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) may be transferred from the existing authorisation/licence/ registration holder to another holder using a transfer procedure. An MA transfer to a company related to the existing holder or to an unrelated company may occur before a product is authorised or after authorisation. The transfer procedure must be used where the legal entity of an authorisation/licence/registration holder is changed as product authorisations are transferred to a new company number.
In this guide the term marketing authorisation (MA) includes parallel import licence (PPA) or dual pack import registration (DPR).

1.1 Transfer before authorisation

Where an MA is transferred before authorisation, the new holder must notify the Health Products Regulatory Authority (HPRA) using this procedure.

1.2 Transfer after authorisation

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 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 In relation to transfer of ownership of a product licence 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.

6 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 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 (except name and address of the holder and the (P)PA number) or the introduction of a new manufacturer, must be applied for by a variation application or an Article 61(3) notification.

For procedures involving organisation or location information, applicants should check that the relevant details match the Organisation Management Service (OMS) and that any required OMS change request has been submitted before submitting the variation to the HPRA.

Where the transfer procedure concerns a medicinal product constructed as international non-proprietary name (INN)/common name and name of the MAH, the name of the medicinal product needs to be changed to reflect the MAH change. As a result, the variation to change the name of medicinal product should be submitted in parallel with the transfer procedure.

On expiry, the transferred authorisation/licence/registration is renewed in the usual way by the new holder.

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

To transfer an authorisation/licence/registration, the proposed holder or another person acting on their behalf must submit an application, as per the HPRA's '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 of an Authorised (Parallel) or Dual Pack Import Registration (DPR) Product'.

  - 'Application Form B for Transfer before Authorisation of a Marketing Authorisation for Human Medicines'.

- 'Fee Application Form for Human Products' and proof of payment.

- Revised module 1.2 application form, SmPC, labels and leaflet (only for transfers before authorisation).

- Revised package leaflet bearing the new name and address of the holder. A Word version of the package leaflet is acceptable. Please note that the revised package leaflet mock-ups will not be subjected to review at this time. It is assumed that there is no change to the currently approved labels and package leaflet with the exception of the change in name/address of the MAH.

- 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

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

New 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
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HPRA
~~30 SEPTEMBER~~ 14 OCTOBER 2026