



# Summary Report for Importation of Unlicensed Medicines

01 Jan 2018 – 31 Mar 2018

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# 1 Introduction and summary

This report<sup>1</sup> covers the period 01-Jan-2018 to 31-Mar-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.

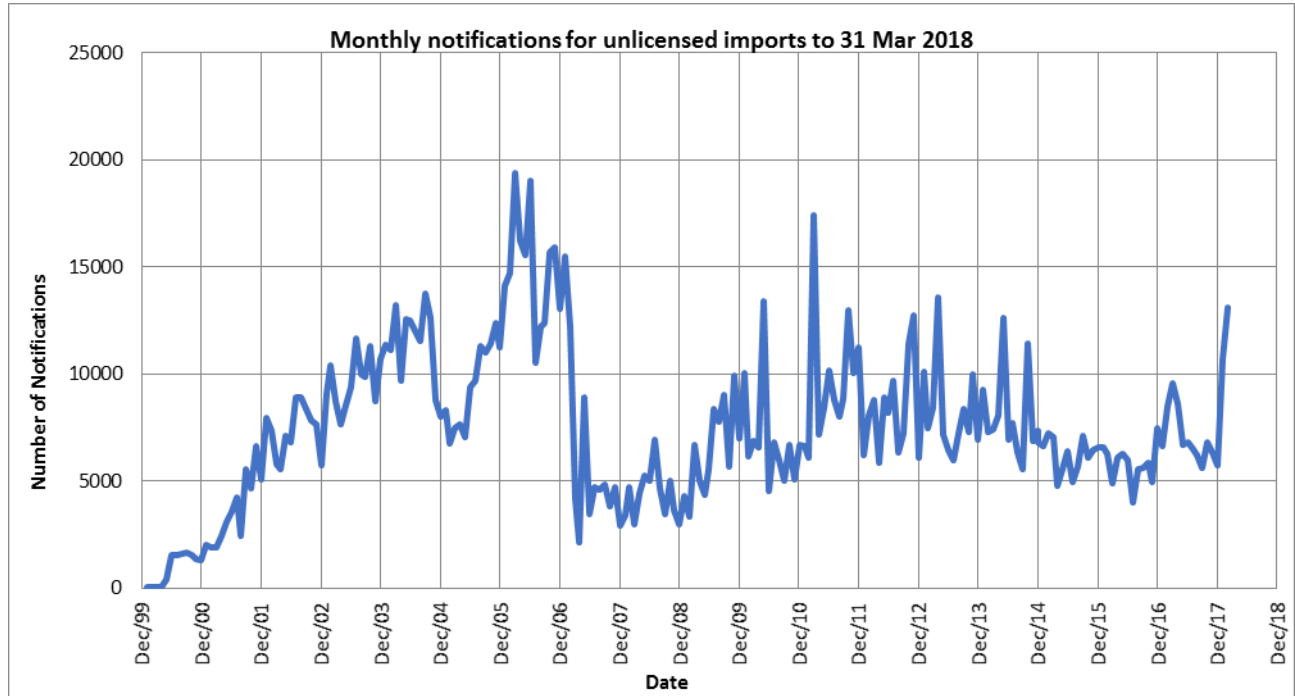
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<sup>1</sup> The data for this report were compiled in October 2018 and reflect the Import Notification System at this date.

