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

PLEASE USE THE GUIDELINES FOR FURTHER INFORMATION

A separate application form needs to be completed for each product (from each source country), for each strength, and for each pharmaceutical form.
Forms should be submitted through the Common European Submission Portal (CESP).

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1. Indicate public health reason for application in accordance with article 126(a):

☐ **a) There are no other authorised products for this active substance in the same strength or pharmaceutical form**

☐ **b) Authorised products with the same active substance, pharmaceutical form and strength are not marketed or offered on tender (attach evidence/correspondence as relevant to demonstrate this)**

☐ **c) There is an international shortage of the active substance or product (attach evidence as relevant to demonstrate this)**

☐ **d) Other (attache evidence/ documentation as relevant to demonstrate reason):**

2. Justification for not using the established legal bases for applying for a marketing authorisation:

- Mutual Recognition Procedure (MRP) (including Day 0 procedures)
- Marketing Authorisation or Line extension application to an existing Marketing Authorisation in Malta

Justifications for not applying through the above mentioned regulatory procedures:

3. Proposed date for placing the product on the market in Malta:

4. Proposed Retail Price

5. PRODUCT DETAILS

5.1 (a) Product (invented) Name:

5.1 (b) Pharmaceutical Form[1]:

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

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

5.2 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).

5.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code:

Group:

5.4 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)

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

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

☐ **Subject to medical prescription.**

☐ **Not subject to medical prescription.**

5.7 Additional Risk Minimisation Measures in accordance with GVP (tick as applicable):

☐ **Educational programmes**

☐ **Controlled access programmes**

☐ **Other risk minimisation measures**

☐ **Not applicable**

[4]Use current list of Standard Terms.

6. Authorisation Holder / Contact Persons / Manufacturers

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

Name:	
Address:	
Telephone:	
E-mail:	

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

Name:	
Address:	
Telephone:	
E-mail:	

6.3 Authorisation is being requested on behalf of the Marketing Autorisation Holder:

☐ **Yes**

☐ **No**

6.4 Person/ Company authorised for Communication/ Signing of documents on behalf of the Authorisation Holder (Annex 1) (if applicable).

Name:	
Address:	
Telephone:	
E-mail:	

[5]"Member State (EEA) source country" means the Member State) in which the medicinal product concerned is authorised.
[6]The proposed Authorisation Holder must be established in a Member State (EEA) country.

6.5 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:	
E-mail:	

6.6 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:	
E-mail:	

[7]For the purposes of this application form the person in the EEA responsible for reporting Adverse Drug Reactions and implementing Additional 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.

6.7 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, e-mail:

EUDRA GMP document reference:	

6.8 Contact person in the EEA for products defects and recalls

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

6.9 Local wholesale distributor placing the product on the market in Malta (if different from the proposed authorisation holder)

Name:	
Address:	
Telephone:	
E-mail :	

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

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

7.2 State the marketing authorisation number[10] of the product authorised in the EEA country of source:

7.3 How is the product authorised in the Member State?

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

☐ **National Procedure.**

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

8 MARKETING INFORMATION FOR THE PRODUCT

8.1 Where is the product authorised and marketed in the EEA apart from the source country? (Tick as appropriate. More than one option is possible):

☐ **AT**	☐ **BE**
☐ **BG**	☐ **CY**
☐ **CZ**	☐ **DE**
☐ **DK**	☐ **EE**
☐ **EL**	☐ **ES**
☐ **FI**	☐ **FR**
☐ **HR**	☐ **HU**
☐ **IE**	☐ **IS**
☐ **IT**	☐ **LI**
☐ **LT**	☐ **LU**

☐ LV

☐ NL

☐ NO

☐ PL

☐ PT

☐ RO

☐ SE

☐ SI

8.2 The product is intended for:

☐ Private market

☐ National Health System

☐ Both Private market and National Health System

8.3 Quantities to be available on the Maltese Market (choose appropriate section based on the response included in section 7.2):

8.3.1 For the private market:
Estimated amount of units for three years:

8.3.2 For the National System:
Estimated amount of units for three years:

8.4 If the product is intended for the National Health System, provide:

☐ **8.4.1 The complete Letter of Award form he Department of Contracts together with the corresponding reference number**

☐ **8.4.2 Official letter requesting first delivery of products**

[10]**This number can be obtained from a valid Marketing Authorisation issued by the national competent authority in the Member State (EEA) country of source.**
[11]**Mutual Recognition Procedure (according to Article 28(2) of Directive 2001/83/EC). 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:

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:

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):

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:

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:

1. 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

2. Is not authorised with a marketing authorisation granted through the centralised procedure according to Regulation (EC) No 726/2004.

3. Is not authorised as a THMP (Traditional Herbal Medicinal Product) in the Member State (EEA) source country.

4. Is not a parallel import in the Member State (EEA) source country.

5. Is not authorised through an authorisation in accordance to article 126(a) of Directive 2001/83/EC in the Member State (EEA) source country.

6. Will be in line with the 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.

7. Is made available with package leaflet and immediate and outer labelling) in one of the official languages of Malta (English or Maltese). The Summary of Product Characteristics is also made available in one of the official languages of Malta (English or Maltese). The most recently approved product information as approved in the source country is being provided andhave been translated correctly (in situations when the source country language is not English/Maltese)

8. Is considered to have fulfilled 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 source country as well as reporting of Adverse Drug Reactions and implementation of Risk Minimisation Measures for the product authorised in Malta. All urgent safety measures shall be implemented simultaneously in Malta as in the source country , and any quality defects and batch/product recalls shall be notifed to the Medicines Authority, without unnecessary delay.

Annex 3

Documents to be included with the application form.

☐ **1. Proof of payment (copy with each application form).**

☐ **2. Proof of establishment of the proposed Authorisation Holder in a Member State (EEA) country of source.**

☐ **3. 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.**

☐ **4. 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).**

☐ **5. 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).**

☐ **6. 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)).**

☐ **7. Risk Minimisation Measures as applicable in English and/or Maltese (electronic copy).**

☐ **8. Copy of GMP certificate of site of re-labelling/ re-packaging, if applicable.**

☐ **9. Flow chart including all current manufacturers (names, addresses and function of each) involved in the production of the medicinal product (API manufacturer, finished product manufacturer, packaging sites etc) as authorised in the source country.**