e-form

Application for a Certificate of a Pharmaceutical Product

To be completed only by Medicines Authority staff - Application Number:

To be completed only by Medicines Authority staff – Certificate Number:

SECTION 1

1.1. Date of application:

1.2. Enter the Marketing Authorisation number and date of issue if applicable:

1.3. Name and dosage form of the product:

1.4. Applicant details:

Name:

Company Name:

Phone no:

Address:

Postcode:

1.5. Importing country for which the certificate is required:

1.6. Name of the product in the importing country (if different from 1.3.):

1.7. Number of copies of the certificate required:

Up to two copies of the certificate will be supplied at no additional cost to the fee for the selected service. Further copies are available at a cost of 11.65 € per additional copy. Please enter in the box(es) below the number of copies of the certificate required. If no entry is made in either box one copy will be supplied.

Number of certificates required (up to two at no additional cost):

Number of additional copies at 11.65 € per copy:

Proof of payment should be attached to the application form using the add files button at the bottom of the page.

SECTION 2

2.1. Please list active ingredient(s) and amount(s) per unit dose:

Active ingredient:	Amount per unit dose:

Please list excipients.

Excipient:	Amount per unit dose:

☐ TICK THIS BOX IF YOU WANT EXCIPIENTS TO BE EXPRESSED QUALITATIVELY ONLY

Please write in the following box the number of supplementary pages attached (if any):

2.2. Is this product actually on the market in Malta? (Please select from the following box)

If (b) is selected go to 2.3. If (a) is selected go to Section 3.

2.3. Indicate the reason the product is not on the market in the Malta by ticking the appropriate box:

☐ a. The product has been developed exclusively for the treatment of conditions- particularly tropical diseases- not endemic in Malta.

☐ b. The product has been reformulated with a view to improving its stability under tropical conditions.

☐ c. The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import.

☐ d. The product has been reformulated to meet a different maximum dosage limit for an active ingredient.

☐ e. For commercial reasons this product is not marketed in Malta.

☐ f. The product is licensed but awaiting launch.

g. The product Marketing Authorisation is under assessment by the Medicines Authority.

h. Any other reason.

If box (h) is ticked, explanatory text (not exceeding 180 characters including spaces) for inclusion on the certificate may be entered here.

2.4. Status of the applicant (Please tick the appropriate box):

a. Manufactures the dosage form.

b. Packages and/or labels a dosage form manufactured by an independent company.

c. Is involved in none of the above.

2.5. For categories a, b, and c in question 2.4, the name and address of the manufacturing site where the dosage form is produced are:

Name:

Address:

If required, please use the section below to provide further names and addresses:

Name:

Address:

Manufacturer

Assembler / Packager

Name:

Address:

Manufacturer

Assembler / Packager

Name:

Address:

☐ Manufacturer ☐ Assembler / Packager

Name:

Address:

☐ Manufacturer ☐ Assembler / Packager

SECTION 3

3.1. Name and address of the Marketing Authorisation holder:

Name:

Address:

Postcode:

3.2. Status of the Marketing Authorisation holder (Please tick the appropriate box):

☐ a. Manufactures the dosage form.

☐ b. Packages and/or labels a dosage form manufactured by an independent company.

☐ c. Is involved in none of the above.

3.3. For categories a, b, and c in question 3.2. the name and address of the manufacturing site where the dosage form is produced are:

Name:

Address:

If required, please use the section below to provide further names and addresses:

Name:

Address:

☐ Manufacturer. ☐ Assembler / Packager.

Name:

Address:

☐ Manufacturer. ☐ Assembler / Packager.

3.4. If there is no approved Summary of Product Characteristics (SPC) for this product is any verifiable supplementary information appended? (Please tick the appropriate box)

3.5. Company name to appear on the certificate (the exporter) if different to the Marketing Authorisation Holder:

Name:

Address:

Postcode:

SECTION 4

Does the Medicines Authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (Please tick the appropriate box)

☐ a. Yes the Medicines Authority arranges periodic inspections of the manufacturing plant in which the dosage form is produced.

☐ b. Manufacture is taking place in a country other than Malta and inspection is conducted under the aegis of the country of manufacture.

☐ c. Manufacture is taking place in a country other than Malta and inspections are not carried out by any regulatory authority.

If the answer to question 4.1 is (a) proceed to question 4.2.
If the answer to question 4.1 is (b) or (c) proceed to Section 5.

4.2.Has the manufacture of this type of dosage form been inspected? (Please select the appropriate box)

4.3. Do the facilities and operations conform to GMP as recommended by the World Health Organisation? (Please select the appropriate box)

SECTION 5

5.1. If the answer to question 4.1 is (b) or (c) has any information been supplied to satisfy the Medicines Authority on all aspects of the manufacture of the product? (Please select the appropriate box)

Please use this page to list further excipients and further active ingredient(s) if required.

If required, please list excipients, active ingredient(s) and amount(s) per unit dose.

Excipient:	Amount per unit dose:

Active Ingredient:	Amount per unit dose: