



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

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 healthcare 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.

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, sponsors are encouraged to provide data sheets for pharmacy-only and general sale 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 as hard copy together with the NMA, CMN or Self-assessable Change Notification (SACN).

In the case of a CMN that is not self-assessable, approval for the data sheet will be included in the consent issued by Medsafe for the changes.

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

The following should be noted when preparing a data sheet.

- ☞ The heading "Data Sheet" should be included at the top of the front page of each data sheet.
- ☞ If a medicine is marketed under two or more trade names, a separate data sheet is required for each trade name.
- ☞ It is preferred that separate data sheets are provided for different dose forms, strengths and formulations of the same medicine where this promotes safe use of the medicine. If different strengths or dose forms are to be included on the same data sheet, it should be clear when some information only applies to a certain dose or form.
- ☞ Formulations of a medicine that have been approved, but are not yet marketed may be listed 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. However, the medicine may be mentioned by active ingredient name or International Non-Proprietary Name.
- ☞ If reference to any other medicine is required in the data sheet, it should be by the active ingredient name or International Non-Proprietary Name.
- ☞ If a medicine is not interchangeable, or has the potential for individual differences in bioavailability, the data sheet must include advice regarding switching between formulations and the need for individual patient monitoring if switching is unavoidable.
- ☞ For biosimilars, refer to the Medsafe policy (www.medsafe.govt.nz/profs/Rlss/Biosimilars.asp).
- ☞ Attention should be paid to the indications in the data sheet to ensure they reflect the clinical trial population and include the ages for which the medicine is approved.
- ☞ All dosages proposed in the data sheet should be attainable with the approved strengths.

- ☞ Promotional statements are not permitted in data sheets.
- ☞ Registration or trademarks may be included in data sheets provided their use does not adversely affect the layout of the data sheet.
- ☞ Bibliographic references are not to be included in data sheets.
- ☞ The term 'medicine' is used 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).
- ☞ The draft data sheet should be proof-read before it is submitted. It is the responsibility of the sponsor to ensure that the data sheet does not contain spelling, grammatical or typographical mistakes. 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 may use the innovator overseas as the reference source for safety information.

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

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.

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.

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 should remember to 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. Any required changes to the data sheet are communicated to the sponsor by Medsafe.

- ☞ Updates to the draft data sheet should be provided both as a clean version and as 'tracked-changes'.

2.7 Submitting an approved data sheet for publication

The sponsor should supply an electronic copy of the approved data sheet in Portable Document Format (PDF) within 10 days of gazettal of consent for a new medicine, approval of a CMN or payment of the invoice for a SACN.

- ☞ The PDF 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.

The data sheet should be accompanied by a completed and signed [Declaration to accompany a data sheet](#).

- ☞ The data sheet and declaration form should be submitted to Datasheet.cmi@moh.govt.nz with the email subject line "Data sheet: <inset trade name>".
- ☞ Each data sheet should be submitted in a separate email, and 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.

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

2.8 Publication of data sheets

Data sheets are published on the Medsafe website. All data sheets should be maintained by their sponsors. If a medicine is not currently available, this should be indicated on the declaration form. “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 only be published if the sponsor commits to maintaining the data sheet.

2.9 Notification of publication

The publication of data sheets on the Medsafe website is notified via the weekly ‘Additions to Medsafe’s website’ email. Those involved in the submission of data sheets for publication are encouraged to subscribe to receive this weekly email at www.medsafe.govt.nz/regulatory/subscribe.asp.

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 are expected to maintain their data sheets published on the Medsafe website. Sponsors should incorporate new information to support the safe and effective use of their medicines as it becomes available.

Data sheets should be updated when the information is no longer current, for example when there is new information available on an aspect of the medicine, new contraindication, additional precautions, changes to sponsor details, appearance of the medicine, dosages etc.

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

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 has received acknowledgement of the notification from Medsafe and has validated the notification by payment of the invoice. 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 data sheets amended via a SACN are not routinely assessed by Medsafe. 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 carries out random audits of published data sheets. If problems are identified, these are 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.

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

3.1 Introduction

Safe selection and use of medicines depends on consumers and healthcare professionals having access to balanced and accurate medicine information. Consumer Medicine Information (CMI) is accessible and understandable 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.

Information about the benefits and risks associated with a medicine will empower consumers to participate in making decisions about their own healthcare. To make informed choices, consumers need to know of the benefits and risks of medicines and to feel able to compare these with information about other treatment options, including the option of 'no treatment'.

CMI is expected to:

- ☞ Increase consumers' knowledge of medicines.
- ☞ Assist consumers to distinguish between the symptoms of their illness and any possible side effects induced by a medicine.
- ☞ Assist consumers in recognising any interactions between different medicines that they are taking.

By achieving the above and de-mystifying medicines, CMI is expected to enhance the partnership between consumers, healthcare professionals and the pharmaceutical industry and improve consumers' health management skills.

CMI is additional to the information provided to consumers by healthcare professionals, and is not intended to reduce or replace the role of healthcare professionals in counselling consumers about medicines. CMI should be considered an adjunct to verbal counselling.

CMI is an interpretation of the approved data sheet (or other source document if there is no data sheet) for the medicine, written for the New Zealand consumer in an easily understandable manner.

CMI informs the consumer what the medicine is intended for, how to use it, what adverse effects may be experienced and what precautions should be exercised.

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 and, in particular, for Prescription Medicines, Restricted Medicines and Controlled Drugs which require prescription, as medicines in these categories present the highest risk if taken inappropriately.

CMI for Pharmacy Only and General Sale medicines will also be accepted if they are based on an approved source document (see Section 3.4 of this guideline).

3.3 Who is responsible for preparing CMI?

The sponsor of each medicine is responsible for preparing Consumer Medicine Information 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 New Zealand 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

The recommended section headings to be used and the information which should be included under each section heading when preparing CMI are provided in the **Template for preparing Consumer Medicine Information for New Zealand consumers** (see Template 10.4 in Schedule A of the *Guideline on the Regulation of Therapeutic Products in New Zealand*). Sponsors are encouraged to use this template when preparing new CMI for New Zealand consumers.

3.4.2 Language

CMI must be written and published on the Medsafe website in English.

CMI may also be published in Maori and other languages. However 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 Style consistency in CMI

It is desirable for CMI published on the Medsafe website to be in a standardised format. Sponsors are therefore encouraged to prepare CMI using the **Template for preparing Consumer Medicine Information for New Zealand consumers** (see Template 10.4 in Schedule A of the *Guideline on the Regulation of Therapeutic Products in New Zealand*).

3.6 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 a language consumers find easy to understand.
- ☞ There should be consistency of content in CMI for medicines with the same non-proprietary name and between medicines of the same therapeutic group.
- ☞ CMI must be brand-specific.
- ☞ Where practicable, all dose forms marketed under the same trade name should be included in a single CMI.
- ☞ CMI need not be strength-specific.
- ☞ If a medicine is marketed under two or more trade names, a separate CMI is required for each trade name.
- ☞ 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.
- ☞ Each CMI must include the “Date of Preparation”. 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.
- ☞ The term ‘medicine’ is used to indicate a therapeutic substance. In New Zealand, the term ‘drug’ indicates a substance of abuse.

3.7 Submitting CMI for publication

All CMI must be supplied to Medsafe via email in Portable Document Format (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** form (see Form 10.5 in Schedule A of the *Guideline on the Regulation of Therapeutic Products in New Zealand*).

The CMI and declaration form must be submitted to datasheet.cmi@moh.govt.nz with the subject line “CMI: [inset trade name]”.

Each CMI should be submitted in a separate email, and 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.

3.8 Notification of publication

Publication of CMI on the Medsafe website is notified via the weekly 'Additions to Medsafe's website' email. Those involved in the submission of CMI for publication are encouraged to subscribe to receive this weekly email. Following publication, the sponsor should check the CMI on Medsafe's website to ensure that it is correct.

3.9 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.

3.10 Auditing of published CMI

Medsafe carries out random audits of published CMI from time to time. If problems are identified, these are brought to the attention of the sponsor concerned and the appropriate corrective action is requested.

3.11 Complaints procedure

Complaints about CMI will be assessed by Medsafe. Medsafe will advise the sponsor that it is assessing a complaint and provide them with an opportunity to comment on the complaint.

If a CMI complaint is upheld by Medsafe, the sponsor must submit a revised CMI and a declaration stating that the revised CMI complies with the guidelines, within 60 days of receiving notification of the complaint being upheld.

3.12 Advertising the availability of CMI

All sponsors should promote the concept of CMI and where CMI can be accessed to both healthcare professionals and consumers. Individual sponsors should ensure that the availability of specific CMI is promoted to healthcare professionals.