Medsafe consultation submission

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

Name and designation	
Company/organisation name and address	
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	☐ 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

Medsafe is seeking comments on:

Section 1: Legislation eg,

- Are the guidance documents appropriate?
- Are there other guidance documents that would be relevant to the conduct of pharmacovigilance in New Zealand?

Section 2: Roles and Responsibilities eg,

- Does the information adequately describe the roles and responsibilities of the various parties?
- Was the information appropriately presented?
- Was the information easy to find?
- Are there any changes you would like to suggest?

Please include additional pages if necessary.

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.

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?

Please include additional pages if necessary.

Section 5: Significant Safety Issues eg,

- Does the text in this section adequately explain what is required?
- Are there other pharmacovigilance-related safety issues or safety concerns about medicines that you consider should be included in this section?

Section 6: Submission of Safety Monitoring Documents eg,

- Are there other suggestions or recommendations that could be included in this section?

Please include additional pages if necessary.

Section 7: Safety Communications eg,

- Are there other suggestions or recommendations that could be included in this section?
- Is it appropriate to use the European template for safety communications?

Additional Comments

- Is the order of the information presented in each section appropriate?
- Do you agree with the proposed structure of the guideline?
- Is the information easily understood?
- Is there any other information or subject that should be included in this guideline?

Please include additional pages if necessary.