



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 5:

**Labelling of medicines and
related products**

Edition 1.5

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Section 1: Legislation relating to the labelling of medicines and related products

Section summary

This section lists the legislation regulating the labelling of medicines and related products.

The following legislation governs the labelling of medicines (including Controlled Drugs used as medicines) and related products supplied in New Zealand.

Medicines Act 1981:

- ☞ [Section 2](#): Interpretation (definition of container, label and package)
- ☞ [Section 17](#): Manufacturers, wholesalers, packers of medicines, and operators of pharmacies to be licensed
- ☞ [Section 44](#): Containers and packages of medicines
- ☞ [Part 7](#): Related Products

Medicines Regulations 1984:

- ☞ [Regulation 2](#): Interpretation
- ☞ [Regulations 12 to 25](#) inclusive

Misuse of Drugs Regulations 1977:

- ☞ [Regulation 25](#): Labelling of Containers

Section 2: Mandatory labelling requirements for medicines and related products

Section summary

This section provides information on the mandatory content and format of labels for medicines and related products, explains when an exemption from a particular labelling requirement may be available, and describes matters that need to be taken into account in developing compliant labelling.

2.1. Introduction

[Section 44 of the Medicines Act 1981](#) requires that all medicine containers are labelled “in the prescribed manner”. [Part 4 of the Medicines Regulations 1984](#) sets out detailed requirements for the content and layout of labels for medicines and related products.

Product sponsors must ensure labels include all of the required information and that the appearance and layout of the label are designed to maximise the safe use of the medicine. An exemption from compliance with particular labelling requirements for medicines may be granted in certain circumstances.

This section of the guideline provides information on the labelling requirements set out in the Medicines Regulations and the Misuse of Drugs Regulations and the way that those requirements are applied in particular situations. It also provides guidance on how and when labels should be submitted for approval and when a labelling exemption may be requested.

[Section 4](#) of this guideline provides guidance on labelling practices that, while not mandatory, are considered best practice for medicine labelling. Sponsor companies are **strongly recommended** to apply best practice concepts when designing labels.

2.2. Label content requirements for medicines and related products

Labels for all medicines and related products must:

- contain all the mandatory requirements in English
- present information in the required position and style, if this is specified
- be legible and durable.

The Medicines Act 1981 defines the terms *container* and *package*. A medicine can have only one *container*. Bottles, tubes, ampoules, sachets and blisters are examples of containers. A container may be enclosed in a package, and there may be multiple layers of packaging. Cardboard boxes are a common form of package used for medicines.

The Medicines Regulations 1984 set specific requirements for the labelling of medicine containers and packages. Controlled Drugs used as medicines must be labelled in compliance with the Medicines Regulations 1984 and the Misuse of Drugs Regulations 1977. However, where there is conflict between the two sets of requirements (eg, a different classification statement), the Misuse of Drugs labelling requirements prevail.

The legislation specifies the minimum information requirements for labels. It does not prohibit the inclusion of other information relevant to the safe use of the medicine (for example statements about the presence of allergens such as lactose or gluten).

The information requirements for containers and packages are generally the same. However, reduced requirements apply if the medicine or related product is supplied in one of the types of container specified in [regulation 15 of the Medicines Regulations](#), provided the container is only to be supplied in a fully labelled package.

The types of container to which the reduced labelling requirements apply are:

- an individual container enclosing a single dose, where that container is made of sheet material and is not attached to other containers (eg, a sachet or foil pouch enclosing a trans-dermal patch, a single tablet or a single dose of a powder)
- a container that is made of sheet material and is part of a strip of containers, where each compartment in the strip encloses a single dose (eg, strip or blister packs)
- a small container that is not made of sheet material and has a volume of not more than 20 mL (eg, vial, ampoule, cartridge, single-dose eye drops).

The minimum information required to appear on the label of such containers is the name of the medicine, the names and quantities of the active ingredients, the batch number and the expiry date. In the case of a strip pack the name of the medicine and the names and quantities of the active ingredients must appear at least once in relation to every two dose units if individual doses are readily detachable. Otherwise, the information is only required to appear once on each strip of containers.

