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) |
| declarationI 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.

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| 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. |