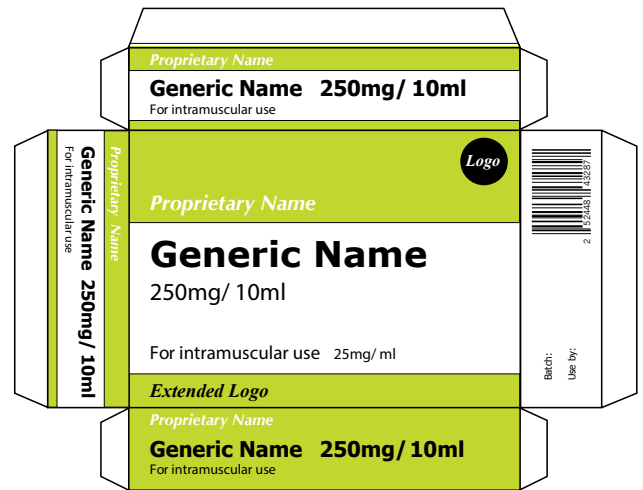




This document provides guidance on the naming and labelling preferences of PHARMAC and its clinical advisors when reviewing a pharmaceutical for funding. The preferences in this document address the issues with labelling that cause the most concern to PHARMAC, and PHARMAC's preferred approach to these.

These preferences are in addition to, and intended to be consistent with, labelling requirements set out in the Medicines Act 1981, the Medicines Regulations 1984 and Medsafe's Labelling of medicine and related products *guidelines*. In the unlikely event of an inconsistency between PHARMAC's preferences and regulatory requirements, the latter takes precedence.

PHARMAC recommends applying best practice concepts when designing labelling.



Legislation relating to the labelling of pharmaceuticals

The following legislation currently governs the labelling of pharmaceuticals (medicines, including controlled drugs used as medicines) and related products supplied in New Zealand:

- > Medicines Act 1981
- > Medicines Regulations 1984
- > Misuse of Drugs Regulations 1977

Pharmaceutical labelling must comply with the "Guideline on the Regulation of Therapeutic Products in New Zealand: Part 5: Labelling of Medicines and Related Products"

Naming

Particular care must be taken when designing a pharmaceutical name. Failure to do so can lead to communication and selection error which could cause harm.

1. International non-proprietary names (INNs)

PHARMAC supports the World Health Organization's initiative to *protect INNs*.

The use of the INN should be in accordance with the *WHO INN guidance*.

- 1.1. PHARMAC prefers that proprietary (trade) names for pharmaceuticals are derived from INNs (generic names).
- 1.2. Where the trade name is the INN name in combination with the company name as an identifier, PHARMAC prefers:
 - 1.2.1. The company name to be a suffix
 - 1.2.2. The company name to be written in full to avoid confusion with formulation type. For example, 'ibuprofen-companyx' not 'ibuprofen-com'

It is expected that with two exceptions (adrenaline and noradrenaline) the INN will be used on medicine labels in the New Zealand market. PHARMAC recommends the New Zealand Universal List of Medicines (NZULM) be consulted when designing a pharmaceutical name.

2. Umbrella naming

An umbrella segment is a section of a proprietary (trade) name that is used in the name of more than one pharmaceutical to create a brand for a range of products. Current best practice discourages the use of umbrella naming.

- 2.1. PHARMAC prefers that suppliers develop new proprietary (trade) names or use the full INN name. PHARMAC recommends suppliers familiarise themselves with the approach taken by Medsafe outlined in its *guideline*.

Labelling

3. Essential Information

This is the information essential for the safe use of the pharmaceutical. The National Patient Safety Agency (England and Wales) has provided a series of useful design examples.

3.1. Pharmaceutical name

The name of the pharmaceutical should include both the generic name and the propriety (trade) name (where applicable).

- 3.1.1. PHARMAC prefers that the generic name appears prominently alongside the proprietary (trade) name (if any).
- 3.1.2. PHARMAC prefers that the generic name appears prominently on at least three non-opposing faces of the outer packaging.

3.2. Pharmaceutical form and dose/strength/concentration

- 3.2.1. PHARMAC prefers that dose strength and pharmaceutical form be given due prominence and be included in all labelling and packaging components where the generic name appears.
- 3.2.2. PHARMAC prefers that the pharmacopeia standard terms be used for pharmaceutical form. These should include standard expression for long acting dose forms.
- 3.2.3. PHARMAC prefers that the formulation type be written in full on labelling.
- 3.2.4. PHARMAC prefers that strength is not represented in percentages, eg %w/w and %w/v.
- 3.2.5. PHARMAC prefers that the strength of single dose injectable and liquid preparations should be stated as the total quantity of the active pharmaceutical substance per total volume and per ml. If the volume in the container exceeds 1ml, the concentration (quantity of active pharmaceutical substance per one ml) should be indicated immediately below the strength, either in brackets or in less prominent letters.

3.3. Route(s) of administration

- 3.3.1. PHARMAC prefers that positive messages be used to describe route of administration, such as “give by...”
- 3.3.2. PHARMAC prefers that negative statements, such as “not for ... use”, be avoided.

3.4. Specific Warnings

New Zealand legislative requirements for certain pharmaceuticals may require that specific warnings essential for safe use, are provided on the front face of the package.

The Medsafe label statements database, which provides a list of warning and advisory statements that are required on pharmaceuticals and related products, should be adhered to as required by section 13(1)(i) of the regulations.

- 3.4.1. In addition to these warning statements, PHARMAC prefers that
 - 3.4.1.1. cytotoxic drugs have “cytotoxic” clearly identifiable on packaging
 - 3.4.1.2. neuromuscular blocking agents have “warning: paralyzing agent”
 - 3.4.1.3. penicillin products have “contains penicillin”.
 - 3.4.1.4. Oral methotrexate products have “usually taken once a week”.

4. Other information required by regulation

- 4.1. PHARMAC prefers that mandatory information required on the packaging does not obscure the essential information as noted above.

Medsafe have provided a comprehensive guideline on the minimum requirements for labelling.

5. Error-prone abbreviations, symbol and dose designations

The use of abbreviations and acronyms may save time but can increase the potential for medication errors. The Health Quality and Safety Commission New Zealand (HQSC)'s error-prone abbreviations, symbols and dose designations should be considered when designing labelling.

- 5.1. PHARMAC prefers that the HQSC-preferred term is used in labelling where space allows.

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6. Colour used in labelling

Colour can help correctly identify, classify, and differentiate between pharmaceuticals. However, relying totally on colour to do this can lead to mistakes.

- 6.1. PHARMAC prefers that when designating different colours between strengths there is no pattern in the colour scheme in the labelling.
- 6.2. PHARMAC prefers that colour differences between strengths of a pharmaceutical are clearly distinguishable from one another. The same tone or hue should be avoided. This colour difference also needs to be clearly identifiable when the product is:
 - 6.2.1. in isolation
 - 6.2.2. in different lighting conditions
 - 6.2.3. alongside other pharmaceuticals.

There are a number of sources of best practice guidelines for colouring on packaging. The National Patient Safety Agency (England and Wales) has provided a series of useful design examples in its graphic design guidelines.

7. Braille

- 7.1. PHARMAC prefers the use of braille on packaging

8. Expiry date

- 8.1. PHARMAC prefers expression of the expiry date as an exact date or otherwise add the words “use before”.

9. Space for a dispensing label and machine readable codes

- 9.1. For packaging designed to be used by the patient, PHARMAC prefers a clearly designated space for affixing a patient label.
- 9.2. PHARMAC prefers that there are space allowances for machine readable codes and that the information contained within the machine readable code includes:
 - 9.2.1. batch number
 - 9.2.2. expiry date
 - 9.2.3. Global Trade Item Number (GTIN).

10. Blister containers

- 10.1. PHARMAC prefers that each blister pocket include both the generic name, proprietary (trade) name (where applicable), and the strength of the pharmaceutical.
- 10.2. Where blisters are small, PHARMAC prefers repetitive diagonal use of generic name and strength over the blister covers with expiry date and batch number on the side to assist with identification of partly used packs.

11. Other considerations

PHARMAC takes a pragmatic approach when considering a pharmaceutical for funding. PHARMAC and its clinical advisors may have additional preferences not covered in this document, however these would be advised on a case by case basis.



