MALTA
MEDICINES AUTHORITY

BD001/05 APPENDIX 2 VERSION 1

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. In case of doubt on whether a product may be a medicinal product, the BCC will be able to assist in classification before a product is placed on the market in Malta.

A medicinal product is defined as:

'A substance or combination of substances

a. presented as having properties for treating or preventing disease in human beings, or

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 Malta Medicines Authority for classification. A completed separate application form is required for each product.

Language to be used

The application form should be compiled in English or Maltese. Requested information should be submitted in English or Maltese (translations from other languages are required of any information on product cartons, labels, and leaflets).

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

1. Product

a. Product name

b. Dosage form and route of Administration:
The (pharmaceutical) form should be given e.g. tablet, capsule, oral solution, powder, etc.

Route of administration: Example: oral, topical, rectal, etc.

c. A list of all the 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.

d. Type of container (e.g. plastic bottle, carton) and pack size (e.g. 20 tablets, 100ml)

e. Product claims (uses):
List all the indications, uses or claims of the product as specified on the pack, information leaflet and promotional material. If website links are included in the product information or pack, information from the websites should also be provided.

2. Importing company

a. Name of importing company in Malta referring product for classification.

b. Address of importing company

3. Contact Person

a. Name of contact person and designation within the company

b. Address of contact person

4. Name and address of Manufacturer

Name and address of the manufacturer of the product should be included.

5. Exporting Member State (MS) or third country

MS or country from where the product is imported (source country) which may be different from the country where it is manufactured.

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.

Whether the product is placed on the market in the source 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) The packaging of the product (the carton, bottle or box) or sample of the product.

(b) The information leaflet (if relevant) (annex 2)

(c) Any other literature available on the product (annex 3)

(E.g. promotion material to provide information to health care professionals, consumers, etc.)

(d) Certificates - as per section 6 (annex 4)

Certificates issued in other member states relevant to the product registration status in the country (if applicable) as food supplement, medicinal, device, etc.

(e) Proof of payment (annex 1) (Please refer to the following link for the fees http://www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11284&l=1)

D. Postal details

The application form should be completed, signed and submitted in electronic format only via email to classcom.adm@gov.mt. If required, the postal address of the Malta Medicines Authority is the following:

Malta Medicines Authority
Sir Temi Żammit Buildings,
Malta Life Sciences Park,
San Ġwann SĠN 3000,
MALTA

E. Bank details

Bank Details:	HSBC Malta plc. Gzira Branch, Malta
Account Name:	MEDICINES AUTHORITY
Account Number:	039-011176-002
IBAN:	MT78MMEB44392000000039011176002
Swift Code:	MMEBMTMT

Kindly note that whenever a payment is effected in respect of an application which is submitted to the Malta Medicines Authority, the following details need to be submitted to Ms. Analisa Buttigieg at analisa.buttigieg@gov.mt :

- The name of the company effecting payment
- The name of the company on behalf of which the payment is effected (when applicable).
- The amount paid.
- Date of payment.
- Payment details eg type of application and reference no; invoice no, etc.

F. Any queries should be addressed to mailbox classcom.adm@gov.mt