



Summary Report for Importation of Unlicensed Medicines

01 Apr 2018 – 30 Jun 2018

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1 Introduction and summary

This report¹ covers the period 01-Apr-2018 to 30-Jun-2018 and shows the import notification system to be operating substantially within the requirements of SI 2012/1916.

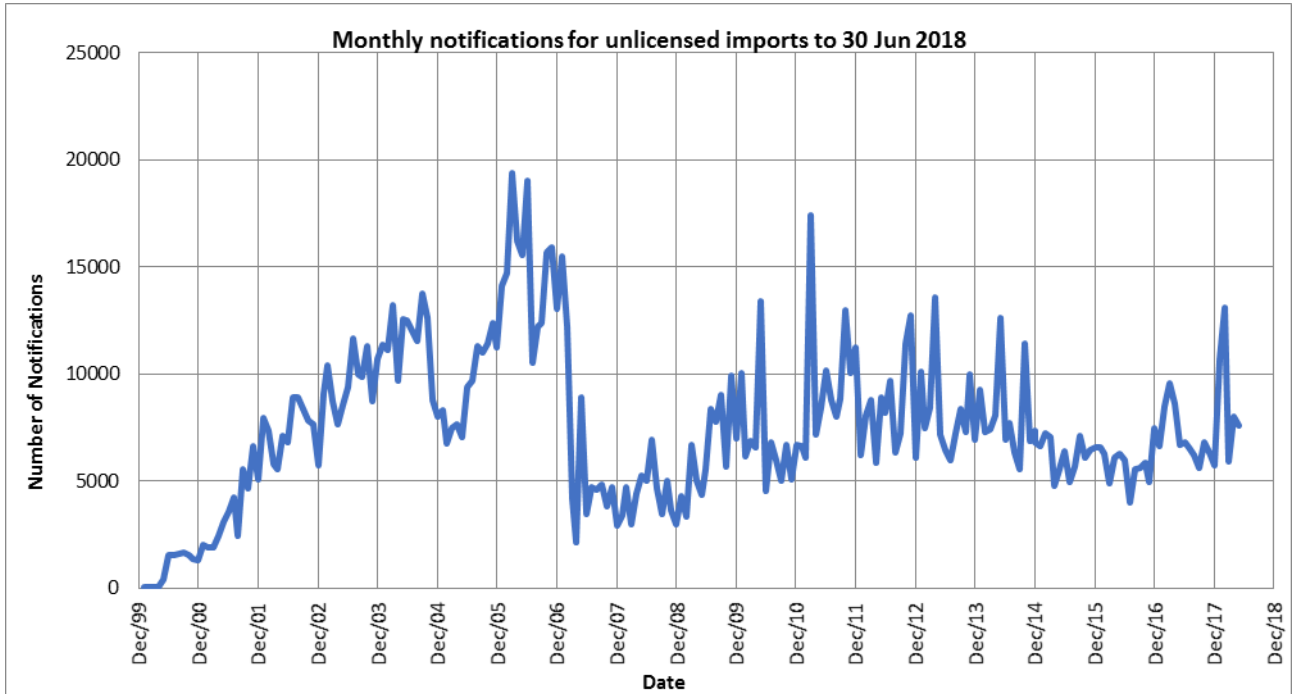
Due to issues with new software, not all statistics normally reported in previous reports are able to be presented in the current report.

¹ The data for this report were compiled in November 2018 and reflect the Import Notification System at this date.

