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	Pfizer New Zealand Limited [redacted] [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 (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?

Pfizer advises that the company core data sheet (referred to as the Core Data Sheet (CDS) is the source document for preparing the Data Sheet for new medicines and subsequent updates including additional indications and safety updates.

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?*

In comparison to the current general requirements, the information presented in section 2.4 is more easily understood. Consideration should be given to whether a date of revision should be included for version control.

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?

No, Pfizer is not in agreement with the adoption of the EU SmPC format and will itemise its concerns below:

Pfizer supports all initiatives to look for opportunities to achieve consistency in Data Sheet format and content requirements. It also supports initiatives that ensure that prescribers can easily access information that is required for safe and effective prescribing of medicines.

With this in mind, Pfizer encourages Medsafe, rather than adopt a new format in isolation from Australia, look to initiate joint negotiations with TGA to develop a fit for purpose, harmonised format for Data Sheets (New Zealand) and Product Information documents (Australia). In the interim, we would favour maintaining the status quo whilst due consideration is given to a common ANZ format endorsed by both Medsafe and TGA. The ultimate goal of both agencies should be that these documents reflect international best practice instead of simply adopting an existing format such as the EU SmPC format which includes the introduction of additional content to meet New Zealand legislative requirements (further details provided in response 4).

The responses obtained during the Therapeutic Goods Administration's consultation on "Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)" held in 2013 have provided valuable input for both agencies to consider. Despite the Australia New Zealand Therapeutic Products Agency not proceeding, this does not preclude both agencies working together to develop a common format. This would represent a pragmatic approach that would ultimately benefit not only industry, but also healthcare professionals and ultimately consumers and patients.

Impact on Supply and Cost

It is important to recognize that a large proportion of New Zealand and Australian products are sourced from the same suppliers/manufacturers, which in the case of New Zealand patients, ensures access to a broader range of medicines at affordable prices. It is for this reason that many international companies supply product to New Zealand in joint ANZ packaging and labelling. A divergence between the content and format of Australian and New Zealand documents is likely to impact negatively on the above situation.

The population of New Zealand is quite small relative to other countries. As New Zealand sponsors are unable to meet the minimum order quantities required by international manufacturing sites this is overcome by placing orders for stock in conjunction with Australian stock requirements. This reduces the cost of the medicine in New Zealand and ensures access of these medicines to patients. The alternatives would be for sponsors to place orders for the minimum order quantities. This will have a knock-on effect by increasing the price to patients as excess stock will need to be destroyed due to batch expiry. The other alternative is not to make these medicines available in New Zealand.

The above also impacts the cost of funded medicines through PHARMAC. For low cost medicines, it may impact the availability of the medicine. The implications of this initiative to the pricing authority should also be considered.

Impact on prescribers and other health care professionals

Pfizer supports initiatives that ensure that prescribers can easily access information that is required for safe and effective prescribing of medicines. Due to the close relationship between New Zealand and Australia in terms of trade and knowledge sharing, Pfizer believes that a harmonised format for Data Sheets and Product Information documents is preferable for healthcare professionals to navigate, and will eliminate confusion as to where to find specific information. This would also meet Medsafe's objective of developing a data sheet that provides information on how to use medicine safely and effectively.

Impact on Sponsor burden

Pfizer believes that content and format uniformity between New Zealand and Australia is an important objective, since many international companies supply product to New Zealand in joint ANZ packaging and labelling. The cost to maintain 2 formats of prescribing information and the impact on products with pack inserts are significant.

