



Summary Report for Importation of Unlicensed Medicines

01 Oct 2018 – 31 Dec 2018

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1 Introduction and summary

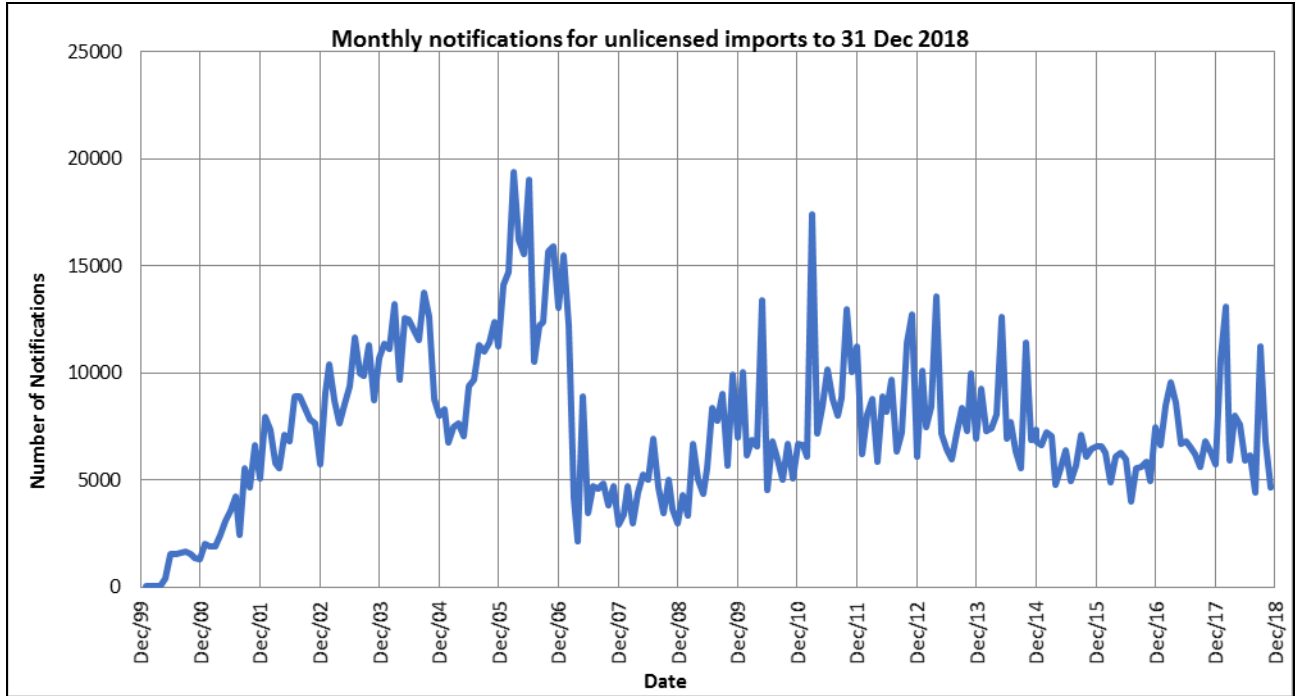
This report¹ covers the period 01-Oct-2018 to 31-Dec-2018 and shows the import notification system to be operating substantially within the requirements of SI 2012/1916.

¹ The data for this report were compiled in February 2019 and reflect the Import Notification System at this date.

