

Internet Supply List

First Time Registration for a Non-Retail Pharmacy Business



Version 1

August 2023

Introduction

This guide outlines the steps for first-time entry to the PSI Internet Supply List (ISL).

Anyone who wishes to sell non-prescription medicines over the internet in Ireland must register with the PSI and have their name listed on the approved Internet Supply List. Those websites must also display the EU common logo on every web page that offers non-prescription medicines for sale.

Please familiarise yourself with the requirements for Internet Suppliers on PSI's website before you first apply to register on the Internet Supply List: <u>Internet Supply-Medicines-PSI (thepsi.ie)</u>

Note that the registration on the Internet Supply List (ISL) must also be renewed annually <u>before</u> the expiry date of the current ISL registration.

This guide includes the following sections:

- Section 1: First time registration on the the Internet Supply List for a non-retail pharmacy business
- Section 2: How to cancel a registration on the Internet Supply List

A guide on how to complete the renewal of the ISL Registration can be accessed here: <u>Helpful Resources</u> · <u>The PSI Registration Portal</u>

In order to make an application for entry on to the Internet Supply List, you must access <u>The PSI</u> <u>Registration Portal</u> by creating a new account (navigate to the sign in option in the top right-hand corner and choose 'sign up now', you will need access to your phone number due to two-factor authentication). Alternatively, you may log in using your existing login details.

The applicant will become the nominated person for the non-retail pharmacy business, and any communication from the PSI, including reminders for the annual renewal, will be sent to the provided email address. Renewal is completed annually via the existing account.

Once you have access to the PSI Registration portal, follow the steps outlined below to complete and submit your ISL registration application.

You can find our FAQ and other resources that might assist you on the registration portal: <u>Helpful</u> <u>Resources · The PSI Registration Portal</u>. Here you can also find our 24/7 chatbot. For queries, please contact PSI on <u>info@psi.ie</u> or by phone at 01 218 4000.

1. First time registration on the Internet Supply List for a non-retail pharmacy business

Step 1: Log into/Sign up to your account on the PSI Registration Portal and navigate to the '*Apply for entry on Internet Supply List*' tab.

User Name - Your Account	• Pharmacies	Internet Supply List
1 Your Profile	G First Time Registration	O Apply for entry on Internet Supply List
Your Notifications	H Manage My Pharmacies	

• Step 2: Click on 'Add or Renew Non-Retail Pharmacy Business'.

Internet Supply List Dashboard
The EU common logo was brought in by the Falsified Medicines Directive.
The Falsified Medicines Directive was adopted by the EU in July 2011. The objective of the Directive is to strengthen the EU legal framework which regulates medicines to prevent falsified (counterfeit) medicines being supplied to patients through the legal supply chain.
The purpose of Article BSc of the Directive is to introduce negulatory controls on the supply of medicines over the internet in order to reduce the risks associated with the supply of counterfeit medicines, thereby protecting public health. In Ireland this will apply to pharmacies and other nonpharmacy retailers involved in the internet supply of non-prescription medicines only.
In order to transpose Article 85c of the Falsified Medicines Directive into Irish Law the following amendments to legislation have been made:
The European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S1 No. 86 of 2015) make it a principal function of the PSI to establish and maintain a list of persons entitled to supply non-prescription medicinal products via internet supply (entitled the ISS (Information Society Service) supply list or internet Supply List)
The Medicinal Products (Prescription and Control of Supply)(Amendment) Regulations 2015 (S.I. No. 87 of 2015) will require all pharmacies and other entities engaged in internet supply of non-prescription medicines to notify the PSI of their internet activities.
Add or renew an entry on the Internet Supply List
Add or Renew Retail Pharmacy Business Add or Renew Non-Retail Pharmacy Business
Application Application ISL Registration Number 1 Account Name Address Application Type Status 1 Number Created On Created By
There are no records to display.

• **Step 3:** Choose 'No' for 'Is this application to renew an existing Internet Supply List registration?' question and proceed by clicking 'Next'.

