e-form

Application for the Classification of a Borderline Product

Please refer to 'Guide on how to complete the application form requesting classification of a borderline product' when filling in this information – Filling in the information incorrectly will lengthen the classification process unnecessarily.

1a. Product Name:

1b. Dosage form and route of administration:

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

Active ingredient/s:	Amount per unit dose:

Excipients:	Amount per unit dose:

1d. Container and pack size:

1e. Product indications, uses and/or claims (if any):

2a. Name of importing company in Malta:

2b. Address of importing company in Malta:

Town: Postcode:

Telephone:

Email:

3a. Name of Contact person and designation within the company:

3b. Address of Contact Person:

Town: Postcode:

Telephone:

Email:

4. Name and address of Manufacturer:

5. Member State (MS) in Europe or third Country from where product is imported:

6. Does the product have a Marketing Authorisation or any type of Certificate in the exporting MS or third country?

7. Is the product available on the market in the exporting MS or third country?

8. Status of the product in Malta:

- i. Product was on the market. — until year:
- ii. Product is currently on the market. — since year:
- iii. Product is currently held at customs.
- iv. Product is currently held in warehouse.
- v. To start importation of Product

9. Attached please find:

- a. Proof of payment (annex 1).
- b. Carton or box (labels are acceptable) (or sample) (annex 2).
- c. Information leaflet (annex 3).
- d. Any other literature available on the product (annex 4).
- e. Any promotional/advertising material (including references to websites).
- f. Certificate (specified in Section 6) (annex 4).

I confirm that all above information is true and accurate to my best knowledge.

Name and Surname:	
Signature:	Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications A Declaration form should be submitted for each signatory.
Designation within the company:	
Date:	

