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	New Zealand Formulary [redacted]
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)	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	☒ Yes ☐ No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	☐ Yes ☒ 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:

☒ New Zealand ☐ Australia ☐ Other (*please specify*):

I am, or I represent, a: ***(tick all that apply)***

☐ Importer	☐ Manufacturer	☐ Supplier	☐ Sponsor
☐ Government organisation	☐ Researcher	☐ Professional body	☐ Industry organisation
☐ Consumer organisation	☐ Member of the public	☐ Institution (eg university, hospital)	
☐ Regulatory affairs consultant	☐ Laboratory professional		

☐ Health professional – *please indicate type of practice*:

☒ Other - *please specify*:

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?

NZF agrees with this approach

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?

The information is generally clear and the new format will be easier to use and the important information more accessible than the current formats. The proposed data sheet format is much improved with the important clinical information consistently placed at the start of the data sheet. We agree with moving the clinical trial data and other detailed clinical particulars to the end of the document.

Apart from the logical restructuring that is proposed, the most important requests from the NZFs perspective are as follows:

- A complete history of all changes (assessable and non-assessable) for each individual medicine should be available to the end user. This change history should be easily accessible online as for example; http://www.medicines.org.uk/emc/history/17095
  A tab on the data sheets home page to "updated medicines" similar to that on the EMC web site should be provided. These features are vitally important for the NZF to keep important information in the drug monographs up to date and relevant to New Zealand.
- If changes to data sheets are in response to requests from MARC or Medsafe a reference to the source document should be included in the change history document.
- The search for data sheets on the Medsafe web site should cover trade and generic names by default. Links to data sheets and CMIs should be on the same page as on the EMC (https://www.medicines.org.uk/emc/) web site.

- Data sheets for discontinued products (with appropriate flagging) should remain available for an agreed period of time. A similar format to the EMC web site which has a tab to "Retired Medicines" on the home page is recommended

Additional comments from NZF staff:

- The order of information should be consistent and data sheets should be presented as html documents with a side-bar menu pane for ease of navigation to the required section. This could also be achieved in a PDF with a bookmark navigation pane.
- NZF agrees with the format of European SPC. NZF editors have found the datasheets available on the https://www.medicines.org.uk/emc/ web site to be very user friendly.
- Pregnancy: there has been increasing movement away from pregnancy categorisation systems such as that used by the TGA. See AMH statement available at https://www.amh.net.au/resources/public/AMH_notice_pregnancy_categories_2016.pdf?menu=home The NZF recommends the FDA approach (or similar) which also provides information on the trimester of risk.
- When a medicine is not approved for use in a specific group this should be stated more clearly in the data sheet. For example, if a medicine is not approved for use in pregnancy, the detailed pregnancy information is still helpful, but the data sheet should also clearly state that the medicine is not approved for use in pregnant women. Explicit statements on approval status for doses and indications in children are also recommended. The NZF experience in looking for this information in a large number of data sheets is that the information is often implied and difficult to find.
- Clarity is required on the definition of an adult patient; currently some data sheets indicate that an adult is over 16 years whereas others suggest over 18.
- Synonyms in addition to the rINN are recommended if appropriate; in some cases synonyms may promote medication safety.
- Inclusion of a complete list of excipients in the product is important. The NZF also recommends that for specific excipients such as ethanol and benzyl alcohol the actual amount or percentage of the excipient is included to allow assessment of safety in certain groups such as neonates. Amounts of sugar and salt would be useful for those on restricted diets.
- The data sheet should also include information on residual substances used in manufacture and other inactive ingredients not classed as excipients. Where this substance could cause hypersensitivity this information should be placed in the cautions section.

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?

NZF generally agrees and supports the proposed format, particularly following the EMC model. The amendments outlined above appear logical. Some general comments crossover to point 2.4 above.

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?

Yes, agree

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.

Yes, agree

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.

NZF is agreeable with retaining the term data sheet

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?

The NZF has recently become aware of the Risk Minimisation Materials on the EMC web site; see - http://www.medicines.org.uk/emc/rmmdirectory

These outline general and product specific information on safe use of medicines and explain any associated potential harms in easy to understand terms. This approach, adapted for the New Zealand context, would be very useful. This could also be backed up by instructional videos for consumers linked from CMIs.

There is also the potential to link from data sheets to appropriate instructional material such as images or videos. For example, when there is a significant safety concern associated with the administration of the medicine such as dilution, method/site of injection or rate of administration.

At some stage, it may be useful to consider incorporating SNOMED terminology into the data sheet to enable interoperability with electronic systems.

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?

N/A

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, agree.

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?

NZF would like to emphasise the requirement for a change history to be available for data sheets as outlined in section 2 above.

Please include additional pages if necessary.