

Guide to NDS Web 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

NDS Web is a highly secure online licence application system for controlled drugs. This system allows users to apply for import and export licences for Schedule 1, 2, 3 and 4, Part 1 controlled substances, and letters of no objection (LONOs) for Schedule 4 part 2 controlled substances.

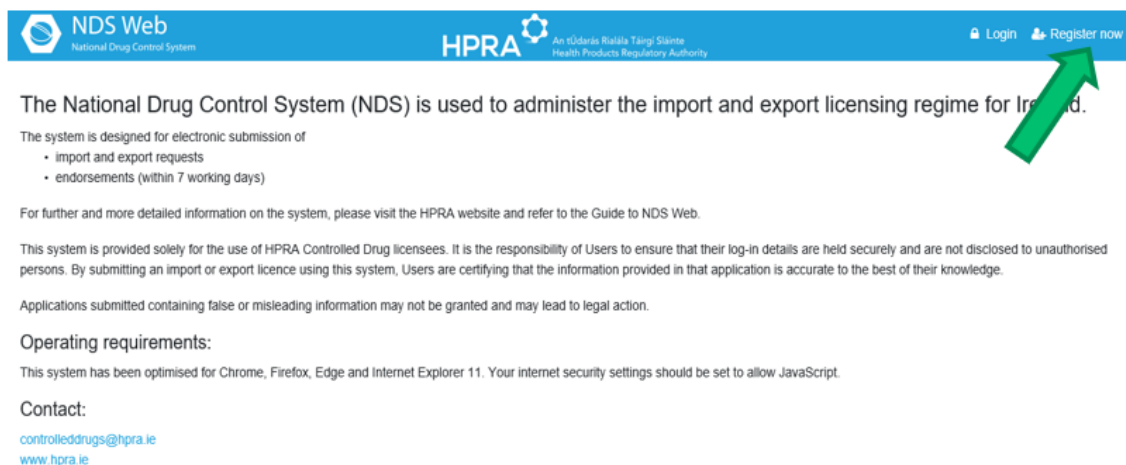
This guidance document outlines the information available on NDS Web and the procedure to apply for an import licence, export licence or LONO (for Schedule 4 part 2 controlled substances) on NDS Web.

2 USER REGISTRATION FOR NDS WEB

To register for NDS Web, the applicant should firstly provide the following information for review by email to controlled drugs@hpra.ie:

- Name of company
- Name of contact person and email address (It is recommended that this email address is a group email that can be accessed by all staff who will have a role in applying for controlled drug licences)
- List of all controlled drugs products/substances to be imported or exported containing the following Information:
 - o Product name (including brand name if there is one)
 - o Name of controlled drug active ingredient
 - o Product strength
 - o Package size (i.e. how many tablets or capsules per pack)
 - o Volume of product (if it is a liquid)
- Names and addresses of foreign companies from/to which drugs or products requiring a licence are to be imported/exported, respectively

Once the review has been completed and it has been determined that the applicant will require an NDS Web account, they will be provided with a website link for NDS Web. Once they have received the link, the user should proceed to the NDS Web homepage and click 'Register now' at the top right-hand side on the NDS Web homepage.



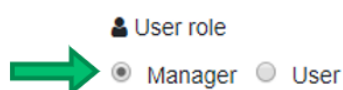
The screenshot shows the NDS Web homepage. At the top is a blue header with the NDS Web logo, HPRA logo, and links for 'Login' and 'Register now'. A green arrow points to the 'Register now' link. Below the header, the text states: 'The National Drug Control System (NDS) is used to administer the import and export licensing regime for Ireland.' It then lists the system's purpose: 'The system is designed for electronic submission of' followed by a bulleted list: '• import and export requests' and '• endorsements (within 7 working days)'. Further text provides information on where to find more details, the system's sole purpose for HPRA Controlled Drug licensees, and a warning about false information. It also lists operating requirements (Chrome, Firefox, Edge, Internet Explorer 11) and contact information (email: controlleddrugs@hpra.ie, website: www.hpra.ie).

2.1 User's role

The new user will need to select their user role. Each establishment must have at least one Manager on NDS Web. It is recommended to set up the manager using an email address for a shared mailbox (for example controlleddrugslicences@companyname.ie) rather than using one individual's email address. This will enable all personnel involved in the application process for import and export licences to access the applications and their status.

Manager: The manager can submit requests, such as a request for import or export licences, to the competent authority for controlled drugs.

User: The user can create requests which are then saved as drafts and may use filters to review previously issued licences. The user account cannot submit licence requests. Any application requests created by the user must be reviewed and submitted by the establishment's NDS Web manager.