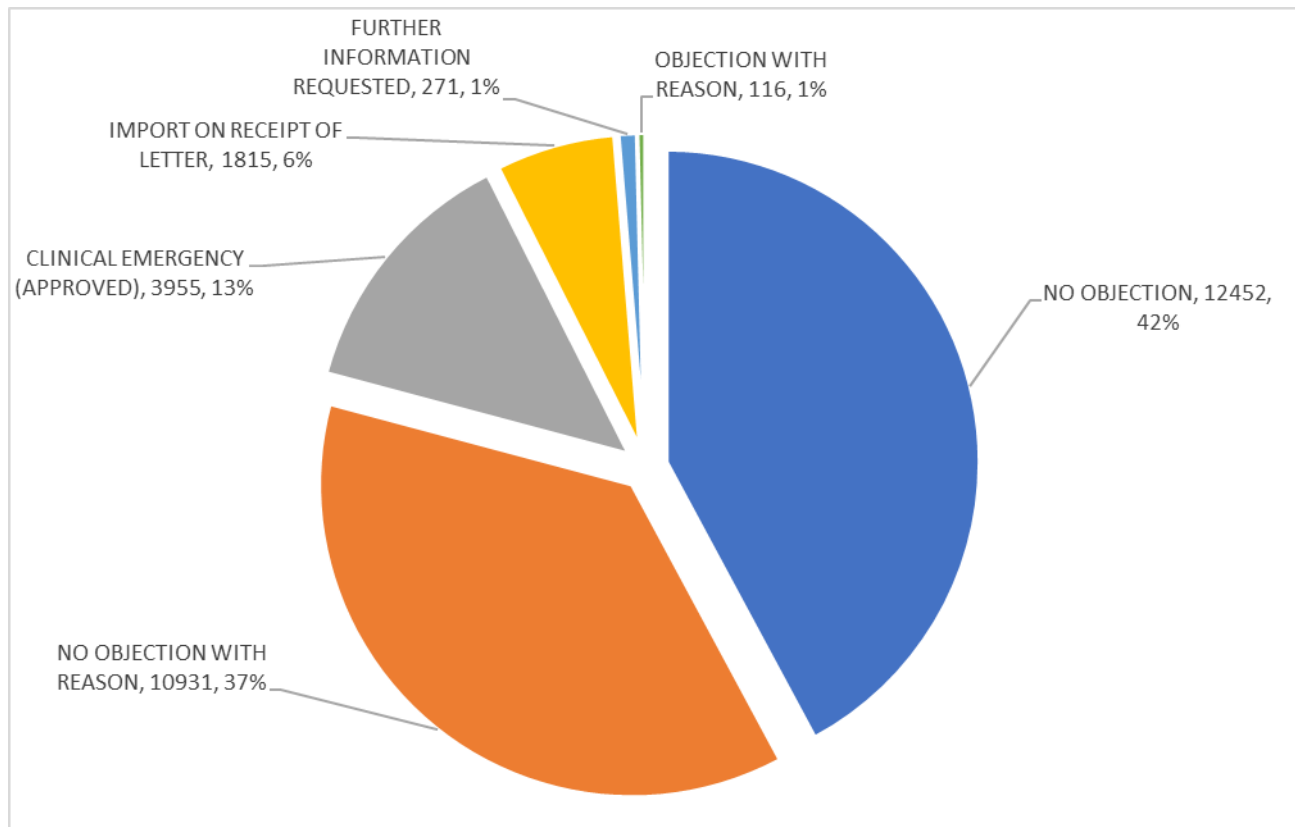
## 2 Notifications for importation

**Graph 1 Monthly notifications for unlicensed imports**

Note: Excludes invalid and cancelled notifications



**Graph 2 Breakdown of valid notifications by status, 01 Jan – 31 Mar 2018**



## 2.1 Importers

A total of 29540 notifications were received from 87 importers for the period 01 Jan 2018 to 31 Mar 2018. Of these, 5 importers accounted for approximately 80%.

**Table 1 Valid notifications by importer 01 Jan – 31 Mar 2018**

Importer Name	Number of Notifications	Percentage Share
87 importers	29540	100%
Of which 5 importers	24684	78.7%

## 2.2 Countries of export of products

**Table 2 Countries of export 01 Jan – 31 Mar 2018**

Rank	Exporting Country	Number of Notifications	Percentage Share
1	Germany	6433	21.78%
2	United States of America	4196	14.20%
3	Italy	3768	12.76%
4	France	2457	8.32%
5	Canada	2428	8.22%
6	Spain	2100	7.11%
7	Switzerland	1919	6.50%
8	Belgium	1091	3.69%
9	Australia	1063	3.60%
10	The Netherlands	817	2.77%
11	Austria	590	2.00%
12	Poland	540	1.83%
13	Denmark	331	1.12%
14	India	301	1.02%
15	Czech Republic	245	0.83%
16	Japan	243	0.82%
17	Portugal	213	0.72%
18	Norway	136	0.46%
19	Republic of Ireland	122	0.41%
20	Israel	82	0.28%
21	Sweden	72	0.24%
22	Hungary	68	0.23%
23	Lithuania	68	0.23%
24	Greece	58	0.20%
25	New Zealand	54	0.18%
26	China	40	0.14%
27	Romania	37	0.13%
28	Bulgaria	18	0.06%
29	Finland	17	0.06%
30	Taiwan	9	0.03%

Rank	Exporting Country	Number of Notifications	Percentage Share
31	Costa Rica	8	0.03%
32	South Africa	8	0.03%
33	Latvia	5	0.02%
34	Russia	2	0.01%
35	Taiwan RoC	1	0.00%
	<b>Sum:</b>	<b>29540</b>	<b>100.00%</b>

## 2.3 Most frequently notified products

**Table 3 Top 50 frequently notified products 01 Jan – 31 Mar 2018**

Rank	Product name	Number of Notifications	% all Notifications
1	Oral thyroid preparations, all combinations/strengths	1526	5.17%
2	Homoeopathic preparations	1004	3.40%
3	Clindamycin 150mg/ml parenterals	968	3.28%
4	Sucralfate oral preparations (tablets/suspensions)	865	2.93%
5	Clindamycin 75mg/5ml oral suspensions	592	2.00%
6	Co-trimoxazole injections/infusions, all strengths	549	1.86%
7	Vitamin oral/nasal preps	541	1.83%
8	Pirenzepine 50 mg tablets	488	1.65%
9	Melatonin oral preps	444	1.50%
10	Allergy tests	433	1.47%
11	Tretinoin/vitamin A and hydroquinone (all combinations incl monocomponent) topicals (creams oints., gels etc., some with hydrocortisone)	386	1.31%
12	Isoprenaline 0.2 mg/ml injections	380	1.29%
13	Progesterone injections	344	1.16%
14	Insulin injections, all strengths	340	1.15%
15	Indigo carmine 20mg/5ml injections	339	1.15%
16	Lidocaine 10% pump sprays	311	1.05%
17	Sodium nitroprusside 50mg injections/infusions	310	1.05%
18	Vitamin injections	273	0.92%
19	Povidone iodine ophthalmic solutions	272	0.92%
20	Mexiletine capsules all strengths	271	0.92%
21	BCG vaccines and instillations	268	0.91%
22	Rurioctocog alfa pegol infusions, all strengths	256	0.87%
23	Chlorpromazine tablets, all strengths	247	0.84%
24	Betamethasone sodium phosphate 4mg/1ml injections	235	0.80%
25	Disulfiram 250 & 500 mg tablets	233	0.79%
26	Paclitaxel 100mg (6mg/ml) inj/inf	232	0.79%
27	Benzathine benzylpenicillin injections	227	0.77%
28	Human chorionic gonadotrophin injections	225	0.76%
29	Benzatropine mesylate 1 & 2 mg tabs	213	0.72%
30	Flunarizine tablets & capsules, all strengths	209	0.71%
31	Ubidecarenone (co-enzyme Q-10) oral preparations	206	0.70%
32	Digoxin immune fab (ovine) 40mg lyophilisate for sol for infn	201	0.68%
33	Hepatitis B vaccines	200	0.68%
34	Hyoscine butylbromide 20mg/ml solution for injection	195	0.66%
35	Apalutamide 60 mg tablets	190	0.64%
36	Cytarabine injections/infusions	182	0.62%
37	Vincristine injections	181	0.61%
38	Methotrexate injections, all strengths	180	0.61%