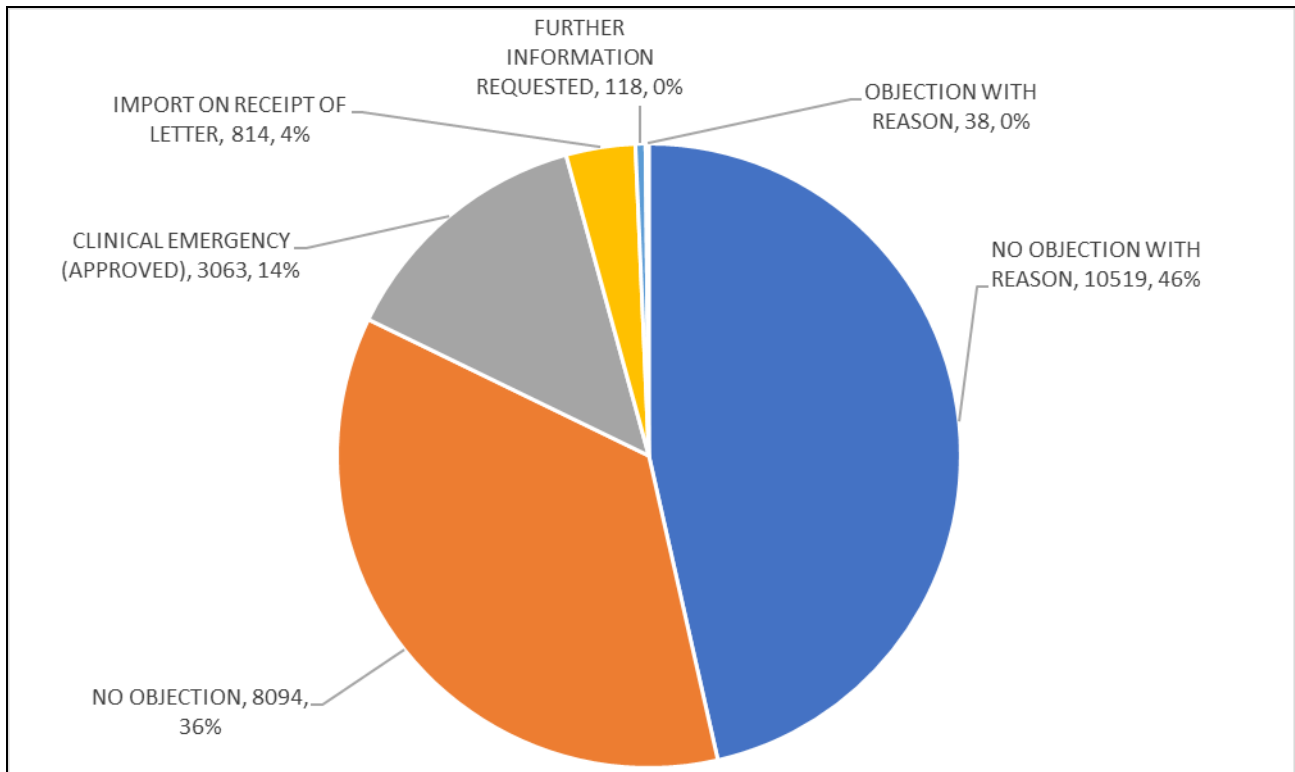
2 Notifications for importation

Graph 1 Monthly notifications for unlicensed imports

Note: Excludes invalid and cancelled notifications



Graph 2 Breakdown of valid notifications by status, 01 Oct – 31 Dec 2018



2.1 Importers

A total of 22646 notifications were received from 85 importers for the period 01 Oct 2018 to 31 Dec 2018. Of these, 10 importers accounted for approximately 80%.

Table 1 Valid notifications by importer 01 Oct 2018 - 31 Dec 2018

Importer Name	Number of Notifications	%
85 importers	22646	100%
Of which 10 importers	18084	~80%

2.2 Countries of export of products

Table 2 Countries of export 01 Oct 2018 - 31 Dec 2018

Rank	Exporting Country	Number of Notifications	Percentage Share
1	United States of America	5955	26.30%
2	Germany	5553	24.52%
3	Italy	2381	10.51%
4	France	1411	6.23%
5	Canada	1307	5.77%
6	Spain	868	3.83%
7	Australia	825	3.64%
8	The Netherlands	564	2.49%
9	Greece	449	1.98%
10	Portugal	395	1.74%
11	Switzerland	395	1.74%
12	Republic of Ireland	345	1.52%
13	Belgium	295	1.30%
14	India	278	1.23%
15	Poland	224	0.99%
16	Lithuania	219	0.97%
17	Austria	199	0.88%
18	Denmark	198	0.87%
19	Norway	146	0.64%
20	Japan	123	0.54%
21	Bulgaria	112	0.49%
22	Hungary	76	0.34%
23	New Zealand	72	0.32%
24	Czech Republic	60	0.26%
25	Cyprus	50	0.22%
26	Romania	30	0.13%
27	United Arab Emirates	26	0.11%
28	Slovenia	20	0.09%

Rank	Exporting Country	Number of Notifications	Percentage Share
29	Sweden	13	0.06%
30	China	12	0.05%
31	Guernsey	10	0.04%
32	Mexico	10	0.04%
33	Finland	8	0.04%
34	South Africa	6	0.03%
35	Latvia	4	0.02%
36	Russia	4	0.02%
37	Slovakia	2	0.01%
38	Republic of China	1	0.00%
	Sum:	22646	100.00%
	EEA	13622	60.15%
	Non-EEA	9024	39.85%

