Writing about medicines for people 3rd edition

Usability Guidelines for Consumer Medicine Information

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Published by the **Australian Self-Medication Industry**
www.asmi.com.au

Design by **Alex Tyers**
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This project was funded by the Australian Government Department of Health and Ageing

First published in 1994

Canberra ACT Australia

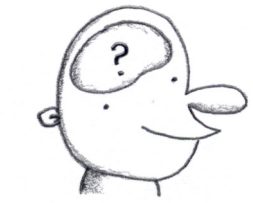
Second edition 1997

Pharmaceutical Benefits Branch, Department of Health and Family Services, Canberra ACT Australia

Third edition 2006

ISBN 0-646-46580-5

Contents



Module 1

Essential background knowledge

Welcome

Welcome to the 3rd edition of *Writing About Medicines for People: Usability Guidelines for Writing Consumer Medicine Information* (the *Guidelines*). These *Guidelines* are for everyone with an interest in Consumer Medicine Information (CMI), but most particularly for people who write the individual CMIs for medicines.

The *Guidelines* give you a set of procedures to follow for writing, testing, implementing and monitoring CMIs, whether you are new to the experience or you have written CMIs before.

How to use these Guidelines

The* Guidelines *are structured as separate Modules.

There are many cross-references to give you added information on many items.

Some information and principles appear more than once, so that you are less likely to miss them if you only scan or skim read any Module.

Depending on your experience, you will use these *Guidelines* in different ways.

Inexperienced CMI writers

If you have little or no experience of writing CMIs, you should do the following:

1. before you write your first (or next) CMI, quickly read all the Modules in the order in which they have been presented, to become acquainted with the material

2. when you are ready to write the CMI, use the Table of Contents and Index to go back over the Modules as you need the information.

Experienced CMI writers

If you have had a lot of experience in writing CMIs, you should:

1. read Module 1 (this Module) and Module 2); they contain new material and provide a useful perspective
2. use the Table of Contents and Index to remind you how to write the CMI, and to update your knowledge.
3. read Module 11 (Checklist) before you test your CMI with consumers.

Why another edition of these Guidelines?

Many of you will be familiar with the hard copy 2nd edition (1997), which was an important publication in the history of consumer-focused medicine information. Responses to that edition have been favourable, in the main. So why is it necessary to provide a new edition?

- Fewer CMIs are being written by dedicated CMI writers. Instead, many if not most CMIs are now written or revised by people with no previous skills in this area.
- The technology available to produce CMIs has changed since 1997, and the methods for producing and publishing CMIs have radically changed with it, requiring new specifications for formats and printing.
- This new edition of the *Guidelines* will not be published in book form; it will be available as PDF modules only, reflecting the changes in technology and work practices.

- The changes in technology will allow us to provide graphics and other devices to help consumers, which would have been impossible eight years ago. At present (2006), graphics are not practicable (though possible), as many pharmacists and other CMI users do not have easy access to the applications, but these online *Guidelines* were written to be easily modified to meet new situations and needs.
- QARG, the group responsible for assessing CMIs to ensure that their content complies with Schedules 12 and 13 to the Therapeutic Goods Regulations 1990 (Cth) ('the Regulations'), rarely sees a CMI that does not need some amendment or improvement. In particular, writers often fail to distinguish between the parts of the CMI, each with its own function and needing its own distinctive typographic style. These *Guidelines* have been rewritten to make these distinctions clearer.
- Many CMI writers have requested reasons for the need to write CMIs in accordance with these *Guidelines*. While they may have little difficulty in following the writing rules, writers would feel more in control if they knew why they were doing it. This new edition of the *Guidelines*, therefore, explains in more detail why the recommended procedures should be followed.
- CMI writers have asked for more examples in the recommended formats. This has been done.

This new edition of the *Guidelines* has been written with reference to Australian therapeutic goods legislation. At the time of writing, new draft legislation is under consideration to form a joint regulatory authority between Australia and New Zealand.

Consequently, references to the Regulations will change when the new legislation comes into force.

What is the purpose of CMIs?

The purpose of CMIs is to help consumers to use their medicines safely and effectively. Consumers and health professionals can be assured that a CMI contains authoritative information produced by the medicine's sponsor* and supported by legislation.

*The sponsor has responsibility for all matters related to the import, export and supply of a medicine in Australia, including writing and maintaining the PI and CMI.

CMIs are designed to *support* the counselling activities of health professionals and carers. They are one part of a process to encourage people to take a greater responsibility for and interest in managing their medicines.

The word *support* has been deliberately stressed in the paragraph above. Indeed, it cannot be stressed enough that CMIs are only one part of the process to help consumers to use their medicines safely and effectively. CMIs do *not* take the place of counselling by health professionals or carers. They are there to supplement and help these counselling activities. CMIs are part of a dialogue: one of the voices within a dialogue between consumers and those who provide medicines and care. Dialogue is an essential component of reading information.
See Module 2 How consumers read CMI)

CMI content

Consumer medicine information is subject to Regulation 9A and Schedules 12 and 13 to the Regulations. Schedule 12 lists all the information that must be contained in CMIs for prescription medicines (S4 and S8). Schedule 13 lists all the information that must be contained in CMIs for pharmacist-only medicines (S3).

The Therapeutic Goods Administration (TGA) strongly encourages CMI writers and designers to follow the principles in *Writing About Medicines for People: Usability Guidelines*, as the publication provides the optimal way of designing CMIs so that they can be most useful to consumers.

In particular, CMIs should be designed so that consumers can dip into them when they want to and locate the specific information they need without having to search.

CMIs for some medicines may be quite long, particularly if you need to add Explanations. These *Guidelines* will help you present the information so that consumers, carers and health professionals can easily find and use what they want, irrespective of the length of the CMI.

Content-focused and consumer-focused approaches

Medicine information has until recently been focused on the content of the information. That is, discussion has centred around what sort of information is provided, but not how the information is used. Recently, the focus has shifted to the user of the information, whether consumers, carers or health professionals. The new *consumer-focused* approach specifies what we want people to do with the information-the tasks we want them to be able to perform.

In other words, the appropriate model for medicine information is not content-focused but *performance-focused*.

Different questions are asked, different answers are provided, and different methods are used to check whether the CMI is likely to allow quality use of medicines by consumers.

- A content-focused approach asks *What do we want to tell people about the medicine?*

  This leads to medicine information that simply tells people about the medicine.

  The measure of success is the publishing of the information on a CMI and the wide-scale distribution of the information to people. As long as the required information is on the CMI, the model is compliant with the regulations.

- A consumer-focused approach asks *What do we want people to do with the information?*

  This leads to medicine information that people can use to perform certain tasks.

  The measure of success is the empirical evidence that they can indeed use the information to perform those tasks.

Importantly, it is the CMI that has to perform well, not the user. A CMI that performs well allows users to act appropriately, so it is the CMI that is judged on its performance, not the user. This may seem like a minor quibble, or playing with words, but the distinction is important during the testing stages.

What English-literate consumers should be able to do with CMIs

Performance-focused medicine information design is concerned with how people use CMIs:

1. Can consumers find what they are looking for?
2. Can they act on this information appropriately?
3. Can you provide evidence to show that they can do this?

'English-literate' users

CMIs are directed at English-literate consumers. Literate consumers, in this context, means *consumers who say they are able to read English*.

Research has shown that:

- *all* of us who describe ourselves as English-literate can make mistakes

when information is designed badly or inappropriately, but often we don't realise we are wrong

- people who say they are not English-literate are not under any such illusions, and will use other strategies to get the information.

(The research on how people read information is discussed in more detail in Module2, How People Use CMI.)

If you develop or revise a CMI using these *Guidelines*:

1. at least 90% of literate consumers should be able to find information on the CMI quickly and easily
2. at least 90% of those who find the information should be able to act appropriately on the information
3. thus at least 81% of literate consumers should be able to use the CMI appropriately.

[Note that the above performance requirements are replicated from the second edition of the Guidelines (1997), but no longer reflect the views of the authors.]

The testing methods included in these *Guidelines* will help you find out whether at least 81% of literate consumers can use the CMI according to pre-determined requirements (see benchmarking), and if not, what changes you need to make to the CMI to ensure that they can.

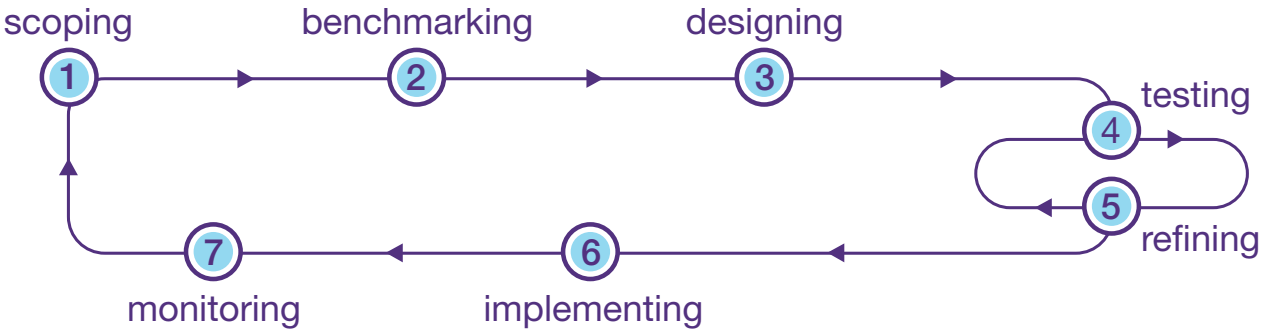
CMIs, carers and health professionals

These *Guidelines* recognise that carers and health professionals have different roles.

Carers are people who provide support to children or to adults who have a disability, a mental illness or a chronic condition, or who are frail-aged. A carer acts on behalf of a person who is using or taking a medicine, and can be a parent, partner, brother or sister, son or daughter, or friend. Carers can use CMIs to explain medicine information

in simple terms, and help consumers remember information given in professional counselling sessions.

Health professionals are doctors, pharmacists, nurses and others who use a CMI to counsel consumers about their medicines.



While a CMI is written for consumers, writers need to consider that carers and health professionals are also CMI users.

Overview of the design and writing process

FIGURE 1 – STAGES OF INFORMATION DESIGN

Figure 1 above shows the stages involved in information design.

Scoping is making sure that as far as possible, all factors necessary for the design or redesign of the CMI are known and taken into account.

Benchmarking involves using diagnostic testing to find out how an existing CMI is performing against the agreed performance requirements set in the scoping stage,

Some aspects of Scoping and Benchmarking have already been undertaken for CMI design.

However, as the context of every CMI differs, you will need to do some scoping and benchmark testing of your own (see Scoping and Benchmarking).

The third stage, Designing, includes the layout and typography (the format) and the content. The layout and typography have already been developed for CMIs.

Do not change the layout and typography:

- CMI format has been specially designed to support the technology used at the point of dispensing by pharmacists
- CMI format has been tested with consumers and shown to work

Click here for a description of the styles.

Click here for a template/style sheet.

As a CMI writer, you can concentrate on writing (Module 7) and testing (Module 11) the CMI, withou t having to deal with the structure and layout as well.

Finally, you will be in charge of refining, implementing and monitoring the CMI.

Writing a CMI

Revising an existing CMI

A CMI is likely to need revising if any of the following happens:

- the PI has changed
- consumers have reported problems with the CMI
- there is evidence that the CMI is not usable, including results from benchmark testing
- QARG has recommended changes.

Ideally, before revising an existing CMI, it should be tested to see whether it performs according to the approved benchmark of at least 81% of literate consumers being able to use it appropriately (see above):

- testing may reveal that the CMI is performing well, and needs little or no revision
- testing tells you which aspects of the CMI need to be changed, so saving time and money in the long run.

Creating a new CMI

You are involved in the development of a complex dialogue. This can be difficult and time-consuming.

Ideally, you should take the following into account.

Consumers have a distinctive point of view, as do professionals in the fields of design, business, health, regulation, marketing, technology and law. You will be in the unique position of being able to see this complex dialogue from multiple view points.

Professional people often make assumptions about how consumers behave, based on their professional judgment rather than immediate observation of consumers' actions.

When you test a CMI with consumers, you will be able to give your fellow professionals

evidence of actual consumer behaviour to help them to develop well-informed ideas specific to the CMI.

Making sure that the consumers' voice is heard can be challenging, so be prepared to negotiate with skill and sensitivity.

Writing a CMI: 9 steps

1. Dialogue with interested parties (Scoping)

Make a list of all parties with an interest in the CMI. This will be your reference group.

Inform them about what you are doing, the methods you will be using, and what you would like them to do.

Once you have created or revised a CMI, you should discuss it with this reference group to make sure that everything you have done is known, agreed to, and understood (see below 5. Reviewing the test results)

Whilst each voice is important, never forget that CMIs are designed for consumer use, so their voice must take priority.

2. Preparing for writing

Whether you are revising an existing CMI or creating a new one, you will need the following material to write it:

- the PI
- these *Guidelines*
- Core CMIs (see Module 17), available on the following websites:
  www.medicinesaustralia.com.au
  www.asmi.com.au/CMI.htm
- Schedule 12 for prescription (S4 & S8) medicines
- Schedule 13 for pharmacist-only (S3) medicines
- the vocabulary of lay-language terms
- guides to pharmaceutical products, e.g:
  USP DI Drug Reference Guide: Volume II, Advice for the Patient
  APF (*Australian Pharmaceutical Formulary*) for counselling points
- any internal information relevant to this CMI
- any data from previous testing of the CMI (revising only)
- any data from consumer enquiries regarding the CMI (revising only).

Before revising a CMI, it is advisable that you do a *benchmarking test* using the procedure outlined in Module 10. Then:

- if the benchmarking test shows that you need to revise it, use these *Guidelines* to write and test the revised version
- if the benchmarking test shows that the existing CMI is performing satisfactorily, you need do nothing more.

3. Writing the CMI

These *Guidelines* provide principles (see Module 6) and examples throughout.

4. Testing the CMI with consumers

Use the procedures outlined in Module 13 of these *Guidelines* to test the CMI with consumers.

However, you may not always have to test.

To test, or not to test

If your CMI follows the advice in these *Guidelines* on language, structure, layout and typography, then you may not need to test it. Using the advice in the *Guidelines* will, in most cases, ensure that your CMI is usable by consumers.

However, there are some special circumstances where you will need to undertake diagnostic testing and refinement to ensure that consumers can use the CMI.

The special circumstances are as follows:

1. **Deviation from Guidelines.** If for any reason you do not follow the advice in the Guidelines on language, layout, and typography, then you may be creating a CMI that will be difficult for consumers to use. Testing will tell you whether or not the CMIs are usable.
2. **Changes to structure and order.** The most common problem consumers have with CMIs is navigation: finding the information they are looking for. Structure and order of information are the most important contributors to successful navigation. If you use a structure or order that is different to what has already been tested, you should test the CMI with consumers.
3. **Increased complexity.** If the instructions for use of the medicine are more complex than those already tested, you may need to test the CMI to ensure that that consumers can handle the additional complexity.
4. **New method of administration.** If the method of administration of the medicine is one that has not been tested, you will need to test the CMI to ensure that the instructions are usable.
5. **Problems detected during monitoring.** If during the monitoring stage you collect reports of consumers having

difficulty choosing or using the medicine, you should test the CMI to determine the cause of the difficulty, and then refine and retest the CMIs to ensure that the difficulty has gone.

What can go wrong

Broadly, there are two types of tasks that people can get wrong when using a CMI:

- they may be unable to find the information they are looking for on a CMI
- having found the information, they may be unable to use it appropriately.

In each instance, a failure can be dangerous. Testing is designed to spot if people fail or have difficulty with any of these types of tasks so that the design fault giving rise to the failure or difficulty can be rectified before the CMI is in production. This is why testing is an intrinsic part of designing CMIs.

However, if data exist from testing CMIs that are known to be usable within a particular social context, then within certain limits, those CMI designs can be 'reused' for other products without impairing the CMI's overall usability, and without the need for further testing. Outside those limits, testing will still be necessary to ensure a CMI is usable.

Risks of not testing

In the end, the decision to test or not to test is a business decision with public health implications. Pharmaceutical companies must weigh up the risks of not testing against the very small amount of time and effort involved.

5. Reviewing the test results

If the results show that fewer than 81% of literate consumers can use the CMI appropriately, make recommendations for changing the CMI to improve its performance

If possible, send copies of the CMI, test results, and any recommendations for changing the CMI to your medical, regulatory, marketing, and legal advisers

If you are having difficulty developing recommendations, seek advice from QARG (contact details: Ms Deborah Monk, Chair, QARG, c/- Medicines Australia, 16 Napier Close, Deakin, ACT 2600. Tel: (02) 6282 6888, Fax: (02) 6282 6299, E-mail: deborah.monk@medicinesaustralia.com.au)

Conduct an internal review of the CMI with your reference group (see above **1. Informing interested parties**) and reach agreement to any changes.