The Director-General has issued a labelling exemption under [regulation 12\(5\)](#) so that only the trade name or appropriate designation of the medicine or related product is required to appear on the label of:

- a container (other than an aerosol container) of a medicine that is a gas, with a capacity not exceeding 250 litres water capacity, that is of a type commonly

used for storing or transporting gases in compressed, liquefied or dissolved form.

[Regulation 16](#) specifies the information that must appear on the Principal Display Panel (PDP), which is the portion of the label that is clearly visible in a normal storage situation. All other required information may be placed either on the PDP or on another part of the label.

Requirements for the content of medicine and related product labels and the positioning of label statements are set out in [Part 4 of the Medicines Regulation 1984](#).

A diagrammatic and summarised representation of the labelling requirements for medicines and related products is provided in the following figures:

Figure A shows the labelling requirements for medicine labels.

Figure B shows the labelling requirements for related products.

The boxes in the diagram are coloured as follows:

- ☞ the numbered dark blue boxes¹ show the information that must appear on the Principal Display Panel (PDP) of the label (see [regulation 15](#) for further information)
- ☞ the numbered light blue boxes² show the information that must appear somewhere on the label, but not required to appear on the PDP
- ☞ the pink boxes³ provide additional guidance on meeting the labelling requirements
- ☞ the yellow box at the bottom of the diagram indicates when reduced requirements apply to certain types of container labels.

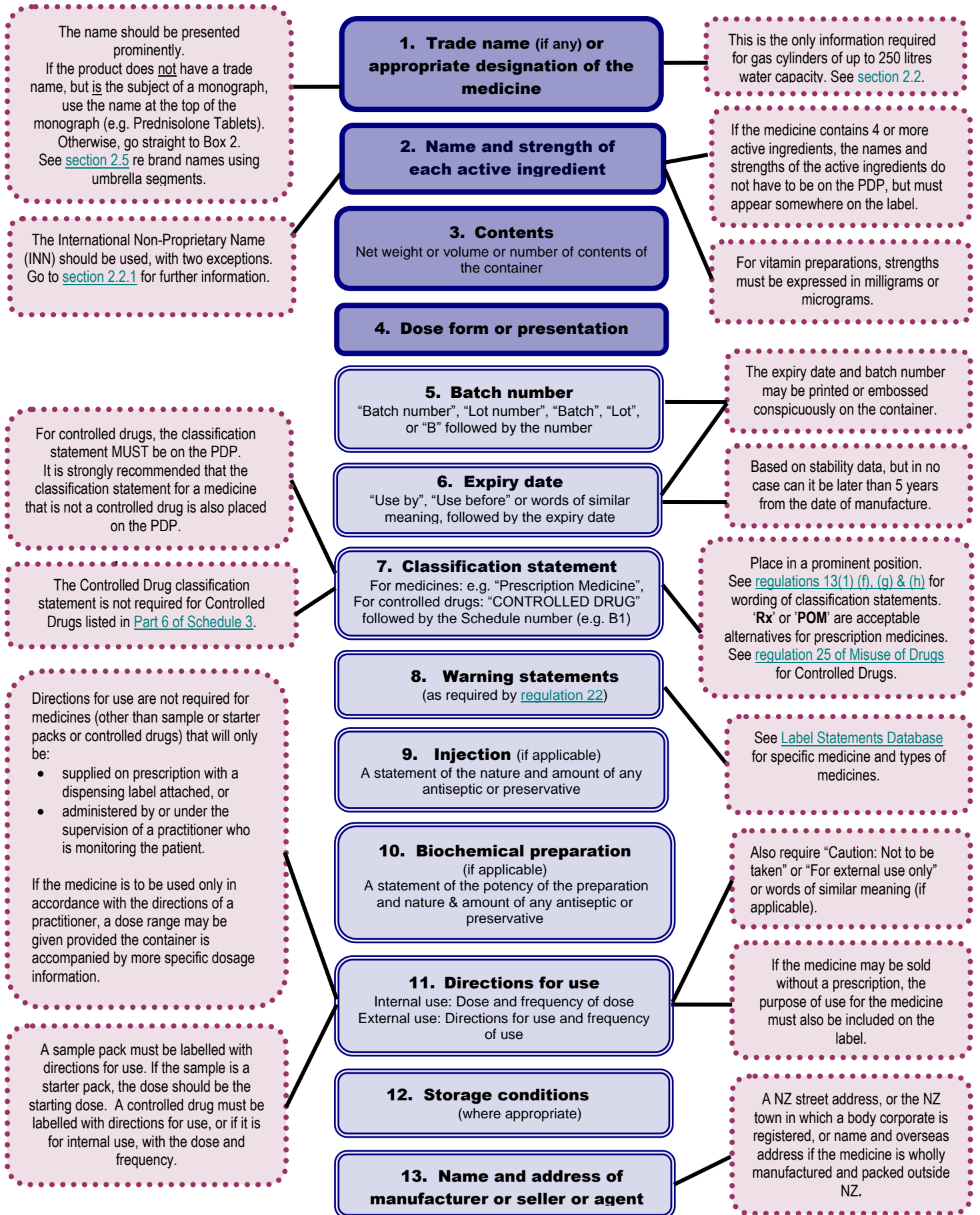
The figures are intended as a ready reference for those designing labels or assessing labels for compliance with the regulations. Because the information in the diagrams is in summarised form, the regulations should be consulted for further detail on the requirements for the labelling of medicines and related products.

