MEDSAFE

NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY

A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Guideline on the Regulation of Therapeutic Products in New Zealand

Part 10:

Requirements for information for prescribers and consumers

MINISTRY OF HEALTH
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Section 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 should be read in conjunction with Section 2 of this part of the guideline:

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

1.2 Legislation relating to CMI

There is no legislation specifically relating to the requirements for CMI. This guideline should be read in conjunction with Part 2 of the Guideline and should not be read in isolation.

Section 2: Data sheets

Section summary

This section:

- *provides detailed 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. Data sheets are reviewed by Medsafe and subsequently approved by the delegate of the Director-General of Health. 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. Data sheets are supplied to Medsafe for publication on Medsafe's website.

2.3 When is a data sheet required?

An approved data sheet is required for every prescription medicine and restricted medicine for which the Minister's consent for distribution in New Zealand has been granted.

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. It is desirable for the sponsor to provide data sheets for these medicines especially if they are prescribed regularly.

A proposed data sheet is required to 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.

Data sheets are not required for related products. Medsafe will not review, approve or publish data sheets for related products.

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

2.4 General requirements for data sheets

Sponsors should note the following when preparing a data sheet.

- Data Sheets should follow the data sheet template (see Section 2.5).
- Include the heading 'Data Sheet' at the top of the front page of each data sheet.
- 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.
- List formulations of a medicine that have been approved, but are not yet marketed with a qualifier statement that notes the medicine is not currently available.
- The data sheet must not refer to brands of medicines that are not approved in New Zealand, as this constitutes advertising of unapproved medicines.
- Use the active ingredient name or International Non-Proprietary Name when referring to any other medicine in the data sheet.
- If a medicine has the potential for individual 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 (https://www.medsafe.govt.nz/profs/riss/biosimilars.asp).
- 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.
- Only include registration or trademarks in data sheets where their use does not adversely affect the layout of the data sheet.

- 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 (under heading 8 Sponsor).
- Include the date of revision in the data sheet, which is to be the date the sponsor prepares the changes to the information in the data sheet. This is not the date the data sheet is submitted or acknowledged by Medsafe. The only exception to this is the date of approval for new data sheets.
- Proof-read the draft data sheet before submitting. It is the responsibility of the sponsor to 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 a Self-Assessable Change Notification to be submitted to correct the errors.

2.4.1 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, the data sheet for complex products such as biosimilars should include results from relevant comparative studies that can help clinicians with their prescribing decisions. The sponsor should discuss any differences with the reference medicinal product.

2.5 Format and style consistency in data sheets

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

- Sponsors should use the Data sheet template (and the Data sheet template explanatory guide) when preparing their data sheets.
- A serif font (eg, Times New Roman) is preferred.
- Section headings should be of font size 14.
- ‘Normal’ text should be of font size 11.
- **Bold** or *italics* may be used as required.
- Tables, bullets and numbered lists may be used as appropriate.
- The data sheet should be submitted in Portable Document Format (PDF).
- The document should be set at a security setting which 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.

2.5.1 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 Centre for Adverse Reaction Monitoring (CARM) reporting form
- the sponsor's contact point (preferably the 'Contact Us' information on the sponsor's web page).

2.6 Submitting a data sheet for approval

Whenever an NMA is submitted for a medicine for which a data sheet is required, the application should include a draft data sheet. Updates to the draft data sheet should be provided both as a clean version and as 'tracked-changes'.

Similarly, whenever a CMN or Self-Assessable Change Notification (SACN) is submitted that involves a change to an approved data sheet, the draft revised data sheet should be submitted with the notification.

Sponsors must complete their data sheet declarations in the NMA or CMN forms. The proposed data sheet is assessed along with the NMA or CMN and supporting data. Medsafe will communicate to the sponsor any required changes to be made to the data sheet.

2.7 Submitting an approved data sheet for publication

The sponsor should 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.

A completed and signed Declaration should accompany the data sheet.

