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	NEW ZEALAND SELF-MEDICATION INDUSTRY ASSOCIATION
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
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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:

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I am, or I represent, a: ***(tick all that apply)***

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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

23rd March 2016

Clinical Risk Management
Medsafe
PO Box 5013
WELLINGTON 6145

Email: medsafeadrquery@moh.govt.nz

Dear Sir / Madam

CHANGES TO THE DATASHEET PROCESS AND GUIDELINE ON THE REGULATION OF THERAPEUTIC PRODUCTS IN NEW ZEALAND – PART 10: REQUIREMENTS FOR INFORMATION FOR PRESCRIBERS AND CONSUMERS

NZSMI (New Zealand Self Medication Industry Association) is pleased to be able to respond to the above consultation with our submission.

NZSMI is the premier body in New Zealand representing companies that are involved in the manufacture, distribution, marketing of consumer healthcare products. We represent approximately 85% of the companies who trade in over the counter (OTC) medicines in New Zealand and specifically 65% of companies in the Complementary Healthcare Product space.

Yours faithfully,

New Zealand Self-Medication Industry

EXECUTIVE SUMMARY

- NZSMI congratulates Medsafe on the datasheet template and its layout with key information to the fore. We support the choice of the EU format in preference to either the US or Australian format. We also believe the datasheet template explanatory guide to be particularly helpful.

- NZSMI believes that where the revision to the datasheet only involves reformatting and no content change, it could follow the Self-Assessable Change Notification process, however we would seek a fee waiver for this change.

- NZSMI believes marketed products should be dealt with first and would request that there is no update or revision required for non-marketed products until their status reverts back to being a marketed product.

- NZSMI agrees with the recommendation to use the EU SPC format for datasheets, however, we would like to have assurance that in the interests of harmonisation with Australia, the package inserts for injectable products can be in the Australian PI format. In that instance, the sponsor will provide an assurance that the package insert is consistent with the New Zealand datasheet. Despite the fact that ANZTPA is not progressing we are of the view that harmonisation with Australia wherever possible is a strong driver as a large proportion of NZ and Australian products are sourced from the same suppliers/manufacturers which allows New Zealanders access to a broader range of medicines at affordable prices

- NZSMI has serious concerns with regard to the date proposed for implementation (1 January 2017). We would propose that a date 18 months from when the consultation process is concluded and implementation has begun, is a more practical solution.

- NZSMI would encourage Medsafe to work in conjunction with the TGA to see if they are willing to look at the proposed format as a means of harmonising their PI / datasheet layout.

ANSWERING SPECIFIC QUESTIONS POSED

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 datasheet 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 datasheets.***

   Q: Do you have any comments on this change?

   NZSMI supports this proposal. However, we believe generic companies should have the flexibility to reference market innovators or market leaders from another jurisdiction where relevant. Harmonisation with Australia and international best practice should also be considered. Many of the sponsors operating in New Zealand and Australia source products from the same suppliers and manufacturers. It is for this reason that many international companies supply product to New Zealand in joint ANZ packaging.and labelling

2. ***Section 2.4: general requirements for datasheets:***

   Q: Are the general requirements appropriate?

   Is the information easily understood?

   Are there other general requirements that you think should be included in the guideline?

   We believe the general requirements are appropriate and easily understood. However, there are a number of points that we wish to make.

   Under 2.4 on page 3, general requirements for datasheets, bullet point 3: We believe the words "strengths and formulations" needs to be added in the second sentence of this paragraph, which would then read, *"If different dose forms, strengths and formulations are to be included..."*

   - Currently it is permissible to reference a datasheet of another company where the dose form or dose strength is not registered by a specific company.It is requested that bullet 9 under 2.4 is revised to clarify the expectation of Medsafe.

   An additional point we propose to add to this section is that as an option 'in vivo' bioavailability data supporting interchangeability should be allowed and not considered as promotional information.

3. ***Section 2.5, format and style consistency in datasheets***

   Rather than restate that particular part of the guideline, we will make reference to it where appropriate.

   Q: Do you agree with the adoption and adaptation of the European summary of product characteristics format as summarised above and presented in the datasheet template and the datasheet template explanatory guide? If you do not

agree, please explain why and suggest a suitable alternative. Are there any changes you would like to suggest?

To the first two questions, NZSMI is in support. However, there are a number of changes that we would like to suggest.

In the template, Provisional Consent information is wrongly placed in our view. This should move from 5- Pharmacological Properties to 7- Medicine Schedule.

Further, we seek clarification around the issue of adverse event information moving to Frequency of Occurrence in percentages and how these may vary between different sponsors of the same molecule in their respective datasheets. We question whether companies would be required to make the change when reformatting their datasheets.

Further, in the datasheet template guide 6.1, para 6, it is indicated that any component of flavour and/or fragrance which are known to have a required action or effect, should be included in the datasheet. This however would not be possible where the formulation of such flavours and fragrance has been provided "in confidence" to Medsafe by the manufacturer. We require greater clarification around what components are considered to have an action or effect.

4. ***Medsafe considers that the proposed switch to the adapted EUSPC format should involve only formatting and layout changes and does not involve changes to the content of the datasheet. Medsafe proposes the following timelines for implementing the changes to the new process and switch to the new datasheet format.***

The following options of new medicine applications, changed medicine notifications and all other instances we would comment on separately.

For new medicine applications (NMA'S) we are happy with the proposal outlined.

With regard to changed medicine notifications (CMN'S), we challenge again the proposed date of 1 January 2017. We believe that this is unrealistic and would again state as commented in the executive summary, that 18 months from the date of finalisation and implementation of the results of the consultation be a far more suitable option. For all other instances we would suggest following the line we have suggested for changed medicine notifications dating. Further, we would again re-emphasise the point that a fee waiver should be made in the case of datasheet reformatting only, and again reiterate that only marketed products as outlined in the executive summary should require attention.

5. ***Medsafe proposes that current datasheet 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.***

Q: Do you agree with this proposal and the deadline? If not, please explain.

We refer Medsafe to our earlier comment with regard to timing in both question 1 and question 4 responses.

6. ***The current medicines legislation mandates the use of the term "datasheet". One objective of this consultation is to help inform the thinking for the new Therapeutic Products Bill. Would you prefer the term "datasheet" to continue to be used, or for the use of an alternative terms, such as "product information", "prescribing information", "summary of product characteristics" or another term altogether?***

   Q: Please advise us of your preference if you consider that a different term to "datasheet" should be used.

   NZSMI would request a change from the current "datasheet" terminology. We believe the use of either "prescribing information" or "product information" would be more desirable as these align New Zealand with international best practice and would also be terminology that healthcare professionals are familiar with.

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 datasheets or consumer medicine information to instructional how to use video or further educational materials.***

   Q: How do you see the expansion of e-information contributing to patient safety?

   How to you see e-technology in 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?

   NZSMI supports the use of QR codes. Further, we are also supportive of embracing technology to increase access for patients wanting information with regard to a medicine, as long as the information sourced through these tools is in a legally approved format. The information needs to be regularly updated to ensure best practice.

8. ***Q: If you are a medicine sponsor as well as a medical device sponsor, do you think that a datasheet (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?***

   NZSMI does not believe this is an area where we have expertise and would prefer not to comment.

9. ***Q: Would you support making device datasheets a requirement for medical devices when they are notified to one?***

   NZSMI believes this should only occur for high risk devices.

10. ***Q: 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 datasheet guideline?***

NZSMI would reference page 25 of the datasheet template explanatory guide, section 10 Date of Revision of the Text.

Clarification is sought on the type and depth of detail that needs to be listed in the Summary of Changes. In the US, for example, the requirement is only to indicate what section was updated, e.g. warnings and precautions as opposed to providing the full detail of that change.

Clarification is also sought around the format of the Summary of Changes, e.g. whether the requirement is to replace the current Summary of Changes with the new summary, or add to a tabulated format similar to a "version history". We assume that this proposed requirement is for future datasheet updates and sponsor companies are not required to include obsolete version updates.