3 REGISTRATION FORM

Once the user role has been selected the applicant will then be prompted to complete the registration form as shown in the image below.

First name

Required

Last name

Required

User name

Required

Email

Required

Please re-enter your email address

Required

Occupation

Establishment

Establishment

Required

Phone

Required

Allowed symbols - numbers, spaces, '+', '-', '(', ')', '/'

Establishment

The establishment is the name of the company/premises requesting the NDS Web account. Search for your establishment by typing the establishment name in the establishment box (seen in the image below). The Controlled Drugs team must add the establishment name to the NDS Web platform before a company/premises may select it from the dropdown. If you do not see your establishment on the dropdown menu, please contact controlleddrugs@hpra.ie.

EAN Code	Estab. Name ↓	City	Address
	HPRA	Dublin	Earlsfort Centre, E...

HPRA

4 PASSWORD

The password for your NDS Web account should:

- have at least one digit
- have at least one uppercase letter
- have at least one lowercase letter
- have at least one special character
- be between 8 and 32 characters in length

Once you have created a password and submitted the registration request, you will receive an email request to validate the email address you are using to register the account. After the validation is completed, your registration request will be submitted to be reviewed by the HPRA. A second notification email will be sent once your request has been approved.

5 LOGIN

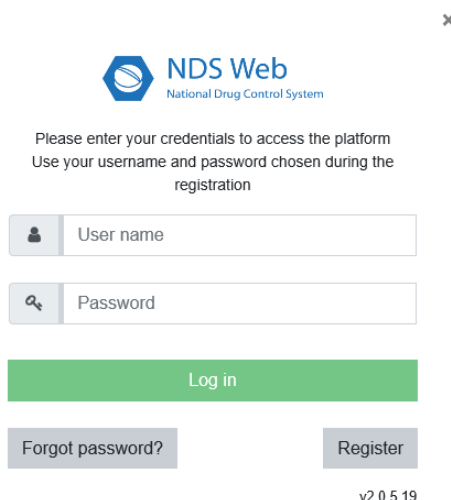
Once you have registered your account, and it has been approved by the HPRA, you can 'Login' at the top right-hand side of the NDS Web homepage.



The screenshot shows the NDS Web homepage. At the top, there is a blue header bar. On the left, it says 'NDS Web' and 'National Drug Control System'. In the center, it says 'HPRA' and 'An tÚdairís Rialála Táirgí Sláinte Health Products Regulatory Authority'. On the right, there are two links: 'Login' and 'Register now'. A green arrow points to the 'Login' link. Below the header, the main content area starts with the text 'The National Drug Control System (NDS) is used to administer the import and export licensing requirements for Ireland.' followed by a bulleted list of services: 'import and export requests' and 'endorsements (within 7 working days)'. Below this, there is a paragraph about the system's purpose and a note about the responsibility of users. At the bottom, there is a 'Contact:' section with the email 'controlled.drugs@hpra.ie' and the website 'www.hpra.ie'.

You will then be prompted to enter your username and password as shown below:

Note: You cannot enter your email address instead of your username.



x

NDS Web
National Drug Control System

Please enter your credentials to access the platform
Use your username and password chosen during the registration

