



Summary Report for Importation of Unlicensed Medicines

01 Jul 2018 – 30 Sep 2018

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1 Introduction and summary

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

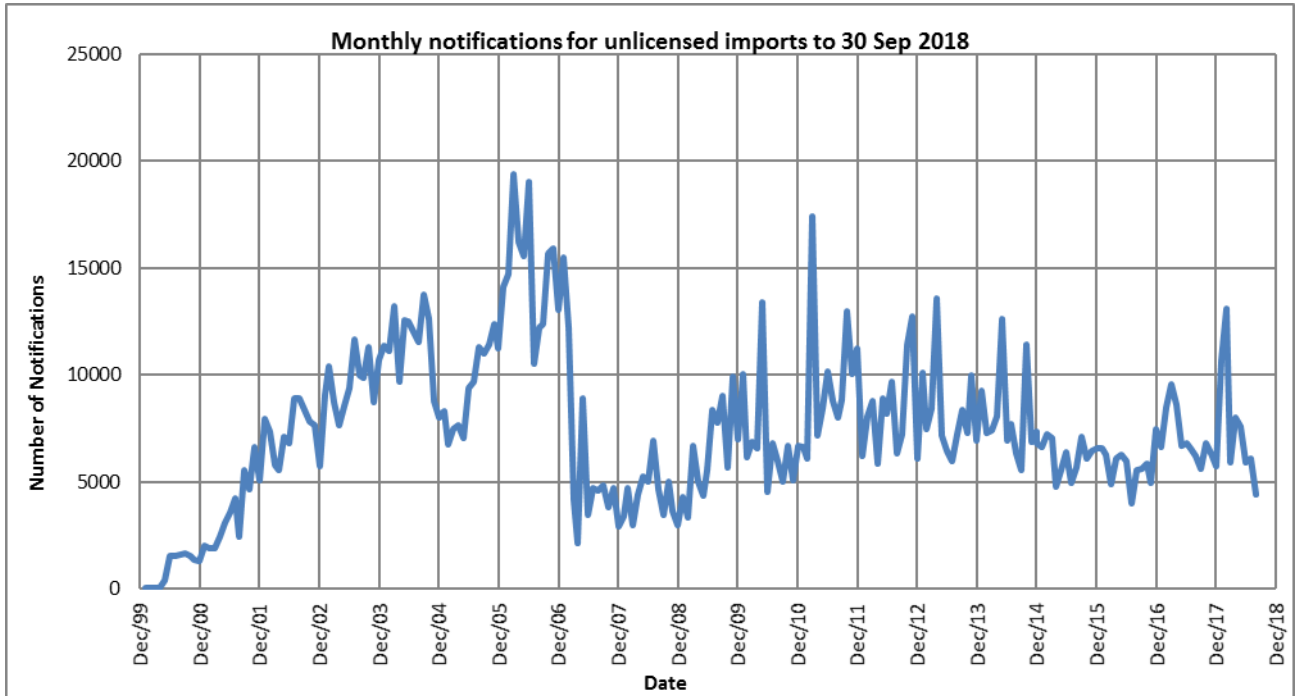
Due to issues with new software, not all statistics normally reported in previous reports are able to be presented in the current report.

