Using Consumer Medicine Information (CMI)

A guide for consumers and health professionals
About this guide

This guide is about consumer medicine information (CMI) and how it can be used by consumers and health professionals to build better relationships and achieve the quality use of medicines.

The guide was written as a result of a workshop in which consumers, doctors, nurses, pharmacists, industry and government representatives shared their views and practical experiences of using CMI.

The workshop Using Comsumer Medicine Information effectively was run by the Consumer Sub-Committee of the Pharmaceutical Health And Rational use of Medicines (PHARM) Committee in Sydney on 30 and 31 October 1998.

If you would like to read the report of that workshop, contact the Quality Use of Medicines Section at the address given at the end of this guide. This guide is also available through the Quality Use of Medicines website at http://www.health.gov.au/hbd/qum

Sue’s story

As a person with two chronic conditions, being a long-term user of the health system in many of its forms and long-term user of medications, I feel that CMI is one tool, in combination with an understanding of my conditions, that allows me to talk effectively with my health team and together make decisions that are relevant and right for my life, not just my disease.

“There is lots of talk at this workshop of the user’s inability to understand complex information and the need to put information in simple and accessible language. I believe it’s not the inability to understand, but the lack of information to allow understanding which is the real issue. CMI is one source of information.

“Give me information and I’ll feel comfortable and confident enough to enlighten you about my concerns and life goals. Together we will achieve them.”
About CMI

What is CMI?

CMI stands for consumer medicine information. CMI is designed to inform consumers about prescription and pharmacist-only medicines. CMI provides information about the medicine and how to use it wisely. CMI is also a tool for health care professionals and carers.

Who produces CMI?

CMI leaflets are produced by the pharmaceutical company that makes the particular medicine and they are available from different sources. The CMI leaflet may be:

- enclosed within the medicine package
- supplied by the pharmacist as a leaflet or computer print out
- provided by the doctor
- available from the pharmaceutical manufacturer, or
- in future, available from libraries and via the Internet.

Acknowledgements

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Regulations set out what CMI must contain and how it should be presented. No advertising or product branding is allowed on any CMI and standards have been developed to make CMI easier to understand and use.

By 2002 CMI leaflets will be available for all prescription medicines sold in Australia.

The information in CMI leaflets must be:
- accurate and up-to-date
- easy for consumers to use, and
- consistent with the technical product information (PI) that medicine manufacturers have to submit to the Government when they seek approval for a medicine to be used in Australia.

A well-written CMI leaflet contains:
- clear headings (to help users find information quickly and easily)
- simple instructions, and
- straightforward explanations of what consumers need to do.

There are other types of information available, such as product information or advertising. These are not CMI. A typical CMI should look like this.

A typical CMI contains...
- accurate and up-to-date
- clear headings
- simple instructions
- straightforward explanations of what consumers need to do
- easy for consumers to use.
How can CMI improve health care?

Consumers are becoming more informed about their health and health care options and want to take a more active role in their relationships with their doctor and other health care providers.

CMI is an important tool for consumers and for health care professionals. It supports information exchange and helps to develop good relationships between these groups, bringing about better health outcomes.

CMI can help foster informed decision making and better compliance. It can have many different uses, both before and throughout a course of treatment.

CMI can:

- Help consumers make an informed commitment to a course of treatment after considering all the pros and cons. CMI can empower consumers to express any concerns they may have about taking the medicine.

- Encourage information exchange between consumers and their health professionals. CMI encourages consumers to tell their doctor important information they need to be aware of, for example, about other conditions or medicines. It can also alert consumers to the importance of reporting possible problems or adverse effects rather than discontinuing the medicine.

- Put consumers in the picture by giving them important information about what to expect, what effects are likely and how the drug works. The

Karen’s story

Frank’s story

Karen’s story

Frank’s story

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Karen’s story

Frank’s story

Karen’s story

Frank’s story
How you can use CMI—
if you are a consumer...

Where do you get CMI leaflets?

- At the pharmacy or chemist
  When you have your prescription filled, ask the pharmacist for the CMI leaflet (it may already be in the medicine package).

- At the doctor’s
  If your doctor prescribes a medicine for you, ask for the CMI leaflet and ask the doctor to explain it to you while you are there.

- In hospital
  If you need a medicine in hospital, make sure you ask for the CMI to go with it.

- From the pharmaceutical company
  You can ring or write to the manufacturer of your medicine and ask for a copy of the CMI.

In future, CMI should also be available from libraries and via the Internet.

Five things to remember about CMI leaflets:

1. Make sure that the leaflet you have been given is a CMI
   Look for the heading Consumer Medicine Information (or on some it may say Consumer Product Information). Look also for the standard headings that all CMI leaflets contain, as shown on page 5.

2. Understand the structure of a CMI leaflet
   The structure of all CMI leaflets is similar, to make it easier for you to find the information you need, when you need it:
   - headings guide you to different topics, such as ‘What [the medicine] is for’
   - topics are in the order in which you would normally deal with a medicine
   - each topic gives you instructions telling you what to do, followed (where necessary) by explanations that help you understand the instructions.

3. Understand the medicine
   The CMI leaflet will tell you:
   - how the medicine works
   - what it can be used for
   - its chemical composition
   - its known side effects, and
   - whether it has any interactions with other medicines.
How you can use CMI—If you are a consumer

**What do I do if a CMI leaflet is not offered automatically?**
If you are not given a CMI with your medicine, ask your doctor, pharmacist or nurse for one or request one from the manufacturer. CMI leaflets are available for over 700 medicines.

**When should I ask for the CMI leaflet?**
Ask for a CMI at the time your medicine is prescribed or dispensed. If you are concerned about the information you receive with your medicine, talk with your pharmacist or doctor before you use the medicine.

**If I want more information about side effects, such as how likely they are to occur, who should I talk to?**
Your pharmacist or doctor can provide more information about possible side effects and how likely they are in your case. You may need to ask for a longer appointment than usual to talk to your doctor about your individual situation and to ask any questions you may have.

**What if some of the information in the CMI leaflet is not relevant to my age or condition?**
CMI leaflets contain information about all the uses for which the particular medicine has been approved, some of which may not relate to you personally. Remember, CMI leaflets are a tool for helping all consumers get the best out of their medicine and you may need to talk to your doctor about your individual situation.

**What if I am concerned about taking my medicine over a long period?**
Ask your doctor about long term use of your medicine. CMI leaflets only include information about the medicine itself, not about managing

### How can you make CMI work for you?

The following answers to questions will help make CMI work for you:

1. **Use the CMI leaflet to talk through your treatment**
   By going through the CMI thoroughly, you will be able to single out any issues that concern you. This may include side effects, possible interactions with other medicines, or questions about how you should take the medicine.
   You can use the CMI as a prompt to talk through anything that is unclear to you. Referring to the CMI will help you ask the right questions about your treatment.

   Your doctor may recommend that you use the medicine for treatment of a condition that is not mentioned in the CMI. This is called a non-approved use. This may happen when the doctor knows of research and clinical experience showing a use for the medicine that has not yet been approved but that may help to treat your condition.

2. **Refer to the CMI leaflet when you’re at home**
   Referring to the CMI leaflet can help you:
   - remember what the doctor or pharmacist said
   - prepare and look out for possible side effects
   - find out information when you need it, and
   - decide whether to tell your doctor or pharmacist if something changes.
   Keep your CMI leaflet in a safe place where you will be able to find it if you need to refer to it later.
   Arming yourself with relevant, reliable information is a good way to really understand your treatment.
your condition in the long term. Ask for a longer appointment than usual so that your doctor has plenty of time to talk to you about this.

- **What if my doctor prescribes a different brand of my medicine and the CMI leaflets are different?**

  Some medicines are made by more than one company, under different brand names. They will all have the same generic name underneath the brand name on the package. The CMI leaflets may be slightly different as they will have been prepared by different companies, but the essential information will be the same.

  Some manufacturers are working together to make their CMI as similar as possible for different brands of the same medicine. If you are concerned about any differences, talk to your pharmacist about any questions you may have.

- **What if the print on the CMI leaflet is too small for me to read?**

  This may be a problem, particularly with older package inserts. Call the company that produced the medicine and ask them to send you a CMI leaflet that is written in larger print.

- **Are CMI leaflets available in languages other than English?**

  So far, most of the effort has gone into making sure that English language CMI leaflets are of a high standard. Translator services are available through many health services and family members or friends may be able to help with translations.

