



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

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)

(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)

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 :

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

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Yes ___ No ___

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(vii) security _____

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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 :

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:

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or legal representative in case of a company: _____

Date: _____

Name and Surname: _____

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