¹ On black and white print-outs dark blue boxes can be identified by their single solid boundary line

² On black and white print-outs light blue boxes can be identified by their double solid boundary line

³ On black and white print-outs pink boxes can be identified by their dotted boundary line

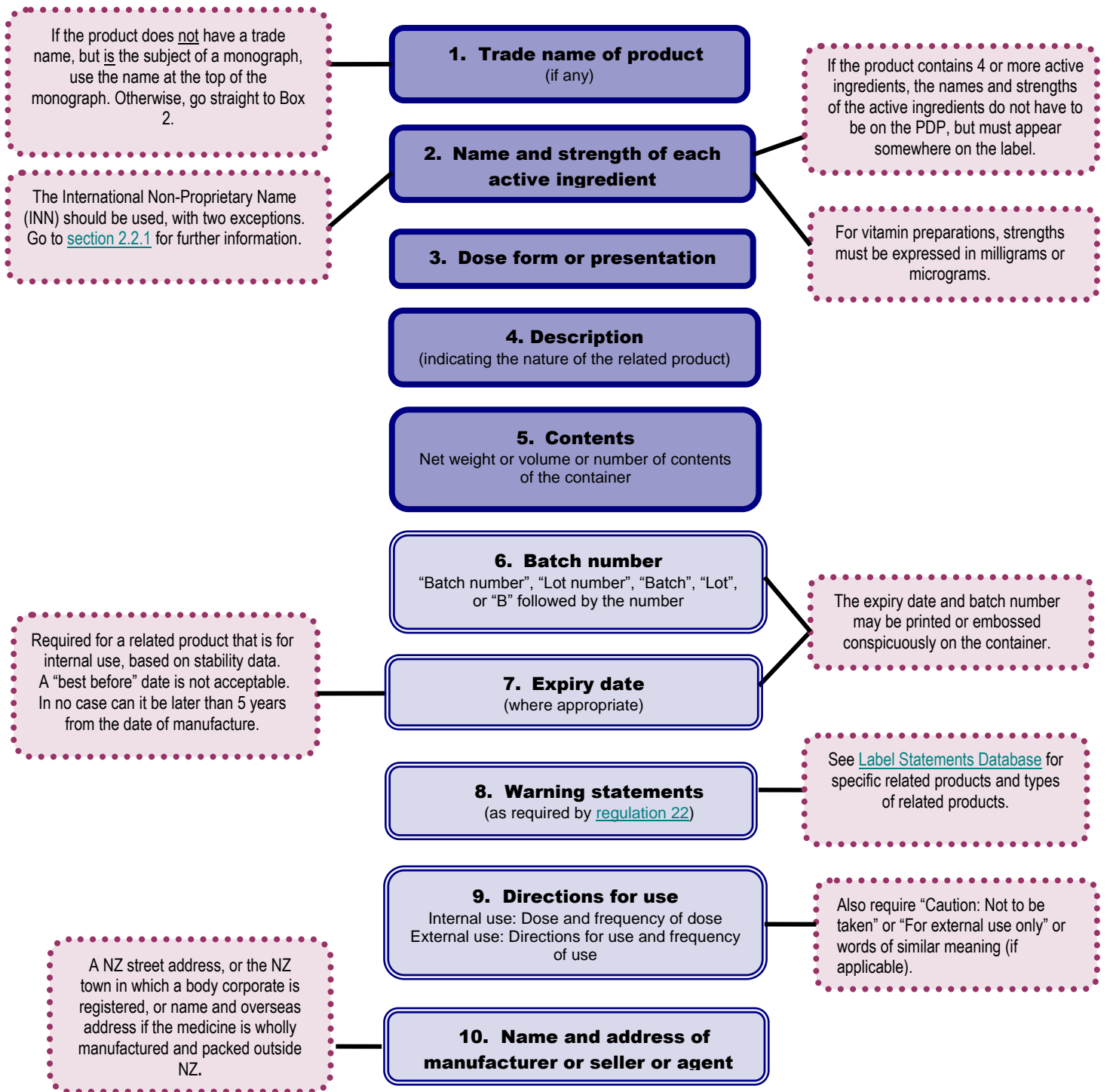
Figure A: Requirements for medicine labels



The following reduced minimum requirements apply to the labelling of certain types of containers, provided the container is to be supplied in a fully labelled package:

- A container made of sheet material that encloses a single dose of medicine – boxes 1, 2, 5 & 6.
- A small (maximum 20 mL) container not made of sheet material – boxes 1, 2, 5 & 6.
- A container made of sheet material each enclosing a single dose of medicine - boxes 1, 2, 5 & 6 on each strip plus boxes 1 and 2 at least once in relation to each two dose units where the containers are readily detached from the strip, or otherwise once per strip (e.g. on a calendar pack).

Figure B: Requirements for related product labels



The following reduced minimum requirements apply to the labelling of certain types of containers, provided the container is to be supplied in a fully labelled package:

- A container made of sheet material that encloses a single dose of a related product – boxes 1, 2 & 6. Box 7 if for internal use.
- A small (maximum 20 mL) container not made of sheet material – boxes 1, 2 & 6. Box 7 if for internal use.
- A strip of containers made of sheet material each enclosing a single dose of a related product - boxes 1, 2, & 6 on each strip plus box 7 if applicable.

2.2.1. Use of international non-proprietary names

Use of International Non-proprietary Names (INNs), both for active ingredients and as the generic name for a medicine, has been commonplace on medicine labels in New Zealand for many years. There has also been an international movement away from country-specific terminology systems to use of the INN.

In keeping with that trend it is expected that, with two exceptions, the INN will be used on medicine labels in the New Zealand market. Those exceptions are:

- ☞ Adrenaline, which should be used instead of its INN epinephrine
- ☞ Noradrenaline, which should be used instead of its INN norepinephrine.

The decision to continue using adrenaline and noradrenaline has been taken on safety grounds and is in keeping with the approach taken in the UK.

It is expected that sponsors of the small number of medicines that are not currently labelled using INN nomenclature will take active steps to move to INN terminology over a short transition period.

The use of the INN should be in accordance with the [WHO INN guidance](#).

2.2.2. Mandatory warning statements for medicines and related products

The Medicines Regulations specify that a medicine or related product label must include any warning statements that may be required by guidelines issued from time to time by the Ministry of Health (see [regulation 22](#)).

To assist sponsors in designing and self-assessing labels for compliance with the Medicines Regulations, Medsafe publishes the warning statements guidance referred to in [regulation 22](#) in the form of a [searchable database of labelling statements](#) that are required for specific medicines or related products or for specific types of medicines or related products.

Sponsors should check the database and ensure that all relevant statements are included on the label before submitting an application for approval of a medicine.

2.2.3. Labelling of safety containers

[Regulations 37\(4\) and 37\(5\)](#) list the specific medicines and classes of medicines that must be supplied in a safety container. The labelling requirements for safety containers are the same as those applying to other single-dose containers or strip packs.

While paracetamol is one of the medicines required to be supplied in a safety container, a dispensation has been granted for tablets and capsules that are not in a safety container to be distributed to pharmacies for use in unit-dose dispensing. The following warning is required to be on the label of such packs:

“Not for general dispensing or retail sale. For unit dose dispensing only.”

2.2.4. Labelling of sample packs

Packs intended for distribution as samples or gifts must be approved and be labelled in accordance with the regulations. The label on a sample pack for a prescription medicine must include the dose and frequency of dose. If a sample pack is intended

as a 'starter pack', the dose stated on the label must be the starting dose approved for the product.

2.2.5. Use of package inserts for medicines

The Medicines Regulations provide for the use of a separate information sheet where it is impractical to put all the required information on the label because the container is too small (see [regulation 13](#)).

For some medicines (eg, cytotoxic agents) it will be necessary to provide information about safe handling and disposal as part of the labelling of the product. This information may be provided on a separate information sheet included with the medicine. The information sheet is considered to be part of the product labelling and must comply with any applicable requirements. It is recommended that, wherever possible, the medicine data sheet is used as the package insert.

2.3. Exemption from specified labelling requirements for a particular product

[Regulation 12\(5\) of the Medicines Regulations 1984](#) provides for the Director-General of Health to grant a labelling exemption to allow a particular medicine to be sold in a specified type of container with a label that is not fully compliant with the labelling requirements set out in the Medicines Regulations.

2.3.1. When is a labelling exemption available?

Labelling exemptions can be granted for medicines. The legislation does not allow exemptions to be granted for related products or controlled drugs.

All other avenues for achieving compliant labelling (eg, using over-labelling – see [Section 2.4](#)) should be exhausted before a labelling exemption is requested.

Labelling exemptions are generally granted in situations where:

- low sales volume for the product (3000 or less units per year, or a greater volume if the sponsor can justify the need for an exemption) mean that the cost of amending the label to achieve full compliance with the regulations would not be recoverable
- temporary unforeseen stock shortfalls occur, necessitating the importation of a product with a non-compliant label in order to maintain continuity of supply of a clinically important medicine.

A labelling exemption will not be granted if it is considered that use of the non-compliant label may be unsafe or cause confusion, creating a safety risk for New Zealand prescribers, pharmacists or consumers.

A labelling exemption is not granted in situations where over-labelling is able to be used to bring the label into compliance with the regulations (see below).

2.3.2. Obtaining a labelling exemption

A request for a labelling exemption may be submitted with a New Medicine Application (NMA) or with a Changed Medicine Notification (CMN). The application or notification must specify the areas of non-compliance for which an exemption is being sought.

Requests for labelling exemptions are considered on a case-by-case basis. An exemption is given for a period of up to two years. The letter granting the exemption will show the period for which the exemption is valid.

Before a labelling exemption expires, the sponsor should check whether an exemption is still required (ie, that there has not been a change to the labelling requirements that mean the previously non-compliant label is now compliant). If an exemption is still required, a new CMN must be submitted, as above.

2.3.3. What does a labelling exemption provide?

A labelling exemption applies only to the particular medicine product label in relation to which it was granted. If that medicine label is subsequently changed, but the changed label is still not fully compliant with the labelling requirements set out in the Regulations, a new labelling exemption must be requested. It should be noted that a change to a label that is the subject of a labelling exemption is not self-assessable.

A labelling exemption does not permit the use of a product information leaflet or CMI leaflet that is inconsistent with the approved New Zealand data sheet or approved product details.

2.4. Use of over-labelling to achieve compliance with labelling requirements

Oversticking of labels to make them compliant with New Zealand legislation is permitted. New Zealand and overseas sites where labelling (including over-labelling) is carried out must comply with Good Manufacturing Practice requirements. All labelling activities carried out in New Zealand must occur at a site that is covered by either a licence to manufacture medicines or a licence to pack medicines.

2.5. Brand names using umbrella segments

An umbrella segment is a section of a brand name that is used in the name of more than one medicine to create a brand for a range of products.

Medsafe's approach to the use of umbrella segments in existing brand names is based on the approach used by the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) and the Australian Therapeutic Goods Administration (TGA).

Medsafe encourages applicants to develop new product names that do not use umbrella segments but does not intend to impose unnecessary impediments to companies using a particular name where other features (such as pack design, labelling etc) can provide adequate distinction between products.

2.5.1. Components of a product name

The 'name' of a product is made up of the following:

☞ the **Proprietary name** (ie, the trade mark of the medicine or the unique name assigned to the medicine by the sponsor and placed on a label)

or (if there is no proprietary name)

the **Non-proprietary name** (ie, the name, including dose form, used to describe the medicine in a pharmacopoeial monograph).

If no monograph exists, the non-proprietary name comprises the name(s) of the active ingredient(s) and the name of the dosage form (eg, Promethazine 25mg tablets)

↳ any **unique word or code** given to the product.

For products that are approved with a generic name, the name of the sponsor or distributor (as it appears on the label wherever it is located) may be regarded as part of the name of the product or as an identifier. For example, a product labelled *Cold and Flu Tablets* with a sponsor identified on the label as *Acme Pharmaceuticals* may be regarded as having the name *Acme Pharmaceuticals Cold and Flu Tablets* or as *Cold and Flu Tablets* (with *Acme Pharmaceuticals* as the identifier). Medsafe takes this approach to distinguish between generically named products marketed by different companies.

2.5.2. Assessing the suitability of a proposed product name

Medsafe will consider each application for a new product name that includes an umbrella segment on the merits of the data and accompanying justification provided. The focus will be on ensuring that any proposed name supports the safe and appropriate use of the medicine, complies with legislative requirements and is unlikely to cause confusion or be misleading.

The whole presentation of the medicine will be taken into account when considering the suitability of a proposed new product name involving an umbrella segment. Presentation includes features such as the name of the medicine, its labelling and packaging, and any informational material associated with the medicine.

Product names including umbrella segments should not be misleading with respect to the therapeutic effects, safety or composition of the product and should not be confusingly similar to the names of other medicines previously approved in New Zealand.

Where an umbrella segment is to be used for more than one product, the segment should not be used if its use is likely to result in safety or efficacy concerns resulting from confusion between the products sharing the same umbrella segment. Such concerns may arise for example if the products contain different active ingredients, if the products can be used in different patient populations, if their safety profile is different in different populations (eg, one can be used in pregnancy or in patients with renal impairment or in elderly people, and the other cannot), if their interactions are different, if their features of and treatment for overdose are different, or if their speeds of onset are different.

When developing labels, companies are encouraged to give less prominence to the umbrella segment and greater prominence to the active ingredient(s).

2.5.3. Recommended approach to umbrella branding in specific situations

The following table sets out acceptable approaches for dealing with specific situations.

Situation where an umbrella segment will be used in the name	Recommended approach
The proposed product contains additional active ingredients and is	The proposed product name should be different to the name of the existing product,

<p>for use in the same therapeutic areas as the existing product using the same umbrella segment.</p>	<p>usually by the use of a suitable suffix or prefix. The suffix or prefix should not give rise to inappropriate impressions of superiority or ambiguity.</p>
<p>The proposed product contains the same or additional active ingredients and is for use in a different therapeutic area than the existing product using the same umbrella segment in the name.</p>	<p>If the existing product name is associated with a particular therapeutic area, it will be necessary to provide reassurance that extension to a different therapeutic area will not give rise to safety issues. Where the new product contains the same active ingredient as the original product, reassurance could be provided by differentiating the packs using a suitable descriptor indicative of the new therapeutic area (eg, <i>Acme Cold and Flu Capsules</i> and <i>Acme Headache Capsules</i>).</p>
<p>The proposed product contains different active ingredients and is for use in the same or a different therapeutic area as the existing product.</p>	<p>If the existing product name is associated with a particular active ingredient, it will be necessary to provide assurance that the use of the umbrella segment will not give rise to safety issues or efficacy issues due to differential efficacy and speed of onset of effect. This situation is likely to be the most difficult one to obtain approval for. Applicants are therefore encouraged to develop new product names without umbrella segments for each product.</p> <p>If no such association exists, the name should be clearly different from the existing product using, where possible, the name of the active ingredient.</p>