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**Understanding the consumer’s perspective**

An important part of building a good relationship with consumers is understanding their perspective and expectations.

There is a great deal of evidence to support the benefits of a partnership approach to health care. Research shows that consumers want doctors who:

- listen
- understand them
- encourage and give them the opportunity to ask questions (consumers are often reluctant to ask)
- can give simple information in language they can understand
- are sensitive to cultural differences, and
- are sensitive to their changing information needs over time.

**Consumers don’t want information as an end in itself, for its own sake. We want it as a tool for being in control of our own health and for being a partner with our health professionals. We do not usually want to take total responsibility for our health care— that’s why we consult health professionals, for your information, expertise and skills. But we do want you to respect our expertise.**

-Sarah Fogg, Australian Pensioners’ and Superannuants’ Federation, CMI workshop, October 1998
Where do you get CMI leaflets?

You can get CMI from your pharmaceutical company representative. In future, CMI should also be available on CD ROM and via the Internet.

You can use CMI to

Structure a consultation or counselling session with your patient

"Before I prescribe some medicine for you, let's just make sure that the medicine I have in mind is not going to react badly with any other medicines you are taking.

"Here is the consumer medicine information leaflet for this medicine. Let's go through each of these items and check if they apply to you... "

Explain conditions and treatments to your patients, using language they will understand

"Mrs Jones, you have a condition called osteoporosis. 'Osteo' means bone, and 'porosis' means something that has holes in it, like a sponge. So, osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break. "Early on, osteoporosis usually has no symptoms. However, if left untreated it can result in broken bones, also called fractures. Although fractures usually cause pain, fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone.

"I'm going to prescribe a medicine for you that works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone.

"This medicine not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. It reverses the progression of osteoporosis. It starts working on the bone cells immediately, but we don't expect to see any measurable effects on bone mass for several months or more.

"When you get your prescription filled, ask your pharmacist for a CMI leaflet. Have a look at it and bring it with you next time so we can go through it together."
- Reassure your patients about side effects

  "There is a risk with every medicine that it will have side effects, but the one I’ve prescribed for you has very few, and most of them are not serious.

  "If you look at the list of side effects in the Consumer Medicine Information leaflet that goes with this medicine, you will see what they might be. As I said, most of them are not serious. But there are a few rare ones that are serious. Here they are on this list.

  "Now, if any of these happen, stop taking the medicine immediately and let me know straight away. It’s very unlikely that these side effects will happen to you, but just in case, keep this leaflet handy, so that you know what to do if they happen."

- Help patients remember how to take their medicine

  "I’ve just written a prescription for you for angina. It’s very important that you take this medicine exactly as I’ve just explained.

  "But don’t worry if you cannot remember everything I said. When you get the medicine from the chemist, the pharmacist will give you a consumer medicine information leaflet about this medicine. It repeats everything I’ve just told you, and it gives you a lot of other useful information about this medicine."

- Work with other health professionals in a team approach to your patient’s health care

  Dr to community nurse: "I’ve just diagnosed Mr Marsden with diabetes. I’ve prescribed [medicine] for him, but he was obviously distressed with the diagnosis and I don’t think he was paying much attention to what I said about taking it.

  "As you know, it’s very important that he takes it properly and at the right times. When you visit him, could you please check that he has a copy of the CMI handy, and talk him through the instructions for taking the medicine? Thanks."

Where do you get CMI leaflets?

CMI leaflets can be found in many medicine packages, and you can also get them from hospital and community pharmacists, doctors and pharmaceutical manufacturers. In future, they should also be available on CD ROM and via the Internet.

You can use CMI to

- Help educate consumers and carers about the medicines they are using

  Nurse: "Mary, you’re looking after your husband all on your own and I know he’s on several medicines. How are you managing with those?"

  Mary: "I’m glad you asked. Sometimes I’m so tired at night that I forget to wake up and give him his medicine. What should I do in the morning?"
I get worried about it. Should I give him double the dose, or just carry on with the same amount and forget about the missed dose?"

Nurse: “No need to worry, Mary. Did you look at the leaflets that came with the medicines?”

Mary: “No, I thought they’d be full of technical language.”

