Medsafe consultation submission

New Zealand Medicines and Medical Devices Recall Code	
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and for my name not to be included within the list of submissions 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, a: *(tick all that apply)*

☐ Importer	☐ Manufacturer	☐ Supplier	☐ Sponsor
☐ Government	☐ 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: recalls@moh.govt.nz

OR

Mail:

Recall Code Update

Medsafe Product Safety team

Medsafe

Ministry of Health

PO Box 5013

Wellington 6145

Medsafe is seeking comments on:

Question 1: Do you support the adoption of the proposed Recall code? If not why not?

Medicines New Zealand companies generally support the adoption of the proposed Recall Code, on the condition that the requirements in 6.1 Part 2 for compensation for the return and replacement of product reflect the current requirements for consideration of compensation for product costs, and postage and packaging costs.

Question 2: Appendix 6 of the draft provides comment on certain legal aspects in relation to recalls. This type of information would not normally be presented in such a document. An alternative would be to provide it separately on the Medsafe website. Would you prefer this information to be incorporated within the code or be separately published?

Medicines New Zealand companies support including an explanation of the legal aspects incorporated within the Code so that all of the relevant information is located in one place.

Additional Comments

1. INTRODUCTION

- *Page 4*. We consider that an overarching general statement already contained in Section 6 of the proposed code "All recalls must be carried out with the knowledge and consent of Medsafe" be repeated upfront in the introduction of the code.

- *Page 4.* The first dot point "An Initiation Phase" includes contacting the funding body when appropriate, but does not mention "contact with the regulator or Medsafe". We consider "contact with the regulator" should replace "contact with the funding body" as recalls are a regulatory issue and not a funding issue. Contact with the funder should be considered separate and dealt with via individual supplier contracts.

2.COMMON RECALL PROCESS TERMINOLOGY

- *Page 7. 2.2.1 Safety Alert*. We understand that safety alerts are not confined to medical devices, but they may also apply to medicines. This may occur, when for example it is known that clinical practices are contrary to label instructions and a safety alert is required.

- *Page 7. 2.2.2 Product Alert*. Patient risk may not be limited to there being no alternative product available, but may also include issues associated with switching between products. We suggest amending the wording to "… a product recall may put the patient at greater risk; e.g. no alternative product …"

- *Page 10.* In 4.2, we suggest changing the last bullet point to *"Will also include wholesale";* in 4.3 the last bullet should be *"Will also include: wholesale level and hospital/laboratory levels";* in 4.4 the last bullet should be *"Will also include: wholesale, hospital/laboratory, and retail levels."*

5.RECALL ACTION PROCESS

- *Page 12. Phase 1. Initiation*. We suggest adding the words "with Medsafe" to make it clear the initiation phase is to be carried out in consultation with Medsafe e.g. "notification and problem identification, hazard/risk assessment, recall action assessment and agreement with Medsafe (strategy, classification and level, and communication plan).

- *Page 12, last paragraph*. Suggest amending to include the fact that healthcare professionals, DHBs, wholesalers and Medsafe have responsibilities in relation to medicine recalls.

OVERVIEW OF THE RECALL PROCESS diagram

- *Page 13. Phase II IMPLEMENT Box "(4).* This states that "Medsafe may also issue own communication". We consider the sponsor should have the opportunity to know what Medsafe is planning to communicate to the public prior to publication to ensure alignment of messaging. The second bullet point could be expanded to include "Medsafe may also issue own communication in consultation with the Sponsor".

- Page 13. *Actions of the recall letter addresses may include* and *Actions for sponsors may include,* suggest deleting the word "may" and add the words "but not are limited to:" to remove any ambiguity that actions (if applicable) are optional. e.g."Actions of the recall letter addressee include but are not limited to: ". Under *Actions of the recall letter addresses may include:,* we suggest amending bullet 3 to "Returning affected stock to wholesaler and/or sponsor". This is because sometimes stock is returned to the wholesaler who then returns the stock to the sponsor.

6. RESPONSIBILITIES OF SPONSORS

6.1 Recall Preparation and Planning.

- *Page 15, 3rd bullet. Part 2 Describe how a recall action will be conducted*. We agree that first contact is with Medsafe, however we consider that contact with the funder should be considered a separate issue and dealt with via individual supplier contracts. Therefore we consider that contact with the funder is removed.

- *Page 15, 13th bullet*. In order to reflect the current situation and clarify this section, insert "As a guide, sponsors are expected to reimburse the product costs and postage and packaging costs associated with the recall", to reflect the current obligations.

- *Page 15, 17th bullet*. This refers to sponsors requirements to keep records for 6 years. We note on page 26 there is reference to wholesale requirements to keep records for 7 years. We query why the retention time differs, and to be consistent the minimum legal requirement for retaining records could be included for other stakeholders such as Medsafe, DHB's or HCPs. Can you please clarify the minimum retention time.

6.2 Initiation Phase

- *Page 19. Conducting a Consumer Level Recall*. Suggest it is clarified that a consumer level recall relates to a defective product on the market. Suggest adding the words along the lines of "on the market" or "in the market place", after "defective product".

6.3 Implementation Phase.

- *Page 22, Sponsor Media release.* Suggest adding an overarching statement as the first sentence under this heading along the lines of "It is recommended the text should be agreed by Medsafe". This to ensure the same requirements for the text to be agreed with Medsafe for paid advertisements is applied to sponsor media releases.

- *Page 23, Publication of a Consumer Level Recall action Advertisement.* The *"Uniform Recall Procedure for Medicines* and Medical Devices" should presumably be replaced by "New Zealand Medicines and Medical Devices Recall Code".

- Page 19, 22, 23. There is discrepancy as to where any consumer level recall action must be advertised. Page 19, section 2. C) says "all daily newspapers", page 22 under Paid Advertisements says "The choice of daily newspapers should be made in consultation with Medsafe." Page 23 under Publication of a Consumer Level Recall action

Advertisement it is “all regional daily newspapers”. We suggest “all daily newspapers” as this would get the most coverage.

6.4 Review Phase

- *Page 24*. Progress Reports. Under Follow-up Report. Spell out CAPA as “Corrective and Preventative Actions (CAPA)”, or add CAPA as a common term under section 2.

- *Page 28.* Section 8.3. This should be a new section because it is covering responsibilities of DHBs and Private Hospitals.

9. RESPONSIBILITIES OF MEDSAFE.

- *Page 31.* Suggest amending the wording to the final point to: “Medsafe will review the Recall Code on a regular basis and update where necessary, in consultation with relevant stakeholders.

Typographical errors found

- *Page 17, d). For Both Medicines and Medical Devices.* Typographical error - delete “are” ie “For consumer level recalls see the additional requirements ~~are~~ described later in this section.”

- *Page 17. Information Requirements*. Typographical error - the information in bold required for initial contact is not in bold so it is not clear what information is required for initial contact with Medsafe.

- *Page 24*. Typographical error - last bullet point, replace “where“ with “when”.

- *Page 24*. Final Report. Last bullet point, delete the second “a”.

- *Page 27.* Second para, 4th line – add “the” ie …that is the subject of a recall action…

- *Page 28, section 8.3.* Typographical error - last bullet point. Delete “action”.

- *Page 32, Section 10.* First line, underline “other”.

- *Page 33.* Suggest c) should be a separate section as it is referring to when it is unclear whether the problem is a defect or not. Page 35 under issue need to close > ie <device/medicine>

- *Page 39.* “Affected product (Catalogue Number, , Order Code Lot number….” There are commas in the wrong place that needs correcting. The same error occurs on page 41.

- *Appendix 6. The main section headings are incorrectly numbered.*