About this document

Purpose of this document
This document outlines how to communicate effectively with consumers using the revised Consumer Medicine Information (CMI) template developed through usability testing with consumers and seeking input from key stakeholders.

These guidelines on how to use the CMI template provide short form guidance on how to use the CMI template including key communication principles and tips and tricks on using the revised template. Further resources are in development and will be made available.

Audience
This document is intended for industry stakeholders involved in the writing and development of CMI.

Please note:
These guidelines are designed for use with the improved CMI template but the key communication principles are relevant to any CMI format and other consumer-oriented communications.

Writers and developers of CMI documents will need to ensure compliance with Schedules 12 and 13 of the Therapeutic Goods Regulations 1990.

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Other essentials for writing CMI

In addition to the principles and examples used in this guide, the following are essential to developing CMI documents:

1. These guidelines relate to the *Therapeutic Goods Regulations 1990*. Writers should refer to Schedule 12 and Schedule 13 for all sections of the CMI for prescription and pharmacist-only medicines, respectively. For more information visit: https://www.legislation.gov.au/Series/F1996B00406

   ![This symbol indicates reference to specific parts of the Regulations where further information about CMI content can be found.]

2. These Guidelines are intended to be used with *Writing about medicines for people: Usability Guidelines for Consumer Medicine Information, 3rd edition* by David Sless and Ruth Shrensky, which contains more detailed guidance on how to communicate with consumers of CMI documents.

   ![This symbol tells you which section to go to in Writing about medicines for people to find more extensive guidance.]

3. User test new CMI or changes to existing CMI, with consumers, to ensure that those documents communicate information effectively to consumers. The principles and examples used in this guide are high-level guidance for writing CMI and do not replace the need for further evaluation of the effectiveness of CMI in communicating understandable and actionable medicine information.

4. Keep the CMI summary to one page to ensure the most important and relevant information is provided to consumers upfront for easy access. Use the links in the CMI summary page to refer consumers to the full CMI if they require further and more detailed information.
Part 1

Key communication principles

This section outlines five key principles for effectively writing CMI documents using the improved template.
How to: Using the principles

The example below explains how each principle page is laid out.

**Part 1: Key communication principles**

**Keep your message clear and to the point**

**Because of this we**
- Use plain English in your writing by:
  - Using short sentences and paragraphs
  - Using common words
  - Being direct
- Provide a plain language explanation of necessary medical terms. Don’t assume a person using a medicine has knowledge of their condition or the medicine they are taking.
- Use active voice rather than passive voice in the CMI document, to support consumers to take action.
- Minimise the use of acronyms whenever possible. Many people scan CMI for the information they want rather than reading it from top to bottom, therefore acronyms spelled out earlier in the document may get missed and cause confusion if found only in acronym form later in the document.
- Using medical terminology without a plain English explanation when communicating with consumers as it can lead to confusion, disengagement with the content which could result in overlooking important information.
- Using unnecessarily complicated words or phrases as this can confuse consumers.

**Examples**

**Plain English**
- Contact your doctor if you are taking other medicines, vitamins or supplements.

**Plain language explanation**
- **Active ingredient:** Ingredient(s) that make the medicine work
- **Hypoglycaemia:** Low blood sugar.

**Active voice**
- Discard any medicine that is frozen (rather than, frozen medicine should be discarded).

**Because of this we avoid**
- Using medical terminology without a plain English explanation when communicating with consumers as it can lead to confusion, disengagement with the content which could result in overlooking important information.
- Using unnecessarily complicated words or phrases as this can confuse consumers.
Our communication principles

The communication principles below provide a foundation for user-centred content. You can use this page as a quick reference checklist.

The five principles

1. **PRINCIPLE 1 Keep your message clear and to the point**
   - When you use short sentences, plain English and action-oriented language, consumers will better understand your messages and know what they need to do.

2. **PRINCIPLE 2 Use suitable language for the consumer**
   - Most consumers don’t understand medical language and find it confusing. Using language that is easily understood will help improve their understanding about their medicine.

3. **PRINCIPLE 3 Use consistent language and messaging**
   - When you use the same words for the same thing, people can find what they are looking for, they will retain the information more easily.

4. **PRINCIPLE 4 Provide information that helps consumers make safe and appropriate decisions**
   - Too much information confuses consumers and potentially hides key information. Targeted information with important messages first helps consumers make safe and appropriate decisions.