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

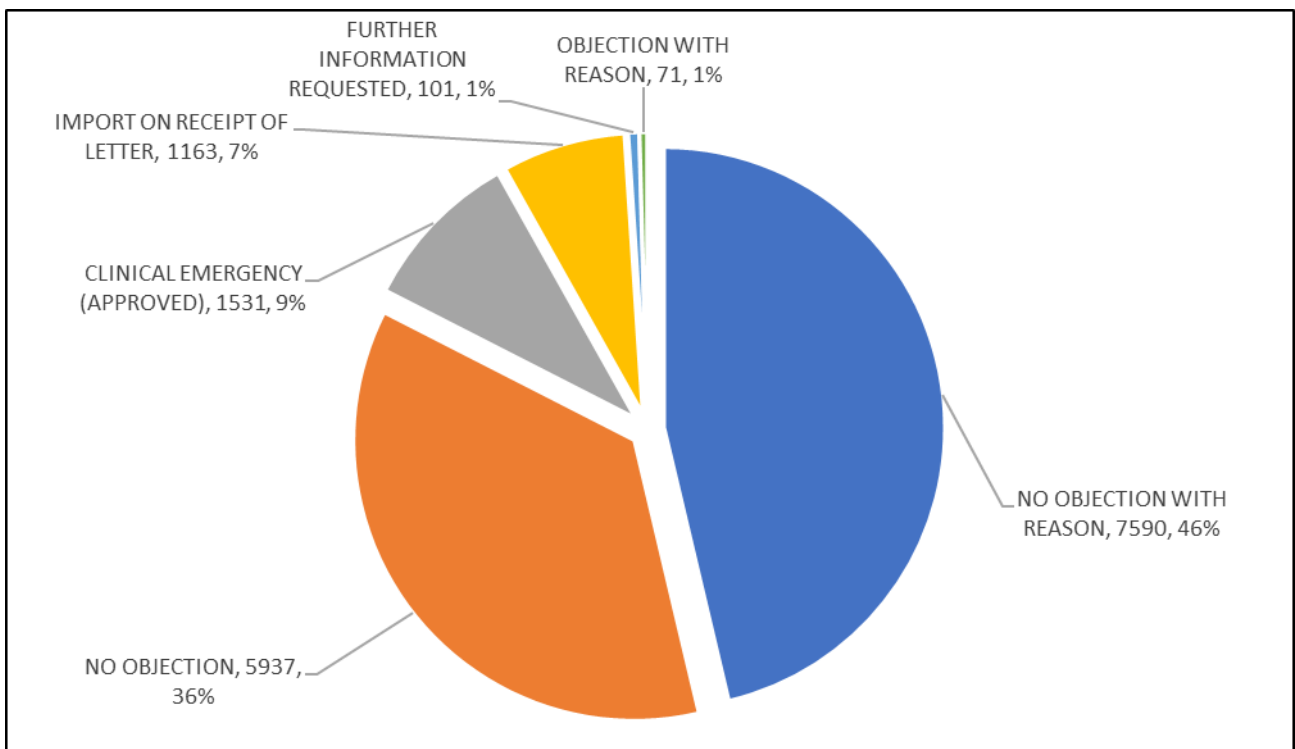
2 Notifications for importation

Graph 1 Monthly notifications for unlicensed imports

Note: Excludes invalid and cancelled notifications



Graph 2 Breakdown of valid notifications by status, 01 Jul – 30 Sep 2018



2.1 Importers

Table 1 Valid notifications by importer 01 Jul 2018 - 30 Sep 2018

Importer Name	Number of Notifications	Percentage Share
89 importers	16393	100%
Of which 9 importers		~80%

2.2 Countries of export of products

Table 2 Countries of export 01 Jul 2018 - 30 Sep 2018

Rank	Exporting Country	Number of Notifications	Percentage Share
1	United States of America	3297	20.11%
2	Germany	3774	23.02%
3	Italy	1587	9.68%
4	Canada	1270	7.75%
5	France	1135	6.92%
6	Spain	970	5.92%
7	Switzerland	688	4.20%
8	Australia	489	2.98%
9	Japan	371	2.26%
10	Denmark	369	2.25%
11	Belgium	342	2.09%
12	The Netherlands	328	2.00%
13	Lithuania	237	1.45%
14	Austria	221	1.35%
15	Guernsey	180	1.10%
16	Norway	149	0.91%
17	Poland	140	0.85%
18	Bulgaria	107	0.65%
19	Portugal	106	0.65%
20	Greece	99	0.60%
21	Republic of Ireland	91	0.56%
22	Israel	89	0.54%
23	India	65	0.40%
24	Turkey	65	0.40%
25	New Zealand	51	0.31%
26	Romania	37	0.23%
27	Hungary	28	0.17%
28	Czech Republic	26	0.16%
29	Latvia	21	0.13%
30	Finland	20	0.12%

Rank	Exporting Country	Number of Notifications	Percentage Share
31	Slovakia	10	0.06%
32	China	9	0.05%
33	Cyprus	8	0.05%
34	Mexico	4	0.02%
35	Sweden	4	0.02%
36	Singapore	2	0.01%
37	South Africa	2	0.01%
38	Russia	1	0.01%
39	Taiwan	1	0.01%
	Sum:	16393	100%
	EEA	9989	60.93%
	Non-EEA	6404	39.07%