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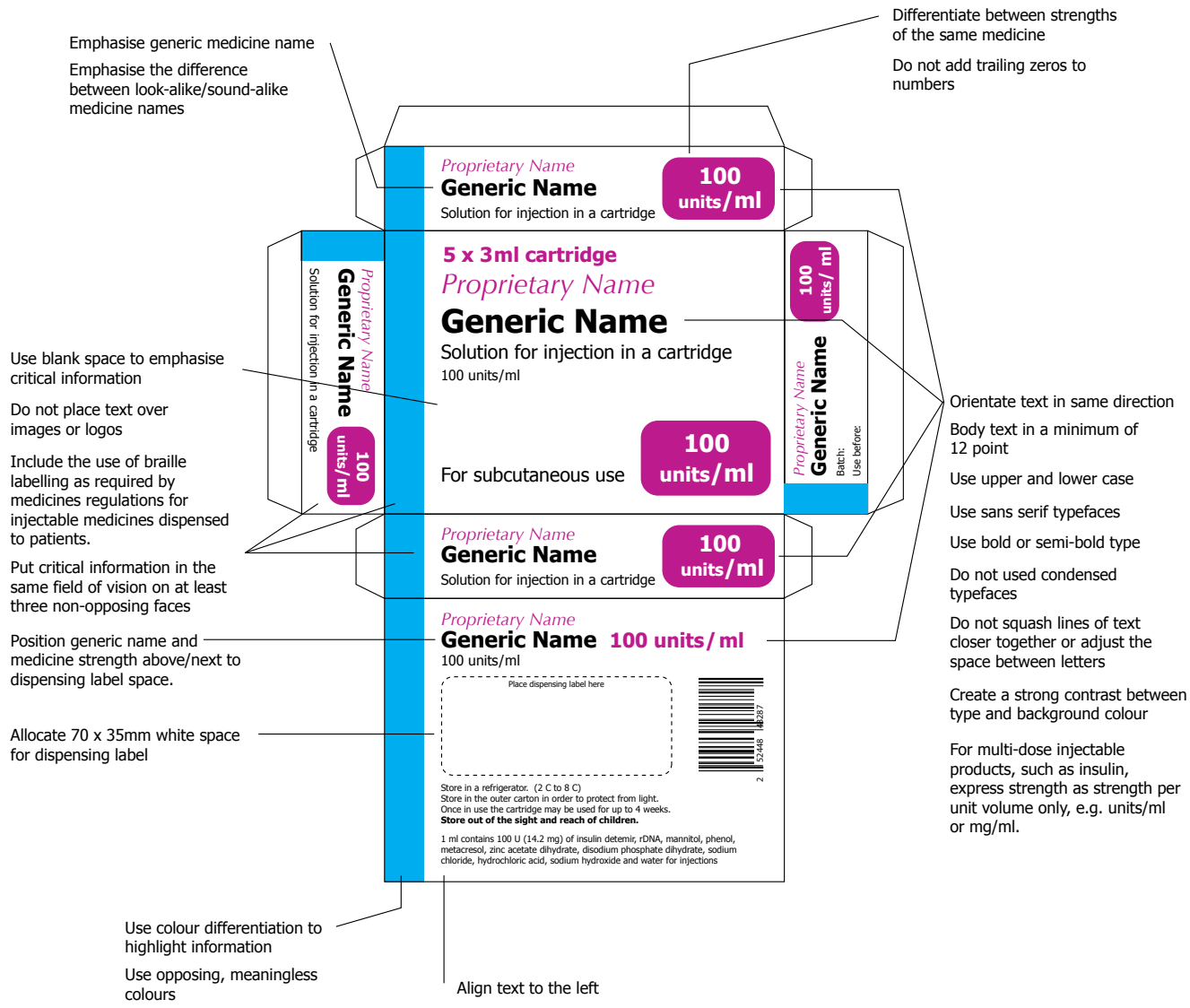


Figure 1. Adapted from Recommended best practice design (National Patient Safety Agency, 2008)



Resources used in the development of these preferences

The following resources have been used in the development of the PHARMAC labelling preferences and go into further detail on best practice:

1. International Medication Safety Network. Position Statement Making Medicine Naming, Labelling and Packaging Safer. Available at: http://english.prescrire.org/Docu/Images/IMSN/IMSN_MakingMedicinesNamingLabelingAndPackagingSafer2013.pdf
2. Medsafe New Zealand Medicines and Medical Devices Safety Authority. Guideline on the Regulation of Therapeutic Products in New Zealand Part 5 Labelling of medicines and related products. Edition 1.4 February 2015. Available at <http://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part5.doc>
3. World Health Organisation. Essential medicines and health products, Guidance on INN. Available at <http://www.who.int/medicines/services/inn/innguidance/en/>
4. World Health Organisation. Essential medicines and health products, Publications: Publishing INN Lists. Available at <http://www.who.int/medicines/services/inn/innguidance/en/>
5. New Zealand Universal List of Medicines. Available at <http://www.nzulm.org.nz/>
6. Medicines and Healthcare Products Regulatory Agency (UK). Best Practice Guidance On The Labelling and Packaging Of Medicines. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328404/Best_practice_guidance_on_the_labelling_and_packaging_of_medicines.pdf
7. National Patient Safety Agency (England and Wales) Helen Hamlyn Research Centre. Design for patient safety: A guide to the graphic design of medication packaging. London (2007). Available at: <http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=63053>
8. National Patient Safety Agency (England and Wales) Helen Hamlyn Research Centre. Design for patient safety: A guide to the labelling and packaging of injectable medicines. London. 2008. Available at: <http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59831>
9. Health Quality and Safety Commission New Zealand. Error-prone abbreviations, symbols and dose designations, May 2012. Available at: <http://www.hqsc.govt.nz/assets/Medication-Safety/Alerts-PR/Poster-error-prone-abbreviations-not-to-use.pdf>
10. Best practice guideline on prescription medicine labelling (published by the Australian Therapeutic Goods Administration November 2005) <http://www.tga.gov.au/industry/labelling-pm-best-practice.htm>
11. 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) http://ec.europa.eu/health/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf



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