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	Bayer Australia Ltd [redacted]
Contact phone number and email address	[redacted] [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 (e.g. 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?

While Bayer agrees that medicine labelling should be prepared in accordance with company core data set, flexibility should be exercised to allow the use of contents from the approved Australian Product Information as the basis of Data Sheet in line with the registration process. Considering applications that are submitted via Abbreviated Evaluation Route whereby overseas evaluation reports including approved product details are part of the submission package, it is a pre requisite to allow contents of the respective overseas label to be adopted in the Data Sheet as an outcome of evaluation.

Furthermore, to maintain product supply sustainability, it is more cost effective to supply harmonised (Trans-Tasman) product across Australia and New Zealand. Thus it is imperative to be able to refer to the approved Australian Product Information as the source document for Data Sheet in order to align the product details and maintain a common Consumer Medicines Information.

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?

Bayer in general agrees that the general requirements set forward are appropriate and easily understood, however would like to highlight a couple of points for consideration:

- 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.

- Although it is not a new requirement in this edition of amendment, Bayer still wishes to make a comment regarding marketing status stated on data sheets. Marketing status of products by presentation is actively maintained by the sponsors by means of CMN and/or notification to publish data sheet on Medsafe website which is then reflected in Medsafe Product Database and presented in the Medsafe Product Detail. Bayer is of the view that the Medsafe Product Database is sufficient to inform consumer and prescriber of product availability by presentation, thus it is redundant to include a qualifier statement with respect to marketing status of registered presentations in the data sheet.

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?

Consistent with the guidance document 'A guideline on Summary of Product Characteristics', the Data sheet template explanatory guide provides a detailed and prescriptive guidance on how a data sheet is prepared. It is particularly useful when a data sheet is prepared based on a company core data sheet which follows the format of a SmPC. However, it poses challenges on sponsors if an Australian PI is used as a source document especially if application undergoes abbreviated evaluation route whereby Australian product registered details are referred to in support of a New Zealand application. It is emphasized that the contents in the Product Information are not always consistent with those described in the SmPC guidance in every aspect. In addition, as mentioned previously, for commercial reasons company may supply Trans-Tasman product in Australia and New Zealand, thus it is important to align prescribing information to maintain harmonised products.

Bayer proposes the option to allow flexibility to adopt **content** from approved Australian PI (or other) as the basis and have consistency in the **format** in accordance with guidance set out for SmPC, with the changes captured above.

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?

Bayer considers any planned data sheet updates and draft data sheets that are already in the evaluation process can be prepared in the new format once an effective date is announced.

For existing data sheets where format change is identified as the only update, the currently proposed transition timeframe should be extended to two years to allow sponsors to introduce the change. Bayer is of the view that conversion to the SmPC format is not as simplistic as it appears for every product, especially data sheet for older products where information may not be compliant with the guidance as described in the Explanatory Guide.

It is reassuring that Medsafe does not foresee any changes to the content as a consequence of data sheet reformat which defines the scope to relocation of text. However clarity is sought if it is acceptable that the content is non-compliant with the Explanatory Guide, if so, Bayer suggests that the first bullet point under section 2.5 in *Guideline on the Regulation of Therapeutic Products in New Zealand* be revised to the effect:

"Sponsors should use the Data sheet template when preparing their data sheets, the Data sheet template explanatory guide may be used to assist with data sheet preparation, information in boxes is for information only."

With regard to the proposal to provide an overview of the last change(s) to the data sheet under section 10, Bayer is of the view that while it is good practice to notify prescribers of important updates, there is a risk that important information is lost when there are numerous changes to

the document and the list of changes can become exhaustive with every single change described. The focus should always be on the currency of information and information should be read in its totality; Bayer considers a full list of changes is of little value to the prescriber when important changes cannot be differentiated from the rest. In light of that, it is sufficient to list out the sections affected which enables the prescribers to refer to the relevant section, with less risk of loss of detail or undue prominence to changes.

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.

Similar to comments made to Point 4, transition period of 2 years is proposed.

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.

Bayer's preference is to continue to use the term Data Sheet.

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?

Bayer supports the use of technology such as QR codes to direct patients to the CMI or instructions for use. An obvious benefit is to allow access to up-to-date information. As smartphones and mobile devices are more commonly used, use of QR code gives the patient the convenience to access information anytime anywhere.

It would be encouraging for the sponsors to explore and invest in the technology if Medsafe holds an open view on the adoption and partner with the industry on how this should be regulated rather than applying a set of stringent regulations from overseas jurisdiction.

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?

Bayer has no comments in relation to this question.

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?

Bayer has no comments in relation to this question.

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?

Bayer has no further comments to add.

Please include additional pages if necessary.