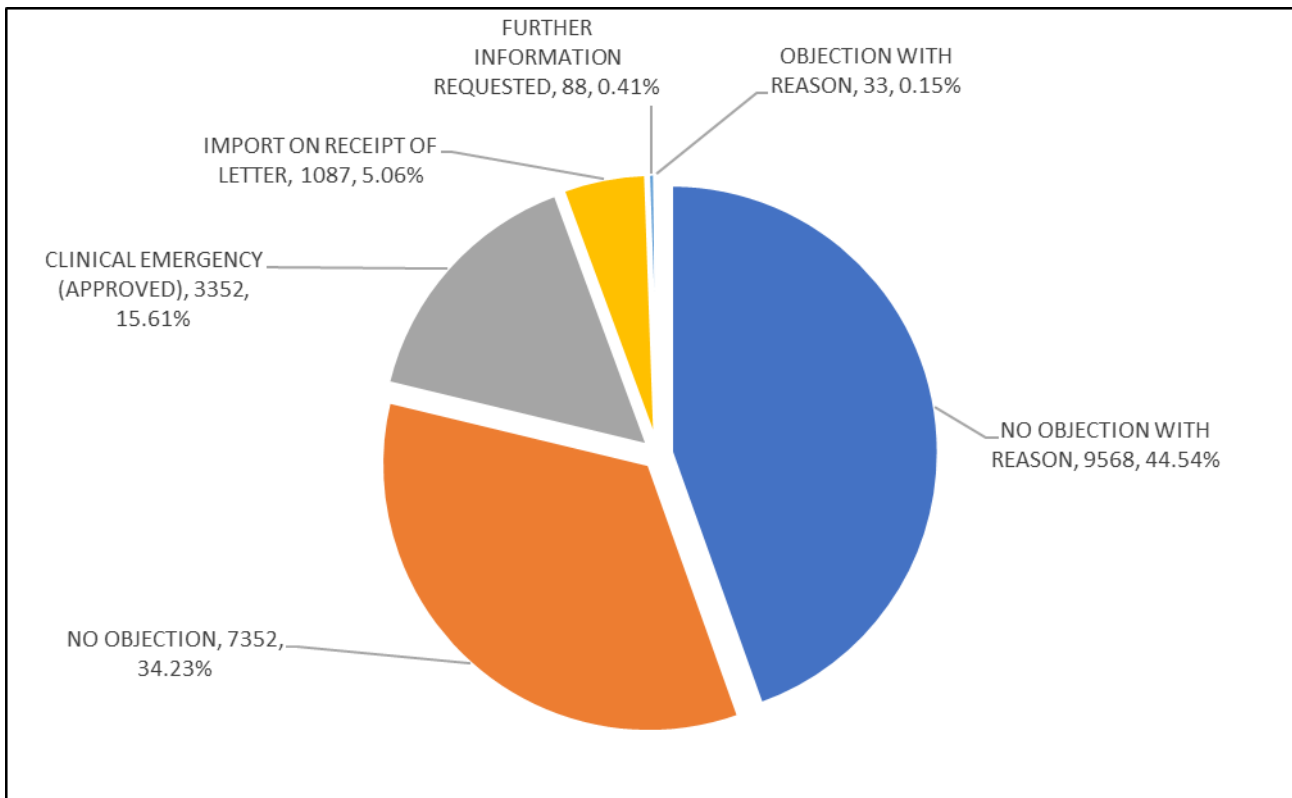
2 Notifications for importation

Graph 1 Monthly notifications for unlicensed imports

Note: Excludes invalid and cancelled notifications



Graph 2 Breakdown of valid notifications by status, 01 Apr – 30 Jun 2018



2.1 Importers

Table 1 Valid notifications by importer 01 Apr – 30 Jun 2018

Importer Name	Number of Notifications	Percentage Share
81 importers	21480	100%
Of which 8 importers		80.34%

2.2 Countries of export of products

Table 2 Countries of export 01 Apr – 30 Jun 2018

Rank	Exporting Country	Number of Notifications	Percentage Share
1	Germany	4225	19.67%
2	United States of America	3847	17.91%
3	Italy	2695	12.55%
4	Australia	1753	8.16%
5	France	1723	8.02%
6	Spain	1242	5.78%
7	Canada	1179	5.49%
8	Switzerland	1017	4.73%
9	Denmark	384	1.79%
10	Belgium	354	1.65%
11	Portugal	349	1.62%
12	India	385	1.79%
13	The Netherlands	321	1.49%
14	Austria	275	1.28%
15	Norway	235	1.09%
16	Czech Republic	231	1.08%
17	Republic of Ireland	187	0.87%
18	Slovakia	163	0.76%
19	Lithuania	163	0.76%
20	Japan	141	0.66%
21	Poland	132	0.61%
22	Cyprus	120	0.56%
23	Israel	100	0.47%
24	New Zealand	64	0.30%
25	Hungary	49	0.23%
26	Bulgaria	42	0.20%
27	Greece	33	0.15%
28	Sweden	26	0.12%
29	Romania	21	0.10%
30	Finland	12	0.06%
31	China	5	0.02%
32	Singapore	4	0.02%
33	Latvia	3	0.01%

