e-form

Authorisation in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations in accordance with article 126(a) of Directive 2001/83/EC
APPLICATION FORM/ RENEWAL APPLICATION FORM*

Office use only:
Application Form/ Renewal Application Form received on:

PLEASE USE THE GUIDELINES FOR FURTHER INFORMATION FOR RENEWAL, please indicate authorisation number.

A separate application form needs to be completed for each product (from each source country), for each strength, and for each pharmaceutical form.
Forms can be sent through the Common European Submission Portal (CESP) or by sending the documents on any electronic medium (e.g. CD/DVD).

☐ Application to be fast-tracked.

*This form should also be used for application for a renewal for an Authorisation granted in line with regulation 4(2) of the Medicines (Marketing Authorisation) Regulations. For renewals, the form has to be completed in its entirety including the parts outlined as being specific for renewal applications.

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1.PRODUCT DETAILS

1.1 (a) Product (invented) Name:

1.1 (b) Pharmaceutical Form[1]:

1.1 (c) Strength(s) of the active substance(s):

1.1 (d) Route(s) of administration[2]:

1.2 Active Substances and Excipients[3]

Active Substance/s:	Amount of active substance/s per unit dose:	Reference / Monograph / Standard:

Name of the excipient/s:	Quantity per unit dose:	Reference / Monograph / Standard:

[1]Use current list of Standard Terms.
[2]Use current list of Standard Terms.
[3]For each active substance and excipient, only one name should be given in the following order of priority. The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details consult the Notice to Applicants Guideline on the Summary of Product Characteristics).

1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code:

Group:

1.4 Container, closure and administration device(s)[4] , of product to be placed on the market in Malta (including description of material from which it is constructed)

1.5 For each type of pack, give package size/s to be placed on the market in Malta

1.6 Legal Status: (Classification under Article 1(19) of Directive 2001/83/EC)

Subject to medical prescription.

Not subject to medical prescription.

ADDITIONAL INFORMATION - FOR RENEWAL APPLICATIONS ONLY:

Authorisation Number:

Authorisation Holder:

Name:

Address:

Telephone:

Fax:

Email address:

[4]Use current list of Standard Terms.

2 Authorisation Holder / Contact Persons / Manufacturers

2.1 Marketing Authorisation holder for the medicinal product authorised in the Member state (EEA) source country[5]

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

2.2 Proposed Authorisation Holder[6] responsible for placing the medicinal product on the market in Malta with an Authorisation

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

2.3 Person/ Company Authorised for Communication/ Signing of documents on behalf of the Authorisation holder (Annex 1) (if applicable)

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

[5]"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 that authorised to be placed on the market in that Member State.

[6]The proposed Authorisation Holder must be established in a Member State (EEA) country.

2.4 Person in EEA responsible for reporting Adverse Drug Reactions and implementing Risk Minimisation Measures for the product authorised in Malta (must reside and operate in the EEA)[7]

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

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

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

[7]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.

2.6 Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA[8] 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])

Name, address, telephone, fax, e-mail address:

2.7 Contact person in the EEA for product defects and recalls

Name:	
Address:	
24-hour contact telephone number:	
Fax:	
E-mail address:	

2.8 Local Representative of the Authorisation Holder for the medicinal product

Name:	
Address:	
Telephone:	
Fax:	
E-mail address:	

[8]Batch release sites must be in the EEA. More than one batch release site may be listed, as applicable.

3 DETAILS OF THE PRODUCT AS AUTHORISED IN THE EU/EEA COUNTRY OF SOURCE

3.1 Specify the Member State (EEA) source country for the product. Only one country may be listed as the country of source:

3.2 State the marketing authorisation number[9] of the product authorised in the EEA country of source:

3.3 How is the product authorised in the Member State?

☐ **Mutual recognition[10] / Decentralised Procedure[11].**

☐ **National Procedure.**

3.4 If the product is authorised by the Mutual Recognition/ Decentralised Procedure, indicate the Reference Member State and the procedure number:

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 proposed Authorisation Holder:

Signature/s:

Position:

Place and Date:

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

[10]**Mutual Recognition Procedure (according to Article 28(2) of Directive 2001/83/EC).**

[11]**Decentralised Procedure (according to Article 28(3) of Directive 2001/83/EC).**

Annex 1
Letter of authorisation for communication/ signing on behalf of the Authorisation Holder (to be filled in only if applicable).