2.3 Most frequently notified products

Table 3 Top 50 frequently notified products 01 Oct 2018 - 31 Dec 2018

Rank	Product name	Number of Notifications	% all Notifications
1	Melatonin oral preparations	2910	12.85%
2	Homoeopathic preparations	1055	4.66%
3	Paclitaxel 100 mg (6 mg/ml) inj/inf	761	3.36%
4	Ondansetron 2 mg/ml injections	744	3.29%
5	Co-trimoxazole injections	665	2.94%
6	Calcium folinate 100 mg/10 ml solution for injection	602	2.66%
7	Progesterone injections (incl depot)	516	2.28%
8	Oral thyroid preparations, all combinations/strengths	495	2.19%
9	Tretinoin/vitamin A and hydroquinone (all combinations incl monocomponent) topicals (creams, ointments, gels etc., some with hydrocortisone)	435	1.92%
10	Sucralfate tablets & oral suspensions	409	1.81%
11	Mexiletine capsules & tablets	361	1.59%
12	Isoprenaline injections	337	1.49%
13	Bisacodyl 10 mg/30 ml enemas	329	1.45%
14	Pirenzepine 50 mg tablets	321	1.42%
15	Phenytoin oral suspensions	320	1.41%
16	Oxaliplatin 5 mg/ml infusion concentrate	319	1.41%
17	Triamcinolone acetonide, neomycin sulfate, nystatin, gramicidin ear ointments	310	1.37%
18	Vitamin oral preparations	291	1.28%
19	Allergy tests	278	1.23%
20	Potassium chloride oral controlled release preparations	266	1.17%
21	Human insulins	243	1.07%
22	Vitamin parenteral preparations	238	1.05%
23	Human chorionic gonadotrophin injections	230	1.02%
24	Saline in glass 0.90%	228	1.01%
25	Artesunate 60 mg injections	223	0.98%
26	Sodium nitroprusside injections	216	0.95%
27	Iloprost injections	196	0.87%
28	Metolazone 2.5 & 5 mg tablets	190	0.84%

Rank	Product name	Number of Notifications	% all Notifications
29	Clindamycin 75 mg/5 ml oral suspensions	184	0.81%
30	Furosemide 20 & 40 mg tablets	171	0.76%
31	Diazoxide oral preparations (capsules, suspensions)	170	0.75%
32	Durvalumab 500 mg conc for inf soln 50 mg/ml	166	0.73%
33	Bleomycin 15 000 IU injections	158	0.70%
34	Indigo carmine 10mg/ml 1% topical mucosal sprays	150	0.66%
35	Adrenaline pre-filled syringes	144	0.64%
36	Podophyllotoxin 0.15% creams	140	0.62%
37	Mercaptopurine 10 mg tablets	139	0.61%
38	Flunarizine tablets & capsules, all strengths	127	0.56%
39	Nimodipine 30 mg tablets	118	0.52%
40	Benzathine benzylpenicillin injections	117	0.52%
41	Talc for pleurodesis	111	0.49%
42	Povidone-iodine 5% ophthalmic solutions	106	0.47%
43	Cefoxitin injections	104	0.46%
44	Risperidone tablets, all strengths	104	0.46%
45	Lonafarnib 50 & 75 mg capsules	96	0.42%
46	Procaine benzylpenicillin injections	96	0.42%
47	Betamethasone 4 mg/ml injections	94	0.42%
48	Polymyxin B and bacitracin zinc ointments	92	0.41%
49	Sultiame 50 & 200 mg tablets	92	0.41%
50	Tetracosactide injections (incl depot)	92	0.41%
	Sum	16259	71.80%

2.4 Vaccines and immunoglobulins

Table 4 Vaccines & immunoglobulins 01 Oct 2018 - 31 Dec 2018

Rank	Proprietary name	Number of Notifications
1	Tetanus immunoglobulin human 250iu/ml injections	49
2	Lymphocyte immune globulin anti thymocyte globulin (equine) 50 mg/ml injections	21
3	Tuberculin purified protein derivative	20
4	Influenza vaccines	17
5	Human varicella-zoster immunoglobulin 25iu/ml solution for infusion	8
6	Tetanus, diphtheria, pertussis and polio (TDAP/IPV) vaccines	8
7	Human normal immunoglobulin 160 g/l solution for injections	7
8	DTAP/IPV-HIB vaccines	6
9	BCG vaccines & instillations	4
10	Ebola Zaire vaccines	4
11	Snake antivenoms	4
12	Diphtheria+tetanus+pertussis vaccines	2
13	Diphtheria antitoxin	1
14	Hepatitis B immunoglobulin (human) 50iu/ml	1
15	Human varicella immunoglobulin IM injection	1

