



MALTA

**MEDICINES  
AUTHORITY**

**IN033/06 Appendix 1 Version 1**

**APPLICATION FOR REGISTRATION OF AN IMPORTER OR  
WHOLESALE DEALER OF ACTIVE PHARMACEUTICAL  
INGREDIENTS (APIs), FOR MEDICINAL PRODUCTS FOR  
HUMAN USE**

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**This document is not valid without all the number of pages specified  
Security Marking: Public/Unclassified**



### 3 DETAILS OF IMPORTER CONTACT

3a Name \_\_\_\_\_  
Surname \_\_\_\_\_

#### 3b Address of Importer 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 Name of Importer (Site Name)

\_\_\_\_\_

#### 4b Site Address of Importer

Name/No. \_\_\_\_\_  
Street \_\_\_\_\_  
Locality \_\_\_\_\_  
Postcode \_\_\_\_\_

**4c Site contact (if different from 3)**

Name \_\_\_\_\_

Surname \_\_\_\_\_

Telephone number \_\_\_\_\_

Mobile number \_\_\_\_\_

E-mail address \_\_\_\_\_

**4d Site type**

i) Proposed Importer operations (please tick where applicable)

Procurement Holding Supply Export 

Other activities - please specify \_\_\_\_\_

ii) Does the Importer also hold a Manufacture Import Authorisation naming this site?

**YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

iii) Is this site shared with any other importer or wholesale dealer (Finished dosage form or APIs)? **YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

iv) Does this importer use a contract wholesale dealer site?

**YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

#### **4e Scope of importation activity**

i) APIs (please tick where applicable)

Used for the manufacture of medicinal products with a marketing authorisation in EU member state

Used for the manufacture of medicinal products without a marketing authorisation in the EU and intended for EU market

Used for the manufacture of medicinal products without a marketing authorisation in the EU and not intended for EU market

ii) APIs with additional requirements (please tick where applicable)

Sterile APIs

Narcotic or psychotropic APIs

APIs derived from blood or other biological origin

APIs for use in Radiopharmaceuticals

APIs requiring a cold chain (requiring low temperature handling)

Other products – please specify \_\_\_\_\_

(iii) Please list here the list of APIs which will be covered by this registered activity: (if required, continue with the list by Annexing to this application on a separate sheet a list of the APIs which will be covered by this activity)

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(iv) Does the site carry out the importation or wholesale distribution of any other chemicals used in other industries, apart from the pharmaceutical industry:

Yes \_\_\_ No \_\_\_

If you have answered Yes, please specify here the type of activity and list the other chemicals which are dealt with: (if required, continue with the list by Annexing to this application on a separate sheet a list of these chemicals)

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#### 4f Method of distribution

Please tick where applicable:

Own courier/van service

Third parties  Please specify \_\_\_\_\_

Other  Please specify \_\_\_\_\_

#### 4g Facilities and Equipment on Site

Please provide a brief description of the facilities and equipment available for the storage and distribution of APIs:

(i) siting of the premises \_\_\_\_\_

- (ii) approximate floor area in square metres \_\_\_\_\_
- (iii) security \_\_\_\_\_
- (iv) describe type of cold storage facilities, if any \_\_\_\_\_

**5. SECTION C: The Technical Responsible Person**

Please give the following details of the person who is to carry out the functions of the technical responsible person for the operations;

**5a** Name \_\_\_\_\_  
Surname \_\_\_\_\_  
Pharmacy Council Registration Number or any other professional registration number \_\_\_\_\_

**5b Contact details:**

Home telephone number \_\_\_\_\_  
Mobile number \_\_\_\_\_  
E-mail address \_\_\_\_\_

**5c (i) Position held with the company, if any:**

\_\_\_\_\_

**(ii) Type of employment with the company:**

- Full time
- Part time
- Contract basis

**5d** Experience :

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**Signed (technical responsible person):**

**Date:**

**5e** I confirm that the above is to the best of my knowledge and belief accurate and true.

**Signed (Applicant):**

**Date:**

## **6 SECTION D: DECLARATION**

I/We are hereby registering the importation activities to which the application refers.

1. The importation activity shall be subject to all the Standard Provisions applicable to the importation of APIs 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 undertake to inform the Medicines Authority immediately should there be any change to the information submitted in this application and in any case shall inform the Medicines Authority on an annual basis of any other change which is not listed in this application, including NIL replies.

**Signature of applicant**

**or legal representative in case of a company:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Name and Surname:** \_\_\_\_\_

**(BLOCK CAPITALS)**



**ANNEX A – Documents to be attached with Application**

A) Curriculum Vitae of technical responsible person

B) Site plan

C) Premises plan (including all storage areas)

D) Police conduct of applicant

If the applicant is representing a company:

E) Original Memorandum and Articles of Company issued by MFSA

**Please note that a MEPA permit must be supplied by applicant before this activity can be registered.**

**PART II – WHOLESALE DEALERS** (i.e. for APIs sourced and imported from countries **within** the EU). These activities are subject to the EU guidelines on Good Distribution Practice for Active Substances.

