Medicines
New Zealand

20 May 2015

Chris James
Manager, Clinical Risk Management
Medsafe
PO Box 5013
WELLINGTON

By email: medsafeadrquery@moh.govt.nz

Dear Chris

Re: Review of Guideline on the Regulation of Therapeutic Products in New Zealand – Part 8: Pharmacovigilance (Edition 2.0)

Thank you for providing an opportunity to comment on this Guideline review.

Medicines New Zealand is the industry association representing companies engaged in the research, development, manufacture and marketing of prescription medicines and vaccines. A central objective of Medicines New Zealand is to promote the benefits of a strong research based industry in New Zealand.

Our members generally support the revised Guidelines. Our main comments concern acknowledging international guidelines in pharmacovigilance management; responsibility for monitoring adverse events on internet sites and in social media; and clarifications to improve sponsors understanding of what is a mandatory requirement verses what is best practice guidance.

Please refer to the feedback form for more details.

We would also like to make an additional comment regarding PBRERs and RMPs. While routine submission of PBRERs and RMPs is not mandatory, going forward we would support future leveraging of PBRER and RMP reviews by recognised regulators. We are not aware of any work sharing arrangements in pharmacovigilance with regard to them, however Medsafe could consider work sharing PBRER and RMP reviews along the lines of what is being considered for medicines assessments.

We would be happy to provide further information on our submission if you require. We would also value being on any working groups on pharmacovigilance requirements that may be developed for the new medicines framework.

Yours sincerely

Philippa Davies
Regulatory, Compliance and Market Access Manager

Medsafe consultation submission

Guideline on the Regulation of Therapeutic Products in New Zealand - Part 8: Pharmacovigilance (Edition 2.0)

Name and designation	Philippa Davies
Company/organisation name and address	Medicines New Zealand Level 8, 86-90 Lambton Quay Wellington
Contact phone number and email address	Philippa Davies Philippa.davies@medicinesnz.co.nz

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: medsafeadrquery@moh.govt.nz including 'Pharmacovigilance guideline' in the subject line

Or Post: Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

Section 3: Reporting eg,

- Do you have any suggestions regarding the definitions and interpretations used in this section?
- Do the subsection headings appropriately and adequately describe each reporting circumstance?
- Is each reporting circumstance and the process involved adequately described and explained?
- Would it be easy to find the information you need in each particular reporting circumstance?
- Are there circumstances that are not in this guideline but should be? If yes, please provide more details.

3.3.2 Suggest a minor clarification here to make it clear that this describes a valid report from a sponsor's perspective, which is separate from a CIOMs report.

3.3.3 It should be noted that in the absence of a CARM number, additional information may only be able to be referenced to the date of the initial report.

3.4 The allowance to report "shortly after 15 days" is open to interpretation, we suggest deleting this and referring to section 3.3.3 for the process for following up incomplete reports.

3.5 For clarity, including that this section refers to serious ARs would be beneficial.

3.5.12 Suggest rewording to "*All valid serious ICSRs identified by the sponsor after suspension or withdrawal, but occurring before the suspension or withdrawal should be reported to CARM".*

3.5.13 2nd para. Our members have concerns with the requirement to monitor lay internet sites and non-company sponsored digital media and social media. This is because it is an onerous task with little perceived benefit, there are risks of duplicate reporting, and there are concerns around feasibility and appropriateness of follow up. We strongly recommend that the advice in this section follows the EU GVP module VI and require sponsors to report AEs if they become aware of them, rather than require routine monitoring. Indeed, following a review of Medicines New Zealand Code of Practice, revisions included strengthening the requirement for companies to report AEs reported by users on company-owned social media sties; and AEs discovered on third-party sites.

We recommend the first sentence be changed to align with the final EU GVP module "*If a sponsor becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it requires reporting."*

3.8.15 For your noting, our members have commented that they are required to monitor databases for AEs and do monitor the SMARS database, however we agree it should not be a mandatory requirement and agree with the proposed wording.

Section 4: Signal Management Process eg,

- Does the content of each subsection adequately explain what the steps in the process involve?
- Do the subsections on the Early Warning System and Medicines Monitoring adequately explain how these tools can be used?
- Do you understand what the role of the sponsor is in these situations?

Our sponsors are aware of the requirement to monitor all pharmacovigilance data etc, however for some sponsors new to New Zealand's regulatory environment, we suggest the following sentence is added: *"Sponsors should not solely rely on local reports for signal detection".*