

## Summary Report for Importation of Unlicensed Medicines

01 Jan 2014 – 31 Mar 2014

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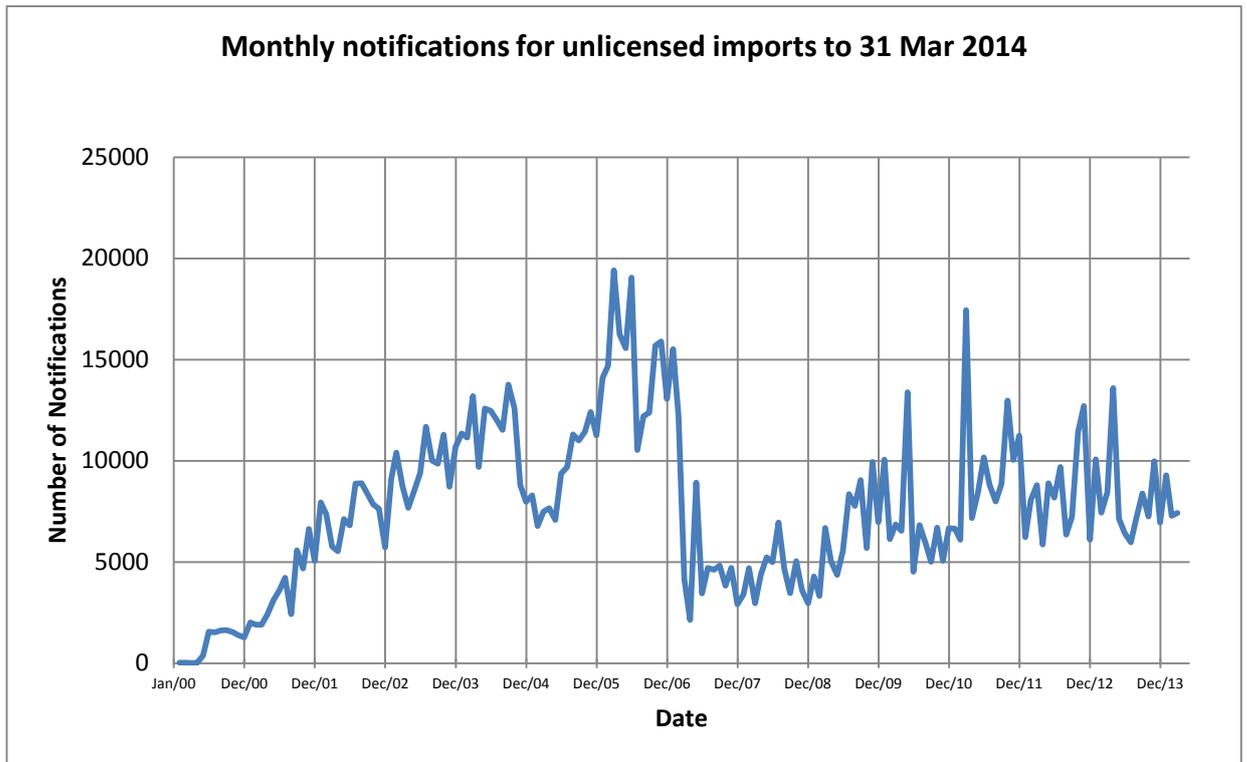
# 1 Introduction and Summary

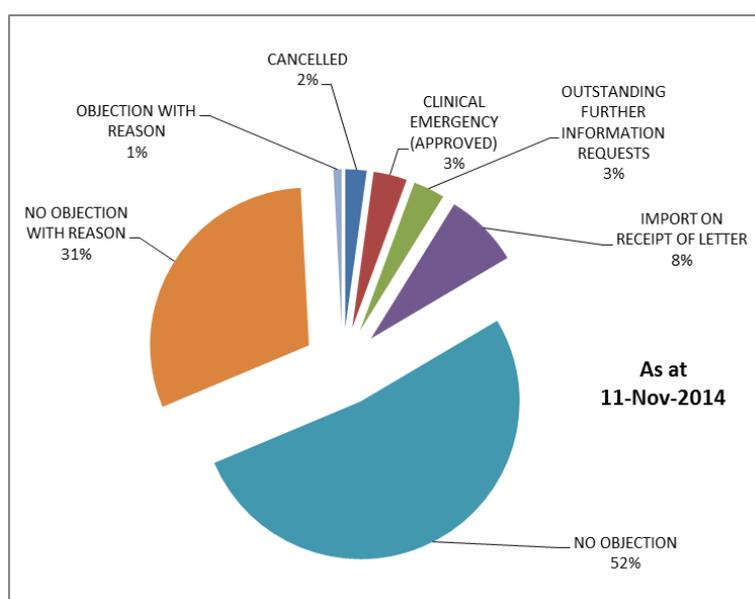
During the period in which these quarterly reports were not published, there have been many requests for reports or for data that were normally available through these reports. It has therefore been decided to resume publications of these reports and it is hoped that readers will find them interesting and useful.

# 2 Notifications for importation

**Graph 1 Monthly notifications for unlicensed imports**

Note: Excludes invalid and cancelled notifications



**Graph 2 Breakdown of notifications by status, 01 Jan – 31 Mar 2014**

24,939 valid notifications were received from 94 importers for the period 01-Jan-2014 to 31-Mar-2014.

## Countries of export of products

**Table 1 Breakdown of valid notifications by country, 01 Jan – 31 Mar 2014**

Rank	Exporting Country	Number of Notifications
1	GERMANY	5285
2	UNITED STATES OF AMERICA	4421
3	ITALY	2471
4	FRANCE	2337
5	SPAIN	1871
6	AUSTRALIA	1618
7	CANADA	1168
8	AUSTRIA	919
9	INDIA	846
10	SWITZERLAND	547
11	REPUBLIC OF IRELAND	488
12	THE NETHERLANDS	459
13	BELGIUM	454
14	DENMARK	434
15	POLAND	369
16	CZECH REPUBLIC	306
17	NEW ZEALAND	199
18	JAPAN	160
19	GREECE	141
20	NORWAY	130
21	SWEDEN	68
22	HUNGARY	51
23	FINLAND	50
24	CYPRUS	44

Rank	Exporting Country	Number of Notifications
25	PORTUGAL	44
26	VANUATU	20
27	MALTA	18
28	LITHUANIA	10
29	SLOVAKIA	8
30	BRITISH ISLES*	1
31	CHILE	1
32	CROATIA	1
	<b>Sum:</b>	<b>24939</b>
	<b>EEA</b>	<b>15959</b>
	<b>Non-EEA</b>	<b>8980</b>

\* Not valid country of export!

## 2.1 Most frequently notified products

Table 2 lists the 50 most frequently notified products during Q1 2014 in rank order. The data are for valid notifications only and do not include cancellations or incomplete notifications. The listing includes notifications which may not be intended for placing on the UK market. It includes both acceptable products and those to which objections to import have been raised. It is therefore not an indicator of product acceptability.

**Table 2. Top 50 Products by rank order of number of notifications received**

Note: These rankings were obtained manually and although believed to be representative may contain errors

Rank	Proprietary Name	Number of Notifications
1	Vitamins - oral preps	1266
2	Homoeopathics & herbals	1167
3	Midodrine oral preps	843
4	Melatonin oral preps	836
5	Bicnu injections 100mg	623
6	Rifaximin oral preps	536
7	Allergy diagnostic tests	533
8	Fosfomycin injections	524
9	Hyoscine hydrobromide 300mcg tablets	501
10	Indigo carmine injections	488
11	Povidone-iodine 5% ophthalmic soln	445
12	Acetylcysteine oral preps	435
13	Fosfomycin oral preps	393
14	Ibrutinib 140 mg capsules	390
15	Oxytocin injections/infusions	372
16	Bisacodyl enemas 10mg	321
17	Vasopressin injections 20 units/ml	319
18	Oral thyroid preparations	295
19	Vitamin injections	294
20	Carbimazole tablets 5 & 10mg	281
21	Fumaric acid ester tablets all strengths	276
22	Talc for pleurodesis	238

Rank	Proprietary Name	Number of Notifications
23	Mexiletine capsule all strengths	210
24	Benzathine penicillin injections	207
25	Flunarizine tablets/capsules all strengths	191
26	Pirenzepine 50mg tablets	188
27	Patent blue injections	186
28	Metolazone 2.5 & 5 mg tablets	184
29	Idebenone tablets & capsules, all strengths	183
30	Betamethasone 0.5mg tablets	174
31	Oral Potassium chloride controlled release preps	174
32	Prilocaine hydrochloride 30mg/ml+ octapressin 0.54 mcg/ml dental preps	174
33	Progesterone injections 100mg/ml	169
34	Clindamycin suspension & granules for suspension 75mg/5ml	167
35	Glycopyrrolate tablets & oral solutions	164
36	Rubella monocomponent vaccines	162
37	Isoprenaline injections	157
38	Oral magnesium preps	155
39	Streptomycin injections	154
40	Trifluoperazine tablets all strengths	151
41	Tretinoin/vitamin A & hydroquinone topicals (creams oints., gels etc.)	145
42	Reslizumab 100 mg injection soln	143
43	Pentosan polysulfate capsules all strengths	142
44	Ciproflaxacin 0.3 % ear drops	140
45	Nystatin preps, all routes of admin	140
46	Mercaptopurine tablets all strengths	137
47	Iloprost injections and infusions	136
48	Thioridazine tablets, all strengths	135
49	Lu-DOTA, Tyr ocfreotate, lutetium-177 (177 Lu) labelled 22-25ml	130
50	Colchicine tablets 0.5mg	124

## 2.2 Vaccines

It should be noted that for vaccines, where any second administration is more than 3 months after the first, the maximum quantity permitted per notification is 25 unit doses.

Table 3 gives a summary of vaccine notifications for Q1 2014. As with the listings for other products, the data are for valid notifications only and do not include cancellations or incomplete notifications. The listing includes notifications which may not be intended for placing on the UK market. It includes both acceptable products and those to which objections to import have been raised. It is therefore not an indicator of product acceptability.

**Table 3 Vaccines/Immunoglobulins notified by rank order of number of notifications**

Rank	Non-Proprietary Product Name	Number of Notifications
1	Rubella monocomponent vaccines	162
2	Measles monocomponent vaccines	57
3	Diphtheria, tetanus, acellular pertussis (DTaP)	25

Rank	Non-Proprietary Product Name	Number of Notifications
4	Diphtheria & tetanus vaccine adsorbed (paediatric)	20
5	Inactivated polio injection	20
6	Preservative-free tetanus toxoid vaccine-adsorbate	18
7	Yellow fever vaccine	17
8	Adsorbed diphtheria and tetanus vaccine	8
9	Diphtheria + tetanus + pertussis + poliomyelitis vaccine	8
10	Diphtheria-tetanus-acellular pertussis (DTPA) and inactivated poliovirus vaccine	8
11	Rabies immunoglobulin injection	8
12	Tuberculin PPD	8
13	Immunoglobulin normal 5g/100ml injection	4
14	Tetanus toxoid 20 iu + diphtheria toxoid 2 iu + perussis toxoid 8 mcg + pertactin 2.5 mcg	4
15	Varicella-zoster vaccine	4
16	BCG live vaccine	2
17	Diphtheria antitoxin injection	1
18	Rabies vaccine	1
19	Rotavirus vaccine (live, oral pentavalent vaccine)	1
20	Tetanus immunoglobulin	1
21	Typhoid vaccine (VI capsular polysaccharide)	1

## 2.3 Shortages

**Table 4. Products notified claiming UK product shortages, 01 Jan – 31 Mar 2014**

Proprietary Name	Number of Notifications
Oxytocin injections/infusions	336
Vasopressin injections	286
Hyoscine 0.3 mg tablets	203
Potassium chloride 600 mg SR tablets	171
Povidone iodine 5% ophthalmic solution	112
Tetracosactrin 1 mg/ml injection susp	104
Progesterone injection 100mg/ml	80
Trifluoperazine 1 mg film coated tabs	42
Ketamine inj/10mg/ml	40
Clonazepam 1 mg/ml injection soln	36
Cyproheptadine tablets 4mg	32
Diphenoxylate hydrochloride + atropine sulfate 2.5mg + 25 mcg tablets	32
Pizotifen malate 0.25mg/5ml bottles	32
Testosterone implant 100 mg	24
Vecuronium bromide injection 10mg	24
Methotrexate sodium 1g/10ml infusion conc	22
Isoprenaline 0.2mg/ml ampoules	20
Protirelin 200mcg/ml ampoules	20
Acetazolamide 250 mg tablets	16
Gadoteric acid 279.32mg/ml pre-filled syringe	16
Procarbazine 50mg capsules	13

