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	Alexion Pharmaceuticals Australasia Pty Limited [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)* (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?

Alexion support this change.

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?

It is understood from point 4 (below) that approved, but not marketed medicines, will be indicated as "not currently available" by a qualifying statement.

> Formulations of a medicine that have been approved, but are not yet marketed may be listed with a qualifier statement that notes the medicine is not currently available. A CMN will need to be submitted to update the data sheet prior to commencement of marketing

It was not clear however, where this will be indicated? It is inferred by the subsequent statement, that this will be on the Data Sheet "a CMN will need to be submitted to update the Data Sheet prior to commencement of marketing" however Sponsors 1) may maintain the currency of Data Sheet content despite the medicine not being available and 2) can communicate this change via the "Declaration to publish" document

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?

Yes. This Sponsor agrees with the proposed format based on the EU SmPC

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?

This Sponsor has no concerns with the proposed implementation timeline

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.

This Sponsor has no concerns with this implementation deadline.

However, this Sponsor wishes to note that it was not clear when reading the Guideline (Part 10; Requirements for Information to the Prescriber and Consumer) what the requirements are for the package insert, clearly a common manner in which to provide such information.

Whilst it was clearly stated in the consultation that this change does not impact the Consumer Medicine Information (CMI) or the package leaflet, this should be reflected in the guideline (Part 10). Not only for completeness, but because the labeling Guidance document (Part 5) states; It is recommended that, wherever possible, the medicine data sheet is used as the package insert.

For those instances, when Sponsors can include the Data Sheet as the package insert, many have done quite a bit of work in the lead up to ANZTPA to harmonise packaging with Australia. However, ANZTPA aside, for smaller Sponsors and lower volume products, an AU-NZ harmonised pack is critical for supply chain purposes. Therefore, this Sponsor requests for Medsafe and/or Guidance to confirm the following are acceptable;

o Sponsors can submit the Aus PI content "shuffled" into the NZ SmPC format, however the package leaflet can remain the TGA approved PI or

o Sponsors can submit the NZ SmPC (aligned with the CCDS or EU SmPC) and give an assurance that the package leaflet to be supplied is aligned with the NZ SmPC

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.

This Sponsor's preference is NZ Summary of Product Characteristics (NZ SmPC) to reflect the revised format and alignment with the EU SmPC.

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?

Further to above (Question 5) Sponsors require more guidance about the provision of Product Information (NZ SmPC and CMI) as a package insert (as suggested in the current Labeling Guidance, Part 5 - refer above). Ideally, confirmation that such a requirement is not mandatory.

The provision of medicine information in this manner (hard copy package insert) is outdated and with more electronic mechanisms becoming available there are better ways to communicate the latest information to prescribers and consumers. E-information provides another avenue for consumers and prescribers to access safety information/educational materials which aim to minimise potential risks and enhance the safe use of medicines.

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?

No comment

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?

No comment

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?

Please include additional pages if necessary.