New Zealand Hospital Pharmacists' Association (Inc)

Te Kāhui Whakarite Rongoā Hōhipera o Aotearoa

31st March 2016

Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

Thank you for the opportunity to comment on the revision of the *Guideline on the Regulation of Therapeutic Products in New Zealand - Part 10: Requirements for information for prescribers and consumers.*

The New Zealand Hospital Pharmacists' Association (NZHPA) was established in 1952 and is a not for profit organisation that represents the professional interests of hospital pharmacists and support staff. NZHPA has over 300 members, drawn from sectors such as hospital (public and private), primary care, academia, community pharmacy, defence forces, research and industry. The Association's vision statement is 'Supporting innovation in the practice of pharmacy and promoting effective medicines management'.

A key role of hospital pharmacists is to influence prescribing and medicines use in order to improve patient health outcomes. This influence includes:

- Advising members of the healthcare team on prescribing decisions
- Provision of medicines information and advice
- Development of best practice prescribing guidelines and drug administration protocols
- Provision of education on medicines to prescribers and healthcare professionals, such as nurses, who administer and supply medicines.
- Undertaking of medication safety initiatives such as the development of a national medication chart
- Prescription reviews to identify potential or actual medicine-related problems.

Hospital pharmacists' substantial expertise and experience with these activities had led to a clear understanding of the value and importance of accurate, up-to-date information about medicines being accessible to both patients and health professionals.

This submission incorporates responses received from NZHPA members, who were consulted widely on the proposals. I hope the submission adds value in the development of guideline.

Yours sincerely

[redacted]

[redacted]

On behalf of the New Zealand Hospital Pharmacists' Association

Our vision statement:

Supporting innovation in the practice of pharmacy and promoting effective medicines management

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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 Hospital Pharmacists Associations (NZHPA) [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*: Professional Association

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?

No comment on this change.

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?

The general requirements seem appropriate and the information is easily understood. There are no suggestions for additional general requirements to be included.

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?

The NZHPA is supportive of the proposed adoption and adaption of the *European Summary of Product Characteristics* format. Sample comments from members:

"Fully support the proposed new template – I have worked with the eMC template in the UK and find that it is so much easier to find the information that you are looking for when all datasheets follow a standardised layout/format; I also feel like the order of the information in the new template is much more logical" AND "I think it is a great idea for the data sheets to be in a standardised format with the important dosing and CI upfront."

Further specific comments:

Excipients | To reduce unnecessary exposure of potentially harmful excipients to at risk patients (particularly neonates and pre-terms), it is suggested that greater clarity is needed about which excipients should be quantified. One option is a requirement to include *quantitative* information for a defined set of excipients that have been associated with toxicity such as ethanol, benzoate preservatives, and sorbitol (especially when the product may be used in neonates).

Relevant sections that would benefit from clarification:

- **Section 2 Qualitative and Quantitative Composition** - There is a heading 'excipients with known effect' – could be more specific here about what constitutes a 'known effect'.
- **Section 2 Qualitative and Quantitative Composition** - States that 'full details of the qualitative and quantitative composition in terms of the actives substance(s) and *excipients, knowledge of which are essential for proper administration of the medicine*, should be provided in section 2.' However, later under qualitative and quantitative declarations, there is no mention of excipients.
- Note **Section 4.4 Special Warnings and Precautions for Use** already states that "for formulations containing alcohol, information about the ethanol content in the medicines should be included" but should this be mentioned/cross-referenced in section 2 also?
- In **Section 6.1 List of Excipients**, it is stated that "a list should be given of the excipients, expressed qualitatively only." The reader should be referred to section 2 if excipients of concern have been quantified there.

Displacement Values | Section 2 Qualitative and Quantitative Composition - Under the heading '*Powders for reconstitution prior to parenteral administration*', suggest the instructions be explicit about the need to include a displacement value or other information that enables health professionals to calculate and reconstitute to an exact known final concentration.

Therapeutic Indications – Section 4.1. |The final sentence in the third paragraph is confusing – Should the target population be specified? Does this only refer to a prevention indication or other indications as well?

Pregnancy & Lactation | Section 4.6 Fertility, pregnancy and lactation –The FDA has decided to eliminate pregnancy categories because they are often viewed as confusing and overly simplistic and don't effectively communicate the risk a drug may have during pregnancy. It seems that pregnancy categories are not routinely used in the European SPCs either, has the place of 'pregnancy categories' been considered as part of this review?

Effects on ability to drive and operate machinery - Section 4.7 | The specific terminology provided for different levels of influence is helpful, but identification/description of the potential influence could also be included.

Date of Revision of the Text - Section 10 | The NZHPA is very supportive of the inclusion of a summary of changes made to datasheets. However, it is noted that the 'data sheet template' contains the heading 'summary table of changes' but in the 'data sheet template explanatory guide' this heading is omitted and the text refers to an over view of *last* changes to the datasheet. Should the explanatory guide include the heading 'summary table of changes' and the accompanying text read 'an overview of *all* changes to the datasheet should be included here'? Does this summary of changes include non-assessable changes and will it be stated whether the change has been reviewed by Medsafe or not?

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?

Agree with timeline.

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.

Agree with proposal and deadline.

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.

There seems no strong reason to change the term 'Data Sheet'. The term 'Product Information' could be a reasonable alternative if change is deemed necessary. The term 'Summary of Product Characteristics' is a rather verbose and tends to be abbreviated which is not so helpful. The term 'Prescribing Information' is less than ideal because information contained in medicine data sheets is used for activities other than prescribing (such as dispensing and administration). One suggestion that may be considered is expansion to the term 'Medicine Data Sheet'. If, in the future, it is deemed appropriate to require data sheets for medical devices, the corresponding term could be 'Medical Device Data Sheet' could be considered.

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?

The NZHPA believes it is vital for patients and health professionals to have access to reliable information about medicines, and the use of e-technology is certainly a method to facilitate this. The New Zealand Universal List of Medicines provides a strong platform from which to use technology to design and deploy medicines/patient safety initiatives.

There is potential benefit in the use of different forms of educational material such as instructional how-to-use videos as they may be able impart certain information more effectively. It will be important that standards remain high, which may require an additional regulatory framework. Other important considerations would include keeping the information up-to-date and removing access to out-dated information.

Medsafe has traditionally, based on the current legislation, had less of a role in consumer medicine information. There is scope for improvements in this area. The expansion of e-information to increase points of access would ideally be co-ordinated with systems that foster communication between patients and health professionals to ensure information has been understood, allow adaption of information to individual circumstances as necessary, and respond to further information needs. Pharmacy and medicines information services for consumers which make use of electronic communication have been explored in other countries (Australia and Denmark). Likewise, technology could be used to co-ordinate and improve the accessibility of responsive medicines information services for health professionals in New Zealand.

The NZHPA would welcome further engagement on these topics with our specialist networks (e.g. medicines information and medication safety pharmacists).

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?

Though not medicine or medical device sponsor, as a professional organisation the NZHPA would support data sheets or similar being available for higher-risk medical devices.

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

Yes.

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?

Declaration to accompany a data sheet submitted for publication:

This is a declaration for when a data sheet is submitted for publication on the Medsafe website but there is a question asking whether the datasheet is to be published on the Medsafe Website. This seems contradictory.

Consumer Medicine Information:

Consider including a reminder for sponsors to review corresponding CMI when a datasheet is changed.