

Medsafe consultation submission

Guideline on the Regulation of Therapeutic Products in New Zealand - Part 10: Requirements for information for prescribers and consumers (Edition 7.0)	
Name and designation	
Company/organisation name and address	
Contact phone number and email address	
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
(Reasons for requesting confidentiality must meet Official Information Act criteria)	
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input type="checkbox"/> Yes <input type="checkbox"/> No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	<input type="checkbox"/> Yes <input type="checkbox"/> No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:	
<input type="checkbox"/> New Zealand	<input type="checkbox"/> Australia <input type="checkbox"/> Other <i>(please specify):</i>
I am, or I represent, a: <i>(tick all that apply)</i>	
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Sponsor
<input type="checkbox"/> Government organisation	<input type="checkbox"/> Researcher <input type="checkbox"/> Professional body <input type="checkbox"/> Industry organisation
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Member of the public <input type="checkbox"/> Institution (eg university, hospital)
<input type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional
<input type="checkbox"/> Health professional – <i>please indicate type of practice:</i>	
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Please return this form to:

Email: medsafeadrquery@moh.govt.nz including “Data sheet guideline” in the subject line

Or Post: Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

Medsafe is seeking comments on the following:

1. References to overseas prescribing information or using a source document have been removed from this revision of the Guideline. The reason for this is that medicine sponsors should rely on their own core data set or reference safety information in order to prepare their data sheet provided they are entirely consistent with the New Zealand approved particulars for the medicine, or follow the market innovator or market leader in preparing their data sheets.

- Do you have any comments on this change?

2. *Section 2.4: General requirements for data sheets*

- Are the general requirements appropriate?
- Is the information easily understood?
- Are there other general requirements that you think should be included in the guideline?

Please include additional pages if necessary.

3. Section 2.5: Format and style consistency in data sheets

The EU SPC format that is proposed to be adopted has been adapted in order to meet New Zealand requirements (see [Data sheet template](#) and particularly the [Data sheet template explanatory guide](#)). These adaptations are summarised below.

- References to herbal medicines have been removed.
- Sections on dosimetry and radiopharmaceuticals have been deleted (these are not currently medicines in New Zealand).
- A 'black triangle' system for warnings is not used.
- The data sheet can cover more than one dose form / strength / formulation.
- The EU SPC does not allow registration and trademarks to be included. In New Zealand, sponsors may include such markings in the data sheet if they wish, provided this does not adversely affect the layout of the final data sheet.
- Information regarding biosimilars and non-interchangeable medicines required by current Medsafe regulatory policy has been inserted in Section 1, Section 2, Section 4.2 and Section 5.1.
- Section 4.2 heading Posology and administration is changed to Dose and method of administration.
- In Section 4.8, a link (web address) for reporting suspected adverse reactions to the New Zealand Pharmacovigilance Centre is required to be included.
- In Section 4.9, NZ Poisons Centre details are required to be added in the Overdose subsection.
- In Section 5, information to state whether the medicine is approved under "Provisional Consent" is required.
- In Section 5.2, antibiotic specific information (which is in the current data sheet checklist) is required to be included.
- In Section 5.3, reference to environmental risk assessment is not necessary and should not be included.
- In Section 7, medicine classification is required to be included.
- Section 8 heading Marketing authorisation holder is changed to Sponsor, and as authorisation number (as used in Europe) does not apply, this should not be included in New Zealand data sheets.

- Do you agree with the adoption and adaptation of the European Summary of Product Characteristics format as summarised above and presented in the [Data sheet template](#) and the [Data sheet template explanatory guide](#)?

- If you do not agree, please explain why and suggest suitable alternatives.

- Are there any changes you would like to suggest?

Please include additional pages if necessary.

4. Medsafe considers that the proposed switch to the adapted EU SPC format should involve only formatting and layout changes and does not involve changes to the content of the data sheet. Medsafe proposes the following timelines for implementing the changes to the new process and switch to the new data sheet format:

New Medicine Applications

- a) New Medicine Applications where evaluation has not commenced – a data sheet in the proposed format should be submitted with the response to the initial Request For Information (RFI 1), or the Outcome of Evaluation letter.
- b) New Medicine Applications where evaluation has commenced or are in the final stages of assessment – a data sheet in the new format should be submitted in response to the Outcome of Evaluation letter.
- c) New Medicine Applications where evaluation has been completed and a recommendation for consent is made – data sheets should be submitted in the new format within 10 days of consent to distribute being notified in the New Zealand Gazette.

Changed Medicine Notifications

- d) Changed Medicine Notifications already submitted to Medsafe – data sheets do not have to be updated to the new format until 1 January 2017.
- e) Changed Medicine Notifications yet to be submitted to Medsafe – where the change(s) affects the data sheet, the data sheet should be submitted in the new format with the notification.

All other instances

- f) A Self-Assessable Change Notification for reformatting all existing data sheets to the new format should be submitted by 1 January 2017.
- g) Where there are other material changes instead of just a reformatting of the data sheet (such as content changes), the Changed Medicine Notification process should be followed.

- Do you agree with these proposals?
- If not, what do you suggest?

Please include additional pages if necessary.

5. Medsafe proposes that current data sheets in the Australian format should be revised to the proposed format by 1 January 2017. This is expected only to involve a “shuffling” of existing content. Medsafe emphasises that these proposals do not affect package inserts or consumer medicine information.

- Do you agree with this proposal and the deadline? If not, please explain.

6. The current Medicines legislation mandates the use of the term “Data sheet”. One objective of this consultation is to help inform the thinking for the new Therapeutic Products Bill. Would you prefer the term “Data sheet” to continue to be used, or for the use of an alternative term such as “Product Information”, “Prescribing Information”, “Summary of Product Characteristics”, or another term altogether?

- Please advise us of your preference. If you consider that a different term to “Data sheet” should be used, please explain.

Please include additional pages if necessary.

7. It is envisaged that greater use of technology will facilitate communication about products distributed in New Zealand, and the dissemination of information about how to use medicines appropriately, for example current use of QR codes to access information. For example, internet links included in data sheets or consumer medicine information to instructional how-to-use video or further educational materials.

- How do you see the expansion of e-information contributing to patient safety?
- How do you see e-technology and medicine information being used in the future?
- What do you think are the benefits or drawbacks of these advances?
- Where do you think Medsafe should be heading?

8. If you are a medicine sponsor as well as a medical device sponsor, do you think that a data sheet (or similar) should be available for higher-risk medical devices? Is there alternative or suitable terminology that could be used for such an information sheet?

Please include additional pages if necessary.

9. Would you support making device data sheets a requirement for medical devices when they are notified to WAND?

10. *Additional Comments*

- Is there any other information or subject that you would like to raise?
- Is there anything else that should be included in the data sheet guideline?

Please include additional pages if necessary.