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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)** |

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| 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 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.