User name

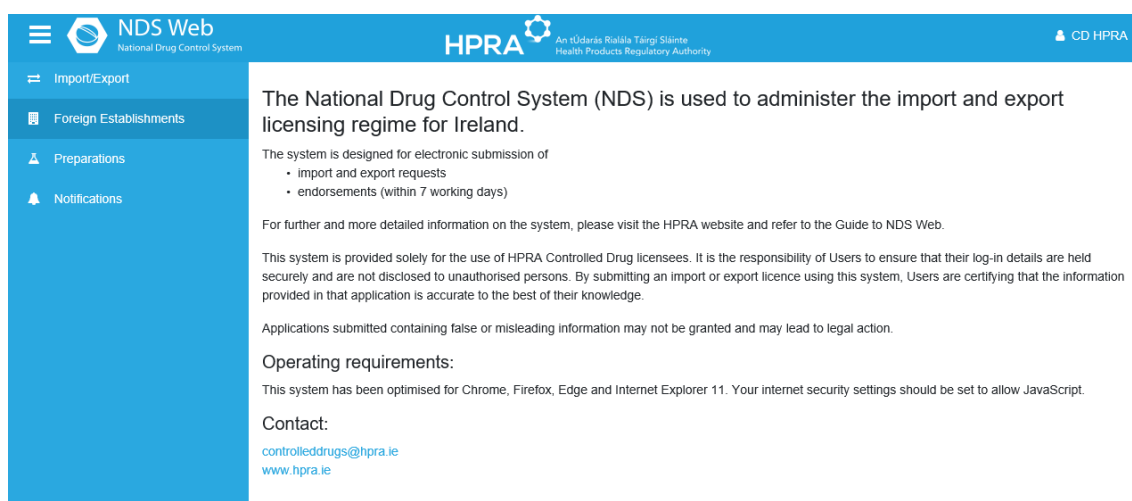
Password

Log in

Forgot password? Register

v2.0.5.19

Once the log in details have been entered correctly the NDS Web menu page will appear on the screen, as seen in the image below.



NDS Web
National Drug Control System

HPRA
An tUdarás Rialaithe Táirgí Sábhaithe
Health Products Regulatory Authority

CD HPRA

Import/Export

Foreign Establishments

Preparations

Notifications

The National Drug Control System (NDS) is used to administer the import and export licensing regime for Ireland.

The system is designed for electronic submission of

- import and export requests
- endorsements (within 7 working days)

For further and more detailed information on the system, please visit the HPRA website and refer to the Guide to NDS Web.

This system is provided solely for the use of HPRA Controlled Drug licensees. It is the responsibility of Users to ensure that their log-in details are held securely and are not disclosed to unauthorised persons. By submitting an import or export licence using this system, Users are certifying that the information provided in that application is accurate to the best of their knowledge.

Applications submitted containing false or misleading information may not be granted and may lead to legal action.

Operating requirements:

This system has been optimised for Chrome, Firefox, Edge and Internet Explorer 11. Your internet security settings should be set to allow JavaScript.

Contact:

controlleddrugs@hpra.ie
www.hpra.ie

5.1 Resetting a password

If you forget your password, or your password expires, please go to the NDS Web homepage and select login. Enter your username and select the option 'Forgot password?'. An email will then be sent to your registered email address allowing you to reset the password. Please note the HPRA does not have access to your passwords and cannot reset a password for any users. A user's password for their NDS Web account will expire every 90 days if unused.

6 MAKING AN APPLICATION

6.1 Fees

There is a charge for the issuance of import and export licences for controlled substances in Schedule 1, 2, and 3 of the Misuse of Drugs Regulations 2017 (as amended). These fees must be paid to the Department of Health.

Please contact controledrugs@hpra.ie for details of how to pay the Department of Health.

It is advisable to submit sufficient credit to cover a number of licence applications based on your previous licence application volumes. Please be advised it is the establishment's responsibility to ensure there are sufficient funds in its account.

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 ⁵⁰ per consignment	Department of Health

Controlled drug import and export licences (Schedule 4 part 1):

Operation	Application fee	Payable to:
Export licence	N/A	N/A
Import licence	N/A	N/A

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

6.2 Requirements

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 of any kind should not be made to the licence. If changes are required, a new application should be submitted.

7 APPLYING FOR A LICENCE OR LONO (FOR SCHEDULE 4 PART 2)

7.1 Procedure

- (i) Select 'Import/Export' from the menu on the left-hand side of the NDS Web menu page.



- (ii) From the dropdown list, you will be given the option to 'Request Import Controlled Drugs' or 'Request Export Controlled Drugs'. 'Import' and 'Export' include both licences and LONOs (for Schedule 4 part 2). The HPRA will issue the appropriate licence type.



Please do not request import or export licences for precursors via NDS Web at present.

7.2 General information

Once you have selected the appropriate request for an import/export licence application, you will be asked to fill in the details regarding your request.

- (i) Select single as the type of permit being applied for.
- (ii) For general notes, specify if the licence will be used as 'import for re-export' (within the calendar year), or if it is intended for 'domestic use'.

General Information

Type of Permit Single ✕ ▼	General Notes For Domestic Use ✕ ▼
--	---

Note: It is extremely important that the information provided is correct as it will influence Ireland's and the importing country's (in the case of export authorisation requests) International Narcotics Control Board (INCB) estimate requirements for that substance for the calendar year. The estimate for each substance is the maximum amount of the substance that the country is permitted to import within that calendar year as set out by the INCB. If the substance is imported and subsequently re-exported within the same calendar year, it is not included in the estimate. However, if it is imported for domestic use it will consume some of the estimate for that substance within that calendar year. Please contact controlledsubstances@hpra.ie if you require further clarification on this point.

- (iii) Attach any files or supporting documentation required for the application.