- Submit the data sheet and declaration form Datasheet.cmi@health.govt.nz

  with the email subject line 'Data sheet: <inset trade name>'.
- Submit each data sheet in a separate email.
- Each email should contain only the data sheet in 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.

2.8 Publication of data sheets

Data sheets are published on the Medsafe website only for medicines that are generally available. 'Generally available' is defined in Part 2 of the Guideline on the Regulation of Therapeutic Products in New Zealand.

A data sheet for a medicine that is not currently available will be published if the sponsor commits to maintaining the data sheet.

2.9 Notification of publication

Medsafe notifies subscribers of data sheets published on the Medsafe website via the 'Additions to Medsafe's website' email. Those involved in the submission of data sheets for publication are encouraged to subscribe to receive this email at www.medsafe.govt.nz/regulatory/subscribe.asp.

Sponsors can also check for updates to data sheets on Medsafe's website.

Following publication, the sponsor should check the data sheet on Medsafe's website to ensure that it is correct.

2.10 Maintenance of data sheets

Sponsors should maintain 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 be cognisant of updates to the innovator medicine data sheet and update their own data sheets accordingly.

The sponsor must maintain the data sheet, or the medicine will be listed as being unavailable and not being marketed.

2.10.1 Changes affecting only data sheets

Miscellaneous changes that only apply to data sheets are submitted as SACNs. These changes include, for example, an update to safety data, sponsor name change or additional pharmacokinetic/pharmacodynamic data.

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 an electronic copy of the data sheet for publication (see Section 2.7 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.

2.11 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. 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 Removal of data sheets from the Medsafe website

Sponsors should notify Medsafe when a product is no longer available and all stock has been depleted in the New Zealand market, so that the data sheet can be removed from the website.

Any request for a data sheet of a medicine that is not available will be directed to the sponsor.

2.13 Data sheets for previously unavailable medicines

Refer to Section 4.8 of Part 2 of the Guideline on the Regulation of Therapeutic Products in New Zealand. Companies must complete the Product Status Change Request form. If there have been no changes to the data sheet a CMN or SACN is not required.

Section 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. Consumer Medicine Information (CMI) provides accessible easily understood information about medicines written for consumers in accordance with this guideline, to help them use medicines safely and effectively. Although the development and publication of CMI is not mandatory, Medsafe encourages the pharmaceutical industry to produce CMI and publishes CMI on its 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 medicines they are taking.
- Assist consumers to distinguish between the symptoms of their illness and any possible side effects induced 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 about taking the medicine.

CMI should be considered an adjunct to verbal counselling by health care providers.

CMI is an interpretation of the approved data sheet (or other source document if there is no data sheet - see Section 3.4) for the medicine, 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 that in 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 etc, that are approved in New Zealand).

3.4.1 Content required in CMI

If preparing CMI, use the **Template for preparing Consumer Medicine Information for New Zealand consumers** for the section headings and information to be included. Medsafe suggests the use of the TGA's template as the 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 datasheet. New Zealand specific information, such as contact details, 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 should be noted 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 which 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**, or the CMI will be returned.

Submit the CMI and declaration form to datasheet.cmi@health.govt.nz with the subject line 'CMI: [inset trade name]'.

Submit each CMI in a separate email. Each email should not contain anything other than the CMI in 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

Medsafe notifies subscribers when CMI are published on the Medsafe website via the 'Additions to Medsafe's website' email. Those involved in the submission of CMI for publication are encouraged to subscribe to receive this email at www.medsafe.govt.nz/regulatory/subscribe.asp.

Following publication, the sponsor should check the CMI on Medsafe's website to ensure that it 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.

3.9 Complaints procedure

If a CMI complaint is received by Medsafe, Medsafe will advise the sponsor and provide them with an opportunity 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 the guidelines, within 60 days.

3.10 Advertising the availability of CMI

All sponsors should promote the concept of CMI and where CMI can be accessed to both health care professionals and consumers. Individual sponsors should ensure that the availability of specific CMI is promoted to health care professionals. Sponsors may reference the availability of CMI on any label of their medicines, although it is preferable for this reference to be on the outer label.