Medsafe Regulatory Update

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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

Outline

- Introduction
- Therapeutic Products Bill
- Medsafe & Medicines Act 1981
- Dietary Supplements Regulations 1985
- Regulatory Statement to Foreign Government

Therapeutic Products Bill

- Parliamentary process
- Submissions
- Timeframes

The Medsafe Team

- Approximately 85 FTE (including Medsafe, MCA)
- Multidisciplinary and predominantly technical including:
  - Chemists
  - Biochemists
  - Medical Drs
  - Pharmacists
  - Pharmacology
  - Molecular medicine
  - Regulatory practice and analysis

Medicines Act 1981


Version as at 5 April 2023

Medicines Act 1981

Public Act 1981 No 118
Date of assent 23 October 1981
Commencement see section 1(2)

- Section 3; A medicine for a therapeutic purpose. Its action is pharmacological, immunological, or by metabolic means.
- Section 4; The definition of therapeutic purpose is wide, and includes *preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury*
- Section 20; Generally, medicines must be approved before they are sold in New Zealand.
- There are no general provisions / exemptions for natural health products.

Dietary Supplements


Reprint as at 1 March 2016

Dietary Supplements Regulations 1985

(SR 1985/208)

- Sit under the Food Act 2014, by administered by Medsafe.
- Section 2A; a dietary supplement is normally derived from food
- There are restrictions on labelling, preservatives, antioxidants, sweeteners, vitamins, minerals, enzymes.
- Many, if not most, natural health products do not meet the definition of a dietary supplements or are not compliant with the above requirements.
- Medsafe takes a pragmatic approach for enforcement, with the greatest emphasis on products with therapeutic claims, or scheduled substances.

Dietary Supplements Regs

3 Maximum daily doses

(1) Every dietary supplement described as or containing minerals or vitamins specified in the first column of the table of this subclause shall be so manufactured that each daily dose (for an adult) does not contain more than the maximum specified in the second column of the table.

Table of subclause (1)

Dietary supplement	**Maximum daily dose**
Minerals	
Copper	5 mg
Iron	24 mg
Selenium	150 mcg
Zinc	15 mg
Vitamins	
Vitamin A or retinol	3000 mcg
Niacin (and salts) or nicotinic acid (and salts)	100 mg
Vitamin B_{12} or cyanocobalamin or hydroxocobalamin	50 mcg
Vitamin D	25 mcg
Folic acid	500 mcg in the case of a dietary supplement that the Director-General of Health has confirmed has been prepared in a way that accords with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods 300 mcg in the case of a dietary supplement that the Director-General of Health has not confirmed has been prepared in a way that accords with the New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods

Dietary Supplements Regs

7 Size of letters

(1) The lettering of every word or statement required by these regulations to appear on labels shall be—

(a) all capital letters; or

(b) all lower case letters; or

(c) lower case letters with an initial capital letter.

(2) In every case to which paragraph (a) or paragraph (b) of subclause (1) applies, the height of the lettering shall be uniform in every word or statement that is separately required.

(3) In every case to which paragraph (c) of subclause (1) applies, the height of the lower case lettering shall be uniform in every word or statement that is separately required.

(4) Except as otherwise provided in these regulations, the lettering of any word or statement required by these regulations to appear on labels shall be not less than 1.5 mm in height, except where the package or container to be labelled is so small as to prevent the use of letters of that height, in which case letters of not less than 0.75 mm in height may be used.

13 Preservatives

(1) In these regulations **preservative** means any substance that, when added to a dietary supplement, has the property of arresting or impeding fermentation, putrefaction, or decomposition.

(2) Dietary supplements may contain any of the following preservatives and no others:

- benzoic acid or sodium benzoate:
- parahydroxybenzoic acid and its esters:
- sorbic acid, or its sodium, calcium, or potassium salts:
- sulphur dioxide, or sulphites calculated as sulphur dioxide.

Regulatory Statements

Regulatory Statement to Foreign Government
about the free sales status of the product(s) described below

Document Number: [20xx/xxxx]
Issue Date: [date month year]
Destination Country: [name of country]

Medsafe, a business unit of the New Zealand Ministry of Health, assumed responsibility for administration of the Dietary Supplements Regulations 1985 on 31 March 2010. These regulations are promulgated under the Food Act 2014.

Standard statement

Medsafe has been advised by [name of company] that the dietary supplement product(s) listed below are manufactured by [name and address of company] and that the product(s) are manufactured for SELECT FROM LIST.

Under New Zealand law, dietary supplements are not assessed by a Government agency. This statement cannot therefore provide any assurance that the product(s) listed meet any quality or safety standards, are of New Zealand origin, or meet the regulatory requirements of the importing country. Further information on the regulation of dietary supplements and these statements can be found on Medsafe's website, under the heading *Information about our Regulatory Statements for Foreign Governments*:
https://www.medsafe.govt.nz/regulatory/dietarysupplements/regulation.asp

If the product(s) listed comply with the requirements of the New Zealand Dietary Supplements Regulations (and any other applicable legislation) the product(s) are legally able to be freely sold in New Zealand.

Dietary supplements are prohibited from making therapeutic claims in New Zealand. Products for which a therapeutic purpose is intended must instead be approved under the Medicines Act 1981. Therapeutic purpose is defined in section 4 of the Medicines Act 1981 and means any of the following purposes, or a purpose in connection with any of the following purposes:

(a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
(b) influencing, inhibiting, or modifying a physiological process; or
(c) testing the susceptibility of persons to a disease or ailment; or
(d) influencing, controlling, or preventing conception; or
(e) testing for pregnancy; or
(f) investigating, replacing, or modifying parts of the human anatomy.

[Company name] has declared to Medsafe that the products listed on this certificate are not for a therapeutic purpose. Medsafe has not undertaken any premarket assessment of these products, rather this certificate is based on the declaration provided by the company. Overseas regulators are advised to ensure they are satisfied the products(s) are fit for purpose and comply with their own legislation.

Signed at WELLINGTON

[Name]
[Designation]
Medsafe

Helping exporters

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Products we regulate **Product safety** **How we regulate** **Guidance and resources**

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Listed medicines

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Listed medicines are usually considered to be relatively benign, so the regulations allow for sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment.

They are all unscheduled medicines with well-known low-risk ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. These are assessed by the TGA for quality and safety but not efficacy.