e-form

Parallel Import New Application / Parallel Import Renewal Application

☐ NEW APPLICATION

☐ RENEWAL APPLICATION

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

Name:	
Address:	
Country:	
Telephone:	
E-Mail:	

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

Name:	
Address:	
Country:	
Telephone:	
Fax:	
E-Mail:	

Contact person in case of quality problems and defective batches:

Name:	
Address:	
24 hour contact number (phone/ mobile):	
Fax:	
E-Mail:	

Contact person for pharmacovigilance issues as relevant:

Name:	
Address:	
24 hour contact number (phone/ mobile):	
Telephone:	
E-Mail:	
Fax:	

2. PRODUCT DETAILS

Name of the product to be marketed:

Pharmaceutical form:

Strength:

Active Substance/s:

Amount of active substance/s per unit dose:

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

Source country:

Marketing Authorisation Holder:

Name and Address:

Marketing Authorisation Number (in the source country):

Parallel Import Licence Number (for Renewal Applications only):

3. INFORMATION ABOUT THE EXISTING MARKETING AUTHORISATION IN MALTA WHICH COVERS THE PRODUCT (DIRECTLY IMPORTED) WHICH THE APPLICANT REFERS TO:

Name of the product:

Pharmaceutical form:

Strength:

Name and address of the Marketing Authorisation Holder:

Marketing Authorisation Number (MA) (for the Maltese-market product):

Describe the differences between the above product (including labeling) and that to be imported.

Existing Marketing Authorisation in Malta:

Product subject of this application:

4. DOCUMENTS AND PACKAGING SAMPLES/ MOCK UPS APPENDED TO THIS APPLICATION (tick as applicable)

- Summary of Product Characteristics (ANNEX C).
- Proposed label for immediate container and outer packaging (colour mock-ups) (ANNEX D).
- Label for immediate container and outer packaging of the original pack in source country (colour mock-ups) (ANNEX H).
- Proposed package leaflet (ANNEX E) (colour mock ups).
- Package leaflet in country from which the product is to be imported (ANNEX F).
- Copy of the Wholesale Dealer's Licence (ANNEX G).

Declaration by the applicant stating that his supplier will always keep him informed of any Pharmacovigilance issues related to the product requesting a parallel import licence and that there is a system in place for handling pharmacovigilance issues as per the Parallel Importation of Medicinal Products Regulations[4] (ANNEX I).

Written declaration from the applicant stating that the marketing authorisation holder of the original 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. A copy of the letter sent to the Marketing Authorisation Holder should also be attached with the application form[5] (ANNEX J) - APPLICABLE TO NEW APPLICATIONS ONLY.

Specimen of there-packaged product- MANDATORY

5. MANUFACTURER/S RESPONSIBLE FOR RELABELLING/ REPACKAGING OF THE PRODUCT [2]:

Name:

Address:

Country:

Telephone:

E-Mail:

Fax:

Details of operations carried out:

☐ **Re-labelling (including over-stickering).**

☐ **Re-packaging to change the number of blister strips in one outer carton.**

☐ **Inserting a new leaflet.**

Re-packaging the product:

☐ **in a new container.**

☐ **or in a new outer container.**

Other:

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

Please supply a copy of the manufacturing authorisation of the above-mentioned manufacturer(s) responsible for re-labelling/re-packaging issued by the Competent Authority in the Member State (ANNEX B).

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.

7. I hereby apply for the parallel importation of a medicinal product for which a Marketing Authorisation has already been granted. I confirm that the clinical particulars in the SmPC and package leaflet are in accordance with the currently marketed SmPC and package leaflet of the originator (Maltese- market) product.

I declare that fees have been paid[3]. (Attach proof of payment- Annex A)

Signature of Applicant:	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.
Name in Block Letters:	
Capacity in which signed:	
Telephone number:	
Fax number:	
Date:	

EXPLANATORY NOTES

[1] Name as mentioned on the wholesale dealer's licence.

[2] The ECJ has defined "repackaging" as including operations such as "removal of blister packs from original external packaging and their insertion into new external packaging" or "addition to the packaging of new user instructions or information or the fixing of self-stick labels" (ECJ, 11 July 1996, MPA Pharma GmbH vs Rhone Poulenc Rorer GmbH (C-232/94) and BMS vs Paranova A/S (C-427/93, C-429/93, C-436/93) and joined cases C-71/94, C-72/94, C-73/94).

[3] Payment of the relevant fee is to be made at: (when executing the payment the amounted should be remitted in full, net of all bank charges).

Bank Details - HSBC Malta plc.
Account No. 039-011176-002
Swift Code MMEBMTMT
IBAN MT78MMEB44392000000039011176002

[4] Parallel importers are required to ensure that there is a clear audit trail from the supplier in the source country. In the event of a recall of a batch of the parallel imported medicinal product in the source country, it is imperative that the importer is informed by the supplier so that the importer can take appropriate action. In addition, there should be a Standard Operating Procedure that covers the respective responsibilities of the supplier and importer. The Medicines Authority requires a declaration by the wholesale dealer that his supplier is going to keep him informed of any Pharmacovigilance issues and that the parallel importer has a system in place to handle pharmacovigilance issues. The documents and systems will be requested in the course of inspections of manufacturers and wholesalers and parallel importers, respectively.

[5] As per Communication from the Commission COM (2003) 839 final.

List of annexes:

ANNEX A: Proof of Payment

ANNEX B: Copy of the manufacturing authorisation of the manufacturer(s) responsible for re-labelling/re-packaging issued by the Competent Authority in the Member State mentioned in Section 5 of the application form.

ANNEX C: Proposed Summary of Product Characteristics.

ANNEX D: Proposed Label for Immediate Container and Outer Packaging (colour mock ups).

ANNEX E: Proposed Package Leaflet (Colour Mock Ups).

ANNEX F: Package Leaflet in the Country from where the Product is to be Imported.

ANNEX G: Copy of Wholesale Dealer's Licence.

ANNEX H: Label for the Immediate Container and Outer Packaging of the Original Pack (colour mock ups).

ANNEX I:

Declaration by the applicant stating that his supplier will always keep him informed of any Pharmacovigilance issues related to the product for which a parallel import licence is being requested.

Declaration must include that the Parallel Importer has in place a system for handling of pharmacovigilance issues in accordance with the Parallel Importation of Medicinal Products Regulations.

ANNEX J - Applicable to New Applications:

Written declaration from theapplicant stating that the marketing authorisationholder of the original product marketed in Malta has been notified about theproduct being put on sale in Malta, one month prior to submitting theapplication to the Medicines Authority.

Please attach a copy of the letter sent to the Marketing Authorisation Holder.

ANNEX K (if applicable)

Letter of authorisation for communication/signing on behalf of the proposed Parallel Import Licence Holder (to be filled in only if applicable).

Name of the product, pharmaceutical form and strength:

Name & address of the proposed Parallel Import License Holder

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 Licence 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 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:

Signature of the proposed Parallel Import Licence 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 proposed Parallel Import Licence 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: