



**APPLICATION FOR AN IMPORTER'S LICENCE
FOR MEDICINAL PRODUCTS FOR HUMAN USE**

DEFINITIONS

Importation of medicinal products is the procuring of medicinal products from a third country that is countries outside the EEA.

The Qualified Person is that person responsible for ensuring that each production batch of medicinal products coming from third countries (i.e. countries outside the EU and EEA) that do not have a Mutual Recognition Agreement has undergone full qualitative analysis, a quantitative analysis and all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation . In the presence of a Mutual Recognition Agreement, the QP must batch release the medicinal product.

SECTION A:

GENERAL INFORMATION

1a NAME OF PROPOSED LICENCE HOLDER

NOTE: Import 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 _____

Telephone number _____

Fax number _____

4 RECALLS AND RETURNS PROCEDURE

Please provide a copy of your procedures with your application form for handling complaints, customer returns and recalls.

SECTION B

SITE INFORMATION

5a SITE NAME (if different to name of the licence applicant)

5b SITE ADDRESS

5c SITE CONTACT

Surname _____

Initials _____

Title _____

Telephone Number _____

Fax Number _____

5d 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.

5e 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 _____

5f PRODUCT CLASSES

Please indicate by ticking

– Importation of Medicinal Products

- authorised importation activities without manufacturing activity _____
- authorised importation activities include storage and distribution unless informed to the contrary _____

Quality control testing of imported medicinal products

- Microbiological : sterility _____
- Microbiological: non-sterility _____
- Chemical/Physical _____
- Biological _____

Batch certification of imported medicinal products

Sterile products

- Aseptically prepared _____
- Terminally sterilised _____

Non-sterile products

Biological medicinal products

- Blood products _____
- Immunological products _____
- Cell therapy products _____
- Gene therapy products _____
- Biotechnology products _____
- Human or animal extracted products _____
- Other biological medicinal products _____

Other importation activities (*any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.*)

- _____ - Radiopharmaceuticals
- _____ - Medicinal gases
- _____ - Herbal products
- _____ - Homeopathic products
- _____ - Biological active starting materials
- _____ - Other
- _____

Any restrictions or clarifying remarks related to the scope of these importing operations

5g LIST OF PRODUCTS TO BE IMPORTED, PHARMACEUTICAL FORM, MARKETING AUTHORISATION HOLDER, MARKETING AUTHORISATION NUMBER AND COUNTRY OF ORIGIN

5h 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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-
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5i 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)

5j 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 _____

5k ANALYTICAL TESTING SITES AND CONTRACT MANUFACTURING SITES

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- Address of contract laboratories -

This refers to the site/s at which testing of finished products takes place prior to batch release. The name, site address and list of tests carried out should be included.

- Address of contract manufacturing sites -

**SECTION C
PERSON**

THE QUALIFIED

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

6a Surname _____
Initials _____
Title _____

6b BUSINESS ADDRESS

Home Telephone Number _____
Business Telephone Number _____

6c DATE OF BIRTH _____

**6d LENGTH OF PERIOD OF EMPLOYMENT WITH THE LICENCE
HOLDER** _____

6e POSITION HELD WITH THE COMPANY

6f QUALIFICATIONS

6g 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)

6h 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).

6i Professional Association

Please submit a copy of the candidate's basis of eligibility with this application.

6j If the QP is not a full-time employee of the company please give details of the hours spent on this site.

Signed(nominee):

Date:

6k I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

Signed(licence holder):

Date:

SECTION D

DECLARATION

I/We apply for the grant of an Import 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 Import 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 Qualified Person _____

C) Recall procedure _____