<b>Proprietary Name</b>	<b>Number of Notifications</b>
Perphenazine 2 & 4 mg tablets	12
Hyoscine 1.5mg transdermal patches	10
Disulfiram 500 mg tablets	9
Lorazepam 2 mg/ml injection soln	8
Rabies immunoglobulin 1000-2000 iu injection soln	8
Liothyronine tablets	6
Chorionic gonadotrophin 5,000iu/1ml	5
Idarubicin hydrochloride 10mg pow/sol for inj	4
Sucralfate 1 g tablets	4
Varicella-zoster vaccine 0.65ml pfs	4
Pentamidine isetionate injection 300mg	3
Tuberculin 5 iu/0.1ml injection soln	3
Fluorescein sodium 10% vials	2
Dihydroergotamine mesylate 1mg/ml inj	1
Griseofulvin 125mg/5ml oral suspension	1

NOTE: This listing is indicative only and not exhaustive. It is based upon text comments in the imports database.

### 3 Issues arising

#### 3.1 Administrative matters

##### 3.1.1 Process timings – Clinical Emergencies

Normally, Clinical Emergency notifications can be processed within one working day. This can be up to four calendar days if the notification is received on a Friday afternoon. Some notifications can take longer if there are queries or if a medical assessment is required. A number of notifications originally submitted as non-emergencies have been processed as emergencies resulting from changes in circumstances. These show as extended processing times.

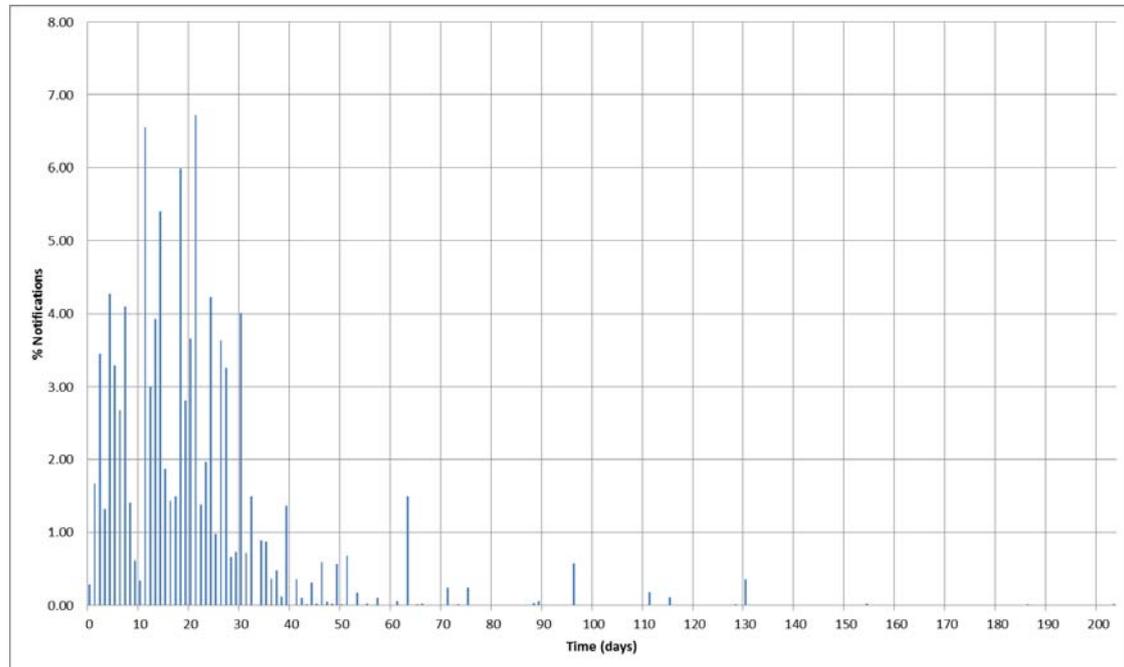
**Table 5 Summary of Timings for Issuing Clinical Emergency Letters, 01 Jan – 31 Mar 2014**

	<b>Number of Notifications</b>	<b>% Notifications</b>
<b>% ≤ 4 days</b>	609	72.76
<b>% ≤ 1 day</b>	472	56.39
<b>Total Clinical Emergencies processed</b>	837	

### 3.1.2 Process timings – Routine notifications

Graph 3 shows statistics for 8172 notifications for Q1/2014 where both received and acknowledgement letter issue dates are available and provides an estimate of the time taken to enter data onto the database after the received date of the notifications.

