



MEDSAFE

NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY

A BUSINESS UNIT OF
THE MINISTRY OF HEALTH

Guideline on the Regulation of Therapeutic Products in New Zealand

Part 1:

Overview of therapeutic product regulation

Edition 1.0

October 2014

Section 1: Legislation

Section summary

This section lists the legislation that applies to therapeutic products (medicines, medical devices and related products) in New Zealand.

1.1. Legislation

The principal legislation governing the regulation of therapeutic products (medicines, medical devices and related products) that are manufactured, sold or supplied in New Zealand comprises the:

- ☞ [Medicines Act 1981](#)
- ☞ [Medicines Amendment Act 2013](#)
- ☞ [Medicines Regulations 1984](#)
- ☞ [Medicines \(Database of Medical Devices\) Regulations 2003](#)
- ☞ [Medicines \(Approved Laboratories and Analysts in Charge\) Notice 2000](#)
- ☞ [Medicines \(Related Products \(Exempted Foods\)\) Regulations 2003](#)
- ☞ [Medicines \(Standing Order\) Regulations 2002](#)
- ☞ [Medicines \(Designated Prescriber: Nurse Practitioners\) Regulations 2005](#)
- ☞ [Medicines \(Designated Prescriber – Registered Nurses Practising in Diabetes Health\) Regulations 2011](#)
- ☞ [Medicines \(Designated Pharmacist Prescribers\) Regulations 2013](#)
- ☞ [Medicines \(Designated Prescriber: Optometrists\) Regulations 2005](#)

In addition, the following legislation imposes additional controls on particular types of therapeutic product and / or activities relating to them:

- ☞ [Misuse of Drugs Act 1975](#) (in relation to Controlled Drugs)
- ☞ [Misuse of Drugs Regulations 1977](#)
- ☞ [Misuse of Drugs \(Approved Laboratories and Analysts in Charge\) Notice 2000](#)
- ☞ [Misuse of Drugs Order \(No 2\) 1978](#)
- ☞ [Misuse of Drugs \(Restricted Substances\) Regulations 2008](#)
- ☞ [The Hazardous Substances and New Organisms \(HSNO\) Act 1996](#) (in relation to medicines that are new organisms and to medical devices that contain hazardous substances)

- ☞ [Contraception Sterilisation and Abortion Act 1977](#) (in relation to mandated standards for natural latex rubber condoms, polyurethane condoms and intra-uterine contraceptive devices).
- ☞ [Electricity \(Safety\) Regulations 2010](#) (in relation to mandated standards for electro-medical devices)

Copies of all New Zealand Acts and Regulations may be downloaded for free from www.legislation.govt.nz

Section 2: Types of Therapeutic Product

Section summary

This section explains what is meant by the terms therapeutic purpose, medicine, herbal remedy, related product and medical device.

2.1. Therapeutic Purpose

Therapeutic product is an umbrella term for products that are intended to be used in or on human beings for a therapeutic purpose. The term *therapeutic purpose* is defined in [Section 4 of the Medicines Act](#) to mean:

- ☞ Preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or
- ☞ Influencing, inhibiting, or modifying a physiological process; or
- ☞ Testing the susceptibility of persons to a disease or ailment; or
- ☞ Influencing, controlling, or preventing conception; or
- ☞ Testing for pregnancy; or
- ☞ Investigating, replacing, or modifying parts of the human anatomy.

Products that are intended to be used for a therapeutic purpose can be categorised as *medicines, related products or medical devices*. A product is considered to be intended for a therapeutic purpose if:

- ☞ The product contains one or more ingredient(s) that have a pharmacological action
- ☞ A therapeutic purpose is claimed for the product (usually on the label or in promotional material)
- ☞ A therapeutic purpose is implied for the product (usually on the label or in promotional material)
- ☞ The product contains a medicine listed in the [First Schedule to the Medicines Regulations](#) or a Notice in the *New Zealand Gazette* issued under [section 106 of the Medicines Act](#) (unless the product is in a form that cannot be administered to a human being for a therapeutic purpose).

Typical indicators that a product has a therapeutic purpose include use, on the label or in promotional material, of:

- ☞ A trade name that conveys an intended therapeutic purpose
- ☞ Words such as *remedy, medicated or therapeutic*

- ☞ Statements that a product will/can/may prevent or treat a disease or condition or give relief from symptoms of a disease or condition
- ☞ Statements of traditional therapeutic use, or use by ethnic groups for a therapeutic purpose
- ☞ Directions for use that infer a therapeutic purpose such as “dosing instructions” or instructions to “apply to the affected area”
- ☞ Statements to the effect that the law prevents the supplier from making therapeutic claims that they consider they should be able to make about the product.

Nutritional statements, or statements relating to the normal biochemical or nutritional function of a substance, are not considered to be therapeutic claims.

2.2. Medicines

The term *medicine* is defined in [Section 3 \(1\) of the Medicines Act](#). In simple terms, most medicines are products that exert their influence primarily through a pharmacological, metabolic or immunological effect when administered to a human being.

Radioactive materials used for a therapeutic purpose (which would generally be regulated as medicines overseas) are **not** regulated under the Medicines Act. The import and use of radiopharmaceuticals in New Zealand is regulated under the [Radiation Protection Act 1965](#) administered by the Office of Radiation Safety within the Ministry of Health. Further information can be obtained from <http://www.health.govt.nz/our-work/radiation-safety>.

If a product is administered to humans and exerts its primary effect by pharmacological, metabolic or immunological means, that product is considered to be a medicine, irrespective of whether therapeutic claims are made on the label or in advertising material. For example, a product that contains a hormone and is intended for use in human beings is a medicine, regardless of the purpose for which it is being promoted.