Rank	Exporting Country	Number of Notifications	Percentage Share
	Sum:	21480	100.00%
	EEA Countries	15917	74.10%
	Non-EEA Countries	5563	25.90%

2.3 Most frequently notified products

Table 3 Top 50 frequently notified products 01 Apr – 30 Jun 2018

Rank	Product name	Number of Notifications	% all Notifications
1	Furosemide injections & infusions	1495	6.96%
2	Oral thyroid preparations, all combinations/strengths	1075	5.00%
3	Homoeopathic preparations	889	4.14%
4	Melatonin oral preps	661	3.08%
5	Rurioctocog alfa pegol infusions	588	2.74%
6	Potassium chloride oral controlled release preps	509	2.37%
7	Fluphenazine decanoate injections 25 & 100 mg/ml	495	2.30%
8	Benzathine benzylpenicillin injections	437	2.03%
9	Allergy treatments (SCIT, SLIT)	431	2.01%
10	Ropivacaine hydrochloride injections/infusions	372	1.73%
11	Calcium folinate 100mg/10ml solution for injection 1x10ml	370	1.72%
12	Lidocaine 10% 100 mg/ml sprays	349	1.62%
13	Allergy tests	334	1.55%
14	Sucralfate tablets & oral suspensions	328	1.53%
15	Isoprenaline injections	312	1.45%
16	Durvalumab 500mg concentrate for infusion 50mg/ml	306	1.42%
17	Progesterone injections (rapid & depot)	300	1.40%
18	Co-trimoxazole 480mg/5ml injections	294	1.37%
19	Povidone-iodine 5% ophthalmic solutions	286	1.33%
20	Pirenzepine 50 mg tablets	283	1.32%
21	Bisacodyl 10mg/30ml enemas	278	1.29%
22	Inotersen 189 mg/ml solution for injection	265	1.23%
23	Vitamin oral/nasal preps	250	1.16%
24	Human chorionic gonadotropin injections	238	1.11%
25	Paclitaxel 100mg (6mg/ml) injections/infusions	232	1.08%
26	Binimetinib 15 mg tablets	230	1.07%
27	Hepatitis B vaccines	225	1.05%
28	Clindamycin granules/suspension 75mg/5ml	208	0.97%
29	Metolazone tablets (all strengths)	205	0.95%
30	Tretinoin/vitamin A and hydroquinone (all combinations incl monocomponent) topicals (creams oints., gels etc., some with hydrocortisone)	204	0.95%
31	Insulin injections	200	0.93%
32	Pristinamycin 500mg tablets	193	0.90%
33	Sodium nitroprusside 50mg injections/infusions	175	0.81%
34	Triamcinolone acetonide, neomycin sulfate, nystatin, gramicidin otic ointments	171	0.80%
35	Testosterone 1% w/v creams	160	0.74%
36	Flunarizine 5 & 10 mg tablets & capsules	154	0.72%
37	Encorafenib 75 & 50 mg capsules	152	0.71%
38	Streptozocin 1g injections	150	0.70%
39	Mexiletine capsules all strengths	137	0.64%
40	Pentosan 50 & 100 mg capsules	136	0.63%