2.5.4. Factors to be addressed in applications for product names using umbrella segments

In order to allow a risk-based assessment of proposed product names including umbrella segments, Medsafe, in its assessment of an application, will consider the factors listed below, as appropriate, when determining whether it considers a product name that includes an umbrella segment to be acceptable. Medsafe will also take into account the classification status of the product (ie, whether pharmacist only, pharmacy only, or unscheduled), noting that the classification status of a product may change over time.

In order to facilitate Medsafe's consideration of the application, applicants should consider and address the type of factors listed below in their application. A risk analysis for the new application, that takes into account all of these points and also considers the impact on existing products sharing the same umbrella segment within their name would facilitate Medsafe's consideration of the application. It would be helpful if, as part of the risk assessment, the applicant addresses how they propose to deal with any potential risks that are identified or explain why, in their opinion, they do not represent a problem.

- ☞ Rationale for the use of the name.
- ☞ Results of any consumer testing undertaken using methodologies designed to demonstrate consumer understanding of the label and the instructions for use.
- ☞ Description of other products within the company's own range or from another company with the same or similar (either in spelling or phonetic terms) umbrella segment.
- ☞ Indications for each relevant product.
- ☞ Discussion of any safety issues that may arise from use of the umbrella segment for the new application, should the new product be confused with other products with the same or similar umbrella segments, based on consideration of the safety profile of the active ingredients.
- ☞ Any association between safety and relevant brand(s).
- ☞ Specific populations of patients/consumers where differences between products with the same umbrella segment exist eg, children, pregnant women, elderly people, those with renal or hepatic impairment.
- ☞ Differences in interaction with other medicines.
- ☞ Differences in indications, contraindications, warnings, posology (including dosing frequency, different strength) and other product information.
- ☞ Differences in effects of and management of overdose.
- ☞ Differences in the mode and speed of action between active ingredients in products sharing the same umbrella segment of their product name (eg, heartburn and indigestion containing alginate and antacid or H2 antagonist respectively).
- ☞ Use of different suffixes/prefixes etc and how these may differentiate between products, addressing issues such as strength, population, therapeutic area etc.
- ☞ Details of the pack including
 - Pack overall colour and design
 - Pack design shape
 - Placement and prominence of active ingredient and usage information
 - Dose form(s) of product
 - Inner pack colour, design and shape
 - Pack size(s)
 - Ability to differentiate between products sharing the same umbrella segment in their product name.

Section 3: Obtaining approval for new and changed medicine and related product labels

Section summary

This section provides information on how and when labels need to be submitted for approval.

3.1. When is approval required for a label?

All labels for new medicines and related products (including container and package labels) are required to be submitted with the application for consent to distribute the new product and are assessed during the evaluation of the NMA or NRPA.

Prior approval, through the CMN/CRPN process, is required whenever a change:

- is made to the actual information appearing on the label relating to the name, strength of active ingredient, dosage instructions or warning statements. This does not apply if the change is only to the colour or print style used for this information
- is made to the label as a result of the medicine being re-classified under the Medicines Regulations or as a Controlled Drug. However, prior approval is not required if the only change is to the classification statement.
- is made to a label for which a labelling exemption has previously been granted

or

- results in the label becoming non-compliant. Note that a label may become non-compliant as the result of changing the position of certain information.

Any other change to a label is required to be notified using the Self-Assessable Change Notification (SACN) process. Changes notified through the SACN process may be implemented as soon as the notification has been validated by payment of the invoice issued by Medsafe. Medsafe carries out random audits of self-assessed labelling changes, and if any problems are identified, sponsors are required to submit a CMN to obtain approval for the changes needed to bring the label into compliance.

