

28 MAR 2017

Ref: H201700697

Dear [REDACTED]

Response to your request for official information

Thank you for your request of 1 March 2017 under the Official Information Act 1982 (the Act) for

"...data on erectile dysfunction drugs being stopped at the NZ border. I would like, if possible, the data divided out into known sildenafil/Viagra and all others, in case there is a greater effect on sildenafil/Viagra that is not affecting others. I would appreciate the data to be by number of packages intercepted, and provided by month for the last five years."

The information relating to this request is described below and provided as tables attached to this letter. I have decided under section 18(f) of the Act to refuse to provide information that cannot be made available without substantial collation or research. This information is identified below.

Medsafe's operations at the border

The Medsafe Investigation and Enforcement team (IET) operates a Border Control Programme at the New Zealand Post International Mail Centre (IMC) where the New Zealand Customs Service (Customs) refers parcels to Medsafe that are suspected of containing prescription medicines. Between 9,000 and 13,000 parcels have been referred each year for the last 5 years.

The IET Border Pharmacist inspects the parcels referred and takes action in accordance with the law and the IET policies and procedures. Erectile dysfunction medicines may be counterfeit, adulterated (that is they purport to be herbal yet contain a prescription medicine that is not on the label), or be unapproved "generics". It is exceedingly rare for genuine erectile dysfunction medicines (Viagra and Cialis) to be intercepted.

The counterfeit and adulterated medicines are seized and destroyed and a letter sent to the importer advising them of this. For medicines that are suspected to be adulterated, the importer is sent a letter requesting proof of ingredients, such as a certificate of analysis. All other erectile dysfunction medicines, which are the vast majority referred,

are treated as prescription medicines. A letter is sent to the importer advising that the medicines have been detained, but will be released on receipt of an authority from a NZ Authorised Prescriber.

The data that I am providing excludes adulterated and suspected adulterated medicines. All references to erectile dysfunction medicines relate to counterfeit and "generics".

As one parcel may contain more than one type of medicine, our data is based on the number of medicines rather than number of parcels. Also we rely on the product labels to determine the ingredients.

Response to your questions

The information provided is for imports through IMC in Auckland. All international mail entering New Zealand passes through this facility. While the majority of the imports through the IMC are personal, some are commercial.

There are much smaller flows of imports, both personal and commercial, that Medsafe is also involved with. However, information about these is not readily available so I have refused to supply this under section 18(f) of the Act, as the information requested cannot be made available without substantial collation or research.

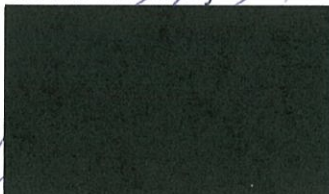
Table 1 attached is a summary by year of the number of parcels inspected and the number of different types of medicines that the parcels contained. Information is then provided of total erectile dysfunction medicines, which are then broken down into sildenafil, tadalafil and other.

For example in 2016, 8981 parcels were referred to and inspected by Medsafe. These parcels contained 13,328 different types of medicines. Thirty percent (4,037) were erectile dysfunction medicines, of which 2,349 (58%) were sildenafil, 1,449 (36%) were tadalafil and 239 (6%) contained other active ingredients.

Tables 2 through 6 provide more in depth information showing all the different active pharmaceutical ingredients broken down by month, with each table being for one calendar year. It has become common to see dapoxetine included along with an erectile dysfunction medicine. We have also inspected medicines containing dapoxetine as its sole ingredient. Although this is an anti-depressant, it is also used for treatment of premature ejaculation. We include it in the same coding as medicines for erectile dysfunction and for this reason it remains on these tables.

I trust this information fulfils your request. You have the right, under section 28 of the Act, to ask the Ombudsman to review my decision to withhold information under this request.

Yours sincerely 



Group Manager
Medsafe

Table 1 - Summary of parcels and number of medicines inspected 2012-2016					
	2016	2015	2014	2013	2012
Number parcels inspected	8,981	10,154	13,044	11,297	10,419
Number medicines inspected	13,328	14,823	18,466	15,608	14,353
Number ED medicines*	4,037	4,381	5,545	3,666	3,257
Percentage of ED medicines of total	30	30	30	23	23
Number ED medicines released	1,305	1,315	1,447	977	936
Percentage ED medicines released	32	30	26	27	29
Number of Sildenafil*	2,349	2,788	3,725	2,521	2,160
Percentage of Sildenafil as total of ED	58	64	67	69	66
Number Sildenafil released	656	715	866	573	526
Percentage of Sildenafil released	28	26	23	23	24
Number of Tadalafil*	1,449	1,378	1,515	966	917
Percentage of Tadalafil as total of ED	36	31	27	26	28
Number Tadalafil released	577	545	513	361	369
Percentage of Tadalafil released	40	40	34	37	40
Number of other ED*	239	215	305	174	180
Percentage of other Ed	6	5	6	5	6
Number other ED released	73	55	68	43	41
Percentage of other ED released	31	26	22	25	23
* excludes medicines that were adulterated or suspected to be adulterated					