Export licence only

In the case of an export licence application, a scanned copy of the original corresponding foreign import licence (also known as import permit), or a statement issued by the competent authority confirming the substance is not controlled within the importing country, is required to export the product and should be submitted along with any export application.

Upload a scanned copy of the foreign import licence/letter as a PDF attachment (~~see~~by clicking on 'Please attach a file' option (as seen in the image below). Please ensure that the scanned document is fully legible. Any issues with the scanned licences may result in delays.

General Information

Type of Permit

Single

General Notes

For Domestic Use

Authorization Attachments

File Name	File Size (Kb)
No data	

Please attach a file

7.3 Importer or exporter details

- (i) Select the country that the controlled drugs will be exported to or imported from. It is possible to free-type in the box to narrow the search.
- (ii) Select the establishment from which, or to which, the consignment will be imported or exported. Again, it is possible to free-type in the box to narrow the search.

If the establishment is not listed, please see section 8 below for instructions on how to request for an establishment to be added to your account. If the details listed are incorrect, email controlleddrugs@hpra.ie. You will be notified when the details have been updated and can continue with the application.

Export licence only

- (iii) Select the competent authority (CA Department) that has issued the import licence. If unsure of the competent authority details, email controlleddrugs@hpra.ie.

Exporter Details

Country

Country

Required

CA Department

CA Department

Establishment

Establishment

Required

Address

City

State

Zip Code

- (iv) For an export licence application, enter the number of the import licence issued by the competent authority of the importing country in the space provided. The number and characters entered on the application must match **the exact numbers and characters** on the import licence. For the import authorisation date, enter the **date of issue** of the foreign import licence.

Import Authorization Document

Number

Required

Date

Required

7.4 Shipping details (optional)

- (i) This is an optional section where details of the itinerary can be included (for example flight number).

Shipment Details

Itinerary

Notes

7.5 Substance/preparation details

- (i) To select the substance or preparation that will be imported/exported select the + symbol in the image below top right-hand corner of the screen.

Substance/Preparation Details

Required

Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty
No data					

- (ii) You will then be prompted to search the name of the substance or preparation you intend to import/export. Search from the list by selecting the dropdown in the 'Subst/Prep. Name' box shown above. You can also narrow the search by typing the name of the substance in this box.

Notes:

- Either a substance or a preparation can be selected from the dropdown list.
- A list of all substances is pre-populated on NDSWeb by substance name only, with no other details. Only select the substance if you intend to import/export the substance as a neat form all in one container.
- A preparation will appear on the list as the product name, strength, and type. Details such as the Preparation Type and No of Units will also be visible in the dropdown list. Preparations will only appear on the dropdown list once they have been added to your establishment.

If the preparation you wish to select is not available in the dropdown list, see section 9 of this guide for instructions on how to request a preparation on NDS Web.

- (iii) After the substance or preparation has been selected, the following will be auto-populated:
- the EAN code
 - the UOM and preparation type
 - the number of units, i.e. pack size

The quantity of the substance or preparation to be imported/exported should then be entered.

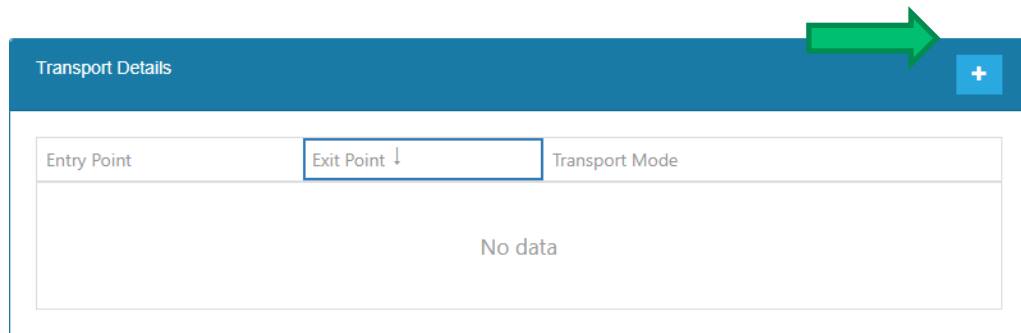
Note:

- For a preparation, provide the quantity of units to be imported or exported, e.g. 300 means 300 packs.
- For a substance, enter the quantity in grams, e.g. 3 means 3 grams.

- (iv) Click 'Save' once all the relevant information has been entered.

