Application Form B for Transfer of a Veterinary Marketing Authorisation Application

This form is based on the new veterinary Regulation 2019/6 and is applicable from 28 January 2022. For details of the requirements, see the ‘Guide to Transfers of Veterinary Marketing Authorisations and Applications’.

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| 1. Details of the proposed Marketing Authorisation Holder (MAH) after transfer

Name and address:      Proposed trading style:      Name and address of the applicant acting on behalf of the proposed MAH, if different:       |
| 1. Details of the company currently proposed as MAH

Name and address:       |
| 1. Details of the product
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| Provisional VPA number:      Name of product:      Pharmaceutical form:       | Target species:      Name of active substance(s):      Strength(s):       |

4 Statement to be signed by the company currently proposed as MAH

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| Reason for transfer application:      1. I hereby notify the Health Products Regulatory Authority that the application for <insert product name> <insert Provisional VPA number>is to be transferred to <insert name of the proposed MAH>.
2. I confirm that the entire dossier for the product (with the exception of Annexes 5.5 and 5.20 (or the summary of the PSMF) of Part 1A) has been transferred to <insert name of the proposed MAH>.

This dossier includes all of the data in support of the original application (with the exception of Annexes 5.5 and 5.20 (or the summary of the PSMF) of Part 1A) together with all correspondence with the Health Products Regulatory Authority and any correspondence with the Department of Agriculture, Food and the Marine concerning the product.Signed: Date:      Status of signatory:      Telephone:      Email:       |

5 Statement to be signed by the proposed MAH after transfer

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| 1. I confirm that with reference to Article 42 of Regulation (EU) 2019/6 transfer of this application to the proposed MAH does not invalidate the application, that is, the proposed MAH does not already have a Marketing Authorisation for the same product\* within the EEA or an application pending for the same product\* under consideration within the EEA.
2. I will have the sole responsibility for the product including obtaining approval for any changes subsequent to the grant of this product authorisation.
3. I have received the entire dossier for <insert product name> from <insert name of originally proposed MAH>.
4. I have been assured by the currently proposed MAH that, apart from the change of name and address of the MAH, the proposed VPA number and Annexes 5.5 and 5.20 (or the summary of the PSMF) of Part 1A, the dossier on which the transfer is based is identical in every respect to that submitted by the original applicant.
5. I confirm that I/we have adequate procedures in place to recall the veterinary medicinal product from the Irish market.
6. I confirm that a summary of the Pharmacovigilance System Master File (PSMF) has been provided with this application.

Additional statement for proposed MAH who do not hold a Marketing Authorisation in Ireland:1. I confirm that I/we am/are established in the European Community and evidence of establishment in the EU has been provided with this application.

Signed: Date:      Status of signatory:      Telephone:      Email:       |

\*For an explanation of what constitutes the ‘same product’ in this context, see Section E.3 of Commission Communication on the Community marketing authorisation procedures for medicinal products (Official Journal C 229, 22.07.1998, P.4-17).