



e-form

Application for a Variation to a Parallel Import Licence



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

Name:

Address:

Country:

Telephone:

Fax:

E-Mail:

2 PRODUCT DETAILS

Name of the product:

Pharmaceutical form:

Strength:

Parallel import licence
number:

3 NATURE OF THE CHANGE

The change affects:

SmPC (provide electronic copy of SmPC amended with track changes and a clean electronic version of the new proposed SmPC).

Labels (provide electronic copy of mock ups amended with track changes and a clean electronic version of the new proposed mock ups).

Leaflet (provide electronic copy of package leaflet amended with track change and a clean electronic version of the new proposed package leaflet).

Marketing Authorisation number of Maltese-Market product.

Parallel import licence holder's name and/or address.

Manufacturer(s) responsible for repackaging/ relabelling.

Marketing authorisation number of the product in the source Country.

Other.

Please specify:

Background (Please give brief background information for the proposed change to the parallel import licence):

4 I hereby apply to vary the Parallel Import Licence. I confirm that no changes have been made to the medicinal product particulars other than those notified to the Medicines Authority. I declare that all changes have been identified and that there are no other changes in the amended documentation.

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:

MEDICINES AUTHORITY USE ONLY:

Variation is approved.

Rejected.

Signature of reviewer: 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: