Australian Government
Department of Health
Therapeutic Goods Administration

Using the TGA CMI template

Guidance for sponsors

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TGA Health Safety Regulation

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Overview

Purpose

The purpose of this guidance document is to provide sponsors of medicines supplied to the Australian market and other interested stakeholders information about preparing Consumer Medicine Information (CMI) documents that comply with current regulations. The focus of this resource is providing instructions for using the TGA CMI template for prescription medicines and non-prescription medicines.

Compliance with this template will be required for newly registered medicines from 1 January 2021 and all previously registered medicines will be required to adopt the new format by 30 December 2025. These requirements apply to all medicines that are required to have CMI, including prescription medicines and some non-prescription (over-the-counter) medicines, which are established in Schedules 12 and 13 of the *Therapeutic Goods Regulations 1990*.

This document is also intended to be a companion resource to the *Consumer Medicine Information (CMI) – How to use the improved CMI template* published in August 2019. That document provides general information and guidance regarding the current template, including key communication principles and tips and tricks for using the template (please note that it pre-dates development of the template for non-prescription medicines, but that the information provided will assist with creating CMI for any product).

This document will provide more specific instructions on using the template, based on whether a product is a prescription medicine or a non-prescription product. It will include details of minimum requirements and exemptions to requirements where applicable.

It is important to note that sponsors remain fully responsible for creating the content in their CMIs and ensuring that they are effective. The template is designed to assist sponsors to create CMI documents that are shorter and better laid-out. The exact wording in the headings and the body text is suggested rather than mandatory. Sponsors have discretion to change wording for practical reasons or to maximise the effectiveness of the communication, but the type of information indicated under each heading must be included.

While not required by the regulations, the TGA encourages sponsors to undertake activities designed to improve and test the effectiveness of CMI, such as user testing or similar activities.

Regulations

Schedules 12 and 13 of the *Therapeutic Goods Regulations 1990* were updated on 12 December 2019 to standardise CMI requirements and improve consistency of these documents for the benefit of consumers.

The updated regulations maintain the previously established general requirements that CMI documents must be:

- written in English
- clearly legible
- written in language that will be easily understood by consumers
- consistent with Product Information about the product.

The changes now require that CMI must also set out all of the information required by the *TGA Consumer Medicine Information (Prescription Medicine) Template* (for prescription medicines, as described in Schedule 12) or the *TGA Consumer Medicine Information (Non-prescription Medicine) Template* (for non-prescription medicines, as described in Schedule 13).

No new or additional information compared to what was previously required under the regulations has been added to the template. The revisions relate exclusively to formatting in the interests of improving readability and reducing complexity for the benefit of consumers. However, the TGA strongly encourages sponsors to embrace continual improvement of CMI. Adopting the new template provides an opportunity to review the content and language to try to improve readability and increase the effectiveness of this information.

The regulatory changes take effect from 1 January 2021 for newly registered medicines. All previously registered medicines must be in the revised format by 30 December 2025. No new or additional information, compared to the previous format, is required under the updated regulations. However, adopting the new template is an opportunity to review and improve CMI.

Producing CMI using the revised templates

Exemptions and key differences between prescription and non-prescription medicine templates

CMI enclosed within packaging or similar

For CMI for both prescription and non-prescription medicines which is enclosed within or affixed to a surface of the packaging, it must set out all of the information required by the applicable template, but is not required to:

- set it out in the same order as the template
- include any summary that forms part of that template, if applicable.

As no new or additional information compared to what was previously required under the regulations have been added to the templates, it is expected that CMI enclosed within packaging or similar prior to these regulatory changes should continue to be compliant under the revised regulations. However, the TGA encourages sponsors of any such products to consider reviewing their CMI with the objective of improving readability and reducing complexity for the benefit of consumers.

CMI that is in enclosed within packing or similar is not required to have a one-page summary or set out the information in the same order as in the applicable template. However, it must still address all of the information required by the template.

Non-prescription (over-the-counter) medicines

Two separate templates have been prepared for prescription and non-prescription medicines in recognition of the different requirements for these different types of products.

The most significant difference between the two templates is that the one-page summary for non-prescription medicines is optional. In response to industry feedback, the TGA accepted that CMI for many non-prescription medicines are less complex than their prescription counterparts.

In some situations, this means the CMI for those products is already concise and that inclusion of a one-page summary would add considerable length and duplication to the document, without providing a significant benefit to consumers. However, the TGA encourages sponsors of non-prescription medicines to still consider adoption of a one-page summary.

The one-page summaries user tested as part of the project to develop the revised templates received very positive feedback from participants. If a summary in a CMI for a non-prescription medicine would provide a significant benefit to consumers, then one should be provided. However, this is at the discretion of the sponsor.

The one-page summary is optional for non-prescription medicines, but is still encouraged. The summary was user tested with consumers and received very positive feedback.

General principles

The templates provide sponsors a useful resource to assist with the preparation of CMI documents that comply with applicable regulatory requirements.

