

Guide to PharmaTrust Extranet

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.



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1 INTRODUCTION

The Compliance department has developed a highly secure online licence application system for controlled drugs known as the HPRA PharmaTrust extranet. This system allows users to apply for import and export licences and letters of no objection (LONOs).

This guideline outlines the information available on the PharmaTrust extranet and the procedure for making an electronic application for an import licence, export licence or LONO.

2 REGISTERING TO USE THE PHARMATRUST EXTRANET

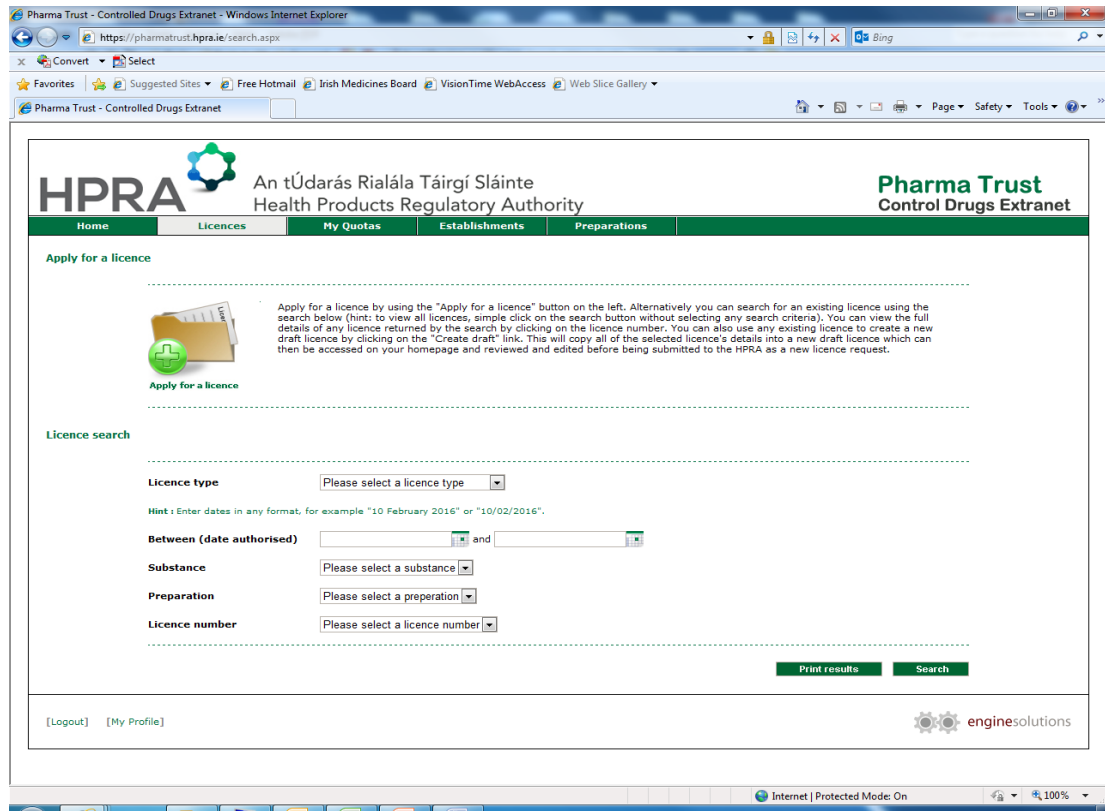
To register to use the on-line application system, the applicant should e-mail controledrugs@hpra.ie or enter the organisation's details on-line at: <http://www.hpra.ie/registration.aspx>.

The system is subject to a high degree of security. Registration is only finalised after the HPRA has vetted the organisation to establish the legitimacy of the operation. After submitting the organisation's details, the applicant will receive a username and password by e-mail, along with a security certificate which needs to be installed. After installing the security certificate, the applicant can apply for licences online. For any problems with installation, please contact the Compliance department or the HPRA IT department (see section 9).

3 ACCESSING THE PHARMATRUST EXTRANET

To access PharmaTrust, go to <https://pharmatrust.hpra.ie>. Enter the username and password. The organisation's homepage will then appear on the screen (see image on the following page).

Select the appropriate link at the top of the screen e.g. Apply for a Licence, Establishments or Preparations.



4 MAKING AN APPLICATION

4.1 Fees

There is a charge for the issuance of import and export licences. Please contact controlled drugs@hpra.ie as the fees may be subject to change by the Department of Health. There is no charge for LONOs. It is advisable to submit sufficient credit to cover a number of licence applications based on your previous licence application volumes.