2.3 Most frequently notified products

Table 3 Top 50 frequently notified products 01 Jul 2018 - 30 Sep 2018

Rank	Product name	Number of Notifications	% all Notifications
1	Oral thyroid preparations, all combinations/strengths	904	5.52%
2	Homoeopathic preparations	876	5.35%
3	Melatonin oral preps	856	5.23%
4	Paclitaxel (6mg/ml) injections/infusions	664	4.06%
5	Tretinoin/vitamin A and hydroquinone (all combinations incl monocomponent) topicals (creams ointments., gels etc., some with hydrocortisone)	535	3.27%
6	Potassium chloride oral controlled release preparations	520	3.18%
7	Vitamin oral preps	470	2.87%
8	Co-trimoxazole 480mg/5ml injection	412	2.52%
9	Sucralfate tablets & oral suspensions	353	2.16%
10	Allergy tests	329	2.01%
11	Bisacodyl 10mg/30ml enemas	310	1.89%
12	Progesterone injections (incl depot)	302	1.85%
13	Tolvaptan (OPC-41061) 15 & 30 mg tabs	293	1.79%
14	Povidone-iodine 5% ophthalmic solutions	247	1.51%
15	Lorazepam 2 mg/ml injections	239	1.46%
16	Sibelium 5 & 10mg tablets and capsules	225	1.38%
17	Pirenzepine 50mg tablets	213	1.30%
18	Benzathine benzylpenicillin injections	196	1.20%
19	Rurioctocog alfa pegol infusions	195	1.19%
20	Vinblastine injections	171	1.05%
21	Allergy treatments (SCIT, SLIT)	166	1.01%
22	Talc for pleurodesis	160	0.98%
23	Ampicillin + sulbactam 1.5 g injection	140	0.86%
24	Clindamycin 75mg/5ml suspensions	139	0.85%
25	Mexiletine capsules & tablets	138	0.84%
26	Metolazone 2.5 & 5 mg tablets	131	0.80%
27	Human insulin 500 IU injections	130	0.79%
28	Triamcinolone acetonide, neomycin sulfate, nystatin,	130	0.79%

Rank	Product name	Number of Notifications	% all Notifications
	gramicidin ear ointments		
29	Tetanus immunoglobulin 250 IU/ml injections	123	0.75%
30	Vitamin parenteral preps	120	0.73%
31	Diazoxide suspensions and capsules	117	0.72%
32	Isoprenaline injections	109	0.67%
33	Mercaptopurine 10 mg tablets	106	0.65%
34	Human chorionic gonadotrophin injections	101	0.62%
35	Hepatitis B vaccines	96	0.59%
36	VX-445/ Tezacaftor/ ivacaftor tablets	96	0.59%
37	Chlorpromazine 25 & 100 mg tablets	95	0.58%
38	Sodium nitroprusside injections	94	0.57%
39	Triheptanoin 0.96g/ml	91	0.56%
40	Sultiame 50 & 200 mg tablets	88	0.54%
41	Ciclosporine 0.2% eye ointments	80	0.49%
42	Oral magnesium products	79	0.48%
43	Palovarotene capsules all strengths	77	0.47%
44	Artesunate 60mg injections	71	0.43%
45	Ubidecarenone oral preps	71	0.43%
46	Testosterone creams & gels	70	0.43%
47	Trifluoperazine 1 & 5 mg tablets	69	0.42%
48	Pristinamycin 500mg tablets	68	0.42%
49	Co-phenotrope 2.5 mg + 25 mcg tablets	64	0.39%
50	Potassium canrenoate 200mg/10ml injection	62	0.38%
	Sum	16363	69.61%

2.4 Vaccines and immunoglobulins

Table 4 Vaccines & immunoglobulins 01 Jul 2018 - 30 Sep 2018

Rank	Proprietary Name	Number of Notifications
1	Tetanus immune globulin	123
2	Hepatitis B vaccines	96
3	Pneumococcal polysaccharide 23-valent vaccine (PPV23)	40
4	Lymphocyte immune globulin anti thymocyte globulin (equine)	35
5	Snake antivenoms	11
6	Inactivated poliomyelitis vaccine	9
7	Varicella zoster immunoglobulin (human)	9
8	Haemophilus influenzae type B conjugate vaccine	8
9	BCG vaccines & instillations	6
10	Tuberculin purified protein derivative	5
11	V920 Ebola vaccine 20,000,000 pfu/ml	4
12	Smallpox vaccine	3
13	Hepatitis A vaccines	2
14	Measles (live) vaccine Edmonston-Zagreb strain	1

2.5 Shortages

Table 5. Products notified claiming UK product shortages, 01 Jul 2018 - 30 Sep 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
Sucralfate tablets & suspensions	288
Liothyronine 20mcg tablets	60
Co-trimoxazole injections/infusions 480 mg/5ml	58
Co-phenotrope 2.5 mg + 25 mcg tablets 1 x 20	56
Lorazepam 2mg/ml injections	41
Potassium chloride retard 600 mg tablets	40
Human chorionic gonadotropin injections	35
Progesterone 100 mg/ml injection solutions	33
Trifluoperazine 1 & 5 mg tablets	33
Largactil 25 & 100 mg tablets	22
Ketotifen oral solutions 1mg/5ml	16
Haloperidol 5mg/ml injections	8
Bee venom allergy tests	5
Wasp venom allergy tests	5
Benzathine benzylpenicillin 2 400 000 IU injections	3
BCG vaccines & instillations	2
Ketamine 200mg/2ml injections	2
Phenobarbitone 200mg/ml injections	2
Sulfinpyrazone 200 mg tablets	2
Amino acid infant solutions for infusion	1
Arsenic trioxide injection concentrate 10mg/10ml	1
Lidocaine hydrochloride + adrenaline bitartrate 10mg/ml, 0.005mg/ml parenteral solutions	1
Pimozide 1 mg tablets	1
Taurolidin 2% solution	1
Tuberculin PPD	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 Jul 2018 - 30 Sep 2018