Rank	Product name	Number of Notifications	% all Notifications
39	Potassium chloride oral controlled release preps	179	0.61%
40	Canrenoate 200mg/10ml injections	171	0.58%
41	Phenylephrine 10 mg/ml injections	163	0.55%
42	Aciclovir injections	162	0.55%
43	Iloprost trometamol injections/infusions	162	0.55%
44	Acetylcysteine oral preps	158	0.53%
45	Diphenoxylate 2.5 mg + 25 mcg tablets	156	0.53%
46	Allergy treatments SCIT/SLIT etc	152	0.51%
47	Talc for pleurodesis	152	0.51%
48	Durvalumab injections/infusions	151	0.51%
49	Povidone iodine ointments & topical liquids	147	0.50%
50	Mercaptopurine	136	0.46%
	<b>Sum</b>	<b>16405</b>	<b>55.53%</b>

## 2.4 Vaccines and immunoglobulins

**Table 4 Vaccines & immunoglobulins 01 Jan – 31 Mar 2018**

Rank	Product Name	Number of Notifications
1	BCG vaccines & instillations	268
2	Hepatitis B vaccines	200
3	Human normal immunoglobulin	93
4	Hepatitis A vaccines	69
5	Diphtheria and tetanus toxoids and acellular pertussis vaccine	57
6	Lymphocyte immune globulin, anti-thymocyte (equine)	49
7	Diphtheria-tetanus-acellular pertussis (DTPA) and inactivated poliovirus vaccine	36
8	Tuberculin PPD	25
9	Rabies vaccines	21
10	Haemophilus influenzae type B vaccines	20
11	Diphtheria+tetanus+acellular pertussis+inactivated poliomyelitis+haemophilus influenza type B conjug vaccines	16
12	Meningococcal group b vaccine (rDNA,multi component,adsorbed)	10
13	Anti-D (rho) immunoglobulin (human)	9
14	Measles (live) Edmonston-Zagreb strain vaccines	9
15	Diphtheria tetanus & poliomyelitis inactive adsorb vaccine	8
16	Meningitis C vaccines	8
17	Tetanus immunoglobulin	7
18	Botulism immune globulin intravenous (human) (BIG IV)	1
19	CMV immunoglobulin	1
20	Diphtheria antitoxin	1
21	IgM enriched normal human immunoglobulin	1
22	Influenza vaccine (inactivated)	1

## 2.5 Shortages

**Table 5. Products notified claiming UK product shortages, 01 Jan – 31 Mar 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
Co-trimoxazole injections/infusions 480mg/5ml	100
Chloramphenicol sol for injection 1g	86
Human chorionic gonadotrophin all strengths	55
Hepatitis A vaccine	50
Liothyronine 20mcg tablets	40
Trifluoperazine tablets, 1 mg & 5 mg	39
Tuberculin PPD	25
Tetanus, diphtheria, pertussis and polio vaccines	20
Aztreonam injection 1g	16
Ketotifen oral solution 1mg/5ml	16
Sulfinpyrazone 200 mg tablets	13
Vinblastine sulphate injection 1mg/ml	13
Flecainide acetate 10 mg/ml injections	12
Rabies vaccine	12
Vincristine sulfate injection 1mg/1ml	11
Bacillus calmette guerin (BCG) vaccines & instillations	10
Etoposide 50 mg capsules	9
Flucytosine 2.5 g/250 ml infusion solns	9
Methotrexate injections	9
Nandrolone decanoate injection 50mg/ml	9
Diphtheria tetanus & poliomyelitis inactive adsorb vaccine	8
Fluorescein 10% soln for injection	8
Tetracosactide depot 1mg/ml injection	8
Haloperidol 5mg/ml injections	7
Ketamine hydrochloride 200mg/2ml injection	7
Taurolidin 2% solution	7
Cytarabine 100mg/ml injections	6
Amikacin sulfate solution for injection 500mg/2ml	3
Edrophonium 10mg/ml injection	3
Clindamycin solution for injection 150mg/ml	2
Ribavirin inhalation solns	2
Arsenic trioxide injection concentrate 10mg/10ml	1
Bee venom allergy tests	1
Fomepizole 1g/ml solution for injection	1
Lipid emulsions for infusion	1
Mupirocin nasal ointment	1
Phenazopyridine 100 mg tablets	1
Vasopressin 20 USP units/ml injection	1
Wasp venom allergy tests	1

