HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Transfers of Marketing Authorisations, Parallel Import Licences and Dual Pack Import Registrations for Human Medicines

1 INTRODUCTION

A marketing authorisation (MA), parallel import licence (PPA) or Dual Pack Import Registration (DPR) may be transferred from the existing authorisation/licence/registration holder to another holder using a transfer procedure. An MA transfer may occur before a product is authorised or, for MAs, PPAs and DPRs, after authorisation, to a company related to the existing holder or to an unrelated company.

The transfer procedure must be used where the legal entity of an authorisation/licence/registration holder is changed as (P)PA [(Parallel)Product Authorisation] and DPR (Dual Pack import Registration) product authorisations are transferred to a new company number.

1.1 Transfer before authorisation

Where an authorisation is transferred before authorisation, the new holder must notify the HPRA using this procedure.

1.2 Transfer after authorisation

In order to avail of this procedure for transfer after authorisation, the following conditions must be met:

1 For transfer to a related company, the new authorisation/licence/ registration holder must be an individual or company, which is either:
- a subsidiary of an existing holder or
- formed due to the merger of previous holders

2 The existing authorisation/licence/registration must have a remaining period of validity of more than three months. If the period is less than three months, the existing authorisation/licence/registration must be renewed first before the transfer application can be processed.

3 No change may be made, as part of the transfer application, to the authorisation/licence/registration schedule or approved SmPC. No change may be made to the technical data in Modules 3, 4 and 5.

4 No change may be made to the texts of the labels and leaflet, other than the (P)PA/DPR number, the holder's name and address and the company logo, as applicable. Any change to the layout and design must not adversely affect the readability of their contents.

5 Once the new authorisation/licence/registration has been granted no further stocks bearing the old (P)PA/DPR number may be manufactured or released for sale by the qualified person. Batches of the original product may be sold for a period of six months after issue of the transferred authorisation/licence/registration. At the end of this period, any remaining stocks of the original product must be recalled from wholesale level.

6 In relation to transfer of ownership of a product license where there is no manufacturer specified in the licence being transferred, a declaration will be sought with the transfer application from the proposed marketing authorisation holder (MAH), confirming they are aware of the conditions of the licence in respect of the manufacturing site. The new company will be required to subsequently submit a variation application to add the manufacturing site in order to market the product after the transfer has taken place.

7 For bulk transfer applications, only one application form is required. If necessary provide an annex listing of the (P)PA/DPR numbers, product names and strengths.

For (P)PAs, the transferred authorisation/licence is authorised with the same schedule (authorisation document) as the existing one, except for the name and address of the holder and the (P)PA number. It is issued for the remaining period of validity of the existing authorisation/licence.

Any change to the transferred authorisation/licence/registration, e.g., revised label/leaflet text or the introduction of a new manufacturer, must be applied for by a variation application or Article 61(3) notification.

On expiry, the transferred authorisation/licence/registration is renewed in the usual way by the new holder. The DPR annual compliance declaration is due within 12 months of registration or previous declaration.

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 authorisation/licence/registration under conditions other than those specified, it may be transferred by applying for a new authorisation/licence/registration under the usual national procedure.

2 MAKING AN APPLICATION

2.1 Documentation

In order to transfer an authorisation/licence/registration, the proposed holder or another person acting on his behalf must submit an application as per the 'Guide to Electronic Submissions – Human Medicines' consisting of the following:

- Transfer application form and signed statements from the existing holder/applicant and proposed new holder
    - 'Application Form A for Transfer after Authorisation of a Marketing Authorisation/Parallel Import or Dual Pack Import Registration Product'
    - 'Application Form B for Transfer before Authorisation of a Marketing Authorisation for Human Medicines'
- 'Fee Application form' or proof of payment (Human Medicines)
- Revised Module 1.2 Application form, SmPC, labels and leaflet - only for transfers before authorisation
- Covering letter specifying the proposed transfer date
- Evidence of establishment in the European Union, e.g. certificate of incorporation or equivalent - only for companies or individuals not already holding an authorisation/licence in Ireland

Note that the HPRA Receipts and Validation unit can provide the new (P)PA/DPR numbers in advance in order to facilitate the preparation of the application.

2.2 Fees

Fees for transfer of an existing authorisation/licence to a related company, to an unrelated company or to a company which does not already hold an authorisation/licence are detailed in the HPRA's 'Guide to Fees for Human Products'.

Fees are payable to the Health Products Regulatory Authority.
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 transfer application.

Fees for transfer application before authorisation are subject to an administrative fee. In the 'fee application form', the fee code 393 should be used, specifying a two-hour charge.

2.3 Address for submitting applications

Applications should be sent to:

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