

## Summary of Changes Made to GRTPNZ Part 10: Requirements for information for prescribers and consumers Edition 7.1

The data sheet and CMI guideline has been updated as part of the review of Medsafe's quality system documents. The following changes have been made.

Section	Summary of changes
Cover page	Month and year, and Edition number updated to March 2021, Edition 7.1. Ministry of Health logo updated.
Page 1	Added a Table of Contents to aid navigating.
Throughout	Hyperlinks to web documents in the text have been added or updated. Edition number in the footnote updated to Edition 7.1. Minor grammatical and formatting changes. "Healthcare professional" changed to "health care professional" following the Ministry of Health communications standard. Double quotation marks " " changed to single quotation marks ' ' following the Ministry of Health communications standard Change of language style to active voice.
1.2	Added a recommendation that the guideline on CMI should be read in conjunction with Part 2 of the Guideline.
2.3	Changed to require submitting draft data sheets in electronic format.
2.4	Addition of a bullet point to explain the date of revision of a data sheet.
2.4.1	Added advice to use the innovator overseas as the reference source for safety information if there is no innovator product on the market in New Zealand, and not the New Zealand market leader. Added advice that the data sheet for complex products such as biosimilars should include results from comparative studies that can help clinicians with their prescribing decisions. The sponsor should discuss any differences with the reference medicinal product.
2.5	Bullet points from Section 2.7 now included in Section 2.5 as these relate to the format and style requirements of the data sheet.
2.6	Moved the bullet point further up into the body of this section.
2.7	Bullet points relating to format and style have been moved to Section 2.5
2.8	Guidance revised to reflect that data sheets will only be published for approved medicines that are generally available.
2.9	Addition of advice that sponsors can also check for updates to data sheets on the Medsafe website.
2.10	Paragraph shortened and removed examples of instances when changes to a data sheet might be needed. Added a sentence that sponsors must maintain their data sheets, or the medicine will be listed as being unavailable and not being marketed.

2.11	Revised to state that Medsafe monitors medicines safety signals as part of its pharmacovigilance programme and will check data sheets as part of the programme's signal management process. If issues or problems are identified, these will be brought to the attention of the sponsor concerned and the appropriate corrective action is requested.
2.12	Added a sentence that any request for a data sheet for a medicine that is not available will be directed to the sponsor.
2.13	Added a link to the Product Status Change Request form.
3.1	<p>Removed paragraph about information about the benefits and risks empowering consumers to participate in making decisions, as the information is paraphrased in the opening paragraphs.</p> <p>Removed the paragraphs relating to CMI enhancing the partnership between consumers, health care professionals and the pharmaceutical industry.</p> <p>Removed the paragraph that CMI is additional to information provided to consumers by health care professionals, as this idea is summarised in the last sentence of the paragraph.</p> <p>Replaced the sentence that CMI informs the consumer what the medicines used for, how to use it, what adverse effects may be experienced and what precautions should be exercised, with a bullet point.</p>
3.2	Shortened this section as CMI is not mandatory.
3.4.1	<p>Shortened this section as the idea is encapsulated in the simple instruction to use the Template for preparing Consumer Medicine Information for New Zealand consumers.</p> <p>Added advice that sponsors may use the CMI template from any of the recognised jurisdictions listed in Section 3.4, but that the TGA' template is the preferred alternative.</p> <p>Added requirement that if an alternative template is used, the information must be consistent with the New Zealand data sheet and include New Zealand specific information.</p>
3.5	Removed the old Section 3.5, as the advice to use the Template for preparing Consumer Medicine Information for New Zealand consumers is already in Section 3.4.1. Subsequent sections are renumbered.
New 3.5	<p>Removed the bullet point 'There should be consistency of content in CMI for medicines with the same non-proprietary name and between medicines of the same therapeutic group' because they may not always have the same characteristics.</p> <p>Removed the bullet point that where practicable, all dose forms marketed under the same trade name should be included in a single CMI. This is because some dose forms may not be approved for the same indications.</p> <p>Removed the bullet point that CMI need not be strength specific.</p> <p>Rephrased 'Where a brand of medicine has more than one medicine classification depending on the indication(s), strength, etc a separate CMI must be produced for each classification' to 'A separate CMI is required for each medicine classification if a brand of medicine has more than one classification'.</p>

New 3.6	<p>Created a link to the Declaration to accompany a CMI submitted for publication on the Medsafe website.</p> <p>Changed the sentence to read “The CMI must be accompanied by a completed and signed Declaration to accompany a CMI submitted for publication, or the CMI will be returned.”</p> <p>Removed the sentence “CMI submitted incorrectly (incorrect format or incomplete declaration form) will be returned to the submitter for correction and re-submission”. This is because only the declaration is being checked.</p>
New 3.7	<p>Rephrased to reflect the wording in Section 2.9 Notification of publication (of data sheets).</p> <p>Added a link to Medsafe subscription service.</p>
(old) 3.10	<p>As Medsafe is not carrying out random audits of published CMI, this old section 3.10 has been removed.</p>
New 3.9	<p>Changed the procedure for complaints about CMI. Medsafe will refer the complaint to the sponsor and may request a revised CMI and declaration to be submitted within 60 days.</p>
New 3.10	<p>Added a sentence to the effect that sponsors may state on the labels of their medicines that a CMI for the medicine is available.</p>