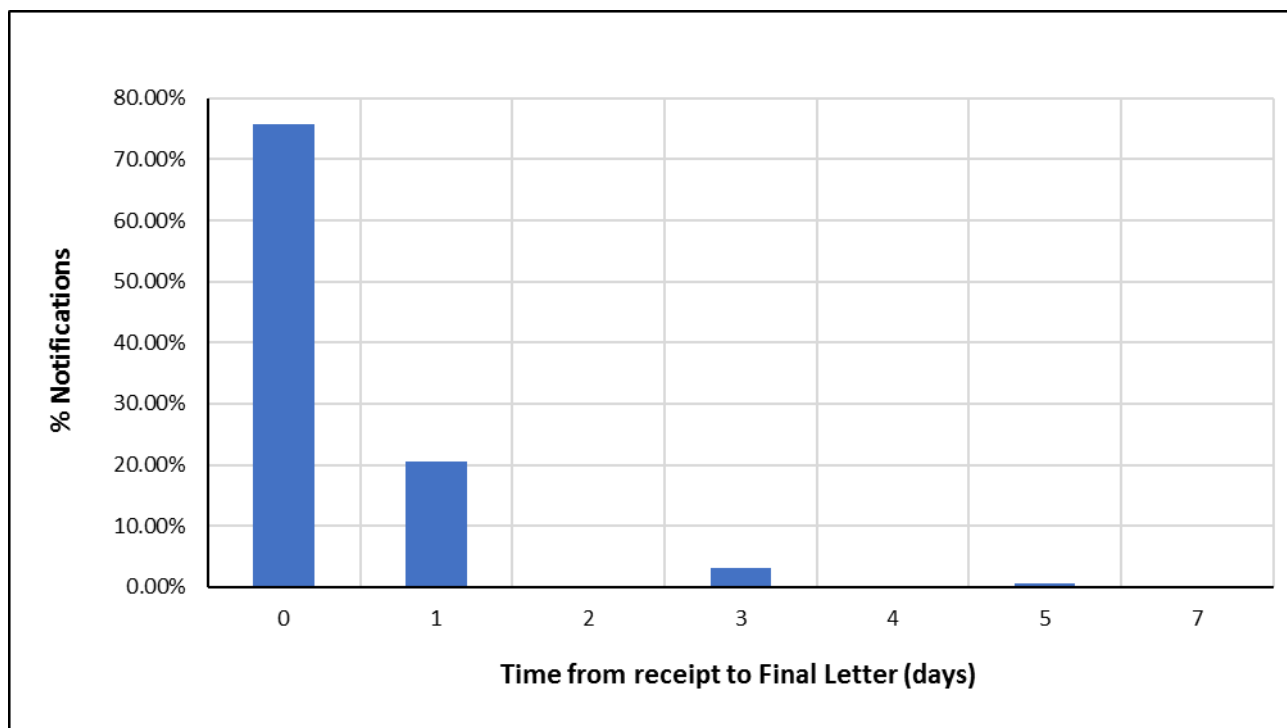


### 3 Administrative matters

#### 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 Jan – 31 Mar 2018**



**Table 6 Clinical Emergency Letter Timings,**

Time to Process from Receipt	% Notifications
≤ 1day	96.18% issued within 1 day
≤ 3 days	99.37% issued within 3 days

## 3.2 Process timings – Objection letters

A total of 116 Objections with Reason were issued in Q1/2018. 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
Quantity notified exceeded that permitted in SI 2012/1916	3
Equivalent UK licensed product available	63
Product was Centrally Authorised and therefore not unlicensed	50

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.

## **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. 3 inspections were supported in Q1/2018 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 1, 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.