6. Retesting the CMI

If you have made changes likely to have an impact on consumers' ability to find and use information in the CMI, test again to see the impact.

If your changes do not increase the CMI's performance to at least 81%, you may have to make further modifications and retest it before moving on to the next stage.

7. Reviewing the test results externally

You might find it useful to review the test results in consultation with an external group such as a health consumer organisation in the therapeutic area, or QARG (contact details above, 5. Reviewing the test results).

If any changes are likely to have an impact on consumers' ability to find and use information in the CMI, you may have to repeat **Step 6** above (see iterative testing).

8. Implementing the CMI

Make arrangements for distribution of the CMI.

Notify other agencies, as appropriate.

9. Monitoring the CMI in use

Using the procedures in these *Guidelines*, set up a history file for the CMI.

Module 2

How consumers read CMI

How people read information in general

Information designers have spent many years undertaking both theoretical and empirical research into how people read information. Their research has led to practical solutions to the problem of designing documents that people can actually use. The research has provided, and continues to develop, the means of improving communication between organisations and the general public.

Information designers describe the dynamic interplay between a document and a user as part of a dialogue (a 'conversation') because written or graphic communication is similar to spoken communication in many respects, especially in that, if any kind of communication is to succeed, the actors involved have to take into account each other's characteristics (actual and perceived), agree on the purpose and context of their communication, and become involved in the negotiation of meanings.

Readers are highly selective

Information design researchers have observed countless readers using many kinds of information, and have discovered some important characteristics about the way people use information documents and leaflets:

- information users rarely, if ever, read a whole document through from beginning to end
- they are reluctant to read more than they think they need
- if they know, or think they know, how to use a product, they may not look at the document at all until a problem occurs

- users will quickly glance at a document to start with
- if the document looks disorganised, cluttered, wordy, or poorly printed, they may not use it
- faced with a badly-written document a user feels insulted, and loses respect for the producer
- a badly-written or poorly-presented document loses credibility
- if a document is well ordered, with instantly readable headings that have substantive content and are sequenced in a way that is logical to consumers, they can see immediately what kind of information is present and in what ways the document can be helpful
- when people do use documents, they use them to look for:
  - what interests them
  - what they need, or think they need
- they regularly scan documents to find what they want or need
- there is no way of predicting the order in which people read the information in a document, but generally it is not sequential.

Document design for information users

For optimum usefulness, information documents must be structured and written to match the way people read.

Writers must be particularly careful of the following:

- where they place the items of information
- how they present the items of information

Placing the information

The placing of various items of information can only be judged by observing where people actually look for information in a

document. Information design researchers, who have observed people using documents, advise the following:

- information should be placed under meaningful, appropriate headings so readers can easily find what they want
- the headings must be in a clearly identifiable, logical sequence which follows the order in which people expect to find information

  (NB: the logical sequence is that of the readers, not the writer, and should be based on observation of, and discussion with, readers)
- if an item is placed outside such a sequence, it is often not noticed
- if the writer wants to draw particular attention to certain items, these should appear more than once in the document.

Presenting the information

Any information document has many uses. It can provide people with information about what to do and how to do it, why it should be done in that way, which items are essential, which are important, which are advisable, and which are inconsequential. It can provide advice on alternatives and where to get further information, and provide warnings of risk when necessary. These are only a selection of the different uses any one document can have.

Each use must be clearly differentiated from the others. Information users must be able to separate what they have to do from why they have to do it; they must be able to tell at a glance what is important from what is not important; they must be able to tell which item is a piece of advice, and which is an urgent warning; and so on.

Placing and presenting taken together

Always remember that the placing of the information is important. So a writer cannot

just present essential information in large, bold characters at the beginning or end of a document, or in a box, or anywhere outside an appropriate heading. Research has shown repeatedly that such information is ignored or not noticed (reference).

The best way to present information is:

- to place all items of information under headings and subheadings
- to ensure that all headings have the same format, and that all subheadings have the same format, and that the format of headings and subheadings is different and reflects the hierarchy
- to clearly differentiate between the functions of the document by using different fonts, font sizes and spacings.

How people read CMIs

CMI readers are no different to other information readers, and use their CMIs in the same way as they use other documents and leaflets. But as most of the information in a CMI is particularly important, writers must ensure that they present the information carefully, following the advice given in the previous section.

A CMI leaflet has one essential primary use, namely:

> **to provide consumers with Instructions on how to use their medicine safely and effectively.**

It has another important use, taking second place to the Instructions, namely:

> to explain the Instructions where necessary.

For this reason, Instructions must be easily found and recognised as Instructions, and must be written in such a way that

consumers know what to do, even if they read nothing else in the leaflet.

This is why these *Guidelines* recommend that:

- Instructions are always written in bold font
- nothing else in the body of the CMI is in bold font
- Instructions always come first, before any Explanation
- important Instructions can appear more than once, under different headings.

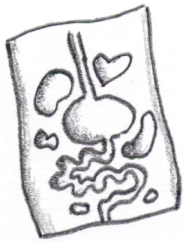
With regard to the final dot point: do not use boxes around text about side effects or other warnings. There is a good deal of evidence to show that people are likely to ignore or miss information in boxed warnings.

Instead, a warning to, say, pregnant women of the dangers of taking the medicine should be written as an Instruction and Explanation.

For example:

> **Tell your doctor if you become pregnant whilst taking the medicine.**
> It could affect your baby's development.

This sequence of words could appear under the Headings What [Brand name] is used for, While you are using [Brand name], Things you must do, and possibly Side effects. There is no way of telling which of these headings consumers will read; and if they read it more than once, this will emphasise the importance of the information. But they are more likely to see it if it is under one of those headings than if it is placed in a box outside the sequence of headings.



Module 3

The composition of a CMI

This Module describes the CMI layout and lists its different parts, explaining the functions and characteristics of each part. Each part has a distinct role in the overall performance of a CMI.

The CMI design recommended in these *Guidelines* has already been tested with consumers for legibility and usability, and will result in CMIs that are legible and usable. If you follow these *Guidelines*, literate* consumers, including older people and others at risk, will be able to find their way to particular parts of a CMI, read the information clearly, and distinguish easily between different types of information, such as Headings, Instructions, or Explanations.

*Literate consumers, in this context, means *consumers who say they are able to read English*. See Module 1 for further explanation of 'literate'

However, although the CMI design has already been tested with consumers, you may still have to test your CMI for its content. You may not have to test for content if you have used a Core CMI (see Module 17).

The layout of a CMI

Figure 2 on the following page shows the layout of the front page of a CMI. It is not shown full size.

The CMI in the illustration has a Table of Contents, which is not necessary on a CMI of 4 pages or less, but has been included to show how it would relate to the rest of the text if needed.

FIGURE 2 –
THE LAYOUT OF A CMI

Brand name® pronunciation

Name of active ingredient (pronunciation)

Consumer Medicine Information (CMI)

Johnny Stressed
26 Overton Avenue
Mainline NSW 2345

Date of Dispensing*
Johnson's Pharmacy*
24 Main Street
Mainline NSW 2345

What is in this CMI

This CMI answers some common questions about [Brand name]. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this information with the medicine.

You may want to read it again later.

What [Brand name] is used for

[Brand name] is an antibiotic used to treat urinary tract infections.

Urinary tract infections are caused by the presence of bacteria in the urinary system. Etc…

BRAND NAME

Explanation

Explanation

Before you take it

Before you start to use it

Instruction

Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation

Explanation after Instruction

Instruction before explanation

- here is an example of instruction dot point
- instruction dot point
- instruction dot point

Using it

Instruction

Instruction before explanation

1. here is an example of List number instruction
2. List number instruction
3. List number instruction

Instruction before explanation
Explanation after Instruction

Instruction

Instruction

Instruction

Subheading top of column

Instruction

Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation

- here is an example of instruction dot point
- instruction dot point
- instruction dot point

Using it

Instruction

Instruction before explanation

1. List number
2. List number

Instruction

Instruction before explanation
Explanation after Instruction

Main Heading

Subheading

Instruction before explanation

1. List number instruction
2. List number instruction
3. List number instruction

continued...

Page specifications

The page and margin sizes have been carefully calculated so that the CMI text fits properly.

It is important that the following sizes are used. Use 'Document' from the Format menu to set them:

- Page size: A4 (210mm wide x 297mm tall)
- Margins: left 15mm, right 15mm, top 15mm, bottom 20mm
- Columns: 3 columns in text section with 10mm space between columns
- Footer: 7.8mm from bottom of page.

The parts of a CMI

Every CMI is built up out of the same parts.

Each part has its own function.

Each part must be clearly distinguishable from the other parts by font (Helvetica, Times), point size, weight (bold, italic, regular), and spacing.

Figure 3 on the next page shows the front page of a CMI with the parts labelled.

Each part is described in detail in other Modules:

- Title Section and Headings in Module 4 and Module 7
- Instructions and Explanations in Module 5, Module 6, Module 7 and Module 8
- Table of Contents and other parts in Module 9

Examples are given throughout.

FIGURE 3 –
PARTS OF A CMI

The parts of a CMI are:

- Title Section *(consisting of several elements)*
- Headings *(two levels: Main Headings and Subheadings)*
- Table of Contents on a long CMI *(two levels corresponding to Headings levels)*
- Introductory statement
- Instructions
- Explanations
- continued...
- Footer

Brand name® pronunciation

Name of active ingredient (pronunciation)

Consumer Medicine Information (CMI)

Johnny Stressed
26 Overton Avenue
Mainline NSW 2345

Date of Dispensing*
Johnson's Pharmacy*
24 Main Street
Mainline NSW 2345

What is in this CMI

This CMI answers some common questions about [Brand name]. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

Keep this information with the medicine.

You may want to read it again later.

What [Brand name] is used for

[Brand name] is an antibiotic used to treat urinary tract infections.

Urinary tract infections are caused by the presence of bacteria in the urinary system. Etc…

Explanation

Explanation

Before you take it

Before you start to use it

Instruction

Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation

Explanation after Instruction

Instruction before explanation

- here is an example of instruction dot point
- instruction dot point
- instruction dot point

Using it

Instruction

Instruction before explanation

1. here is an example of List number instruction
2. List number instruction
3. List number instruction

Instruction before explanation
Explanation after Instruction

Instruction

Instruction

Instruction

Subheading top of column

Instruction

Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation
Explanation after Instruction

Instruction before explanation

- here is an example of instruction dot point
- instruction dot point
- instruction dot point

Using it

Instruction

Instruction before explanation

1. List number
2. List number

Instruction

Instruction before explanation
Explanation after Instruction

Main Heading

Subheading

Instruction before explanation

1. List number instruction
2. List number instruction
3. List number instruction

continued...

Module 4

Parts of CMI 1: Title Section and Headings

Note: references to Styles are linked to the Style sheet

Title Section

FIGURE 4 – WHAT A TITLE SECTION LOOKS LIKE

Brand name® pronunciation

Name of active ingredient (pronunciation)

Consumer Medicine Information (CMI)

	Date of Dispensing*
John Zill*	Everyone's Pharmacy*
26 Jacaranda Avenue	24 Main Street
Mainline NSW 2345	Mainline NSW 2345

* optional fields

The Title Section appears at the top of the first page, and spreads across the three columns.

The Title Section comprises the following:

- the Brand name (the principles for writing Brand names are in Module 6)
- the phonetic pronunciation of the Brand name (see below)
- the active ingredient(s) in the medicine
- the phonetic pronunciation of the active ingredient(s) (see below)
- The words Consumer Medicine Information (CMI)
- spaces for:
  i. date of dispensing medicine (optional)
  ii. name and address of the consumer (optional)
  iii. name and address of the medicine dispenser (optional)

These optional fields are added by the technicians responsible for electronic distribution.

Guide to pronunciation

Include a pronunciation guide for the Brand name and active ingredient(s).

Use the pronunciation system in Webster's International Dictionary as a guide to writing out the pronunciation of the name. The Webster system is the only pronunciation guide in widespread use designed for non-experts. It also uses the characters in the alphabet, not special symbols.

Put the stressed syllable in capitals (phenoxide: fe-NOK-side)

Test the phonetic spelling to make sure that people can pronounce a name closely enough so that a pharmacist, doctor, nurse or Poisons Information Centre can understand what medicine consumers are talking about.

Main Headings (Main Heading and Main Heading top-of-column)

FIGURE 5 – WHAT MAIN HEADING AND MAIN HEADING TOP-OF-COLUMN LOOK LIKE

Main Heading:

↑

(includes a large 36pt space before)

↓

Before you take it

Main Heading top-of-column:

Before you take it

(has 0pt space before)

Function

Main Headings provide the framework holding a CMI together, making it easy for consumers to navigate it.

Every Main Heading must be carefully written:

- it should be short and easy to read
- it should *not* be a question:

  correct: 'How to take it'

  incorrect: 'How should I take it?'

  correct: Side effects

  Incorrect: What unwanted effects might it cause?

The Main Headings in the list below (Standard Main Headings) have been tested with consumers. The *Guidelines* therefore recommend that you use them.

Main Headings must be well ordered:

- they must be in a sequence that is logical to consumers

- the sequence of the Main Headings in the list below follows the sequence of actions and events involved in the responsible use of medicines before, whilst, and after a consumer takes, uses or is given the medicine
- this sequence makes it easier for consumers to find what they want when they need it
- this sequence has been tested with consumers.

Standard Main Headings

What is in this leaflet

What (Brand name) is used for

The principles for writing Brand names are in Module 6.

Before you take it/are given it/use it

Use:

- **Before you take it** for medicines taken orally
- **Before you are given it** for injected medicines
- **Before you use it** for all other types of medicine

How to take/use it/ How it is given

While you are taking/ using it

Side effects

After taking/using it

Product description

These Main Headings provide a strong temporal order for you to follow.

A series of Main Headings acts like a road map, giving a means of navigating through a CMI. Not everyone will take the same route at the same time or be interested in going to the same place. But by using the Headings, anyone will be able to go where they want to go, quickly and easily.

They are also like chapters in a story, organised so that they follow the sequence of actions a consumer will take to use their medicine appropriately.

Where possible, all the information under a Main Heading should be on one page with the Heading at the top of a page or column. This will help readers find the information easily.

If you must continue the information over a page, use 'continued' so that consumers know there is more under that Heading.

Refer to Module 7 for what to write under these Main Headings.

Main Headings and Schedules 12 and 13

There are some differences between the Main Headings here and those suggested in Schedules 12 and 13 to the Regulations. This is because when all Headings were tested with consumers, the consumers could find information more easily using the Headings and sequence recommended in these *Guidelines* than they could using the Headings and sequence in Schedules 12 and 13. See Module 12 for the Schedule 12 Headings.

Despite the change in the wording and sequence, all the information under each Main Heading is as described in Schedules 12 and 13.

Subheadings (Subheading and Subheading top-of-column)

FIGURE 6 – WHAT SUBHEADING AND SUBHEADING TOP-OF-COLUMN LOOK LIKE

Subheading:

↕ (includes a 12 pt space before)

When you must not take it

Subheading top-of-column:

When you must not take it

(has 0 pt space before)

Subheadings come beneath Main Headings (Figure 7, next column):

FIGURE 7 – HEADINGS AND SUBHEADINGS TOGETHER

Before you take it

When you must not take it

Instructions

Explanations as needed

How to take it

How much to take

Instructions

Explanations as needed

If you forget to take it

Instructions

Explanations as needed

Functions of subheadings

Subheadings make it easier for the writer to keep related items together.

They make it easier for a consumer to navigate a CMI.

Standard Subheadings

Following is a list of standard Subheadings related to standard Main Headings.

The list is not exhaustive: you may have to create Subheadings specifically for the CMI you are writing.

FIGURE 8 – SUBHEADINGS INCLUDED UNDER SOME MAIN HEADINGS

Before you take/use it, or Before you are given it

When you must not take/use it, or When you must not be given it

Before you start to take/use it, or Before you are given it

Taking other medicines

How to take/use it, or How it is given

How much to take/use/be given

How to take it

When to take it

How long to take it

If you forget to take it

If you take too much (overdose)

While you are taking/ using it

Things you must do

Things you must not do

Things to be careful of

Things that may help your condition

After taking/using/giving it

Cleaning

Storage

Disposal

Product description

What it looks like

Ingredients

Manufacturer/Sponsor

Creating other Subheadings

For most CMIs, the Subheadings above are sufficient. Instructions or Explanations that follow them can be listed by dot points or numbers.

But you may sometimes need to create a new or different Subheading. This might be when:

- the PI describes any procedures that require special Instructions or lengthy but essential Explanations
- the medicine has complex contraindications
- the medicine has complex side effects
- you need to highlight its use in groups at risk, such as pregnant women, children or the elderly.

As far as possible, keep headings short so they fit on one line within a column.

Module 5

Parts of CMI 2: Instructions and Explanations

The heart of a CMI

> Hours of aggravation could be avoided if Instructions provided a little guidance to help users constrain their search. (Karen Shriver 1997. *Dynamics in document design: Creating text for readers.* New York: Wiley, page 245)

The heart of a CMI consists of Instructions and Explanations. These two parts must be clearly distinguishable from each other, so that consumers can identify them immediately.

