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	
Company/organisation name and address	New Zealand Medical Association
Contact phone number and email address	

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

NZMA
New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

31 March 2016

Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

By email: medsafeadrquery@moh.govt.nz

Changes to the data sheet format and process

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our submission has been informed by feedback from our Advisory Councils and Board.

We note that Medsafe is proposing a standard format for data sheets based on the European Summary of Product Characteristics (SPC), with minor adaptations. This will include the clinically relevant information at the start of the data sheet. The NZMA is supportive of the proposal to standardise data sheets in a way that aligns with an international standard. We welcome the repositioning of clinically relevant information to the start of data sheets. Our responses to specific questions in the consultation document are given follow.

1. *References to overseas prescribing information or a source document*
We agree with removing references to overseas prescribing information; it is likely that a medicine sponsor's own core data sets or reference safety information may be less subject to the vagaries/bias associated with prescribing from other jurisdictions.

2. *General requirements for data sheets*
The general requirements seem reasonable; they are easy to follow and are easily understood. There are no other requirements that we think should be included in the guideline.

3. *Format and style consistency in data sheets*
We agree with the adoption of the EU SPC format and the adaptations to meet New Zealand requirements.

Level 13, 39 The Terrace, PO Box 156, Wellington 6140 | Tel: (04) 472 4741 | Fax: (04) 471 0838 | Email: nzma@nzma.org.nz | www.nzma.org.nz

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

We agree with the proposals relating to timelines. It seems sensible to start the changes with New Medicine Applications and allow some time for Changed Medicine Notifications.

5. Timeline for data sheets in the Australian format

We agree with the timeline that data sheets in the Australian format should be revised to the proposed format by 1 January 2017. We note that these proposals are expected to involve only a shuffling of existing content.

6. Terminology

Our preference is to retain the term 'Data Sheet' rather than adopt an alternative. However, there may be a need to specify whether it is a medicine or a device data sheet in the event Medsafe adopts similar requirements for medical devices.

7. Greater use of technology

QR codes in the data sheets could be utilised to provide links to Consumer Medical Information (CMI) for patients and their families. Such information could take the form of a how-to-use video; these would have be constructed/regulated in a similar way to existing CMI—ie, they should be simple and easy to understand. Subtitles may be required. We acknowledge that videos linked from data sheets are likely to be costly and time-consuming to create and update.

8. Medical devices

We consider that providing data sheets for higher-risk medical devices would be useful. These could be called 'Medical Device Data Sheets' to differentiate them from 'Medicines Data Sheets'.

9. Data sheet requirements for medical devices at notification

We support making device data sheets a requirement for medical devices when they are notified to WAND.

10. Additional Comments

Given the rapid advances in mobile information and communications technology, we consider that Data Apps, not Data Sheets, may be the way of the future. We envisage a time where an App on a smartphone or other mobile device provides access to all relevant medicine or device information. This could be linked to the QR code printed on the medicine box or bottle or device. Health providers and patients could then scan the code and upload relevant information into their phone, tablet or laptop. Medicine and medical device providers will be able to upgrade the data electronically in real-time—and alert those who have the App of any changes. We suggest that Medsafe give consideration to the development and encouragement of such a Data App. Shifting to such a system would be consistent with moves to an electronic health record and would also reduce the environmental impact associated with printed material.

Finally, we seek clarification on whether data sheets will continue to include information about efficacy. While existing data sheets appear to provide explicit evidence of efficacy, the EMEA guidelines, upon which Medsafe bases its current data sheet template, or the EU SPC guidelines Medsafe proposes using, make no mention of the need to include evidence of efficacy. We contend that efficacy information is useful in data sheets and should be retained. However, we are concerned about the existing convention whereby Medsafe relies on material provided by companies to support data sheets for their products. When such data are provided by companies, we seek clarification on what safeguards are in place to ensure complete information is used. This

relates to issues of publication bias—ensuring that all trials are registered and then reported[1]—and potential publication bias within trials.[2] There is also the issue of post-publication peer review including non-publication of post-publication critiques.[3] While we appreciate that these issues probably extend beyond the current consultation, we consider it an opportune time to examine the sources of evidence used by Medsafe and address potential shortcomings due to a reliance on material provided by pharmaceutical (and, potentially, device) companies.

We hope our feedback has been helpful and look forward to learning the outcome of this consultation.

Yours sincerely

[redacted]

[redacted]

[1] The NZMA has signed the ALLtrials petition, part of the AllTrials initiative which attempts to address the issue of publication bias. Further details are available at http://www.alltrials.net/

[2] Concerns about publication bias relating to trastuzumab are outlined in the following paper: Metcalfe S, et al. Trastuzumab: possible publication bias. Lancet. 2008 May 17;371(9625):1646-8. Available from https://www.pharmac.govt.nz/assets/lancet-2008-trastuzumab-possible-publication-bias.pdf

[3] The COMPare Trials Project is monitoring clinical trials for switched outcomes. Further details are available from http://www.cebm.net/compare-trials-project/. Of concern is the lack of response by the NEJM to attempts at correcting 20 misreported trials. Further details are available from http://compare-trials.org/blog/how-did-nejm-respond-when-we-tried-to-correct-20-misreported-trials/