



**AWTORITA'  
DWAR IL-MEDIĊINI**

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

## **DEFINITIONS**

**Wholesale distribution of medicinal products** shall mean all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public; such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the member state concerned. The holder of a wholesale dealer's licence shall provide and maintain adequate staff, premises, equipment and facilities to handle, store and distribute medicinal products to avoid unnecessary deterioration prior to reaching the end user or patient. The premises should not be used for any other purpose than those laid down in the licence.

**The Responsible Person** is that person responsible for safeguarding product users against potential hazards arising from poor distribution practices, thus ensuring that the conditions of the wholesale dealer's licence are met and the guidelines on Good Distribution Practice are complied with.

**SECTION A:**

**GENERAL INFORMATION**

**1a NAME OF PROPOSED LICENCE HOLDER**

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**NOTE:** Wholesale Dealer's Licences are granted to persons who, in the course of a business, sell or supply medicinal products. This can include:

- (i) A limited company
- (ii) An individual
- (iii) A group of individuals (i.e. a partnership)
- (iv) A body corporate
- (v) Any of the above with a trading style

**1b LICENCE NUMBER (if known)**

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**2a ADDRESS OF PROPOSED LICENCE HOLDER**

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**2b CONTACT ADDRESS FOR ACCOUNTS COMMUNICATIONS (if different from above)**

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**3 LICENCE HOLDER CONTACT**

Surname \_\_\_\_\_

Initials \_\_\_\_\_

Title \_\_\_\_\_

**ADDRESS IF DIFFERENT FROM QUESTION 2a**

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TELEPHONE NUMBER \_\_\_\_\_

FAX NUMBER \_\_\_\_\_

**SECTION B**

**SITE INFORMATION**

**4a** **SITE NAME** (if different to name of the licence applicant)

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**4b** **SITE ADDRESS**

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**4c** **SITE CONTACT**

Surname

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Initials

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Title

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Telephone Number

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Fax Number

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**4d SITE TYPE**

Is this site used for distribution (the onward

Dispatch of ready packed orders) only

**YES/NO**

Or Is this site used for other purposes

**YES/NO**

Please specify these other purposes below (e.g. order receipt, invoicing, assembly/  
picking of orders, handling of goods returned from customers).

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Does the proposed licence holder also hold a Manufacturer's Licence naming this  
site?

**YES/NO**

Is this site named on any other wholesale dealer's or manufacturer's licence?

If so please give the name of the company and their licence number.

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**4e USE OF PRODUCTS STORED OR DISTRIBUTED FROM THIS SITE**

Are the products for:

- (i) Administration to human beings? **YES/NO**
- (ii) Administration to animals? **YES/NO**

**4f CATEGORIES OF PRODUCTS HANDLED AT THIS SITE**

Please indicate by ticking

- (i) OTC \_\_\_\_\_
- (ii) Prescription only medicines \_\_\_\_\_
- (iii) Veterinary Pharmacy Products \_\_\_\_\_
- (iv) Narcotics and Psychotropic Drug \_\_\_\_\_
- (v) Biological Products \_\_\_\_\_

If you have ticked IV. of Question 4f above, please indicate if you are requesting a  
Narcotic and Psychotropic Wholesale Dealer's Licence. **YES/NO**

**4g PRODUCT CLASSES**

Please indicate by ticking

- (i) Large volume sterile liquids \_\_\_\_\_
- (ii) Small volume sterile liquids (including eye drops) \_\_\_\_\_
- (iii) Semi-solid sterile dosage forms \_\_\_\_\_  
(includes sterile creams and ointments)
- (iv) Solid sterile dosage forms (includes sterile powders) \_\_\_\_\_
- (v) Other sterile products \_\_\_\_\_
- (vi) Non-sterile liquids (includes solutions, syrups and \_\_\_\_\_  
Suspensions) and semi-solid non-sterile dosage  
forms (includes non-sterile creams and ointments \_\_\_\_\_
- (vii) Solid non-sterile dosage forms (includes tablets, capsules, \_\_\_\_\_  
suppositories & powders)
- (viii) Medical gases \_\_\_\_\_