4.2 Basis

A separate licence/LONO is required in respect of each consignment.

Any licence issued in response to the application will be for a specific quantity of drug(s). It is not permitted to import or export greater quantities than are specified on the licence, or materials that do not fit the description on the licence.

Amendments should not be made to any kind of licence. Should an amendment (e.g. to quantity or description) be required, all copies of the licence must be returned to the Compliance department for amendment.

4.3 Accompanying documentation

In the case of an export licence application, the original corresponding import permit or licence issued by the Competent Authority of the importing country must be submitted to the Compliance department. Import licences are accepted in electronic format and should be submitted via Eudralink to controlleddrugs@hpra.ie. For Eudralink registration and information, contact the Eudralink helpdesk at eudralink@ema.europa.eu.

5 APPLYING FOR A LICENCE OR LONO

5.1 Procedure

- (i) On the homepage, select 'Apply for a licence'.
- (ii) From the drop-down list, select the licence type (import or export) and click 'Continue'. 'Import' and 'Export' refer to licences and also to LONOs. The HPRA will issue the appropriate licence type.
- (iii) For an import licence application, use the drop-down list to select the country from which the drugs are being imported. For an export licence application, select the country to which the drugs are being exported from the drop-down list. Click 'Continue'.
- (iv) Select the establishment from which or to which the consignment will be imported or exported. Click 'Continue'. If the establishment is not listed, or the details listed are incorrect, e-mail the name and address of the establishment to controlleddrugs@hpra.ie and it will be added to the company's profile. You will be notified when the details have been updated and can continue with the application. If the details of the establishment do not appear on the PharmaTrust drop-down menu, do not type in the details as these applications will not be accepted.
- (v) From the drop-down list, select the annual licence or registration which gives the primary authority to apply for this licence. The organisation will have hard copies of these licence documents and should use these for reference. For information and application forms, please contact the Compliance department.
- (vi) Select the mode of transport for the importation or exportation of the consignment. Do not select 'Road or Rail' unless the consignment is being imported or exported by this mode of transport to/from Northern Ireland.

- (vii) Enter, in the format dd/mm/yyyy, the date on which the importation or exportation will occur.
- (viii) For an import licence application, select the appropriate 'point of entry' from the drop-down list. For 'point of exit' select the relevant country name from which the consignment will be exported. For an export licence application, enter the relevant country name at which the consignment will enter for 'point of entry', and select the appropriate exit point from the drop-down list for the 'point of exit'.
- (ix) For an export licence application, enter the number of the import licence/permit issued by the Competent Authority of the importing country in the space provided for the 'Import document reference'. Enter the date of issue and date of expiry of this import licence/permit in the spaces. Click 'Continue'.
- (x) Click 'Add to consignment' to select the preparation and/or drug/substance to be imported/exported.
- (xi) Select the preparation from the drop-down list at 'Preparation' or the drug/substance (if importing raw material) from the drop-down list at 'Substance'.
- (xii) If the preparation to be imported/exported is not listed, e-mail the name, strength, active ingredient, form, pack size and MA number/internal code to controlleddrugs@hpra.ie and the preparation will be added to the company's profile. You will be notified when the details have been updated and can continue with the application. If the details of the preparation do not appear on the PharmaTrust drop-down menu, do not type in the details as these applications will not be accepted.
- (xiii) Enter the quantity to be imported or exported in the space provided at 'Quantity'.

For a preparation, provide the quantity of units to be imported or exported e.g. 300 means 300 packs.

For a drug/substance, provide the quantity in grams e.g. 100,000. It is not necessary to include the word 'grams'.
- (xiv) Select 'Add to consignment' to add another drug/substance or preparation to the licence application, and repeat steps 5.1.11 to 5.1.13 above.
- (xv) Select 'Submit application' at the bottom of the screen to submit the completed application.

5.2 Draft applications

It is possible to save a draft version of the application at various stages throughout the procedure by selecting 'Save Draft' at the bottom left hand side of the screen. Any drafts saved can be accessed at a later date on the home page under 'Drafts' at the bottom of the page.

Once a draft has been submitted to the Compliance department, it will no longer be listed in the drafts section.

5.3 After submitting the application

A notification e-mail will be sent confirming that the application has been received and is being reviewed. If no licence number appears on the notification e-mail, contact the Compliance department.

