



**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

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)

2a ADDRESS OF PROPOSED LICENCE HOLDER

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

3 LICENCE HOLDER CONTACT

Surname _____

Initials _____

Title _____

ADDRESS IF DIFFERENT FROM QUESTION 2a

TELEPHONE NUMBER _____

FAX NUMBER _____

SECTION B

SITE INFORMATION

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

Appendix 1

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4b SITE ADDRESS

4c SITE CONTACT

Surname

Initials

Title

Telephone Number

Fax Number

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).

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.

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) Narcotics and Psychotropic Drug

(iv) Biological Products

(v) Radiopharmaceuticals

(vi) Investigational medicinal 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**

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:

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)

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).

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)

6b SITE ADDRESS

Does this site hold any licence under the Medicines Act **YES/NO**
If yes please give licence number _____

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 – 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.