7.6 Transport details (required)

- (i) — To add the mode of transport, select the + symbol ~~as displayed~~ in the ~~image below~~. top right-hand corner of the screen. For an import licence application, select the appropriate 'point of entry' from the dropdown list. For 'point of exit' select the relevant country name from which the consignment will be exported. If this 'point of entry/point of exit' is not available from the dropdown menu, email controlled drugs@hpra.ie before continuing with your application request.



(ii)(v) Enter the relevant custom point at which the consignment will enter for 'point of entry', and select the appropriate custom point from the dropdown list for the 'point of exit'.

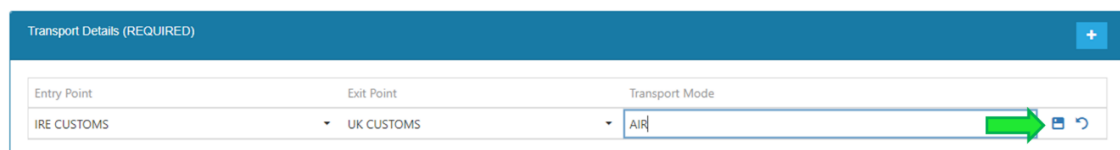
(iii)(vi) Please type in the mode of transport for the importation or exportation of the consignment as:

- sea
- air
- road (see note below)
- rail (see note below)

Note: Do not type 'road' or 'rail' unless the consignment is being imported or exported by this mode of transport to/from Northern Ireland.

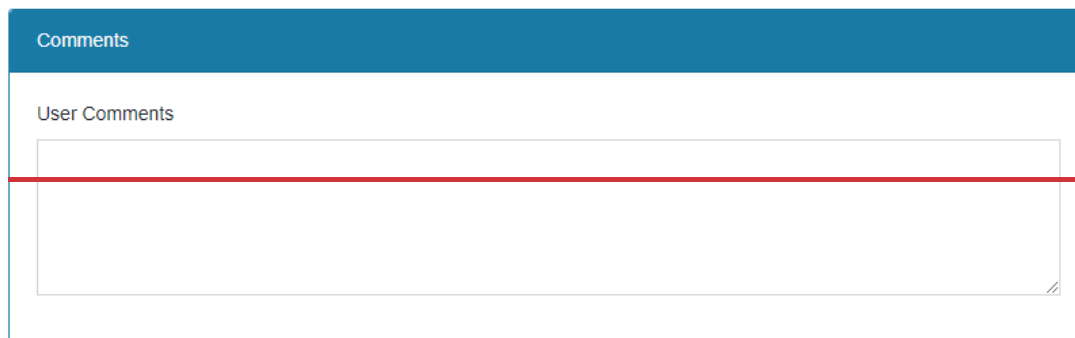
(iv)(vii) Once the transport details have been correctly entered, ensure to click the blue save button (in the shape of a floppy disk, as shown in the image below) to save the transport details before submitting an application.

The transport details are a **required field** and must be entered and saved correctly for a licence to be progressed.



7.7 Comments

Users may add comments to the application under the comments section of the application.



7.8 Submitting the application

Once the above sections have been completed and the information checked for accuracy by the user, the import/export licence request may be submitted by selecting 'submit request'.

Note: An application **cannot be amended** once it has been submitted. Please double-check that all the details have been entered correctly before submitting the request.

7.9 Draft applications

It is possible to save a draft version of the application at various stages throughout the procedure by selecting 'save as draft' at the bottom left-hand side of the screen. Any drafts saved can be accessed at a later date on the homepage under the 'status' tab within the 'import/export' section on NDS Web menu page.

7.10 Application status

The submitted licence will appear under the 'Status' tab within the 'Import/Export' section on NDS Web menu page.

On receipt of the application, the HPRA will verify that all the information required has been provided.

Cancelled applications

Applications may be cancelled if there are errors, or if required information is missing, within the licence application.

~~In order to~~To view the licence, go to 'Import/Export', then click on 'Status' and click on 'More', as shown ~~in the image~~ below.

Import/Export Status (FILTERED)

Export General | Export Detailed | Search...

Paper Required	Requ... Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA
	17		Cancelled	Export Controlled Drugs	17/09/2020				(All)

More...

The reason the application was cancelled will be detailed within the notes of the shipment details section of the licence (see [examples seen](#) in the [imageexample](#) below).

Shipment Details

Itinerary

Notes

CANCELLED BY NDS Authorisation Number on application does not match number on import permit

Please be advised that neither the HPRA, nor the establishment, can amend the details of an import/export licence once it has been submitted via NDS Web.

