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	Roche Products (NZ) Limited
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?

Roche proposes that the ability to reference overseas prescribing information as the source document for the content of the New Zealand data sheet is important to be retained.

The ability to use an overseas source document is particularly important in cases where registration details are aligned between Australia and New Zealand. The harmonisation of registration details between Australia and New Zealand provides increased efficiencies in cases where supply is shared between Australia and New Zealand and in those companies where the regulatory affairs department supports activities in both countries.

Flexibility to use the overseas prescribing information as a source document for content is particularly important in those cases where the New Zealand approval is based on an abbreviated evaluation process.

It is noted that significant safety updates must be made within the timelines required by the relevant Pharmacovigilance guidelines.

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 provided under Section 2.4 is appropriate and easily understood.

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?

Roche agrees in principle to a data sheet format whereby the most important information is presented earlier in the document, such as that outlined in the EU-SPC. Roche also supports the principle of a single format for the data sheet in New Zealand in which information is presented with a consistent style and layout wherein the important information for prescribing is easily located.

In adopting an EU-SPC format, it is important that the content of the New Zealand data sheet be reflective of the data evaluated by Medsafe. The adoption of an EU-SPC format should not diminish the important role of Medsafe's evaluation and ensure the content of the data sheet is consistent with the assessment of the benefit risk in a New Zealand context.

New Zealand specific adaptions to the EU-SPC should be avoided to retain the consistency and simplicity of the template.

Roche does not support the inclusion of the proposed Summary of Changes table due to its potential to cause confusion. Mechanisms are already in place to alert healthcare professional and consumers of important and significant safety updates to medicines. There may be value in transparency of other updates to the data sheet and this could be achieved with the inclusion of more details on the changes in the application search section of the Medsafe website.

In implementing the proposed EU-SPC format, there will potentially be cases of gaps in content, i.e. sections where there may be no information to include under a particular sub-heading, more likely with older products. Roche proposes that the sponsor state 'not applicable' under the particular heading in these cases with no requirement to submit additional information. The content of the data sheet must be based on Medsafe's evaluation at the time the original supporting dossier was evaluated. Updates to the content of the data sheet should only be required in cases where the source document has been updated.

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?

Roche supports the prospective adoption of the EU-SPC format once finalised. Roche proposes that the deadline for the transition of all data sheets to the proposed EU-SPC format be extended. Re-formatting of current data sheets will be a resource intensive project and adequate time for resource planning, allocation and coordination with other planned submission activities and supply timelines (for those products where a package insert is supplied and may require new artwork) is required. At a minimum, a two year transition period from the date of adoption of the updated Guideline should be considered for those data sheets where there is no proposed change otherwise.

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 see comments above.

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.

Roche supports the alignment of terminology with titles used in other countries for example, New Zealand 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?

Roche agrees that technology can help facilitate communication about products distributed in New Zealand and encourage the greater use of e-technology. Roche would welcome the opportunity to engage with Medsafe and industry to investigate the technology available and how it may be used to engage with healthcare professionals and patients.

At this time the introduction of expanded e-technology platforms should be voluntary, as not all healthcare professionals or consumers have equal access to the ability to use various tools and maintaining a variety of communication mediums is important.

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?

Not applicable.

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?

Not applicable.

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.