Rank	Product name	Number of Notifications	% all Notifications
41	Trifluoperazine 1 & 5 mg tablets	132	0.61%
42	Clonidine transdermal patches	125	0.58%
43	Povidone-iodine ointment 100mg/g	122	0.57%
44	Rifampicin 150 & 300 mg capsules	120	0.56%
45	Ampicillin + sulbactam 1.5g injections	119	0.55%
46	Labetalol 5 mg/ml injections	117	0.54%
47	Chlorpromazine tablets all strengths	115	0.54%
48	Betamethasone sodium phosphate 4mg/1 ml injections	114	0.53%
49	Diazoxide tablets & oral suspensions	114	0.53%
50	Co-phenotrope 2.5 mg + 25 mcg tablets	105	0.49%
	Sum	15260	71.04%

2.4 Vaccines and immunoglobulins

Table 4 Vaccines & immunoglobulins 01 Apr – 30 Jun 2018

Rank	Product name	Number of Notifications
1	Hepatitis B vaccines	225
2	Tetanus immunoglobulin	26
3	Rabies vaccine	17
4	Tuberculin purified protein derivative	16
5	BCG vaccines & instillations	14
6	Hepatitis A vaccines	11
7	Lymphocyte immune globulin anti thymocyte globulin (equine)	9
8	Diphtheria + tetanus toxoids + acellular pertussis adsorbed + hepatitis B (recombinant) + inactivated polio	2
9	Diphtheria, tetanus, and acellular pertussis adult vaccine	2
10	Zoster vaccine recombinant	2
11	Anti human-T-lymphocyte immunoglobulin 20mg/ml	1
12	CMV immunoglobulin	1
13	IgM enriched normal human immunoglobulin	1

2.5 Shortages

Table 5. Products notified claiming UK product shortages, 01 Apr – 30 Jun 2018

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

Proprietary name	Number of Notifications
Fluphenazine 25 & 100 mg/ml injections	495
Sucralfate tablets & oral suspensions	262
Human chorionic gonadotrophin injections, all strengths	188
Ropivacaine injection, all strengths	160
Co-trimoxazole injections/infusions 480mg/5ml	120
Trifluoperazine 1 & 5 mg tablets	116
Furosemide injections & infusions	68
Co-phenotrope 2.5 mg + 25 mcg tablets	64

Proprietary name	Number of Notifications
Chlorpromazine tablets all strengths	61
Liothyronine 20mcg tablets	60
Progesterone 100 mg/ml injections	56
Chloramphenicol 1g injections	50
Potassium chloride slow release tablets 600mg	22
Clindamycin 600 mg/4ml solution for injection	20
Hepatitis B vaccines	20
Rabies vaccines	16
Lidocaine + adrenaline injections	10
Sulfinpyrazone 200mg tablets	10
Haloperidol 5mg/ml injections	8
Fluorescein 10% injections	3
Ketamine 200mg/2ml solution for injection	3
Wasp venom allergy tests	3
Bee venom allergy tests	2
Ribavirin inhalation solutions	2
Arsenic trioxide injection concentrate	1
Flucytosine 2.5 g/250 ml infusion solutions	1

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 or longer if the notification is received on a Friday afternoon or before a public holiday. Some notifications can take longer if there are queries, if a large number have been submitted, or if a medical assessment is required. Notifications originally submitted as non-emergencies may be processed urgently resulting from changes in circumstances. These will show as extended processing times. Graph 3 and Table 6 provide further information on timings.

