MEDSAFE

New Zealand Medicines and Medical Devices Safety Authority

Guidelines on the Regulation of Therapeutic Products in New Zealand

Requirements for information for prescribers and consumers

Edition: 7.2

October 2024

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Contents

List of abbreviations

Abbreviation or term	Definition
CARM	Centre for Adverse Reactions Monitoring
CMI	Consumer medicine information
CMN	Changed medicine notification
GRTPNZ	Guidelines on the Regulation of Therapeutic Products in New Zealand
INN	International non-proprietary name
NMA	New medicine application
SACN	Self-assessable change notification
TPDR	Therapeutics Products Database Record

1. Legislation

Section summary

This section identifies the legislation relating to the preparation and publication of data sheets and Consumer Medicine Information (CMI) for New Zealand health care professionals and consumers.

1.1 Legislation relating to data sheets

The following legislation applies to data sheets, and should be read in conjunction with section 2 of this Guideline:

- Medicines Regulations 1984, Part 10: Data Sheets (Regulations 51–53).

1.2 Legislation relating to CMI

There is no legislation specifically relating to CMI.

However, along with section 3 of this Guideline, sponsors should also read the following GRTPNZ documents published on the Medsafe website:

- *GRTPNZ: New Medicine Applications*
- *GRTPNZ: Changed Medicine Notifications and Non-notifiable Changes*.

2. Data sheets

Section summary

This section:

- provides guidance on the preparation of data sheets
- explains when and how draft data sheets should be submitted for approval
- explains when and how approved data sheets should be submitted for publication.

2.1 Introduction

A data sheet contains information relating to the safe and effective use of the medicine. Medsafe reviews data sheets and the delegate of the Director-General of Health approves them. Part 10 of the Medicines Regulations 1984 sets out the requirements for the preparation, approval and publication of data sheets.

2.2 Who is responsible for supplying and maintaining data sheets?

Medicine sponsors are responsible for the preparation of data sheets and ensuring that they are kept up to date.

Sponsors then supply data sheets to Medsafe for publication on Medsafe's website.

2.3 When are data sheets required?

Prescription medicines and restricted (pharmacist-only) medicines must have data sheets.

- A proposed data sheet must be submitted as part of the New Medicine Application (NMA).
- A draft revised data sheet should be submitted with the Changed Medicine Notification (CMN) for material changes that affect the data sheet.
- Draft data sheets should be submitted in electronic format together with the NMA, CMN or Self-Assessable Change Notification (SACN).
- Medsafe will approve the data sheet when issuing consent to the changes for the CMNs that are not self-assessable.

Information in the data sheet must match the approved details in Medsafe's Therapeutic Products Database Record (TPDR), including shelf-life details.

2.4 When are data sheets not required?

Data sheets are not required for pharmacy-only or general sale medicines, unless the Director-General has specified that a data sheet should be provided pursuant to a notice issued under section 36 of the Medicines Act 1981. However, some general sale or pharmacy-only medicines are also prescribed. Medsafe recommends that sponsors provide data sheets for these medicines, especially if they are prescribed regularly.

Data sheets are not required for related products. Medsafe will not review, approve or publish data sheets for related products. For information about related products, refer to the following GRTPNZ documents published on the Medsafe website:

- *GRTPNZ: Overview of Therapeutic Product Regulation*
- *GRPTNZ: New and Changed Related Products*.

2.5 General requirements for data sheets

Sponsors should note the following when preparing a data sheet.

- Data sheets should follow the Data sheet template. Refer to section 2.6 of this Guideline for more information.
- If marketing a medicine under two or more trade names, each trade name product requires a separate data sheet.
- Provide separate data sheets for different dose forms, strengths and formulations of the same medicine, where this promotes safe use of the medicine. In any situation, the data sheet should make it clear as to the use of the dose form or strength.
- If the sponsor wishes to include formulations of a medicine that have been approved but are not yet marketed, a qualifier statement should be included that notes the product is not currently available.
- If the product name for a generic medicine is composed of the International Non-Proprietary Name (INN), with the company (or other) name used as a separate identifier, this identifier should be stated in brackets next to the product name throughout the data sheet. Brackets are not necessary if the identifier is approved as part of the product name.
- Use the active ingredient name or INN when referring to any other medicine in the data sheet. The data sheet must not refer to brands of other medicines.
- If a medicine has the potential for individual patient differences in bioavailability, the data sheet must include advice regarding switching between formulations or brands and the need for individual patient monitoring if switching is unavoidable.
- For biosimilars, refer to the Medsafe policy.
- Indications in the data sheet should reflect the clinical trial population and the ages for which the medicine is approved.
- All dosages for the approved indications in the data sheet should be attainable with the approved strengths of the medicine.
- Do not include or use promotional statements in data sheets.
- Do not include bibliographic references in data sheets.
- Use the term 'medicine' to indicate a therapeutic substance. In New Zealand, the term 'drug' indicates a substance of abuse.
- The sponsor must provide New Zealand contact details, including a New Zealand phone number in the data sheet (in data sheet section 8: Sponsor).
- For revised data sheets, include the date of revision in section 10. This is the date the sponsor prepares the data sheet changes – it is not the date the data sheet is submitted to or acknowledged by Medsafe. The only exception to this is the date of first approval (section 9), which is the date of publication in the New Zealand Gazette of consent to distribute the medicine.
- Proof-read the draft data sheet before submitting it to Medsafe. The sponsor must ensure that the data sheet does not contain spelling, grammatical or typographical

