MALTA MEDICINES AUTHORITY

e-form

Notification of Changes Form for an Authorisation in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations, in accordance with article 126(a) of Directive 2001/83/EC.

Office use only
Notification Form received on:

Forms can be received either through the Common European Submission Portal (CESP) or by sending electronic documents on any electronic medium (e.g. CD/DVD).

This form is only required for changes to the authorisation document details, product information (Summary of product characteristics, package leaflet, and labelling) and information submitted for initial authorisation or for renewal of the authorisation (as detailed in this application form). No other changes need to be notified.

N.B. New applications for an authorisation in accordance with article 126(a) of Directive 2001/83/EC are required for changes in Member State (EEA) country of source.

Notification of change(s) approved in the EEA Member State[1] following the granting of an Authorisation in Malta in line with regulation 4 (2) of the Medicines (Marketing Authorisation) Regulations.

Name of the product/s*, pharmaceutical form and strength:

AA*:

*** Insert list of products and corresponding authorisation numbers if changes being notified to the Medicines Authority affect more than one medicinal product.**

I, Authorisation Holder

following the issue of the Authorisation/s, hereby notify the Medicines Authority, of the following change(s) to the above-mentioned medicinal product licensed in Malta with said Authorisation.

I declare that this/these change(s) has/have been approved in

Member State

N.B. Only those types of changes included in this application form should be submitted to the Medicines Authority.

[1]"Member State (EEA) source country" means the Member State in which the medicinal product concerned is authorised. Only a product with a valid marketing authorisation in the said Member State (EEA) country of source can be eligible to be licensed in Malta with an Authorisation in line with Regulation 4(2) of the Medicines (Marketing Authorisation) Regulations in accordance with article 126(a) of Directive 2001/83/EC. The medicinal product placed on the market in Malta should be exactly the same as that authorised to be placed on the market in the Member State.

A. Has the change affected the product information (please fill in as applicable)?

No

If yes, what has it affected (tick as applicable the following; to be accompanied with appropriate updated documents as applicable)?

- [ ] Summary of Product Characteristics (SmPC)
- [ ] Package Leaflet (PL)
- [ ] Labelling (immediate and/or outer)

Submit variation/ notification approval/ acknowledgement or copy of renewed MA from national competent authority of the Member State source country accordingly.
Submit revised product information accordingly.

B. Has the change affected details in the Authorisation/Licence Document in Malta (please fill in as applicable)?

If yes, what has it affected (tick as applicable the following; to be accompanied with appropriate documents as applicable)?

1. Marketing authorisation number/s[2] in Member State (EEA) source country

Present:	Proposed:

Submit approval of change in marketing authorisation number from national competent authority of the Member State source country – N.B. the product must be the same as previously approved and the change in marketing authorisation number is a consequence to another approved change in source country.

2 Marketing Authorisation Holder details (name, address, contact information) for product from the source country in the EEA

Present:	Proposed:

a) Change in marketing authorisation holder details for the product in the Member State country of source as a result of a variation in the source country (i.e. change in name and/or address, where the change is not a change in legal entity i.e. not a transfer) where the Authorisation Holder in Malta for the said Authorisation may or may not be the Marketing Authorisation Holder for the product authorised in the source country.

Submit variation approval from national competent authority of the Member State source country
Submit a formal document from a relevant official body in which the new name or new address is mentioned i.e. proof of establishment.
Submit revised product information.

b) Change in marketing authorisation holder details for the product in the Member State country of source as a result of a transfer (change in legal entity) of marketing authorisation in the source country, where the Authorisation Holder in Malta for the said Authorisation may or may not be the Marketing Authorisation Holder for the product authorised in the country of source.

Submit approval of change in legal entity from national competent authority of the Member State source country.
Submit also proof of establishment of new legal entity.
Submit revised product information.

[2]This number can be obtained from a valid Marketing Authorisation issued by the national competent authority in the Member State(EEA) country of source.

3 Authorisation Holder[3] responsible for placing the medicinal product on the market in Malta with an Authorisation in accordance with article 126(a)] details (name, address and contact details)

Present:	Proposed:

N.B. Changes in authorisation holder as a result of changes in the marketing authorisation holder (whether a transfer and thus change in legal entity OR change in name and/or address and thus same legal entity) for the product from source country are acceptable. In such a case, submit the relevant documentation as highlighted above, accordingly in previous section (section 2(a) and (b)).