Some products that meet the definition of *medicine* are excluded from regulation under the Medicines Act (see Section 4.6 of this guideline for further detail).

2.2.1. Herbal Remedies

A herbal remedy is a sub-category of medicine, defined in [Section 2](#) of the Medicines Act. It is a medicine that does not contain a prescription, restricted or pharmacy-only medicine ingredient, and consists of a substance derived from plant material that has been dried or crushed (or derived through any other similar process). It may also be an aqueous or alcoholic extract of the dried or crushed plant material, or a mixture of that material with another inert substance.

2.3. Related Products

This term is defined in [Section 94](#) of the Medicines Act. In simple terms it is a product that is primarily a food, dentifrice or cosmetic, that also has a therapeutic use. A related product may not contain a prescription, restricted or pharmacy-only medicine ingredient.

Examples of related products include the following:

- ☞ Antiseptic throat lozenges
- ☞ Antiseptics used for cleaning wounds, cuts, abrasions, stings, insect bites and superficial burns.

Some products that meet the definition of *related product* are excluded from regulation under the Medicines Act (see Section 4.6 of this guideline for further detail).

2.4. Medical Devices

The term medical device is defined in [Section 3A](#) of the Medicines Act. In simple terms it is any device, instrument, apparatus, appliance, or other article that is intended to be used primarily on human beings for a therapeutic purpose and does not achieve its principal intended action by pharmacological, metabolic or immunological means.

Section 3: Overview of the Regulatory Framework

Section summary

This section provides a brief explanation of the key control elements in the legislation, which type of therapeutic product they are applied to and hyper-links to other parts of the guideline where more detailed information on particular regulatory requirements and processes are located. It also explains the interfaces between the Medicines legislation and other statutes.

3.1. Key Elements of the Regulatory Framework

The regulatory framework administered by Medsafe applies a number of inter-related controls that are intended to ensure that the therapeutic products available in New Zealand meet acceptable standards of safety, quality and efficacy or performance. Products are therefore expected to have greater benefits than risks if used appropriately.

Other aspects of the regulatory framework (such as a licensing system for: medicine wholesalers and certain retailers; those who hawk medicines; and those who operate a pharmacy as well as oversight of the requirements relating to prescribing and dispensing) are undertaken by Medicines Control Officers working within another unit of the Ministry of Health. Further details are available at <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control>.

The four key elements of the regulatory framework (that are administered by Medsafe and applied to varying extents to medicines, related products and medical devices) are outlined below.

3.1.1. Availability, Controls on Market Entry and Exit

The mechanisms to control availability of medicines and related products are a pre-marketing approval system requiring products to be assessed for safety, quality and efficacy and the Minister to grant consent to their distribution, before they can be advertised or supplied; and post-marketing mechanisms that enable products to be removed from use if they are found to be unsafe or ineffective.

Under current legislation, the pre-marketing product approval system applies to new and changed medicines and related products (with some exemptions, such as those for certain herbal remedies and for medicines used in clinical trials). See Parts 2A and 2B of this guideline for details of the application and evaluation processes and timelines. The costs of evaluation are cost-recovered through fees payable by applicants. A fees schedule is provided on the Medsafe website (<http://www.medsafe.govt.nz/regulatory/fees.asp>).

The provisions in the Medicines Act that relate to Ministerial consent processes are found in:

☞ [Sections 20 to 24G](#) (new and changed medicines)

☞ [Section 96](#) (related products).

Pre-market evaluation and approval is not currently required for medical devices. The Medicines (Database of Medical Devices) Regulations 2003 do, however, require sponsors to notify devices to a Medsafe-maintained database within 30 working days of becoming the sponsor for the device. Further information on this process is available at <http://www.medsafe.govt.nz/regulatory/wand.asp>

The post-market mechanisms to control availability include: powers to revoke or suspend Ministerial consents; prohibit or impose conditions on the sale or supply of a product; and prohibit the import, manufacture, packing, sale, possession, supply, administration or other uses of products. Manufacturers and importers also have a duty to report any substantial adverse events arising from the use (in New Zealand or overseas) of a medicine. The Medicines Regulations also provide powers in relation to the recall of products (or particular batches or models of a product).

The provisions in the Medicines Act and the Medicines Regulations that relate to these post-market regulatory mechanisms are found in:

☞ [Section 35](#) (revocation and suspension of Ministerial consents for medicines and related products)

☞ [Section 36](#) (prohibition of supply or imposition of conditions for medicines)

☞ [Section 37](#) (prohibition of import, manufacture etc for medicines, related products and medical devices)

☞ [Section 38](#) (restrictions on the supply of medical devices)

☞ [Regulation 50](#) (recall powers for medicines, related products and medical devices).

3.1.2. Quality

The regulatory mechanisms to control quality include: establishing quality standards through the pre-market approval system for medicines; the adoption of New Zealand or ISO standards; an audit and licensing system for manufacturers and packers; and enforcement of quality standards through surveillance and monitoring. In addition, before distributing a medicine a manufacturer or importer of a medicine is required to hold specifications for testing the medicine and a certificate of analysis for every batch of medicine to be distributed. Part 4 of the Guideline on the Regulation of Therapeutic Products in New Zealand (GRTPNZ) provides details about the licensing system for medicine manufacturers and the associated Good Manufacturing Practice requirements.

The provisions in the Medicines Act and Medicines Regulations that relate to these regulatory mechanisms are found in:

☞ [Section 17](#) (requirement to hold a licence)

- ☞ [Part 3 of the Medicines Act](#) (provisions relating to licensing)
- ☞ [Section 40](#) (compliance with standards)
- ☞ [Section 42](#) (specifications and certificates of analysis)
- ☞ [Regulation 4](#) (compliance with standards)
- ☞ [Part 8 of the Medicines Regulations](#) (licences).