2.5 Shortages

Table 5. Products notified claiming UK product shortages, 01 Oct 2018 - 31 Dec 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
Ondansetron hydrochloride injections	480
Sucralfate tablets & suspensions	265
Co-trimoxazole injections/infusions 480mg/5ml	110
Co-phenotrope 2.5/0.025mg tablets	78
Progesterone 100mg solution for injection	63
Human chorionic gonadotrophin injections	44
Disulfiram tablets 200mg	40
Fluphenazine decanoate injections	16
Influenza vaccines	14
Haloperidol 5mg/ml injections	12
Perphenazine tablets 2 mg	10
Tetanus, diphtheria, pertussis and polio low dose (TDAP/IPV) 0.5ml PFS	8
Atropine sulfate 0.4mg/ml injection	4
Bleomycin injection 15,000iu	4
C1 esterase inhibitor 1500iu powder for solution for injection	4
Glycopyrronium bromide/neostigmine methylsulfate 0.5mg/ml + 2.5mg/ml injections	4
Ketotifen oral solution 1mg/5ml	4
Sulfinpyrazone 200 mg tablets	3
Tobramycin injections 1.2g	3
Etoposide 50 mg capsules	2
Potassium chloride retard 600mg tabs	2
Risperidone 0.5 & 1mg tablets	2
Trifluoperazine 5 mg tablets	2
Tuberculin purified protein derivative	2
Bacillus calmette guerin (BCG) 40 mg/ml lyophilisate for suspension for bladder instillation	1
Gadopentetate dimeglumine 2mmol/l injection	1
Ketamine hydrochloride 200mg/2ml injection	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 Dec 2018 - 31 Dec 2018

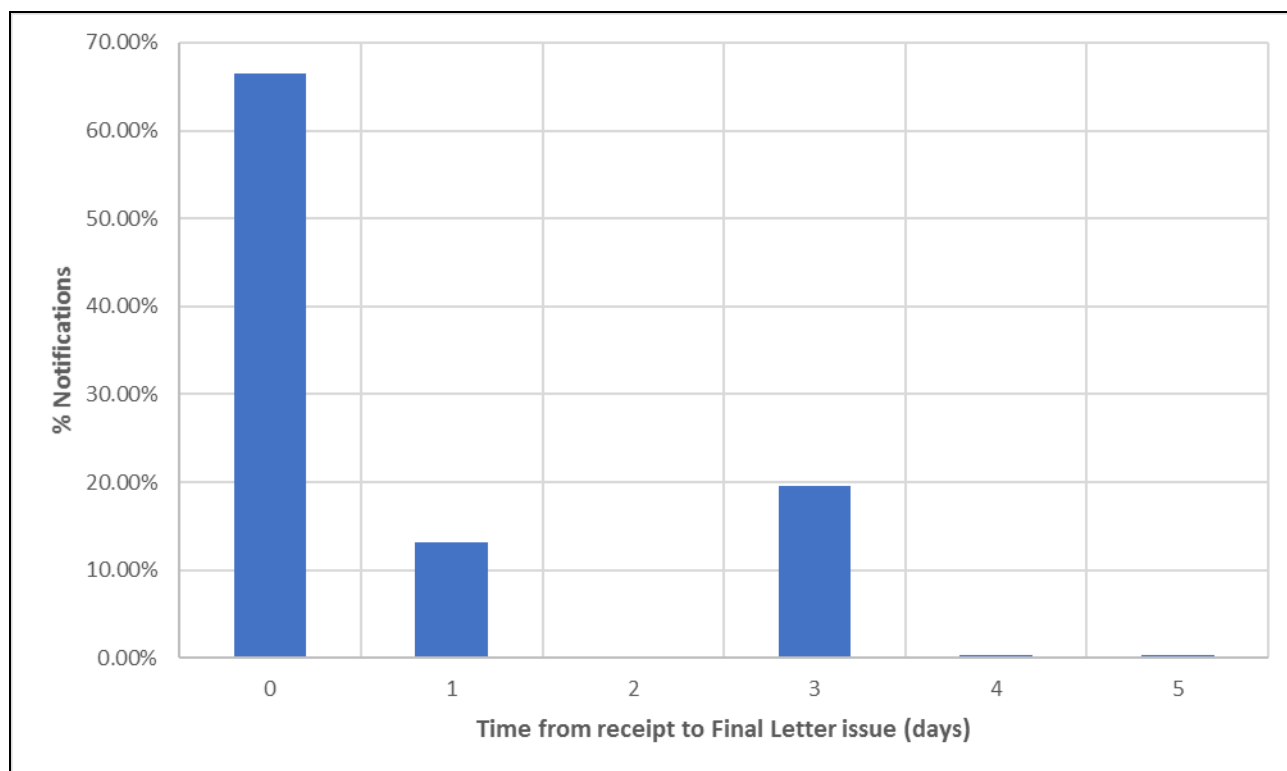


Table 6 Clinical Emergency Letter Timings,

Time from submission to final letter (days)	% of Urgent Notifications
≤ 1	79.63%
≤ 3	99.58%