N.B. Changes in authorisation holder when this is not the Marketing Authorisation Holder for the product authorised in the source country, are acceptable only when there is no change in legal entity of the former authorisation holder but there is only a change in name and/or address of the former authorisation holder. In the latter case, submit a formal document from a relevant official body in which the new name or new address is mentioned.

4 Change (addition, deletion, replacement) in manufacturing site/s responsible for batch release* (name, address and contact details)

*Authorised manufacturer(s) (or importer(s)) responsible for batch release[4] in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC,for the product to be placed on the market in Malta (must be already approved as the EEA site for batch release in the Member State (country of source)).

Present:	Proposed:

Submit variation/notification approval/acknowledgement or copy of renewed MA from national competent authority of the Member State source country accordingly.
Submit revised product information accordingly.

[3]The Authorisation Holder must be established in a Member State(EEA) country.
[4]Batch release sites must be in the EEA. More than one batch release site may be listed, as applicable.

5 Change in the Product Name in source country

Submit approval of change in product name from national competent authority of the Member State source country.
Submit revised product information.

Present:	Proposed:

C. Has the change affected pack sizes and/orcontainer-closure system?

If yes, what has it affected (tick and fill in as applicable the following)?

Pack sizes

Container-Closure System

a) For changes in pack sizes and container-closure systems which are already approved in the source country as a result of a variation please list below and submit the following documentation.

Present:	Proposed:

Submit approval of change/s in pack size and/or container-closure system from national competent authority of the Member State source country.
Submit revised product information as approved in the Member State source country.

b) For introduction of new pack sizes and container-closure systems which are already approved in the source country but were not previously applied for in Malta, please list below.

Present:

Proposed:

Submit the outer and immediate labelling for the added pack types which have not yet been submitted previously to the Medicines Authority; such labelling has to be approved in the Member State source country.

D. Has the change affected other details as submitted in the original application form (please fill in as applicable)?

If yes, what has it affected (tick and fill in as applicable the following)?

Person in the EEA (name, address and contact details) responsible for reporting Adverse Drug Reactions and implementing Risk Minimisation Measures for the product authorised in Malta (must reside and operate in the EEA)[5].

Present:

Proposed:

Official Batch Release for Blood Products and Vaccines: details of theOMCL (Official Medicines Control Laboratory) or laboratory designated for the purpose of official batch release [in accordance with Articles 111(1), 113,114(1)-(2) and 115 of Directive 2001/83/EC].

Present:

Proposed:

[5]For the purposes of this application form the person in the EEA responsible for reporting Adverse Drug Reactions and implementing Risk Minimisation Measures, "resides" in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

Contact person in the EEA (name, address and 24 hour contact details) for product defects and recalls.

Present:	Proposed:

Local representative of the authorisation holder (name, address and contact details).

Present:	Proposed:

DECLARATION

I, hereby confirm that to the best of my knowledge and belief, all the particulars I have given in this application form, its annexes and all documentation submitted, are correct and complete.

Name of the Authorisation Holder (Block Letters):	
Signature/s:	
Position:	
Place and Date:	

If applicable, Person/Company authorised for communication /signing on behalf ofthe Authorisation Holder and/or receipt of Authorisation Document/s for the purpose of this application and during the review process of this application.

If applicable fill in this section and provide a suitable letter of authorisation for communication with the Medicines Authority / signing on behalf of the authorisation holder / receipt of authorisation document/s (include as applicable).

Name, Address, Telephone, Fax, Email:

Annex I

Declaration for placing a medicinal product on the market in Malta with Authorisation.

Name of the product, pharmaceutical form and strength:

I, the Authorisation Holder hereby declare that:

The medicinal product to be placed on the market in Malta with said Authorisation, at any point in time during the validity of this Authorisation, is the same product as that authorised to be placed on the market in

the EEA Member State country of source

with a marketing authorisation.

The medicinal product to be placed on the Market in Malta with said Authorisation is not a parallel import in the Member State (EEA) source country.

I am fully aware of my obligations as per the Medicines (Marketing Authorisation) Regulations and the Medicines Act, 2003 and will fully abide by them and by the conditions of this Authorisation.

