations or authorisations obtained for the same veterinary medicinal product in other EU Member States  Labelling and package leaflet texts (preferably electronic versions) |
| declaration  I hereby declare that,   * the applicant is legally established in an EU Member State, * a pharmacovigilance system is in place that fulfils EU requirements including a Pharmacovigilance System Master File (PSMF) in accordance with Chapter 5 of Section IV of Regulation (EU) 2019/6, * to the best of my knowledge and belief, all the particulars given in this application are correctly stated.  |  |  | | --- | --- | | Signature: | Date: | |  |  | | Print name: | Title/position: |   *Note:*  Applications must bear the signature of the applicant. Where the application is on behalf of a limited company, the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner. | |