Name of the product, pharmaceutical form and strength:

Name & address of Authorisation Holder

hereby authorise, until further notice,

Name of contact person

whose business address is

Business address of contact person

to represent Name of Authorisation Holder

and to undertake the following actions (tick as applicable):

- ☐ **Communication with regards to missing information/clarification of information in application forms and documents submitted.**
- ☐ **Signing of documents during the licensing process, if necessary.**
- ☐ **Receipt of Authorisation.**

Name (In Block Letters) of the Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date:

Name (In Block Letters) of the person authorised to communicate/sign (as applicable) on behalf of the Authorisation Holder):

Signature of person authorised to communicate/sign (as applicable) on behalf of the Authorisation Holder):

Date:

Annex 2

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

Name of the product, pharmaceutical form and strength:

I the proposed 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.

I the proposed Authorisation Holder

hereby declare that the medicinal product to be placed on the market in Malta with said Authorisation, is not authorised with a marketing authorisation granted through the centralised procedure according to Regulation (EC) No 726/2004.

I the proposed Authorisation Holder

hereby declare that the medicinal product to be placed on the market in Malta with said Authorisation, is not authorised as a THMP (Traditional Herbal Medicinal Product) in the Member State (EEA) source country.

I the proposed Authorisation Holder

hereby declare that the medicinal product to be placed on the market in Malta with said Authorisation, is not a prallel import in the Member State (EEA) source country.

I the proposed Authorisation Holder

hereby declare that the medicinal product to be placed on the market in Malta with said Authorisation, is not authorised through an authorisation in accordance to article 126(a) of Directive 2001/83/EC in the Member State (EEA) source country.

I the proposed Authorisation Holder

hereby declare that 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.

I the proposed Authorisation Holder

hereby declare that 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 or Maltese language.

Name (In Block Letters) of the Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date:

Annex 3

(A) For ALL products:

Declaration of the proposed Authorisation Holder on the documentation submitted.

Name of the product, pharmaceutical form and strength:

I the proposed Authorisation Holder

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

Name (In Block Letters) of the Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date:

Annex 3 cont.

(B) For products to be re-labelled and/or repackaged in English/Maltese: correct translation of the Product Information.

I, the applicant

also declare that the submitted proposal of the Summary of Product Characteristics (SmPC), package leaflet (PL) and labelling of the product to be licensed 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 Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date:

Annex 4

Declaration of the proposed Authorisation Holder to fullfil post-licensing obligations.

Name of the product, pharmaceutical form and strength:

I the proposed 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

the EEA Member State

and I shall notify any quality defects and batch/product recalls to the Medicines Authority, without unnecessary delay.

Name (In Block Letters) of the Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date:

Annex 5

Documents to be included with the application form.

- [ ] Proof of payment (copy with each application form).

- [ ] Proof of establishment of the proposed Authorisation Holder in a Member State (EEA) country of source.

- [ ] Copy of a valid Marketing Authorisation (MA)** for the concerned medicinal product, issued by the competent authority in the Member State (EEA) country of source. If not in English, a notarised/certified translation of the MA in English and/or Maltese is to be submitted.

- [ ] The most recently approved Summary of Product Characteristics (SmPC) of the product authorised in the Member State (EEA) country of source (electronic copy). For products to be re-labelled or repackaged in English/Maltese, the SmPC in the original language as well as the notarised/certified translation in English and/or Maltese are to be submitted (electronic copy).

- [ ] The most recently approved Package Leaflet (PL) of the product authorised in the Member State (EEA) country of source (electronic copy). For products to be re-labelled or repackaged in English/Maltese, the PL in the original language as well as the notarised/certified translation in English and/or Maltese is to be submitted (electronic copy).

- [ ] The most recently approved labelling (outer and immediate labelling) of the product authorised in the Member State (EEA) country of source (electronic copy). For products to be re-labelled or repackaged in English/Maltese, the labelling in the original language as well as the notarised/certified translation in English and/or Maltese are to be submitted (electronic copy)).

** 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 proposed 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 Proposed Authorisation Holder:

Signature of the proposed Authorisation Holder:

Date: