



**GUIDE ON HOW TO COMPLETE THE
APPLICATION FORM REQUESTING
THE CLASSIFICATION OF A BORDERLINE PRODUCT**

A. Purpose of the application form

A product should be referred to the Borderline Classification Committee (BCC) if it does not clearly fall under the definition of a medicinal product as per Medicines Act, Act III of 2003, as amended by Act III of 2004. A medicinal product is:

'A substance or combination of substances

- a. presented as having properties for treating or preventing disease in human beings*
- b. which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'*

The Application Form

The application form should be filled in for every product referred to the Medicines Authority for classification. A completed separate application form is required for each strength and dosage form.

Language to be used

The application form should be compiled in English. Requested information should be submitted in English or Maltese.

B. Information to be submitted in order for product to be assessed by the BCC:

1. Product

1a. Product Trade Name:

When not applicable the generic name should be stated.

1b. Dosage Form and Route of Administration:

The pharmaceutical form should be described as in the current version of standard terms from the Ph. Eur.

Route of administration: Example: oral, IV and IM

1c. Active ingredient/s and excipients and amount/s per unit dose:

The amount of active ingredients per unit dose should be stated E.g. 5mg per tablet, 250mg/5ml.

1d. Container and pack size

1e. Product claims:

List all the indications or claims of the product as specified on the pack, patient information leaflet and promotional material.

2. Importing company

- 2a. Name of importing company referring product for classification.
- 2b. Address of importing company

3. Contact Person

- 3a. Name of contact person and designation within the company
- 3b. Address of contact person

4. Name and address Manufacturer

5. Exporting member state (MS) or third country

MS or country from where the product is imported.

6. Any type of certificate in the exporting member state or third country:

If the product has any type of certificate submit a copy with the application form e.g. food certification or Marketing Authorisation.

7. Availability on the market in the exporting member state or third country.

8. Status of the product in Malta:

Please indicate whether the product:

- i. was previously on the market and the year the marketing was terminated
- ii. is currently on the market and the year marketing commenced
- iii. is currently held at customs
- iv. is currently held in warehouse
- v. is a new importation

C Together with the application form please submit:

- a. Proof of payment (annex 1)** (Please see website for fees)
- b. A mock-up of the packaging or sample of the product.**
- c. The patient information leaflet (annex 2)**

d. Any other literature available on the product (annex 3)

(e.g. used as promotion material, to provide info to health care professionals, consumers etc)

e. Certificates - as per section 6 (annex 4)

Certificates issued in other member states relevant to the product's registration in the country (if applicable)

D. Postal details

The application form should be completed, signed and returned by the applicant in a sealed envelope to the address below:

Borderline Classification Committee

Medicines Authority

198, Rue D'Argens

Gzira – GZR03, Malta

E. Bank details

Bank Details: HSBC Malta plc. Gzira Branch, Malta

Account Name: MEDICINES AUTHORITY

Account Number: 039-011176-002

IBAN: MT08 MMEB 44392 0000000 39011176002

Swift Code: MMEBMTMT