Home > Internet Supply List > Application List > Application Details
Application Details
0
Note: If there have been any material changes (change to trading name, relocation etc.) to the <u>current internet Supely. List entry</u> please contact us at info@toskie prior to submitting an application for reneval as an application for first time entry might be required.
ADD OR RENEW AN INTERNET SUPPLY LIST REGISTRATION
Is this application to renew an existing Internet Supply List registration?
NEXT

• **Step 4:** Enter Supplier details, then click '*Next*'.

Home > Internet Supply List > Application List > Application Details
Application Details
11%
Permanent address of the fixed premises at which the medicinal products are to be stored and from which they are to be supplied. This premises cannot be a dwelling. Tixed premisen' does not include a vehicle, trailer, caravan, or other thing which may be transported on, in, or attached to a vehicle, or, a tent, awning, or hut, shed, or an unrooted or temporary structure or stall or a yand, field readway, or casual trading area
SUPPLIER DETAILS
Name to be entered on the Internet Supply List *
ISL Name
Street 1*
P.S.L House
Street 2
Fenian Street
Street 3
Town
Dublin 2
County
Co. Dublin
Country *
Ireland
Ercode
002 1072.
Telephane
+353(0)1 218 4000
Email Address
Description of Premises
~
Office Warehouse
Shop Other
PREVIOUS

• **Step 5:** Upload floor plan by clicking on 'View details' icon and following the required steps, then click '*Next*'.

Iome > Internet Supply List > Application List > Application Details		
Application Details		
22%		
DOCUMENT UPLOAD		
Please attach a floor plan of the premises detailing all areas where i	nedicines or records are to be stored.	
Application Document 🕈	Uptoaded	
Floor plan	No View de	ete ile
		etails
PREVIOUS	NEXT	

• **Step 6**: Choose Ownership type, then click '*Next*'.

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Application Details	
33%	
OWNERSHIP DETAILS	
Ownership Type *	
Sole Tooler Concerny	Please select an item in this list
PREVIOUS]

• **Step 7:** Enter Owning Company/Sole Trader details, then click '*Next*'.

	44%
Re	gistered Name of Company (as stated on the Company's Certificate of Incorporation) *
Co	mpany Registration Number *
St	reet 1 *
St	reet 2
St	reet 3
То	wn
Co	unty
Co	untry *
Eir	rcode
	Under the Companies Act 2014 all existing private companies limited by shares must convert to either a LTD or a DAC (new company types introduced by the Act) by 30th November 2016. Please contact your accountant or solicitor if you are unsure if your company has converted or not.
Co	mpany Type
	v
	Private Limited Company LTD under the Companies Act 2014 DAC under the Companies Act 2014
	Dubic Limited Companys Act 2014 Other

• **Step 8:** Add Internet Supply Details; Website Trading Name, web address and proposed opening date. <u>Please note:</u> Website trading name and website address will be displayed on the published PSI ISL Register once your application has been approved by the PSI.

Application Details	
55%	
INTERNET SUPPLY DETAILS	
Website Trading Name *	
Website Address for Internet Supply *	
Proposed Starting Date of Internet Supply * DDMM/YYYY	
PREVIOUS	NEXT

• Step 9: Please select an option from the dropdown menu, then click 'Next'.

	66%			
0 of 2007) of the non-prescription non-pharmacy retailer is only perm	medicinal products offered for sale at	a distance to the public over the es. The list of medicines on gener	roducts (Control of Placing on the Marka internet i.e. pharmacy only modicines or al sales can be accessed on the HPRA s	general sales list medicines.
LASSIFICATION O	F MEDICINAL PROD	UCTS TO BE SUP	PLIED BY MEANS OF	THE INTERNET
General Sales Medicines				
				~

• Step 10: Complete the declarations as appropriate, then click 'Next'.

	50%
DEC	CLARATIONS
l bein	g the person duly authorised to complete this application on behalf of the company/sole trader declare as follows:
The	particulars given in this application are, to the best of my knowledge, true and correct. *
0'	No 🛞 Yes
I und	lertake to notify, in writing, the PSI of any changes in, or additions to, the aforementioned particulars. *
0'	io 🛞 Yes
l am	aware that this person/entity may be removed from the ISS Supply List if any of the information submitted is false or materially inaccurate.*
01	No 🛞 Yes
	the supply of medicinal products to the public at a distance by means of information society services (internet supply) will be conducted in compliance with the icinal Products (Prescription and Control of Supply) (Anendment) Regulations 2015.
0	io 🛞 Yes
PRE	NEX

Step 11: Agree to the Conditions for use of Common Logo and then click '*Next*' to be taken to the payment page (see step 12).