## **SECTION A: GENERAL INFORMATION**

Please tick whether this is an already established activity at time of application or whether it is a new proposed activity (i.e. not established as yet):

Established: Yes \_\_\_ No \_\_\_ (if yes please insert date when activity was established: \_\_\_\_\_)  
dd/mm/yyyy

### **1 DETAILS OF WHOLESALE DEALER**

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 \_\_\_\_\_

*Fill either Section 1a or 1b(not both)*

### **2 LEGAL ADDRESS OF WHOLESALE DEALER**

Name/No. \_\_\_\_\_

Street \_\_\_\_\_

Locality \_\_\_\_\_

Postcode \_\_\_\_\_

*If individual – address on ID card*

*If company – address registered with MFSA*

**3 DETAILS OF WHOLESALE DEALER CONTACT**

3a Name \_\_\_\_\_  
Surname \_\_\_\_\_

3b Address of Wholesale dealer 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 Name of Wholesale dealer (Site Name)**

\_\_\_\_\_

**4b Site Address of Wholesale dealer**

Name / No. \_\_\_\_\_

Street \_\_\_\_\_

Locality \_\_\_\_\_

Postcode \_\_\_\_\_

**4c Site contact (if different from 3)**

Name \_\_\_\_\_

Surname \_\_\_\_\_

Telephone number \_\_\_\_\_

Mobile number \_\_\_\_\_

E-mail address \_\_\_\_\_

**4d Site type**

i) Proposed Wholesale dealing operations (please tick where applicable)

Procurement Holding Supply Export 

Other activities - please specify \_\_\_\_\_

ii) Does the Wholesale dealer also hold a Manufacture Import Authorisation naming this site? **YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

iii) Is this site shared with any other importer or wholesale dealer (Finished dosage form or APIs)? **YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

iv) Does this Wholesale dealer use a contract wholesale dealer site?

**YES/NO**

If yes, please specify:

Name of company: \_\_\_\_\_

Licence number: \_\_\_\_\_

#### **4e Scope of Wholesale dealing activity**

i) APIs (please tick where applicable)

Used for the manufacture of medicinal products with a marketing authorisation in EU member state

Used for the manufacture of medicinal products without a marketing authorisation in the EU and intended for EU market

Used for the manufacture of medicinal products without a marketing authorisation in the EU and not intended for EU market

ii) APIs with additional requirements (please tick where applicable)

Sterile APIs

Narcotic or psychotropic APIs

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APIs for use in Radiopharmaceuticals

APIs requiring a cold chain (requiring low temperature handling)

Other products – please specify \_\_\_\_\_

(iii) Please list here the list of APIs which will be covered by this registered activity: (if required, continue with the list by Annexing to this application on a separate sheet a list of the APIs which will be covered by this activity)

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Yes \_\_\_ No \_\_\_

If you have answered Yes, please specify here the type of activity and list the other chemicals which are dealt with: (if required, continue with the list by Annexing to this application on a separate sheet a list of these chemicals)

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#### 4f Method of distribution

Please tick where applicable:

Own courier/van service

Third parties  Please specify \_\_\_\_\_

Other  Please specify \_\_\_\_\_

#### 4g Facilities and Equipment on Site

Please provide a brief description of the facilities and equipment available for the storage and distribution of APIs:

- (v) siting of the premises \_\_\_\_\_
- (vi) approximate floor area in square metres \_\_\_\_\_
- (vii) security \_\_\_\_\_
- (viii) describe type of cold storage facilities, if any \_\_\_\_\_

## 5. SECTION C: The Technical Responsible Person

Please give the following details of the person who is to carry out the functions of the technical responsible person for this activity:

**5a** Name \_\_\_\_\_  
Surname \_\_\_\_\_  
Pharmacy Council Registration Number or any other professional registration  
number \_\_\_\_\_

**5b Contact details:**

Home telephone number \_\_\_\_\_  
Mobile number \_\_\_\_\_  
E-mail address \_\_\_\_\_

**5c (i) Position held with the company other than technical responsible person, if any:**

\_\_\_\_\_

**(ii) Type of employment with the company:**

- Full time
- Part time
- Contract basis

**5d** Experience :

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**Signed (proposed RP):**

**Date:**

**5e I confirm that the above is to the best of my knowledge and belief accurate and true.**

**Signed (Applicant):**

**Date:**

## **6. SECTION D: DECLARATION**

I/We are hereby registering the wholesale dealing activities to which the application refers.

1. The wholesale dealing activity shall be subject to all the Standard Provisions applicable to the wholesale dealing of APIs 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 undertake to inform the Medicines Authority immediately should there be any change to the information submitted in this application and in any case shall inform the Medicines Authority on an annual basis of any other change which is not listed in this application, including NIL replies.



**Signature of applicant**

**or legal representative in case of a company:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Name and Surname:** \_\_\_\_\_

**(BLOCK CAPITALS)**

**ANNEX A – Documents to be attached with Application**

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