Of the two, Instructions take priority; they tell consumers what to do in order to use their medicines appropriately. Consumers should be able to use medicines appropriately even if they read only the Instructions.

Explanations are not always necessary, but when they are used, they take second place.

Figure 9 shows an example of a Subheading followed by an Instruction, which is followed by an Explanation.

FIGURE 9 – INSTRUCTION AND EXPLANATION STYLES

Things you must not do

Do not stop taking it without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as muscle stiffness, fever and mental changes.

Subheading style

Instruction style

Explanation style

Instructions

Function

- Instructions reflect the performance-focused approach
- they tell consumers what to do
- they make it easier for consumers to use their medicines correctly.

Writing Instructions

Use Instructions to tell people what to do.

Instructions should be easily understandable, usually without an Explanation

An Instruction must be written in **bold**:

- to show the priority of the information
- to make it stand out from an Explanation or other information.

An Instruction always comes first (followed by an Explanation if necessary) because:

- the Instructions are the most important part of the CMI
- research has shown that readers of information generally search for, and read, only what is important to them
- readers assume that the most important matter will come first in a sentence or paragraph, and often only read the first part
- readers can become frustrated or anxious if they cannot quickly find the information they want, especially busy, stressed or unwell people, who comprise the majority of CMI users.

Do not use an Instruction to justify or explain an action.

Explanations

An Explanation for an Instruction is not always necessary, but when you give one, make sure it follows the Instruction.

Functions

- Explanations can give further information about the medicine, the Instruction, or the CMI
- they can help users understand the reasons for particular Instructions.

When to use Explanations

(see Figure 10)

- use Explanations to expand on Instructions or to give further information
- use them immediately after Instructions when:
  - an Instruction is contrary to what consumers might be expected to do
  - the reasons for an Instruction are not self-evident
  - an Instruction can be made more memorable by using an Explanation

FIGURE 10 – EXAMPLES SHOWING WHEN AN EXPLANATION IS USEFUL AND WHEN IT IS NOT

1) The Explanations below might help consumers understand the importance of the Instructions:

Drink at least one full glass of water when taking the tablet.

If you do not drink enough water while taking it, you may feel faint, lightheaded, or sick because your blood pressure is dropping.

Make sure that you understand how often your doctor wants you to take the medicine to treat your medical condition.

It is important not to take it more often or in higher doses than your doctor has prescribed. Overdoses may cause serious illness or death.

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Tell your doctor if you are pregnant or intend to become pregnant.

It is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.

2) The Instruction below is unexpected, so an Explanation is useful:

Do not lie down for at least 15 minutes after taking the medicine.

If you lie down you may suffer a throat irritation, making it hard for you to swallow or speak.

3) The following Instruction is probably self-evident, so no Explanation needed:

If you feel faint or dizzy when getting out of bed or standing up from a sitting position, get up slowly.

- do not overburden consumers with Explanations. Most Instructions you write should be understandable without an Explanation
- use Explanations sparingly or you may find your CMI is very long
- keep an Instruction and its related Explanation next to each other, on the same page, without a page break
- keep related groups of Instructions and Explanations on the same page.

Module 6

Principles for writing

If you follow these principles, you will have fewer changes to make after testing a CMI.

Brand name

Do not keep repeating the Brand name. Use 'it', 'the medicine' or 'the tablets/ointment/etc' where possible:

- this avoids repetition and can shorten the length of sentences
- take care that the context makes clear what 'it' refers to.

Do not put the Brand name of the medicine in bold, except when it has to be used in the Title Section, Main Headings, Subheadings, or Instructions, which are themselves in bold.

Do not put the Brand name in capital letters unless capitals are part of the registered name.

Figure 11 below shows illustrations of correct and incorrect use of Brand name.

FIGURE 11 – CORRECT AND INCORRECT USE OF BRAND NAME

Correct:

> **Use Nilvomit exactly as your doctor has prescribed. ***
>
> It could harm your stomach if you take too much, and will not help your condition if you take too little.

* This is an Instruction, so the whole sentence is in bold, including the Brand name.

Incorrect:

> **Use *Nilvomit*/NILVOMIT/*NILVOMIT* exactly as your doctor has prescribed.**
>
> *Nilvomit*/NILVOMIT/*NILVOMIT* could harm your stomach if you take too much, and will not help your condition if you take too little.

Word usage

Use language that consumers will understand. Use a vocabulary of lay-language terms as a guide to appropriate language.

Testing will tell you whether you have chosen the right words.

Sentence length

Keep the number of items of information in each sentence to a minimum—one to a sentence is best.

Keep sentences short. If a sentence is over 20 words long, try to reduce it.

Instructions as commands

Write Instructions as commands, with the action word first. In the following examples, the action word(s) are in ***italics*** (*the use of italics here is for the example only; action words* ***must not*** *appear in italics in the CMI itself):*

> ***Keep*** **the medicine away from bright sunlight.**
>
> ***Use*** **the exact amount your doctor tells you to, no more or less.**
>
> ***Push*** **the suppository gently, blunt end first, into your rectum (back passage).**

You can change the action-first rule in the case of 'If...then' Instructions. Separate the condition (the 'if' part of the statement) from the Instruction (the 'then' part of the statement) using a comma, as in the following examples. The action word(s) (a negative in one case) is in ***italics*** *(italics used here as in the previous example)*:

> **If you forget to take it before going to bed, and wake up in the night, *do not take* it.**
>
> **If you become pregnant, *tell* your doctor.**

If you want consumers to carry out two or more separate actions, give them two or more separate Instructions. Do not try to compress more than one action into a single sentence:

Swallow the tablets whole with a glass of water.

Do not chew them.

Do not eat anything for at least half an hour after you have swallowed them.

- Do not refer consumers to Instructions in another section. You can refer consumers to previous steps in a clearly numbered list of Instructions. In the example adjacent, Step 10 refers back in this way:

Read all the following steps before using your inhaler.

1. Take the cap off the mouthpiece by gently squeezing the sides of the cap.
   Make sure the mouthpiece is clean inside and outside.
2. Hold the inhaler upright. Shake it well.
3. Put the mouthpiece between your teeth and close your lips around it. Do not bite it.
4. Breathe out slowly and gently through the inhaler until your lungs feel comfortably empty.
5. Tilt your head back slightly and breathe in slowly through your mouth.
6. Press down firmly on the top of the can as you start to breathe in.
7. Continue to breathe in steadily and deeply until your lungs are full.
8. Remove the inhaler from your mouth but do not breathe out.
9. Hold your breath for as long as is comfortable – about 10 seconds.
   This gives time for the medicine to settle in the lower parts of your lungs.
10. Breathe out gently.
    If you need to take a second puff, wait about one minute, then repeat steps 2 to 10.
11. Replace the cap on the mouthpiece by clicking it into place.
12. Rinse your mouth with water after using the inhaler and spit out the rinsings.
    Any medicine left in the back of your mouth can irritate your throat.

- Use positive rather than negative Instructions wherever possible.

Correct:

Remember to take your tablets when you go to bed.

Incorrect:

Do not forget to take your tablets when you go to bed.

Correct:

Drink the mixture slowly.

Incorrect:

Do not drink the mixture quickly.

Use negative Instructions only when you want consumers to avoid specific actions.

If you suffer from diabetes, do not take this medicine.

Do not leave this medicine in a car on a hot day.

Dot points and numbering

Sometimes Instructions or Explanations consist of lists of information. When this happens, you can use dot point or numbered structures.

Dot points

Put the dot point Instructions in plain text rather than bold. They will still be noticed because of the dot points.

In the following example, the dot points are part of the Instruction **Do not take it if you have...**, but are written in plain font:

When you must not take it

Do not take it if you have:

- a viral skin infection, such as cold sores, shingles or chicken pox
- a fungal skin infection, such as thrush, tinea or ringworm
- acne.

Punctuating dot points:

1. Introduce them with a colon (:)

Correct:

Tell your doctor if you notice any of the following:

Incorrect:

Tell your doctor if you notice any of the following

Tell your doctor if you notice any of the following,

Tell your doctor if you notice any of the following;

2. Do not place semicolons, commas, or full stops at the end of each entry:

(note that numbering has different punctuation rules, see next page)

Correct:

- a viral skin infection, such as cold sores, shingles or chicken pox
- a fungal skin infection, such as thrush, tinea or ringworm

The following three are **incorrect:**

- a viral skin infection, such as cold sores, shingles or chicken pox;
- a fungal skin infection, such as thrush, tinea or ringworm;

- a viral skin infection, such as cold sores, shingles or chicken pox,
- a fungal skin infection, such as thrush, tinea or ringworm,

- a viral skin infection, such as cold sores, shingles or chicken pox.
- a fungal skin infection, such as thrush, tinea or ringworm.

3. Place a full stop at the end of the group:

Correct:

- a viral skin infection, such as cold sores, shingles or chicken pox
- a fungal skin infection, such as thrush, tinea or ringworm
- acne.

4. The list items should begin with a lower case initial:

Correct:

- a viral skin infection, such as cold sores, shingles or chicken pox
- a fungal skin infection, such as thrush, tinea or ringworm
- acne.

Incorrect:

- A viral skin infection, such as cold sores, shingles or chicken pox
- A fungal skin infection, such as thrush, tinea or ringworm
- Acne.

As far as possible, use no more than 9 list items.

For medicines used in chronic conditions such as diabetes, medicine users may need longer lists. In this case, it is better to break up the list into related items with separate headings. If you must use a longer list, always test it.

For dot points listing side effects, see Module 8.

Numbering

If you want consumers to follow a series of Instructions in a particular order, number the Instructions and put them in the exact order in which you want consumers to follow them.

Write and punctuate each item as a full sentence.

Put the numbered Instructions in plain text, not bold:

Read all the following steps before you use the eye drops:

1. Wash your hands well with soap and water.
2. Shake the bottle.
3. Remove the lid.
4. Sit or lie down to make it easier to put the drops in.
5. Hold the bottle upside down in one hand between your thumb and index finger.
6. Using your other hand, gently pull down your lower eyelid to form a pouch.
7. Tilt your head back and look up.
8. Put the tip of the bottle close to your eye. Do not let it touch your eye.
9. Release one drop onto your eye by gently squeezing the bottle.
10. Close your eye. Do not blink or rub your eye.
11. Replace the lid, sealing it tightly.
12. Wash your hands again with soap and water to remove any residue.

Active voice and passive voice

Avoid writing Instructions in the passive voice. In passive sentence constructions:

- it is often not clear who is to take a particular action
- the action gets lost in the sentence
- the sentences are generally longer.

Correct – active voice:

Keep your eye drops away from sunlight.

Incorrect – passive voice

The eye drops should be kept away from sunlight.

Correct – active voice:

Drink plenty of water with your medicine.

Incorrect – passive voice:

The medicine should be taken with plenty of water.

Correct – active voice:

Return any unused medicine to your pharmacist.

Incorrect – passive voice:

Unused medicine must be returned to your pharmacist.

Grammar and punctuation

Avoid run-on sentences (two sentences written as one):

Correct – two separate instructions:

Keep your tablets in a cool dry place.

Do not keep them in a bathroom or near a sink.

Incorrect – one sentence:

Keep your tablets in a cool dry place, do not keep them in a humid bathroom.

Avoid subordinate clauses (adding information to the Instruction):

Correct – instruction with explanation:

Keep your eye drops away from sunlight.
Sunlight will destroy the effectiveness of the medicine.

Incorrect – information added with a subordinate clause

Keep your eye drops away from sunlight, because light can damage the drops.

If you need a dash, use the ordinary hyphen (minus sign, -) with a space either side:

> Nilvomit comes in two types of tablets:
>
> - Nilvomit 5 - white and barrel-shaped with XYZ712 marked on one side.
> - Nilvomit 10 - rust-red and barrel-shaped with XYZ713 marked on one side.

Note the difference:

the hyphen used as a hyphen has no spaces:

> rust-red
> barrel-shaped

the hyphen used as a dash has a space either side:

> Nilvomit 5 - white
> Nilvomit 10 - rust-red

- Avoid the use of unusual or unfamiliar symbols (such as § ¶ ‡ ζ) or familiar symbols that have no place in medicine information (such as ♣♦♥♠, £, ✱). These kinds of symbols cannot be printed consistently by the technology available.

Module 7

What to write under the Headings

This Module gives more details of what to write under the Main Headings and Subheadings (see Module 4 The parts of a CMI 1). Each of these Headings is introduced by relevant passages from Schedules 12 or 13 (for ease of reference only the passages from Schedule 12 have been used in this edition), and gives further details of the wording, content and style, including examples. Refer to Module 6 for principles of writing and punctuation.

Main Headings

- **What is in this leaflet**
- **Before you take/use it**
  or **Before you are given it**
  - Use ***Before you take it*** for medicines taken orally
  - Use ***Before you are given it*** for injected medicines
  - Use ***Before you use it*** for all other types of medicine
- **How to take/use it**
  or **How it is given**
- **While you are taking/using it**
- **Side effects**
- **After taking/using it**
- **Product description**

What is in this leaflet

Relevant passage in Schedule 12:

> a direction to consumers to discuss any aspect with the doctor or pharmacist

1. This Heading introduces the following Introductory Statement in all CMIs (Figure 12):

FIGURE 12 – 'WHAT IS IN THIS LEAFLET' AND THE STANDARD INFORMATION THAT FOLLOWS

What is in this leaflet

This leaflet answers some common questions about [Brand name].*

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. **

You may need to read it again.

* Use 'Explanation Style' for the information.
** Use 'Instruction Style' for the Instructions.

2. In a long CMI, this Heading introduces a Table of Contents listing all Main Headings and Subheadings (see Module 9).

What [Brand name] is used for

Relevant passages in Schedule 12:

the expected effect of using the medicinal product

the therapeutic indications, unless a competent authority determines that the dissemination of such information may have serious disadvantages for consumers

the pharmaco-therapeutic group, or type of activity if there is a term that is easily comprehensible to consumers. If not, a simple description of what the medicinal product is for and how it works, in one or two sentences

habit forming potential

a direction to consumers to discuss any aspect with the doctor or pharmacist

Consistency with PI and approved use

Your CMI must be consistent with the PI. The information under this Heading must refer only to the uses of the medicine which have been approved by the TGA.

Use the Standard Statement regarding non-approved uses:

> Your doctor, however, may prescribe [Brand name] for another purpose.
>
> **Ask your doctor if you have any questions about why it has been prescribed for you.**
>
> This medicine is only available with a doctor's prescription.

Using an appropriate glossary of lay-language terms (see Vocabulary), write non-technical Explanations of:

- what the medicine is used for
- how it works
- standard wording regarding non-approved uses
- a statement about its habit-forming potential (see Figure 13).

  If a medicine is habit-forming or addictive, this information should be repeated under other headings in the CMI (e.g. Side effects).

It is important to give details of what the medicine is used for and how it works. This enables the consumer to weigh up the benefits against the side effects.

If as a consequence the Explanation is very long, you can break it up into sections, using Subheadings such as ***What it is used for*** and ***How it works***.

Make sure that you avoid writing anything that can be interpreted as promotional.

FIGURE 13 – SOME EXAMPLES OF NON-TECHNICAL EXPLANATIONS OF MEDICINES

1. Urinary infections

[Brand name] is an antibiotic used to treat urinary tract infections.

Urinary tract infections are caused by the presence of bacteria in the urinary system. The bacteria often come from the intestines where they are necessary for normal function.

In women, the most common infection involves the bladder and is called cystitis. In men, the infection may involve the prostate which is called prostatitis. In both men and women, the bacteria can travel up to the kidneys and infect them.

The symptoms of a urinary tract infection may include an urge to urinate frequently and in small amounts, and a painful burning when passing urine. If urinary tract infections persist, they should be treated to avoid the kidneys being infected.

[Brand name] is an antibiotic that belongs to a group of medicines called quinolones (pronounced KWIN-o-lones). These antibiotics work by killing the bacteria that are causing your infection.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

[Brand name] is non-addictive.

2. Glaucoma

[Brand name] is used to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is a condition in which the pressure of fluid in the eye is unusually high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build-up of the fluid which flows through the eye. This build-up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye, resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve, and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

[Brand name] is used, either alone or in combination with other eye drops/ medicines, to lower raised pressure within your eyes.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

It is not addictive.

3. Depression

[Brand name] is used to treat depression.

Depression is longer lasting or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

[Brand name] corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

[Brand name] may be habit-forming, so it is important to take it exactly as directed by your doctor.

Before you use/take/are given it

Use the Heading 'Before you take it' for medicines taken orally, 'Before you are given it' for injected medicines, and 'Before you use it' for other types of medicines.