Nurse: “Actually, they’re relatively simple and practical. Look, there’s a whole section here on what to do if you miss a dose.”

Mary: “Oh, I see. That’s just what I need.”

Nurse: “Why don’t you keep the leaflets in that drawer where you keep all the medicines, next to Fred’s bed, and if anything else worries you, have a look at them—there’s probably something there that can help you. I’m happy to help you understand them, to make sure Fred’s using the medicine in the best possible way.”

Mary: “That’s wonderful, thanks!”

Discuss the use and effects of medicines with consumers

Nurse: “How are you feeling today?”

John: “Not so good.”

Nurse: “That’s odd, John, you should be feeling better.”

John: “I just feel sick and dizzy all the time.”

Nurse: [takes pulse and feels forehead] “I wonder if it’s a side effect of the prescription medicine you are taking. Let’s have a look at the information leaflet that came with that medicine. Oh, look, John, it says that nausea and dizziness is a possible side effect, but it also says this should wear off after a few days.”

John: “Oh, that’s a relief! I thought I was coming down with something else, just as I thought I might be getting better.”

Nurse: “You’re doing really well. Your blood pressure, temperature and pulse are all normal, you just need to build up your strength. If you still feel dizzy and sick in a couple of days, we’ll do something about it. OK?”

John: “Yes, thanks. I feel better already!”

Check for possible side effects and adverse events

Nurse: “Jane, I see you’ve got some new headache tablets.”

Jane: “Yes, I wasn’t very happy with those other ones that the chemist down the road gave me when I picked up my prescription, so I thought I’d go to this other chemist and see if he could give me something stronger.”

Nurse: “Yes, I can see these headache pills are quite different. Have you looked at the consumer medicine information for them? It says that you shouldn’t take them if you’re also taking pills for your blood pressure.”

Jane: “I didn’t know that! Why didn’t the chemist say anything?”

Nurse: “Did you tell him about your blood pressure pills?”

Jane: “No. He asked me if I was taking any other medicine and I said no. I didn’t think he needed to know.”

Nurse: “Jane, if you look at the consumer medicine information leaflet for a medicine, it will tell you which medicines don’t go together. If you’re taking any medicine at all, it pays to check what the leaflet says under the heading ‘Before you take this medicine’. That will help you avoid ill effects, and guide you on how to use the medicine in the best way.”

Jane: “Thanks, I’ll remember that.”

Further information is available in a pamphlet produced by the Royal College of Nursing Australia—Guidelines for the use of consumer medicine information by registered nurses.
You can use CMI leaflets to:

- Help you talk with consumers
- Provide an adjunct to verbal counselling
- Improve inter-professional relationships
- Assist in clarifying other disease states that patients are suffering from
- Be competitive by giving information and encouraging consumers to ask for information, and
- Increase your own satisfaction and that of consumers and staff.

If you are a pharmacist...

How can you use CMI?

- Discuss consumers’ needs with prescribers and pharmacists
  Nurse: “Doctor, I’m concerned about the potential for an adverse event between these two medicines. I’ve checked the CMI and it does suggest there might be a problem.”
  Doctor: “Good point, I hadn’t seen that with this formulation. Could you ask the pharmacist to do a medication review and advise on a better combination?”
  Nurse: “I’ll contact the pharmacist to do that right away.”

Do you have some reservations about CMI?

Consumers and health professionals have voiced some reservations about CMI. These are addressed here.

- CMI can place too much emphasis on side effects
  CMI only lists side effects that are reported in the Product Information, which consumers have a right to know. Consumers should be encouraged to make an informed decision about taking a medicine, in full knowledge of the potential risks and benefits. If you explain the likelihood and relative importance of side effects, consumer compliance should not be affected.

- CMI is too general
  CMI has to be consistent with the Product Information. This makes CMI leaflets general in nature, but it ensures that they are accurate and authoritative about the medicine.

- CMI are too formal
  If the CMI follows the writing style recommended in the guidelines, ‘Writing about medicines for people’, testing has shown that this style is easy for consumers to understand and use.

- CMI leaflets are impersonal and too detailed
  CMI leaflets are for reference. They are not intended to be read from start to finish but rather to be used specifically by consumers when they want to find out something about their medicine. If you want your patients to take particular note of something, go through the CMI leaflet with them, using a highlighter to emphasise the important points and those of particular relevance to them.

