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MALTA MEDICINES AUTHORITY

LI018/05 Appendix 01 Version 01

Application Form for the withdrawal of a Marketing Authorisation, an Authorisation in accordance with Article 126(a) of Directive 2001/83/EC or a Parallel Import Licence

A separate application form needs to be completed for each product, but different strengths of the *same pharmaceutical form* or *different vial sizes* can be grouped into one form. An electronic copy of the application form and pertaining documentation should be submitted through CESP or via email.

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(a) Name/s of product/s to be withdrawn:

(b) MA/AA/PI numbers:

(c) Marketing Authorisation/Licence Holder:

(d) Proposed date of withdrawal:

(e) Pharmaceutical form:

(f) Active substance(s):

1. Are there other products containing the same active substance/s authorised to be placed on the Maltese market in the same pharmaceutical form and strength/s?

☐ Yes

☐ No

You can add further information below (if, for example, there is no alternative for one or more, but not all, strengths being withdrawn.

2. Is the Summary of Product Characteristics (SmPC) or Package Leaflet (PL) of one or more the product/s for which the Marketing Authorisation / License is to be withdrawn combined with the SmPC or PL of one or more strengths or forms of the product?

☐ Yes *(Go to Question 3)*

☐ No *(Go to Question 4)*

3 Following withdrawal of the Marketing Authorisation/License for this product/these products, is it still possible to comply with the dosage schedule given in the SmPC using the products which are to remain in the market?

☐ Yes
(Provide as enclosures a new version of the SmPC and PL (as applicable)

☐ No, but a request for withdrawal of the Marketing Authorisation/License for all other products mentioned in the SmPC (and PL, if applicable) has been submitted simultaneously.

☐ No; to comply with at least part of the dosage regimen patients will need to use the product of another MAH.

4. Reasons for withdrawal

Specify Reason/s for withdrawal:

5. Current usage data for the product in the past two years (volume of sales in units)

Last year:

Central Procurement & Supplies Unit:

Private market:

Current year (to date):

Central Procurement & Supplies Unit:

Private market:

6. Will the MAH/local representative inform the prescribers / pharmacists / other health care professionals?

☐ Yes

☐ No

This will be done by (specify how relevant health care professionals will be informed):

7. Signature

I, the undersigned declare, on behalf of the Marketing Authorisation/License Holder, that I have answered the above questions to the best of my knowledge and that all of the required additional information is enclosed with this form.

Name:

Email address:

Signature :

Date:

8. Appendices to be attached to application form:

Annex 1

Declaration by Marketing Authorisation/License Holder

☐

Annex 1
Declaration by Authorisation/License Holder requesting withdrawal

Declaration by Authorisation/License Holder requesting withdrawal

I, the undersigned declare that I am aware that once a product authorisation or license is withdrawn:

- The authorisation or license cannot be re-instated and an Authorisation for the same product can only be requested by the Marketing Authorisation/License Holder using procedures as stipulated in Article 4(1) of Legal Notice 324 of 2007 (Marketing Authorisation) Regulations (Mutual Recognition Procedure). i.e. through a new application for a marketing authorisation (MA)

- The product can no longer be brought into Malta or distributed

- The Authorisation/License Holder, together with the distributor, remains responsible for any stock distributed in Malta until it is exhausted or expired, whichever is the latest

Name of the Authorisation/License Holder:

Signature of the Authorisation/License Holder:

Date: