



IRISH MEDICINES BOARD

## Controlled Drugs

### Licensing and Reporting

#### *Key Features and Expectations*

---

*Wholesale Distribution Information Day , 25/2/2010*

---

Deirdre Ryan  
Controlled Drug Scientific Officer

# Controlled Drugs Licensing and Reporting

## Key Features and Expectations concerning

- Import and Export Licensing
- Managing Estimates
- Quarterly Statistics
- Annual Statistics
- Future changes and improvements - *Pharmatrust*



IRISH MEDICINES BOARD

# Import and Export Licensing

## ***Aim to issue all valid import/export licence applications within 7 working days***

Some reoccurring problems include:

- Incorrect foreign importer/exporter address
- Consignment imported/exported post licence expiry date
- Greater quantities imported/exported than approved on licence

Companies should:

- ✓ Always provide foreign address where consignment is physically imported from or exported to
- ✓ Inform IMB straight away
- ✓ Highlight these issues in S.O.Ps – ensure staff are trained
- ✓ Bring up issues with suppliers



IRISH MEDICINES BOARD

# Statistical Reporting Requirements



## ***IMB is required to regularly report to the International Narcotics Control Board (INCB)***

- In accordance with the United Nations Single Convention on *Narcotic Drugs*, 1961
  - ❖ Form A – Quarterly Statistics
  - ❖ Form B - Annual Estimates
  - ❖ Form C – Annual Statistics
- In accordance with the United Nations Convention on *Psychotropic Substances* , 1971
  - ❖ Form A/P – Quarterly Statistics
  - ❖ Form B/P - Annual Estimates
  - ❖ Form P – Annual Statistics



INCB Website: <http://www.incb.org/>




IRISH MEDICINES BOARD

# Managing Estimates



The **INCB Estimates System** limits the use and distribution of drugs to an adequate amount for medical and scientific purposes and ensures their availability for such purposes

Companies should:

- 
- ✓ Inform IMB of any new products being supplied
  - ✓ Provide a forecast of imports and stocks of new products
  - ✓ Inform IMB of increases or decreases in demand for current products

IMB can apply to INCB to supplement estimates during the year – approx. 6 week approval timeline




IRISH MEDICINES BOARD

# Quarterly Statistics

Reconciliation of import and export licences issued in the previous quarter

Licence Number	Exporting Country	Company	Substance Name	Approved Qty	Date Received
N322/2010	UK	ABC Ltd	Morphine		

Companies should:

- 
- ✓ Endorse all licenses within 7 days of execution
  - ✓ Return all endorsed licences to IMB
  - ✓ Return quarterly statistics forms promptly – even if consignment has not yet been imported/exported

Quarterly Statistics must be completed not later than 1 month after the end of the quarter to which they relate



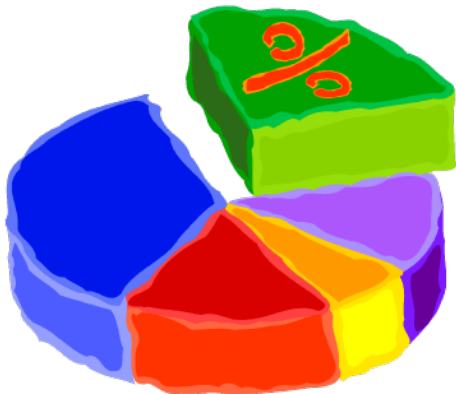
IRISH MEDICINES BOARD

# Annual Statistics



Wholesale Annual Statistics provide vital information for the measurement of Ireland's consumption of each drug

A Drug is regarded as '**consumed**' when it has been supplied to a person for retail distribution, medical use or scientific research



IRISH MEDICINES BOARD

# Annual Statistics

## Wholesale companies submit Annual Statistics electronically



- Complete a pre-set excel spreadsheet with following headings
  - Drug
  - Product
  - Amount of drug per unit dose (mg)
  - Pack Size
  - Number of Packs
- End of year stock count must include **all stock** held on premises
  - ✓ Quarantine Stock
  - ✓ Damaged Stock
  - ✓ Waste



IRISH MEDICINES BOARD

# Pharmatrust

*Pharmatrust* is a secured extranet which has been developed by the IMB to provide a more efficient process for submission and management of estimates and license applications for controlled drugs

Benefits include:

- ✓ Ease of application
- ✓ Easier access to information
- ✓ Quicker turn around times
- ✓ Less opportunity for errors



<https://pharmatrust.imb.ie/>



IRISH MEDICINES BOARD

### About Pharma Trust

As part of an IT initiative the IMB has created this extranet to allow you to apply for licences to import and export drugs into and out of Ireland. This Extranet will streamline the current paper based system and will ensure timely and accurate applications to us. If you have any question please contact us at [controlleddrugs@imb.ie](mailto:controlleddrugs@imb.ie).

### Pharma Trust Assistance

Tel: +353 1 6764971  
Fax: +353 1 6767836  
Email: [controlleddrugs@imb.ie](mailto:controlleddrugs@imb.ie)

### Welcome Patrick to your Controlled Drugs Extranet.



**Apply for a licence**

Apply for a licence by using the "Apply for a licence" button on the left. Licence applications can be saved as drafts. This means that you may return to them before submitting them to the IMB to start the application process. Below you will see a list of these draft applications. Clicking on the draft number will bring you back to that application and you may continue with the application process.



**My quotas**

Below is a list of your current draft applications.

Draft licences	Date	Licence type
You have no drafts saved		

Browser navigation bar showing address bar with URL <https://pharmatrust.imb.ie/apply.aspx>, a 'Certificate Error' warning, and search engines like Google. The menu bar includes File, Edit, View, Favorites, Tools, and Help. The tab bar shows 'VisionTime WebAccess', 'TZ-UK • View topic - Sp...', 'Pharma Trust - Con...', and 'Controlled Drugs Extranet'.

<a href="#">Home</a>	<a href="#">Licences</a>	<a href="#">My Quotas</a>	<a href="#">Establishments</a>	<a href="#">Preparations</a>
----------------------	--------------------------	---------------------------	--------------------------------	------------------------------

### Applying for a licence

Licence type

Please select a licence type  
Please select a licence type  
**IMPORT**  
EXPORT  
MULTI CONSIGNMENT EXPORT  
ANNUAL

[Continue](#)

[\[Logout\]](#) [\[My Profile\]](#)

Browser navigation bar with address bar: <https://pharmatrust.imb.ie/apply.aspx#establishmentid>. Includes navigation icons, a 'Certificate Error' warning, a search box with 'Google', and a menu bar with 'File', 'Edit', 'View', 'Favorites', 'Tools', 'Help'. Below the menu bar are several tabs: 'VisionTime WebAccess', 'TZ-UK • View topic - Sp...', 'Pharma Trust - Con...', and 'Controlled Drugs Extranet'. There are also icons for home, RSS, print, and page settings.

**Step 2: Applying for an IMPORT licence to import from UNITED KINGDOM**

- 1
- 2**
- 3
- 4

**Establishment**

If you do not see the establishment that you wish to trade with in the drop down list above then you may still proceed with your application but you will need to fill in the details of the establishment in the form below.

**Establishment name**      BR PHARMA LTD., UNIT 3, MANOR POINT

**Street**                      MANOR WAY

**City**                            BOREHAMWOOD

**State**                         HERTS WD6 1EE

**Zip code**

**Country**                     UNITED KINGDOM

Browser navigation bar showing address bar with <https://pharmatrust.imb.ie/apply.aspx>, navigation buttons (back, forward, refresh, stop), and search bar with "Google".

Browser tabs: VisionTime WebAccess, TZ-UK • View topic - Sp..., Pharma Trust - Con..., Controlled Drugs Extranet.

Browser menu: File, Edit, View, Favorites, Tools, Help.

**Step 3: Applying for an IMPORT licence to import from UNITED KINGDOM**

- 1
- 2
- 3
- 4

Annual licence

Mode of transport

Date of import hint : All dates should be supplied in the format dd/mm/yyyy.

Date of import

Point of entry

Point of exit

- Please select an item
- IRE CUSTOMS
- N.I. CUSTOMS
- UK
- UK CUSTOMS
- UK CUSTOMS

**Save draft**

**Previous**

**Continue**

Navigation bar showing browser address (https://pharmatrust.imb.ie/apply.aspx), navigation icons, and tabs for VisionTime WebAccess, TZ-UK, Pharma Trust - Con..., and Controlled Drugs Extranet.

### Step 4: Applying for an IMPORT licence to import from UNITED KINGDOM



**Show licence details (summary)**

In this step you should supply the details of the consignment. Consignments can consist of preparations and/or substances. Use the "Add to consignment" button supplied on this page to add new preparations or substances to your consignment. If you do not see the preparation that you wish to add to your consignment in the preparation drop down list then you may proceed with your application by checking the checkbox marked "new preparation" and filling out the details of that preparation.

#### You are currently adding a preparation or substance to the licence

**Preparation**

Please select a preparation

- Please select a preparation
- EUTHATAL SOLUTION FOR INJECTION 100ml (20%w/v)
- ADDERALL TABLET (10mg)**
- ADDERALL TABLET (20mg)
- ADDERALL XR CAPS (10mg)
- ADDERALL XR CAPS (20mg)
- DUROGESIC D-TRANS PATCH 12mcg/hr

----Or----

**Substance**

----Or----

**New preparation**

If you have selected from either of the dropdown lists above, you will see the details of the preparation or substance you are about to add below. **(N.B.** When a preparation is selected you should select the pack size you require). If you have selected the new preparation option you will need to provide the details of that preparation in a form that will be provided below.

**Cancel**

<b>Imp / Exp Flag</b> Import	<b>Reference#</b> P169/2009		
<b>Import Details</b>		<b>Export Details</b>	
<b>Imp Country Code</b> IRE	<b>Imp Country Name</b> IRELAND	<b>Exp Country Code</b> UK	<b>Exp Country Name</b> UNITED KINGDOM
<b>Imp CA Code</b> 79121	<b>Imp CA Department Name</b> Department of Health and Children	<b>Exp CA Code</b> 5007945	<b>Exp CA Department Name</b> HOME OFFICE
<b>Imp Establishment</b> 14/5/999	<b>Imp Establishment Name</b> Patrick Keating Limited	<b>Exp Establishment</b> BRPUK2	<b>Exp Establishment Name</b> BR PHARMA LTD., UNIT 3, MANOR POINT

1 / 1
Filtered

Remarks | 
 Import Authorization Request | 
 **Import Authorization** | 
 Endorsements | 
 Additional Establishments

<b>Request Number</b> P169/2009	<b>Request Date</b> 20-OCT-2009	<b>Approval Date</b> 00- -0000	<b>Itinerary</b> Date of import: 31 October 2009
<b>Valid From</b> 20-OCT-2009	<b>Valid To</b> 20-JAN-2010	<b>Signature</b>	

Substance Code	Substance Name	Preparation Type	No of units	Requested Qty	Approved Qty	UOM
NDC54092/032/01	ADDERALL TABLET (10MG)	TABLETS	100	10.		GRAMS

1 / 1
Filtered

Point of Exit	Point of Entry	Mode of Transport
UK CUSTOMS	IRE CUSTOMS	AIR

1 / 1

ADD | 
 DELETE | 
 UPDATE | 
 **EDITING**

# Thank you for listening

Please feel free to contact me with any controlled drug related queries



[deirdre.ryan@imb.ie](mailto:deirdre.ryan@imb.ie)



IRISH MEDICINES BOARD