Relevant passages in Schedule 12:

a list of factors that are useful to consider before taking the medicinal product, including, if appropriate:

- contraindications, including consideration of whether the consumer has experienced previous allergic reactions
- precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions
- interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product

a reference to the expiry date indicated on the label, with a warning against using the medicinal product after this date; if

appropriate, a warning against visible signs of deterioration

a direction to consumers to discuss any aspect with the doctor or pharmacist

Under this Heading, you give Instructions and Explanations which consumers need to attend to before they start taking the medicine.

It is often useful to group these Instructions and Explanations under Subheadings (see Module 4 for standard Subheadings).

Writing Contraindications

Below are some examples:

When you must not take it

Do not take [Brand name] if you have:

- a viral skin infection, such as cold sores, shingles or chicken pox
- a fungal skin infection, such as thrush, tinea or ringworm
- acne.

Do not take [Brand name] if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Do not take it after the expiry date (EXP) printed on the pack.
If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

Writing Precautions

Particular care must be taken regarding children and young adults. Here are some statements you can use to warn people about giving medicines to this group :

Before you start to use/take it

Do not give [Brand name] to a child or adolescent.
There is no experience with its use in children or adolescents under 18 years old.

Do not give [Brand name] to a to a child aged eight years and under.
It may cause enamel loss and staining on developing teeth.

Another group at extra risk are women who are breastfeeding or pregnant (and sometimes their male partners are at risk, if the couple are planning to have a baby). When you write information about using the product while pregnant or breast-feeding, work closely with the PI as this information varies considerably among different medicines. Here are some examples of different ways you might write warnings on pregnancy and breast-feeding.

Tell your doctor if you are pregnant or intend to become pregnant.
Like most medicines of this kind, [Brand name] is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed.
It is not known whether [Brand name] passes into breast milk.

Do not place warnings or precautions in boxes.

Advise consumers to take precautions in case of interactions:

Tell your doctor if you have allergies to:

- any other medicines including aspirin or other NSAID medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart failure
- kidney or liver disease
- high blood pressure or heart problems
- heartburn, indigestion, stomach ulcer or other stomach problems.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you use [Brand name].

In a long list, to avoid repeating 'Tell your doctor if...' you can list each group of conditions under a single Instruction, numbering each one, as in the following example:

Tell your doctor if:

1 **you have allergies to:**
   - any other medicines including aspirin or other NSAID medicines
   - any other substances such as foods, preservatives or dyes.

2 **you are pregnant or intend to become pregnant.**
   Like most NSAID medicines, [Brand name] is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

3 **you are breast-feeding or planning to breast-feed.**
   It is not known whether [Brand name] passes into breast milk.

4 **you have, or have had, the following medical conditions:**
   - heart failure
   - kidney or liver disease
   - high blood pressure.

If you have not told your doctor about any of the above, tell them before you use [Brand name].

It is a good idea to include the Instruction to 'tell your doctor' at the end, even though it repeats the earlier Instruction. This helps reinforce the importance of taking appropriate action.

This Instruction is one place in the CMI where the temporal order of actions is disrupted. Consumers have probably already seen their doctor, yet in this Instruction they are being told to go back under certain circumstances. But the Instruction in this case may act as a useful safety net for cases where consumers have not informed their doctor about important conditions that might affect their use of a medicine.

Interactions with other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with the absorption of [Brand name]. These include:

- aspirin, salicylates or other NSAID medicines
- warfarin, a medicine used to stop blood clots
- digoxin, a medicine used to treat heart failure
- cimetidine, a medicine used to treat ulcers.

These medicines may be affected by [Brand name], or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking [Brand name].

How to take/use it

Use the Main Heading ***How to take it*** for medicines taken orally, ***How it is given*** for injectable medicines, and ***How to use it*** for other types of medicines.

Relevant passages in Schedule 12:

the necessary and usual Instructions for proper use of the medicinal product, in particular:

- the dosage, together with an indication that this may not always apply and may be modified by the prescriber
- the method, and if necessary, route of administration
- the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product should or must be used

in addition, depending on the nature of the therapeutic goods:

- the duration of treatment, if it should be limited
- the expected effect of using the medicinal product
- what to do if one or more doses have not been taken
- the way treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects

the action to be undertaken in case of overdose (for example, symptoms and emergency procedures).

a direction to consumers to discuss any aspect with the doctor or pharmacist

The Instructions under this Heading are the core of the CMI, reflecting the consumer actions previously determined at benchmarking (see Module 12 for consumer actions.)

Under this Heading you will need Subheadings (see Module 4 for a list of standard Subheadings). Following are some examples of the appropriate wording under these Subheadings.

How much to take/use

While it may not be possible or advisable to give precise doses, consumers find it helpful to know how much they can be expected to

take. This is also a useful place to include a statement that the doctor or pharmacist will tell them exactly how much to take and where to check this information.

The standard dose for this medicine is one tablet three times a day with water.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, [Brand name] may not work as well and your problem may not improve.

This ointment works best when you apply a thin layer to the affected skin.

Ask your doctor or pharmacist if you are not sure how much to apply.

They will tell you exactly how much to use for each application.

Follow the Instructions they give you.

If you use less than you should, it will not improve your skin condition.

If you use too much, it will not improve your skin condition and may cause or increase side effects.

How to take/use it

Instructions on how to take or use a medicine are best if they follow the exact sequence of actions that a consumer needs to take.

Rub a thin layer of the ointment on the rash or affected area of skin two to four times each day.

Use it at the same time every day.

Stop using it when the redness and itching have gone.

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use a suppository:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep it in the foil, and chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil wrapper while you are chilling it.
4. Put on a disposable glove, if desired. Gloves are available from pharmacies.
5. Remove all of the foil wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository gently, blunt end first, into your rectum (back passage).
9. Remain lying down for a few minutes so that the suppository dissolves.
10. Throw away used materials and wash your hands thoroughly.

A combination of Instructions and Explanation can help consumers understand why they have to comply with Instructions.

Swallow the tablets whole with a glass of water.

Do not chew them.
These tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines, where they start to work. If you chew them, the coating is destroyed.

When to take/use it

Use this section to provide information to consumers on the normal times to take the medicine, particularly in relation to food or sleeping. You may also want to provide an Instruction to follow the doctor's or pharmacist's Instructions, particularly if they may differ from the normal times when the medicine is taken. Here are some examples:

Take [Brand name] on an empty stomach. For example, one hour before food or two hours after food.
This will help the tablets fight the infection. Food can interfere with their absorption.

Take [Brand name] during or immediately after a meal, at about the same time each day.
It you take it on an empty stomach, it may cause stomach upset.

Take [Brand name] before or after food.

Take [Brand name] at about the same time each day.
Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.

[Brand name] is usually taken first thing in the morning before breakfast. However, your doctor may have given you different Instructions.

If you are not sure when to take it, ask your doctor.

How long to take it

Some examples:

For treatment of [condition], the length of treatment may vary from three to ten days.

Ask your doctor if you are not sure how long to take the medicine for.

Continue taking your medicine for as long as your doctor tells you.
The medicine helps control your condition, but does not cure it. Therefore, you must take it every day.

To help to prevent [the condition] returning, you may need to take the tablets for up to 12 weeks.

Take the tablets every day, for as long as your doctor tells you to.
They help control your condition, but do not cure it.

Stop using the ointment when the itching and redness have gone.

Continue taking the tablets until you finish the pack or until your doctor tells you to stop.

For antibiotics, Instructions such as the following are necessary:

Continue taking the tablets, even if you feel better.
Your condition may return if you stop taking them.

Your doctor will tell you when you can stop.

Do not stop taking the tablets because you are feeling better.

If you do not complete the full course prescribed by your doctor, some of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply, so your infection may not clear up completely or it may return.

These antibiotics Instructions can also go under ***Things you must do*** or ***Things you must not do***. Testing will help you decide whether they should go under both, or under one or the other.

If you forget to take/use it

This is important information, highly valued by consumers.

Some examples:

If you forget to take the tablet before you go to bed, and you wake up late in the night or very early in the morning, do not take it.

You may have trouble waking at your normal time.

If you have any questions about this, ask your doctor or pharmacist.

Do not try to make up for missed doses by taking more than one dose at a time.
This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

When the consequences of overdose are serious and require hospitalisation:

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much [Brand name].

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

When the consequences of overdose are less serious and users do not need hospitalisation:

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much [Brand name].

Do this even if there are no signs of discomfort or poisoning.

While you are using it

Relevant passages in Schedule 12:

> potential effects of the medicinal product on the ability to drive vehicles or to operate machinery
>
> precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions
>
> interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product
>
> the way treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects
>
> special warnings, such as the effects on sensitivity to sun exposure
>
> a direction to consumers to discuss any aspect with the doctor or pharmacist

Repeating information

Notice that the third point in Schedule 12 about interactions with other medicines is also listed under 'Before you use it', and the fourth point about stopping has been repeated from 'How to use/take it'.

In some cases, you may want to include information under both headings about medicine interactions and the way to stop treatment. But this is not always necessary. To decide whether or not you should repeat this information, test to see if consumers look in just one place or both. If they look in just one, you don't need to repeat it.

Things you must do

Some examples:

If you develop severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after you have stopped taking [Brand name].
Diarrhoea may mean that you have a serious condition affecting your bowel.
You may need urgent medical care.

Do not take any diarrhoea medicine without checking with your doctor.

Protect your skin when you are in the sun, especially between 10am and 3pm.

If you are outdoors, wear protective clothing and use a 30+ sunscreen.

If your skin appears to be burning, stop taking [Brand name] and tell your doctor.
It may cause your skin to be much more sensitive to sunlight than it is normally.
This could cause a skin rash, itching, redness, or severe sunburn.

Things you must not do

Some standard examples:

Do not give the capsules to anyone else, even if they have the same condition as you.

Do not use the ointment to treat any other complaints unless your doctor tells you to.

Do not stop taking [Brand name], or lower the dosage, without checking with your doctor.
Your doctor may want you to gradually reduce the amount you are using before stopping completely. This may help reduce the possibility of withdrawal symptoms such as muscle stiffness, fever and mental changes.

Do not stop taking your tablets because you are feeling better, unless advised by your doctor.
If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not completely clear or it may return.

See also How long to take it and Before you take it

Things to be careful of

Use this section to tell consumers about issues that they might need to watch out for. Place information about things that they must not do in the previous section. Here are some examples:

Some 'things to be careful of' have already been listed under 'Before you take it', especially for interactions with other medicines and for groups at risk. It is a good idea to place this kind of important information in more than one place, as you cannot tell in advance where people will look for it.

Here are some other examples:

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.
You may feel light-headed or dizzy when you begin to take these tablets. This is because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. The problem usually goes away after a few days.

Be careful driving or operating machinery until you know how [Brand name/the medicine/the tablet/etc] affects you.
It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.
[Brand name] may cause false test results with some urine sugar tests.

Be careful not to overdo physical activities when you first start taking the medicine.
Angina resulting from physical activities and exercise is usually reduced or prevented by this medicine. This may tempt you to be overly active. Talk to your doctor about the amount of exercise you can do.

At-risk groups (people over 65 years, infants and children, pregnant and breastfeeding women, and people with specific pathological conditions) may need to take particular care with some medicines.

Here are some examples of statements you can use to caution and warn the elderly:

Be careful if you are older than 65 years of age.
Older people may become confused when taking [Brand name]. Families and carers should be aware of this. Special care may be needed.

Be careful if you are over 65 and unwell or taking other medicines.
Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Things that may help your condition

For some medicines, there may be lifestyle, food and exercise changes that consumers can make that improve the effectiveness of the medicine. Providing information about these can also help consumers ask more informed questions of their doctor and pharmacist.

An example for high blood pressure:

Some self-help measures suggested below may help your condition.

Talk to your doctor or pharmacist about them:

- Alcohol
  Your doctor may advise you to limit your alcohol intake.
- Diet
  Eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise
  Regular exercise helps reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of program for you.
- Salt
  Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking
  Your doctor may advise you to stop smoking or at least cut down.

Side effects

See Module 8 for writing under this Main Heading.

After using it

Relevant passages in Schedule 12:

> an indication of the appropriate storage conditions
>
> a direction to consumers to discuss any aspect with the doctor or pharmacist
>
> the way treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects

Examples of Instructions about how the treatment should be stopped if stopping leads to adverse effects can be found under the Subheading 'How long to take/ use it'. As with so many Instructions, it is worthwhile repeating if the information is important. Otherwise find out through testing where consumers are more likely to look for it.

Another Instruction which can come under After using it, even if it appears elsewhere in the leaflet, is:

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Examples of other useful Instructions:

Cleaning

After each use, clean your inhaler:

1. Remove the metal can.
2. Rinse the plastic holder and cap in warm water.
3. Dry the plastic holder and cap.
4. Put the can back into the plastic holder.

Storage

Keep your tablets in the blister pack until it is time to take them.
If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 30˚C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

Relevant passages in Schedule 12:

> the dosage form or strength, or both, of the product
>
> where further information may be obtained
>
> a statement of the active ingredients expressed quantitatively and excipients expressed qualitatively, using their common names, in the case of each presentation of the product
>
> the pharmaceutical form and contents by weight, volume or number of doses of the product, in the case of each presentation of the product, together with its identifying Australian Register number

Information under this heading is highly standardised and falls into three subheadings: ***What it looks like***, ***Ingredients***, ***Manufacturer/Sponsor***

In some CMIs, tables have been used to organise this type of information. However, many tables presented using Microsoft Word and laser printers are difficult for consumers to use and for writers to design.

You can use the following layouts which consumers can access easily, and which are easier to write using Explanation and Explanation dot point Styles.

What it looks like

Your [Brand name] inhaler is a dark brown plastic holder with a mouthpiece. The mouthpiece is covered by a light brown cap. In the holder is a small metal can.

The plastic holder has [Brand name] written on it.

The label on the can has [Brand name] printed on it in dark brown.

[Brand name] comes in three types of tablets:

- [Brand name] 5 - white and barrel-shaped with XYZ712 marked on one side.
- [Brand name] 10 - rust-red and barrel-shaped with XYZ713 marked on one side.
- [Brand name 20 - peach coloured and barrel-shaped with XYZ714 marked on one side.

A box contains 30 tablets.

Ingredients

Active ingredients:

- [Brand name] 5 - 5mg enalapril maleate per tablet
- [Brand name] 10 - 10mg enalapril maleate per tablet
- [Brand name] 20 - 20mg enalapril maleate per tablet

Inactive ingredients:

- lactose
- sodium bicarbonate
- magnesium stearate
- iron oxide red (CI 77491)
- iron oxide yellow (CI 77492)

[Brand name] does not contain gluten, sucrose, tartrazine or any other azo dyes.

Add that the product does not contain lactose, gluten, sucrose, or azo dyes if these are not included as one of the ingredients in the medicine.

You can also include the food additive numbers; these are listed in Identifying Food Additives issued by the National Food Authority.

Manufacturer/Sponsor

[Brand name] is made in Germany and supplied in Australia by:

Europan Pty Ltd (ACN 002 458 785)
19 Hamilton Road
Eastlakes, NSW 2457

This leaflet was prepared in [month, year].

Australian Register Number:

10mg tablets: AUST R 45879
20mg tablets: AUST R 45880
50mg tablets: AUST R 46018

Module 8

Writing about side effects

Relevant passages in Schedule 12:

> a description of the undesirable effects that can occur under normal use of the medicinal product and, if necessary, the action to be taken if experienced
>
> the consumer should be expressly invited to communicate any undesirable effect, especially if it is not mentioned in the consumer information document, to his or her doctor or pharmacist

Reassuring consumers

In testing with consumers to develop these *Guidelines*, it was found that the phrase 'side effects' is widely understood.

Everybody feels some concern when they see a list of side effects. It is important that consumers of medicines feel confident and understand the benefits of the medicine that has been prescribed for them, and that they know what to do in the case of an adverse reaction.

To reassure them, it is advisable to place a statement like one of the following at the beginning of the list of side effects:

> All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.
>
> **Do not be alarmed by this list of possible side effects.**
> You may not experience any of them.

> All medicines can have side effects. You may need medical treatment if you get some of the side effects.
> **Ask your doctor or pharmacist to answer any questions you may have.**

Grouping side effects

Side effects can be grouped into two major categories: general and specific.

General

You can include a general statement about side effects, tailoring the statement in your CMI to the type of side effects associated with the medicine you are writing about.

Two examples of general statements:

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking [Brand name].
It helps most people with [condition], but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking [Brand name].
It helps most people with [condition], but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

Specific

The correct grouping of specific side effects is essential. The side effects should be grouped by the actions that the consumer needs to take, NOT by their frequency.

Incorrect grouping

Do not group them by frequency.
The following Headings are ***incorrect***:

Common side effects

Less common side effects

Rare side effects

Correct grouping

Group the side effects by **Instructions** about the kinds of action consumers need to take. This tells them exactly what to do, and is more useful to them than grouping the side effects by frequency.

List the side effects in order of increasing *urgency*.

For serious conditions that require immediate attention, use the word 'immediately'.

For less serious conditions, use the phrase 'as soon as possible'.

The following group of Instructions, ordered from least urgent to extremely urgent, is ***correct.***

You may not have to use all of them.

Correct grouping:

Tell your doctor if you notice any of the following and they worry you:

Tell your doctor as soon as possible if you notice any of the following and they worry you:

Tell your doctor immediately if you notice any of the following:

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

If any of the following happens, stop taking [Brand name] and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

Here is an example of how side effects can be grouped under these Instructions:

Tell your doctor if you notice any of the following and they worry you:

- headache
- dizziness and light-headedness
- tiredness
- dry cough
- muscle cramps
- mild stomach upsets such as feeling sick (nausea), diarrhoea, or stomach pains.

These are mild side effects of the medicine, and usually short-lived.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- chest pain
- angina
- changes in the way your heart beats, for example if you notice it beating faster
- difficulty breathing
- signs of frequent infections such as fever or sore throat
- passing less urine than is normal for you.

These may be serious side effects of [Brand name]. You may need urgent medical attention.

Serious side effects are uncommon.

If any of the following happen, stop taking [Brand name] and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes (jaundice).

These are very serious side effects. If you have them, you may have had a serious allergic reaction to [Brand name]. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Another way to group side effects under the Instructions is by symptom type.

For example:

Tell your doctor immediately if you notice any of the following:

stomach or bowel problems such as:

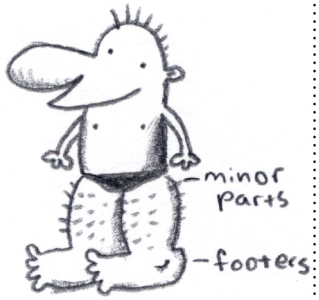
- vomiting
- stomach cramps
- flatulence or wind
- diarrhoea.

difficulty thinking or working because of:

- persistent headache
- dizziness
- trembling
- sleeplessness
- drowsiness
- confusion.

changes in your sight, hearing, taste or touch such as:

- blurred or double vision
- poor hearing, or buzzing or ringing in the ears
- altered taste sensation
- tingling or numbness of arms or legs.



Module 9
Parts of CMI 3: Table of Contents and other parts

Minor parts

Footer

Module 9

Parts of CMI 3: Table of Contents and other parts

Table of Contents

FIGURE 14 – TABLE OF CONTENTS (PART) FOLLOWING TITLE SECTION AND FIRST MAIN HEADING

† optional entries

*This is in Main Heading top-of-column Style

** This is in Contents-1 Style

*** This is in contents-2 Style

Brand name® pronunciation

Name of active ingredient (pronunciation)

Consumer Medicine Information (CMI)

Date of Dispensing†

John Zill†
26 Jacaranda Avenue
Mainline NSW 2345

Everyone's Pharmacy†
24 Main Street
Mainline NSW 2345

What is in this leaflet*

Function

If the CMI consists of more than four pages, its length and complexity can be daunting to consumers. On a long CMI, a TOC can be extremely useful because:

- it exactly reflects the structure of the CMI
- it is an extra navigational aid for consumers looking for specific Instructions and Explanations in a long CMI.

Constructing a TOC

When consumers read a TOC, they are not only reading the individual items but also comparing the items with each other. This provides them with valuable clues about where to look for particular information.

The TOC and the structure it reflects may be the critical factor in determining whether or not a consumer can successfully find information in a long, complex CMI.

A TOC consists of 3 elements:

- Main Heading (**What is in this leaflet**)
- Contents 1 (listing the CMI's Main Headings)
- contents 2 (listing the CMI's Subheadings)

Take care to apply the following rules when constructing the TOC. A poorly-structured or incomplete TOC is confusing and misleading:

- the TOC comes immediately after the Title Section
- it is headed by **What is in this leaflet** in Main Heading Style
- it lists every Main Heading and Subheading in the CMI (but not **What is in this leaflet**), in the order of those Headings
- in the TOC, Main Headings are printed in Contents-1 Style, and Subheadings in contents-2 Style
- the TOC uses exactly the same words as each Main Heading and Subheading (except for **What is in this leaflet** which is not included in the TOC).

Minor parts

Footer

At the bottom of each page, place a footer which contains the Brand name of the medicine on the left, and the page number on the right (Figure 15, below). The Brand name is written in capitals. This is the only item in the leaflet which uses capital letters.

The Footer is separated from the rest of the CMI by a rule.

FIGURE 15 – WHAT THE FOOTER LOOKS LIKE

BRAND NAME 1

Functions

- the Brand name at the foot of each page reminds consumers of the medicine they are reading about
- page numbers are useful when consumers discuss the leaflet with health professionals
- they are essential on a long CMI with a Table of Contents.

continued...

When a section under a Main Heading or Subheading is broken by a page break, place '*continued...*' at the right-hand end of the page before the break.

FIGURE 16 – WHAT '*continued...*' LOOKS LIKE

Main heading

Subheading

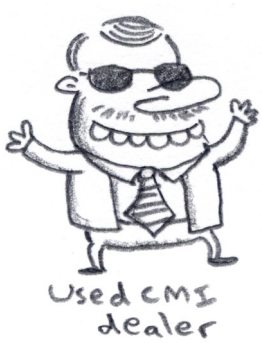
Instruction before explanation

1. List number instruction.
2. List number instruction.
3. List number instruction.
4. List number instruction.

continued...

Function

- *continued...* tells consumers that they have not yet reached the end of a section
- it helps writers keep Styles consistent.



Module 10

Checklist before testing both currently-used and new CMIs

Print out this page when you are ready to test the CMI, and check every item

Testing a CMI in current use (Benchmarking test)

A CMI that is currently in use went through the stages of design before it became public. The benchmark (that is, performance requirements and critical actions) were determined before it was designed.

If it has now become advisable to retest to see if it still performs according to the benchmark (see Revising), perform the following:

- skip the rest of this Module
- read Module 11 Understanding diagnostic testing
- carry out the procedures in Module 12 and Module 14 for creating the protocol, Module 13 for running the test, and Module 15 for analysing the results.

Testing a new CMI

It is essential that you test a CMI that is in exactly the same format (paper quality, print sizes, fonts, etc) as the one that consumers will use.

Testing an incomplete one, or one that has several errors, or one that has a different format, will be a waste of time.

To ensure that you have the best possible copy for testing, check all the following items.

Layout and appearance

❑ the consumer's first impression will be that this is an uncluttered, well-ordered leaflet

- ❑ the Title Section spreads across the whole first page
- ❑ the rest of the leaflet is divided into three columns
- ❑ the page specifications are as listed in Module 3 Layout
- ❑ Helvetica and Times are the only fonts
- ❑ there is a footer with Brand name (in capitals) and page number
- ❑ 'continued' appears at the end of the page when the writing under a Heading carries over to the next page

Brand name of medicine

- ❑ this is always in plain font, except in the Title Section
- ❑ it is never in capitals, except in the footer (unless capitals are part of the registered trademark)
- ❑ the Brand name is replaced by 'it' or 'the medicine/tablets/inhaler/etc' where possible
- ❑ nothing in the leaflet can be interpreted as a promotion for the product

Title Section

- ❑ the formatting of the different items is exactly as described
- ❑ consumers can pronounce the Brand name and the name of the active ingredient

Table of Contents

- ❑ if the CMI has more than four pages, there is a TOC
- ❑ every Main Heading and Subheading is present, in the correct contents formatting
- ❑ page numbers are correct

Introductory Statement

- ❑ the Introductory Statement is the first item (or comes after the TOC if there is one)
- ❑ its wording is exactly as described
- ❑ its **Instruction** is the only item in **bold**

Main Headings

- ❑ all the standard Main Headings are present
- ❑ they are in the recommended order
- ❑ they are in the recommended format, including spacing before and after

Subheadings

- ❑ these are as recommended, in the correct format, including spacings
- ❑ Subheadings with no text under them have been deleted
- ❑ added Subheadings, if present, are concise and meaningful

Instructions

- ❑ **Instructions** are in **bold** font
- ❑ dot point lists following Instructions are in plain font
- ❑ each Instruction comes before its Explanation, if there is one
- ❑ Instructions are written as commands for action
- ❑ Instructions directed towards groups at risk are repeated as necessary under different Headings
- ❑ Instructions directing consumers to talk to their doctor or pharmacist are repeated as necessary under different Headings

Explanations

- ❑ these are in plain font only
- ❑ Explanations always follow an Instruction, and take second place

Bold font is used only for

- ❑ the Brand name in the Title Section (Helvetica)
- ❑ the words 'Consumer Medicine Information (CMI)' in the Title Section (Helvetica)
- ❑ Main Headings and Subheadings (Helvetica)
- ❑ Instructions (Times)

Capitals are used only for

- ❑ the footer

Module 11

Understanding diagnostic testing

Testing is essential

There are two compelling reasons why you should test CMIs using these *Guidelines*:

- you cannot predict how consumers will read the CMI
- you will have evidence to show that you have taken reasonable care to develop a CMI that is useful and usable for consumers.

(See also To test or not to test)

There is no way of knowing how a CMI user will act

CMIs are complex documents and each one is different. Consumers, too, are complex and highly varied. Put a CMI and a consumer together and the resulting dialogue can at times be unpredictable and surprising.

Unpredictable, because there is no way of knowing how well a document will perform or how a consumer will act. No universal principles of good writing and design, no readability scores, and no measures of reading age have been found that can predict these things. Even if you are following an international standard for consumer information that has been tested overseas, local consumers may have a different understanding of words and medicine use.

But surprising? Not really: people are not machines programmed to act similarly in all situations. That's why each CMI should be tested thoroughly in accordance with these *Guidelines*, and monitored throughout its life.

The best type of test

A CMI is a flexible instrument designed to be used by all sorts of people. It is essential that it performs well in all its aspects,

especially that users can quickly find what they need and appropriately act on what they find. If a CMI is not usable it could lead to poor quality use of medicines.

Consequently, a CMI should be tested to find out if anything is wrong with it before it goes to the public.

The most useful type of testing for CMI is *diagnostic testing*, used *iteratively*. (For further details, see *Choosing the right method for testing).*

As the name suggests, *diagnostic testing* is concerned with finding out what is wrong with a document. It takes the actions of people using the document as symptoms of the document's health.

The testing should be *iterative*: that is, it should be repeated following any changes to a CMI until the CMI performs at optimum level.

Diagnostic testing consists of:

- asking users to carry out the tasks they might normally carry out when using the CMI
- observing and recording in detail how they navigate the CMI to find information
- probing to find out whether they can appropriately use the information they have found
- recording anything they say, either about particular tasks they are undertaking or the CMI in general.

Diagnostic testing does not allow you to make precise predictions about how users will treat CMI (as noted above, no such predictions are possible). But repeated experience has shown that the conclusions from such testing work well in practice.

Diagnostic testing is widely used where usability is a critical concern. It is cheaper than more traditional methods, such as surveys and focus groups, and the quality of data from diagnostic testing is good.

The person who conducts the test

The best person to develop and conduct a diagnostic test is the person who wrote the CMI. Writers learn a great deal from the experience of testing which cannot be learnt from reading research reports; there is nothing quite like the experience of observing someone struggling with a document you have created and beginning to understand why they find it difficult. This experience is valuable when it is later applied to modifying a poorly-performing document, and is readily transferable to writing new documents.

If you (as tester) are not the writer, it is extremely important that you work closely with the person who is. A CMI tester needs the skill to be able to judge consumer behaviour with a professional eye, and to decide whether a particular action will result in appropriate use of the medicine.

Diagnostic testing is not difficult to learn. However, you do need to be a good listener and observer, with a sense of humility about your own writing skills.

Before reading further, always bear in mind...

- you are testing the CMI, not the users
- you are testing to find the problems in the CMI
- you are *not* testing to see if the medicine works
- you will *not* be using Plain English principles (see *Plain English problems*)
- you will *not* use readability or reading age measurements

  (see Redish, J. C. and J. Selzer. 1985. The place of readability formulas in technical communication. *Technical communication* 32, no. 4:46-52.)
- you will *not* use any psychometric instruments. This is because you do not want to know the participants' preferences or attitudes, you want to observe what they *do*.

The participants in the test

You should aim to recruit from the population(s) at risk—those people who are likely to have problems with using the medicine. For example, in many instances it is appropriate to recruit older consumers, because they are more likely to have problems with medicines.

You do not necessarily have to recruit people who suffer from the ailment which the medicine treats. Often it is sufficient if the participant is reasonably able to imagine they might need to use the medicine in the future. This is especially so for more common ailments.

However, if the medicine is for a less common ailment, or if it is for some long-term condition which might entail some particular knowledge, then it may be better to test the CMI on actual sufferers (for example people with diabetes or asthma).

Avoid recruiting from a population of convenience, such as fellow workers.

But you can use such people to pilot your test questions, to check that you are eliciting the sort of answers that you expect to gain from your questions.

What you are testing

Formatted CMIs

Test the CMI in the layout and on the same paper stock as it will be presented to consumers. This will give you a good basis for assessing how consumers use the CMI. If you use a layout for testing that is different from the final layout, or if you use a different grade of paper, your test results may not reflect the performance of the CMI in use.

If you are not sure which is the best way to set out some information, or which is a better expression, test different options. By observing participants using different designs, you should get a sense of which is performing better. But do not give more than one option to any one participant; experience with the first design may assist them locate or interpret the other(s).

Module 12
Schedule 12, consumer actions, and test questions

Layout of this Module

Module 12

Schedule 12, consumer actions, and test questions

Conceivably, you could test every consumer action that can be extrapolated from Schedules 12 or 13 and which is relevant to the particular medicine. But in many instances this would entail asking consumers over 70 questions. This is neither practical nor necessary.

To find out what parts of the CMI can be usefully tested, examine the consumer actions in this Module and select the ones that you believe to be critical for the appropriate use of the medicine in question.

The list of consumer actions is not exhaustive. You could identify and add other actions. Critical consumer actions are often located under these Main Headings:

- What [Brand name/it] is used for
- Before you use it
- How to use it
- While you are using it
- Side effects

Once you have identified the critical actions, you may decide not to test certain sections if they are the same as:

- examples in these *Guidelines,* which have already been tested
- examples in the Core CMIs
- equivalent sections in other CMIs which you have previously tested satisfactorily (but only if these CMIs are for a similar class of medicine and used in similar contexts and in similar ways by similar populations at risk).

As a rough guide, aim to select about 15 actions for consumers to perform with the CMI. When you have experience in diagnostic testing of CMIs, you may not need to test all critical actions, because some may be similar to those you have

tested before. But only experience will allow you to tell what is 'similar' and what needs testing. With experience, you may only need to test 6 or 7 critical actions.

Layout of this Module

Performance-focused testing

The Module is divided into eleven Sections. Each Section is subdivided into three subdivisions: the Schedule 12 Heading and relevant passages from this Schedule; Actions (consumer actions related to the passages); and Questions (test questions designed to see whether the CMI is designed so that a consumer can find the information quickly and easily and perform the actions appropriately).

The Headings in the order of their presentation are as in Schedule 12.

In very long Sections, such as Section 3, the Actions and associated Questions are grouped for easier use.

Numbers in square brackets refer to the questions.

1. Identification

the name of the medicinal product, which is the name given to the product by the sponsor, including or followed by the non-proprietary name(s) of the active ingredient(s) and the dosage form or strength, or both, of the product

a statement of the active ingredients expressed quantitatively and excipients expressed qualitatively, using their common names, in the case of each presentation of the product

the pharmaceutical form and contents by weight, volume or number of doses of the product, in the case of each presentation of the product, together with its identifying Australian Register number

1. Actions

Consumers should be able to **find**, **read** and **be able to use** the following information on the CMI:

- the proprietary name of the product [1.1]

- the active ingredient of the product [1.1]
- the non-proprietary name(s) of the active ingredient (s) [1.3]
- the form of the dosage (e.g. tablets, syrup, suppository, patch etc) [1.2]
- the strength of the product [1.4] and/or
- the amount of drug each form of the dosage contains [1.4]
- the quantity of the active ingredients in each dose [1.4]
- the other non-active components of the medicine [1.5]
- the Australian Register number [1.6].

1. Questions

1.1 What is the name of the medicine?

1.2 What form does this medicine come in? (e.g. tablets, liquid)

1.3 What is the active ingredient?

1.4 How much of the active ingredient is in each dose (e.g. in one tablet)?

1.5 What are the other ingredients in this medicine?

1.6 What is the Australian Register number of this medicine?

2. What the medicine is used for and how it works

the therapeutic indications, unless a competent authority determines that the dissemination of such information may have serious disadvantages for the consumer

the pharmaco-therapeutic group, or type of activity if there is a term that is easily comprehensible to the consumer. If not, a simple description of what the medicinal product is for and how it works, in 1 or 2 sentences

2. Actions

The consumer should be able to **find** and **read** information on the CMI about:

- the action that the drug takes in the body [2.1]
- how the drug works [2.2]

- information about the drug family (e.g. NSAIDs, ACE inhibitors) [2.3]
- the conditions a product is approved to cure, alleviate, prevent or diagnose [2.4]
- the possibility that the product may also be prescribed by a doctor or pharmacist to alleviate other (possibly unrelated) conditions.

2. Questions

2.1 What does this medicine do?

2.2 How does it work?

2.3 What family of medicines does this medicine belong to? (e.g. NSAIDs, ACE inhibitors)?

2.4 What can this medicine be used for? Can it be used for anything else?

3. Advice before using the medicine

a list of factors that are useful to consider before taking the medicinal product, including, if appropriate:

- contraindications, including consider-ation of whether the consumer has experienced previous allergic reactions
- precautions for use, taking into account the particular condition of certain categories of users, such as the elderly, children, infants, pregnant or breastfeeding women, persons with specific pathological conditions
- potential effects of the medicinal product on the ability to drive vehicles or to operate machinery
- interactions with other medicinal products or other forms of interaction (for example with alcohol, tobacco, foodstuffs) which may affect the action of the product
- special warnings, such as the effects on sensitivity to sun exposure

3(a) Actions

Contraindications and precautions for use

Consumers should **work out** if:

- they have had any previous adverse reactions or allergies to either the active or non-active ingredients [3.1]

- they are taking any other medicines [3.2] which may be contraindicated because of their effect on the performance of this medicine, or because they would be affected by the use of this medicine [3.3]
- they are taking any medicine [3.2] that, in conjunction with this medicine, would affect their health
- they have any ailments or physical problems (e.g. asthma) or conditions (e.g. pregnancy) that could be affected by the use of this medicine, or would affect the performance of the medicine (e.g. kidney disease) [3.3]
- they have a previous history of usage which indicates that the present medical regimen may not be effective

and if so, consumers should **know** not to use this medicine until they talk to their doctor or pharmacist.

Consumers should also **know** to **seek** further advice from a doctor or pharmacist if they:

- are unsure about whether it is safe toffitake a particular medicine
- suffer from any serious illnesses or conditions
- are taking any other medicines (either prescription or OTC (over-the-counter).

Consumers should **know** when it may be unsafe to drive vehicles or operate machinery because of the effects of their medicine. Consumers should **understand** the reasons for these activities being unsafe (e.g. drowsiness, slower reaction times, inability to reason properly) [3.4, 3.5].

3(a) Questions

3.1 Can you take this medicine if you are allergic to [ingredients]?

3.2 Suppose you've been taking [other medicine]. When your doctor prescribes [Brand name], what should you do?

3.3 Can you take this medicine if you are (e.g. breastfeeding/pregnant/ taking a medicine that may interact with [Brand name]), or have (e.g. asthma/ kidney disease/)? What do you need to do?

3.4 Are you able to drive a car while taking this medicine? Why or why not?

3.5 Are you able to operate machinery while taking this medicine? Why or why not?

3(b) Actions

Interactions with food and drink

Consumers should be able to **work out** whether a medicine interacts with substances such as food, alcohol or tobacco [3.6-3.8]. If it does, they must be able to **select** an appropriate course of action [3.9-3.11] such as:

- **reducing** the amount of alcohol drunk or tobacco smoked
- **not** drinking or smoking
- **avoiding**, or **eating** more of, particular foods (e.g. drinking more milk, taking medicine with water, mixing medicine with meals, not consuming medicine with milk)
- **limiting** medicine-taking either to coincide with or avoid mealtimes (e.g. taking medicine one hour before meals, taking medicine with breakfast and dinner)
- **maintaining** a balanced diet
- **avoiding** binge eating.

3(b) Questions

3.6 Can you take this medicine with [food, either general or of a specific type]?

3.7 Can you drink alcohol if you are on this medicine? Why, or why not?

3.8 Do you need to make changes to your diet while taking this medicine? Why, or why not?

3.9 What should you do if you accidentally took/ate/drank [a substance that interacts] while you are using [Brand name].

3.10 Is there anything you should avoid eating or drinking of while taking [Brand name]?

3.11 Is there anything you should eat or drink more of while taking [Brand name]?

3(c) Actions

Interactions with medicines

Consumers should be able to **work out** whether a medicine interacts with other medicines, and if it does, they must be able to **select** an appropriate course of action [3.2, 3.3, 3.12] such as:

- **stopping** the use of other types of medicine after **consulting** a doctor or pharmacist (this will involve consumers **telling** the doctor or pharmacist what other medicines, both prescription and OTC, they are taking)
- **not taking** this medicine after **consulting** a doctor or pharmacist
- **timing** their medicine-taking to fit in with present medicine-taking routines.

Consumers should be able to **carry out** these actions properly.

3(c) Questions

3.12 You have (a condition such as a tummy upset) and you want to take (an OTC medicine, e.g Quick-Eze). Is it okay to do this?

3(d) Actions

Activities to avoid

Consumers should also be able to **work out** whether there are any other activities that they do that may:

- affect the performance of the medicine

- be affected by the performance of the medicine
- have to be avoided while the consumer is taking the medicine (e.g. sunbathing) [3.13].

Consumers should **know** that they may have to **modify** or **stop** those activities, **know** to **seek** medical advice of the course of action to take, and be able to **carry out** an appropriate course of action (such as avoiding activities or changing medicine).

Consumers should be able to **work out** whether any other special precautions need to be taken when using this medicine, and to **act** accordingly (e.g. avoiding exposing themselves to sunlight).

Consumers should **understand** the benefits of **carrying out** these actions properly, and **consulting** a doctor or pharmacist when appropriate.

3(d) Questions

3.13 You want to do (some gardening on a sunny day or some other activity e.g. go for a picnic/play tennis). Is it okay to do this? What if you use a sunscreen (or take some other precaution)?

3(e) Actions

At-risk groups

Consumers should be able to **work out** if they (or the person being treated) are in an at-risk or non-standard medicine group such as:

- the elderly
- children and infants
- pregnant or breastfeeding women
- consumers with other unrelated medical conditions (e.g. kidney disease)
- habitual drug users

and if so, they need to **know** that they may need to **change** their medicine regimen. [3.2, 3.3, 3.14]

Consumers in at-risk groups should **know** to **consult** a doctor or pharmacist before changing the amount of medicine they are taking.

If they are in one of these groups, consumers should **know** to **consult** a doctor or pharmacist, so that they can **select** a course of action such as:

- **not using** the medicine [4.14]
- **reducing** the amount of each dose, which may involve **calculating** the amount of drug to be taken [4.5]
- **reducing** the number of applications, which may involve **calculating** the amount of drug to be taken [4.5]

and **carry it out** properly.

In cases where medicine regimens have to be changed, consumers should **know** to **seek** the advice of a doctor or pharmacist (preferably one that is familiar with their case) before they change the amount and type of medicine they are taking.

3(e) Questions

3.14 Let's say you are a breastfeeding mother (or some other condition) and have just read in the leaflet that you need to (exercise caution) if you take this medicine. What should you do?

4. How to use the medicine properly

the necessary and usual Instructions for proper use of the medicinal product, in particular:

- the dosage, together with an indication that this may not always apply and may be modified by the prescriber
- the method, and if necessary, the route of administration
- the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product should or must be used

In addition, depending on the nature of the therapeutic goods:

- the duration of treatment, if it should be limited
- the expected effect of using the medicinal product
- what to do if one or more doses have not been taken
- the way treatment should be stopped, if stopping the treatment may lead to withdrawal or other adverse effects.

4(a) Actions

Calculating the dose

Consumers should **know** what the normal dose [4.1] and method of application [4.2] is for them (or the person they are treating). Consumers should **know** to **seek** medical advice if the dose they have been told to take [4.3] or the method of application [4.4] they have been shown is significantly different to that on the CMI. Consumers should also be able **to recognise** what a 'significant difference' is [4.3].

Consumers should be able to **calculate** the appropriate dose [4.5] (if necessary). This may involve:

- **reading** the insert (or label or package) to find what the standard dose is
- **weighing** themselves (or the consumer)
- **multiplying** weight by dose per kilogram
- **dividing** by dosage strength per tablet or volume.

Alternatively, consumers may have to:

- **read** the dose, based on weight, from a table.

Consumers in an at-risk group should be able to **modify** the standard dose by **following** Instructions from their doctor or pharmacist, in conjunction with the Instructions on the CMI [4.5].

4(a) Questions

4.1 What is the normal dose for this medicine?

4.2 How would you normally take this medicine?

4.3 What should you do if your doctor or pharmacist tells you to take a different dose to that given in the leaflet?

4.4 What should you do if your doctor or pharmacist tells you to take this medicine differently from that described in the leaflet?

4.5 How much of this medicine do you need to take? How did you work that out?

4(b) Actions

When to take it

Consumers must also **work out** how often, for how long [4.8], and at what time [4.6] [4.7] treatments must be taken or applied. They must be able to **take** medicines at the right times. In particular, they must **know**:

- whether medicines must be taken with meals [4.7] [4.9]
- whether medicines must be taken at a specific time before or after meals, treatments, activities and other medicine [4.9], and if so, how long before or after
- whether they must wake in the night to take a dose [4.6] [4.7].

Consumers must **know**:

- how long treatment is to continue [4.8]
- to **carry out** treatment for the duration [4.8].

To do this, consumers must be able to **work out** the length of treatment, based on:

- the information supplied by their doctor or pharmacist
- the number of days treatment has to last for [4.8]
- the number of courses to be taken.

Consumers should be able to **work out** a daily timetable for themselves, in consultation with their doctor or

pharmacist, so that they can carry out these actions properly.

4(b) Questions

4.6 How often do you have to take this medicine?

4.7 What time of day do you have to take this medicine?

4.8 How long would you have to take this medicine for?

4.9 Are there certain times when you shouldn't take this medicine? What are they?

4(c) Actions

Measuring out the dose

Having calculated an appropriate dose and the time to take it, consumers must be able to **measure** it [4.10]. This may involve:

- **counting** the right number of tablets, vials, sachets, etc
- **breaking** tablets into smaller pieces
- **measuring** a volume of liquid or powder using a measuring glass or spoon, or calibrated bottle-cap
- **approximating** the volume of an ointment or other cream (possibly by referring to the size of a standard object, such as a twenty cent coin)
- **counting** the number of drops (from an eye, ear or nose dropper)
- **counting** the number of inhalations or squirts (e.g. for asthma packs)
- **measuring** the volume using a syringe.

Consumers should also be able to **carry out** any other pre-preparation necessary [4.11] such as:

- **dissolving** tablets in water
- **mixing** powders with food
- **mixing** a hair-rinse with a sinkful of water
- **finding** a container in the case of an emetic

- **using** a peak-flow meter in the case of asthma.

4(c) Questions

4.10 Let's say it's time to take your medicine. How much would you have to take/measure out? (if there are placebos available—Can you show me?)

4.11 Do you need to do anything to/with the medicine before you take it?

4(d) Actions

Taking/using the medicine

Consumers must then be able to **take** or **apply** the medicine properly [4.13], in the right quantity, at the right time, in conjunction with any other requirements (for instance taking tablets with a glass of water, but not milk).

The range of actions includes:

- **swallowing** tablets or capsules (with water, milk or some other liquid)
- **chewing** tablets
- **dissolving** tablets in water, or other liquid, and then **drinking** all of the liquid
- **rubbing** on or in an ointment or cream
- **injecting** medicine (e.g. insulin)
- **eating** a full meal with medicine incorporated into the food
- **putting** drops into eyes, ears, nose or mouth
- **swallowing** liquids (e.g. cough mixtures)
- **sticking** a patch to the skin
- **rinsing**, either with a lotion, or a concentrate mixed with water
- **gargling** (in the case of mouth rinses)
- **inhaling** either from inhalers, puffers or steam baths
- **inserting** a nasal puffer, and **squirting**
- **inserting** a suppository or pessary.

4(d) Questions

4.13 How do you take this medicine? (if placebos are available—Can you show me how?)

4(e) Actions

After taking the medicine

Consumers should be able to **carry out** any post-administration necessary [4.12], such as:

- **rinsing** the mouth after using steroid asthma inhalers
- **applying** a bandage or covering.

4(e) Questions

4.12 Is there anything you need to do after you take the medicine?

4(f) Actions

How not to take it

Consumers should **know** how **not to take** medicines [4.14], where there is a reasonable likelihood that consumers may do otherwise through familiarity, prior knowledge, or reasonable possibility of accident. For instance:

- tablets that are to be taken only with water, not with milk or fruit juices
- ointments that must not be used on the face, or near the eyes and mouth
- suppositories and pessaries must not be swallowed.

4(f) Questions

4.14 Are there any ways that you should not take/use this medicine?

4(g) Actions

Effects

Consumers must be able to **say** what the expected effects of a treatment are [4.15], and when they are likely to happen [4.15]. Consumers must **check** that the expected effects happen as predicted. If they do not,

they should **know** to **seek** the advice of a doctor (preferably the one that prescribed the medicine) or a pharmacist (preferably the one that dispensed the medicine) [4.15].

4(g) Questions

4.15 What are the effects of this medicine? When are they likely to happen? What should you do if they do not happen?

4(h) Actions

Missing a dose

If one or more doses have been missed [4.16, 4.17], consumers should be able to **choose** which of the following actions needs to be carried out:

- **seek** advice of a doctor or pharmacist
- **take** or **apply** another dose of the medicine immediately, and then continue to take the medicine as before
- **take** a multiple dose to make up for the loss, and then continue to take the medicine as before
- **take** another dose immediately, but alter the timing of subsequent doses to take into account the change (if any) in medicine times
- **begin** the course of treatment over again
- **do nothing** and **continue** the course of medicine unaltered.

Consumers should be able to **carry out** these actions appropriately.

4(h) Questions

4.16 What should you do if you forget to take a dose?

4.17 Let's assume that you were supposed to take [Brand name] at breakfast time, but you forgot. Should you take it now?

4(i) Actions

Modifying and stopping

Consumers should be able to **stop** or **modify** treatment appropriately, and **know** when to do so based on the appearance or disappearance of symptoms [4.18].

They should also **know** the reasons for following Instructions and the implications for not following Instructions correctly (e.g. adverse effects, withdrawal) [4.18].

They should **know** to **talk to** their doctor or pharmacist (if appropriate).

4(i) Questions

4.18 Suppose you've been feeling great for the last month. Can you stop taking the medicine?

5. Further information

for example, habit forming potential, whether a doctor's prescription is necessary

5. Actions

Consumers should be able to **find** any other further information necessary to their use of the medicine, such as:

- whether a doctor's prescription is needed to obtain the medicine or further courses of medicine or variations in the strength of the medicine [5.1]
- any long-term effects such as a habit-forming potential [5.2]
- lifestyle changes that may be required [5.3]
- having regular tests or check-ups done [5.4]
- diet [5.3]

and **take** appropriate **action** (such as seeking a doctor or pharmacist's advice).

5. Questions

5.1 Do you need a doctor's prescription to obtain the medicine, or further courses of medicine, or a different strength of the medicine?

5.2 How long can you take this medicine for? What might happen if you take it for longer?

5.3 Do you have to (specific implication for lifestyle or diet) while taking this medicine?

5.4 What check-ups do you have to have?

6. Unwanted effects

a description of the undesirable effects that can occur under normal use of the medicinal product and, if necessary, the action to be taken if experienced

consumers should be expressly invited to communicate any undesirable effect, especially if it is not mentioned in the consumer information document, to his or her doctor or pharmacist

6. Actions

Consumers should be able to **recognise** the signs and symptoms of undesirable side effects that can occur under normal use, if they occur to them (e.g. dizziness, nausea, vomiting, drowsiness) [6.1].

Consumers **should know** to:

- **report** any undesirable effects, whether mentioned in the package or not, to their doctor or pharmacist [6.2], and
- **seek** advice before using other medicines to deal with side effects [6.2].

Consumers should be able to **work out** how urgent it is to tell their doctor or pharmacist about side effects and what to do about them [6.3].

Consumers should be able to **select** options for dealing with side effects [6.2], including:

- **seeking** advice from a doctor or pharmacist
- **taking** other medicines

- **not taking** other medicines (if they are contraindicated)
- **stopping** the use of the medicine

and to **carry out** these actions properly.

6. Questions

6.1 How would you know if you were suffering from the side effects of this medicine?

6.2 What would you do if you developed [a side effect]?

7. In case of overdose

the action to be undertaken in case of overdose (for example, symptoms and emergency procedures)

7. Actions

Consumers should be able to **recognise** the symptoms of overdose [7.1].

In the case of overdose, consumers should be able to **select** a course of action [7.2] such as:

- **carrying out** immediate first aid (e.g. washing affected areas, vomiting, taking milk, applying bandages)
- **seeking** further information (e.g. by calling their, or any, doctor or pharmacist, a Poisons Information Centre, or the casualty/Accident & Emergency department of their nearest hospital)
- **hospitalising** themselves and **carrying out** actions properly.

