Unlicensed Imports	Jan 2015

Summary Report for Importation of Unlicensed Medicines

01 Jul 2014 – 30 Sep 2014

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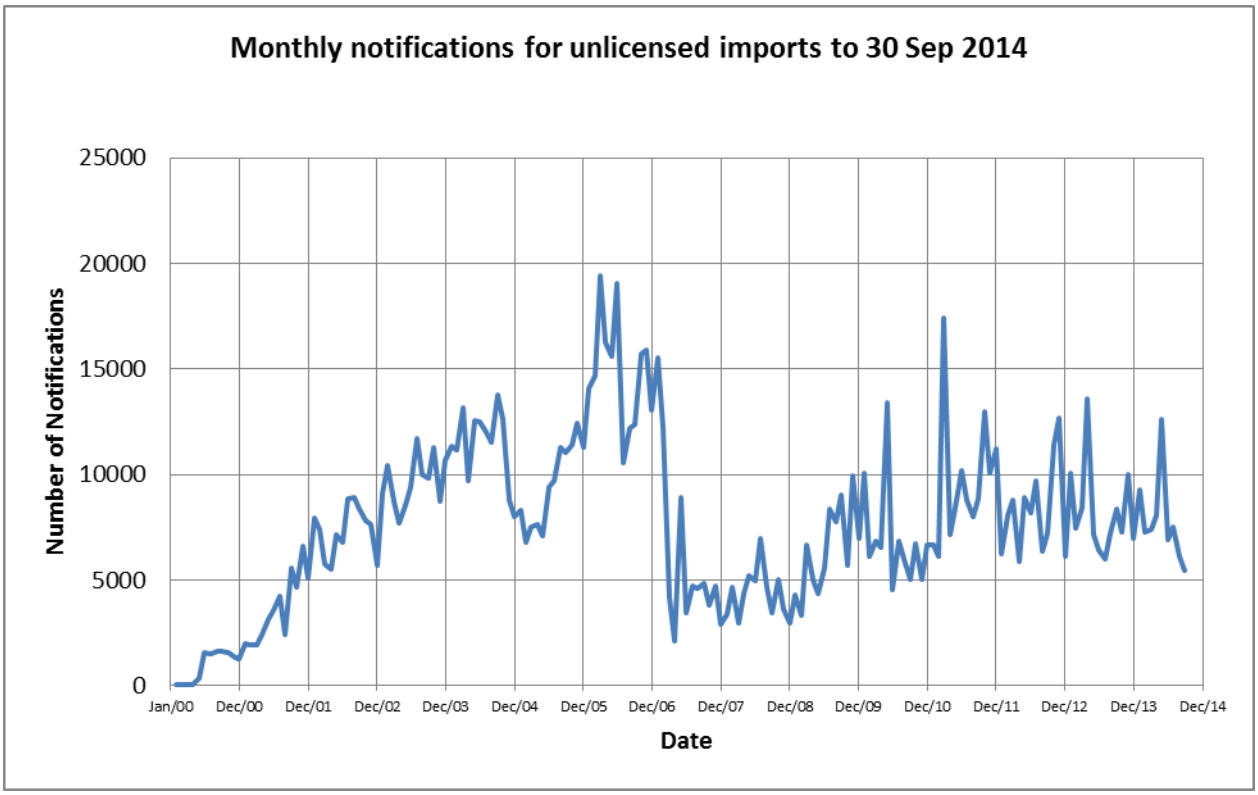
1 Introduction and Summary

The current report covers the period 01-July-2014 to 30-September-2014 and shows the import notification system to be operating substantially within the requirements of SI 2012/1916

