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	Medicines Australia
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?

We would like to propose re-naming this document to 'New Zealand Product Information (PI)'.

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?

1. Digital info = Medsafe proposes the use of QR codes to access information, internet links included in DS or CMIs to instructional how-to-use video or further educational materials. Agree with this proposal if this is on a voluntary basis. For shared packs this could be an issue as TGA have specific guidelines on the use of QR codes, web links etc.

2. Medical Devices = Medsafe proposes to make DS a requirement for higher-risk medical devices when they are notified to WAND, as part of the new Therapeutic Products legislation. Also, if you open the "Medsafe Data sheet guideline consultation submission template" you will see that Medsafe have asked sponsors to comment on the below two questions: Medsafe proposes to make DS a requirement for medical devices when they are notified to WAND. Instructions for use seem more appropriate for Medical Devices.

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.

Timelines to implement are proposed according to the application type (NMA, CMNs, others) with a 1st Jan 2017 overall deadline. We would like to propose a 2 year transition period for all approved medicines (marketed and non-marketed) from the date the new EU SPC 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 the 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. However it is not proposed to include this activity within the transition period as timelines for artwork implementation 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 this transition will be greatest for those sponsors who have a large number of approved medicines (with a registered Data Sheet).

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.

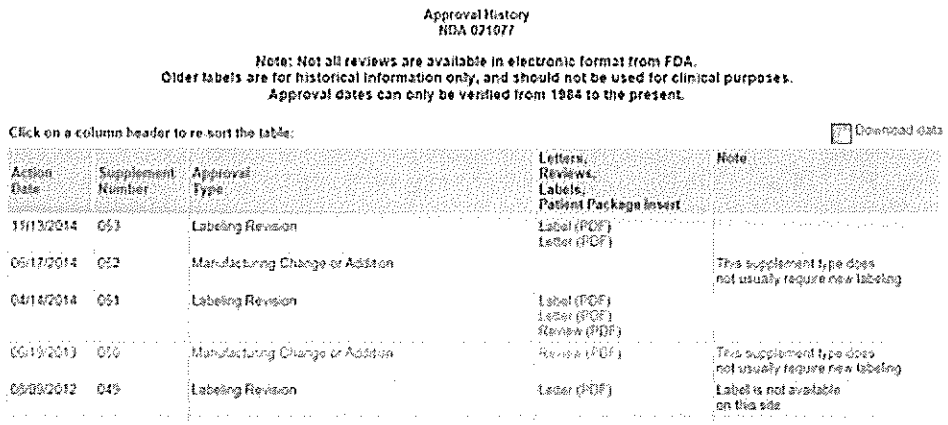
9. Would you support making device data sheets a requirement for medical devices when they are notified to WAND?

Position on the above questions relating to medical devices is that for lower risk medical devices, where notification only is required to Medsafe via WAND, instructions on how to use the device would be more appropriate rather than a Data Sheet. This approach is similar to the current TGA medical device requirements. For higher-risk medical devices there may be some value and benefits of having a Data Sheet available for such devices.

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?
    - Medicines Australia agree that current Data Sheets (DS) are variable in format and greater consistency would be beneficial with the proposed SPC format if all that is intended is to reshuffle the currently approved information.

- Medsafe have previously indicated that information will be reused when requested for an existing DS. For current DS switched to the proposed format, some headings may be left blank or as 'n/a'. Is Medsafe expecting a full SPC for new products? When converting the current NZ Data Sheet to the new EU SPC format, there is likely to be instances where the information is not always contained within the current NZ Data Sheet but required for inclusion in the new EU SPC format. This may be due to historical reasons (given the age of some of the medicines) or an inadvertent omission. For example, when the shelf life is not contained within the current NZ Data Sheet and this detail is required in the new format of the Data Sheet (ie sub-heading 6.3 Shelf life of the template). Another example is the need to include non-clinical data within the new format (ie sub-heading 5.3 preclinical safety data of the template). Often this level of detail is not contained within the current Data Sheets for older products. We therefore would like to request clarification from Medsafe on how to manage and document such missing information. For example, will Medsafe expect the sponsor to add this information when re-formatting existing information into the new EU SPC format, or will it be sufficient to omit the particular heading from the new EU SPC format, or is it expected that the sponsor will state 'not applicable' under the particular heading?
- More detailed information is generally included in SPCs compared to Global Datasheet Sheets as a result of EMA review. Is there an expectation that all information from the SPC would be in the DS? In Europe the SPC is submitted based on the company's Global Data Sheet, however often additional or more detailed information is requested during review by EMA. Given this, we would like clarity from Medsafe whether they intend simply adopting the SPC format or will they also be expecting more comprehensive information to be included under each of the sections compared to their current practice.
- We would like to recommend Medsafe give consideration to alerting Health Care Practitioners (HCPs) of the proposed format changes to the NZ Data Sheet by way of an article/news item publication on their Medsafe website, highlighting the order of the information to be presented in the NZ Data Sheet.
- We do not believe it is appropriate to include a summary of the changes within the Data Sheet document, this could be confusing not only to the HCP but also consumers who are able to access the document from the public domain, particularly if it is intended to be a running list of changes. 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 consider adopting a similar approach that is, developing 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

- Additionally, we note that the Medsafe consultation document on Data Sheets does not specify whether the new format should be used when submitting an Abbreviated NMA. We are in favour of submitting the Data Sheet in the proposed 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.

- We believe there would be value to the HCPs and pharmacists in including statements on the interchangeability of a biosimilar medicine and its reference product within the Data Sheet.
- There is a need for harmonization between AU & NZ. Implementing this SPC format in NZ could create potential major differences in the content of AU PIs and NZ DS that would be a negative outcome. There are ongoing meetings with the TGA on the format of the Australian PI and we would encourage Medsafe to continue dialogue with the TGA and confirm their position before implementing any change.
- Until such time as pack leaflets are no longer required in AU, there would need to be an agreement that the AU PI can be used as a pack insert in the case of injectables to avoid rework. The understanding being that the medicine consent is the same in both countries. Looking forward there may be an opportunity for Medsafe to consider removing hardcopy datasheets from the packs and move to electronic and other means of dissemination, which will increase HCPs and patients access to important up to date information.
- The requirement to provide separate data sheets for different dose forms, strengths and formulations of the same medicine is acceptable as long as it does not become mandatory regardless of practicality.
- It is an administrative burden to maintain multiple data sheets where deemed unnecessary (e.g. same safety information and indications across strengths or formulations etc) for both the sponsor and Medsafe.
- Medsafe should accept one data sheet for multiple strengths or formulations in a single document for the purpose of website publication, document management and the associated administrative procedures.

Please include additional pages if necessary.