Consumers need to **understand** the urgency associated with overdosing on a particular medicine [7.3].

7. Questions

7.1 What are the signs that you (or someone else) has taken too much of this medicine or has overdosed?

7.2 What does the leaflet tell you to do if you overdose on this medicine?

7.3 How soon should you do anything?

8. Storage conditions

an indication of the appropriate storage conditions; a reference to the expiry date indicated on the label, with a warning against using the medicinal product after this date; if appropriate, a warning against visible signs of deterioration

8(a) Actions

Date of expiry

Consumers should be able to **find** the expiry date for the medicine [8.1]. If the expiry date has passed, consumers should be able to **select** a course of action [8.2] to deal with the medicine such as:

- **returning** the remainder to a pharmacist
- **throwing** the remainder away
- **pouring** the remainder down the sink

and to **carry out** their action properly.

8(a) Questions

8.1 What is the expiry (use-by) date of this medicine?

8.2 If the expiry date had passed, what should you do with this medicine?

8(b) Actions

Storage

Consumers should be able to **store** the medicine appropriately [8.3]. This may involve:

- **storing** it in a locked cupboard where children cannot accidentally get to it
- **storing** it in a cool place (e.g. below 30°C)
- **storing** it in a dark place, or out of direct sunlight
- **storing** it away from household cleaners or poisons
- **not leaving** medicines in hot places (such as cars)

- **keeping** the medicine in the original packaging
- **storing** it in a refrigerator or freezer
- **not storing** it in a refrigerator or freezer.

Also, consumers should be able to **store** small units of medicine such as half tablets left over as part of the dosage (because only half a tablet was to be taken). This may include:

- **putting** the remainder back in the bottle
- **wrapping** the remainder
- **discarding** the remainder.

Consumers should **understand** the reasons for storing medicines in these ways [8.4] (e.g. because the medicine may lose effect, become poisonous), and the risks associated with not carrying them out.

8(b) Questions

8.3 How should this medicine be stored?

8.4 Why does it need to be stored this way?

8(c) Actions

Deterioration of medicine

Consumers should be able to **recognise** medicines that have deteriorated by [8.5] noticing:

- a change in the usual colour of the medicine
- a bad or unusual smell
- a bad or unusual taste

and **know** not to use them [8.6].

Consumers should also be able to **recognise** conditions that may lead to the deterioration of medicines [8.5] (e.g. foil wrappers not intact, seals on bottles broken). Consumers should **know** how to **dispose** of spoilt medicines safely.

8(c) Questions

8.5 If this medicine had deteriorated (gone off), how would you know?

8.6 If you thought that the medicine had gone off, what should you do?

8(d) Actions

Unused medicines

Consumers should also **know** what to do with unused medicines [8.7], for instance:

- **return** them to the pharmacist or hospital
- **dispose** of them
- **store** them

and **act** appropriately.

8(d) Questions

8.7 What should you do with any medicine that is left over after you finish your treatment?

9. Where to go for further information

a direction to consumers to discuss any aspect with the doctor or pharmacist and, if appropriate, where further information may be obtained

9. Actions

Consumers should:

- **know** where to obtain further information if they need it [9.1]
- **select** the most appropriate source of information [9.1], and
- **know** how to obtain information [9.2].

Consumers should **know** at least some of the following are potential sources of information: [9.1]:

- their (or any other) doctor
- their (or any other) pharmacist
- hospitals
- Poisons Information Centres
- drug information centres
- health clinics
- Departments of Health
- books, pamphlets and other literature

- the manufacturer (or sponsor if appropriate).

Consumers should be able to **select** [9.2] an appropriate way of requesting information:

- by seeking face-to-face advice from their doctor or pharmacist
- by writing to any of these sources
- by telephoning or faxing any of these sources.

Consumers should know to discuss the medicine and any aspects of the medicine regime with their doctor or pharmacist [9.3].

9. Questions

9.1 If you wanted more information about this medicine, who could you get it from, or where would you go to get it?

9.2 How would you get hold of it?

9.3 If you wanted to more information about your treatment and the medicines you were taking, who would you talk to?

10. Sponsor

the name and address of the Australian sponsor of the medicinal product

10. Actions

Consumers should be able to **find** the name and address of the Australian sponsor [10.1], manufacturer or importer of the product, and the appropriate person in the organisation to contact for further information.

10. Questions

10.1 What is the name and address of the manufacturer?

11. Date of information

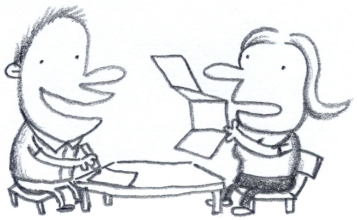
the date on which the consumer information was last revised

11. Actions

Consumers should be able to **find** the date on which the information was most recently prepared [11.1].

11. Questions

11.1 When was this information prepared or last updated?



Module 13
The testing procedure

What to ask

The purpose of the test questions

The aim of diagnostic testing is to find out how consumers will go about using the CMI and what processes they use. The questions you ask should lead into a dialogue with potential users that allows them to demonstrate how they are navigating and using the CMI. It is important to avoid asking closed-ended or 'yes/no' questions that limit the participants' responses. While closed-ended questions might tell you whether people can or can't use the CMI, they will provide you with very little information about why people can't use the CMI, or what you could do to make it easier to use.

Translating consumer actions into questions

Once you have identified the critical consumer actions, you need to compose your questions.

Module 12 provides possible test questions for each consumer action. Until you gain some testing experience, you should use these questions as the basis of your testing.

In general, these questions test whether or not the CMI has been designed in a way that allows users to find and act on any information. Importantly, the ability of participants to access and act depends also on the expectations, experience, and skills that participants bring to the CMI. Part of testing always involves checking what expectations and skills they bring to the task, and how you can adjust the CMI to best suit their expectations and needs.

Depending on your experience and needs, you may choose to develop alternative questions. Developing a question requires you to think about the potential answers

as much as the question itself. A question should be aimed at helping you open up a dialogue with potential users, who can provide you with data on how to improve the performance of the CMI. Your principal interests are the accessibility of the information and the capacity of the CMI to allow participants to act appropriately on the information. Is the information in the CMI? Can the participant quickly and easily access the relevant information and, if not, why? Is the information in one place or several? Can they show that they understand it by saying how they would act on the information, and if not, why not?

Note that you will not ask the participants directly if they understand what they read; knowing that they understand is not in itself useful to you. You will know that they understand when they can tell you how they would act, and that is the most important thing.

How to ask

Always be specific

The people you interview may interpret your question in ways you didn't foresee, and give answers which don't help you. For this reason:

- make sure that your questions are specific and can only be answered one way
- ask people about the interpretations they are making, which will help you identify what sort of questions they think they have been asked, and will suggest ways of modifying your test questions.

Locating and acting, or locating only

There are several ways you can ask questions, depending on what answers you want.

Example 1

When asking about the compatibility of this medicine with others, you can ask:

1. "What medicines mustn't you take at the same time as [Brand name]?"

In response to this question, participants can do one of two possible things: successfully locate and cite any incompatible medicines, or be unable to find the incompatible medicines at all. If you were primarily concerned about the location of the incompatible medicines list within the CMI, this may be all that you require.

Or you can ask:

2. "Let's say you've been taking [another medicine] for a while. When your doctor prescribes [Brand name] for you, what should you do?"

For some medicines, this alternative question may be more appropriate, especially if the dangers associated with an adverse reaction are high. The likely responses from this second question will not only tell if participants can locate the list of incompatible medicines, but also if they are likely to act appropriately.

Example 2

When you wanted to know if consumers will take the medicine correctly, you can ask:

1. "How should you take this medicine?"

This question will tell you if they can locate and correctly interpret the "How to take it" information.

For a medicine with complex dosage requirements, you could ask a scenario question:

2. "You've just finished your breakfast when you remember that you've forgotten to take your medicine. What would you do?"

This question will not only reveal if participants can locate the information, but will also show if they are likely to act on it appropriately.

The number of questions

The number of questions you ask depends on how many critical consumer actions you have identified. As a rough guide, aim to ask

about 15 questions. Be wary of interviewing for much longer than this, as participants may start to tire after about 30-35 minutes.

Refining your questions

Once you have drafted your questions, consider the following checks:

- use everyday, colloquial English; avoid the formalities of written English
- keep your sentences short
- limit the number of questions where the question indicates an answer (whether right or wrong) such as, "Should you take two tablets?" or "Should you store the medicine in a locked cupboard away from children?". Such questions can inhibit the participant interpreting the information, thus reducing the dialogue to something like a closed yes/no or tick-box interview
- mostly ask open-ended questions, such as "How much would you take?" or "How would you store this medicine?" This helps you to find out how they interpret the information and to identify possible inappropriate actions (for instance, "It says to store it in a locked cabinet but I keep all my medicine in the fridge")
- avoid preference or opinion questions that seek to find out if participants like the way something is written or set out (for instance "Do you like the bold headings?" or "Would you prefer it if the dosage information was set out in a table?"). Research has shown that responses to such questions are generally a poor indicator of performance; a design that is well-liked or preferred is often the one that performs the worst.

Ordering your questions

Once you have composed your questions, you need to think about the order in which you will ask them. Unfortunately, the principles for ordering questions can be contradictory and are perhaps best preceded by an illustration.

Imagine a CMI with five sections—A, B, C, D and E—presented in that order. Now imagine you have five test questions, one for each section. If you asked your questions in the order of Q.A, Q.B. Q.C, Q.D and Q.E, the participants would soon learn that to answer the next question they need only read on from where they found the last answer. Hence, you would not be testing the accessibility of the information fairly.

Thus, some jumbling of the questions is good. It avoids a rhythmical or sequential accessing of the CMI. But it can also be overdone. For example, suppose that sections A, B, C, D and E of our imaginary CMI are the ones that follow a temporal order of before, during and after. If this were the case, you could confuse participants if you first asked them about section E, then B, then D, then A and finally C.

The matter of ordering is further confounded when we also take into account the fact that it is generally a good idea to initially ask two or three easy questions so as to allow the participant to settle in. So what should you do?

As a guide, follow these principles:

1. Open the interview with two or three easy questions; you do not have to be especially interested in the answers (for instance "What is the name of this medicine?", "Have you used this medicine before?" and "What is it used for?"). This puts participants at ease.

2. Ask your questions about 'before', 'during' and 'after' use, to cover the basic structure. This allows participants to become comfortable with the CMI in a manner similar to how they might interrogate it at home.

   Remember the order in which you asked the questions when you analyse your results.

   You may relocate a particular question if you think the accessibility of the relevant information is a particularly critical issue.

3. Once the basic structure of the CMI has been covered, jumble the order of your questions, especially if you want to avoid asking two questions in sequence that refer to adjacent information.

4. Close the interview with some general questions that allow the participant to raise any problems not already discussed (for instance "What are the bad points about this CMI?", "Any there any good points?", "How can we improve it?" and "Is there anything that we haven't already discussed that you'd like to mention?").

5. Once you have formally completed the interview you can briefly discuss your views of particular problems with the participant. Suppose you have already observed several participants making the same mistake or misinterpretation, but you do not know why. If so, you could say to the participant something like "The interview is now formally over. But before you go, can we switch roles? I've got some hunches about this document and I'd like you to tell me if I'm right or way off the mark", then present the problems and potential solutions as you see them. Some of the most valuable insights from testing can come from such discussions.

Protocol (Questionnaire): to format, or not to format?

Click here for an example of a formatted protocol.

Advantages of formatting

If you are interviewing for the first time, a formatted protocol can help you structure the interview and maintain a test results database.

If you are instructing others on how to test, it could also be advantageous to format your protocol, especially if your instructions for the interviewer on how to proceed are complex (for instance "if xx occurs, skip the next yy questions and go to zz").

Disadvantages of formatting

First, preparing a formatted questionnaire can be a time-consuming task.

Second, and more important, a formatted protocol is restrictive. Interviewers must be flexible and resourceful, because they need to create questions and jot down answers on the run, probing any observed errors or misinterpretations. Formatted protocols can discourage interviewers from being flexible and resourceful, encouraging an inappropriate reliance on tick boxes or summarised answers rather than detailed notes.

The experienced interviewer

If you are the only person conducting the interviews, and you have some experience and confidence in diagnostic testing, you will probably find that simply typing your questions and Instructions onto one or two A4 pages will be adequate to remind you of everything you want to cover. To record your observations and the participants' responses to each question, use a notepad. This will give you unrestricted room to record valuable data. Be sure to keep thorough notes of everything you ask and observe.

Trial interviews

There is nothing like a trial or pilot interview to check the appropriateness and ordering of your questions. For such interviews, it is generally acceptable to use someone close at hand, such as a fellow office worker, friend or family member. To get the most from a trial interview, treat the interview as though it were the real thing, following the suggestions discussed in *Conducting interviews*. In addition, at the end of the interview, ask your volunteer if there were any Instructions they did not understand or if there was anything that made them feel uncomfortable.

Recruiting participants

From where?

Some possible sources for recruiting participants include clubs, associations and professional recruiting agencies.

Professional recruiting agencies will generally charge a small fee per person. In addition, you will need to pay each participant a similar amount, depending on the amount of time that you book them for.

If you decide to recruit from a club or association, you may be asked to make a small donation to the organisation. You should also offer to cover each participant's transportation costs, and also possibly offer them some form of remuneration for their time.

How many to recruit

A single round of diagnostic testing will not allow you to make precise predictions about how well users will be able to interpret and act on a CMI, though experience has shown that conclusions from such tests do work well when used as part of an iterative design process. However, a single round of diagnostic testing will detect most of the more serious problems, as well as many lesser ones. How many to test then, is not a statistical question, but a practical one.

As a general rule, you should seek to recruit 10 participants. This number of participants will not only help you identify the problems, but they should also give you sufficient data to be able to consider possible solutions.

You may be able to reduce your testing costs by testing more than one CMI on each participant. For example, you may have two short and relatively simple CMIs for which you have identified only a few critical consumer actions. In such an instance, you could test both CMIs—one after the other—on each participant, thereby getting two tests for the price of one.

If you are testing just one CMI, don't let the interview go for more than about 30-

35 minutes, because people begin to tire after this time. If there is more than one document involved, you can extend the attention of participants beyond 30-35 minutes. However, be wary of testing a participant for more than 45 minutes.

Conducting interviews

Test one participant at a time

Group tests, such as focus groups, tend to say more about how people react with input from others rather than provide insights into how people will react with a CMI.

Schedule your interviews about 15 minutes apart. This should be enough time for you to conduct the interview, write up any notes afterwards and to catch your breath. Tightly scheduled interviews can be excessively tiring, while interviews scheduled too far apart can disrupt your concentration on possible design solutions.

Make the participant comfortable

You are aiming to open a dialogue—to have a chat, so to speak—with participants about the CMI. To encourage this, it is important that you make them feel comfortable. Some points to consider include:

- use a quiet room for the testing with a table, chairs and few distractions.
- wear appropriate clothing. In many instances, a corporate wardrobe can be intimidating. Definitely do not wear a suit jacket
- if you have the facilities, offer them a cup of tea, coffee or water. Tea and coffee are especially good for breaking the ice

Part of the process of making the participants comfortable is to inform them about the testing. Use an introduction before testing (see Module 14 for the protocol introduction). Minimally, you will inform them of:

- who you are and who you work for

- what you will be asking them about
- how what they say will help you improve the document
- how they can best help you (by telling you of any problems they experience).

Depending on what you are testing, you could also tell them:

- that you are not running a speed or time trial, and that they can look at the document for as long as they want, and can refer back to it at any stage
- that anything they say will be treated confidentially, and will only be used for learning about how to improve the document.

Reading or not reading the entire CMI

Should the participant be allowed to read the entire CMI before being asked questions about it? The answer depends on what you are testing.

Consider the following possibilities.

If the participant is anxious to read the whole CMI, it may be a good idea to let them do so. This will help to make them comfortable with the exercise, but you should record the fact that they read the whole CMI in your notes. Remind the participants that this is not a memory test or speed trial and that they can refer to the CMI as much as, and whenever, they like.

The contexts in which the medicine is normally used are also important. Do people normally sit down and read it thoroughly, or are they likely to want to know some critical information quickly during some sort of emergency? Knowing the contexts of use will help you decide how much of the document you should let participants read: the more urgent the context, the less you should allow them to read.

Not letting participants read the entire CMI can be useful if you want to concentrate on issues of accessibility. Asking participants to answer questions using a CMI they have not entirely read places an emphasis in the

testing on how the Headings either aid or hinder the structural transparency. Do they know which section to turn to, by reading just the Headings? Or do they also need to read the text before knowing if they are in the right or wrong section?

What data should you record?

The interview in a diagnostic test is not like other interviews. You are not simply recording what the participants say. You need to record:

- what they say
- how they say it
- what they do
- how they do it.