7.11 Physical import licence

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

The import licence provides an authority solely for the importation of the particular consignment. If the company receives an electronic import licence (e-l licence), it is the company's responsibility to print the required copies of the licence to travel with the consignment.

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.

The import licence should be endorsed and returned to the Compliance department in the HPRA within seven days of the receipt of the consignment. A physical copy of the endorsed e-l licence must also be returned to the HPRA.

The importer may make a copy of the endorsed licence for their records.

7.12 Physical export licence

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

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

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

If the company receives an electronic export licence (e-l licence), it is the company's responsibility to print the required copies of the licence to travel with the consignment.

The licence should be endorsed and returned to the Compliance department within seven days of the export of the consignment. A physical copy of the endorsed e-l licence must also be returned to the HPRA.

The exporter may make a copy of the endorsed licence for their records.

7.13 LONOs (for Schedule 4 part 2)

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 the endorsed licence for their records.

7.14 Endorsing licences

Endorsing a licence refers to the reconciliation of a licence and consignment, i.e. reporting the date that a licence was used and reconciling the quantity of controlled drug that was imported/exported under that given import/export licence.

Once the consignment has been imported/exported, the licensee must fill out the back page of the licence entitled 'Endorsement' for import licences and 'Endorsement by Customs' for export licences with the following details:

- The date that the consignment was imported/exported (known as the endorsement date) should be clearly written on the back page of the licence. For example, the date should be written as: 'DD/MM – Imported' for imports, and 'DD/MM – Exported' for exports.

- The quantity of units that have been imported or exported under that licence. If the full quantity of units that was approved to be imported/exported under that licence is imported/exported, it is acceptable to write 'Received in full (for imports) or 'Shipped in full (for exports)'.
- The back page of the licence should be signed and dated by the individual that is endorsing the licence within seven days of the date the consignment was received (for imports) or shipped (for exports).

Note: For LONOs (for Schedule 4 part 2) as there is only one page, please fill out the information described above on the front page of the LONO.

Import, export licences and LONOs that have been applied for on NDS Web must be endorsed on NDS Web within seven days of the importation/exportation of the consignment.

To endorse a licence or a LONO that has been used, click on 'Import/Export' on the menu available on the NDS Web Home page and click on 'Status'.

Search for the licence you intend to endorse in the search bar available at the top of the 'Auth. Number' column, then click 'More...' on the licence you intend to endorse.

Import/Export Status (FILTERED)

Export General Export Detailed Search...

Paper Required	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA
	17		Cancelled	Export Controlled Drugs	17/09/2020				
	15		Cancelled	Export	31/08/2020				

More...

Click on the calendar icon in the endorsement date box in the general information section and enter the date the consignment was **physically imported/exported to/from the site** (the endorsement date).

Note: the endorsement date is **not** the date that the licence is being endorsed on NDS Web. The endorsement date is the date that the consignment was received/shipped depending on whether it is an import or export.

General Information

Type of Permit

Single

General Notes

For Domestic Use

Endorsement Date

Required

Customs Declaration

Authorization Attachments

The endorsed import/export licence should be filled in by the establishment, scanned as a PDF (one document) and should be uploaded and attached to the endorsement on NDS Web. This PDF can be uploaded in the 'general information' section under 'Endorsement Attachments'.

General Information

Type of Permit

Single

General Notes

For Re-export

Endorsement Date

Required

Customs Declaration

Authorization Attachments

File Name

File Size (Kb)

Endorsement Attachments

File Name

File Size (Kb)

No data

Please attach a file

To enter the endorsed quantity, go to the 'Substance/Preparation Details' section of the licence and select the pencil icon.

Substance/Preparation Details							
EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM	
7611746092001		0	1	1	0	gram(s)	

Enter the quantity imported or exported under the licence in the 'Endorsed Qty' box then press save. The unused/expired licences should be endorsed for a quantity of '0', with the 'endorsement date' selected as the date that the licence was endorsed for '0' on NDS Web. Enter the comment 'unused/expired' in the comments section.

Requested Qty

1

Approved Qty

1

Endorsed Qty

1

Save

Cancel

It is a condition of the approval of import/export licences and LONOs that an establishment endorse each import/export licence or LONO on NDS Web within seven days of the importation/exportation.

The physical copy of all controlled drug import and export licences and LONOs, duly endorsed, must also continue to be surrendered to the Minister of Health and the HPRA offices, within seven days of the date of importation/exportation.

