



# Summary Report for Importation of Unlicensed Medicines

01 Apr 2016 – 30 Jun 2016

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# 1 Introduction and summary

This report<sup>1</sup> covers the period 01-Apr-2016 to 30-Jun-2016 and shows the import notification system to be operating substantially within the requirements of SI 2012/1916.

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<sup>1</sup> The data for this report were compiled in November 2016 and reflect the Import Notification System at this date.

## **2 News and current issues**

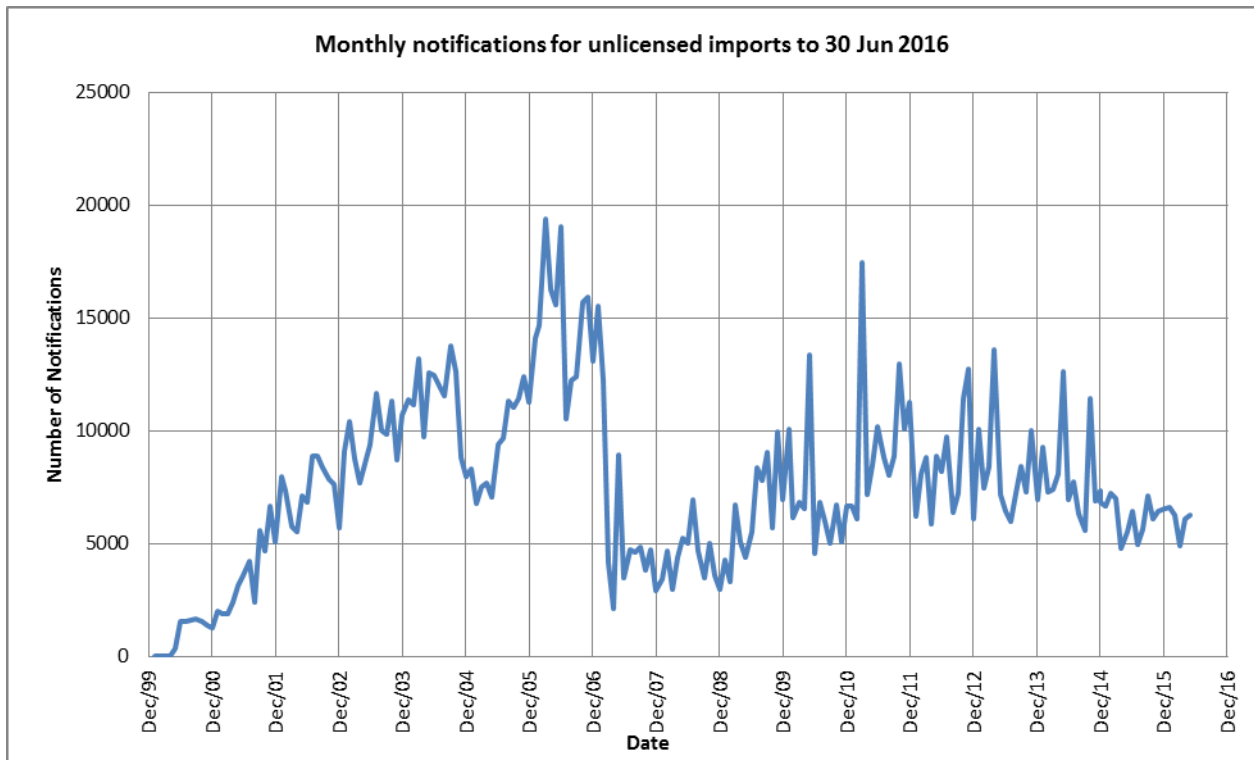
We continue to receive notifications for import from the UK. Importers are reminded to ensure that import notifications are in fact for imports.

Similarly notifications continue to be received for products with Centrally Authorised licences valid in all EEA Member States. These are therefore not unlicensed medicines and cannot be imported as such.

