

designing medicine labels for people

a code of practice for developing usable labels for non-prescription medicines

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who is this code of practice for?

This code of practice is for everyone with an interest in non-prescription medicine labelling, but most particularly for people who write and design labelling for non-prescription products.

In Australia, non-prescription products—over-the-counter (OTC) and complementary products—are available without a prescription and may be purchased either from pharmacies or general sales outlets, without the intervention of a medical practitioner.

The guidelines that accompany this code of practice will help you create and modify labels that consumers can use effectively, and which are consistent with current Australian regulations.

the principles used in this code of practice are:

- ▶ based on established good practice and research in information design
- ▶ supported by evidence gained from reliable research with Australian consumers
- ▶ developed through broad consultation with consumers, industry, government, and health professionals
- ▶ intended to provide information on labels for the benefit of Australian consumers, that equals or exceeds established standards in Canada, the USA and the European Union
- ▶ benchmarked against the performance of current Australian medicine labels, with a view to:
 - monitoring implementation
 - measuring the improvements that are achieved following the introduction and use of this code of practice
- ▶ consistent with and complementary to current Australian legislative requirements.
- ▶ based on the Quality Use of Medicines principles of the Australian National Medicines Policy.

what is the label

In this code of practice we define the label in accordance with current Australian labelling regulations:

The label includes a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods. (Therapeutic Goods Order No. 69, clause 2, Interpretation)

The label should contain information that enables users to perform all tasks listed on page 5. It must also be consistent with the existing legal requirements which include:

- ▶ The [Therapeutic Goods Order No. 69](#)
- ▶ The [Therapeutic Goods Act 1989](#) and [Therapeutic Goods Regulations](#)
- ▶ The [Therapeutic Goods Advertising Code](#)
- ▶ The [Australian Regulatory Guidelines for OTC Medicines](#) (ARGOM)
- ▶ [Listing Guidelines](#) (ELF)
- ▶ The [Standard for the Uniform Scheduling of Drugs and Poisons](#) (SUSDP)

It is envisaged that the development of other legal requirements will need to be reflected in this code of practice as they become available.

what should people be able to do with labels

Consumers who say they are able to read English should be able to use the label as stand-alone information, without help, to:

- ▶ find at least 90% of what they look for on a label
- ▶ use appropriately at least 90% of what they find.

Specifically, consumers should be able to:

- ▶ quickly and easily make a choice about the appropriateness of this medicine for their needs, at the point of sale
- ▶ find and appropriately use instructions for using the medicine safely and effectively, at the point of use
- ▶ access further information, if they want to know more about the medicine, at any point.

Retailers in addition to the above, should be able to use the label to identify and price the item at point of sale.

Sponsors should be confident that labels enable appropriate and effective use of medicines. Labels also enable them to brand and display the product.

consumers using labels

All consumers who say they are able to read English should be able to perform a number of tasks with a label. These tasks will differ from one product to another. Below is a list of tasks that consumers should be able to perform with any non-prescription product at the point of sale, and later at the point of use.

AT THE POINT OF SALE

identify and select

- can locate and read product name
- can locate and read quantity
- can identify what the product is used for
- can identify circumstances under which the product should not be used

AT THE POINT OF USE

use

- can locate, read and understand product description
- can locate and read product ingredients
- can locate, read and understand dosage and usage instructions
- can locate, read and understand any warnings
- can locate and read information/enquiry number

store

- can locate, read and understand storage instructions

dispose of

- can locate and read expiry date

parts of the label

Label parts are described from a consumer's perspective. The parts are:

- ▶ named to reflect what consumers do with them
- ▶ shown in the order in which research suggests they are likely to be used
- ▶ ordered independently of the regulatory requirements for what has to appear on front/back of labels
- ▶ important at the time of purchase and through the life of the product

consumer choice

Product name	recognised when making a choice of product
Technical /Generic name/s	helps choice of product
Pack size	number of items in pack
Weight/size/quantity	strength of product/amount per item
Type of product*	helps choice of product
What it's used for (indication)	helps choice of product
Qualified claim for product*	helps choice of product
Do not use (contraindications)	helps choice of product
How it works*	reinforces choice of product
Dosage form	helps choice of product

<i>consumer instructions</i>	How to use	provides instructions on use
	How much and when (dosage)	provides instructions on dosage
	How to store	provides instructions on appropriate storage
	Expiry date	provides instruction on how long to use and store
<i>Ingredients</i>	Active ingredient/s	provides exact ingredient information
	Inactive ingredients (excipients)	provides information on presence of specified excipients and additives
	About ingredients*	history of usage (on complementary medicines)
	Absent ingredients*	may provide information on absent ingredients
<i>Administration</i>	Availability heading	where product can be sold, purchased and stored
	Barcode*	used by retail
	Product number*	sometimes used for stacking products in code number order in the shelf layout - planogram
	Label number	used by sponsor to identify label version
	ARTG number	used when TGA registration/listing number is needed
	Batch number	used by retail and sponsor in the event of recall
	Device starburst*	used by retail
	<i>Brand</i>	Brand*
Brand descriptor*		non-promotional reinforcement of brand value
Brand Tag Line*		non-promotional reinforcement of brand value
<i>Sponsor</i>	Supplier	identifies the product sponsor and contact information
	Manufacturer*	identifies the product's manufacturer

* non-mandatory information according to the therapeutic goods legislation

labels in context

The scenarios below illustrate some typical solitary moments in ordinary life where people and labels come together in dialogue. There is often no doctor, pharmacist or friend to take part in the conversation, only the small voice of the label. This code of practice together with the [guidelines](#) will help develop labels so that people can choose medicines appropriately, and use their medicines more safely and effectively.

choosing the appropriate medicine at point of sale

Mother with 3 children, from 12 months to 8 years goes into a pharmacy to purchase a pain reliever for the children. The pharmacy assistant explains the differences between the various products, and that it would be best to buy different presentations for the baby and the older children.

A worried parent, trying to quickly find some pain reliever in a busy supermarket for a sick family member, running late to pick up a child from child-care.

A shy and embarrassed teenager in a pharmacy for something for athlete's foot or jock itch, but too embarrassed to ask for the assistant's advice.

A man who is taking a number of prescription medicines has been advised to take St Johns Wort. He reads on the label that it should not be taken with prescription medicines without first consulting a doctor because of possible interactions.

A busy mother, who is feeling tired and run-down, wants to buy a multi-vitamin product with good iron supplementation at the supermarket. The label is important in helping identify the most appropriate product.

finding information

Mother with 3 children, from 12 months to 8 years is at home and needs to give some pain reliever to the baby. She recently purchased some medicines for the children, but can't remember which product was specifically for the baby. Clearly set out information on the label helps her quickly decide on the appropriate product.

An executive rushing between meetings has developed heartburn in the middle of a busy day. He has some tablets for hyperacidity in his briefcase, but can't remember dosage and how often they can be taken.

An older person irritated by pain, rummages through the medicines in the cupboard, looking for something to relieve the pain. Without glasses, the person has to squint to read instructions while the packet is held in a shaking hand.

using medicine safely and effectively

Mother with 3 children, from 12 months to 8 years has chosen the appropriate product, read and understood the label and is able to measure out the appropriate dose for her child. After dosing, she carefully stores the product where the other children cannot access it.

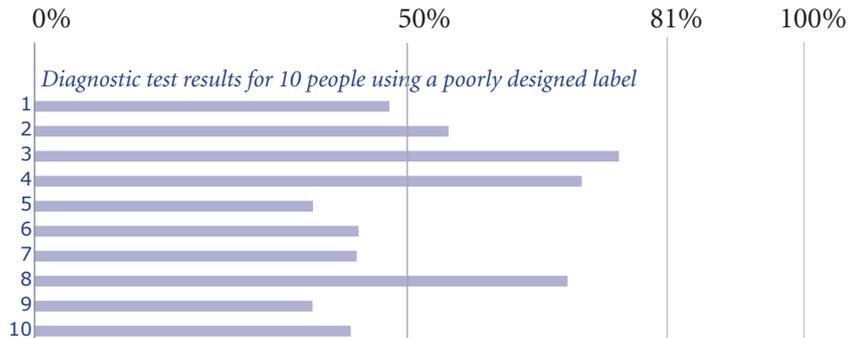
A child is coughing in the middle of the night. A half-awake concerned parent is looking in the medicine cabinet for the appropriate medicine and then needs to look for dosage instructions so as to give the child the correct dose.

measuring label performance

If consumers find at least 90% of what they look for, and can use at least 90% of what they find, they score at least 81% (90% of 90% = 81%). 81% is the minimum requirement of this code of practice. Testing results from before and after application of this code of practice, should typically look like this:

Before

Each bar shows one person's percentage success using a poorly designed label.



After

Each bar shows one person's percentage success using the redesigned label.



ensuring label performance

This code of practice requires that people who say they are able to read English, should be able to use the label as stand-alone information, without help, to:

- ▶ find at least 90% of what they look for on a label
- ▶ use appropriately at least 90% of what they find.

