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MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH
www.medsafe.govt.nz

Mr Mark Honeychurch

By email: fyi-request-1416-58893cbf@requests.fyi.org.nz

Ref: H201400160 File: TT05-19-8

Dear Mr Honeychurch

Response to your request for official information

Thank you for your request for official information, received by the Ministry of Health on 24 January 2014. You asked a number of questions, which I have listed and responded to below.

1. Please supply me with a list of which sections of the Medicines Act 1981 are relevant to Medsafe and which are not. For any that are not, please can you let me know if there is another MoH department that is responsible.

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and is located within the Ministry of Health. Medsafe is primarily responsible for the following aspects of the regulation of therapeutic products: pre-market approval of medicines for the New Zealand market, maintenance of certain statutory committees, licensing of medicines manufacturers and packers, investigation of and action on quality and safety matters relating to therapeutic products, maintenance of a medical devices database and other ancillary functions. Medsafe's scope of operation is briefly described on the webpage: http://www.medsafe.govt.nz/other/about.asp#pre

The Medicines Control Team located within the Ministry of Health is responsible for the following aspects of regulation under the Medicines Act 1981 (the 'Act'): licensing of pharmacies, licensing of medicines wholesalers, issues in relation to prescribing of medicines and other associated functions. The Medicines Control Team also has various responsibilities under the Misuse of Drugs Act 1975. The Medicines Control Team functions are generally described on the webpage: http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control

As you may be aware, many sections of an Act are not specifically related to a function that a nominated regulator may be responsible for, but provide mechanisms, definitions, information and obligations which apply to the overall purpose of the legislation. It may also be the case that some sections are administered by, or are the responsibility of more than one regulator, depending on the circumstances. For instance, a pharmacy that is advertising an unapproved medicine may be dealt with by Medsafe because advertising issues are primarily Medsafe's responsibility as is approval of medicines for sale, however, Medicines Control may also have an

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interest because pharmacies are licensed by the Medicines Control Team. Below, I have listed the sections of the Act that relate to particular activities or obligations against the part of the Ministry primarily responsible for their administration.

Section	Description	Responsibility
9	Medicines Classification Committee	Medsafe
10	Medicines Review Committee	Medsafe, where this applies to Medsafe functions
11 to 16	Administration of Committees	Medsafe, where this applies to Medsafe functions
17	Licences required for certain activities	Medsafe in relation to medicines manufacturers and packers; Medicines Control in relation to pharmacies and wholesalers
18	Sale of medicines by retail	Medsafe or Medicines Control depending on the circumstances
20 to 24G	Requirement for the Minister to give consent in relation to the sale, supply etc of medicines (pre-market approval of medicines)	Medsafe
25 to 28 and 31 to 34	Exemptions to the requirement for the Minister's consent (pre-market approval of medicines) or the requirement for a licence	Medsafe or Medicines Control depending on the circumstances
29	Exemption in relation to the supply of unapproved medicines	Medsafe in relation to the receipt of information from suppliers; Medicines Control in regard to supply by wholesalers
30	Exemption from the requirement for the Minister's consent in relation to clinical trials and the approval process for clinical trials	Medsafe
35 to 40	Quality requirements for medicines and medical devices including action that can be taken in regard to quality issues	Medsafe
41	Requirement for the reporting of adverse reactions to medicines	Medsafe
42	Requirement for specifications and testing results to be held	Medsafe or Medicines Control depending on the circumstances
42A to 42C	Restrictions on the operation of pharmacies	Medicines Control
43 to 47	Miscellaneous provisions	Medsafe or Medicines Control depending on the circumstances
48 to 49A	Restrictions on prescribers and persons dependent on prescription medicines	Medicines Control

Section	Description	Responsibility
50 to 55	Provisions relating to licences	Medsafe in relation to medicines manufacturers and packers; Medicines Control in relation to pharmacies and wholesalers
55A to 55G	Licensing matters relating to pharmacies	Medicines Control
56 to 62	Provisions relating to medical advertisements	Medsafe
63 to 87	Enforcement provisions	Medsafe or Medicines Control depending on the circumstances
88 to 93	Provisions in relation to appeals	Medsafe or Medicines Control depending on the circumstances
94 to 96	Provisions relating to related products	Medsafe
96A to 96J	Provisions relating to specified biotechnical procedures	Medsafe
97 to 98 and 100 to 105C and 107 to 115	Miscellaneous provisions	Medsafe or Medicines Control depending on the circumstances
99	Publication of lists of general sales medicine	Medsafe
106	Classification of medicines by notice in the Gazette	Medsafe

2. Given that my original request was regarding sections 57 and 58 of the Act (advertising), I would also like to know what Medsafe's current processes and procedures are for dealing with complaints from the public regarding breaches of sections 57 and 58 of the Act.

An advertisement for a medicine may give rise to several potential breaches of the Act. A medicine cannot be advertised unless the Minister has given consent to its sale, supply and advertising (section 20). This means that an advertisement for an unapproved medicine may be a breach of the provisions of Part 4 of the Act (sections 56 to 62). A breach of section 20 is more serious and is likely to be the issue carried forward by Medsafe with the advertiser.