3.2. Submitting applications for approval of new and changed labels

An application for approval of a new medicine or related product, or a changed medicine or related product notification that involves a label change must include the following:

- colour artworks of labels and packaging material. Artwork does not need to be actual size, but must be legible, drawn to scale and include a statement of the label dimensions. If the same label (apart from the contents statement) is to be used for several pack sizes of the same strength of a product, it is only necessary to submit exemplar artwork for one pack size and state that it applies across the pack size range.
- a copy of the current label (if applicable)

☞ a signed labelling declaration (see [section 3.3](#))

3.3. Labelling declaration

Each new medicine or related product application, and each changed medicine or related product notification involving a label change, must include a signed labelling declaration (as part of the declarations and commitments form).

The declaration must either state that the label complies with the legislation in all respects, or identify those aspects in which the label is non-compliant. If the label is non-compliant, the applicant should first investigate the possibility of achieving compliance (eg, by over-labelling). If this is not feasible, and the relevant criteria are met, a labelling exemption may be requested (see [section 2.3](#)).

A separate labelling declaration is required to cover each product or range of products.

In signing the declaration, the applicant is accepting legal responsibility for compliance of the label(s) with the legislation.

Medsafe no longer requires companies to submit completed label check lists.

Section 4: Best practice guidance on labelling of medicines

Section summary

This section provides information on the use of barcodes and other aspects of best practice labelling.

The Medicines Regulations set out the mandatory requirements for the labelling of medicines. These represent the minimum requirements to be met when designing labels. In general, these requirements relate to the information that needs to be included on the label, rather than to the way in which that information is presented.

It is well recognized that good label design plays a significant role in improving the safe use of medicines by enhancing the ability of healthcare professionals and patients to identify, select and use medicines correctly. Barcoding of medicines is also recognised as an important tool in reducing medication errors and is strongly recommended.

There may be situations where it is not possible to label a particular medicine in accordance with best practice recommendations. Sponsors should, however, always utilise the available guidance on best practice for medicine labelling when designing and assessing the suitability of labels for products supplied in New Zealand.

4.1. Recommended best practice guidance on the labelling of medicines

The following resources provide useful guidance on best practice in medicines labelling:

- ☞ [Best practice guidance on labelling and packaging of medicines](#) (MHRA Guidance published 2014)
- ☞ [Best practice guideline on prescription medicine labelling](#) (published by the Australian Therapeutic Goods Administration November 2005)
- ☞ [Guideline on the readability of the labelling and package leaflet of medicinal products for human use](#) (Revision 1 published by the European Commission 12 January 2009)
- ☞ [Design for Patient Safety](#) (A guide to the graphic design of medication packaging) (NHS National Patient Safety Agency 2nd Edition 2007)

4.2. Barcoding on medicine labels

Barcoding is an important tool for ensuring correct identification and selection of medicines and reducing medication errors.

Whilst it is not mandatory for labels on medicines supplied in New Zealand to include a barcode, **sponsors are strongly encouraged to place bar codes on original packs at the point of manufacture/packing**. This recommendation applies to single-dose packs as well as multi-dose packs.

Given that bar coding is increasingly being used internationally, it is expected that most products will have a barcode and that bar coding will become mandatory in the near future.

The following links can be used to find information about barcode types and product identifiers (GTINs):

- [Bar Code Types](#) (published by GS1 Healthcare)
- [New GS1 Product Identification Standard](#) (published by GS1 Healthcare January 2010)
- [Healthcare GTIN Allocation Rules](#) (Issue 9 published by GS1 Global Healthcare User Group November 2014)

Revision Date	Revision Number	Summary of changes
27 January 2015	1.4	<p>Removal of obsolete information relating to products that are medical devices following the implementation of the Medicines Amendment Act 2013.</p> <p>Inclusion of summary of changes table in published guideline.</p> <p>Minor formatting changes.</p>
22 September 2015	1.5	<p>Updated link to Best practice guidance on labelling and packaging of medicines (MHRA Guidance) in section 4.1 Recommended best practice guidance on the labelling of medicines.</p>