errors. Where Medsafe encounters such errors in a submitted data sheet, Medsafe will require the sponsor to correct the errors through a SACN submission or Request for Further Information (RFI), which may increase the time taken to approve the application.

2.5.1 Preparing a data sheet for a generic medicine

The data sheet for the generic medicine should use the New Zealand innovator product as the reference for the indications, dose and safety information.

If there is no innovator product on the market in New Zealand, the sponsor should contact Medsafe to identify the correct indications and dose. The sponsor should use the innovator overseas as the reference source for safety information, and not the New Zealand market leader.

Data from bioavailability studies should not be included in the data sheet.

However, a data sheet for a complex product, such as a biosimilar, should include results from relevant comparative studies that can help clinicians with their prescribing decisions. The data sheet should describe any differences with the reference medicinal product.

2.6 Format and style consistency in data sheets

When preparing a data sheet, sponsors should use the 'Data sheet template' and the 'Data sheet template explanatory guide', available for download from the Forms and Templates page of the Medsafe website.

Data sheets published on the Medsafe website must be in a standardised format so that users can find information easily.

- Include the heading 'Data Sheet' at the top of the front page of each data sheet.
- Use a serif font (eg, Times New Roman).
- Section headings should be font size 14.
- 'Normal' text should be font size 11.
- Bold or italics may be used as required.
- Tables, bullets and numbered lists may be used as appropriate.
- Only include registration or trademarks in data sheets where their use does not adversely affect the layout of the data sheet.
- The data sheet should be submitted in Portable Document Format (PDF).
- The document should be set at a security setting that allows printing and content copying.
- The document should be searchable (NOTE – for this reason scanned documents cannot be accepted).
- The electronic copy of the final data sheet should be clean and should not include tracked changes, highlights or comments.

2.6.1 Use of electronic bookmarks and hyperlinks

Section headings and subsection headings should be bookmarked to aid navigation.

The data sheet can include embedded hyperlinks to:

- the sponsor's adverse reaction reporting form

- the sponsor's contact point (preferably the 'Contact Us' information on the sponsor's web page).

However, please use the full URL for the Medsafe/Centre for Adverse Reactions Monitoring (CARM) reporting form (ie, do not embed it).

2.7 Submitting a data sheet for approval

Whenever a NMA is submitted for a medicine for which a data sheet is required, the application must include a draft data sheet. Any changes to the data sheet occurring during the NMA evaluation process should be provided both as a clean version and as 'tracked changes'. Sponsors must also complete the data sheet declaration in the NMA form.

Similarly, whenever a CMN or SACN is submitted that involves a change to an approved data sheet, the draft revised data sheet (clean and tracked changed versions) must be submitted with the notification. Sponsors must also complete the data sheet declaration in the CMN or SACN form.

Medsafe will assess the proposed data sheet along with the NMA or CMN and supporting data. Medsafe will notify the sponsor if there are any required changes to the data sheet.

2.8 Submitting an approved data sheet for publication

The sponsor must supply an electronic copy of the approved data sheet within **10 days** of gazettal of consent for a new medicine, approval of a CMN or payment of the invoice for a SACN.

When submitting the data sheet for publication, sponsors must also submit a completed and signed 'Declaration to accompany a data sheet' form – available for download from the Forms and Templates page of the Medsafe website.

- Submit the data sheet and declaration form to: Datasheet.cmi@health.govt.nz with the email subject line 'Data sheet: <*insert trade name*>'.
- Submit each data sheet in a separate email.
- Each email should contain only the data sheet PDF and the completed declaration form.

Data sheets submitted incorrectly (incorrect format or incomplete declaration form) will be returned to the submitter for correction and re-submission.

An additional SACN fee may be charged if the data sheet is not received electronically within 10 days of the Gazette notice.

2.9 Publication of data sheets

Data sheets are published on the Data Sheets and Consumer Medicines Information page of the Medsafe website for medicines that are generally available. Refer to section 1.2 of GRTPNZ*: New Medicine Applications* for a definition of 'generally available'.

Medsafe will publish the data sheet for a medicine that is not currently available only if the sponsor commits to maintaining the data sheet.