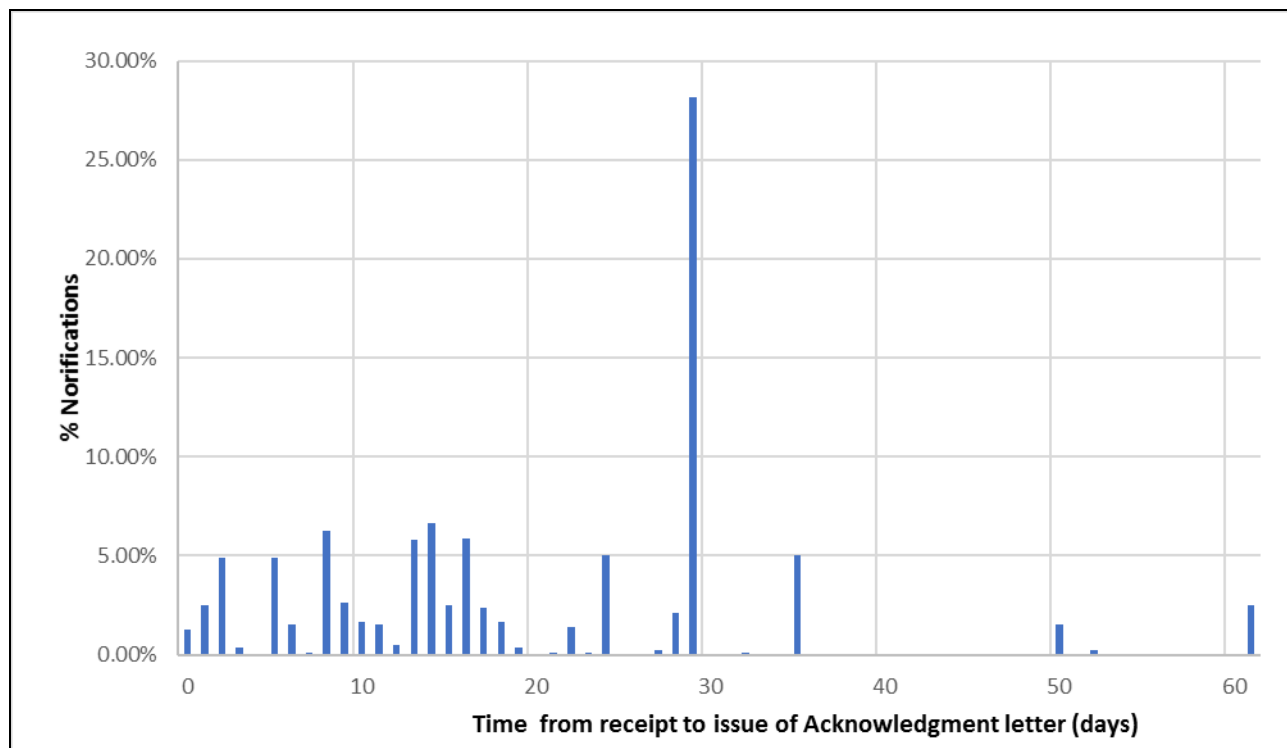
3.2 Process timings – Routine notifications

Graph 4 shows statistics for 796 notifications for Q4/2018 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.

Significant delays can be experienced due to the time taken to obtain any additional information. There may also be delays due to the time taken to enter the data for submissions with large numbers of notifications before acknowledgement letters can be issued.

Approximately 90% of acknowledgements were issued within 29 days of receipt of notifications.

Graph 4 Time to issue Acknowledgements, 01 Oct 2018 - 31 Dec 2018



3.3 Process timings – Objection letters

A total of 38 Objections with Reason were issued in Q4/2018. All were issued with 28 days of acknowledgement where acknowledgments were issued.

3.3.1 Summary of reasons for objections to import

Table 7 Reasons for objection to import

Summary	Number of notifications
Patient safety concerns	18*
Centrally authorised product notified (not unlicensed)	17
Excessive quantity notified	3

* Includes 2 cisapride notifications: The MHRA objects to importation of all cisapride products on grounds of safety following CSM advice of March 2004 and July 2000

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. 6 inspections were supported in Q4/2018 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 4, 2018. All letters of objection to import have been issued within 28 days of acknowledgements where these were issued. The response times for urgent notifications continue to be good.