MALTA
MEDICINES AUTHORITY

LI010/08 Appendix 1 Version 2

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

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)

NOTE: The MMA may request information from other parties during the review of the application. The clock for the processing is stopped and resumes once all the required information is received.

Disclaimer

The applicant is responsible for ensuring, before submitting an application, that all conditions for the application to be processed are satisfied and will remain satisfied throughout its processing, and that

. the information and supporting documentation provided are accurate, complete and valid

The Medicines Authority shall not be responsible for the inability to process or complete an application where such inability arises from circumstances beyond its reasonable control and which are

. not attributable to the Medicines Authority

In such circumstances, the application fee shall not be refunded, in whole or in part, irrespective of the

. stage of processing reached, save as otherwise provided by applicable law

Payment of the application fee does not guarantee that the application will be processed to completion

. or that the requested authorisation or licence will be granted

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

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

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

Please provide a robust and well-substantiated justification for not following the above-mentioned regulatory procedures:

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

4. PRODUCT DETAILS

4.1 (a) Product (invented) Name

4.1 (b) Pharmaceutical Form[1]

4.1 (c) Route(s) of administration[2]

4.2 Active Substances and Excipients[3]

[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).

Active Substance/s	Amount of active substance/s per unit dose

Name of the excipient/s:	Quantity per unit dose

4.3 **Pharmacotherapeutic group** (Please use current ATC code)

ATC code:

Group:

4.4 **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).**

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

[4] Use current list of Standard Terms

4.7 Additional Risk Minimisation Measures as approved in the source country in accordance with GVP *(tick as applicable):*

☐ Educational programmes

☐ Controlled access programmes

☐ Other risk minimisation measures

☐ Not applicable

5. Authorisation Holder / Contact Persons / Manufacturers

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

Name
Address

Telephone
E-mail

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

Name
Address

[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.

Telephone
E-mail

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

Name
Address

Telephone
E-mail

5.5 Person in the 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

5.6 Official Batch Release for Blood Products and Vaccines: details of the OMCL (Official Medicines Control Laboratory) or laboratory designated

[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.

for the purpose of official batch release [in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC].

Name
Address

5.7 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

EUDRA GMP document reference:

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

Name

Address

Telephone
E-mail

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

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

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

6.2 State the marketing authorisation number/s[9] of the product authorised in the EEA country of source.

6.3 How is the product authorised in the Member State?

☐ Mutual Recognition [10] / Decentralised Procedure[11] ☐

☐ National Procedure ☐

6.4 If the product is authorised by the Mutual Recognition / Decentralised Procedure, indicate the procedure number.

[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)

7. MARKETING INFORMATION FOR THE PRODUCT

7.1 The product is intended for:

Private market ☐

National Health System ☐

Both Private market and National Health System ☐

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

7.3.1 For the private market:

Estimated n umber of units for three years

7.3.2 For the National Health System:

Estimated number of units for three years

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

7.43.1 The complete Letter of Award from the Department of Contracts together with the corresponding reference number ☐

I confirm that I have read and understood the disclaimer set .out at the beginning of this application form

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 *[the 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.
- ☐ Communication after the authorisation is issued.
- ☐ Signing of documents related to post-Authorisation activities including notification of changes and withdrawals.

Name (In Block Letters) of the Proposed Authorisation Holder

_____ _____

Date **Signature of the proposed Authorisation Holder**

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

_____ _____

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

Annex 2

Declarations

Regarding:
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 under the specified Authorisation will comply with all requirements at any point during the validity of this Authorisation and acknowledge that dossier is not in possession due to the product being authorised in accordance with Article 126(a) of Directive 2001/83/EC

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 with 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 be fully abided by them and by the conditions of this Authorisation.

7. Will be 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 and have 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 notified 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) in editable word version. 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) in editable word version. 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).	☐