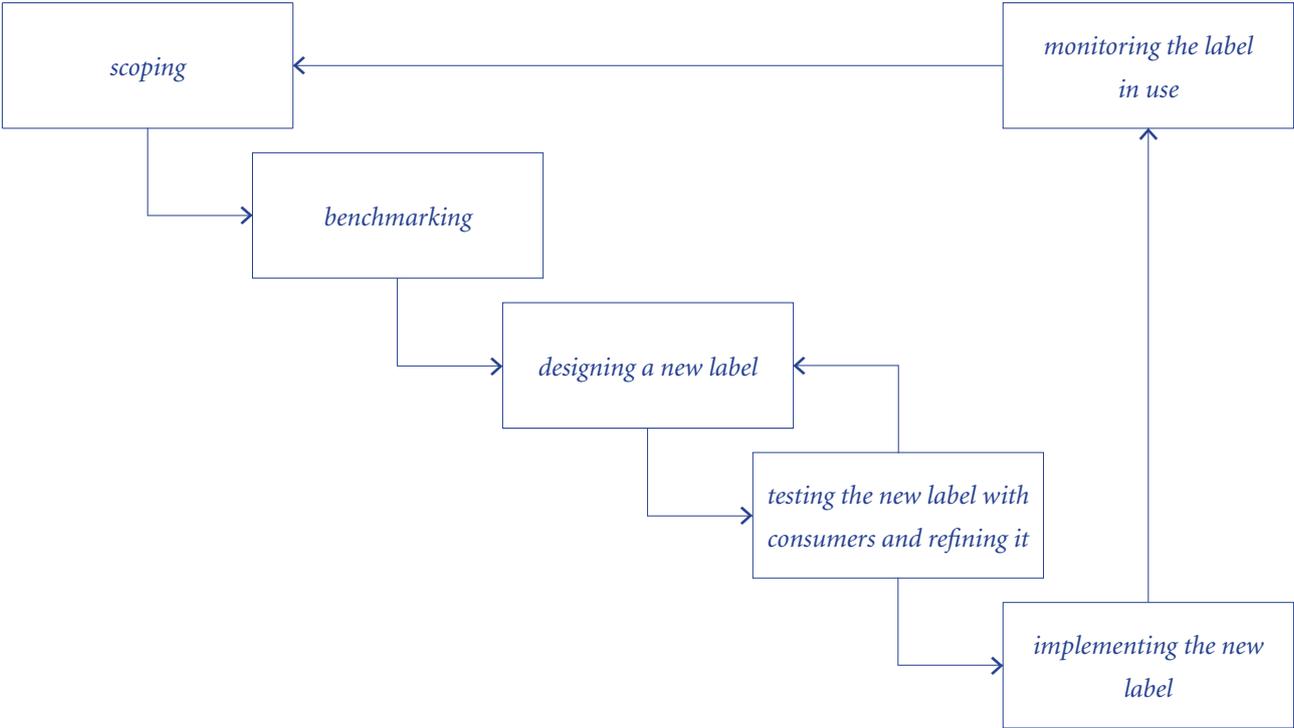
To achieve this performance level you need to follow the [guidelines](#). The guidelines show you how to use typefaces, layout, colour, appropriate language, and structure. They also show you how to use one-on-one diagnostic testing of the labels with consumers in order to find out whether or not the labels perform at the level required by this code of practice.

If a label is changed following testing in minor ways which do not affect consumers' ability to find and use information, then the label may not need to be retested. The [guidelines](#) explain when testing is appropriate in the event of a change to the label..

If in doubt, use one-on-one diagnostic testing as described in the [guidelines](#). Remember, you have a duty of care to ensure that the label meets the performance requirements of this code.

stages in designing labels for people

See the adjacent page for brief definitions of these stages. Full details are in the [guidelines](#)



To follow this code of practice you need to follow the stages on the adjacent page. These are explained briefly below. The [guidelines](#) that accompany this code of practice explain each of the stages in detail.

scoping: ensuring that all factors necessary for the design or redesign of the label are known and taken into account, as far as possible

benchmarking: finding out how an existing label is performing and setting the performance requirements for a new or redesigned label

designing a new label: use typefaces, layout, colour, appropriate language, and structure. so that the label performs at or above the required level

testing the new label with consumers and refining it: where necessary, test the label with consumers using one-on-one diagnostic testing to diagnose and treat any faults in the label's performance

implementing the new label: supervising the printing of the label to ensure that the label used by consumers is of the same quality as the newly designed label, and introducing any customer information or support systems.

monitoring the label in use: collecting data to find out whether or not the label continues to perform at an acceptable level with consumers.

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