18 May 2015

Chris James
Manager Clinical Risk Management
Medsafe
PO Box 5013
WELLINGTON

CONSULTATION RESPONSE
RE: Guideline on the regulation of therapeutic products in New Zealand, Part 8, Pharmacovigilance, Edition 2

The New Zealand Self Medication Industry (NZSMI) is the representative trade organisation for the major *"over the counter"* (OTC) medicine sponsor companies within New Zealand.

We appreciate the opportunity to make comment on the consultation document and hope our comments are taken in a constructive manner to assist in developing the final document.

We are willing to support our comments verbally if required and meet with representatives of Medsafe if appropriate.

Yours faithfully

Tim Roper
Executive Director
New Zealand Self-Medication Industry

Introduction

NZSMI welcomes the opportunity to comment on the guideline proposed for pharmacovigilance.

Medsafe's aim to improve transparency and clarity around pharmacovigilance regulatory requirements for New Zealand is supported. NZSMI has taken the opportunity to comment in detail on the document, which is attached as **Appendix 1.**

Executive Summary

- Overall NZSMI supports Medsafe's initiative in incorporating greater detail into the pharmacovigilance guidelines for New Zealand. We also support and encourage alignment with international best practice.

- NZSMI has commented on areas where there appears to be a lack of consistency or confusion through interpretation in the current document.

- NZSMI supports this review opportunity to move towards greater harmonisation of standards internationally and where practicable alignment with EU Good Pharmacovigilance practice modules.

- NZSMI has attempted by way of **Appendix 1** to provide detailed comments referenced to each section to ensure that any ambiguity is removed and in addition ensure there is an understanding between what might be seen as optional as opposed to mandatory requirements.

- NZSMI is concerned around the need for clarification as to the specific target audience that the guideline is directed at. There appear to be a number of sections where it is not clear to whom the section is referring - whether to sponsors, consumers or health professionals. A clarification of this issue is required

Summary

In summary, NZSMI confirms its support of Medsafe's willingness to initiate harmonisation within the pharmacovigilance guidelines with international best practice. NZSMI is willing to partake in further discussions if areas of clarification are required with regard to the comments made in this submission.

APPENDIX 1

CONSULTATION: GUIDELINES ON THE REGULATION OF THERAPEUTIC PRODUCTS IN NEW ZEALAND
Part 8: Pharmacovigilance Guidelines

Section	Page	Comments
1: Legislation	5	Include reference to which Good Pharmacovigilance Practice Modules are relevant for Medsafe
2: Roles & Responsibilities	9	Confirm if a PV contact person can reside in Australia
3: Reporting	12	3.2 – approved medicines or 'available' medicines (seems contradictory to 3.5.14)
	13	3.2.4 – lack of clarity on who is required to report. No clear distinction between the types of reporting required for different product types eg devices, biologicals, otc, vitamins.
	14	3.3 – Reference Privacy Laws. 3.3.2 – Add email address into Identifiable reporter bullet points
	15	3.3.3 – Significant delays in receipt of CARM # therefore in practice this may not always be possible. 3.4 – Open to interpretation as to what 'shortly after 15 calendar days' may mean. Should either remove or define a specific duration of time. Consider the use of an example to ensure that it is clear, and also to classify 'significant additional information'. Safety databases would also not permit a scheduling of CIOMs for an ambiguous amount of time – need definite number of days
	16	3.5.1 – Potential for receiving the same report multiple times if each HCP, consumer and company report the same case. 3.5.3 – AEFI routinely included in PBRERs, therefore unclear of threshold for notification to Medsafe.
	17	3.5.4 – Clarify product types for lack of therapeutic efficacy cases to be reported to Medsafe, e.g. Antibiotics needs to be added as a separate bullet under vaccines and contraceptives. 3.5.5 – Unclear if only serious cases of misuse or abuse are required to be reported or if all cases require reporting. 3.5.6 - Unclear if only serious cases of off label use are required to be reported or if all cases require reporting.
	18	3.5.8- Unclear if only serious cases are required to be reported or if all cases require reporting. 3.5.9 – Unclear if only serious cases are required to be reported or if all cases require reporting. Unclear if medication error reports required for all product types or just specific ones. Also require more information regarding how MERP would work. Would this info be shared

		with the Sponsor companies? Would all products be included in this program or only some? How would a Sponsor know whether a product has been included or not? 3.5.10 - Unclear if only serious cases of overdose or occupational exposure are required to be reported or if all cases require reporting. 3.5.12 – Unclear as to in which specific situations this would apply. Would be good to cross reference relevant regulatory sections to provide clearer picture.
	19	3.5.13 – NZSMI believes the first sentence of the second paragraph should be deleted" Sponsors should regularly……" 3.5.14 – It may be difficult to verify if a product was funded or in use at the time of the ADR receipt. Could delay submission to Medsafe whilst waiting for clarification. 3.5.14 – The review of scientific and medical literature should be limited to NZ Publications if only cases occurring in NZ are required to be reported. 3.5.15 – Need clarification on reporting adverse reactions associated with suspected or confirmed quality defects. It can be assumed only quality defects of critical nature needs to be reported, but need confirmation from Medsafe. 'Associated' could be a quality defect that may not necessarily directly relate to the adverse reaction. Serious adverse reactions, regardless of whether it is related to quality defects/falsified medicine, should be reported to CARM, as well as to Medsafe Product Safety Team?
6: Submission of Safety Monitoring Documents	28	6.2 – Requires clarity on when PBRERs would require submission. If submission is requested how many years would it be for? Is there a process for ceasing submission of PBRERs?
	29	6.3 – Link to Section 7 as seems like Medsafe want to review risk minimization tools without reviewing the RMP. Is likely to make it difficult to understand context of tools without RMP content?
7: Safety Communications	30	7.1 – Requires clarification as to whether these safety communications would be linked to an RMP or whether any communication tools that are part of an RMP would be out of scope of this section?
	31	7.3 – Unclear as to which situations this would apply in, perhaps the inclusion of some examples may help. Also this type of activity would usually occur within the bounds of an RMP. How would this process work in practice? Are there timelines for review of materials? Would Medsafe review all safety message communications prior to their implementation? How would changes be managed?