#### Graph 3 Time taken to issue Acknowledgement Letters after receipt, 01 Jan – 31 Mar 2014

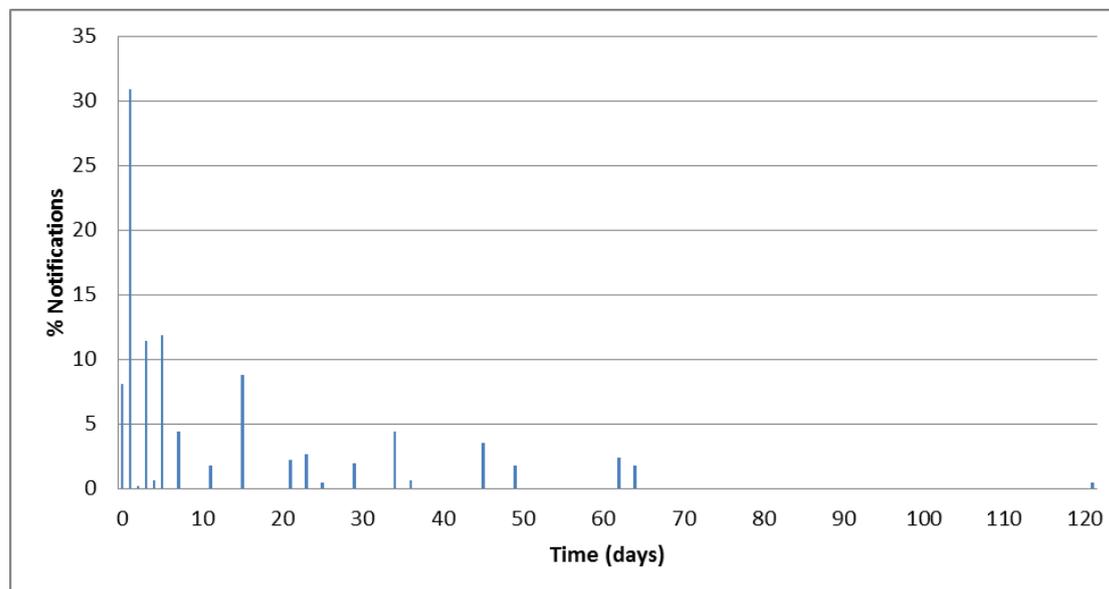


Approximately 90% of notifications were acknowledged within 1 month of receipt by the MHRA.

Significant delays can be experienced due to the necessity to obtain additional information from some importers to enable completion of data entry. Additionally, some spreadsheets have been submitted containing very large numbers of notifications. These can take some time to enter into the database before acknowledgement letters can be issued. As large spreadsheets take significant time for entry of data, this may cause delay to entry of other data.

### 3.1.3 Process timings - Time to issue letters after receipt of further information request responses

**Graph 4 Time to issue letters after receipt of further information request responses, 01 Jan – 31 Mar 2014**



Importers responded to 457 requests for further information from the MHRA in Quarter 1 2014 and letters permitting import were subsequently issued. Approximately 85% of these final letters were issued within 1 month of receiving the importer's response. See Graph 4.

### 3.1.4 Process timings – Objection letters

126 Objection with Reason letters were issued where acknowledgements had previously been issued. 116 of these were issued within 28 days of the acknowledgement. The remaining letters were issued in response to information provided by the importers following requests from the MHRA issued within 28 days of acknowledgments. Hence, all objection letters were issued in compliance with the regulations.

## 4 Inspection liaison

Information in the form of listings of unlicensed products notified for import together with background information including any significant issues is routinely provided to support site inspections of MS and WL holders. Six inspections were supported in Q1 2014 and a number of Inspectorate general queries answered.

## 5 Conclusions

The Import Notification System is operating substantially within the requirements of SI 2012/1916.