MALTA MEDICINES AUTHORITY

LI001/09 Appendix 1 Version 2

Application for the parallel importation of medicinal products

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.

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NEW APPLICATION ☐

RENEWAL APPLICATION ☐

(In case of renewal, include the PI number of the product to be renewed PI)

1 DETAILS OF THE PROPOSED PARALLEL IMPORT LICENCE HOLDER (PARALLEL IMPORTER)

Name:

Address:

Country:

Telephone:

E-Mail:

EudraGMDP Number of Wholesale Dealer's Licence:

Person/Company Authorised for Communication/Signing of documents on behalf of the proposed Parallel Import Licence Holder (Annex I) (if applicable):

Name:

Address:

Country:

Telephone:

E-Mail:

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Contact person in case of quality problems and defective batches:

Name:

Address:

24-hour contact
number (phone/mobile):

E-mail:

Contact person for pharmacovigilance issues as relevant:

Name:

Address:

24-hour contact
number (phone/mobile):

E-mail:

2. **DETAILS OF PRODUCT TO BE IMPORTED**

Name of the product

Pharmaceutical form

Strength

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

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Proposed package size/s to be placed
on the market in Malta

Source country

Marketing Authorisation Holder Name and
Address

Marketing Authorisation Number/s
(in the source country)

3. INFORMATION ABOUT THE MARKETING AUTHORISATION IN MALTA (REFERENCE PRODUCT)

Name of the product

Pharmaceutical form

Strength

Name and address of the MAH

Marketing Authorisation Number (MA)

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4. DOCUMENTS/SAMPLE APPENDED TO THIS APPLICATION *(tick as applicable)*

ANNEX A - Proof of payment ☐

ANNEX B – Proposed Summary of Product Characteristics *(in English word version)* ☐

ANNEX C - Proposed package leaflet *(in English word version)* ☐

ANNEX D - Package leaflet of source country ☐

ANNEX E – Photos or images of the inner and outer labelling as approved in the source country ☐

ANNEX F – Photos of the over-labelled pack, including immediate packaging, as intended for placing on the market ☐

Annex G – Copy of the notification letter sent to the MAH of the Maltese reference product clearly showing the date, address of MAH and MA number of Maltese reference product. ☐

ANNEX H – Additional Risk Minimisation Measures in accordance with GVP, if any (tick as applicable)

☐ Educational programmes
☐ Controlled access programs
☐ Other risk minimization measures
☐ Not applicable

ANNEX I - Letter of authorisation for communication/signing on behalf of the proposed Parallel Import Licence Holder, if applicable ☐

Specimen of the re-packaged product as intended for the market- **MANDATORY** ☐

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5. MANUFACTURER/S RESPONSIBLE FOR RELABELLING/REPACKAGING OF THE PRODUCT

Name:

Address:

Country:

Telephone:

E-Mail:

Details of packaging operations to be carried out:

EUDRAGMP number of sites carrying out re-labelling operations:

Information on any other manufacturer should be given in the format: name, address and operations carried out.

6. BASIS ON WHICH APPLICANT MAKES A PRESUMPTION OF ESSENTIAL SIMILARITY (AS DESCRIBED IN COMMUNICATION FROM THE COMMISSION COM (2003) 839 FINAL) BETWEEN THE LOCAL AND IMPORTED PRODUCT.

The applicant is to compare the product information of the product to be imported with that of the Maltese marketed product. ***If there are any significant differences, they are to be highlighted/pointed out on the proposed SPC and PL and justified.***

7. Declarations for placing the parallel imported medicinal product on the Maltese market.

Name of the product, pharmaceutical form, and strength:

I hereby declare that:

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1. The clinical particulars in the SmPC and package leaflet are in accordance with the currently marketed SmPC and package leaflet of the Maltese-market product.

2. My supplier will **always** keep me informed of any pharmacovigilance issues related to the product and that there is a system in place for handling pharmacovigilance issues as per the Parallel Importation of Medicinal Products Regulations.

3. The Marketing Authorisation Holder of the reference product marketed in Malta has been notified about the product being put on sale in Malta, one month prior to submitting the application to the Medicines Authority.

4. The product will be in line with the obligations as per the Medicines Act, 2003 and relevant subsidiary legislation.

5. All urgent safety measures, including the additional Risk Minimisation Measures, will be implemented in Malta before placing the product on the market.

6. Any quality defects and batch/product recalls shall be notified to the Medicines Authority, without unnecessary delay.

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

Signature of Applicant

Name and Surname

Date

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ANNEX I (if applicable)

Letter of authorisation for communication/signing on behalf of the proposed Parallel Import Licence Holder if applicable)

Name of the product, pharmaceutical form, and strength:

[Name & address of the proposed Parallel hereby authorise, until further notice

[name of contact person]

whose business address is

[business address of contact person]

to represent

the name of proposed Parallel Import

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 the Parallel Import Licence

☐ Signing of any documentation submitted after that the licence has been issued

_____

Name (In Block Letters) of the proposed Parallel Import Licence Holder

_____

Date

_____

Signature of the proposed Parallel Import Licence Holder

_____

Name (In Block Letters) of the Person authorised to communicate/sign (as applicable) on behalf of the proposed Parallel Import Licence Holder

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

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