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	District Health Board
Contact phone number and email address	

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* (Reasons for requesting confidentiality must meet Official Information Act criteria)	☐ No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	☐ Yes
I would like for my name not to be included within the list of submissions published on the Medsafe website. *For clarity - please keep our submissions anonymous*	☐ Yes

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:
☐ New Zealand
I am, or I represent, a: *(tick all that apply)*
☐ Institution (eg university, hospital)
☐ Health professional – *please indicate type of practice*: Pharmacists

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?

In general, if a pharmaceutical company is applying for approval of a new medicine in New Zealand, they will be submitting data from multicentre/multinational trials, so overseas information is needed. It would also be useful to have information in the datasheet about approved uses from other countries, providing those countries also have robust regulatory approval processes, and providing it is clear that these uses are not approved in New Zealand.

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

- Are the general requirements appropriate?

Yes, with the exception of the above, we agree with the recommendations in the explanatory guide, especially the requirements for occupational exposure, and more comprehensive information for special populations. We have some concern over the use and interpretation of 'should' throughout the document - it may allow for non-inclusion of data that is available.

- Is the information easily understood?

Yes

- Are there other general requirements that you think should be included in the guideline?

Although not often directly applicable outside industrial practice, we think links to Material Safety Datasheets would be very helpful for us to ensure compliance with Hazardous Substances legislation requirements.

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?

Mostly agree, caveats below:

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

Section 5.2 It is important to consider geographical variation in susceptibilities/resistance of antibiotics. Such information in a datasheet could conflict with local resistance patterns and misinform appropriate choice.

Section 5.3 Compliance with disposal of medicines according to the requirements of the Hazardous Substances and New Organisms Act would be very useful.

- 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?

Yes

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.

Prefer 'Summary of Product Characteristics'. It encompasses most aspects of importance including manufacturer, formulation, prescribing, administration, toxicity/overdose management, disposal

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?

Ready access to reliable, validated, current, approved information for consumers in clear and simple modern formats would be a significant contribution to patient safety.

- How do you see e-technology and medicine information being used in the future?

Increasingly important – clear and simple information with instructional videos would be helpful to detail correct reconstitution/administration techniques of medicines.

- What do you think are the benefits or drawbacks of these advances?

Drawbacks – development costs

- Where do you think Medsafe should be heading?

To be the go-to portal for reliable evidence based information about approved medicines and medical devices – similar to the UK's NHS Evidence, and the NPS (National Prescribing Service) in Australia.

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?

Yes, definitely.

10. *Additional Comments*

- Is there any other information or subject that you would like to raise?

We think Medsafe and Pharmac should continue their independence but aim to consistently co-ordinate approvals and funding decisions.

We would like to see increased functionality and improved appearance of the Medsafe website to facilitate fast and efficient navigation.

It would be helpful to have a similar layout, searching and document navigation to that of www.medicines.org.uk

Links out to other trusted sources of medicines information would be very useful, such as www.nzf.org.nz, www.healthnavigator.org.nz, www.starship.org.nz and www.dermnetnz.org

Is there anything else that should be included in the data sheet guideline?

We supportive of the change and inclusion of extra data including occupational exposure and handling.

Please include additional pages if necessary.