



REPUBLIC OF CYPRUS

APPLICATION FOR THE GRANTING/RENEWAL OF A WHOLESALE LICENSE FOR MEDICINAL PRODUCTS

[The Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001
The Medicinal Products for Human Use (Procedure and Content of Examination for a Wholesale License) Regulations
of 2001]

Date: _____

**Registrar Drugs Council
Pharmaceutical Services
Ministry of Health
Lefkosia 1475**

For official use	
<i>Application number</i>	
<i>Date</i>	
<i>Amount paid</i>	
<i>G.A. 288 number</i>	
<i>Date</i>	

You are requested to grant me a license for the wholesale of medicinal products pursuant to the provisions of Section 82 of the Medicinal Products for Human Use (Control of Quality, Supply and Prices) Law of 2001 and in accordance to the particulars furnished in the present application. In the case of the granting of the licence, I undertake the obligation to notify the Drugs Council any change on the particulars stated/appended on my application.

APPLICANT'S INFORMATION

Name of applicant: _____
ID Number (Natural persons): _____
Company Registration Number (Legal persons): _____
(the Certificate of Registration from the Registrar of Companies is appended)
Address: _____
Tel.: _____
Fax: _____
Email: _____

PERSONNEL

1. Person responsible for the recall of products from the market

Name: _____
Address: _____
Work telephone: _____
Home telephone: _____
24 Hour telephone: _____
Fax: _____
Email: _____

2. Person responsible for wholesale

Name: _____

Address: _____

Work telephone: _____
Home telephone: _____
Fax: _____
Email: _____

3. Person who has successfully passed the examination for the granting of a wholesale license (if different from the person responsible for wholesale)

Name: _____
Address: _____

Position in the Company: _____
(The Certificate from the Registrar of Companies stating the Directors is appended)
Work telephone: _____
Home telephone: _____
Fax: _____
(the relevant letter from the Registrar Drugs Council is appended)

4. Other personnel

Please append a list of the remaining personnel as well as their respective duties.

STORAGE FACILITIES

Address of storage facilities: _____

Tel.: _____
Fax: _____

(if there are more than one storage facilities, please append a list with their addresses)

The following spaces are available (to be completed for every storage space)

- ☐ Space for the receipt and control of supplies
- ☐ Space for the safe keeping of expired or recalled products
- ☐ Space for keeping narcotic drugs
- ☐ Controlled environment storage spaces (temperature, humidity, light). The conditions are checked and recorded daily.
 - Room storage conditions (maximum 25 Degrees Celsius)
 - Cold storage conditions (2-8 Degrees Celsius)
 - Freezing storage conditions (-20 to -10 Degrees Celsius)
 - Other special storage conditions

(An architectural overview plan of the facilities is appended)

LIST OF EQUIPMENT

Please enclose a list of the main equipment available to ensure the good storage and distribution of medicinal products i.e. air conditioners, refrigerators, air conditioned cars etc.

BOOKS, DOCUMENTS AND PROCEDURES

The following books are kept:

- ☐ Invoices *
- ☐ Narcotics Book
- ☐ Purchases Book *
- ☐ Sales Book *

*(*The invoice books and the sales books must contain at least the following information: 1. Date, 2. Name of Medicinal Product, 3. The received or delivered quantity, 4. Name and address of supplier or receiver, depending on the case, 5. Batch number)*

The following procedures are observed:

- ☐ Procedure for the recall of medicinal products from the market
 - Batch numbers are written on the invoice YES/NO
 - There is a Standard Operating Procedure for recalls YES/NO (*appended*)
- ☐ Procedure of receipt and storage
- ☐ Procedure for stock control
- ☐ Procedure for the sale of older stock by priority (FIFO- First In First Out)
- ☐ Procedure for the handling of returned medicinal products
- ☐ Procedure for cleaning and maintenance

Geographical area to be covered

Signature

Name

Position in company