2.10 Notification of publication

The New/Updates to Data sheets and CMIs page of the Medsafe website provides a list of new and updated data sheets published during the specified time period.

Following publication, the sponsor should check that the published data sheet is correct.

2.11 Maintenance of data sheets

The sponsor is responsible for maintaining their data sheet to support the safe and effective use of their medicines. Changes to data sheets can include addition, modification or removal of information.

Sponsors of generic medicines should monitor for updates to the innovator medicine data sheet and update their own data sheets accordingly.

2.11.1 Self-assessable change notifications

Sponsors submit SACNs for miscellaneous changes to data sheets. These changes include, for example, sponsor name change or update, or addition to safety information to align with the New Zealand innovator (with no change to approved product details).

The revised data sheet is not approved until the sponsor receives and pays the invoice for the notification. Once the invoice is paid, the sponsor should then submit the data sheet for publication, along with the data sheet declaration (see section 2.8 of this Guideline).

Note that Medsafe does not routinely assess data sheets amended via a SACN. Approval is granted on the basis of the sponsor's signed declaration that the data sheet has been prepared in compliance with this Guideline and that it accurately reflects the existing New Zealand terms of approval for the medicine.

2.12 Auditing of published data sheets

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. Medsafe will communicate any data sheet issues or problems to the respective sponsor and request corrections.

2.13 Removal of data sheets from the Medsafe website

As described in section 8 of GRTPNZ: *Changed Medicine Notifications and Non-Notifiable Changes*, sponsors can change the registration status of their products to:

- Not available – if the product is no longer available and all stock has been depleted from the New Zealand market
- Approval lapsed – if the product will not be marketed in New Zealand again.

Sponsors do not have to maintain published data sheets for products with the registration status 'not available'. The data sheet for an 'approval lapsed' product must be removed from the Medsafe website.

To change the registration status of a medicine and remove the data sheet from the Medsafe website, complete the 'Product Status Change Request' form, available for download from the Forms and Templates page of the Medsafe website.

Medsafe will forward data sheet requests for unavailable medicines to the sponsor.

2.14 Data sheets for previously unavailable medicines

When reintroducing a product back into the New Zealand market, sponsors must change the registration status of their medicine from 'not available' to 'consent given' or 'provisional consent'. Refer to section 8 of GRTPNZ: Changed Medicine Notifications and Non-Notifiable Changes. For prescription and restricted medicines, this must be accompanied by the supply of a data sheet for publication on the Medsafe website.

To change the registration status of a medicine, complete the 'Product Status Change Request' form, available for download from the Forms and Templates page of the Medsafe website. If there have been no changes to the data sheet, a CMN or SACN is not required.

3. Consumer Medicine Information

Section summary

This section:

- provides guidance on the preparation of Consumer Medicine Information
- explains when and how Consumer Medicine Information should be submitted for publication.

3.1 Introduction

The safe selection and use of medicines depends on consumers and health care professionals having access to balanced and accurate medicine information. While data sheets provide this information for health care professionals, Consumer Medicine Information (CMI) are written for consumers and provide accessible, easily understood information to help them use medicines safely and effectively. Although CMI are not mandatory, Medsafe encourages the pharmaceutical industry to produce them. Along with data sheets, CMI are published on the Medsafe website.

This Guideline supports the right of consumers (which is endorsed in the Code of Health and Disability Services Consumers' Rights) to make their own decisions about medical treatment or procedures, and to have adequate information available on which to base their decisions.

The purpose of CMI is to:

- increase consumers' knowledge of the medicines they are taking
- assist consumers to distinguish between the symptoms of their illness and any possible side-effects caused by the medicine they are taking
- assist consumers in recognising any interactions between different medicines that they are taking
- remind consumers about warnings and precautions when taking the medicine.

Health care professionals are responsible for using their clinical judgement when providing information to patients. CMI do not replace discussions between healthcare providers to consumers, but are a tool to support these conversations.

CMI is an interpretation of the approved data sheet for the medicine (or other source document if there is no data sheet – see section 3.4 Preparing CMI), written for the New Zealand consumer in a manner that is easy to understand.

3.2 When is CMI required?

Although the preparation of CMI is not mandatory, Medsafe encourages the pharmaceutical industry to prepare CMI for all approved medicines.

3.3 Who is responsible for preparing CMI?

The sponsor of each medicine is responsible for preparing CMI for that particular medicine and for self-assessing CMI against the requirements of this Guideline. Medsafe does not evaluate or approve CMI.

3.4 Preparing CMI

CMI is an interpretation of the Medsafe-approved data sheet for each medicine, and must be consistent with the information contained in the relevant data sheet.