To elaborate on the above points, parenteral products that share common ANZ packaging contain the Australian PI as the pack insert to meet TGA requirements. Uniformity of content and format between New Zealand and Australia prescribing information eliminates the need to either rework or remove the leaflets, both cost and time consuming exercises. It also facilitates an uncomplicated transfer of medicine supply between the two countries when needed. *It is noted that the Consultation advises that "leaflets and CMIs" are out of scope, and Pfizer has interpreted this to mean leaflets intended for patients and not prescribers; otherwise two formats for information to prescribers would cause confusion and defeat the intended aim of adopting the SmPC.*

Whilst it is acknowledged that inserts for parenteral products are not required under current legislation, such inserts provide useful information i.e. injection incompatibilities, cytotoxic details to ward staff at the point of use. Ideally, such leaflets should be provided electronically, however, until such leaflets are no longer required Trans-Tasman, the issues raised above still apply.

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:*

<u>New Medicine Applications</u>

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.

<u>Changed Medicine Notifications</u>

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?

No Pfizer is not in agreement with the above comments.

1. EU SPC format should involve only formatting and layout changes and does not involve changes to the content of the data sheet.

The currently approved New Zealand Data Sheets do not contain all the information that Medsafe is recommending. These will be itemised and discussed below. Therefore, additional resource is needed not only to reformat and change layout but to make additions.

To be specific, this includes:

- Clinical Trial data: whilst the SmPC-styled format allows for the inclusion of clinical trial data in section 5.1, it appears that the intention is to keep this concise and quite succinct. Currently, the Data Sheet allows for substantial information regarding clinical trial data, and this is particularly important for medicines with several indications. The inclusion of detailed information provides valuable information to prescribers and is often important to sales representatives when detailing to healthcare professionals regarding clinical trial results and the observed safety for a given medicine.
- Undesirable Effects: the proposed format includes a tabulated summary of adverse reactions. Whilst some products already present a tabulated summary in the current data sheet, the additional resource required to tabulate adverse reactions for the more mature products on the market would be quite substantial.
- Shelf life: the proposed format includes a requirement for shelf life information. Such information is superfluous in a Data Sheet as it should not influence prescriber choice and has the potential for confusion where multiple presentations may have different shelf lives. It also has the potential for patients reading this information to assume that a 2 year shelf-life means that the expiry is 2 years from the time of purchase.
- Summary table of changes: Pfizer does not agree with the requirement to include a summary table of changes. Any significant safety changes are better communicated to healthcare professionals through a "Dear HealthCare letter". Whilst some updates to the Data Sheet may be quite simple and limited, others may be complex and extensive. The level of detail included in such a summary will vary enormously due to the discretional and subjective nature of this requirement. Furthermore, summarising extensive and complex updates to a Data Sheet will add to the resources required to prepare a Data Sheet.

2. Timelines for implementing the changes to the new process and switch to the new data sheet format.

Pfizer disagrees with the proposed timelines. As this proposal is still in the consultation phase, a transition period should not be established until the suggested inter-agency negotiations and subsequent consultation process has been concluded. The transition period must also take into

account the large number of Data Sheets sponsors will be required to update. In the case of Pfizer New Zealand, this would include more than 300 datasheets.

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.

Pfizer is not in agreement with this proposal.

Rather than introducing a specific requirement for Data Sheets in New Zealand plus additional "minor" adaptations to meet certain New Zealand legislative requirements and current regulatory policy, Pfizer supports the need to establish a transition period to allow for inter-agency, TGA and Medsafe, discussions to work towards a common prescribing information, with respect to ***content and format,*** that can be used in both countries.

As described in response 4, to meet the proposed format, additional resource would be needed to not only "shuffle" existing content but to also add the additional information documented in the proposed template.

It is noted that these proposals do not affect package inserts or consumer medicine information. As explained in response 3, Pfizer has interpreted this to mean leaflets intended for patients and not prescribers. Many international companies supply product to New Zealand in joint ANZ packaging and labelling. In the case of parenteral products, this would include the Australian PI as a pack insert. If the proposal to change to the SmPC style format proceeds, the two formats for information to prescribers would cause confusion and defeat the intended aim of adopting the SmPC. The alternative is to either remove the insert, rework the leaflet or have separate SKU's to Australia, all of which are costly alternatives and risk the increase of cost to New Zealand patients and potential supply.

In regard to the implementation time suggested in the current consultation there is no transition period allowed. The January 2017 timeframe proposed by Medsafe for sponsors to have submitted reformatted Data Sheets will be unachievable for companies that have a large number of products. For Pfizer New Zealand, this would include more than 300 datasheets.

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.

As Pfizer supports a trans-Tasman format for prescribing information then a common name would be preferable.

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?

Pfizer supports the use of technology to facilitate the dissemination of information regarding medicines to healthcare professionals and consumers.

Patient safety can be greatly enhanced with the use of technology to deliver the most up to date prescriber and consumer information. Consideration should be given to how healthcare professionals and consumers access information today and moving into the future, as the advent of the internet has fundamentally changed the way people access health information.

To streamline processes, reduce administrative burden to Sponsors and Medsafe, and to ensure accuracy of Data Sheets published, Pfizer suggests that Medsafe adopt the use of technology to facilitate the electronic distribution of Data Sheets (and Consumer Medicine Information). Currently, and in the proposed guidelines, Sponsors are required to submit an approved DS to Medsafe for publication, with each DS submitted as a separate email and accompanied by a signed declaration. It would be possible to adopt a similar process to that used in Australia by many Sponsors to distribute PI and CMI to government agencies, publishers and industry associations. The service provided allows Sponsors to submit a document to a secure and single centralised repository and on-distributors such as the TGA, to have access to updated documents via real time release. This reduces the risk of out of date medicines information, allows prescribers access to the most current documents, and would meet Medsafe's requirement to submit DS for publication.

The use of QR codes or internet links to direct consumers to CMI or instructions for use would help with maintaining currency of documents however consideration would need to be given to products that use common packaging for Australia and New Zealand and whether or not the information accessed is harmonised.

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?*

The majority of international medical device companies supply the same product for the ANZ region. Given that, Pfizer recommends that Medsafe align with TGA as per the Essential Principle Requirements, specifically EP13.4 which relates to maintenance of a document termed as "Instructions for Use". This would present a pragmatic approach that will provide industry with consistency in the product development process while aiding healthcare professionals and consumers alike.

High-risk devices generally constitute Class IIb and above (EU and TGA classifications). All manufacturers and suppliers of medical devices in Australia are required to maintain an IFU document that contains information outlined with the Essential Principles. Providing this information to MedSafe at the time of WAND notification would not appear to add any significant regulatory burden to the industry given they are requirements for EC certification (EU) as well as ARTG inclusion (TGA).

The IFU generally includes indications, contra-indications, clinical safety statements (if applicable), precautions for use and any other information related to safe use of the device. The provision of this information with a WAND notification may serve to further strengthen pre-market requirements in NZ as currently there is no pre-market assessment and this could lead to potentially unsafe medical devices being provided within the NZ healthcare system. This initiative will further ensure only sponsors with certified quality systems and documentation will only be able to provide medical devices that are safe for patient use in the NZ market.

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?*

As mentioned above, it is recommended that Medsafe adopt the term "Instructions for Use" rather than Data Sheet. The submission of the IFU with a WAND notification will not add any significant regulatory burden to current Sponsors. Given, WAND is a pre-market notification process, it is assumed that this information will not be assessed by Medsafe in the pre-market. Therefore, provision of this information would not delay the WAND notification process. However, further clarification is sought on assessment of the Data Sheet by Medsafe within the pre-market.

Additionally, Medsafe currently does not provide guidelines for development of an IFU/ Data Sheet and Pfizer suggests adoption of industry best practice. It is unclear based on this consultation whether Medsafe now seeks to develop a guideline for information to be provided on the recommended Data Sheet /Instruction for Use. However, it is recommended to closely align these guidelines to the current Essential Principle 13 and Essential Requirements mandated by Therapeutic Goods Act 1989 and Medical Devices Directive 93/42/EEC respectively.

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.