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	[redacted]
Company/organisation name and address	Mylan New Zealand [redacted]
Contact phone number and email address	[redacted]

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* [redacted] (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?

Use of overseas prescribing information as source document

[redacted]

[1] PHARMAC Tender for generic medicines contributes $38 million savings, https://www.pharmac.govt.nz/news/media-2014-08-18-tender/ (Aug. 18, 2014)

[redacted]

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[redacted]

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?

General requirements are appropriate, although we have some additional comments to provide.

We suggest that bullet point 3 of the general requirements should state, "If different dose forms, strengths and formulations are to be included on the same data sheet".

Currently it is permissible to reference a data sheet of another company where the dose form or dose strength is not registered by a specific company. It is requested that bullet point 9 under 2.4 is revised to clarify the expectation of Medsafe.

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?

Mylan supports harmonisation of the data sheet format and implementation of the European SPC structure. However we suggest the following changes to the guideline:

State one product data sheet for all strengths/dose forms is acceptable.

Provisional consent to be listed as applicable in the Medicine Schedule section (not pharmacology – administrative information).

We require clarification regarding adverse event information moving to frequencies from percentages. Data sheets should align between sponsors, however this information may vary between sponsors of the same molecule. For the reasons discussed above, such variations could undermine the purpose of the data sheet and cause confusion amongst health care providers and patients. To overcome this, we propose that this requirement be implemented only for new datasheets, and not implemented retrospectively during the transition.

In the data sheet template guide 6.1, paragraph 6, it is indicated that any component of flavour and/or fragrance which is known to have a required action or effect, should be included in the data sheet. This, however, would not be possible where the formulation of such flavours and fragrances has been provided "in confidence" to Medsafe by the manufacturer. Additionally we require greater clarification around what components are considered to have an action or effect.

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?

Mylan agrees with the NMA proposal for data sheet updates.

However, we wish to propose an alternative time frame of 18 months from the date of implementation of the revised Part 10, for CMN and SACN data sheet updates of marketed products. We also request a fee waiver in the instance of submitting the reformatted data sheet, with no changes to content.

The sponsor could provide a bulk product commitment for non-marketed/not available or published products to update all data sheets prior to any product launch, if required by Medsafe.

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.

Please refer to Question 1 and Question 4 for applicable comments.

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.

Mylan has preference to the term data sheet to avoid further confusion for health care professionals, who will see a data sheet with unfamiliar formatting as a result of the proposal.

However, if Medsafe were to change terminology, we have a preference to harmonise with the Australian term "Product Information".

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?

We would support the flexibility to be able to utilise technology in the provision of further information and education to patients and their care-givers. Examples include:

- Embedded hyperlinks in the data sheet to email the sponsor from the data sheet to allow patients, care-givers and health care professionals to make direct contact with the sponsor of the product.
- Embedded hyperlinks in the data sheet to standardised forms for recording and reporting adverse events

To assist sponsors it would be helpful for Medsafe to provide clear guidance of what would be considered acceptable under this clause and what would be considered promotional material in regards to expansion of e-information.

The use of links to approved electronic information in place of leaflets and package inserts benefits the public by making the most current information quickly available, without any of the delay associated with printing, run-out of existing stock in the market place. Electronic information allows opportunities to widen access to such information for patients unable to read printed instructions. However, consideration must also be given to any disadvantage this may confer to those for whom access to electronic information is limited, such as the elderly, low socioeconomic groups or those living in areas of limited internet coverage.

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?

Mylan has no objections to data sheets for higher-risk medical devices.

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

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?

We propose the date of revision and the sections revised for the previous version to be added in the "Summary Table of Changes" section. The revision history can be included prospectively with any new data sheet updates. We would not support the addition of this information retrospectively given there would be little value for prescribers versus the resource required to retrieve this information by sponsors.

Please include additional pages if necessary.