



MALTA

**MEDICINES
AUTHORITY**

IN033/06 Appendix 2 Version 1

**APPLICATION FOR REGISTRATION FOR BROKER'S ACTIVITY
FOR MEDICINAL PRODUCTS FOR HUMAN USE**

SECTION A: GENERAL INFORMATION**1. DETAILS OF BROKER**

1a If Individual : Name _____
Surname _____
ID or passport number _____

1b If Company : Name _____
Company registration number _____

Legal and judicial representative of company:

Name _____

Surname _____

ID or passport number _____

2. LEGAL ADDRESS OF BROKER

Name/No. _____

Street _____

Locality _____

Postcode _____

If individual – address on ID card

If company – address registered with MFSA

3. DETAILS OF BROKER CONTACT

3a Name _____
Surname _____

3b Address of Broker Contact if different from Section 2

Name/No. _____

Street _____

Locality _____

Postcode _____

3c Telephone number _____

Mobile number _____

E-mail address _____

4. SECTION B: SITE INFORMATION

4a. Site name of brokerage activity

4b. Site address of brokerage activity

Name/No. _____

Street _____

Locality _____

Postcode _____

4c. Site contact (if different from 3)

Name _____

Surname _____

Telephone number _____

Mobile number _____

E-mail address _____

4d. Brokerage involving:

i) Medicinal products (*please tick where applicable*)

With a marketing authorisation in EU member state

Without a marketing authorisation in the EU and intended for EU market

Without a marketing authorisation in the EU and not intended for EU market

ii) Medicinal products with additional requirements (please tick where applicable)

Narcotic or psychotropic products Medicinal products derived from blood Immunological medicinal products Radiopharmaceuticals Medicinal gases Cold chain products (requiring low temperature handling)

Other products – please specify _____

iii) Active Pharmaceutical Ingredients (APIs) **4e Involvement in distribution and / or transport logistics**(i) Are you involved in the distribution chain? YES NO

If yes please tick where applicable:

Own courier/van service Third parties Please specify _____Other Please specify _____(ii) Are you involved in the transport logistics? YES NO

If yes please specify: _____

4f Transactions

(i) Number of transactions per year from previous year statistics: _____

(ii) Volumes of medicines involved in such transactions: _____

(iii) Medicinal products were of:

*Please tick as appropriate*EU Origin Non EU origin (iv) Were you involved in approval processes and/or audit reports: YES NO

If yes please specify: _____

4g Documentation

Record Keeping – Do records exist to provide for all products brokered?

YES NO

If yes:

Site where records are kept: _____

Type of records kept (hard copies/ electronic) _____

Is the following data/information retained for brokering?

(Please indicate by ticking)

- | | | |
|--|------------------------------|-----------------------------|
| a. the date of brokerage: | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| b. the name of the products: | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| c. the quantity of products brokered: | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| d. the name and address of the person from whom and to whom the products are brokered: | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| e. Invoices of brokerage are kept: | YES <input type="checkbox"/> | NO <input type="checkbox"/> |

5. SECTION C: DECLARATION OF NOTIFICATION

I/We are submitting this application form as a notification of brokerage in respect of the activities to which the application refers. Furthermore I/We declare that:

1. The applicant / signatory to be subject to all the Standard Provisions applicable to brokers in the EU GDP guidelines and under regulations currently being in force and which may become in force from time to time.
2. The activities are to be only in accordance with the information set out in the application or furnished in connection with it.
3. I declare that the particulars and information I have given in this form/application are correct and complete.
4. I will notify immediately the Medicines Authority if there are any changes to the information submitted in this notification application form.

Signature of broker or legal representative in case of a company:

Date: _____

Name and Surname: _____

(BLOCK CAPITALS)

For official use only:

Notification Application Number : BNA/

ANNEX A – Documents to be attached with Application

A) Curriculum Vitae of applicant

B) Police conduct of applicant

C) Copy of the VAT certificate, if available.

If the applicant is representing a company:

D) Original Memorandum and Articles of Company issued by MFSA