

Guide to Transfers of Veterinary Marketing Authorisations and Applications

1 INTRODUCTION

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 21(2) of Directive 2001/82/EC, 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 The existing MA must have a remaining period of validity at least three months. If the period is less than three months, the existing MA must be renewed before the transfer application can be processed.

- 2 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. Evidence must be provided that a variation to replace or change an existing detailed description of the pharmacovigilance system (DDPS) has been submitted or an explanation as to why no change or variation is necessary.
- 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.

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. 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, new DDPS, must be applied for using the variations procedure.

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.

In addition, for transfers before authorisation, a revised Part IA, DDPS, SPC, labels and leaflet are required.

HPRA Receipts and Validation can provide the new VPA numbers in advance in order to facilitate the preparation of the application.

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 encourages electronic submissions. Please refer to the 'Guide to Electronic Submissions for Veterinary Medicines'. For further information please see the 'Publications and Forms' section of www.hpra.ie.

If the application cannot be submitted electronically, applications will be accepted in hard copy by post. Send hard copy applications 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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