e-form

Application for the Transfer of a Marketing Authorisation Holder during the Authorisation Procedure – (National Phase)

Please note that submission must be sent electronically 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 for Malta

5. Type IB variation (Type IB C.I.8) 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

**** If the proposed MAH and the previous MAH belong to the same group of companies and the PSMF is going to be shared, a variation to the PSMF may not be required.***

1 DETAILS OF THE PROPOSED MARKETING AUTHORISATION HOLDER AFTER TRANSFER

Name and address:

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

*

Name and address of the local representative for the product in Malta.

Name:

Address of the company:

Contact person:

E-mail:

A letter of the authorised for communication, signing, receipt of licences and/or any other activity is required for the applicant to act on behalf of Marketing Authorisation Holder

2 DETAILS OF THE COMPANY CURRENTLY PROPOSED AS THE MARKETING AUTHORISATION HOLDER IN THE MARKETING AUTHORISATION APPLICATION IN PROCESS.

Name and address:

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

*

A letter of the authorised for communication, signing, receipt of licences and/or any other activity is required for the applicant to act on behalf of Marketing Authorisation Holder

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 COMPANY CURRENTLY PROPOSED AS THE MARKETING AUTHRISATION HOLDER.

REASON FOR TRANSFER APPLICATION:

1. I hereby notify the Medicines Authority that

Product Name

MA number

is to be transferred to **Proposed MA holder**

2. 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.

3. 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.

4. 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:

Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications
A Declaration form should be submitted for each signatory.

Date:

Status of signatory:

Telephone No:

Email:

STATEMENT TO BE SIGNED BY THE PROPOSED MARKETING AUTHORISATION HOLDER AFTER TRANSFER.

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.

2. I have received the entire dossier for Name of product

from

MA holder

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.

4. In case the drug substance of the medicinal product has an Active substance Master File (ASMF), I will provide a new letter of access for the proposed MAH with the next update to the ASMF when the variation is submitted.

Signed: Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications
A Declaration form should be submitted for each signatory.

Date:

Status of signatory:

Telephone No:

Email:

5. name of the person acting on behalf of the MAH if different click here and insert name and surname

Email: *

A letter of authorisation for communication, signing, receipt of licences and/or any other activity is required for the applicant to act on behalf of the Marketing Authorisation Holder.

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