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	AUSTRALIAN SELF MEDICATION INDUSTRY [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

Australian Self-Medication Industry Ltd.
[redacted]

31 March 2016

Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

Email: medsafeadrquery@moh.govt.nz

Dear Sir/Madam,

Changes to the data sheet process and the Guideline on the Regulation of Therapeutic Products in New Zealand. Part 10: Requirements for information for prescribers and consumers

We refer to your call for submissions re the above.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates this opportunity to provide comment on the proposed reforms.

Summary

Many Australian sponsors supply product to New Zealand in joint ANZ packaging and labelling, this provides benefits for sponsors and consumers in both Australia and New Zealand.

ASMI supports:

- Efforts to improve the utility of the available information.
- Collaboration between Medsafe and the TGA to ensure trans-Tasman harmonisation.
- Reforms which acknowledge the differences between prescription and non-prescription medicines.
- Adequate transitional arrangements, noting that even if the requirements are harmonised between Australia and New Zealand, sponsors with trans-Tasman products will have two separate regulatory processes to comply with.

Background

In relation to non-prescription medicines, ASMI makes the following points:

- Data sheets, CMI and pack inserts are only required for certain non-prescription medicines.
- For the majority of non-prescription medicines, the primary source of information about a medicine will be the label.
- Where a data sheet, CMI or pack insert is required for a non-prescription medicine, the information may be less detailed than for prescription medicines.

It is therefore important that any reforms to the data sheet requirements accommodate the differences between prescription medicines and non-prescription medicines.

In relation to the TGA's 2013 consultation on "Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)", ASMI notes that the consultation was considered to be a joint agency project although the Australia and New Zealand joint agency is no longer proceeding. ASMI made a submission to the 2013 consultation supporting (among other things) a revised PI format (with only minor changes to the TGA's proposed format) and a harmonised approach between Australia and New Zealand. While there have been no changes to the PI format from the 2013 consultation, ASMI still supports a revised PI format and a harmonised approach between the two markets.

ASMI Response

The ASMI responses in relation to each of the ten (10) questions are attached.

To those responses, ASMI would like to add the following comments.

In relation to the consultation materials, ASMI notes that:

- This is a proposed change to the data sheet formatting only and that "there is no need for content changes to data sheets under this proposed process".
- The consultation materials acknowledge the TGA's 2013 consultation on "Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)".
- The proposed changes will not affect package inserts or CMI.

Nevertheless, revising the data sheet template to align with the EU SPC format will inevitably reduce harmonisation with Australia and could have a significant impact on sponsors marketing product in both countries.

In ASMI's view, the New Zealand data sheet requirements and the TGA's Product Information requirements should be as closely aligned as possible with each other. Any differences between the two markets will result in difficulties for the supply chain and will add regulatory complexities.

ASMI supports initiatives to look for opportunities to achieve consistency in data sheet format and content requirements. We also support initiatives that ensure that prescribers can easily access information that is required for prescribing or recommending medicines.

However, we do not support Medsafe adopting a specified format in isolation from Australia. 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.

Rather, we encourage Medsafe to initiate joint negotiations with TGA to develop a harmonised format for data sheets (New Zealand) and PI 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 responses obtained during the TGA's consultation on "Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)" held in 2013 will have provided valuable input for both agencies to consider. Despite the Australia New Zealand Therapeutic Products Agency not proceeding, this should 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.

An aligned New Zealand and Australian approach to these documents will ensure the administrative burden for sponsors in initiating data sheets and PIs and maintaining their currency is minimised. A common ANZ format will also ensure that all other impacted documents, including those used as inserts for injectable products, are consistent in content and format, which will reduce the potential for confusion for Healthcare Professionals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

[redacted]

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?

ASMI makes no comment in relation to this question.

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?

ASMI makes no comment in relation to this question.

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 ...
- 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?

ASMI supports reforms aimed at improving the utility of the information provided to healthcare professionals and consumers.

ASMI supports a collaborative approach between Medsafe and the TGA to ensure trans-Tasman harmonisation of requirements.

ASMI does not support reforms aimed at producing a New Zealand specific data sheet.

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 ...
- Do you agree with these proposals?
- If not, what do you suggest?

ASMI agrees with the proposed timelines for New Medicine Applications.

For Changed Medicine Notifications and for all other instances, ASMI suggests a transition period of 24 months from the time at which the new requirements are finalised. In relation to adequate timeframes for transition, ASMI notes that even if the requirements are harmonised between Australia and New Zealand, sponsors with trans-Tasman products will have two separate regulatory processes to comply with.

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.

In our view, 1 January 2017 will not allow sufficient time for sponsors to comply with any new requirements. Instead, ASMI suggests a transition period of 24 months from the time at which the new requirements are finalised.

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.

In the interests of harmonisation between Australia and New Zealand, ASMI suggests that the term "Product Information" be used.

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?

ASMI supports the use of digital solutions to provide consumers with up-to-date information about non-prescription products. Digital platforms will allow businesses to update the information more efficiently, but there are barriers to their implementation, for example, the time needed to maintain another set of data, small pack sizes limiting the space available to fit QR codes and making sure that the digital information complies with the regulatory requirements.

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?

ASMI makes no comment in relation to this question.

9. Would you support making device data sheets a requirement for medical devices when they are notified to WAND?

ASMI makes no comment 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?

Refer to the cover letter for our comments in relation to harmonisation of requirements between Australia and New Zealand and distinguishing between prescription and non-prescription medicines.