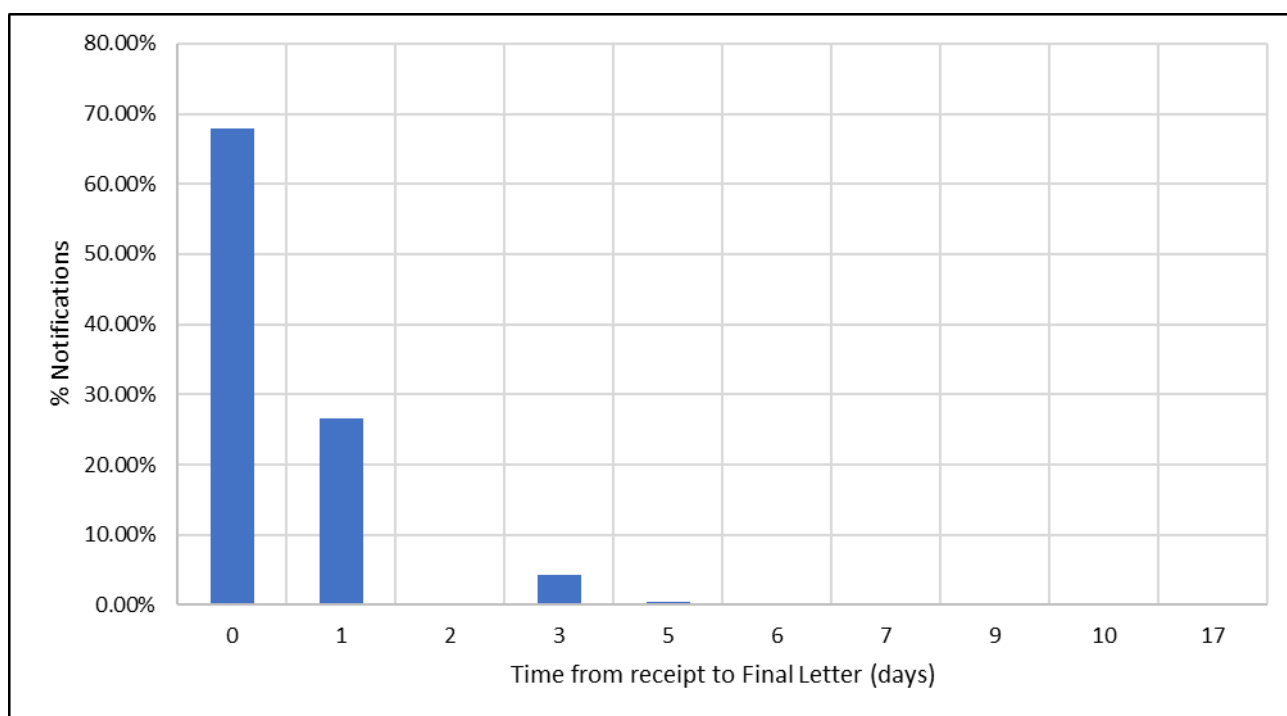


Table 6 Clinical Emergency Letter Timings,

Time to Process from Receipt	% Notifications
≤ 1day	94.51%
≤ 3 days	98.82%

3.2 Process timings – Objection letters

A total of 71 Objections with Reason were issued in Q3/2018. 70 were issued with 28 days of acknowledgement. The single notification outside of the 28 day period arose from concerns that a supplier might not be GDP compliant and was an instruction to cease distribution.

3.2.1 Summary of reasons for objections to import

Table 7 Reasons for objection to import

Summary	Number of notifications
Licensed product available in the UK	51
Inadequate assurance of GMP/GDP	8
Excessive quantity notified	7
Centrally authorised product notified (not unlicensed)	4
Ease of use not a valid special clinical need	1

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.

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.

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. 4 inspections were supported in Q3/2018 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 3, 2018. All letters of objection to import have been issued within 28 days of acknowledgements where these were issued, with 1 exception where an instruction to cease distribution was issued following concerns related to GDP compliance. The response times for urgent notifications continue to be good.