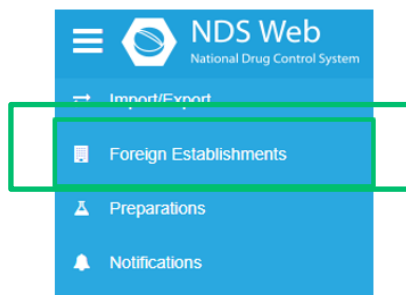
7.15 Unused or expired licences and LONOs (for Schedule 4 part 2)

If a company decides not to use a licence or LONO or if the licence/LONO expires without being used, the documentation should be returned to the Compliance department within seven days of the decision not to use it/the date of expiry. The licence/LONO should be clearly marked 'unused' or 'expired'.

Note: Unused or expired licences or LONOs must also be endorsed following the instructions listed above. The endorsement date should be entered on NDS Web as the date the decision was taken not to use the licence or the date of expiry of the licence.

8 REQUESTING THE ADDITION OF A FOREIGN ESTABLISHMENT

To request the addition of an establishment to an NDS Web account click on 'foreign establishments' on the menu available on the left-hand side of the NDS Web page.



The two options 'Foreign Establishment Requests' and 'Register Foreign Establishment' will then be displayed.

To add a new foreign establishment to the account, select 'Register Foreign Establishment'.



Once selected, you will be asked to enter the details of the new foreign establishment you would like added.

Note: Details should be entered in **capital letters**.

-As shown in the image below, you will have the option to submit the request or save it as a draft.

 Foreign Establishment Request Form - New 

Country

Country

Required

Establishment

Establishment

Required

Street

Street

Required

City

City

Required

State

State

Zip Code

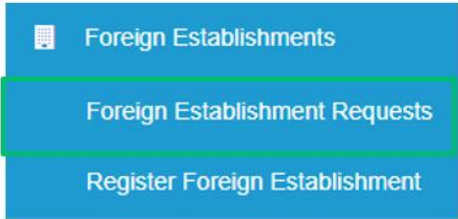
Zip Code

Submit Request

Save as Draft

Close

To view the status of the foreign establishment requests, select the 'Foreign Establishment Requests' tab as shown below.

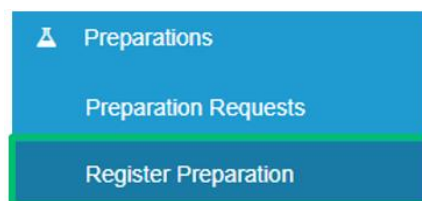


9 REQUESTING THE ADDITION OF A NEW PREPARATION

To request the addition of a new preparation, click on the 'Preparations' tab on the menu shown on the right-hand side of the NDS Web menu page.



The two options 'Preparation Requests' and 'Register Preparation' will then be displayed. To request a new preparation, select 'Register Preparation'.



You will then be required to enter the information regarding the preparation in the **boxes detailed required fields, as shown in the image** below.

 Preparation Request Form - New ?

Preparation

Preparation Type

Preparation Type

Required

Preparation Name

Preparation Name

Required

UOM

UOM

Required

9.1 Preparation

(i) Preparation type

Select the preparation type from the dropdown menu (e.g. injection solution, tablet, capsules, etc.).

Be as specific as possible when entering the preparation type.

(ii) Preparation name

For **solid dosage forms**, write the description in the following sequence:

- The product name 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 form, e.g. tablets as TAB or capsules as CAP
- The strength of the product in milligrams in brackets, e.g. (5mg)

Example: BRANDNAME TAB (5mg)

For **injections**, write the description in the following sequence:

- The product name in capitals, e.g. BRANDNAME
- The injection volume, 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)

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

For **syrups (liquids)**, write the description in the following sequence:

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

Example: BRANDNAME 120ml (10mg/ml)

For **patches**, write the description in the following sequence:

- The product name 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.

Example: BRANDNAME PATCH (2.5mg)

For **products for laboratory or scientific use**, for example, reference standards, write the description in the following sequence:

- The active substance name in capitals, e.g. SUBSTANCE
- The volume (only if it's a liquid), e.g. 1ml
- Reference Standard written as an abbreviation in capitals, e.g. REF STD

- The strength of the product per unit or vial in brackets, e.g. (1mg/ml)
- The solvent medium where applicable, e.g. in Methanol

Example:

- for a liquid reference standard: SUBSTANCE 1ml REF STD (1mg/ml) in Methanol
- for a neat powder reference standard: SUBSTANCE REF STD (15mg)

(iii) Unit of measure

The unit of measure should always be in **grams**. The base quantity of a substance in a preparation may need to be converted from mcg/mg to grams for entry by the user.