5. **PRINCIPLE 5 Set out information to support findability, understanding and action**
   - Structuring information using headings, bold type, tables and setting it out with white space on the page helps consumers to find what they need quickly.
Keep your message clear and to the point

**Because of this we**

- Use **plain English** in writing by:
  - Using short sentences and paragraphs
  - Using common words
  - Being direct
- Provide a **plain language explanation** of necessary medical terms. Don’t assume a person using a medicine has knowledge of their condition or the medicine they are taking.
- Use **active voice** rather than passive voice in the CMI document, to support consumers to take action.
- **Minimise the use of acronyms** whenever possible. Many people scan CMI for the information they want rather than reading it from top to bottom, therefore acronyms spelled out earlier in the document may get missed and cause confusion if found only in acronym form later in the document.

**Examples**

<table>
<thead>
<tr>
<th>Plain English</th>
<th>Active voice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact your doctor if you are taking other medicines, vitamins or supplements.</strong></td>
<td><strong>Discard any medicine that is frozen (rather than, frozen medicine should be discarded).</strong></td>
</tr>
</tbody>
</table>

**Plain language explanation**

- **Active ingredient:**
  - *Ingredient(s) that make the medicine work*
- **Hypoglycaemia:** *Low blood sugar.*

**Because of this we avoid**

- **Using medical terminology** without a plain English explanation when communicating with consumers as it can lead to confusion, and disengagement with the content which could result in overlooking important information.
- **Using unnecessarily complicated words or phrases** as this can confuse consumers.

**Examples**

<table>
<thead>
<tr>
<th>Complicated words</th>
</tr>
</thead>
<tbody>
<tr>
<td>’Non-steroidal anti-inflammatory’</td>
</tr>
<tr>
<td>’Gastrointestinal’</td>
</tr>
</tbody>
</table>
**Use suitable language for the consumer**

**Because of this we**
- Use **pronouns** to direct your message to the consumer.
- Use **common terms for medicine types and medical conditions**, where appropriate, to aid understanding.
- Use **examples of everyday items or concepts** to explain or replace medical terminology and aid understanding, e.g. the use of the term ‘crushing’ chest pain helps consumers understand the condition and highlights the severity of the side effect.
- Use **images or diagrams of the medicine** to help consumers to ensure they are taking the correct medicine by being able to view medicine packaging and the dosage form (e.g. tablet, liquid, injectable).

**Because of this we avoid**
- Speaking in **the third person** when addressing the consumer. Using third person creates distance and unnecessary formality.
- Using **official medical classifications** without supporting plain English explanations to define medicine types or medical conditions. This is not an effective way to communicate information to consumers, as they may miss critical information that applies to them if they do not recognise or understand the terminology used.
- Using **upper case in headings** for emphasis can be seen as heavy handed and aggressive.

**Examples**

**Pronouns**
- In section headings: 1. Why am I using [the medicine]?
- In body text: Tell your doctor immediately if you become pregnant.
- “you will need to…”

**Common terms**
- Medicine type: Medicines that treat depression
- Medical condition: This medicine is used to treat a lung problem that can cause trouble breathing and non-stop coughing.

**Everyday items or concepts**
- Vomiting of blood, or vomiting that looks like coffee grounds.

**Examples**

**Third person**
- Consumers should tell the doctor immediately if they become pregnant.
- “Consumers will need to…”

**Upper case in headings**
- 6. ARE THERE ANY SIDE EFFECTS?
Use consistent language and messaging

**Because of this we**

- Use **consistent messages** between the summary and full CMI to aid clarity and retention, and ensure consumers know where to find information in the full CMI.
- Ensure **consistent expression** of information within the CMI document.
- Provide **medicine specific information** to consumers, e.g. side effects or overdose information.
- Ensure **appropriate information** has been included **under the relevant section** and where the consumer would expect to find this information.

**Because of this we avoid**

- **Unnecessarily repeating information** across multiple sections of the CMI document. This can confuse consumers, as they no longer have a clear framework to understand where to find certain information within the CMI.
- Using **inconsistent expressions to describe a similar or related message**. This can confuse consumers about the best action to take in that situation. It can also raise unnecessary cautions if consumers perceive certain phrases are meant to communicate greater severity when this was not the intention.

**Examples**

**Medicine specific information**

- *Keep unopened [name of medicine] pre-filled pens in the fridge where the temperature is between 2-8°C. Do not freeze.*

**Examples**

**Unnecessarily repeating information**

- *Warnings for pregnancy and breastfeeding are repeated in multiple locations within the CMI.*
**Provide information that helps consumers make appropriate decisions**

**Because of this we**

- Provide **targeted information** that directly relates to a person or their situation so they can take action or make a decision.

- Provide **step-by-step guidance** where consumers need to know how to complete a task. Ensure all steps are within the relevant section, rather than split across sections.

- Provide the **most important information higher up in the relevant CMI section**. Then follow up with supporting information if necessary. Consumers expect critical information to be up-front.

