Application Form A for Transfer of a Veterinary Marketing Authorisation

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 current MAH

Name and address:       |
| 1. Details of the product

For bulk transfer applications, only one application form is required. If necessary, provide an annex listing the VPA numbers, full product names and strengths.  |
| Current VPA number(s):      Name and strength of product(s):      Date of expiry of current product authorisation(s):       |  |
| Pharmaceutical form:       |  |

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| 1. Details of the transfer date
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| [ ]  Date of proposed transfer of the authorisation or certificate\*: <DD/MM/YYYY> Or [ ]  Next management committee date. |
| \*Please note: When a proposed transfer date is provided, transfers of authorisations or certificates will be sent for approval to the next management committee meeting closest to date provided. |

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| 1. Statement to be signed by the existing MAH

Reason for transfer application: 1. I hereby notify the Health Products Regulatory Authority that <insert product name> <insert MA number>is to be transferred to <insert name of the proposed MAH>.

I request that an amended authorisation cover sheet reflecting this transfer be issued to <insert name of the proposed MAH>.1. [ ]  Transfer application

I agree that no new stock of this/these product(s) bearing the current marketing authorisation (MA) number will be QP certified once the transferred authorisation has been granted.Or [ ]  Transfer application is directly related to the UK’s decision to exit the EU, i.e. the transfer is required as the current MAH is located within the UK.I agree that no new stock of this/these product(s) bearing the current MA number will be QP certified once six months have elapsed from the time the transferred authorisation has been granted.1. 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 HPRA (or its predecessors) and the Department of Agriculture, Food and the Marine concerning the product and all pharmacovigilance data both before and after the issue of the original MA.1. I acknowledge our responsibilities in respect of pharmacovigilance obligations or in the event of any quality defect associated with any remaining product bearing our name, address and MA number.
2. Signed: Date:

Job title of signatory:      Telephone:      Email:        |

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| 1. Statement to be signed by the proposed MAH
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 name of product> from <insert name of MAH>.
4. I have been assured by the current MAH that, apart from the change of name and address of the MAH, the product authorisation 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 MAH.
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 Pharmacovigilance System Master File (PSMF) is in place in accordance with Regulation (EU) 2019/6 and that a variation to replace or change an existing summary of the PSMF or introduce a new summary of the PSMF has been/will be submitted, or I have provided an explanation as to why no change or variation is necessary.

Pharmacovigilance System Master File reference number:      CRN for submitted variation:       or Justification as to why no change or variation is necessary:      Additional statement for the proposed MAH who does not hold a marketing authorisation in Ireland:1. I confirm that I/we are established in the European Union and evidence of establishment in the EU has been provided with this application.

Signed: Date:      Job title of signatory:      Telephone:      Email:       |