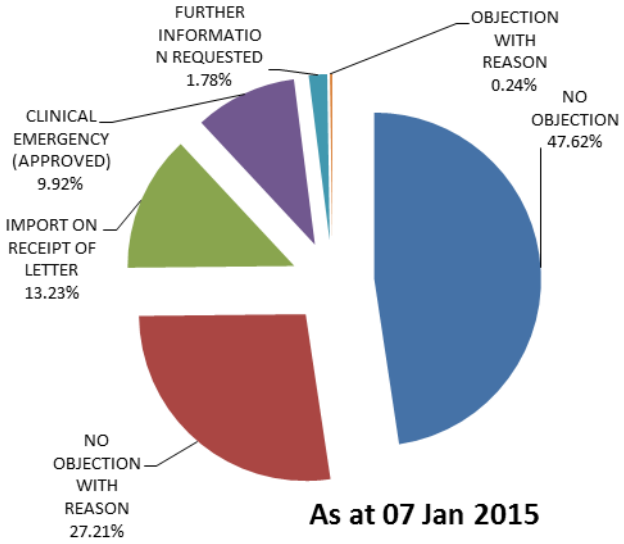
2 Notifications for importation

Graph 1 Monthly notifications for unlicensed imports

Note: Excludes invalid and cancelled notifications



Graph 2 Breakdown of notifications by status, 01 Jul – 30 Sep 2014



18,779 notifications were received from 81 importers for the period 01-Jul-2014 to 30-Sep-2014

2.1 Countries of export of products

Table 1 Breakdown of valid notifications by country, 01 Jul – 30 Sep 2014

Rank	Exporting Country	Percentage Share
1	Germany	30.91%
2	United States of America	19.96%
3	France	8.25%
4	Italy	8.18%
5	Australia	6.84%
6	Spain	5.20%
7	Canada	4.98%
8	Austria	2.90%
9	Belgium	2.43%
10	Switzerland	1.38%
11	Portugal	1.30%
12	The Netherlands	1.27%
13	Poland	1.26%
14	Denmark	0.73%
15	Republic of Ireland	0.68%
16	Slovakia	0.65%
17	Japan	0.54%
18	Czech Republic	0.51%

Rank	Exporting Country	Percentage Share
19	Sweden	0.49%
20	United Kingdom*	0.30%
21	Norway	0.30%
22	Hungary	0.29%
23	Finland	0.23%
24	India	0.18%
25	Cyprus	0.14%
26	Lithuania	0.09%
27	New Zealand	0.01%
28	Turkey	0.01%
	Sum:	**100.00%**
	EEA	**66.11%**
	Non-EEA	**33.89%**

* Not valid country of export!

2.2 Most frequently notified products

Table 2 lists the 50 most frequently notified products during Q3/2014 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	Product Name	Number of Notifications
1	Ibrutinib 140 mg Capsules	1074
2	Midodrine Tablets all strengths	1026
3	Homoeopathics & Herbals	742
4	Thyroid Oral Preps	595
5	Vitamins - Oral Preps	511
6	Co-Trimoxazole Injections/Infusions	483
7	Etoposide Injections	449
8	Allergy Tests	405
9	Fosfomycin Oral Preps	391
10	Ketamine Injections	349
11	Idebenone Tablets	279

Rank	Product Name	Number of Notifications
12	Acetylcysteine Oral Preps	268
13	Sucralfate Tabs & Suspensions	257
14	Bisacodyl Enemas 10 mg	251
15	Betadine 5% Ophthalmic Soln	232
16	Demeclocycline Hydrochloride 150 & 300 mg Tabs & Caps	222
17	Benzathine Benzylpenicillin Injections	220
18	Nortriptyline Tablets	220
19	Carbimazole Tablets all Strengths	214
20	Melatonin Oral Preps	213
21	Potassium Chloride 600 mg Tablets & Caps	210
22	Clindamycin 75 mg/5 ml Oral Suspensions	209
23	BCG Instillations	207
24	Erythromycin Injections/Infusions	201
25	Tretinoin/Vitamin A & Hydroquinone Topicals (Creams Oints., Gels Etc.)	201
26	Fumaric Acid Ester Tablets all Strengths	173
27	Metolazone Tablets 2.5 mg	155
28	Progesterone Injections 100 mg/ml	150
29	Rifaximin 200 mg Tablets	146
30	Flunarizine 5 & 10 mg Tablets and Capsules	139
31	Phentolamine Injections	139
32	Diphenoxylate Hydrochloride/Atropine Sulfate Tablets 2.5 mg/25 mcg	136
33	Pentosan Polysulphate Sodium 50 & 100mg Capsules	135
34	Iloprost Injections & Infusions	134
35	[^{177}Lutetium]-DOTA^{0}-Tyr^{3}-Octreotate Parenteral	130
36	Triamcinolone Topical Preps (Dental & Otic), incl with Neomycin, Gramicidin	127
37	Colchicine 0.5 mg Tablets	120
38	Patent Blue V 2.5% Solution	117
39	Sodium Nitroprusside 50mg Pow/Soln for Injection	115
40	Betamethasone Injections	109
41	Pristinamycin 500 mg Tablets	103
42	Carfilzomib 60 mg Lyophilized Injection	101
43	Mexiletine Capsules	101
44	Gadoteric Acid 279.32 mg/ ml Injections	100
45	Melphalan Hydrochloride 50 mg Pow/Sol for Injection	99
46	Lidocaine 2% Urethral Gel	98