**4h METHOD OF DISTRIBUTION**

- (i) Post **YES/NO**
  - (ii) Courier/Van service **YES/NO**
  - (iii) Own Courier/Van service **YES/NO**
  - (iv) Customer collection **YES/NO**
  - (v) Other, please specify below **YES/NO**
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**4i FACILITIES AND EQUIPMENT ON SITE**

On a separate sheet of paper 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
- (iii) security
- (iv) construction
- (v) equipment available
- (vi) refrigeration equipment(if available)

**4j DOCUMENTATION**

- (i) Record Keeping – Do records exist to provide for all products received and dispatched,
- a. the date of receipt and of dispatch
  - b. the name of the products
  - c. the quantity of products received or dispatched
  - d. the name and address of the person from whom or to whom the products are sold or supplied, as appropriate (that is who sold them to you, and/or to whom you sold them, who supplied them to you and/or to whom you supplied them).

Please indicate by ticking **YES** \_\_\_\_\_  
**NO** \_\_\_\_\_

- (ii) Dispatch Documentation – Do all dispatches enclose, with the products, a document which makes it possible to ascertain:
- a. the date on which the transaction took place
  - b. the name and pharmaceutical form of the products
  - c. the quantity of products supplied
  - d. the name and address of the persons from whom the products were supplied

Please indicate by ticking: **YES** \_\_\_\_\_  
**NO** \_\_\_\_\_

- (iii) Recalls and Returns Procedure –

I confirm that I have prepared in writing an emergency plan in accordance with EEC Directive 92/25. I will hand in this plan to the Medicines Authority with the application form.

Please indicate by ticking **YES** \_\_\_\_\_

NO \_\_\_\_\_

**5 THE RESPONSIBLE PERSON**

Please give the following details of the person who is to carry out the functions of the Responsible Person

**5a Surname** \_\_\_\_\_  
**Initials** \_\_\_\_\_  
**Title** \_\_\_\_\_

**5b BUSINESS ADDRESS**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Home Telephone Number** \_\_\_\_\_  
**Business Telephone Number** \_\_\_\_\_

**5c DATE OF BIRTH** \_\_\_\_\_

**5d LENGTH OF PERIOD OF EMPLOYMENT WITH THE LICENCE  
HOLDER** \_\_\_\_\_

**5e POSITION HELD WITH THE COMPANY**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**5f** If 5d and 5e do not apply state relationship with the company here:

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**5g** **Knowledge:** Please state what knowledge you have of the activities and procedures to be performed under the licence(continue on a separate page if required)

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**5h** **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(continue on a separate page if required).

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**Signed(nominee):**

**Date:**

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

**Signed(licence holder):**

**Date:**

**SECTION C**

**OTHER SITES**

**Please list details of other sites(which are not the subject of this licence and are not under your direct control) from which storage and/or distribution will take place. Please complete this page for each site.**

**6a SITE NAME** (if different to name of the licence applicant)

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**6b SITE ADDRESS**

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Does this site hold any licence under the Medicines Act

**YES/NO**

If yes please give licence number

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**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 for the time being in force.
2. The activities are to be only in accordance with the information set out in the application or furnished in connection with it.
3. To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

**Signed:**

**Date:**

**Name:**

(BLOCK CAPITALS)

State capacity in which signed:

## **ANNEX A – List of Countries**

Austria  
Belgium  
Denmark  
Finland  
France  
Germany  
Greece  
Iceland  
Ireland  
Italy  
Luxembourg  
Netherlands  
Norway  
Portugal  
Spain  
Sweden  
United Kingdom

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

A) Site Licence \_\_\_\_\_

B) Curriculum Vitae of Responsible Person \_\_\_\_\_

C) Declaration of Responsible Person \_\_\_\_\_

D) Site plan \_\_\_\_\_

E) Premises plan \_\_\_\_\_

F) Recall procedure \_\_\_\_\_

G) Police conduct of applicant \_\_\_\_\_

If the applicant is representing a company:

H) Memorandum and Articles of Company \_\_\_\_\_

I) Letter from company directors authorising applicant to be licence holder \_\_\_\_\_

**Please note that a MEPA permit must be supplied by applicant before wholesale dealer's licence is issued.**