- **Explain the why** to help consumers understand why they should act or make a decision. e.g. why not to stop taking a medicine suddenly.

**Because of this we avoid**

- Giving **excessive information** that does not directly relate to consumers, the medicine, or the immediate content as it can cause disengagement with the CMI document.

- Providing **irrelevant information** that does not help consumers make a decision or take action regarding the medicine.

- **Breaking up steps across different sections**, as it can mean that consumers miss critical steps when taking their medicine.

- Providing **generic or vague** statements without tangible details or evidence. Consumers are less likely to act on content they view as generic or only necessary for legal purposes.

**Examples**

<table>
<thead>
<tr>
<th>Targeted information</th>
<th>Most important information first</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Contact your doctor straight away if you notice any of these serious side effects.</em></td>
<td><em>[Name of medicine] prevents blood clots forming in your arteries.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step by step guidance</th>
<th>Explain the why</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Before using a new pre-filled pen, take it out of the fridge and let it come to room temperature for 1 to 2 hours.</td>
<td><em>Tell your doctor if you drink alcohol, as alcohol may mask symptoms of low blood sugar.</em></td>
</tr>
<tr>
<td>2. Check the label on the pen to ensure you have the correct insulin, etc....</td>
<td><em>Do not use a double dose of your insulin. Too much insulin can cause serious side effects.</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Irrelevant information</th>
<th>Generic or vague</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>You may wish to keep this leaflet to read again.</em></td>
<td></td>
</tr>
<tr>
<td><em>Store medicine in a cool, dry place.</em></td>
<td></td>
</tr>
<tr>
<td><em>Dispose of medicine after the expiry date.</em></td>
<td></td>
</tr>
</tbody>
</table>
PRINCIPLE 5

Set out information to support findability, understanding and action

Because of this we

- Ensure action information is highly visible to consumers, by ensuring the call to action is:
  - In tables or at the beginning of related information
  - Bolded in black for important information
  - Short and to the point
- Use meaningful subheadings, bullet points and tables to aid scanning and navigation through the document.
- Provide direct information on where links go and use short URL links to external information. Links need to go directly to the relevant content – and not require additional navigation.

Because of this we avoid

- Overusing bolded text as it causes consumers to skim information, missing key details. It can also cause consumers to disregard critical information.
- Using long sentences as calls to action or burying action in dense text, as this can obscure the meaning of information or make action information difficult to locate.
- Using long or generic URLs as links to external information as it can make it difficult for people to access information, especially when using the paper-based CMI document.

Examples

**Meaningful subheadings**
- Looking after your medicine
- Drinking alcohol
- Getting rid of unwanted medicine

**Information on where links go and use short URL links**
A video providing more information and a demonstration on how to inject [name of medicine] is available at: http://www.simple-steps.com.au

**Name of medicine**
Some medicines may interact with [name of medicine] and affect how it works.

**Examples**

Overusing bolded text
*If you are unsure about any medicine you are taking you should check with your doctor or pharmacist. They will have more information on medicines to be careful with or avoid.*

Long or generic URLs
- Generic URLs: Click here for more information.
Part 2

CMI template tips and tricks

This section uses annotated screenshots of the improved CMI template to demonstrate where and how the communication principles may be used.
Using the annotated walkthrough

The pages shown below are screen shots of the paper based version. In the following section, these pages are used to demonstrate the tips and tricks to completing the template.

Quick annotated tips for using the template

Communication principles most relevant for this CMI page.
1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support readability, understanding and action.

Related guidelines in Writing About Medicines for People
Refer to Module 4 for further detail on how to structure the title section and headings.

Where in the Writing About Medicines for People you can find additional guidelines.
Provide **medicine brand name** in the title of the CMI Summary.

The asterix (*) should be replaced with trademark symbols as appropriate.

Number each heading and match with the heading in the full CMI to support document navigation.

Summary must be kept to one page only. The summary is intended to be provided with the full CMI and therefore is not required to be comprehensive. Only the most important and relevant information should be included in this section.

**[medicine name]**

**Table of Contents**

1. Why am I using [medicine name]?
2. What should I know before I use [medicine name]?
3. What if I am taking other medicines?
4. How do I use [medicine name]?
5. What should I know while using [medicine name]?
6. Are there any side effects?

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**Communication principles most relevant for this CMI page.**

1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support findability, understanding and action.

Related guidelines in *Writing About Medicines for People*.

Refer to Module 4 for further detail on how to structure the title section and headings.

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**Summary** must be kept to one page only. The summary is intended to be provided with the full CMI and therefore is not required to be comprehensive. Only the most important and relevant information should be included in this section.
How to use the improved CMI template

Full CMI – page 2

Communication principles most relevant for this CMI page.