Rank	Product Name	Number of Notifications
47	Procaine Benzylpenicillin Injections	93
48	Diazoxide Suspensions & Capsules	92
49	Streptozocin 1g Injections	91
50	Potassium Citrate Tablets	90

2.3 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 Q3/2014. 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	Product Name	Number of Notifications
1	BCG Instillations	207
2	Yellow Fever Live Attenuated Vaccine	38
3	Lymphocyte Immune Globulin Anti Thymocyte Globulin (Equine)	30
4	Diphtheria + Tetanus + Pertussis + Poliomyelitis + Haemophilus Influenza Vaccines	25
5	Tuberculin PPD	21
6	Rabies Immune Globulin Human	12
7	Meningitis C Vaccine	6
8	Diphtheria + Tetanus + Pertussis Vaccines	4
9	Varicella Zoster Immunoglobulin 500 IU/20 ml Infusion	4
10	Anti Human-T-Lymphocyte Immunoglobulin 20 mg/ml	2
11	Inactivated Polio Vaccine	2
12	Typhoid Vaccine (VI Capsular Polysaccharide) 25 mcg/0.5 ml Injection	1

2.4 Shortages

Table 4. Products notified claiming UK product shortages, 01 Jul – 30 Sep 2014

Product Name	Number of Notifications
Co-Trimoxazole Injections	480
Ketamine Injections	321

Product Name	Number of Notifications
Sucralfate Suspension & Tablets	238
Demeclocycline Tablets 150 mg	219
Potassium Chloride SR Tablets & Capsules	213
BCG Instillations	207
Gadoteric Acid 279.32 mg/ml	100
Vasopressin 20 USP Units/ml Injections	86
Progesterone Injection 100 mg/ml	73
Cytarabine 2 g/20 ml Injection	72
Phentolamine 0.4 mg/1.7 ml Sol For Inj	50
Etoposide 100 mg/5 ml Injections	34
Amsacrine Injections	31
Tuberculin PPD	25
Trifluoperazine 1 mg Tablets	22
Levothyroxine Sodium Tablets	20
Amantadine 10 mg/ml Syrup	17
Dexamethasone Injections 4 mg/ml	16
DTaP/IPV/HIB Vaccines	16
Betamethasone 4mg/1ml Injection	13
Diphenoxylate Hydrochloride + Atropine Sulfate 2.5 mg + 25 mcg Tablets	13
Hyoscine Transdermal Patches	13
Disulfram Tabs	11
Diclofenac Injection 75mg/2ml	9
Cholestyramine Sachets 4g	8
Oxytocin 10 IU/ml Injections	8
Meningitis C Vaccine	6
Liothyronine Tablets 20 mcg	5
Chorionic Gonadotrophin 5,000 IU/1 ml Vials	4
Acetazolamide 250 mg Tablets	3
Chlordiazepoxide Capsules 10 mg	3
Pyrazinamide 500 mg Tablets	3
Vecuronium Injections 10 mg	3
Rabies Immunoglobulin 1000-2000 IU Injection Soln	2
Haloperidol 5 mg Tablets	1
Perphenazine Tablets 4 mg	1
Potassium Chloride 20 mmol in 50 ml	1
Testosterone Injections	1
Tetracosactide 250 mcg/ml Injection	1

