



MALTA

**MEDICINES
AUTHORITY**

IN001-12 APPENDIX 1 VERSION 2

**APPLICATION FOR A WHOLESALE DEALER'S LICENCE FOR
MEDICINAL PRODUCTS FOR HUMAN USE**

SECTION A: GENERAL INFORMATION

1 DETAILS OF PROPOSED LICENCE HOLDER

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 PROPOSED LICENCE HOLDER

Name/No. _____
Street _____
Locality _____
Postcode _____

If individual – address on ID card

If company – address registered with MFSA

3 DETAILS OF PROPOSED LICENCE HOLDER CONTACT

3a Name _____
Surname _____

3b Address of Licence Holder 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 proposed wholesale dealer (Site Name)

4b Site Address of proposed 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 distribution operations (please tick where applicable)

Procurement

Holding

Supply

Export

Other activities - please specify _____

ii) Does the proposed licence holder 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 wholesale dealer? **YES/NO**

If yes, please specify:

Name of company: _____

Licence number: _____

iv) Does this requested wholesale dealer licence use a contract wholesale dealer site?

YES/NO

If yes, please specify:

Name of company: _____

Licence number: _____

4e Scope of wholesale distribution authorisation

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 _____

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 medicinal products:

(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 RESPONSIBLE PERSON

Please give the following details of the person who is to carry out the functions of the Responsible Person (RP):

5a Name _____
Surname _____
Pharmacy Council Registration Number _____

5b Contact details:

Home telephone number _____

Mobile number _____

E-mail address _____

5e (i) Position held with the company other than RP if any:

(ii) Type of employment with the company (please tick):

Full time

Part time

Contract basis

5f Experience : Please state what experience you have had of the activities procedures to be performed under the licence and how this has been acquired, for instance previous jobs.

Signed (proposed RP):

Date:

5g I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

Signed (proposed Licence holder):

Date:

6 SECTION D: DECLARATION

I/We apply for the grant of a Wholesale Dealer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Wholesale Dealer's Licences 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 hereby acknowledge and agree that, upon the processing of the application and the eventual issuance of the Licence, I shall be bound by and comply with the laws of Malta. Any dispute, controversy, or claim arising out of or in connection with this Licence, including any questions regarding its validity, interpretation, or termination, shall be subject to the exclusive jurisdiction of the courts of Malta.
4. I declare that the particulars and information I have given in this form/application are correct and complete.

Signature of proposed licence holder 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 Responsible Person
- B) Site plan
- C) Premises plan (including all storage areas)
- D) Police conduct of proposed licence holder
- E) Planning Authority (PA) Permit

If the applicant is representing a company:

- F) Original Memorandum and Articles of Company issued by Malta Business Registry (MBR)