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	Philippa Davies
Company/organisation name and address	Medicines New Zealand, PO Box 10-447, Wellington
Contact phone number and email address	(04) 499 1159 Philippa.davies@medicinesnz.co.nz

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
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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:

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

☐ Importer	☐ Manufacturer	☐ Supplier	☐ Sponsor
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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?

Our members use Global Data Sheets and core safety data as the basis of the Data Sheet so removing the references would have no impact under this proposal.

- 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?

We support the requirement to include statements on the interchangeability of a biosimilar medicine and its reference product within Data Sheets. It is important that prescribers and other healthcare professionals eg pharmacists, are made aware of this because it affects prescribing and dispensing choice.

2. *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?

We agree that current Data Sheets are variable in format and greater consistency would be beneficial.

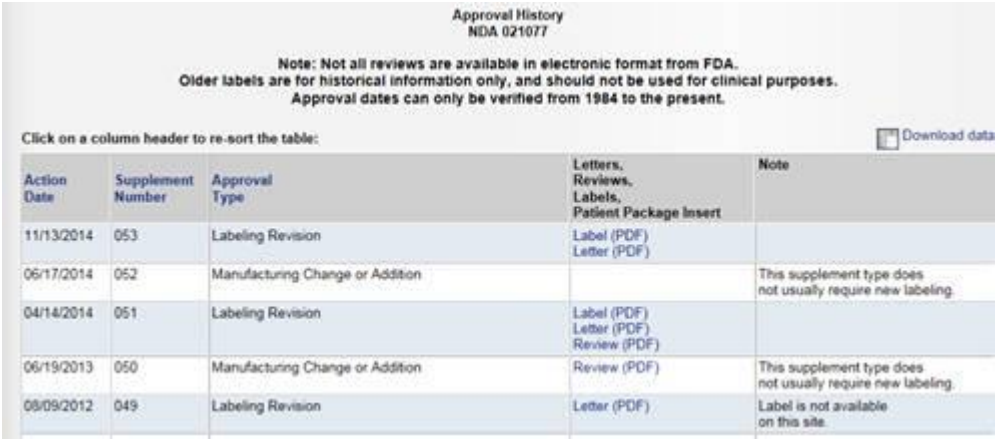
However, we do not agree with the proposal as it stands at this time for the following reasons –

- There is a need for harmonization where possible between Australia and New Zealand. Implementing this SPC format in NZ could create potential major differences in the content of Australia Products Information and New Zealand Data Sheets that would be a negative outcome. We are aware that the TGA is also reviewing the format of product information and we recommend that Medsafe work with the TGA to confirm their direction, before proposing any changes in New Zealand.

- We consider the proposal is more than a 'reshuffle' of existing information. There will be differences in the new requirements based on the EU SPC and what is provided in the current Data Sheets. More information will be required for products that have been registered for some time and some of this information is not included in the current Data Sheet, for example the shelf life is not contained in some current Data Sheets, some non clinical data is not included in some current Data Sheets. For older products, we anticipate that it would be difficult to provide relevant study reports to Medsafe. It is not clear if Medsafe proposes to require or review the supporting data or is Medsafe willing to accept automatic inclusion of data that is already included in the EU SmPC (provided it is consistent with the indication approved in NZ), will it be sufficient to omit headings where information is not available, or can the sponsor state 'not applicable' under the particular heading.

- Further clarification is required on whether additional information/supporting data that is outside of the new requirements may be required as a result of Medsafe review.

- We do not agree to the summary of changes to be included at the end of a Data Sheet. This is not a requirement for EU SPCs. We do not consider it is appropriate to include a summary of the changes within the Data Sheet document, as it would be confusing not only to the HCP but also consumers who are able to access the document from the public domain. We note that other major regulatory authorities (eg Health Canada, FDA or EMA) don't appear to have such a requirement, however, the FDA and EMA do have a running history of the regulatory changes to the prescribing information on their websites. We therefore would like to propose that Medsafe adopts a similar approach and develops a running history of changes to the Data Sheet on their website. An example of what this could look like is provided below in the screen shot from the FDA website, with one minor modification to restrict access to the latest version of the Data Sheet. Previous versions should not be available to the public.



Approval History
NDA 021077

Note: Not all reviews are available in electronic format from FDA.
Older labels are for historical information only, and should not be used for clinical purposes.
Approval dates can only be verified from 1984 to the present.

Click on a column header to re-sort the table: Download data

Action Date	Supplement Number	Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/13/2014	053	Labeling Revision	Label (PDF) Letter (PDF)	
06/17/2014	052	Manufacturing Change or Addition		This supplement type does not usually require new labeling.
04/14/2014	051	Labeling Revision	Label (PDF) Letter (PDF) Review (PDF)	
06/19/2013	050	Manufacturing Change or Addition	Review (PDF)	This supplement type does not usually require new labeling.
08/09/2012	049	Labeling Revision	Letter (PDF)	Label is not available on this site.

3. 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:

<u>New Medicine Applications</u>

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.

<u>Changed Medicine Notifications</u>

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.

<u>All other instances</u>

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?

We maintain that more than just changes to the layout are required, see answer to question 2. Due to the extent of the changes required, the proposed timelines are not sufficient for any changes to a Data Sheet format.

We would propose a 2 year transition period for all approved medicines (marketed and non-marketed) from the date a new format for Data Sheets is adopted by Medsafe. The 2 year transition period takes into account the time required to convert the current NZ Data Sheet into a new format and submission of the required SA-CMN or CMN to Medsafe.

It should be noted that the sponsors will also need to manage the implementation of the new format into the artwork in instances where the NZ Data Sheet is provided as a leaflet within the medicine pack. Whether this activity is included in a transition period depends on any requirements for package inserts, and must take into account that timelines can vary depending on forecasted orders for the medicine, whether the medicine is a high or low volume product, as well as different manufacturing lead times for medicines. For example, some medicines such as vaccines take much longer to manufacture (approx 6 months) compared to pharmaceuticals (approx 3 months).

Additionally, it needs to be recognised that the burden of changing the format of Data Sheets is the greatest for those sponsors who have a large number of approved medicines.

Clarification is needed on the format to be used when submitting an Abbreviated NMA as this is not included in the timelines above.

We are in favour of continuing the option of submitting the Data Sheet in the EU SPC format, prior to formal adoption by Medsafe, with the understanding that changes to the Data Sheet may be required during evaluation if the format requirements are modified following the outcome of the consultation.

4. 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.

We would maintain that more than just changes to the layout due to the reasons above (Question 2).

We note that this proposal does not affect package inserts however we would like Medsafe to confirm that the Australia Product Information can be used as a pack insert (where the medicines consent is the same in both countries) for injectables to avoid rework. This would be until such a time that pack inserts are not required in Australia.

5. 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.

Under the new Therapeutic Products Bill we would propose the term is New Zealand Product Information (PI).

6. 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?

Going forward we agree with including internet links, and /or QR codes to access information. This is on the condition that this would be on a voluntary basis only because where there are shared packs with Australia there may be restrictions at the TGA that prevent this.

We would like to see the move to Data Sheets and Consumer Medicines Information (CMI) only being required to be available online.

7. 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?

For higher-risk medical devices there may be some value and benefits of having an *Instructions for Use* document available for such devices.

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

Our position is that for lower risk medical devices, where notification only is required to Medsafe via WAND, *Instructions on Use* would be more appropriate than a Data Sheet. This approach is similar to the current TGA medical device requirements.

9. *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?

When there is agreement for Medsafe to change the format of Data Sheets, healthcare professionals (HCP) must be alerted to any change in Data Sheet format and content by way of an article/news item on the Medsafe website, highlighting the order in which information may be found, and Prescriber Update.

Medsafe could also leverage this to increase HCP awareness of the importance of Data Sheets as the guiding document for prescribing products.