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	AbbVie Pty Ltd [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?

Removal of the ability to reference a source document has implications for shared packaging between the Australian and New Zealand markets, as highlighted in AbbVie's response to Question 10. A significant number of Sponsors operating in both markets source co-harmonised product from the same manufacturer, in an effort to maintain continuity of supply at an affordable price. As a result, many of the products AbbVie supplies to New Zealand utilises harmonised packaging and labelling with Australia.

Furthermore, AbbVie raises the concern that removing the ability to reference source documents will increase the regulatory burden, especially for older products and those with limited New Zealand distribution.

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?

AbbVie concurs that the content within Section 2.4 is appropriate and easily understood and has no additional comments to provide.

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?

AbbVie is in support of most changes as mentioned above, but have a few comments for Medsafe's consideration:

- Provisional Consent information should move from 5- Pharmacological Properties to 9- Date of First Approval, since this is a more appropriate section to include such information.
- Clarification is sought from Medsafe regarding whether there is an expectation that Companies make appropriate changes to the Adverse Events section to move towards Frequency of Occurrence in percentages, in the instance that such information is not currently presented in such a format.

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?

In the situation where a New Medicine Application (NMA) has undergone evaluation and a recommendation for consent has been made, the proposed timelines of 10 days to provide a Data Sheet in the new format is insufficient time to allow for Sponsor internal review processes. AbbVie challenges this timeline, and proposes that this be extended to 1 month during the transition phase.

With respect to Changed Medicine Notifications yet to be submitted to Medsafe, clarification is sought that revised Data Sheets to be filed during this consultation period and prior to implementation can continue to in the current format.

AbbVie also requests that Medsafe consider implementing a fee waiver in cases whereby the Data Sheet undergoes reformatting only (with no changes to content).

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.

AbbVie respectfully challenges the proposed deadline of 1 January 2017. Implementation by this date provides insufficient time to allow an internal review of all products in the Company's portfolio, followed by an exercise to redraft the Data Sheets in the new format. AbbVie is proposing that a two year implementation period by allowed, following the conclusion of this consultation and commencement of implementation. Whilst Medsafe has suggested that the expectation is to only involve a "shuffling" of existing content, AbbVie has internal review processes that must be adhered to when such a change is initiated, and may include a review of content against core data/reference safety information. Additionally, such an internal review would also be utilised to ensure that the messaging is being communicated clearly and appropriately in accordance with the proposed Data Sheet template, to best support patient outcomes.

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.

AbbVie considers the use of either "prescribing information" or "product information" as the preferred term over "Data Sheet", as these terms more accurately represent the content of the document for which it describes, and further aligns New Zealand with international best practice.

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?

AbbVie is supportive of embracing technology and e-information to increase access for patients wanting more information with regard to a medicine in a timely manner, and proposes that Medsafe consider allowing Companies to include hyperlinks to information related to patient support outcomes, educational materials and instructional videos. Medsafe would need to ensure that such information be regularly updated to ensure best practice and legal compliance.

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?

Although AbbVie is not currently a sponsor of higher-risk medical devices, AbbVie supports a similar approach to making available a revised formatted version of the Instructions for Use (IFU) to include similar information as the Datasheet and enabling access via the Medsafe website. The 'Instructions for Use" could be the term that is still used for such a document as this is a known terminology.

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?

There are a larger number of Medical Devices available in general when compared to Medicines on the market. It would be considered an additional resource and financial burden to Sponsors if such a "data sheet" is made a requirement for all medical devices, especially lower-risk medical devices. At present these lower risk medical devices do not have an instruction for use as they are deemed suitable for use without the need for further instruction. Therefore it could appear that the need for a medical device "datasheet" would not serve the intended purpose, i.e. to

assist the patient or end user with helpful information.

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?

AbbVie commends Medsafe's efforts in identifying the need to make changes to the presentation of the Data sheet, with the intent to improve patient outcomes. AbbVie acknowledges that there are a number of proposed changes to the formatting/presentation of the NZ datasheets and whilst they seem logical, AbbVie believes that the notion of using the EU SPC as a basis for the format of the Data sheet as the most *fit-for-purpose* solution should be validated through prototyping prior to full implementation of the said changes. Whilst the EU SPC is a credible format, there also exists an opportunity for validation to ensure better outcomes for Healthcare Professionals and Patients. To this effect, AbbVie would like to work with Medsafe and offer to prototype one of our PIs through the process to test these assumptions for Medsafe.

AbbVie wishes to provide other comments for Medsafe's consideration:

It is noted that for the purposes of "The Changes to Data Sheet Process", package inserts are excluded. AbbVie wishes to highlight that Companies supply products to New Zealand that share packaging with Australia due to the relatively small New Zealand market. The Australian Product Information is often included as a package insert for these products, especially for injectable products and oral contraceptives. AbbVie wishes to seek clarification of Medsafe's expectations in these situations - Is it expected that the NZ Data Sheet and the Australian Product information are both maintained for the New Zealand registration?

Section 2.6 of the current version of Part 10 of the GRTPNZ specifies that paper copies of the draft Data Sheet as well as the completed *Declaration to accompany a data sheet submitted for approval* form be submitted. This is no longer present in the revised draft of Part 10. Clarification is required in relation to whether this implies that electronic copies are now acceptable in lieu of paper copies.

In the revised consultation document relating to Part 10 of the GRTPNZ, under sub-section 3.1, AbbVie suggests that an explanatory phrase be added for clarity as follows:
"CMI is an interpretation of the approved data sheet (or other source document if there is no data sheet**, e.g. in the case of a general sale medicine**) for the medicine ..."

In the revised consultation document relating to Part 10 of the GRTPNZ, under sub-section 3.4, confirmation is sought from Medsafe that the list of source documents is not according to an order of preference.

Clarification is sought on how the summary of changes to a Data Sheet are to be captured, under the heading "10. DATE OF REVISION OF THE TEXT" in the Data Sheet template, as this is not detailed in the explanatory guide. Two suggestions are proposed:
- Please note changes under [*insert relevant headings and subheadings*]
- Please note changes denoted by *

Please include additional pages if necessary.