



e-form

# Application for a Wholesale Dealer's Licence for Medicinal Products for Human Use



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## 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.**

**Supply.**

**Holding.**

**Export.**

**Other activities - please specify:**

ii) Does the proposed licence holder also hold a Manufacture Import Authorisation naming this site?

No

Yes

If yes, please specify:

Name of company:

Licence number:

iii) Is this site shared with any other wholesale dealer?

No

Yes

If yes, please specify:

Name of company:

Licence number:

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

No

Yes

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:

5c (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

5d 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):** 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.

Date:

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

**Signed (proposed Licence holder):** 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.

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 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:** 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.

**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) Malta Environment and Planning Authority Permit.**

**If the applicant is representing a company:**

**F) Original Memorandum and Articles of Company issued by MFSA.**