



Adopting the improved CMI template

Information for sponsors



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JULY 2020

Welcome

- This webinar is being recorded
- Slides will be made available on the TGA website
- To ask a question, use the message feature on the left of the screen
 - messages will only be visible to the moderator and speaker
 - questions will be answered at the end of the presentation
- Relevant links will be posted in the message box (below)
- Live polls will be conducted throughout this event.



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Australian Government
Department of Health
Therapeutic Goods Administration

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TGA Health Safety
Regulation

Topics for discussion

- New CMI templates
- Main changes
- Regulations – Schedule 12 and 13
- Guidance and advice
- Next steps
- Live poll
- Questions



New CMI templates

- Based on previous research projects
 - I-CMI (Fourth Community Pharmacy Agreement) and EDWG pilot study
- TGA convened a stakeholder forum in February 2019
 - Agreement reached to base new format on I-CMI and EDWG templates
- ThinkPlace/UniSyd user tested new CMIs for three products
 - Ultibro breezhaler, Toujeo and Plavix
 - different dosage forms - an inhaler, injection and tablet (varied complexity)
 - iterative improvements made in response to user feedback received during the project
 - evaluation report published on TGA website
 - www.tga.gov.au/sites/default/files/improved-consumer-medicine-information-template-report.pdf

New CMI templates

- TGA engaged with key stakeholder organisations for targeted consultation before and after user testing and made changes based on feedback
- End result was two new CMI templates
 - prescription and non-prescription medicine formats
 - new one-page summary is optional for non-prescriptions
 - minor changes made in recognition of differences between scheduled products
- Final CMI templates and additional guidance published on 20 April 2020
 - www.tga.gov.au/improved-consumer-medicine-information-template



Main changes

- One-page CMI summary
 - ensures most important and relevant information is upfront for easy access
 - links to more detailed information in the full CMI
 - improved navigation when using digital
- Language
 - Plain English
 - avoiding jargon and medical terminology, defining terms when necessary
 - active language (be direct)
 - short, punchy sentences
 - consistent language and messaging
 - evidence of low health literacy in community

Main changes

- Format changes
 - restructuring information
 - new headings and sub-headings
 - bold type for important information
 - tables
 - less serious and serious side effects in separate tables
 - more white space on the page to help consumers find what they need quickly
 - clearer headings
 - digitally enhanced, external links to websites on how to use



Main changes

- Focus on helping consumers to make safe and appropriate decisions
- Removal of repetition from previous CMI version to decrease length



Microsoft Word
Document



Regulations – Schedule 12 and 13

- *Therapeutic Goods Regulations 1990* amended to change Schedule 12 (prescription medicines) and Schedule 13 (non-prescription medicines)
- General requirements are unchanged, CMI must be:
 - (a) be written in English
 - (b) be clearly legible
 - (c) be written in language that will easily be understood by patients
 - (d) be consistent with Product Information about the product.
- CMIs must set out all of the information required by the applicable template
- No new or additional information, compared to the previous format, is required under the new format
 - although adopting the new template is an opportunity to review and improve CMI

Regulations – Schedule 12 and 13

- For both prescription and non-prescription medicines:
 - if the CMI is enclosed within the packing or similar, it is not required to have a summary or set out the information in the same order as the template (but still needs to include all the types of information required by the template)
 - if the CMI is supplied in electronic form, it must be available in PDF or HTML format
- For non-prescription medicines, the summary is optional, but is still encouraged
 - the summary was user tested with consumers and received very positive feedback
- A summary, if required, must be no more than one page
 - summary is intended to only be supplied with the full CMI and therefore does not need to be comprehensive
 - only include the most critical information about safe and effective use of the medicine

Guidance and advice

- Using the TGA CMI template: Guidance for sponsors (advice on compliance with Regulations)
 - www.tga.gov.au/using-tga-cmi-template-guidance-sponsors
- How to use the improved CMI template (advice on key communication principles)
 - www.tga.gov.au/sites/default/files/improved-consumer-medicine-information-template-guide.pdf
- Templates and guidance documents are not prescriptive
 - sponsors are still responsible for the content of their CMI and have significant discretion
 - sponsors can change the wording in either headings or body text in the summary (if applicable) and full CMI for practical reasons or to improve effectiveness
- Focus is to reduce complexity and improve readability for consumers

Guidance and advice

- Other resources:
 - Consumer Healthcare Products Australia - Writing about Medicines for people: Usability guidelines for consumer medicine information. 3rd edition
 - www.chpaustralia.com.au/Information/Industry
 - Australian Digital Transformation Agency, Content Guide - advice on how to write in plain English and create well-structured, accessible content
 - guides.service.gov.au/content-guide/

Next steps

- Newly registered medicines required to use the new template from **1 January 2021**
- Currently registered medicines required to adopt the new template by **30 December 2025**
 - five-year transition
- EDWG and Medicines Australia to work with academia in obtaining an Australian Research Council grant for developing core CMI templates that will be user tested for key therapeutic classes – collaboration between government, industry and academia
- Continuing collaboration and engagement to further improve medicine information for consumers

Sylvia and Michael

are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation to complete our live poll.

LIVE POLL



Questions?



Website and link references

Information and resources, including the templates

www.tga.gov.au/improved-consumer-medicine-information-template

Using the TGA CMI template: Guidance for sponsors (advice on compliance with Regulations)

www.tga.gov.au/using-tga-cmi-template-guidance-sponsors

How to use the improved CMI template (advice on key communication principles)

www.tga.gov.au/sites/default/files/improved-consumer-medicine-information-template-guide.pdf

Usability evaluation report

www.tga.gov.au/sites/default/files/improved-consumer-medicine-information-template-report.pdf

Legislation Amendments (see Schedule 6)

www.legislation.gov.au/Details/F2019L01660

More information

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Contact us

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