Table 2 - Number of interceptions of erectile dysfunction medicines by month for 2016

API	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
avanafil			1	1									2
dapoxetine	4	4	2		5	4	2	6	4	4	1	3	39
mirodenafil													1
Sildenafil	147	181	197	221	216	192	192	208	224	176	194	201	2349
Sildenafil & Dapoxetine	4	6	3	10	9	4	3	1	5	7	4	4	60
Sildenafil & Duloxetine									1				1
Sildenafil & Fluoxetine											1		1
Sildenafil & Tadalafil			2				1					1	4
Tadalafil	88	88	115	149	156	128	146	120	119	100	113	127	1449
Tadalafil & Dapoxetine			1	2			1	1	1	1		2	9
Vardenafil	7	10	6	16	9	7	6	11	6	19	11	13	121
Vardenafil & Dapoxetine	1												1
TOTAL	251	290	325	401	395	335	351	347	360	307	324	351	4037

Table 3 - Number of interceptions of erectile dysfunction medicines by month for 2015

API	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
Avanafil							1	1	3				5
Dapoxetine	16	8	1	3	6		4	7	2	3	3	5	58
PGE injectable prostaglandin									1				1
Sildenafil	307	315	282	235	267	259	204	182	166	171	218	182	2788
Sildenafil & Dapoxetine	3	3	1	2	1		3	2	1	2	4	1	23
Sildenafil & Fluoxetine							1						1
Sildenafil & Tadalafil	1		3	1					2		1		8
Sildenafil & Vardenafil				2	1	1							4
Tadalafil	125	128	119	99	141	104	118	104	104	103	139	94	1378
Tadalafil & Dapoxetine	2	1	1	1		1					3	1	10
Tadalafil & Phentolamine													1
Vardenafil	9	11	12	6	11	9	8	8	6	8	7	4	99
Vardenafil & Dapoxetine		2	1	1		1							5
TOTAL	463	468	420	351	427	375	339	304	285	287	375	287	4381

Table 5 - Number of interceptions of erectile dysfunction medicines by month for 2013

API	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
Avanafil		2			1								3
Dapoxetine	1		4	3	4	2	4	1	1		1	2	23
Lodenafil			1										1
Sildenafil	17	156	158	166	33	224	261	266	210	156	223	199	2521
Sildenafil & Dapoxetine	2	1	2	3	5		1	3					17
Sildenafil & Duloxetine			1										2
Sildenafil & Fluoxetine	1		1		1			1				2	6
Sildenafil & Lignocaine					1								1
Sildenafil & Vardenafil					1								1
Sildenafil & Tadalafil								1					1
Tadalafil	63	48	59	88	98	87	108	109	72	58	93	83	966
Tadalafil & Dapoxetine					2			1					3
Vardenafil	6	6	6	6	15	14	17	12	4	5	12	9	112
Vardenafil & Dapoxetine								1	2		1		4
TOTAL	244	213	232	267	459	327	391	395	289	219	330	295	3661

Table 6 - Number of interceptions of erectile dysfunction medicines by month for 2012

API	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	TOTAL
Dapoxetine	2			1	3	2			1			1	10
Hydroxyhomosildenafil				1									1
PEG1							1						1
Sildenafil	187	235	232	222	210	169	138	246	154	107	108	152	2160
Sildenafil & Dapoxetine	1	1	2	1	7	3	1	4	3	4	3		29
Sildenafil & Fluoxetine					1						2	1	4
Tadalafil	82	105	92	84	81	97	56	103	44	48	57	68	917
Tadalafil & Dapoxetine		1		1									2
Vardenafil	10	12	17	10	13	18	9	9	6	4	11	8	127
Vardenafil & Dapoxetine				1		1							2
Yohimbine	3		1										4
TOTAL	284	354	344	321	315	290	205	362	208	163	181	230	3257