An advertisement for a medicine that is approved may breach the provisions of Part 4 of the Act in some way giving rise to a 'true' advertising breach. An example of this would be where an advertiser omits certain mandatory requirements (outlined in Part 3 of the Medicines Regulations 1984). Complaints about this type of issue are infrequent; most complaints relating to advertisements are associated with breaches of section 20 of the Act.

Medsafe has a process by which incidents / issues in relation to potential breaches or quality problems reported are recorded, assessed and acted on. The action taken is prioritised to ensure that urgent matters that could affect patient / consumer health

and safety are dealt with promptly. The process in relation to a complaint regarding advertising material can be summarised as follows:

- Information is obtained from the complainant, ideally with evidence of the advertisement or an indication of where the advertisement can be viewed / watched / listened to.
- An assessment of the material with respect to possible breaches of the legislation is made.
- An assessment of the urgency with which the issue should be treated is made.
- Contact with the advertiser. This is likely to be in writing and may comprise a warning letter about the suspected breach.
- Depending on the circumstances, various actions may be required of the advertiser that may include: removal of the advertisement (and any other offending material), recall of product (depending on the likely hazard to patients / consumers) and the taking of corrective action to ensure future compliance.
- The level of follow up by Medsafe will be related to the circumstances including the risks to consumer / patient health and safety. Prosecution is a possible consequence.
- In some cases successful prosecutions have resulted from non-compliances that have presented as advertising issues.

3. It would be great to see some data or statistics regarding Medsafe's responses to complaints. Do you have any numbers regarding incoming complaints that are successfully resolved by Medsafe, ones that have no action taken, etc? The more fine grained the data, the better, so individual records would be great, but totals, percentages and averages would suffice.

Information available from our system allows us to determine the number of 'pure' advertising complaints dealt with, but data for reported advertising issues that indicated a more serious breach (for instance, the advertising and supply of an unapproved medicine) is not readily available as these cases are included within a broader category referred to as regulatory issues. These cases cannot be readily differentiated without examining each case record.

I have provided a table from our system which lists both numbers of received and completed issues in relation to the 'advertising' (that is, 'true' advertising) category and the 'regulatory' category. These issues are from all sources (public, companies, Medsafe investigations, other Government agencies etc).

Action was taken on all cases referred to Medsafe and all cases are eventually closed. In some cases, action can be long-running and cases are not closed until Medsafe is satisfied that appropriate action has been taken; this can lead to a mis-match between received and completed issues. Action taken in response to the issue and the time taken to close the matter reflects the seriousness of the issue with regard to potential harm.

Some examples of cases where Medsafe has taken successful prosecutions where advertising has either been the initiating factor of an investigation or has led to the detection of a more serious offence can be viewed on the Medsafe website. Please refer to:

Pharmacist imprisoned on medicines charges
http://www.medsafe.govt.nz/hot/media/2013/PharmacistImprisoned.asp

Medsafe prosecutes South Auckland traditional Chinese Medical Ltd
http://www.medsafe.govt.nz/hot/media/media2008.asp#9May

Fines against companies found guilty of selling prescription medicines over the internet
http://www.medsafe.govt.nz/hot/media/media2006.asp#8May

I hope you will find the above information a useful description of Medsafe's processes for handling advertising issues.

Yours sincerely

Stewart Jessamine
Group Manager
Medsafe

Medsafe received and closed advertising and regulatory complaints 2012 - 13

Type	Period	Received	Closed
Advertising	Jan-12	1	3
Advertising	Feb-12	2	1
Advertising	Mar-12	1	0
Advertising	Apr-12	2	3
Advertising	May-12	2	3
Advertising	Jun-12	2	1
Advertising	Jul-12	1	0
Advertising	Aug-12	1	2
Advertising	Sep-12	0	0
Advertising	Oct-12	2	0
Advertising	Nov-12	2	0
Advertising	Dec-12	1	0
Advertising	Jan-13	0	1
Advertising	Feb-13	1	0
Advertising	Mar-13	0	2
Advertising	Apr-13	1	1
Advertising	May-13	1	0
Advertising	Jun-13	0	0
Advertising	Jul-13	2	0
Advertising	Aug-13	0	0
Advertising	Sep-13	0	0
Advertising	Oct-13	1	0
Advertising	Nov-13	1	0
Advertising	Dec-13	0	0
Totals		24	17

Type	Period	Received	Closed
Regulatory	Jan-12	2	3
Regulatory	Feb-12	10	1
Regulatory	Mar-12	10	3
Regulatory	Apr-12	5	4
Regulatory	May-12	12	5
Regulatory	Jun-12	8	6
Regulatory	Jul-12	11	7
Regulatory	Aug-12	9	8
Regulatory	Sep-12	5	1
Regulatory	Oct-12	3	11
Regulatory	Nov-12	10	0
Regulatory	Dec-12	7	1
Regulatory	Jan-13	2	1
Regulatory	Feb-13	13	5
Regulatory	Mar-13	13	3
Regulatory	Apr-13	5	7
Regulatory	May-13	11	2
Regulatory	Jun-13	9	2
Regulatory	Jul-13	11	4
Regulatory	Aug-13	8	2
Regulatory	Sep-13	6	7
Regulatory	Oct-13	14	6
Regulatory	Nov-13	6	5
Regulatory	Dec-13	6	6
		196	100