labelling code of practice

designing usable non-prescription medicine labels for consumers

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acknowledgements

A code of practice is the end result of collaboration between many people and organisations. We would like to thank the following organisations and individuals who contributed to the development of this code:

For their comments on drafts of this code, we would like to thank:

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.

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 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

- ▶ developed through broad consultation with consumers, industry, government, and health professionals

- ▶ intended to provide information on labels for the benefit of consumers, that equals or exceeds established standards in Canada, the USA and the European Union

- ▶ benchmarked against the performance of current 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 legislative requirements

- ▶ based on quality use of medicines principles.

what is the label

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

The label includes a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods.

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 and supporting guidelines.

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	AT THE POINT OF USE		
identify and select ▶	*use* ▶	*store* ▶	*dispose of*
can locate and read product name	can locate, read and understand product description	can locate, read and understand storage instructions	can locate and read expiry date
can locate and read quantity	can locate and read product ingredients		
can identify what the product is used for	can locate, read and understand dosage and usage instructions		
can identify circumstances under which the product should not be used	can locate, read and understand any warnings		
	can locate and read information/enquiry number		

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

	Name of part	*Function*
Consumer choice	Product/Brand name	Recognised when making a choice of product and provides brand identity
	Technical / Generic name/s	Helps choice of product
	Pack size	Number of individual items or total volume in pack (tablet, capsules, liquid, etc)
	Dosage form	Helps choice of product
	Dosage information	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

	Name of part	Function
Consumer instructions	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	Gives the date after which the product should not be sold or used
	More information on product*	Used for the consumer to obtain further information about a product e.g. 1800 number or website
	In case of overdose*	Used to obtain advice in case of overdose, eg Poisons Information Centre number
Ingredients	Active ingredient/s	Provides active ingredient details
	Inactive ingredients (excipients)	Provides information on presence of specified inactive ingredients
	About ingredients*	History of usage
	Absent ingredients*	May provide information on absent inactive ingredients
Administrative details	Signal/Availability heading	Where and how a product can be sold and purchased
	Barcode*	Used by retail
	Product number*	Sometimes used for stacking products in code number order on the shelf
	Label number	Used by sponsor to identify label version
	Unique identifier	Identifies the specific product
	Batch number	Used for identification, e.g. in the event of a recall
	Device starburst*	Used to highlight information
Brand	Brand descriptor*	Non-promotional reinforcement of brand value

Name of part	Function
Brand tag line*	Non-promotional reinforcement of brand value
Supplier	Identifies the product sponsor and their address . The sponsor has full responsibility in event of a product recall.
Manufacturer*	Identifies the product's manufacturer, where there is no more than one manufacturer.

Sponsor

* non-mandatory information according to 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.
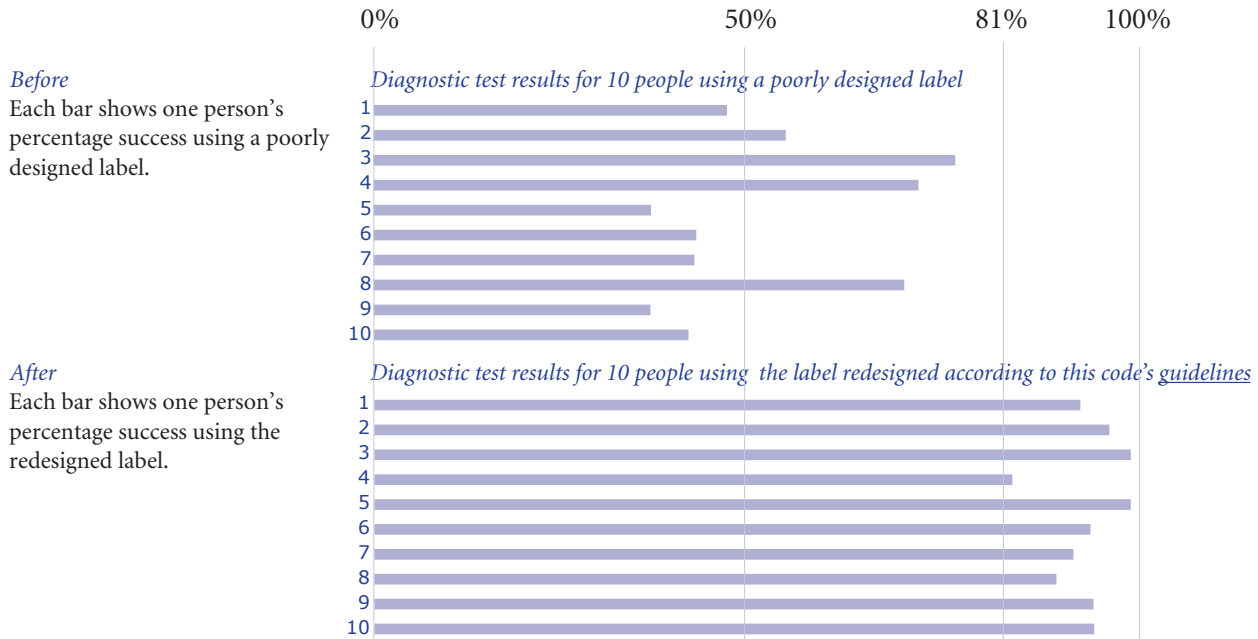
using medicine safely and effectively

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 asto 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:

| | 0% | | 50% | | 81% | 100% |

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

Diagnostic test results for 10 people using a poorly designed label

1
2
3
4
5
6
7
8
9
10

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

Diagnostic test results for 10 people using the label redesigned according to this code's guidelines

1
2
3
4
5
6
7
8
9
10

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 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 consumers

scoping benchmarking designing

1 → 2 → 3 → testing

4

5 refining

7 ← 6 ←

monitoring implementing
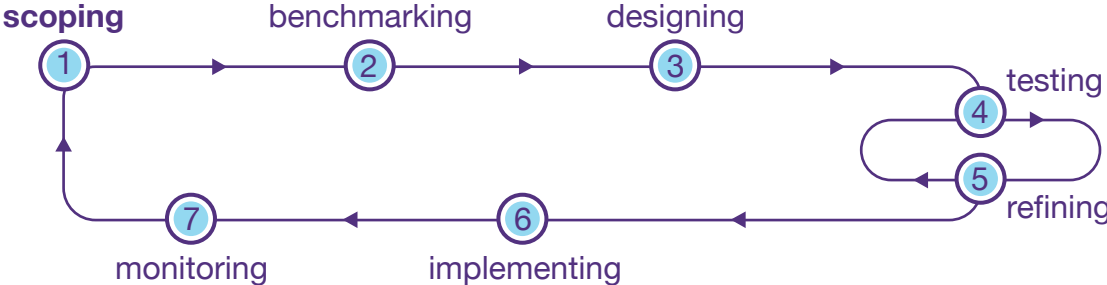
To follow this code of practice you need to follow these stages. They are explained briefly here, and in much greated detail in the *guidelines* that accompany this code of practice.

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

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

(3)   *designing a new label:* using graphics, typography, layout, colour, appropriate language, and structure. so that the label performs at or above the required level

(4)   *testing the new label with consumers:* where necessary, test the label with consumers using one-on-one diagnostic testing to diagnose any faults in the label's performance

(5)   *refining:* making changes to the label following testing to remove any faults in the label's performance

(6)   *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

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