In relation to certain medical devices, it is also mandatory to meet standards that are imposed by other statutes:

- ☞ All contraceptive devices distributed in New Zealand must comply with the applicable standard mandated under the Contraception, Sterilisation and Abortion Act 1977:
 - [International Standard ISO 4074:2002\(E\) Natural Latex Rubber Condoms](#)
 - [New Zealand Standard NZS 7106:1998 Polyurethane Condoms](#)
 - [New Zealand Standard NZS 7102:1980 Specification for Intra-uterine Contraceptive Devices](#)
 - [International Standard ISO 23409:2011](#) - Male Condoms - Requirements and test methods for condoms made from synthetic materials
 - [International Standard ISO 25841:2014](#) - Female Condoms - Requirements and test methods
 - [International Standard ISO 8009:2004](#) - Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms, requirements and tests
 - [International Standard ISO 7439:2011](#) - Copper-bearing contraceptive intrauterine devices - Requirements and tests
- ☞ All electro-medical devices must comply with the standards called up by the [Electricity \(Safety\) Regulations 2010](#) (principally IEC 60601-1 Ed 2.2 as modified by [AS/NZS 3200.1.0:1998](#))

3.1.3. Access

The regulatory mechanism to control access applies only to medicines. It is a classification system that ensures that some medicines are only available through appropriately qualified health professionals. Medicines are classified on the advice of an expert Ministerial advisory committee (the Medicines Classification Committee) which meets twice a year.

Details of the classification process can be located at <http://www.medsafe.govt.nz/profs/class/classificationprocess.asp>

The Medicines Act defines three classification categories for medicines:

- ☞ *Prescription medicines* which may be supplied only on the prescription of an authorised prescriber (as defined in section 2 of the Medicines Act) or veterinarian; or in accordance with a standing order (as defined in [section 2 of the Medicines Act](#))
- ☞ *Restricted Medicines* (also referred to as *Pharmacist-Only Medicines*) which may be sold without a prescription, but the sale must be made by a registered pharmacist, in a pharmacy, and details of the sale must be recorded
- ☞ *Pharmacy-Only Medicines* (also referred to as *Pharmacy Medicine*) which may only be sold in a community or hospital pharmacy, or a shop in an isolated area that is licensed to sell that particular medicine. The sale may be made by any salesperson.

Medicines in each of these classification categories are listed in the First Schedule to the Medicines Regulations and periodic updates that are published in the *New Zealand Gazette*. A searchable database of medicines classifications is also available on the Medsafe website (<http://www.medsafe.govt.nz/profs/class/classintro.asp>)

Medicines not listed in the classification schedules are deemed to be unclassified, and are referred to as *General Sale Medicines*. These medicines may be sold from any outlet.

The provisions in the Medicines Act that relate to classification are found in:

- ☞ [Section 3](#) (definitions of Prescription Medicine, Restricted Medicine and Pharmacy-Only Medicine)
- ☞ [Section 9](#) (Medicines Classification Committee)
- ☞ [Section 106](#) (Power to classify medicines by notice in the *Gazette*).

3.1.4. Information

There are several regulatory mechanisms to ensure that accurate product information is available to support appropriate selection and use of products. They include specifying labelling requirements, requirements for prescribing information (data sheets) for prescription and restricted medicines, and controls on advertising. A searchable database of data sheets is available on the Medsafe website (<http://www.medsafe.govt.nz/profs/Datasheet/dsform.asp>).

In addition, although not currently mandated in law, sponsors are strongly encouraged to produce Consumer Medicine Information (CMI) for prescribed medicines and provide it to Medsafe for publication on the Medsafe website. A searchable database of CMI is available on the Medsafe website (<http://www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp>).

[Part 10](#) of the GRTPNZ details the requirements for the preparation and publication of data sheets and CMI.

The provisions in the Medicines Act and the Medicines Regulations that relate to these information requirements are found in:

- ☞ [Part 4](#) of the Medicines Act (advertising)
- ☞ [Section 44](#) of the Medicines Act (labelling)
- ☞ [Part 4](#) of the Medicines Regulations (labelling)
- ☞ [Part 3](#) of the Medicines Regulations (advertising)
- ☞ [Part 10](#) of the Medicines Regulations (data sheets).

3.2. Controls on Xenotransplantation Procedures

In the medicines legislation, xenotransplantation is defined as a *specified biotechnical procedure* which must be authorised by the Minister of Health. An application for approval must address ethical, cultural and spiritual issues in addition to the safety of both the recipient and the public.

The provisions in the Medicines Act that relate to xenotransplantation are found in:

- ☞ [Part 7A](#) of the Medicines Act (xenotransplantation).

3.3. Access to Unapproved Medicines

The three regulatory mechanisms which provide access to unapproved medicines are: a clinical trials scheme; compassionate use supply on a named patient basis; and a practitioner exemption. These mechanisms are described below.

3.3.1. Clinical Trial

[Section 30](#) of the Medicines Act provides an exemption from the normal product approval requirements when a medicine that has not been granted Ministerial consent to distribution (ie, an unapproved medicine) is used in a clinical trial that has been approved by the Director-General of Health.

The application and approval process for clinical trials is administered by Medsafe and described in detail in [Part 11](#) of the GRTPNZ. Part 11 also explains the ethics approval system (administered by the New Zealand Health and Disability Ethics Committee) which applies to all clinical trials conducted in New Zealand.