In detail, you should record:

- whether they located the information and, if it is appears more than once in the CMI, from where
- how they interpreted the information, in their own words (not simply as correct or incorrect which are labels you apply later in your analysis)
- any comments made by the participant as they are performing each task
- the way in which the participant accesses the CMI, what pages they turn to, what columns they appeared to read and at what point they seemed to get lost or confused
- whether the participant appeared to read in detail, or if they skimmed.

All of these help you with your primary goals:

- to define the problems
- to develop appropriate solutions.

You may find it helpful to develop your own code or shorthand (for instance, an arrow to indicate 'turned the page', or a triangle to indicate 'change needed'). It also can be helpful to have your own copy of the

document on which you can quickly note possible changes.

Managing the participants' responses

Interviewing involves much more than just asking questions and recording responses. You also need to appropriately manage the form of the responses so as to maximise the quality of the data.

The following points describe some of the more common moments where you need to manage the response. You may find it useful to summarise these points in your own terms and have them in front of you when testing.

Some participants will respond to your questions without referring to the document. It is then awkward to ask "Can you please show me where it says that in the document". Establish very quickly in the interview that you want them to show you where the answer is and, if necessary, to interpret it for you.

Once they have located the answer, most participants will read out the information to you. For anything other than very simple or manifest answers, it is a good idea to ensure they can comprehend the information by also asking them "What does that mean?' or "In your own words, what's that telling you to do?". If a placebo is available, you may also like to ask them to demonstrate how they would use it.

Some participants will ask you what something means or what they should do in the scenario you have posed. Avoid giving them the answer immediately. You should first try to establish what is their interpretation, not yours. Useful replies include "What would you do if you read that?" or "Actually I'm not sure. What do you think it means?"

If someone can't find something, you may still find it useful to know if they can use the information. Politely show them where it is located—"It's tucked away here: that's something we'll need to change"—and

ask them to answer your question by interpreting the appropriate passage.

Once a participant has located the answer, avoid asking if they would do the 'right thing' (for instance, "Would you keep the medicine in a locked cabinet away from children?"). Keep any follow-up question more neutral (for instance, "What would you do if you were now at home with this medicine?").

Another way to manage responses is by regulating your note taking. Generally, it is a good idea to take notes as constantly as possible, reducing the risk of unnerving participants with sudden bursts of writing ("Uh oh, what have I done wrong?"). But it can be useful to temporarily cease taking notes when a participant strays too far from the subject (for instance, if they start giving you their full medical history) or, conversely, to ask them to pause while you record something in detail ("That's a really important point. Thanks. I'll just get you to stop for a second while I write down word for word what you've said").

Module 14

The test protocol

Understanding the protocol

Module 12 gives some of the questions you can ask your test participants, and the rationale for them. To test your CMI, you need to:

- decide which actions you want consumers to take
- select appropriate questions
- refine them to suit yourself, your participant and your CMI
- write others if you need
- understand the principles of diagnostic testing (Module 11)
- understand the testing procedure
- design a question protocol.

Use the question protocol provided below as your starting point for developing a protocol specific to the CMI you are testing.

It is called a protocol rather than a questionnaire because it is not a definitive list of questions that must be answered in the given sequence using the exact words. Rather, it is a set of Instructions for guiding a conversation. The aim of the conversation at the heart of diagnostic testing of a CMI is to find out how people will go about using it. The questions are designed to open up a dialogue which will allow potential consumers to demonstrate how they might use the CMI and what difficulties they have using it.

The questions have been developed and progressively refined through prior diagnostic testing of CMIs and many other types of information. The questions are designed to avoid closed-ended or 'yes/no' questions that limit people's responses and bring conversations to a close. While closed-ended questions might tell you whether

people can or can't use the CMI, they provide little information about why people can't use the CMI, or what you could do to make it easier to use.

The questions are only a guide, and may well need adapting for everyone participating in the testing, including the tester. The tester must feel comfortable asking the questions in a way that makes sense to him or her and seems appropriate to the occasion. Equally, the questions must make sense to participants performing a task. It is important that consumers demonstrate how well or how little the CMI helps them carry out the task, rather than their capacity to provide specific answer to a question on a questionnaire.

The ability of people to access information and act on it depends not only on the CMI but also on the skills that participants bring to using the CMI. Part of testing always involves checking what skills and expectations participants bring to the task, and how you can design and redesign the CMI to best suit their expectations.

Building the protocol for use

The traditional way

The traditional way of building a protocol for use is to type it onto a word processor and print out a separate copy for each test participant. The data is then filled in by hand during the testing session and later transcribed onto a spreadsheet for analysis.

A modern way

Data can be entered directly onto a spreadsheet. This saves a great deal of time both in the data entry and analysis of the results. Experience has shown that participants do not find it off-putting to have someone sitting with them tapping on a laptop keyboard. Participants do not seem to be influenced by this technique, and testers find it very easy to use.

A sample spreadsheet is available.

Protocol parts

1. Preliminaries

The questions in this section are intended to put the interview in context, put the interviewee at ease, and provide some initial information.

a) **Framing and Confidentiality**

Below is the standard text to use to frame the testing event. This provides the participants with a context—a frame—within which to conduct the test.

Remember: what is being tested is the CMI, and the participants are there to help you test it, to advise you and guide you. It is a good idea to frequently tell participants that they are helping you and that you greatly value what they say.

Confidentiality is extremely important in testing where people are involved. Always reassure your participants about this.

Adapt the framing to your own style of talking. The most important information for the participant is:

- who you are
- what you are doing
- what you are interested in, why, and what you are trying to find out
- how you will treat what they tell you

Thank you for agreeing to help me. My name is

_____

I'm from _____

We are doing some research to find out whether the design on this CMI works properly.

All the answers you give me will be treated confidentially. We do not pass on names or personal information, only the results from our research.

We are mainly interested in what is wrong with the CMI that we are going to show you, so that we can improve it. So any comments you make will be valuable. If there is anything that you can't understand or doesn't make sense, please tell me. Remember, it's the CMI that we're testing, not you.

In a moment I will show you a CMI and ask you to use it to find and explain some information, and to provide some general feedback. Even if you know the answer without looking, I want you to show me where that information is on the CMI.

b) **Easing-in questions**

These questions, and the expectation questions that follow, are designed to set the scene, introduce the topic of CMI, check that the participants have been recruited appropriately (e.g. if it is important that they have at some time bought medicines from a pharmacy), and to ease the participants gently into the tasks.

Have you ever had medicine prescribed by a doctor?

No___Yes____

If Yes: When you get medicine, are you given printed information (CMI) that tells you what it is and how to use it? No___Yes____

All participants: Do you get information from anywhere else about how to take the medicine(s)? (e.g. from doctor, pharmacist, carer, internet, other sufferers)

Answer _____

c) **Expectation question**

While the major part of diagnostic testing is concerned with a CMI's capacity to help consumers perform a set of agreed tasks, you can also use it to discover if consumers want to perform tasks with it outside the agreed performance requirements. The answers to the next questions are valuable in helping you spot tasks you might have missed, or spot consumer

priorities that are different to those established in the agreed performance requirements.

If you are prescribed medicines, what would you look for in the CMI? Answer_____

d) **A preliminary task**

This task follows naturally from the Expectation question.

Notice how the task is broken down into three parts: finding information, difficulty in finding it, and using the information. This pattern of data collection is repeated throughout the protocol.

I'd like you to have a look at this CMI (hand them the CMI). Can you find [whatever they answered above]?

Can they find what they are looking for? No__ _Yes__

Give details of their search_____

Their answer_____

e) **Opening Impression question**

The answer to this question, coupled with a similar question at the end of the testing (the Closing Impression question), can be quite useful.

Without reading further, what is your first impression of this CMI?

Answer_____

2. Questions/tasks leading to consumer actions

(See Module 12 for consumer actions and relevant questions)

As noted in Module 1, a scoping stage has already been done to determine the basic performance requirements of a CMI. Many performance requirements for CMIs are the same, regardless of the specific product. However, any specific CMI will additionally have its own special performance requirements, which should have been determined previously by the CMI writer.

The purpose of this part of the protocol is to determine whether or not a consumer can act appropriately when using the CMI. The questions are tasks leading to consumer actions. If consumers cannot carry out the tasks easily and quickly, the CMI has failed in its performance requirements and must be redesigned and retested until it succeeds.

Do not forget...

The interview in a diagnostic test is not like other interviews. You are not simply recording what the participants say. You need to record:

- what they say
- how they say it
- what they do
- how they do it

For an example of a formatted test protocol (question sheet) for tetracyclines, click here.

Module 15

Analysing results and controlling quality

After completing all the interviews (optimally 10 interviewees), you should have amassed a considerable number of pages of recorded observations. So how can you efficiently use all these data to identify all problem areas?

Summary table of responses

FIGURE 17 TABLE OF RESPONSES

	Sue	Liam	Francis	Implications for change
Q.1	✓	✓	✓	No change needed
Q.2	✘ did not understand	✓	✘ did not understand	Refine wording. Consider giving more detailed steps
Q.3	✓...but first looked at ...	✘ looked through, couldn't find	✓	Consider adding sub-heading
Q.4	? got lost giving own history	✘ thought had to take with...	? not sure...	Monitor closely in next test

Such summary tables are quick and easy to compile. For each participant, summarise for each question whether they:

- successfully located and interpreted the information (tick)
- failed to give a fully correct answer (use a cross, and indicate whether it was because they could not find the information or whether it was because they failed to correctly interpret it and, if so, how they interpreted it)
- did something else (sometimes participants will misinterpret the question itself and do something seemingly quite bizarre; in such cases, use a '?' and indicate what you think happened).

After compiling such a table, you will quite likely have your main suspicions about the problem areas confirmed. But you will probably also have several other problems brought to your attention.

Identifying changes improves with experience. Start by asking the question "Would the problem go away if I changed..." of each possible variable.

Keep all interview sheets and summary of test results. You may choose to compile a performance database for all CMIs and their components.

When is a 'problem' a problem?

Sometimes only one or two participants will make a certain error in accessing or interpreting your CMI. The error itself may be of marginal importance. Are these 'problems' that you should be concerned about?

Answering this depends on your purpose. If it is to substantiate a claim about your CMI—to prove that it is working—then you can rightly not worry about an individual making an error. But if it is to diagnose, you should view any error as a problem and attempt to resolve it as much as your data and resources allow. But there is a diminishing rate of return, and you will never develop a perfect CMI.

One other type of problem can be with the questions you are asking, not with the CMI you are testing. Sometimes it can be hard to tell the difference. What can happen is that the people you interview may interpret your question in ways you didn't foresee, and give answers which don't help you. This may lead you to think you have a problem when you don't really. Making sure that your questions are specific and can only be answered one way will help reduce these sorts of problems. Asking people about the interpretations they are making will also help you identify what sort of questions they think they have been asked, as well as suggest ways of modifying your test questions.

Common design changes after testing

Given the work and co-operation that has already gone into developing better CMIs, it is unlikely you will encounter major structural problems. The most common reasons for changes are:

- poor or inadequate location of specific items
- poor sentence structure
- passive sentence constructions where the Instruction is not immediately obvious
- insufficient differentiation between Instructions and Explanations.

Iterative design

Diagnostic testing is particularly powerful when it is used as part of an iterative or cyclical design process in which designs are tested, modified and retested.

As in medical diagnosis and treatment, examining a CMI in use can reveal a pathological condition of the CMI, the symptom of which is the consumer's inappropriate action. In order to treat this condition, the CMI is modified and then retested. If the symptoms—in the form of inappropriate actions—do not reappear, the CMI can be pronounced healthy. If the

symptoms remain or new ones appear, further modification and retesting may be needed.

Who to recruit for further testing

You should recruit new participants for each round of testing. The problem with returning to the same participants is that they will have acquired certain understandings from your previous meeting, and they will use this knowledge in interpreting your revised CMI. This can make it difficult to know if it is the revisions that are leading to improvements in performance, or whether it is simply the participants' experience at completing the set tasks.

Quality control

Supervise the production of CMI. The CMI available to consumers when they collect their prescriptions should be the same as the final version you tested. Avoid *ad hoc* and untested changes at this stage. A small variation can affect the entire CMI performance.

Quality control at this stage can sometimes be difficult. Unless you supervise the production, you may not get the quality you want.

Create a history file for each CMI containing all the papers associated with developing and testing the CMI. This is an important source of information for anyone in your organisation who has responsibility for CMI.

Keep a log of all enquiries from consumers about the medicine or CMI, and add these to your history file.

Review each CMI in the light of these enquiries at least once every twelve months.

Share your growing understanding of CMI with other CMI writers and relevant groups.

Module 16

CMI Production

Changes from second edition

CMIs, like all documents, can be presented to users in a variety of ways: as hard copy printed on a dot matrix printer, a laser printer, a pre-printed pad, or a package insert; or online as a PDF, jpg, gif or html document. Each production method imposes its own limitations and opportunities for good design: a good design for a Heading on a laser printer will be different from a Heading on a package insert.

This third edition of the *Guidelines* differs from the second edition (1997) not only because it is available only in the form of PDF Modules which can be downloaded as needed, but also in its Instructions and advice for CMI production. The 1997 edition gave the specifications for two designs: one for dot matrix printers, and one for laser printers. But printing and publishing technologies and usage have changed since 1997: where ten years ago most pharmacists would have used a dot matrix printer, now most pharmacists use a laser printer; and where ten years ago most consumers would not have had access to web-based documents, now many more consumers use the web as their normal way of accessing information.

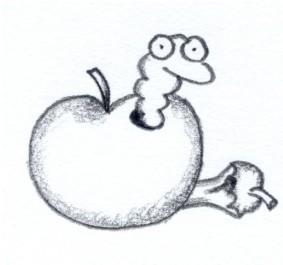
The major changes to the *Guidelines* on CMI production method are:

- they provide the specifications for laser printers only; although some pharmacists may still be using dot-matrix printers, laser printers will soon be universal
- the typographical styles and specifications have been designed for web usage.

This is not the only model that will work. But it takes into account:

- the production limitations of the printing system

- commonly available fonts on the system
- good document design practices that can be applied in this system
- production methods available to pharmacist, health professionals, and carers
- evidence from research with consumers.



Module 17

Core CMIs

Core CMIs are templates for classes of medicines, such as NSAIDs, ACE Inhibitors, Tetracyclines, Antidepressants, etc. They have been designed according to the principles described in the second edition of *Writing About Medicines for People* 1997. Their format and text have been tested with consumers for usability.

They are available on the websites of Medicines Australia

(www.medicinesaustralia.com.au)

and the Australian Self-Medicine Industry (www.asmi.com.au/CMI.htm).

Each Core CMI at these websites includes the recommended formatting, a standard description of the class of medicine, and details of the interactions, contraindications, precautions, Instructions for use, and so on that are shared by all the medicines within that therapeutic class. These are stated under the standard Main Headings and Subheadings as described in these *Guidelines*.

Also included are instructions to the CMI writer, giving alternative wordings and other help for adapting a Core CMI to a particular Brand.

The text of the Core CMIs is applicable to many Brand Name medicines within a therapeutic class. This means that, in some cases, a writer needs only to use the template to write the CMI, substituting the Brand name where necessary. The content has already been tested, so there may be no need to test (see To test or not to test).

It is essential for achievement of QUM outcomes that the information in CMIs for medicines within the same therapeutic classes is as consistent as possible. Figure 16 gives an outline of the process used for creating Core CMIs that are consistent between therapeutic classes.

FIGURE 18 – PROCESS FOR CREATING CONSISTENT CORE CMIS

Process for Achieving Consistency Between Therapeutic Classes

1. **Establish therapeutic class by**
   (i) indication (major)
   (ii) physiological/pharmacological action
2. **Check for the availability of a Core CMI n either the MA or ASMI websites or contact the Chair of QARG**
   Is a Core CMI available?
   Yes *Follow*
   No *Create a new one using this guide*
3. **Through QARG, establish a Consistency Working Group (CWG) and initiate collaboration with all other companies**
4. **Invite and encourage all companies to attend first meeting**
5. **First meeting:**
   - explain objectives and process
   - if appropriate, set up subgroups (3-4 CMI writers)
   - review available CMIs
   - assess areas that may be consistent
   - establish timelines
6. **Organise meetings (options of teleconference or face-to-face meeting) to:**
   - attempt to achieve consistency
   - go through CMI systematically
   - develop draft Core CMI for therapeutic class
   - nominated CMI writer to document changes/additions to Usability Guidelines
7. **Redraft CMIs based on consensus of CWG**
8. **Recirculate draft CMIs to each company for review**

9. **Finalise draft Core CMI**
10. **Each company prepare draft CMI according to the draft Core CMI**
11. **Each company undertake diagnostic testing using the redrafted individual medicine CMIs with an agreed number of consumers (in line with Usability Guidelines)**
12. **If required, repeat steps 7-11**
13. **Core CMI reviewed by healthcare professional in the relevant therapeutic area**
14. **Provide Core CMI to QARG for final approval**

    Note: Development of the draft Core CMI is oversighted by QARG throughout the process.

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