Proposed updates to the Guideline on the Regulation of Therapeutic Products in New Zealand: Pharmacovigilance - Consultation questions

Page 1: Introduction

1. What is your name?	
2. This submission is from: (Required)	A sponsor or an organisation involved in pharmacovigilance activities (ie, on behalf of a sponsor) Other
3. Please provide the name of the sponsor or organisation, and your role. If you selected Other, please specify, and provide your role.	Please add your answer below (Required)
4. What is your email address?	

Page 2: Roles and responsibilities

This page refers to section 3 of the Guideline.

5. Do sections 3.1 'Medsafe' and 3.2 'Sponsors' adequately explain the roles and responsibilities of both parties?	Yes No Please make any comments or suggestions
6. Is Medsafe's process for collecting spontaneous reports (section 3.1.1) clearly explained?	Yes No Please make any comments or suggestions
7. Do you have any other comments or suggested changes for section 3 of the Guideline?	Yes No Please make any comments or suggestions

Page 3: Individual Case Safety Reports (ICSRs)

This page refers to section 4 of the Guideline.

8. Does section 4.1 'Collection of reports' adequately explain the sponsor's role in collecting and collating adverse reaction reports?	Yes No Please make any comments or suggestions
9. Is section 4.2 'How to report' easy to understand?	Yes No Please make any comments or suggestions
10. Are sections 4.4 and 4.5 clear about what to report and what not to report?	Yes No Please make any comments or suggestions
11. Do you have any other comments or suggested changes for section 4 of the Guideline?	Yes No Please make any comments or suggestions

Page 4: Signal management

This page refers to section 5 of the Guideline.

12. Is section 5 'Signal management' clearly explained?	Yes No Please make any comments or suggestions
13. Do you have any other comments or suggested changes for section 5 of the Guideline?	Yes No Please make any comments or suggestions

Page 5: Safety issues

This page refers to section 6 of the Guideline.

14. Do you agree that safety issues can be classified as either 'Significant' (section 6.1.1) or 'Other' (section 6.1.2)?	Yes No Please make any comments or suggestions
15. Do sections 6.1.1 and 6.1.2 clearly explain the difference between significant and other safety issues?	Yes No Please make any comments or suggestions
16. Do you agree with the 72-hour timeframe for reporting significant safety issues to Medsafe (section 6.3.1)?	Yes No Please make any comments or suggestions
17. Do you agree with the 30-day timeframe for reporting other safety issues to Medsafe (section 6.3.2)?	Yes No Please make any comments or suggestions
18. For other safety issues that require data sheet updates, is the option to notify Medsafe via CMN submission (section 6.3.2) helpful to sponsors? If yes, is the 30-day timeframe acceptable?	Yes No Please complete your answer below
19. Does Appendix 1 'Summary flowchart for reporting of safety issues' align with section 6 of the Guideline? If yes, is it a useful summary for sponsors?	Yes No Please make any comments or suggestions
20. Do you have any other comments or suggested changes for section 6 of the Guideline?	Yes No Please make any comments or suggestions

Page 6: Safety Monitoring Documents

This page refers to section 7 of the Guideline.

21. In section 7.1.1, is Table 5: 'Products requiring routine submission of PBRERs' easy to understand?	Yes No Please make any comments or suggestions
22. Do you have any other comments or suggested changes for section 7 of the Guideline?	Yes No Please make any comments or suggestions

Page 7: Safety communications

This page refers to section 8 of the Guideline.

23. Does this section adequately explain the requirements for sponsors when publishing or distributing safety communications?	Yes No Please make any comments or suggestions
24. Do you have any other comments or suggested changes for section 8 of the Guideline?	Yes No Please make any comments or suggestions

Page 8: Best practice guidelines

This page refers to section 9 of the Guideline.

25. Are there any additional guidelines that should be added to this section?	Yes No Please make any comments or suggestions
26. Do you have any other comments or suggested changes for section 9 of the Guideline?	Yes No Please make any comments or suggestions

Page 9: Other feedback and comments

27. Do you have any other feedback or suggested changes for the Guideline?	

Page 10: Publishing submissions and privacy

28. We intend to publish the submissions from this consultation, but we will only publish your submission if you give us permission. We will remove personal details such as contact details and the names of individuals. If you do not want you submission published, please let us know below. (Required)	You may publish this submission Do not publish this submission

29. Your submission will be subject to requests made under the Official Information Act (even if it hasn't been published). If you want your personal details removed from your submission, please let us know below. (Required)	Include my personal details in responses to Official Information Act requests Remove my personal details from responses to Official Information Act requests
30. We will redact commercially sensitive information before publishing submissions or releasing them under the Official Information Act. If your submission contains commercially sensitive information, please let us know below. (Required)	This submission contains commercially sensitive information This submission does not contain commercially sensitive information If you submission contains commercially sensitive information, please let us know where.