3.3.2. Named Patient use

[Section 29](#) of the Medicines Act provides a mechanism to permit the supply of an unapproved medicine to a medical practitioner, at his/her request, in order to treat a particular patient under his/her care. The supply must be initiated by the medical practitioner and the supplier may not advertise the availability of the medicine.

Suppliers of unapproved medicines are required to hold a licence under the Medicines Act (or be exempt from that requirement) and are also required to notify Medsafe as soon as practicable after the end of every month in which the medicine has been supplied, of the following:

- ☞ international non-proprietary name (INN) of the medicine

- ☞ trade name of the medicine
- ☞ pharmaceutical form
- ☞ month and year of supply.

The [form for reporting supply under section 29](#) includes a declaration that the supplier is maintaining more detailed records about the supply (refer [section 29\(2\)](#) of the Medicines Act and that these records are available for audit by Medsafe.

3.3.3. Practitioner exemption

[Section 25](#) of the Medicines Act permits registered medical practitioners, dentists and midwives ("practitioners") or designated prescribers (refer [section 2](#) of the Medicines Act) to procure, and administer or arrange the administration of, an unapproved medicine for a particular patient under his or her care.

The terms of section 25 are inclusive and permissive, allowing the practitioner to 'procure the sale or supply of any medicine' for a particular patient in his or her care. 'Any medicine' includes approved and unapproved medicines. Under the provisions of the [Health Practitioners Competence Assurance Act 2003](#) practitioners must, however, only prescribe within their approved scope of practice.

Further information is available on the Medsafe website (<http://www.medsafe.govt.nz/profs/RIss/unapp.asp>).

3.4. Interfaces with other legislation

3.4.1. Misuse of Drugs Act

Medicines that are also **Controlled Drugs** are controlled under the [Medicines Act](#) and associated [Medicines Regulations](#) as well as the [Misuse of Drugs Act 1975](#) and associated [Misuse of Drugs Regulations 1977](#). In the event of any conflict between the provisions in the two sets of legislation, the Misuse of Drugs legislation takes precedence ([Section 109\(4\)](#) of the Medicines Act refers).

3.4.2. Hazardous Substances and New Organisms Act

Certain medicines must comply, not only with the Medicines legislation, but also with the requirements of the [Hazardous Substances and New Organisms Act 1996](#) (HSNO), its amendments and its associated regulations. This legislation is administered by the Environmental Protection Authority (EPA).

While most medicines in finished dose form are exempt from the HSNO legislation even when they cross the HSNO thresholds for hazardous properties, the following types of medicines are *not exempt* and must comply with the HSNO legislation:

- ☞ Substances that are gases (eg, medical gases) contained in pressure containers of more than 100 mLs **and** at pressures of more than 170 kPa, up until the time they are administered to one or more human beings for a therapeutic purpose.
- ☞ Medicines (eg, vaccines or gene therapy products) that contain live or attenuated viruses or bacteria and are "new organisms" as defined in [section 2\(A\) of the HSNO Act 1996](#). To be a new organism it must be "a species of any organism

which was not present in New Zealand on the date of commencement of this Act” (ie, 29 July 1998). For the purposes of the HSNO legislation, genetic modification of a previously present species (including a micro-organism) produces a new organism.

Substances used in the manufacture of medicines in New Zealand by licensed medicine manufacturers are not exempt and importers and manufacturers must comply with the HSNO legislation.

The [EPA website](#) includes information on EPA procedures together with a [searchable register](#) of applications and approvals under the HSNO Act.

Where a sponsor wishes to distribute a new medicine that is either a medical gas or a new organism as described above, the sponsor must apply separately to both Medsafe and EPA for consent using their respective application forms and procedures. Details of the date and status of the application to EPA must be provided on the [New Medicine Application declaration form](#). The medicine concerned may not be distributed in New Zealand until consent from both agencies has been granted.

In the event of such an application to Medsafe and EPA, the two agencies will work together (subject to any confidentiality limitations imposed by the applicant), sharing relevant information and evaluation reports as appropriate, and co-ordinating their activities as far as is practical to ensure the efficient and effective administration of the requirements of the Medicines and HSNO legislation.

For further information about the HSNO and EPA requirements for obtaining consent to import and or release products controlled under the HSNO legislation, see the topic specific [contact details on the EPA website](#).

3.4.3. Consumer legislation

Medicines, related products and medical devices are regulated by the [Ministry of Health](#) in accordance with the Medicines and Misuse of Drugs legislation. Sponsors should also be aware that, as these products are articles of commerce, they also need to comply with any other relevant consumer legislation (eg, [the Fair Trading Act 1986](#)) administered by the [Ministry of Business, Innovation and Employment](#) and enforced by the [Commerce Commission](#).

3.4.4. Other regulatory interfaces

Distributors wishing to import unprocessed plant or animal material, should contact [Biosecurity New Zealand](#) to determine which import standards apply.

The [New Zealand Customs Service](#) is also able to advise on the requirements for commercial importation.

Section 4: Categorisation of products

Section summary

This section describes the factors that determine the categorisation of a product as a medicine, medical device, related product, dietary supplement, supplemented food or cosmetic. It also provides a tool to assist with categorisation decisions and examples of both therapeutic claims and claims that are not considered to indicate that a product has a therapeutic purpose.

4.1. Products at Regulatory Interfaces

It can sometimes be difficult to determine whether a product is a therapeutic product (and if so which type), or a type of food (dietary supplement or supplemented food) or a cosmetic. However, identifying the correct categorisation for a product is a necessary first step to identifying the appropriate regulatory framework for the product.

The categorisation of a product is determined by its ingredients, its purpose for use, and the manner in which it is presented in the market through its labelling or advertising. The influence of these factors is explained below.