	89%
onditio	ns for use of Common Logo
L. These	conditions must be complied with in order to use the logo. Failure to comply with these conditions could result in withdrawal of permission to use the logo.
2. The lo	go will be issued by the PSI following approval of an application by a Seller to be entered on the internet supply list.
	go can only be used on approved websites owned and operated by an entity that is offering to sell or supply non-prescription medicines to patients and the public ove et from the premises to which the logo / register entry relates.
4. The lo	go must not be replicated or duplicated or used otherwise than in accordance with the site for which it has been granted.
5. Once g	ranted, the logo must not be supplied for use by a third party.
5. No mo	dification of the logo will be permitted, and no words or additional logos may be superimposed on the logo itself.
. The lo	go must not be used in any context that could be regarded as illegal or inappropriate.
3. Inform	ation contained on the website must be legal, appropriate and truthful.
). The w	absite must comply with any relevant legislation (for instance advertising of medicines to the public.
a b c t	vebsite offering the non-prescription medicinal products must contain the following: The contact details for the PSI is A hyperlink to the PSI internet Supply List webpage The common loge on every page of the website which relates to the offer of supply of medicinal products at a distance, including a link to the entry of the person on le Internet Supply List etc. A statement stating that a record of each transaction will be retained for 2 years
11. The F	SI must be notified if the website is to be discontinued or moved to another website address.
12. The F	SI must be notified of any change of ownership, and the new owner must apply for use of the Common Logo.
	the Conditions for Use of the Common Logo above and agree to be bound by these conditions. * $\textcircled{\begin{tabular}{lllllllllllllllllllllllllllllllllll$

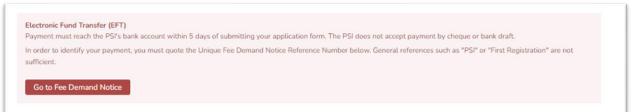
• **Step 12:** Please select your payment method: 'Pay Now' for online card payment, or 'Pay by Electronic Funds' for bank transfer. If paying by card, enter your payment details and proceed with the 'Pay Now' option, then you will be prompted to input card details. For bank transfers, click 'Pay by Electronic Funds' to access the Fee Demand Notice (FDN) with PSI bank details and payment reference that should be used to ensure the payment is processed for the intended application. If the FDN notice hasn't been applied, kindly get in touch with info@psi.ie and provide payment details, including the account from which the payment was made, the payment date, application number, and the reference used.

Payer mobile number					
Ireland (+353)	~				
Search address or Eircode					
Enter Full Address or Eirco	de			Search	
Billing address line 1					
Billing address line 2					
Billing address line 3					
Billing address town					
Billing address country					
					~
Billing address postcode					

• **Step 12a:** Once payment has been made by card you will receive the following confirmation.



• **Step 12b:** Once you have chosen '*Pay by Electronic Funds*' you will have the option to view and print Fee Demand Notice.



Please note: Upon approval of your application, you will receive a notification by email. This email includes the EU ISL logo that must be displayed on the website <u>before</u> the internet supply of non-prescription medicines commences.

The registration will be valid for 1 year and must then be renewed to avoid automatic cancellation at the expiry date. You will receive an email notification 30 and 15 days before the renewal must be completed. Please remember to check your spam folder.

2. Cancelation of Internet Supply List registartion

If the ISL registration is not renewed prior to the expiry of the current registration, the non-retail pharmacy business will automatically be removed from the Internet Supply List at the registration expiry date. The nominated person will be informed by an email.

If you wish to cancel your Internet Supply List registration before the expiry date of your registration, please send an email to <u>info@psi.ie</u> with the following information:

- Retailer name and ISL registration number
- The date you wish to cancel your registration (at least 5 workdays after the email is sent)

Please note that the email must be sent from the nominated person for the non-retail pharmacy business using the email address linked to their respective accounts on the PSI registration portal.