In addition to the general requirements, the regulations require that the CMI set out all of the information required by the relevant template. Except where the CMI is enclosed within or attached to packaging, information must also be presented in the same order as in the template.

The templates were subjected to user testing and, as such, it is strongly encouraged that the headings and body text not be heavily modified. However, the exact wording in the headings and the body text is suggested rather than mandatory. Sponsors have discretion to change wording for practical reasons or to maximise the effectiveness of the communication, but the type of information indicated under each heading must be included.

If a summary is required or included voluntarily, it must be restricted to a single page. The exact wording in the summary of the applicable template is suggested rather than mandatory. However, the summary format received very positive feedback from participants during user testing. As such, it is strongly encouraged that the wording not be heavily modified.

Sponsors can change the wording in either headings or body text in both the summary (if applicable) and full CMI. The templates outline the type of information required and the order in which it must be presented. However, sponsors can make changes for practical reasons or to improve effectiveness.

Producing the summary

We strongly recommend that the summary be written after the content for the full CMI is written and finalised.

The key consideration when producing the summary for a CMI document is to restrict the content to only one page, while still maintaining clear and easy-to-understand information for consumers.

The summary is intended to be provided with the full CMI and therefore is not required to be comprehensive. If the information is too long or detailed, it will lose value to the majority of consumers and be overly repetitive of the full CMI. This in turn is likely to dissuade consumers from reading the full CMI.

The asterisk (*) in the heading of the summary should be replaced with trademark symbols as appropriate and deleted if not required.

Each heading in the summary should match the heading in the full CMI to support document navigation.

When deciding what information to include or exclude from the summary, look for the most critical information about the safe and effective use of the medicine. For example, information about side effects should only include, as appropriate, the most common or very serious potential adverse reactions.

The summary in the templates recommends tabulating key points under the '*5. What should I know while using [medicine name]?*' section. This allows consumers to quickly scan and understand this information. The tabulated information should summarise but correlate to the information provided in the full CMI (the same key points under the same headings and subheadings) to enable easy identification and referral to the more detailed information.

If the product is subject to the Black Triangle Scheme or a boxed warning, then retain the relevant wording provided on the summary template. Otherwise, delete the unnecessary wording. Please note that it is not necessary for the full wording of the Black Triangle statement or an applicable boxed warning to be included at the top of the summary. However, the subject of a boxed warning should be addressed under the '*5. What should I know while using [medicine name]?*' section if it relates to a contraindication or the *'6. Are there any side effects?' section* if it is about an adverse effect.

The summary is required to be one page and should only include the most critical information about the safe and effective use of the medicine. The summary is intended to only be supplied in conjunction with the full CMI and therefore does not need to be comprehensive.

Producing the full CMI

Please note that no new or additional information, compared to what was previously required, has been added to the template. However, adopting the new template provides an opportunity for sponsors to review the content and language to try to improve readability and increase the effectiveness of this document.

If the product is subject to the Black Triangle Scheme or a boxed warning, then that information should appear at the top of the first page of the full CMI. Otherwise, delete that wording.

The asterisk (*) in the heading of the full CMI should be replaced with trademark symbols as appropriate and deleted if not required.

A key consideration when drafting the full CMI is to use consistent language and messaging that is appropriate for a consumer audience. In particular, strive to use Plain English and avoid unnecessary technical terminology (jargon). When technical terminology is required, include Plain English explanations to support understanding.

Present information concisely and in a way that supports:

- findability (does the information appear in the section in which a consumer would normally expect to find it; and are the headings and subheadings clear?)
- actionability (present information that clearly informs consumers what they need to know and do; provide step-by-step guidance where appropriate).

Use bolding judiciously. However, bolding key messages for emphasis or information that requires the consumer to take a specific action can be very effective.

Use tables and subheadings to group information, which makes it easier for consumers to find and understand the content. The template provides suggested table formatting.

As consumers are increasingly accessing medicines information online, sponsors can include hyperlinks and digital functionality in CMIs. However, external links should also be described in case it is received in hard copy. If a link is long, consider the use of URL shortening services.

Under the *'7. Product details'* section include information about how consumers access the medicine (for example, with a prescription), tabulate the list of active and inactive ingredients and other details about the medicine and the sponsor.

Always use consistent language and messaging that is appropriate for consumers. Use Plain English and avoid jargon. Use tables and subheadings to group information (such as 'Less serious' and 'Serious' side effects).

Further information and resources

The following websites, publications and resources are available to assist sponsors:

- TGA website
  - *Consumer Medicine Information (CMI) – How to use the improved CMI template*
  - Black Triangle Scheme
  - Boxed warning guidance
- *Consumer Healthcare Products Australia - Writing about Medicines for people: Usability guidelines for consumer medicine information. 3rd edition*
- *Australian Digital Transformation Agency, Content Guide - advice on how to write in plain English and create well-structured, accessible content*

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance and Special Access Branch	March 2020

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