If there is no approved data sheet (eg, for pharmacy-only medicines, general sale medicines and controlled drugs that do not require a prescription), the CMI is to be based on an overseas source document. Acceptable source documents are listed below, provided they are the currently-approved version:

- MHRA-approved Summary of Product Characteristics or Patient Information Leaflet
- EMA-approved Summary of Product Characteristics or Patient Information Leaflet
- FDA-approved Prescribing Information
- Health Canada-approved Product Monograph (English version)
- TGA-approved Product Information or CMI
- Pharmaceutical company core data sheet (international prescribing information document).

The sponsor must ensure that the safety information in the CMI is consistent with the data sheet or other approved source document, and that the content of the CMI is consistent with the terms of the New Zealand approval for the medicine (eg, refers only to dose forms, indications, dosages that are approved in New Zealand).

3.4.1 Content required in CMI

If preparing CMI, use the 'Template for preparing CMI for New Zealand consumers', available for download from the Forms and Templates page of the Medsafe website. The template provides the section headings and information to be included in the CMI.

Sponsors may use the TGA's template as an alternative to the New Zealand CMI template. Sponsors may also use the CMI template approved for use in any of the jurisdictions above, but the information must be consistent with the New Zealand data sheet. New Zealand specific information, such as contact details for the New Zealand sponsor and National Poisons Centre (where applicable), must be included.

3.4.2 Language

CMI must be in English.

CMI may also be in Te Reo and other languages. It is the responsibility of the sponsor to seek assistance from appropriate person(s) or organisations to ensure that the translation is accurate and reflects the true meaning of the English version of the CMI.

CMI produced by the sponsor in any other language must be sent to Medsafe and be accompanied by a letter declaring that the CMI conforms to this Guideline and is an accurate interpretation of the English version of the CMI.

3.5 General requirements for CMI

The following applies when preparing CMI for New Zealand consumers.

- The heading 'New Zealand Consumer Medicine Information' must be included at the top of the front page of each CMI.
- The CMI must be consistent with the Medsafe-approved data sheet or appropriate source document.
- All statements in CMI must be correct, clear, unambiguous and in language consumers find easy to understand.
- CMI must be brand specific.
- A separate CMI is required for each trade name product.
- A separate CMI is required for each medicine classification if a brand of medicine has more than one classification.
- A 'Date of Preparation' must be included in each CMI. This is the day, month and year that particular version of the CMI was prepared for publication. The date of preparation must be changed each time an updated version is prepared. The date of preparation will be used to identify that particular version of the CMI as it progresses through stages of publication.
- Promotional statements are not permitted in CMI.
- Bibliographic references are not to be included in CMI.
- Use the term 'medicine' to indicate a therapeutic substance. In New Zealand, the term 'drug' indicates a substance of abuse.

3.6 Submitting CMI for publication

All CMI must be supplied to Medsafe via email in PDF with a security setting that allows printing and content copying. The document must be searchable (NOTE – for this reason scanned documents cannot be accepted).

The CMI must be accompanied by a completed and signed 'Declaration to accompany a CMI submitted for publication' form, available for download from the Forms and Templates page of the Medsafe website.

- Submit the CMI and declaration form to datasheet.cmi@health.govt.nz with the subject line 'CMI: <*insert trade name*>'.
- Submit each CMI in a separate email.
- Each email should contain only the CMI PDF and the completed declaration form.

CMI submitted incorrectly (incorrect format or incomplete declaration form) will be returned to the submitter for correction and re-submission.

3.7 Notification of publication

CMI are published on the Data Sheets and Consumer Medicines Information page of the Medsafe website. The New/Updates to the Data sheets and CMIs page of the Medsafe website provides a list of new and updated CMI published during the specified time period.

Following publication, the sponsor should check that the published CMI is correct.

3.8 Removal of CMI from the Medsafe website

Sponsors should notify Medsafe if a product is not available and all stock has been depleted in the New Zealand market, so that the CMI can be removed from the website (refer to section 2.13 of this Guideline).

3.9 Complaints procedure

Medsafe will advise the sponsor of any complaints received about a CMI and ask them to comment on the complaint. Medsafe may require the sponsor to submit a revised CMI and a declaration stating that the revised CMI complies with this Guideline within 60 days.

3.10 Advertising the availability of CMI

All sponsors should promote the concept of CMI, including where CMI can be accessed, to both health care professionals and consumers. Individual sponsors should promote the availability of specific CMI to health care professionals. Sponsors may reference the availability of CMI on any label of their medicines, although Medsafe prefers this reference to be on the outer label.

Document History

Revision Date	Edition number	Summary of Changes
September 2024	7.2	• Editorial and formatting changes throughout for improved readability. • Section 2.5: Convention to follow if the product name for a generic medicine is composed of the INN, with the company (or other) name used as a separate identifier. • Section 2.6.1: Request that the full URL for the Medsafe/Centre for Adverse Reactions Monitoring (CARM) reporting form is used (ie, do not embed it). • Section 2.13 and 2.14: Additional background information added to provide more context.