Example: If one tablet contains 10mg of a substance, the unit of measure should be selected as grams, and the base quantity of the substance per dosage unit in the preparation should be entered as 0.01 g by the user.

9.2 Controlled substance

To select the substance that is contained in the preparation, select the + symbol at the top right-hand side of the 'Controlled Substance' box.

Controlled Substance Required		
Subst. code	Subst. name	Qty/Vol
Substance		▼

Search for the controlled substance by typing in the substance dropdown menu and selecting the relevant substance.

Qty/Volume	UOM
▼	▲▼




The quantity entered should always be the total amount of base controlled substance in **grams**. The base quantity is the quantity of pure anhydrous base of that substance.

Base substance vs salt substance

A controlled substance may be present in its base form, e.g. 10 mg of midazolam where there is 10 mg of midazolam base in the preparation. Alternatively, the controlled substance may be present within the preparation in a salt form, e.g. 10 mg of midazolam hydrochloride.

In this instance a conversion factor must be applied in the calculation of the total controlled substance quantity to account for the percentage of the 10 mg which is made up by the presence of the salt molecules. In the description given above the conversion factor for midazolam hydrochloride is 89.9. Therefore, there is 8.99* mg of midazolam base present in the preparation.

$$*10 \text{ mg} \times (89.9/100) = 8.99 \text{ mg}$$

It is important to select the correct substance when creating a preparation to ensure the base quantity is calculated correctly for the import or export licences. Issues with the base quantity can result in delayed shipments.

Information regarding the active substance in the preparation can be found in the SPC (Summary of Product Characteristics) for the preparation. Please see examples detailed below. The conversion factors on a substance can be found on the Green List (for psychotropic substances) and the Yellow List (for narcotic drugs) on the INCB website.

Please contact controlledsubstances@hpra.ie should you require further clarification on the controlled substance when adding a preparation.

Quantity

The quantity entered for the preparation should be the amount of the controlled substance present per unit, such as the quantity present in one tablet, one ampoule or one bottle of the preparation. The number of tablets/ampoules/bottles present in the pack will be captured in the preparation pack size details.

Examples:

Example 1

Base substance.

1 NAME OF THE MEDICINAL PRODUCT

Controlled Drug 10 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 10 mg of midazolam

The product contains 10 mg of base midazolam. For this preparation, the user should select 'midazolam' as the substance when requesting to add this preparation. The Qty/Volume should be entered as 0.01 grams.

Example 2

The salt of the substance is stated in brackets.

1. NAME OF THE MEDICINAL PRODUCT

Controlled Drug 10 mg/2 ml Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 5 mg of midazolam (as midazolam hydrochloride)

One ampoule of 2 ml contains 10 mg of midazolam

As the salt is referenced in brackets for the product, this means a conversion factor has already been applied in the calculation of the product strength. For this preparation, the user should select 'midazolam' as the substance when requesting to add this preparation. The strength should be entered as 0.01 grams of midazolam per 2 ml ampoule.

Example 3

The substance is listed in its salt form.

1. NAME OF THE MEDICINAL PRODUCT

Controlled Drug 15 mg/ml Solution for injection 1ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 15 mg of midazolam hydrochloride

The product contains 15mg midazolam hydrochloride. For this preparation, the user should select 'midazolam hydrochloride' when requesting to add this preparation. This will allow the conversion factor for this salt substance to be applied. The strength should be entered as 0.015 grams.

Example 4

Calculating the strength of a liquid preparation with a volume of 120 ml-

1. NAME OF THE MEDICINAL PRODUCT

Controlled Drug 20 mg/ml Oral solution 120 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 20 mg of midazolam hydrochloride

For this preparation, the user should select 'midazolam hydrochloride' when requesting to add this preparation. The quantity should be entered as $0.02^* \text{ g/ml} \times 120 \text{ ml} = 0.24 \text{ g}$.

*Note $20 \text{ mg} = 0.02 \text{ g}$

9.3 Package size section

Package Size Required

Package Size

EAN Code

No data

Submit Request

Save as Draft

Close

Detail the number of the preparations per pack, for example, 30 tablets per pack or 5 ampoules per pack.

Please note the EAN code is not required.

Once all the details have been checked for accuracy by the user, the new preparation request can be submitted by selecting 'Submit Request'.

Package Size Required

Package Size

EAN Code

No data

Submit Request

Save as Draft

Close

10 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
 Email: controlleddrugs@hpra.ie

For issues associated with the NDS Web system, e.g. difficulty logging on to the system, contact the Controlled Drugs section in the Compliance department, preferably by email or telephone.

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