HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Import and Export Licences and Letters of No Objection for Controlled Drugs

AUT-G0127-5
02 MAY 2017
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 INTRODUCTION

Operators (manufacturers, wholesalers, authorised persons) require a controlled drugs licence or registration processed by the Health Products Regulatory Authority (HPRA) on behalf of the Department of Health if they wish to produce/manufacture, supply, import, export or possess any controlled drug in the schedules to the Misuse of Drugs Regulations 2017, as shown below:

Activity	Regulatory requirements
Manufacture of any controlled drugs listed in the schedules	Annual licence, renewed each year
Supply, import, export or possess a controlled drug in Schedules 1and 2	Annual licence, renewed each year
Supply, import, export or possess a controlled drug in Schedules 3, 4 and 5	Registration, not subject to renewal
In addition:	
Each import or export of controlled drugs in Schedules 1, 2, 3 and Schedule 4 part 1 into or out of Ireland	Import or export licence (as appropriate), to accompany the product
Each import or export of controlled drugs in Schedule 4 part 2 and Schedule 5 into or out of Ireland	Letter of no objection (LONO)

Application forms for annual licences and registrations can be found on the 'Publications and Forms' section of www.hpra.ie or by contacting controlleddrugs@hpra.ie. Details on how to apply for an import/export licence or LONO are outlined below.

2 HOW TO APPLY FOR AN IMPORT/EXPORT LICENCE OR LONO

2.1 PharmaTrust

Manufacturers and wholesalers must have a PharmaTrust account to apply for any import/export licences or LONOs. PharmaTrust is an electronic application system which allows companies to apply online. It forms part of the National Drugs Control System (NDS) and is designed to improve the processing times for licence and LONO applications and to facilitate the electronic data collection for monitoring trade in controlled drugs.

All other authorised persons wishing to apply for an import/export licence or LONO should contact the HPRA directly on controlleddrugs@hpra.ie for instructions on how to apply for a PharmaTrust account.

A 'Guide to PharmaTrust Extranet' can be found on the 'Publications and Forms' section of www.hpra.ie.

2.2 Applying for a PharmaTrust account

To apply for a PharmaTrust account, the following information should be provided in an e-mail to controlleddrugs@hpra.ie:

- Name of company
- Name of contact person and email address
- List of all controlled drugs the company intends to import or export, including raw material and finished products.
    - In the case of finished products include information on strength of product, name of controlled drug active ingredient, pack size and volume of product (liquid preparations) on this list.
    - In the case of raw material include the estimated quantity of material to be imported/exported each year.
- List of all establishments the company is importing/exporting from or to and the full address of each company.

A credit account must be set up with the HPRA to facilitate the quick processing of licences. Please note that we cannot process any applications until the fee has been received.

2.3 Exportation: licence and LONO applications

Once registration with PharmaTrust is complete the authorised operator can submit an application through their account.

Operators wishing to export controlled drugs must obtain a valid import authorisation from the country to which they are exporting i.e. the importing country. Export licence applications containing the corresponding import authorisation reference number will only be processed once the HPRA has received a copy of the import licence. Electronic copies of the import licences should be submitted via Eudralink to controlleddrugs@hpra.ie. For Eudralink registration and information contact the Eudralink helpdesk eudralink@ema.europa.eu.

The foreign Competent Authority import authorisation (from the importing country) may contain an expiry date. In such cases, the corresponding export licence/LONO will be issued in accordance with the stated expiry date of the foreign import authorisation, i.e. one day before the foreign import authorisation expires. Each export licence/LONO is valid for one exportation consignment only.

If the foreign Competent Authority import authorisation does not contain an expiry date the following timelines will be applied to the export licence/LONO:

- three months from the date of the licence/LONO approval for goods exported to countries within the EEA and Switzerland.
- six months from the date of the licence/LONO approval for goods exported to countries outside the EEA and Switzerland.

Export licence/LONO applications can only be assessed and processed once a complete application has been submitted via PharmaTrust, the import authorisation has been received and the relevant fee has been paid. Inaccurate or incomplete applications will be placed on hold and will not be processed until all required documentation has been received.

The estimated turnaround time for applications is approximately four weeks from date of electronic submission of the completed application, which includes receipt of the foreign import authorisation and the appropriate fee. This timeframe is an estimate to assist with commercial planning; however, it is subject to change, depending on the volume of applications being processed at any one time.

An export licence/LONO is only valid if it bears the official stamp of the Department of Health.

2.4 Importation: licence and LONO applications

Registered PharmaTrust account holders may submit a controlled drugs import licence/LONO application through their PharmaTrust account.

Once issued, import licences/LONOs are valid for the following time periods:
- three months for goods imported from countries within the EEA and Switzerland.
- six months for goods imported from countries outside the EEA and Switzerland.