The pack (package leaflet and labelling) of the medicinal product to be placed on the market in Malta with said Authorisation shall be in the English and/or Maltese language.

All the documentation submitted, including the Summary of Product Characteristcs (SmPC), labelling and package leaflet (PL), of the above-mentioned product are the most recently approved in the Member State (EEA) country of source

the EEA Member State.

Name (In Block Letters) of the Authorisation Holder:

Signature of the Authorisation Holder:

Date: dd/mm/yyy

Annex 2

(To be filled in only for products to be re-labelled and/or repackaged in English/Maltese).

Name of the product, pharmaceutical form and strength:

Correct Translation of the Product Information.

I,

hereby declare that the submitted Summary of Product Characteristics (SmPC), package leaflet (PL) and labelling of the product to be placed on the market in Malta is the correct translation in English/Maltese of the SmPC, PL and labelling approved for the medicinal product in the Member State (EEA) country of source:

The original versions in the language of the country of source and the notarised/certified translated versions of the SmPC, PL and labelling are attached.

Name (In Block Letters) of the Authorisation Holder:

Signature of the Authorisation Holder:

Date:

Annex 3

Declaration of the Authorisation Holder to fulfil post-licensing obligations.

Name of the product, pharmaceutical form and strength:

I, the Authorisation Holder

hereby declare that I shall fulfil all obligations concerning post-authorisation commitments, including notification to the Medicines Authority and subsequent implementation of any variations to the product information, which have been approved in the

EEA Member State

as well as reporting of Adverse Drug Reactions and implementation of Risk Minimisation Measures for the product authorised in Malta. I also declare that all urgent safety measures shall be implemented simultaneously in Malta as in

EEA Member State

The original versions in the language of the country of source and the notarised/certified translated versions of the SmPC, PL and labelling are attached.

Name (In Block Letters) of the Authorisation Holder:

Signature of the Authorisation Holder:

Date: dd/mm/yyyy

Annex 4

Documents to be attached with the application form (as applicable according to the change/s concerned).

If not in English, a notarised/certified translation of relevant documents in English and/or Maltese is to be submitted.

1 Relevant variation/notification approval/acknowledgment or copy of the renewed MA from national competent authority in the Member State source country accordingly.

2 For variations in the name and/or address of the marketing authorisation holder for the product in the Member state (EEA) source country, together with the variation approval from national competent authority of the Member State source country, a formal document is required from a relevant official body in which the new name or new address is mentioned.

3 For changes in the legal entity of the marketing authorisation holder for the product in the EEA source country, proof of establishment of the new legal entity (new Authorisation Holder in a Member State (EEA) country).

4 For changes in legal entity of the marketing authorisation holder for the product in the EEA source country, copy of a valid Marketing Authorisation (MA)** for the concerned medicinal product or approval issued by the competent authority in the Member State (EEA) country of source to the new Marketing Authorisation Holder (i.e. approval of change in legal entity from national competent authority of the Member State source country).

5 For changes in the product information: the most recently approved Summary of Product Characteristics (SmPC) of the product authorised in the Member State (EEA) country of source (electronic copy).

6 The most recently approved Package Leaflet (PL) of the product authorised in the Member State (EEA) country of source (electronic copy).

7 The most recently approved labelling (outer and immediate labelling) of the product authorised in the Member State (EEA) country of source (electronic copy).

8 Letter of authorisation (if applicable) for communication/signing on behalf of the Authorisation holder and/or receipt of authorisation document/s (include details as relevant and applicable).

9 For changes in the name and/or address of the authorisation holder for the product to be placed in Malta in accordance to article 126(a) submit when this is not the Marketing Authorisation holder for the product from the source country, a formal document from a relevant official body in which the new name or new address is mentioned.

** Declaration of authenticity with respect to the copy of the marketing authorisation in force in the Member State (EEA) country of source.

Name of the product, pharmaceutical form and strength:

I, the Authorisation Holder

hereby declare that the copy of the marketing authorisation submitted for the above-mentioned product, is a true copy of the original marketing authorisation issued by the Member State (EEA) country of source.

Name (In Block Letters) of the Authorisation Holder:

Signature of the Authorisation Holder:

Date:

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