

MALTA
MEDICINES
AUTHORITY

LI001/09 Appendix 7 Version 1

Application for a Variation Notification to a

Parallel Import Licence

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

Name:

Address:

Country:

Telephone:

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) ☐

☐ Change in line with source country

☐ Change in line with Maltese market product

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Labels (provide photos of new pack and list changes here:

)

☐ Change in line with source country

☐ Change in line with Maltese market product

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

☐ Change in line with source country

☐ Change in line with Maltese market product

Marketing Authorisation number of Maltese-Market product ☐

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

Manufacturer(s) responsible for repackaging/relabeling ☐

Marketing authorisation number of the product in the source Country

Other ☐

(Please Specify)

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

4. Declaration

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 Malta Medicines Authority. I declare that all changes have been identified and that there are no other changes in the amended documentation.

Signature of applicant:

Name:

Email address:

Date:

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