1 Writing about medicines for people: Usability guidelines for consumer medicine information
2nd edition
David Sless and Rob Wiseman
Communication Research Institute of Australia
Available from Government Info Shops, Cat. No. 97 0868 0
CMI may duplicate the role of pharmacists
While CMI may duplicate some of the advice given by health professionals, it can also remind consumers of what they need to remember when the health professional isn’t on hand to advise.

CMI leaflets are too negative and lack positive information
CMI leaflets are just one voice in the ongoing conversation between health professionals and consumers. They are necessarily limited in what they can say— they cannot contain any advertising for a product and must be consistent with the Product Information. While this limits their usefulness in some ways, in other ways it guarantees the quality of the information they do contain.

CMI gives limited clinical indications
CMI leaflets only list indications which are approved in the Product Information. This is both a limitation of CMI leaflets and a guarantee of the quality of information they do contain. This does not prevent a clinician prescribing a medicine for a non-approved use, but it does place the onus on the clinician to explain their prescribing to the consumer.

CMI is potentially in conflict with other types of information that's available
CMI is written by the manufacturer of the medicine following clear government guidelines. Well written CMI is accurate, authoritative, and an easily understood source of information about a particular medicine. CMI don’t yet cater for the needs of special groups (such as indigenous people and people from non-English speaking backgrounds).

Nurses generally don’t have direct access to CMI
Nurses can request CMI directly from pharmaceutical companies, or obtain them through pharmacies. Nurses can request CMI directly from pharmaceutical companies, or obtain them through pharmacies.

There is a lack of education for nurses about CMI
Promotion of CMI use is a continuing process and nursing professional bodies are partners in this development.

Pharmacists can find CMI hard to use if the prescription does not include the purpose of the medicine
This is not just a barrier to using CMI, it is a symptom of a more general need for improved communication between prescribers and dispensers.

CMI takes too much time
CMI has been developed because consumers have asked for information and have a right to know about their medicines. More than ever, consumers are keen for information to help them understand and manage their health and the health of those close to them. Your patients will appreciate you spending longer with them, if need be, in order for them to fully understand how to use their medicine. While this places more demands on your time, every effort is being made with new technologies and changes to counselling practices incorporating CMI to help you achieve this balance.

This is being addressed. In the meantime, using interpreter services can help communicate CMI information and support dialogue between patients and their health professionals.
The future of CMi

The Pharmaceutical Benefits Branch in the Commonwealth Department of Health and Aged Care in Canberra provides funding and support for a number of bodies. These include:

- the Consumer Sub Committee of the Pharmaceutical Health And Rational use of Medicines (PHARM) Committee which organised the CMi workshop and commissioned this guide, and
- the CMi Quality Assurance Reference Group (QARG) which is responsible for encouraging the development of quality CMi. This group is made up of representatives from consumer groups, health professionals, government, and communication research.

These groups, with the cooperation and goodwill of many professionals and consumers, have been working towards the successful implementation of CMi. The move to have CMi's available for all prescription medicines by 2002 will assist their ready access and acceptance by both health professionals and consumers. Future access to CMi will also be improved by making them available on CD ROM and via the Internet.

Aspects to be addressed in the future include catering for the CMi needs of non-English readers, promoting the benefits of CMi to consumers, and encouraging its greater use in the community.

How can you get involved?

Consumers and health professionals are continually searching for, and finding, ways they can use CMi to achieve better communication, increased understanding and, ultimately, wiser use of medicines.

If you have experiences or suggestions, either positive or negative, that may help others use CMi more productively, please contact:

Quality Use of Medicines Section
Pharmaceutical Benefits Branch
Department of Health and Aged Care
GPO Box 9848
Canberra ACT 2601
Ph (02) 6289 8149

The challenge now is to listen to those who have been finding ways to make CMi work on the ground – consumers, doctors, pharmacists, nurses, industry.

“What successful approaches are there? What effective communication, information and problem solving is needed by all of us to help people stay healthy, regain health or manage a condition?”

Professor Lloyd Sansom, Chair of the Australian Pharmaceutical Advisory Council, speaking at the Using CMi Effectively Workshop, October 1998