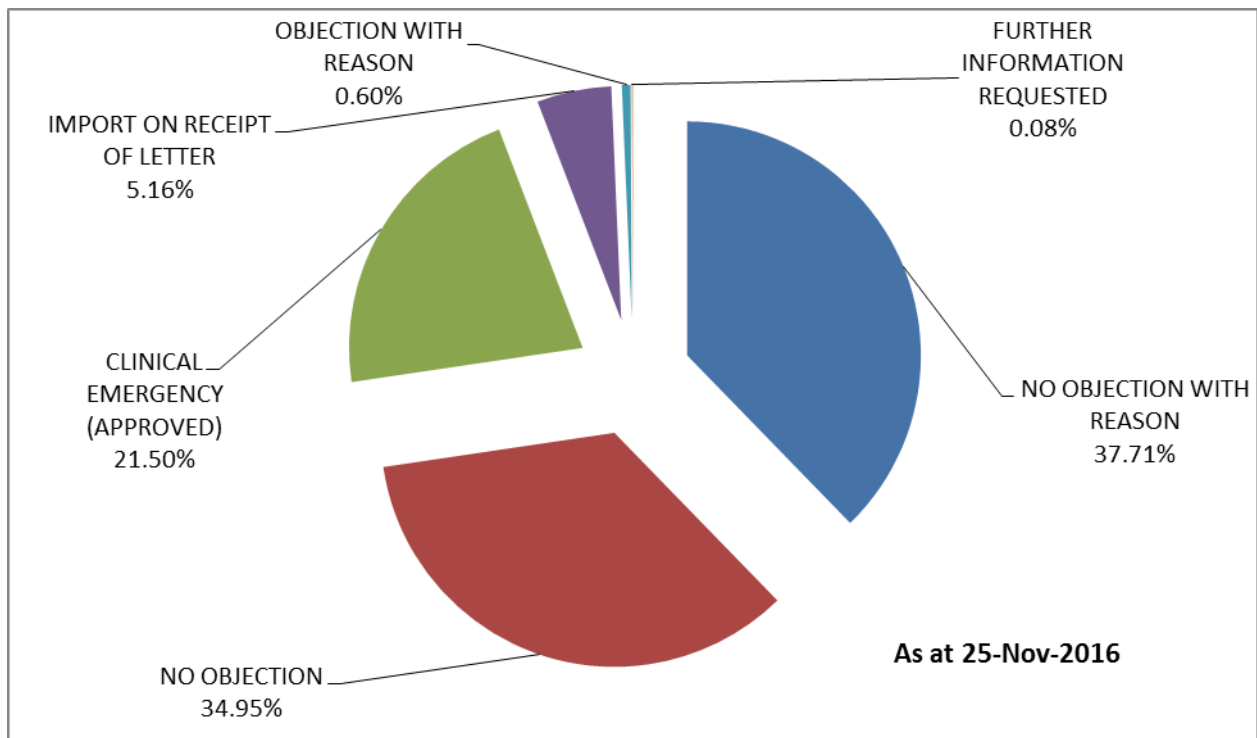
### 3 Notifications for importation

**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 2016**



### 3.1 Importers

A total of 17225 notifications were received from 96 importers for the period 01 Apr 2016 to 30 Jun 2016. Of these, 10 importers accounted for approximately 75%.

**Table 1 Valid notifications by importers 01 Apr 2016 to 30 Jun 2016**

Importer Details	Number of Notifications	Percentage Share
96 importers	17225	100%
Of which 7 importers	12998	~75%

### 3.2 Countries of export of products

**Table 2 Countries of export 01 Apr 2016 to 30 Jun 2016**

Rank	Exporting Country	Number of Notifications	% Share
1	Germany	3512	20.39%
2	United States of America	2948	17.11%
3	Italy	1767	10.26%
4	France	1653	9.60%
5	Australia	1187	6.89%
6	India	913	5.30%
7	Spain	903	5.24%
8	Canada	763	4.43%
9	Belgium	487	2.83%
10	The Netherlands	388	2.25%
11	Denmark	382	2.22%
12	United Arab Emirates	334	1.94%
13	Switzerland	276	1.60%
14	Lithuania	225	1.31%
15	Latvia	219	1.27%
16	Portugal	180	1.04%
17	Czech Republic	121	0.70%
18	New Zealand	114	0.66%
19	Guernsey	98	0.57%
20	Poland	98	0.57%
21	Sweden	96	0.56%
22	Norway	91	0.53%
23	Austria	87	0.51%
24	Argentina	81	0.47%
25	Romania	80	0.46%
26	United Kingdom*	48	0.28%
27	Greece	37	0.21%
28	Japan	31	0.18%
29	Republic of Ireland	25	0.15%

Rank	Exporting Country	Number of Notifications	% Share
30	Finland	20	0.12%
31	Slovakia	20	0.12%
32	Hungary	19	0.11%
33	South Africa	10	0.06%
34	Costa Rica	9	0.05%
35	Mexico	3	0.02%
	<b>Sum:</b>	<b>17225</b>	<b>100.00%</b>
	<b>EEA</b>	<b>10556</b>	<b>61.28%</b>
	<b>Non-EEA</b>	<b>6669</b>	<b>38.72%</b>

\*UK is not an acceptable exporting country!

### 3.3 Most frequently notified products

Table 3 Top 50 frequently notified products 01 Apr 2016 to 30 Jun 2016

Rank	Product name	Number of Notns	% all Notns
1	Melatonin oral preparations	922	5.35%
2	Homoeopathics	793	4.60%
3	Co-proxamol 325/32.5mg tablets	631	3.66%
4	Bacillus Calmette Guerin (BCG) instillations and vaccines	605	3.51%
5	Progesterone injections	511	2.97%
6	Vitamins - oral	478	2.78%
7	Thyroid oral preps	461	2.68%
8	Allergy tests	420	2.44%
9	Melphalan 50 mg injections & infusions	415	2.41%
10	Paclitaxel 100 mg injections	400	2.32%
11	Sucralfate oral suspensions and tablets	351	2.04%
12	Co-trimoxazole inj/inf 480mg/5ml	331	1.92%
13	Potassium chloride 600 mg SR tabs & caps	291	1.69%
14	Gadoteric acid 279.32mg (0.5mmol/ml) injections	250	1.45%
15	Tretinoin/vitamin A and hydroquinone (all combinations) topicals (creams oints., gels etc.)	248	1.44%
16	Venetoclax tablets, all strengths	238	1.38%
17	Imipenem-cilastatin 500mg inj/inf soln	228	1.32%
18	Talc for pleurodesis	213	1.24%
19	Carboplatin 10mg/ml infusion concentrate	200	1.16%
20	Aspirin 300mg suppositories	189	1.10%
21	Remifentanil injections	188	1.09%
22	Tuberculin PPD 5 TU injections	183	1.06%
23	Pentosan polysulphate 50 & 100 mg capsules	175	1.02%
24	Povidone-iodine topical preps	169	0.98%
25	Triamcinalone ear ointments	169	0.98%
26	Cor-00.3 150mg tabs	160	0.93%
27	Clindamycin grans/suspensions for sol 75mg/5ml	157	0.91%
28	Lu-dota, tyr ocreotatate, lutetium-177 (177 Lu) labelled	156	0.91%
29	Metolazone 2.5 & 5 mg tabs	149	0.87%
30	Cefoxitin injections	143	0.83%
31	Fluphenazine injections	131	0.76%
32	Sodium chloride 0.9% w/v injections/infusions	131	0.76%
33	Betamethasone injections	126	0.73%
34	Ustekinumab 130 mg vials	125	0.73%

Rank	Product name	Number of Notns	% all Notns
35	Isosorbide dinitrate 5mg sublingual tablets	120	0.70%
36	Pirenzepine 50mg tablets	118	0.69%
37	Acetylcysteine oral preps	113	0.66%
38	Benzathine benzylpenicillin injections	111	0.64%
39	Allergy treatments SCIT, SLIT etc	107	0.62%
40	Albendazole 400mg tablets	104	0.60%
41	Fumaric acid esters 30 & 120mg tablets	104	0.60%
42	Vitamins - parenteral	99	0.57%
43	Ciclosporine ophthalmic preps	96	0.56%
44	Rifaximin oral suspension 2g/100ml	93	0.54%
45	Idebenone tablets & capsules	91	0.53%
46	Indigo carmine injections	91	0.53%
47	Nadolol 40 & 80mg tabs	89	0.52%
48	Sodium nitroprusside 50mg pow/soln for inj	87	0.51%
49	Bisacodyl enemas	85	0.49%
50	Daratumumab 20mg/ml infus/inj	84	0.49%
	<b>Sum</b>	<b>11929</b>	<b>69.25%</b>

### 3.4 Vaccines and immunoglobulins

**Table 4 Vaccines & immunoglobulins 01 Apr 2016 to 30 Jun 2016**

Rank	Product name	Number of Notifications
1	Bacillus Calmette Guerin (BCG) vaccines & instillations	605
2	Tuberculin PPD 5IU/0.1ml injection soln	183
3	Hepatitis a, inactivated, adsorbed 50 IU/ml suspension for injection	8
4	Inactivated polio vaccine suspension for injection	8
5	IgM enriched normal human immunoglobulin solution for infusion 5%	7
6	Measles vaccine	4
7	CMV immunoglobulin 5% infn soln 100 IU/ml	3
8	Human papillomavirus 9-valent vaccine, recombinant suspension for injection	2
9	Meningitis B vaccination PFS	2
10	Diphtheria and tetanus vaccine	1
11	Diphtheria+tetanus+acellular pertussis+inactivated poliomyelitis+haemophilus influenza type B conjug suspension for injection	1
12	Lymphocyte immune globulin anti thymocyte globulin (equine) 50 mg/ml injection soln	1
13	Rabies vaccine 2.5 IU/0.5ml	1
14	Tetanus toxoid absorbed 40 IU suspn for inj	1



### 3.5 Shortages

**Table 5. Products notified claiming UK product shortages, 01 Apr 2016 to 30 Jun 2016**

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

Proprietary Name	Number of Notifications
Bacillus Calmette Guerin (BCG) vaccines & instillations	604
Progesterone Injections	447
Sucralfate Tablets & Oral Suspensions	349
Co-Trimoxazole Inj/Inf 480mg/5ml	330
Melphalan 50mg Injections/Infusions	302
Potassium Chloride 600 mg SR Tabs & Caps	292
Gadoteric Acid 279.32mg (0.5mmol/ml)	250
Tuberculin PPD 5 IU/0.1ml Injections	183
Fluphenazine Injections	144
Salbutamol 500mcg/ml Injections	58
Trifluoperazine 1 & 5mg Tablets	30
Co-Phenotrope (Diphenoxylate Hydrochloride + Atropine Sulfate) 2.5 mg + 25 mcg Tablets	28
Levomepromazine 25mg & 100 mg Tabs	26
Fludrocortisone 0.1 mg Tablets	24
Liothyronine 20 & 25 mcg Tablets	20
Prednisolone 1% Ophthalmic Drops	16
Betamethasone 0.5mg Eff Tabs	16
Disulfiram 250 & 500 mg Tablets	14
Perphenazine Tablets, all strengths	14
Hydroxyzine 2 mg/ml Syrup	13
Etoposide 50 & 100 mg Capsules	12
Human Von Willebrand Factor 1000 IU Injection	11
Perphenazine Decanoate Injection 108 mg/ml	9
Sotalol 160 mg Tablets	8
Testosterone Capsules 40 mg	8
Fluphenazine Tablets 1 mg	5
Acetazolamide 500 mg Inj	4
Betamethasone Disodium Phosphate 4mg/ml Inj Soln	4
Bleomycin 15000 IE Injections	4
Imipenem-Cilastatin 500mg Inj/Inf Soln	4
Itraconazole 10mg/ml Injection	4
Ketamine 200 mg/2 ml Injection Soln	4
Mivacurium 2mg/ml Injections	4
Quinagolide 75mcg Tablets	4
Haloperidol 5mg/ml Injections	3
Triamcinalone Acetonide 10mg Inj Susp	3
Fluconazole Capsules 50mg	3
Iopamidol IV Contrast Agents	3
Methylprednisolone 100 mg Tablets	3

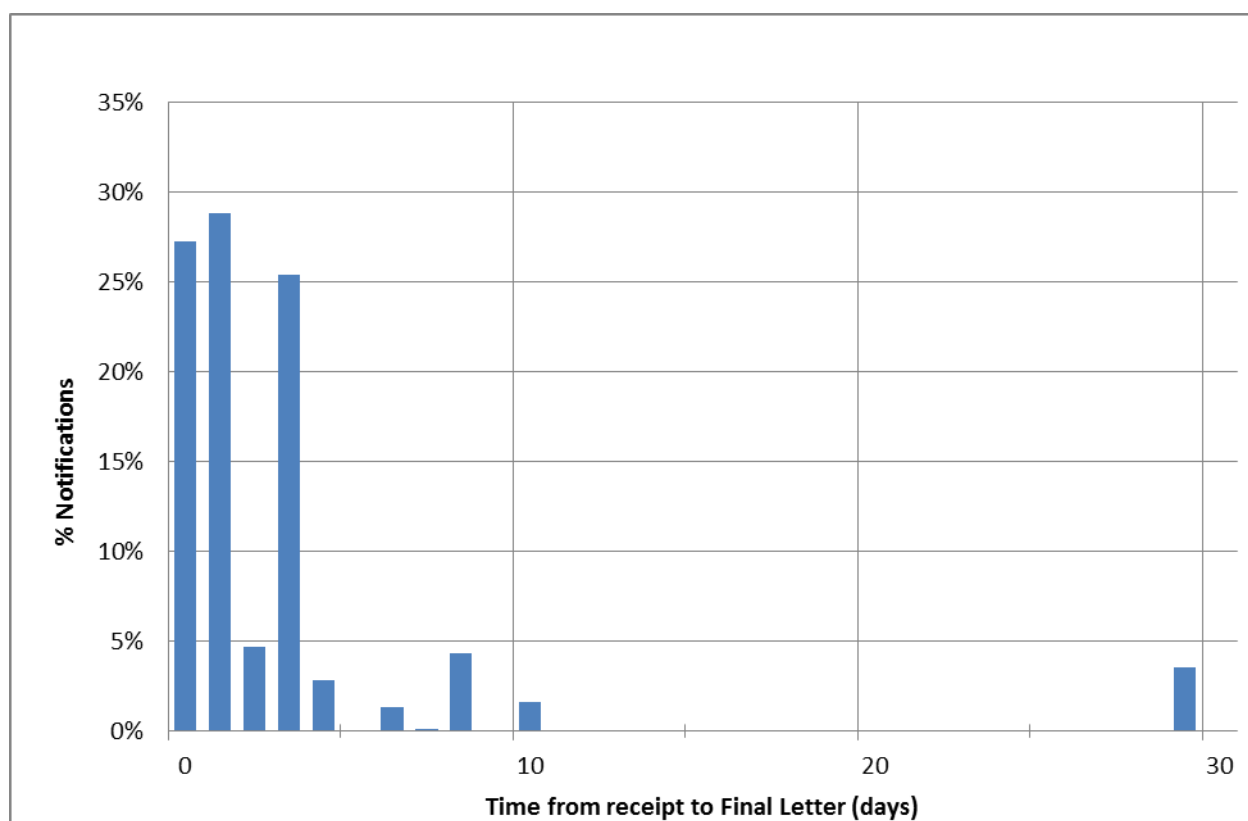
Proprietary Name	Number of Notifications
Lorazepam 2 mg/ml Injection Soln	2
Megestrol 160mg Tabs	2
Sulfinpyrazone 200mg Tablets	2
Aspirin Suppositories 300mg	1
Cefotaxime 1g Inj/Infn Pwdr	1
Chloromycetin Succinate 1 G Powder For Inj	1
Desmopressin Nasal Drops 120mg	1
Oxytocin10 IU/ml Inj/Inf Soln	1
Sulfinpyrazone 200 mg Tablets	1
Vasopressin 20IU/1ml Vial	1

## 4 Administrative matters

### 4.1 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 2016 to 30 Jun 2016**



**Table 6 Clinical Emergency Letter Timings, 01 Apr 2016 to 30 Jun 2016**

Time to Process from Receipt	Number of Notifications	% Notifications
≤ 1 day	2076	56.05% issued within 1 day
≤ 3 days	3190	86.12% issued within 3 days
<b>Totals</b>	<b>3704</b>	<b>100%</b>

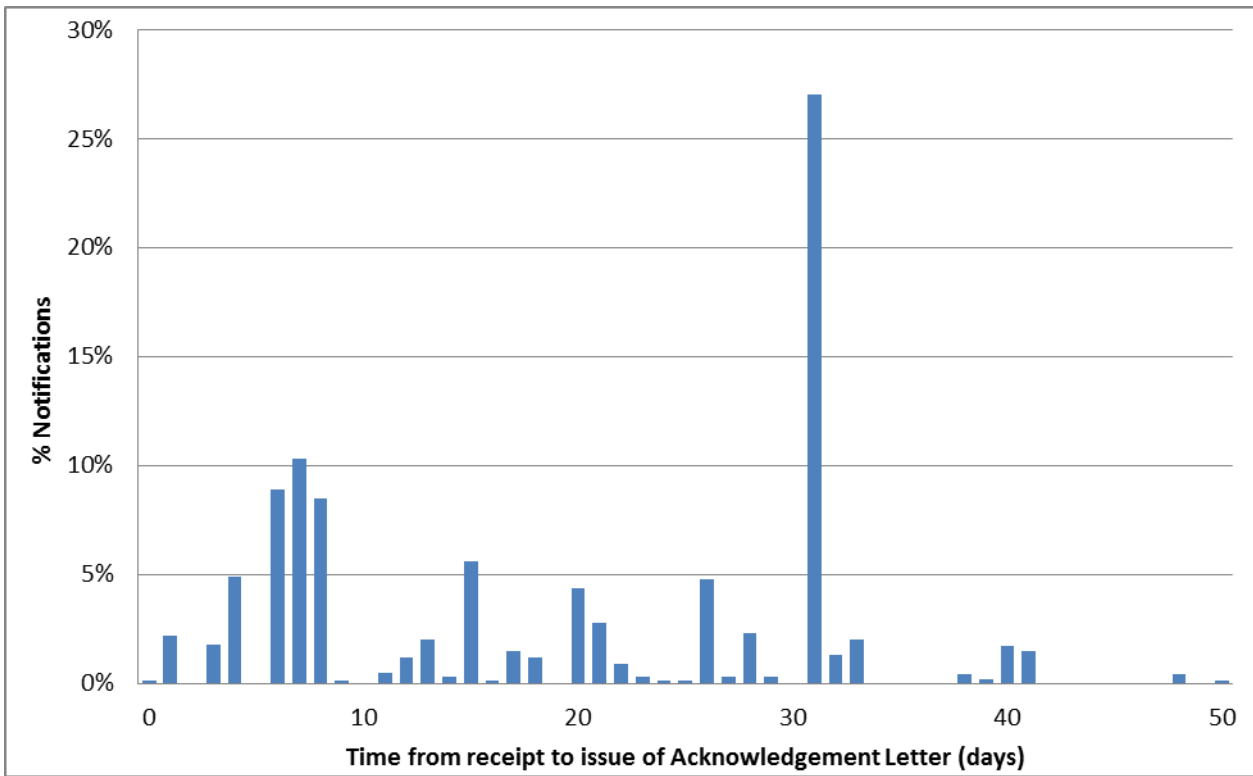
## 4.2 Process timings – Routine notifications

Graph 4 shows statistics for 1002 notifications for Q2/2016 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 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.

Approximately 90% of acknowledgements were issued within 30 days of receipt of notifications.

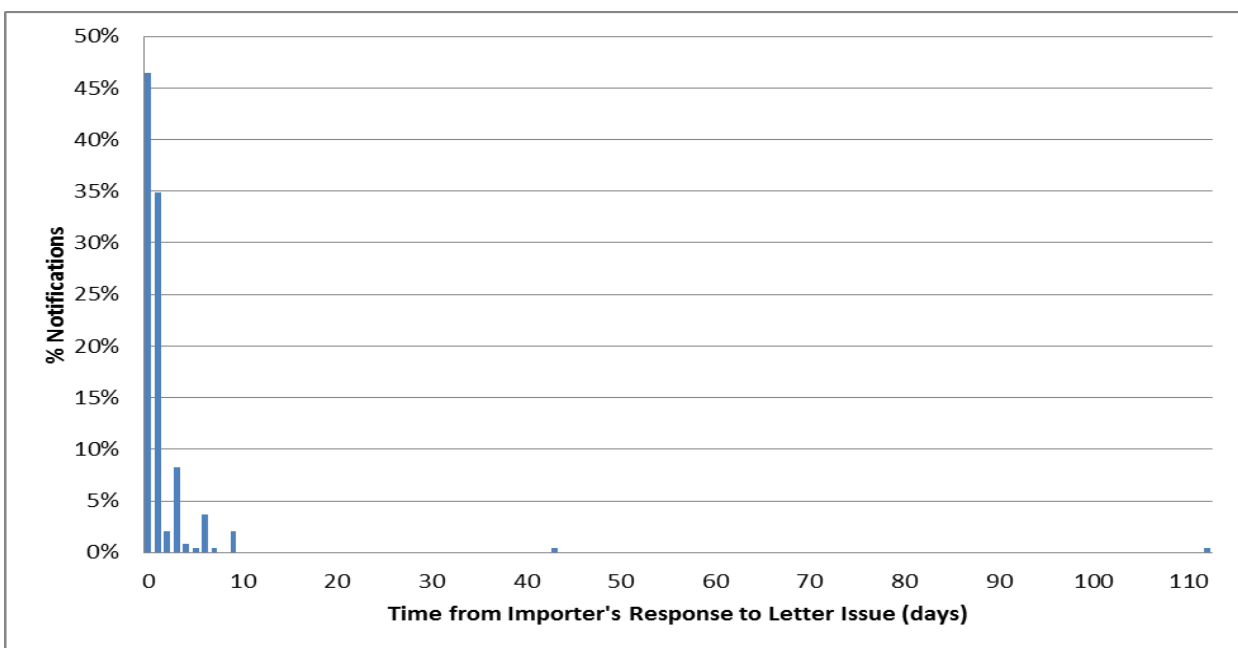
**Graph 4 Time to issue Acknowledgements, 01 Apr 2016 to 30 Jun 2016**



### 4.3 Process timings - Further information request responses

Importers responded to 241 requests for further information from the MHRA in Q2/2016 where letters permitting import were subsequently issued. Approximately 92% of these final letters were issued within 4 days of receiving the importer’s response. See Graph 5.

**Graph 5 Response times to further information provided, 01 Apr 2016 to 30 Jun 2016**



## 4.4 Process timings – Objection letters

A total of 74 Objections with Reason were issued in Q2/2016. All were issued with 28 days of acknowledgement letters where these had been issued.

### 4.4.1 Summary of reasons for objections to import

**Table 7** Reasons for objection to import

Summary	Number of notifications
Notified for import from the UK!	48
Notified for low preservative content, but equivalent Centrally Authorised product is preservative free.	20
Product was Centrally Authorised and therefore not unlicensed	2
Veterinary medicines not intended for human use	2
Quantity notified exceeded that permitted in SI 2012/1916	1
Equivalent UK licensed product available	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.

## **5 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. Eight inspections were supported in Q2/2016 and a number of Inspectorate and Enforcement general queries answered.

## **6 Conclusions**

The import notification system has operated substantially within the requirements of the regulations during Quarter 2, 2016.