e-form

Application Form for the Transfer of a Marketing Authorisation Holder for an Authorised Product

Please note that submission must be sent electronically (CD/DVD or through the Common European Submission Portal – CESP).

This application enables a company to take over responsibility from another company (different legal entity) where the application is in identical terms to the existing marketing authorisation.

DOCUMENTS WHICH HAVE TO BE SUBMITTED WITH THE APPLICATION FORM FOR A MARKETING AUTHORISATION TRANSFER FOR AN AUTHORISED PRODUCT:

Details of documents to be submitted : (Kindly indicate if submitted)

1. Legal document for Transfer (application form).

2. Proof of payment (as per current legal notice on fees).

3. Proof of establishment of the new Marketing Authorisation Holder (from official sources).

4. SmPC (Word format) /Package Leaflet & Labelling bearing the new.

Marketing Authorisation Holder Name:

Address:

Marketing Authorisation Number of Malta:

5. Type IB variation (Type IB C.I.9.z) has been submitted and other relevant variations pertaining to the transfer (e.g. change in name of the medicinal product affected due to transfer).

6. Pharmacovigilance system master file (PSMF) : (Kindly indicate if submitted)

PSMF declaration

Required date for Change of ownership of the existing (as proposed in the Marketing Authorisation application) Marketing Authorisation Holder to the new proposed holder.

Date:

If a transfer effective date is proposed, this date cannot be before the date of submission of the application form by the Medicines Authority. Until the Medicines Authority is informed of a planned transfer and this is approved, the current MAH remains responsible for the product authorised in Malta.

1. DETAILS OF THE PROPOSED MARKETING AUTHORISATION HOLDER AFTER TRANSFER

Name and address:

Proposed trading style (if applicable):

Name and address of the applicant acting on behalf of the proposed Marketing Authorisation Holder, if different:

2. DETAILS OF THE CURRENT MARKETING AUTHORISATION HOLDER

Name and address:

3. DETAILS OF THE PRODUCT

Current MA Number:

Name of product:

Name of active substance(s):

Pharmaceutical form:

Strength(s):

STATEMENT TO BE SIGNED BY THE EXISTING MARKETING AUTHRISATION HOLDER

REASON FOR TRANSFER APPLICATION

1. I hereby notify the Medicines Authority that Product Name and MA number

is to be transferred to Proposed MA holder

I request that an amended authorisation, reflecting this transfer and based on the original dossier and any ongoing or subsequent data submitted by me/us, be issued to

Name of proposed MA holder

2. I agree that stock of this product on the market bearing our name, address and MA number will be actively run down within six months of issuing the MA to the new holder. ***No stock bearing the existing MA number/MAH will be imported after the transfer effective date quoted on the marketing authorisation licence.***

3. I confirm that the entire dossier for the product has been transferred to

Name of proposed MA holder

This dossier includes all of the data in support of the original application together with all correspondence with the Medicines Authority concerning the product and all pharmacovigilance data both before and after the issue of the original MA.

4. I acknowledge our responsibilities in the event of any adverse reaction or quality defect associated with any remaining product bearing our name, address and MA number.

5. I acknowledge our responsibilities in the event of the necessity to recall from the market any remaining product bearing our name, address and MA number.

Signed:

Date:

Status of signatory:

Telephone No.:

E-mail address:

STATEMENT TO BE SIGNED BY THE PROPOSED MARKETING AUTHORISATION HOLDER

REASON FOR TRANSFER APPLICATION:

1. I will have the sole responsibility for the product including obtaining approval for any changes subsequent to the grant of this product authorisation.

I have received the entire dossier for Product Name **from** MA holder

2. This dossier includes all of the data in support of the original product authorisation application together with all correspondence with the Medicines Authority concerning the product and all Pharmacovigilance data both before and after the issue of the original product authorisation.

3. I have been assured by the current MA holder/applicant that, apart from the change of name and address of the product authorisation holder and the product authorisation number, the dossier on which the transfer is based is identical in every respect to that submitted by the original holder.

Signed:

Status of signatory:

Telephone No:

Fax No:

Email address:

Date:

TO BE COMPLETED BY THE NEW PROPOSED MARKETING AUTHORISATION HOLDER

1. I confirm that I/we are established in the European Community and evidence of establishment in the EU has been provided with this application.

2. I confirm that I/we have adequate procedures in place to recall the medicinal product from the Maltese market.

3. I confirm that I/we have adequate procedures in place to meet Pharmacovigilance obligations in accordance with current directives and regulations in force in the European Union and will act in compliance with them.

4. I confirm that I/we have established within my/our undertaking a scientific service in charge of information about the medicinal product within the meaning of the current Medicinal Products (Advertising) Regulations in force.

Signed:	
Date:	
Status of signatory:	
Telephone No:	
Fax No:	
E-mail address:	
5. Name of the person acting on behalf of the MAH if different:	Name and Surname
Email address:	

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