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

3 Administrative matters

3.1 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, if a large number have been submitter, 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

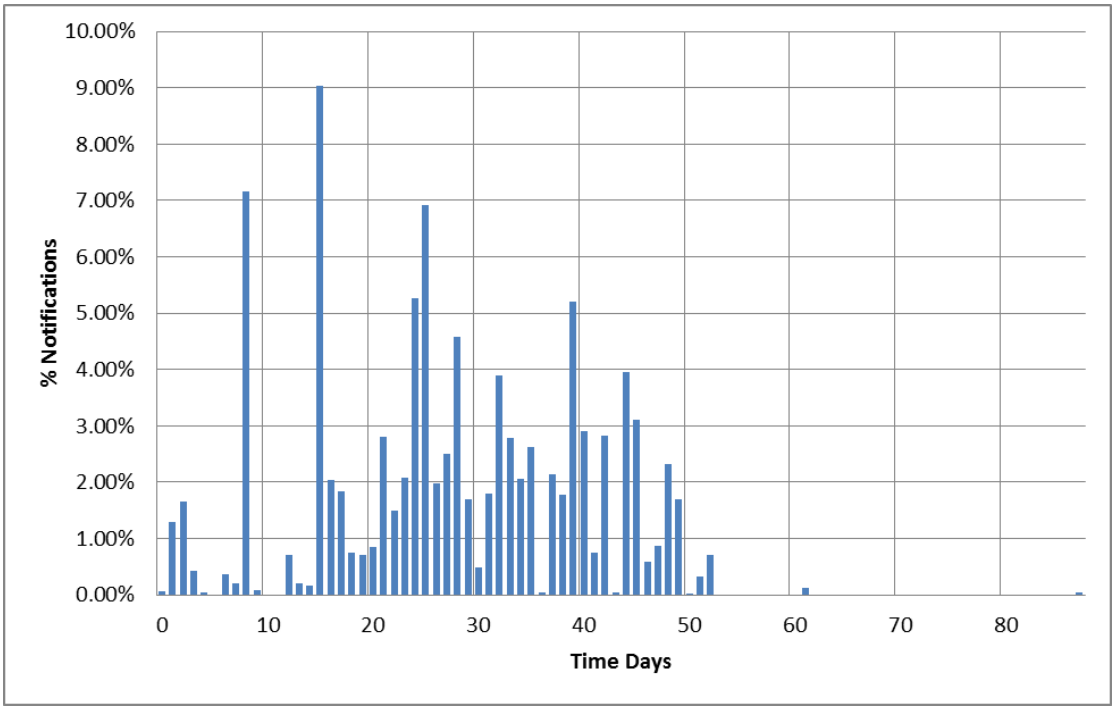
Table 5 Summary of Timings for Issuing Clinical Emergency Letters, 01 Jul – 30 Sep 2014

	Number of Notifications	% Notifications
% ≤ 4 days	1793	96.4
% ≤ 1 day	1642	88.28
Total Clinical Emergencies processed	1860	

3.2 Process timings – Routine notifications

Graph 3 shows statistics for 11162 notifications for Q3/2014 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.