Each import licence/LONO is valid for one importation consignment only.

Import licence/LONO applications can only be assessed once a complete application has been submitted and the relevant fee received. Inaccurate or incomplete applications will be placed on hold and will not be processed until all of the required documentation has been received.

The estimated turnaround time for licence/LONO applications is approximately four weeks from date of electronic submission of a complete application and fee. This timeframe is an estimate to assist with commercial planning; however it is subject to change, depending on the volume of applications being processed at any one time.

An import licence/LONO is only valid if it bears the official stamp of the Department of Health.

2.5 LONOs for non-controlled substances

If a substance is not a controlled drug in Ireland but is a controlled drug in the exporting or importing country, the HPRA may issue a ‘non-controlled LONO’. If this documentation is

required email controlleddrugs@hpra.ie stating the name and address of the importer/exporter and the quantity and description of each substance.

2.6 Endorsement of import and export licences and LONOs

The licensee must comply with the conditions of the licence/LONO. One such condition is that the licence or LONO, duly endorsed, must be surrendered to the Minister for Health within seven days of the date of importation/exportation.
If a licence or LONO is not used it should be endorsed by the licensee, marked as 'UNUSED' and returned to the Controlled Drugs section of the HPRA within seven days of:-

- the decision not to use the licence/LONO or
- the expiry date specified on the licence.

These endorsed licences and LONOs should be returned to:
Controlled Drugs Section,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Terrace,
Dublin 2
D02 XP77

The licence/LONO is valid only for the licensee and may be revoked at any time by the Minister for Health, to whom it must be immediately surrendered.

If any alteration is required to a licence/LONO it should be returned to the Controlled Drugs Section of the HPRA with a request for amendment and the reasons for the request. No alteration by the licensee is permitted.

It is an offence under the Misuse of Drugs Acts 1977 to 2016 to contravene a condition of a licence or LONO.

The licence or LONO must be produced for inspection when required by a member of the Garda Síochána or a person duly authorised under section 24 of the Misuse of Drugs Acts 1977 to 2016, for a period of two years from the date of expiry as specified on the licence/LONO.

2.7 Licence fees

Controlled drug annual licence:

Operation	Application fee	Payable to:
Possess (Schedule 1 and2)	€31.75 per drug	Department of Health
Supply (Schedule 1 and 2)	€63.50 per drug	Department of Health
Produce preparations containing any controlled drugs	€127.00 per drug	Department of Health

Operation	Application fee	Payable to:
Produce any raw drugs	€190.50 per drug	Department of Health

Controlled drug registration:

Operation	Application fee	Payable to:
Possess (Schedule 3,4 and 5)	No fee	N/A
Supply (Schedule 3,4 and 5)	No fee	N/A

Controlled drug import and export licences (Schedule 1, 2, 3):

Operation	Application fee	Payable to:
Export licence	€63.50 per consignment	Department of Health
Import licence	€63.30 per consignment	Department of Health

Controlled drug import and export LONO (Schedule 4 part 2, Schedule 5):

Operation	Application fee	Payable to:
Export LONO	n/a	n/a
Import LONO	n/a	n/a

Fees must be paid prior to or at the time of application. All fees must be received by credit transfer to the Department of Health. Any fees received payable to the HPRA will be returned and this may result in a delay to the application process.

2.8 Exceptional circumstances

In the case of urgent requests for expedited processing of licence and LONOs, operators must provide details of the exact nature of this urgency. The HPRA operates a queuing system for the very high number of import/export licences and LONO applications from operators. In the interests of fairness to all operators, licence applications can only be prioritised in extremely urgent cases, e.g. medicines shortages directly impacting patients. The form 'Request for an expedited import/export licence or letter of no objection' must accompany urgent requests, along with supporting documentary evidence and it is available on the 'Publications and Forms' section of www.hpra.ie.

2.9 Contact information

Operators should appoint a designated person as point of contact for controlled drugs licensing matters. A deputy can also be appointed if necessary. This point of contact should be notified to the HPRA and any changes to these arrangements should be provided in writing to the HPRA within seven days of the change in personnel.

2.10 Restrictions on exports of certain controlled drugs

There are additional controls in place for operators wishing to export any of the following controlled drugs outside the European Union:

- Amobarbital (CAS RN 57-43-2)
- Amobarbital sodium salt (CAS RN 64-43-7)
- Pentobarbital (CAS RN 76-74-4)
- Pentobarbital sodium salt (CAS 57-33-0)
- Secobarbital (CAS RN 76-73-3)
- Secobarbital sodium salt (CAS RN 309-43-3)
- Thiopental (CAS RN 76-75-5)
- Thiopental sodium salt (CAS RN 71-73-8), also known as thiopentone sodium

Operators must contact the HPRA prior to the submission of a PharmaTrust application to export any of these drugs outside the EU.