Graph 3 Time to Issue Clinical Emergencies, 01 Apr – 30 Jun 2018

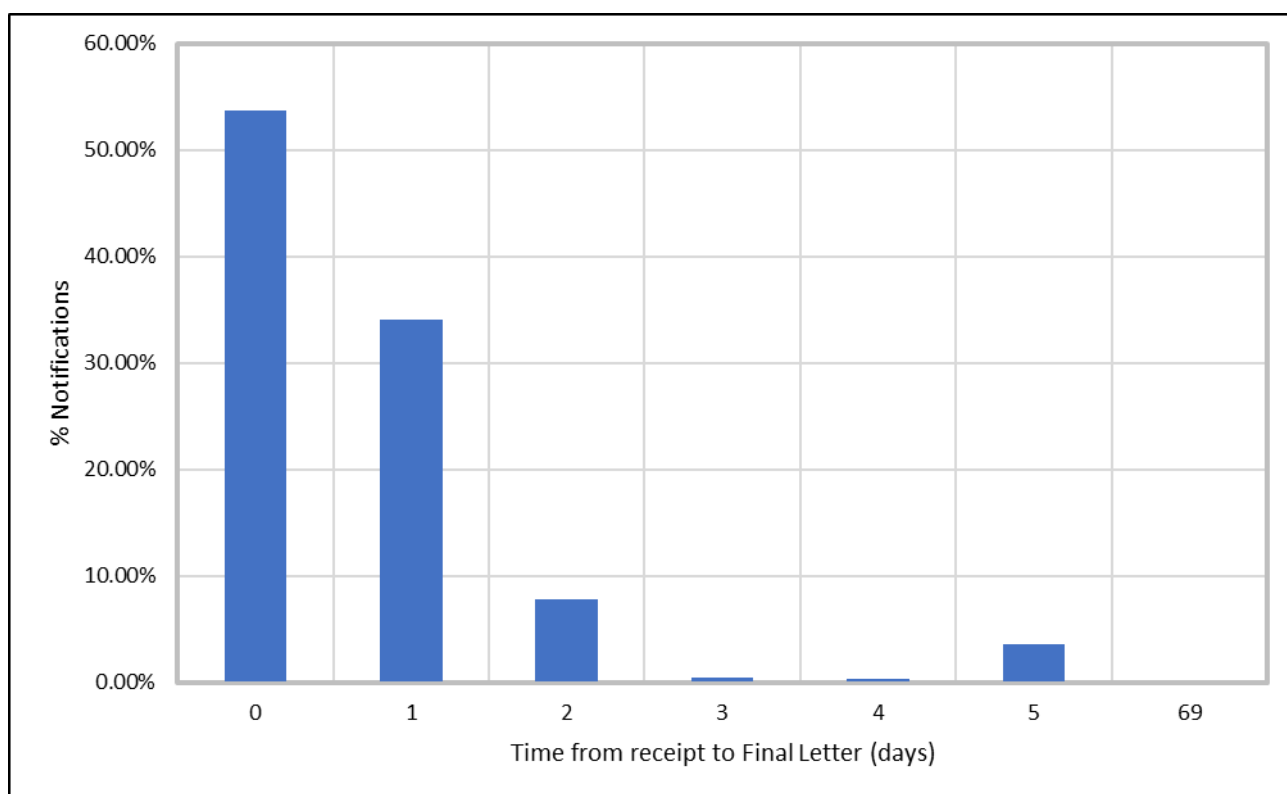


Table 6 Clinical Emergency Letter Timings,

Time to Process from Receipt	% Notifications
≤ 1day	87.80%
≤ 3 days	96.03%

3.2 Process timings – Objection letters

A total of 87 Objections with Reason were issued in Q2/2018. All were issued with 28 days of acknowledgements.

3.2.1 Summary of reasons for objections to import

Table 7 Reasons for objection to import

Summary	Number of notifications
Centrally Authorised medicine available	74
CHM safety concerns (Co-Phenylcaine Forte)	9
Excessive quantity notified	3
Equivalent UK licensed product available	1

The maximum quantity notified for import in a single notification may be 25 individual doses or a quantity that must not exceed that required for 25 courses of no more than 3 months.

Unlicensed medicines must not be supplied if there is an equivalent licensed product available that can meet the patient's clinical needs. This may be a UK licensed product available within the UK or a Centrally Authorised product available within the EEA.

There are safety concerns relating to the multidose presentation of Co-phenylcaine Forte following a review by the Commission on Human Medicines and the MHRA objects to the importation of this unlicensed medicine.

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 and to assist Enforcement investigations. 11 inspections were supported in Q2/2018 and a number of Inspectorate and Enforcement general queries answered.

5 Conclusions

The import notification system has operated substantially within the requirements of the regulations during Quarter 2, 2018. All letters of objection to import have been issued within 28 days of acknowledgements where these were issued, and the response times for urgent notifications continue to be good.