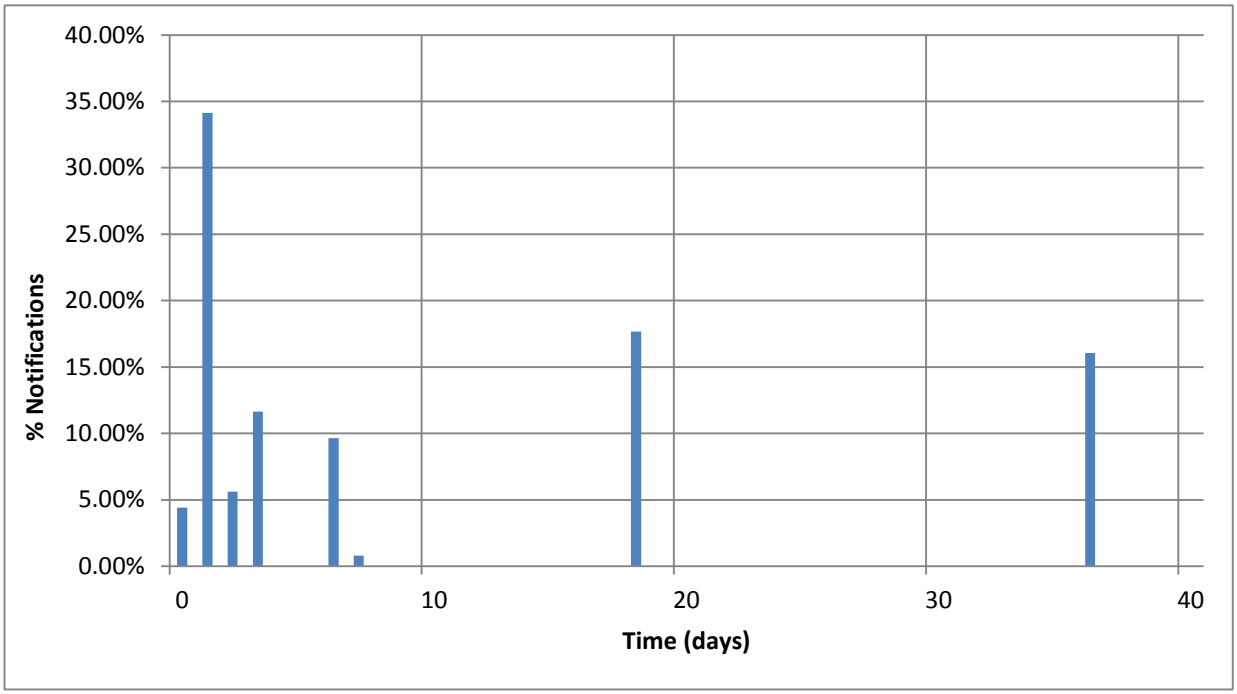
Graph 3 Time taken to issue Acknowledgement Letters after receipt, 01 Jul – 30 Sep 2014



Significant delays can be experienced due to the necessity to obtain additional information from some importers to enable completion of data entry. Where spreadsheets have been submitted containing very large numbers of notifications there may also be delays due to the time taken to enter the data before acknowledgement letters can be issued.

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

Graph 4 Response times to further information provided, 01 Jul – 30 Sep 2014



Importers responded to 249 requests for further information from the MHRA in Q3/2014 and letters permitting import were subsequently issued. Approximately 84% of these final letters were issued within 18 days of receiving the importer's response. See Graph 4.

3.4 Process timings – Objection letters

A total of 45 Objections with Reason letters were issued in Q3/2014. Of these, 34 were issued where acknowledgements had previously been issued. All of these were issued within 28 days of the acknowledgement.

3.4.1 Summary of reasons for objections to import

The most common reason for objections to import in Q3/2014 was submission of notifications by importers with incorrect licences, in particular notifications for import from outside the EEA by holders of Wholesale Distribution Authorisations (the appropriate licence is a Manufacturer's "Specials" Licence enabled for this activity).

There were also a number of notifications where the proprietary names of products were given when generic names or INNs were required.

Finally, a number of notifications were received where an equivalent licensed product was available in the UK.

Table 6 provides a summary of the 45 objections raised in Q3/2014.

Table 6 Reasons for objection to import

Summary	Number of notifications
Invalid Licence	5
Invalid Licence and missing data	4
Missing data (all repeats of same notification)	30
UK Licensed product available	6

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 WDA(H) holders. Eleven inspections were supported in Q3/2014 and a number of Inspectorate general queries answered.

5 Conclusions

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

Delays in printing urgent letters have been highlighted in staff training updates.