The Compliance department will ensure that all the information required has been provided. If any information is missing, the applicant will be requested to provide it and the application will be put on hold until the relevant information has been received. Only then will the application be processed and a licence or LONO be issued.

5.4 Import licence

Once the import application has been approved, the applicant will be issued with an import licence and a certificate of approval of import.

The import licence is an authority solely for the importation of the particular consignment.

The licence should be endorsed and returned to the Compliance department within seven days of the receipt of the consignment. The importer may make a copy of this licence for their records.

The certificate of approval of import must be provided to the exporting company for submission to the Competent Authority in their country with their application for a licence to export the consignment. The importer may make a copy of this certificate for their own records but the original must be sent to the exporting company.

5.5 Export licence

Once the export application has been approved, the exporter will receive two copies of the export licence.

Copy 1 of the export licence is an authority solely for the exportation of the particular consignment.

The licence should be endorsed and returned to the Compliance department within seven days of the export of the consignment. The exporter may make a copy of this licence for their records.

Copy 2 of the export licence must accompany the consignment to the importing company.

5.6 LONO

Once the application has been approved, the company will receive two copies of the LONO.

The LONO is solely for the importation/exportation of the particular consignment.

The LONO should be endorsed and returned to the Compliance department within seven days of the importation/exportation of the consignment. The exporter may make a copy of this licence for their records.

5.7 Unused licences and LONOs

If a company decides not to use a licence/LONO, the documentation should be returned to the Compliance department within seven days of the decision not to use it. The licence/LONO should be clearly marked 'unused'.

6 ESTABLISHMENTS

To view the complete list of foreign establishments with which the applicant has authority to trade, select 'Establishments' on the toolbar.

7 PREPARATIONS

To view the complete list of medicinal preparations which the applicant has previously imported/exported, select 'Preparations' on the toolbar.

8 FORMAT FOR PRODUCT NAMES

8.1 Solid dosage forms

The description should be written in the following sequence:

- The product name written in capitals e.g. BRANDNAME
- In the case of tablets or capsules the product form written as an abbreviation. This is taken as the first three letters in capitals of the product e.g. tablets as TAB

- The strength of the product in milligrams in brackets e.g. (5mg)
 - The pack size written as 'X' (in capitals) followed by the number of units per pack e.g. X 60
- Example: BRANDNAME TAB (5mg) X 60

8.2 Injections

The description should be written in the following sequence:

- The product name written in capitals e.g. BRANDNAME
- The injection size e.g. 2ml
- The product form written as an abbreviation. This is taken as the first three letters in capitals e.g. injection as INJ
- The strength of the product in milligrams in brackets e.g. (1mg/2ml)
- The pack size written as 'X' (in capitals) followed by the number of units per pack e.g. X 10

Example: BRANDNAME 2ml INJ (1mg/2ml) X 10

8.3 Syrups (liquids)

The description should be written in the following sequence:

- The product name written in capitals e.g. BRANDNAME
- The size e.g. 120ml
- The strength of the product in milligrams in brackets e.g. (10mg/ml)

Example: BRANDNAME 120ml (10mg/ml)

8.4 Patches

The description should be written in the following sequence:

- The product name written in capitals e.g. BRANDNAME
- The product form written in full e.g. patch as PATCH
- The active content per patch in brackets e.g. (2.5mg). Note the delivery rate per hour should be included in the comment section.
- The pack size written as 'X' (in capitals) followed by the number of units per pack e.g. X 5

Example: BRANDNAME PATCH (2.5mg) X 5

8.5 Products for laboratory or scientific use

The description should be written in the following sequence:

- The active name written in capitals e.g. BRANDNAME
- The strength of the product per unit or vial e.g. 100mcg/ml
- The solvent medium and its volume where applicable e.g. in 1ml Methanol

Example: BRANDNAME 100mcg/ml in 1ml Methanol

9 CONTACT DETAILS

Further information and assistance can be obtained from the Compliance department.

Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: 01-6764971
Fax: 01-6764061
E-mail: controlleddrugs@hpra.ie

For any problems associated with the PharmaTrust extranet system e.g. difficulty logging on to the system, contact the Compliance department or the HPRA IT department, preferably by e-mail or by telephone.

IT Department
Health Products Regulatory Authority
Tel: 01-6764971
E-mail: IThelpdesk@hpra.ie

The HPRA encourages communication with stakeholders. Please forward any comments relating to the system or any suggestions for future improvements to controlleddrugs@hpra.ie.