e-form

APPLICATION FORM FOR THE TRANSFER OF A MARKETING AUTHORISATION HOLDER FOR AN AUTHORISED PRODUCT

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

* When a Marketing Authorisation has already been issued by the Malta Medicines Authority

THIS APPLICATION ENABLES A COMPANY TO TAKE OVER RESPONSIBILITY FROM ANOTHER COMPANY (DIFFERENT LEGAL ENTITY)ONLY AND DOES NOT RESULT IN ANY OTHER CHANGES TO THE MARKETING AUTHORISATION.

1. DETAILS OF THE PRODUCT

Name of product, dose & pharmaceutical form	
Name of active substance(s):	
Current MA Number:	

***For bulk transfers, only one application form is required.**
Please include a list of products, including the strength, form, and MA numbers.

2. DETAILS OF THE PROPOSED MARKETING AUTHORISATION HOLDER AFTER TRANSFER

a) Name and address (as per latest proof of establishment issued by the official body in the EEA country):

Name and address of company, contact person and email

b) Name and address of the applicant acting on behalf of the proposed Marketing Authorisation Holder, if different when compared to point 2a:

Name and address of company, contact person and email

c) Name and address of the local representative for the product in Malta under the proposed Marketing Authorisation Holder.

Name and address of company, contact person and 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

3. DETAILS OF THE CURRENT MARKETING AUTHORISATION HOLDER

a) Name and address :

Name and address of company, contact person and email

b) Name and address of the applicant acting on behalf of the current Marketing Authorisation Holder, if different when compared to point 3a:

Name and address of company, contact person and email

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

Name and address of company, contact person and 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

4. STATEMENT TO BE SIGNED BY THE EXISTING MARKETING AUTHRISATION HOLDER

REASON FOR TRANSFER APPLICATION:

1. I hereby notify the Malta Medicines Authority that the product/s mentioned in section 1 of this application form [insert MA Number below] is/are to be transferred to the proposed Marketing Authorisation Holder mentioned in Section 2.

Insert MA Number/s

2. I request that an amended authorisation, reflecting this transfer, be issued to the proposed Marketing Authorisation Holder mentioned in Section 2 based on the latest and currently approved information/data in the dossier.

3. I confirm that the entire dossier for the product has been/will be transferred to the proposed Marketing Authorisation Holder mentioned in Section 2.

This dossier includes all of the data in support of the original application together with all correspondence with the Malta 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: 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.:

E-mail address:

5. STATEMENT TO BE SIGNED BY THE PROPOSED MARKETING AUTHORISATION HOLDER

1. I will have the sole responsibility for the product including obtaining approval for any changes subsequent to the transfer effective date present in the new Marketing Authorisation reflecting the proposed Marketing Authorisation Holder .

2. I have received/will be receiving the entire dossier for the products mentioned in Section 1 of the application form from the current MA holder mentioned in 3 of the application forms.

This dossier includes all of the data in support of the original product authorisation application together with all correspondence with the Malta Medicines Authority concerning the product and all Pharmacovigilance data both before and after the issue of the original product authorisation. Furthermore, any other post-authorisation procedures approved and any implementations (in case of changes related to Type IA variations) done prior to the transfer effective date are to be included.

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. I confirm that adequate procedures are 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.

4.1 Until such time when a variation related to the update of the summary of pharmacovigilance system is implemented (in situations when a new PSMF is being used as a result of the transfer), the proposed Marketing Authorisation Holder states that the necessary means to fulfil the tasks and responsibilities listed in Title IX of Directive 2001/83/EC are in place.

5. 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.

6. 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.

7. I declare that healthcare professionals will be informed that a transfer has taken place when both the product containing the previous details of the MAH and product containing the new details of the MAH are marketed at the same time.

I declare as proposed Marketing Authorisation Holder, that variations/implementation of variations (in case of type IA) in relation to this transfer have already taken place or will take place without undue delay following the acceptance of this transfer application.

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.:	
E-mail address:	

8. Name of the person acting on behalf of the MAH if different

Name and surname

Email:

Email address

*** 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**

6. APPENDICES TO BE INCLUDED WITH THIS APPLICATION

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

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

6.3. Product information (SmPC, PL & Labelling) in editable word version bearing the new
- **Marketing Authorisation Holder Name**
- **Marketing Authorisation Holder Address**
- **Marketing Authorisation Number for Malta**