4.1.1. Ingredients

If a product contains one or more ingredients that are scheduled as Controlled Drugs under the Misuse of Drugs Act 1975 or scheduled as Prescription Medicines, Restricted (pharmacist-only) Medicines or Pharmacy-Only Medicines under the Medicines Act the product must be a medicine or a controlled drug or both. It cannot be lawfully supplied as a cosmetic, a related product, a dietary supplement or a supplemented food.

Medsafe's [searchable database](#) can be used to check whether an ingredient is scheduled under the Medicines Act.

Lists of Controlled Drugs can be found in Schedules at the end of the [Misuse of Drugs Act 1975](#).

4.1.2. Purpose for use

Therapeutic claims are not permitted for products supplied as dietary supplements (with the exception of certain folate-containing supplements), supplemented foods, herbal remedies that have not been granted Ministerial consent, or cosmetics (with the exception of limited claims for those cosmetic-type related products that are excluded from regulation under the Medicines Act).

Independent advice is available on whether a claim implies a therapeutic purpose. The [Association of New Zealand Advertisers](#) offers a Therapeutic Advertising Pre-vetting Service (TAPS). For a fee an adjudicator will assess labels and advertising

material and advise if they are compliant with NZ legislation. TAPS also offers advice on how statements could be modified to avoid non-compliance with the Medicines Act. Another useful resource is the [TAPS website](#). This website contains some guidelines on therapeutic claims and provides examples of claims that do not imply a therapeutic purpose.

Alternatively there are a number of regulatory affairs consultants who specialise in advertising compliance. A list is available here: www.medsafe.govt.nz/regulatory/consultants.

4.2. Cosmetics

[Section 2 of the Medicines Act](#) defines a cosmetic as any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering, or cleansing the hair, skin, or complexion of human beings.

The following types of products, when sold without any therapeutic claims and not containing any substance listed in the [First Schedule](#) to the [Medicines Regulations](#) (and amendments) are considered to be **cosmetics**, and the Minister's consent for distribution is not required.

- ☞ Antiperspirants
- ☞ Deodorants
- ☞ Insect repellents
- ☞ Dusting powders
- ☞ Sunscreen and suntan preparations. (Note that companies are encouraged to market only sunscreens that comply with the [Australian/New Zealand Standard AS/NZS 2604:2012 Sunscreen Products - Evaluation and Classification](#). Companies marketing sunscreens should have evidence to support the SPF and broad spectrum protection claimed.)
- ☞ Cleansers for normal or blemished skin
- ☞ Moisturisers for normal, sunburnt or wind burnt skin
- ☞ Hair conditioners
- ☞ Astringents and skin toners
- ☞ Agents to assist in the fading of spots and blemishes
- ☞ Antiseptics for generalised, all-over use, on the body and not on broken skin
- ☞ Solutions which are bathed in to relax the body
- ☞ Anti-wrinkle and anti-ageing products which have a superficial cosmetic effect and not a physiological effect.

4.3. Dietary Supplements

Dietary supplements are controlled under the [Dietary Supplement Regulations 1985, Regulation 2](#) of these Regulations defines a dietary supplement. In practical terms, a dietary supplement is an edible substance, in a controlled dosage form, which is intended to supplement the intake of substances normally derived from food. A product marketed as a dietary supplement may not be promoted for a therapeutic purpose. Companies wishing to make therapeutic claims for such products must apply for consent to distribute the product as a medicine or related product.

4.4. Electronic cigarettes

An electronic cigarette (e-cig) comprises a battery powered cigarette-shaped body with a mouthpiece or “cartridge” holding an absorbent material that is saturated with a flavoured liquid solution that may contain nicotine. E-cigs are commonly sold with a fitted cartridge but are also supplied as a battery powered vapourising unit to which a cartridge of choice can be fitted at a later time.

The categorisation of an e-cig product depends on how it is presented for sale, including the intended use claimed for the product by the supplier and whether this use has a therapeutic purpose as defined in the Medicines Act.

- ☞ Electronic cigarettes are **medicines** when they are supplied for use as an aid to smoking cessation and with one or more cartridges
- ☞ Electronic cigarettes are **medicines** when supplied with one or more cartridges containing nicotine even if they are not represented as aids to smoking cessation
- ☞ Electronic cigarettes are **medical devices** when they are supplied for use as an aid to smoking cessation and without cartridges
- ☞ Electronic cigarettes are **not** therapeutic products when they are supplied as a “gadget” which consumers may choose to use as a social prop or as an item which is to be used interchangeably with cigarettes.

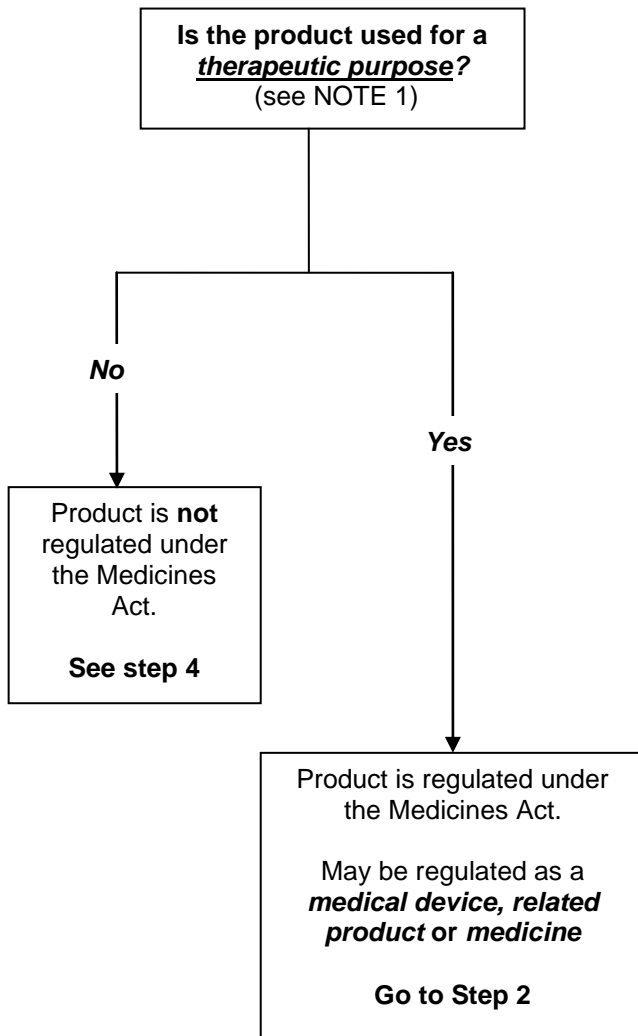
The following provides further guidance on “intended purpose” language or claims that will be regarded as suggestive of a therapeutic purpose:

- ☞ Supports or aids smoking cessation
- ☞ Remedy against/ helps alleviate nicotine addiction or the symptoms of nicotine addiction
- ☞ Helps you quit smoking/ smoke less
- ☞ Reduce your nicotine intake.

4.5. Product Categorisation Decision Tool

The following flowchart can be used as a tool to gauge whether a product is likely to be a type of therapeutic product that is regulated under the Medicines Act, or a cosmetic, or a product regulated under food legislation.

Step 1: Determine whether the product should be regulated under the Medicines Act



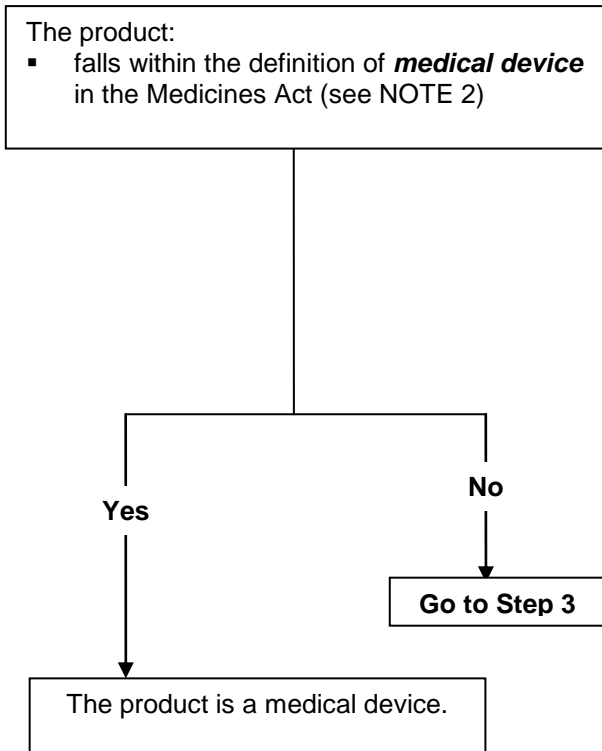
NOTE 1

For a product to be regulated under the Medicines Act, it must be intended to be used in humans for a therapeutic purpose.

Therapeutic purpose is defined in the Medicines Act as:

- (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

Step 2: Determine whether the product is a medical device

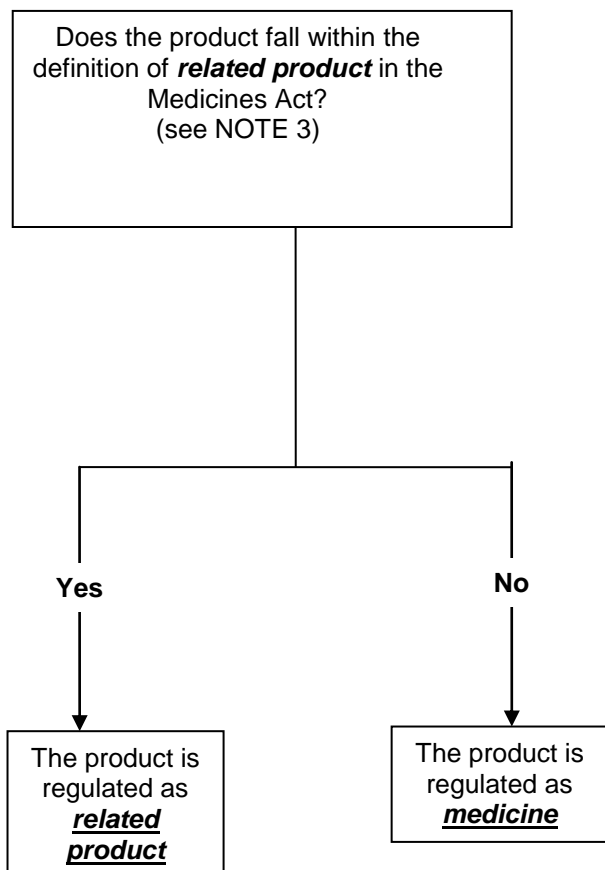


NOTE 2

Medical device is defined in the Medicines Act. It means:

- (a) Any device, instrument, apparatus, appliance, or other article that-
 - (i) Is intended to be used in, on, or for human beings for a therapeutic purpose; and
 - (ii) Does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means) and
- (b) Includes a material that-
 - (i) Is intended to be used in or on human beings for a therapeutic purpose; and
 - (ii) Does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and
- (c) Also includes-
 - (i) Anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and
 - (ii) Any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of this Act; but
- (d) Does not include a device, instrument, apparatus, appliance, article or material of a kind or belonging to a class that is declared by regulations not to be a medical device for the purposes of this Act.

Step 3: Determine whether the product is a related product or a medicine



NOTE 3

Related product is defined in the Medicines Act. A **related product** is a cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose. It does not include any medicine.

A product that is used “wholly or principally” for a therapeutic purpose is a medicine. A related product has a therapeutic purpose that is secondary to its principal purpose.

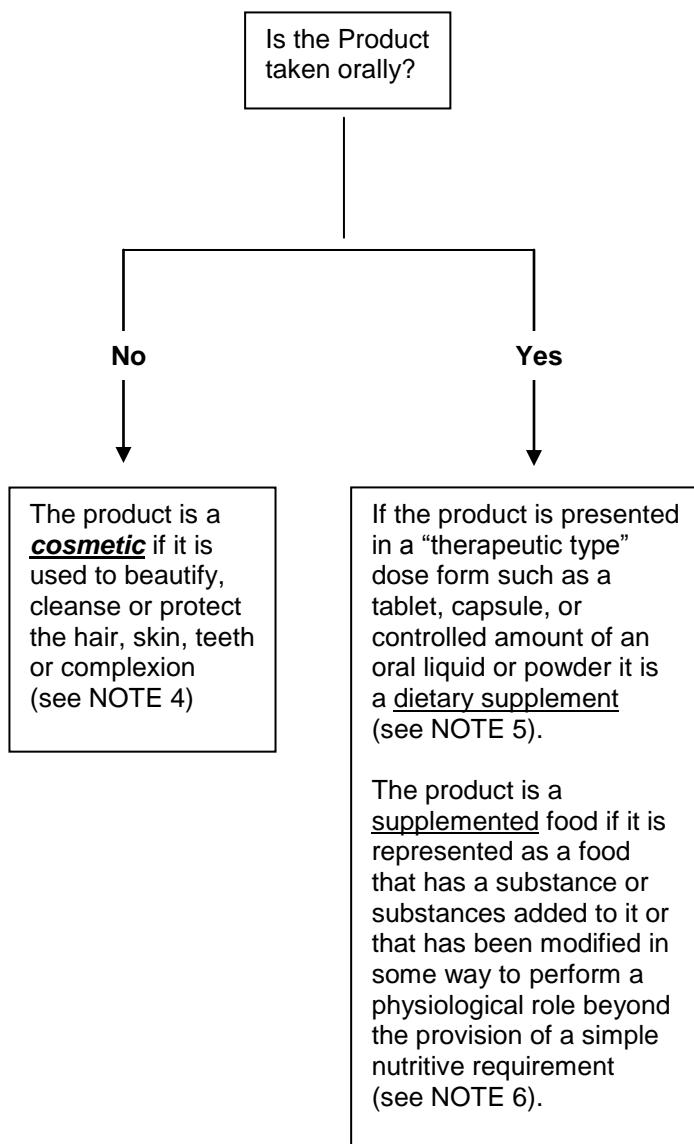
Many products at the food-therapeutic product interface are likely to be related products (e.g. a capsule containing vitamins and minerals where the principal purpose is to supplement the dietary intake of those substances).

Definition of medicine

Medicine is defined in the Medicines Act. A medicine –

- (a) Means any substance or article that –
 - (i) Is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and
 - (ii) Achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means; and
- (b) Includes any substance or article-
 - (i) That is manufactured, imported, sold or supplied wholly or principally for use as a therapeutically active ingredient in the preparation of any substance or article that falls within paragraph (a); or
 - (ii) Of a kind or belonging to a class that is declared by regulations to be a medicine for the purposes of this Act; but
- (c) Does not include –
 - (i) A medical device; or
 - (ii) Any food within the meaning of section 2 of the Food Act; or
 - (iii) Any radioactive material within the meaning of section 2(1) of the Radiation Protection Act 1965; or
 - (iv) Any animal food in which a medicine (within the meaning of paragraph (a) or (b) is incorporated; or
 - (v) Any animal remedy; or
 - (vi) Any substance or article of a kind or belonging to a class that is declared by regulations not be a medicine for the purposes of this Act.

STEP 4: Determine whether the product is a dietary supplement, supplemented food or a cosmetic



NOTE 4

Refer to the Cosmetic Products Group Standard 2006, published by the Environmental Protection Authority (EPA) under the Hazardous Substances and New Organisms (HSNO) legislation. This group standard includes lists of chemicals whose use in cosmetics is prohibited or restricted.

It is available from www.epa.govt.nz
Refer also to regulations 22, 24 and 26-36 of the Medicines Regulations for requirements that apply to cosmetics.

NOTE 5

Dietary Supplements are regulated under the Food Act 1981 and are subject to the Dietary Supplements Regulations 1985 (administered by Medsafe). These regulations specify a number of requirements for dietary supplements relating to matters such as composition, labelling and maximum permitted daily doses for many vitamins and minerals.

NOTE 6

Supplemented foods are regulated under the Food Act 1981 and are subject to the NZ Food (Supplemented Food) Standards 2010. The standards can be downloaded from: www.foodsafety.govt.nz

4.6. Product Categorisation Table

The following table provides categorisation information for various types of product that either lie close to the medicine / medical device interface or are illustrative of product types that changed categorisation on 1 July 2014 following a change to the definitions of the terms *medicine*, *medical device* and *therapeutic purpose*.

Product Type	Category
Absorbable intra-ocular and synovial visco-elastic fluids used in surgery	Medical device
Artificial tears or saliva	Medical device
Blood bags with / without anticoagulant / preservative	Medical device
Bone cement with antibiotic	Medical device
Catheter with heparin / antibiotic coating	Medical device
Contact lens lubricants and solutions	Medical device
Condoms with spermicide / viricide / local anaesthetic	Medical device
Cryogenic gases	Medical device
Dental cement with antibiotic / adrenaline	Medical device
Dermal Fillers (eg, collagen injections) with / without local anaesthetic included in the formulation	Medical device
Douches for body "cleaning"	Medical device
Haemodialysis solutions	Medical device
Haemostatic agents - collagen and non-medicated	Medical device
Haemostatic agents – fibrin	Medicine
Hormone eluting intra-uterine contraceptive devices	Medicine
Injectable contrast agents for use in diagnostic imaging (eg, PET, CAT, NMR, X-Ray, Ultra-sound)	Medicine
Intra-uterine contraceptive devices other than hormone eluting IUCDs (includes copper containing IUCDs)	Medicine
In-vitro pregnancy tests	Medical device
Irradiating apparatus	Medical device
Lubricating gels with / without local anaesthetic included in the formulation	Medical device

Manuka honey dressings provided the primary purpose of the dressing is to cover and protect the wound and provide an environment that supports healing (rather than to suggest the primary function of the honey is an antibiotic / antibacterial action)	Medical device
Medicated dressings where the primary purpose of the dressing is to cover and protect the wound and provide an environment that supports healing (in contrast to being a delivery mechanism for the medication)	Medical device
Peritoneal dialysis solutions and substances	Medicine
Procedure kits (no medicines included)	Medical device
Procedure kits which include an approved medicine that is in its original pack	Medical device
Saline nasal sprays	Medical device
Saline for injection	Medicine
Solutions for irrigation	Medical device
Tamponade solutions for eye surgery	Medical device
Tissue adhesives (including fibrin based)	Medical device
Toothpastes for sensitive teeth where the mode of action is physical (eg, by blocking open pores). Fluoride content (if any) must be no greater than that allowed in a general sales medicine	Medical device
Total Parenteral Nutrition (TPN) solutions	Medicine
Transdermal patches	Medicine
Vascular balloons with / without medicinal coating	Medical device
Urea ointment for nail debridement	Medical device
Ultrasonic therapy apparatus	Medical device
Water for injection	Medicine

4.7. Products that are Excluded from Regulation Under the Medicines Act

An amendment to the Medicines Regulations that was implemented during 2011 excluded (in specified circumstances) certain product types from regulation under the Medicines legislation. The change was implemented to harmonise the therapeutic product/cosmetic interface with major trading partners, particularly Australia. The

product types that have been excluded, and the conditions that must be met for their exclusion, are set out in the following table.

Conditions to be met in order for the product to be excluded from regulation under the Medicines Act	Notes
Oral hygiene products (eg, toothpastes, mouthwashes)	
<p>The product must not contain a substance which, in the amount or concentration present, is a scheduled medicine (ie, if the product were to be considered a medicine, it would be a general sales medicine)</p> <p>The claimed benefits from use of the product relate only to:</p> <ul style="list-style-type: none"> • improvements in oral hygiene and/or • prevention of tooth decay (including reference to the use of fluoride for the prevention of tooth decay) <p>and do <u>not</u> refer to the prevention or treatment of tooth sensitivity.</p>	<p>The labelling or promotional material must not refer to other benefits from use of the product, such as prevention or treatment of tooth sensitivity, gum disease or other oral disease or periodontal conditions.</p>
Anti-dandruff hair care products (eg, shampoos, conditioners)	
<p>The product must not contain a substance which, in the amount or concentration present, is a scheduled medicine (ie, if the product were to be considered a medicine, it would be a general sales medicine)</p> <p>The claimed benefits from use of the product relate only to the prevention or control of dandruff through cleansing, moisturising, exfoliating or drying the scalp.</p>	<p>The labelling or promotional material must not refer to other benefits from use of the product, such as prevention or treatment of fungal infections of the scalp.</p>
Anti-acne skin care products (eg, cleansers, face scrubs and masks, spot treatments)	
<p>The product must not contain a substance which, in the amount or concentration present, is a scheduled medicine (ie, if the product were to be considered a medicine, it would be a general sales medicine)</p> <p>The claimed benefits from use of the product relate only to the prevention or control of acne through cleansing, moisturising, exfoliating or drying the skin.</p>	
Barrier creams (eg, hand creams, nappy rash creams)	
<p>The product must not contain a substance which, in the amount or concentration present, is a scheduled</p>	<p>The labelling or promotional material must not refer to</p>

<p>medicine (ie, if the product were to be considered a medicine, it would be a general sales medicine)</p> <p>The claimed benefits from use of the product relate only to the prevention or control of skin irritation, dryness or damage, by the creation of a protective barrier to moisture.</p>	<p>other benefits from use of the product, such as prevention or treatment of fungal or bacterial skin infections.</p>
Antibacterial skin products	
<p>The product must not contain a substance which, in the amount or concentration present, is a scheduled medicine (ie, if the product were to be considered a medicine, it would be a general sales medicine)</p> <p>The product is only claimed to be active against skin bacteria, and no reference is made to the prevention of treatment of any disease or disorder, or to any named bacterium associated with any disease or disorder.</p>	<p>The labelling or promotional material must not refer to:</p> <ul style="list-style-type: none"> • the product being active against viruses, fungi or microbial organisms other than bacteria • the product being active against a named bacterium that is known to be associated with a disease, disorder or medical condition eg, Salmonella or Escherichia coli • use of the product before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure • use of the product in connection with: <ul style="list-style-type: none"> diseases, disorders or medical conditions; piercing of the skin or mucous membrane (for cosmetic or any other purpose); any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; any procedure involving venipuncture or delivery of an injection.