1. Keep your message clear and to the point
2. Use suitable language for the consumer
3. Use consistent language and messaging
4. Provide information that helps consumers make safe and appropriate decisions
5. Set out information to support findability, understanding and action

Related guidelines in Writing About Medicines for People

- Refer to Module 4 for further detail on how to structure the title section and headings.
- Refer to Module 7 for further detail on writing content for this section: What should I know before I use [medicine name]?
- Refer to Schedule 12 of the regulations for further detail on precautions.

Provide medicine brand name in the title of the full CMI.

The asterix (*) should be replaced with trademark symbols as appropriate.

List links to other sections in the full CMI to improve document navigation.

Subheading “Warnings” in bold at the top of this section highlights key information and aids in scanning.

Use plain English and provide plain language explanations.

For example: Contact your doctor if you are taking other medicines, vitamins, or supplements.

Include Black Triangle statement and/or boxed warnings if applicable in accordance with guidance provided on the TGA website – Black Triangle Scheme and boxed warning.

Provide medicine name in index summary where needed.

Use high contrast headings to aid scanning.

Use appropriate tables and/or subheadings to help group information. Further guidance is in the template itself.
How to use the improved CMI template

**Full CMI – page 2 (continued)**

**Communication principles most relevant for this CMI page.**

1. Keep your message clear and to the point
2. Use suitable language for the consumer
3. Use consistent language and messaging
4. Provide information that helps consumers make safe and appropriate decisions
5. Set out information to support findability, understanding and action

**Related guidelines in Writing About Medicines for People**

Refer to Module 7 for further detail on writing content for this section: 2. What should I know before I use [medicine name]?

Refer to Schedule 12 of the regulations for further detail on precautions.

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**Communication principles**

1. Keep your message clear and to the point
2. Use suitable language for the consumer
3. Use consistent language and messaging
4. Provide information that helps consumers make safe and appropriate decisions
5. Set out information to support findability, understanding and action

**How to use the improved CMI template**

Insert active ingredient, medicine name and therapeutic class with explanation.

Provide medicine name and a plain English explanation of what the medicine is used to treat (in indication).

**For example:** This medicine is used to treat a lung problem that can cause breathing difficulties and non-stop coughing.

**Communication principles most relevant for this CMI page.**

1. Keep your message clear and to the point
2. Use suitable language for the consumer
3. Use consistent language and messaging
4. Provide information that helps consumers make safe and appropriate decisions
5. Set out information to support findability, understanding and action

**Related guidelines in Writing About Medicines for People**

Refer to Module 7 for further detail on writing content for this section: 2. What should I know before I use [medicine name]?

Refer to Schedule 12 of the regulations for further detail on precautions.
Communication principles most relevant for this CMI page.

1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support findability, understanding and action.

Related guidelines in Writing About Medicines for People:

Refer to Module 7 for further detail on writing content for this section: 2. What should I know before I use [medicine name]?

Refer to Schedule 12 of the regulations for further detail on details that could be included in Section 5.

How to use the improved CMI template

Full CMI – Page 3

Communication principles most relevant for this CMI page.

1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support findability, understanding and action.

Related guidelines in Writing About Medicines for People:

Refer to Module 7 for further detail on writing content for this section: 2. What should I know before I use [medicine name]?

Refer to Schedule 12 of the regulations for further detail on details that could be included in Section 5.

How to use the improved CMI template

Full CMI – Page 3

Communication principles most relevant for this CMI page.

1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support findability, understanding and action.

Related guidelines in Writing About Medicines for People:

Refer to Module 7 for further detail on writing content for this section: 2. What should I know before I use [medicine name]?

Refer to Schedule 12 of the regulations for further detail on details that could be included in Section 5.
Communication principles most relevant for this CMI page.

1. Keep your message clear and to the point.
2. Use suitable language for the consumer.
3. Use consistent language and messaging.
4. Provide information that helps consumers make safe and appropriate decisions.
5. Set out information to support findability, understanding and action.

Related guidelines in Writing About Medicines for People

Refer to Module 8 for further detail on writing about side effects and reassuring consumers.

Refer to Schedule 12 of the regulations for further detail on side effects and product details.
List of references
Reference list and further reading


U.S. Department of Health & Human Services, Centers for Disease Control and Prevention (CDC). *Plain writing at CDC*. Available online at: [https://www.cdc.gov/other/plainwriting.html](https://www.cdc.gov/other/plainwriting.html).

Other useful resources for writing medical information

(Online resources accurate and accessible as at 24 June 2019).


