HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Transfers of Veterinary Marketing Authorisations and Applications

1 INTRODUCTION

This guide is based on the new veterinary Regulation 2019/6 and is applicable from 28 January 2022. A veterinary marketing authorisation (MA) may be transferred from the existing marketing authorisation holder (MAH) to another MAH using a transfer procedure. A transfer may occur before a product is authorised or after authorisation, to a company related to the existing MAH or to an unrelated company.

The transfer procedure must be used where the legal entity of a MAH is changed as MAs or applications are transferred to a new MAH.

1.1 Transfer before authorisation

Where an application is received for a transfer of the MAH before authorisation, the proposed new MAH must notify the HPRA using 'Application form B for transfer of a veterinary marketing authorisation application' to transfer an application, which should be accompanied by a revised Part IA, SPC, and label and package leaflet mock-ups.

Transfer of the application to the proposed MAH must not invalidate the application. With reference to Article 46 of Regulation (EU) 2019/6, the proposed MAH cannot already have an MA for the same product within the EEA or an application pending for the same product under consideration within the EEA.

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).

1.2 Transfer after authorisation

Where an application is received for a transfer of the MAH after authorisation, the proposed new MAH must notify the HPRA using 'Application Form A for Transfer of a Veterinary Marketing Authorisation' to transfer an application.

In order to avail of this procedure, the following conditions must be met:

1 No change may be made, as part of the transfer application, to the authorisation schedule other than the MA number and the MAH's name and address. No change may be made to the technical data in Parts II, III or IV of the dossier.

2 Evidence must be provided that a Pharmacovigilance System Master File (PSMF) is in place for the new MAH 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 alternatively, an explanation as to why no change or variation is necessary should be provided.

3 No change may be made to the texts of the labels and package leaflet, other than the MA number, the MAH's name and address, and the distributor (if applicable). Any change to the layout and design must not adversely affect the readability of the product literature.

4 For bulk transfer applications, only one application form is required. If necessary, provide an annex listing the VPA numbers, full product names and strengths.

We strongly advise MAHs to try and ensure no other regulatory activity is ongoing for the product awaiting transfer when the application is submitted to the HPRA. MAHs should coordinate the submission of the application with your intended date of transfer so they are closely aligned.

The transferred MA is authorised with the same authorisation schedule as the existing MA, except for the name and address of the MAH and the MA number. In the event that the existing authorisation does not have an unlimited period of validity, it is issued for the remaining period of validity of the existing authorisation.

Any change to the transferred MA, e.g. revised label/leaflet text or change of name and/or address of the manufacturer, updates to the summary of the PSMF must be applied for through the relevant variation procedure.

In the event that the existing authorisation does not have an unlimited period of validity, on expiry, the transferred MA is renewed in the usual way by the new MAH.

1.3 Transfer using the new application procedure

Where the application does not meet the conditions laid down for this administrative transfer procedure or the applicant wishes to obtain an MA under conditions other than those specified, the applicant must apply for a new MA under the usual national authorisation procedure.

2 MAKING AN APPLICATION

2.1 Documentation

In order to transfer an MA, the proposed MAH or another person acting on their behalf must submit an application consisting of one copy of each of the following:

- Covering letter.
- Relevant transfer application form ('Application Form A for Transfer of a Veterinary Marketing Authorisation' or 'Application Form B for Transfer of a Veterinary Marketing Authorisation Application') and signed statements from the existing MAH/applicant and the proposed new MAH.
- Proof of payment.
- Information relating to the recall procedures of the new MAH as detailed in transfer forms.
- Evidence of establishment in the European Union, e.g. certificate of incorporation or equivalent - only for companies or individuals not already holding an MA in Ireland.
- Updated SPC, labels and leaflet are required, containing the new company information. The SPC, labels and leaflets must be in separate PDF/A format documents.
- PSMF reference number.
- In addition, for transfers before authorisation, a revised Part IA and summary of the PSMF must be provided.

HPRA Receipts and Validation (submissions@hpra.ie) should be contacted before submission in order to provide the new VPA numbers in advance to facilitate the preparation of the application and documents.

2.2 Fees

Fees for transfer of an existing MA to a related company, to an unrelated company or to a company which does not already hold an MA are detailed in the HPRA's 'Guide to Fees for Veterinary Medicines'.

Fees are payable to the Health Products Regulatory Authority.
Account no.: 33712185; sort code 93-10-12
Swift Code AIBKIE2D
IBAN: IE 54 AIBK 931012 33712185
Allied Irish Bank
1-3 Baggot Street Lower
Dublin 2

Payment is to be made with the MA transfer application. Fees for transfer of an application before authorisation are subject to an administrative fee. Please see the 'Publications and Forms' section of www.hpra.ie for the 'Guide to Fees for Veterinary Medicines'.

2.3 Address for submitting applications

The HPRA strongly recommends electronic submission of transfer applications and related information in line with the 'Guide to Electronic Submissions for Veterinary Medicines'.

These applications should be submitted by CESP or email to submissions@hpra.ie, or be sent on CD/DVD or memory stick to:

Receipts and Validation,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2
D02 XP77

HPRA
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