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| **Medsafe consultation submission** |

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| |  | | --- | | **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](http://www.legislation.govt.nz/act/public/1982/0156/latest/DLM64785.html?search=qs_act_official+information+act_resel_25_h&p=3&sr=1) 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.**

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| **I am, or I represent, an organisation that is based in:** |
| New Zealand  Australia  Other (*please specify*): |

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| 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](mailto: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:**

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| *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.

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| *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.

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| *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.

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| *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.