e-form

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

Application received on:

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 on CD/DVD or through CESP.

(a) Name/s of product/s to be withdrawn: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add further information below (if, for example, there is no alternative for one or more, but not all, strengths being withdrawn).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(SmPC) or Package Leaflet (PL) of one or more the product/s for which the Marketing Authorisation / License is to be withdrawn combined with the SmPC or PL of one or more strengths or forms of the product?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:

Low sales.

Production difficulties.

Others, namely:

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 Marketing Authorisation Holder/ 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:	

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

I, the undersigned declare that I am aware that once a product authorisation or license is withdrawn:

• The authorisation or licence 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).

• The procedure used at accession to register products that had been previously on the market is no longer viable, not even for products initially registered through this procedure.

• The product can no longer be brought into Malta or distributed.

• The Authorisation/License Holder remains responsible for any stock available in pharmacies until it is exhausted or expired, whichever is the latest.

Name of the Authorisation/License Holder:

Signature of the Authorisation/ License Holder:

Date: