MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Guidelines on the Regulation of Therapeutic Products in New Zealand

Overview of regulation of therapeutic products

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Abbreviations and definitions

Abbreviation or term	Definition
CMI	Consumer Medicine Information
EPA	Environmental Protection Authority
GRTPNZ	Guidelines on the Regulation of Therapeutic Products in New Zealand
HSNO	Hazardous Substances and New Organisms

1. Introduction

This Guideline provides an overview of therapeutic product regulation in New Zealand. It is one of the Guidelines on the Regulation of Therapeutic Products in New Zealand (GRTPNZ) produced by Medsafe to assist industry meet the legislative and regulatory requirements for marketing a therapeutic product in New Zealand.

2. Legislation

Section summary

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

Table 1 below lists the legislation governing the regulation of therapeutic products (medicines, medical devices and related products) that are manufactured, sold or supplied in New Zealand.

Table 1: Legislation governing the regulation of therapeutic products in New Zealand

Principal therapeutic products legislation
Medicines Act 1981
Medicines Regulations 1984
Medicines (Database of Medical Devices) Regulations 2003
Legislation that imposes additional controls on particular types of therapeutic products and/or activities relating to them
Medicines (Approved Laboratories and Analysts in Charge) Notice 2000
Medicines (Related Products (Exempted Foods)) Regulations 2003
Misuse of Drugs Act 1975 – for controlled drugs
Misuse of Drugs Regulations 1977
Misuse of Drugs (Medicinal cannabis) Regulations 2019
Misuse of Drugs (Approved Laboratories and Analysts in Charge) Notice 2000
Psychoactive Substances Act 2013
Psychoactive Substances Regulations 2014
Hazardous Substances and New Organisms (HSNO) Act 1996 – for medicines that are new organisms and medical devices that contain hazardous substances
Contraception Sterilisation and Abortion Act 1977 – mandated standards for natural latex rubber condoms, polyurethane condoms and intra-uterine contraceptive devices
Electricity (Safety) Regulations 2010 – mandated standards for electro-medical devices
Electricity Act 1992
Health Practitioners Competence Assurance Act 2003
Radiation Safety Act 2016
Human Tissue Act 2008
Health (Needles and Syringes) Regulations 1998
Other legislation referenced in this Guideline
Dietary Supplement Regulations 1985
Fair Trading Act 1986
Sunscreen (Product Safety Standard) Act 2022

Copies of all New Zealand Acts and Regulations may be viewed or downloaded for free from the New Zealand legislation website.

3. 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.

3.1 Therapeutic purpose

Therapeutic product is a term used to describe 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 as:

- preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury
- influencing, inhibiting, or modifying a physiological process
- testing the susceptibility of persons to a disease or ailment
- influencing, controlling, or preventing conception
- testing for pregnancy
- 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. Table 2 contains the factors that are likely to indicate an intended therapeutic purpose.

Table 2: Factors that are likely to indicate an intended therapeutic purpose

The product contains one or more ingredient(s) that have a pharmacological, immunological or metabolic action
A therapeutic purpose is claimed for the product (usually on the label or in promotional material)
The primary purpose of the product is therapeutic regardless of whether a claim is made
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)

Indicators that a product has a therapeutic purpose include its use, label claims or claims in promotional material, such as those shown in Table 3.

Table 3: Indicators that a product has a therapeutic purpose

A trade name that conveys an intended therapeutic purpose
Words such as remedy, medicated or therapeutic
Reference to clinical trials or scientific studies
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
Inclusion of ingredients with a known therapeutic effect

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

3.2 Medicines

The term *medicine* is defined in section 3(1) of the Medicines Act. 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 Safety Act 2016 and administered by the Office of Radiation Safety within the Ministry of Health.

If a product is used in or on humans and exerts its primary effect by pharmacological, metabolic or immunological means, that product is 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 or on humans is a medicine, regardless of the purpose for which it is advertised or supplied.

3.2.1 Excluded products

Some products that meet the definition of a medicine are excluded from regulation under the Medicines Act. Regulation 58A of the Medicines Regulations 1984 excludes some product types from regulation under the Medicines legislation, in certain circumstances.

These include some:

- dentifrice products
- anti-dandruff hair products
- anti-acne skin care products, some barrier creams
- anti-bacterial skin products.

The product types that have been excluded, and the conditions that must be met for their exclusion are published on the Medsafe website: Product Categorisation page.

3.2.2 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.

Herbal remedies are exempt from the medicines approval process if they:

- are provided to a known patient by a natural practitioner
- are labelled with a designation that specifies only the plant from which it is made and the process to which the plant has been subjected during the production of the remedy, and does not apply any other name to the remedy
- do not include any written recommendation (whether by means of a labelled container or package or a leaflet or in any other way) as to the use of the remedy.

Section 28 of the Medicines Act contains further information on exempt herbal remedies.

3.2.3 Medicinal Cannabis

Regulations to enable a Medicinal Cannabis Scheme were passed on 18 December 2019. The Medicinal Cannabis Agency became operational from 1 April 2020 to administer the scheme.

Medicinal cannabis products that have been verified as meeting the minimum quality standard may be supplied as unapproved medicines under the scheme, if prescribed by a medical practitioner.

See the Medicinal Cannabis Agency website for more information.

3.3 Related products

The term 'related products' is defined in section 94 of the Medicines Act. In summary, it is a product that is primarily a food, dentifrice or cosmetic, that also claims a therapeutic use. A related product may not contain a prescription, restricted or pharmacy-only medicine ingredient.

Examples of related products include:

- antiseptic throat lozenges
- antiseptics used for cleaning wounds, cuts, abrasions, stings, insect bites and superficial burns.

3.4 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.

There is more information about medical devices on the Medsafe website.

3.5 More information

See also the Medsafe website for:

- Medsafe's evaluation and approval process
- Categorisation of products – including how to determine if the product is a medicine, medical device or related product.

4. 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 references to other GRTPNZ documents where more detailed information on particular regulatory requirements and processes are located. It also explains the interfaces between the Medicines legislation and other statutes.

4.1 Key elements of the regulatory framework

The regulatory framework includes 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.

The key elements of the regulatory framework are controls on:

- availability, market entry and market exit
- quality
- access
- information.

These elements are applied to varying extents to medicines, related products and medical devices, as outlined below.

4.1.1 Controls on availability, market entry and market exit

There are mechanisms to control the availability of therapeutic products. These mechanisms are the:

- pre-marketing approval system for medicines and related products
- post-marketing mechanisms to remove products from use if unsafe or ineffective.

Pre-market

The pre-marketing approval system requires medicines and related products to be assessed for safety, quality and efficacy, and for the Minister to grant consent to their distribution before they can be advertised or supplied.

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).

For details of the application and evaluation processes and timelines, see *GRTPNZ: New medicine applications* and *GRTPNZ: Changed medicine notifications*, available on the Medsafe website.

The costs of pre-market assessment are recovered through fees payable by applicants. A fees schedule is provided on the Medsafe website.

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

- Sections 20 to 24G – new and changed medicines
- Section 96 – related products.

Medical devices

Pre-market evaluation and approval is not currently required for medical devices. However, the Medicines (Database of Medical Devices) Regulations 2003 require sponsors to notify devices (with some specified exceptions) to a database held by Medsafe, within 30 working days of becoming the sponsor for the device. See the Web Assisted Notification of Devices (WAND) Database page on the Medsafe website for more information.

Post-market

The post-market mechanisms to control availability include powers to:

- revoke or suspend Ministerial consent to distribution (product approval)
- prohibit the import or impose restrictions on supply and request safety data if a device is thought to be unsafe.

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 or a medicine or a medical device. The Medicines Regulations also provide powers in relation to the recall of products (or particular batches or models of a product).

See also *GRTPNZ: Pharmacovigilance* and the New Zealand medicines and medical devices recalls code available on the Medsafe website.

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.

4.1.2 Controls on quality

Medicines

The regulatory mechanisms to control quality include:

- establishing quality standards through the pre-market approval system for medicines

- an audit and licensing system for medicines manufacturers and packers, wholesalers, hawkers, pharmacies and some retail outlets
- enforcement of quality standards through surveillance and monitoring
- a requirement for the manufacturer or importer to hold specifications for testing the medicine and a certificate of analysis for every batch of medicine before it is distributed.

The provisions in the Medicines Act and Medicines Regulations that relate to these regulatory mechanisms for medicines 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
- Regulation 4 – compliance with standards.

Medical devices

Certain medical devices must also meet standards that are imposed by other statutes. For more information, see the Medical Devices – Legislation page on the Medsafe website. It also contains links to the relevant statutes.

The Medsafe website also has information on the mandatory standards for contraceptive devices.

In addition to the above, Medsafe recommends that all medical devices supplied in New Zealand comply with all applicable ISO standard requirements.

4.1.3 Controls on access – medicines only

The regulatory mechanism to control access applies only to medicines. It operates through a classification system that ensures that some medicines are only available in consultation with appropriately qualified health professionals. Substances that are medicines are classified following consideration of the advice of an expert Ministerial advisory committee (the Medicines Classification Committee) which meets twice a year. The classification of a product (that is a medicine) is determined by the classification of the substance or substances it contains.

The Medsafe website has information about the classification process.

The Medicines Act defines three classification categories (levels of access) 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 Medicines*) – 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 medicines in each of these classification categories are listed in the First Schedule of the Medicines Regulations and periodic updates that are published in the *New Zealand Gazette*. The Medsafe website also has a searchable database of medicines classifications.

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 retail outlet if the Minister has given consent to their distribution (the medicine is an approved medicine).

Note: These classifications (levels of access) only apply to medicines that have been approved. Medicines that have not been approved can only be supplied on the authorisation of a medical practitioner unless they meet one of the exemption criteria in sections 25 to 32 of the Medicines Act. See the Medsafe website for further information on the supply and use of unapproved medicines.

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*.

4.1.4 Controls on information for medicines and related products

There are several regulatory mechanisms to ensure that accurate product information is available to support appropriate selection and use of products. These include:

- specifying labelling requirements
- requirements for prescribing information for prescription and restricted medicines (data sheets)
- controls on advertising.

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.

The Medsafe website has a searchable database of data sheets and CMI.

GRTPNZ: Requirements for information for prescribers and consumers describes the requirements for the preparation and publication of data sheets and CMI, and is available on the Medsafe website.

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.

4.2 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 cover xenotransplantation are found in:

- Part 7A – Restrictions on specified biotechnical procedures.

4.3 Access to unapproved medicines

There are regulatory mechanisms that provide access to unapproved medicines .

4.3.1 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 *GRTPNZ: Regulatory approval and good clinical requirements*, available on the Medsafe website. This Guideline 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.

These medicines are only available to patients who are enrolled in an approved clinical trial.

4.3.2 Section 29

Section 29 of the Medicines Act provides a mechanism to permit the supply of an unapproved medicine on the request of a medical practitioner, in order to treat a particular patient under their care. The supply must be initiated by the medical practitioner and the supplier may not advertise the availability of the medicine.

The Medsafe website has information about supply and use of unapproved medicines, including requirements for importers and manufacturers.

Unapproved medicinal cannabis products that have met the minimum quality standard, pursuant to the Misuse of Drugs (Medicinal Cannabis Regulations) 2019, are supplied through this provision.

4.3.3 Section 25

The exemption provisions in Section 25 of the Medicines Act allow all authorised prescribers to "procure the supply of any medicine" for a particular patient in their care. The term "any medicine" can include both approved and unapproved medicines. However, the authorised prescriber must always be working within their scope of practice.

The Medsafe website has information about use of unapproved medicines.

4.4 Interfaces with other legislation

Certain therapeutic products must also comply with requirements imposed by other statutes. These are described below.

4.4.1 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).

4.4.2 Hazardous Substances and New Organisms Act

The Hazardous Substances and New Organisms Act 1996 (HSNO Act), its amendments and its associated regulations apply to some medicines. The Environmental Protection Authority (EPA) administer this legislation.

Even when they cross the HSNO thresholds for hazardous properties, the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 mean that most medicines in finished dose form are exempt from the HSNO Act. However, the following types of medicines are *not exempt* and must comply with the HSNO Act.

- Substances that are gases (eg, medical gases) contained in pressure containers of more than 100 mL **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. 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 Medsafe's New Medicine Application Declaration and Commitments 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 EPA website for specific contact details.

4.4.3 Consumer legislation

Medicines, related products and medical devices are articles of commerce, and therefore, sponsors must 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.

4.4.4 Other regulatory interfaces

Distributors wishing to import unprocessed plant or animal material, should contact the Ministry for Primary Industries to determine which import standards apply.

The New Zealand Customs Service is also able to advise on the requirements for commercial importation.

Some medical devices must also meet standards that are imposed by other legislation and regulations before the devices can be legally supplied in New Zealand. For more information, see the Medical Devices – Legislation page on the Medsafe website.

5. Categorisation of products

Section summary

This section introduces some of the factors that may be used to determine the categorisation of a product as a medicine, medical device, related product, dietary supplement, supplemented food, cosmetic or psychoactive substance. It also provides links to a categorisation tool on the Medsafe website to assist with categorisation decisions.

5.1 Products at regulatory interfaces

It can sometimes be difficult to determine whether a product is a therapeutic product (and if so, which type, ie, medicine, medical device or related product), a type of food (dietary supplement or supplemented food), a cosmetic or a psychoactive substance. 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 purpose for use, its ingredients, its mode of action and the manner in which it is presented in the market through its labelling or advertising. The influence of these factors is explained below, and there is a categorisation tool on the Medsafe website.

5.1.1 Purpose for use

If a product is intended to be used for a therapeutic purpose, then it is a therapeutic product regardless of whether a therapeutic claim is made for the product (refer to section 3.1 of this Guideline).

Therapeutic claims are not permitted for products supplied as dietary supplements or herbal remedies (refer to section 3.2.2 of this Guideline) or cosmetics.

Some health claims may be permitted for supplemented foods, providing the requirements of the Australia New Zealand Food Standards Code or the New Zealand Food (Supplemented Food) Standard 2016 are met. Contact the Ministry for Primary Industries for further information.

5.1.2 Ingredients

A product cannot be lawfully supplied as a cosmetic, a related product, a dietary supplement or a supplemented food if it contains one or more ingredients that are:

- scheduled as Controlled Drugs under the Misuse of Drugs Act 1975, or
- included in Schedule 1 of the Medicines Regulations 1984 as Prescription Medicines, Restricted (Pharmacist-Only) Medicines, or
- Pharmacy-Only Medicines under the Medicines Act.

There are certain limited circumstances where an ingredient scheduled as a Prescription, Restricted or Pharmacy-Only medicine may be included with a medical device to assist the primary function of that device.

Medsafe's searchable classification 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.

5.1.3 Mode of action

The mode of action of a therapeutic product is the means by which it achieves its primary intended effect in or on the human body.

A product that achieves its primary intended effect through a pharmacological, immunological or metabolic mode of action is a medicine.

A product that achieves its primary effect through a mode of action that is not pharmacological, immunological or metabolic is a medical device. When the primary function of a medical device is assisted by a secondary component that acts through a pharmacological, immunological or metabolic mode of action, the product must be presented in a way that is consistent with the primary function of the product.

In some instances, the claimed mode of action may be different from the primary mode of action of the product as a consequence of a pharmacological effect of an ingredient in the product, where the claim is for a physical effect.

It is also possible for a product to have more than one effect in or on the human body. When a product has more than one mode of action, the pharmacological, immunological or metabolic mode of action will be considered the primary mode of action.

5.2 Dietary supplements

Dietary supplements are controlled under the Dietary Supplements Regulations 1985, which are enabled under the Food Act 2014. Regulation 2A 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 make therapeutic claims. Companies wishing to make therapeutic claims for such products must apply for consent to distribute the product as a medicine or related product.

5.3 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.

Products sold as cosmetics are required to comply with the requirements of the Cosmetic Product Group Standard administered by EPA.

Table 4 contains examples of types of products that, 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.

Table 4: Examples of products that are cosmetics*

Antiperspirants
Deodorants

Insect repellents
Dusting powders (powder used to absorb moisture)
Sunscreen and suntan preparations (Note that Sunscreen (Product Safety Standard) Act 2022 requires sunscreens to 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
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

* When sold without any therapeutic claims and not containing any substance listed in the First Schedule to the Medicines Regulations (and amendments).

6. Document History

Revision date	Edition number	Summary of changes
October 2014	1.0	New
May 2024	2.0	Format and legislation references updated; updated organisational information, mandatory standards for medical devices removed and replaced with website links, removal of categorisation tools and information duplicated on the Medsafe website. Added reference to the requirements of the Sunscreen (Product Safety Standard) Act 2022. Added reference to the Medicinal Cannabis Agency, the Smokefree environments and regulated products Act 2021 and the Cosmetic Group Standard.