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| **Medsafe consultation submission** |

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| |  | | --- | | **Joint Medsafe and TGA project: Trans-Tasman early warning system of safety concerns for medicines and medical devices** | | | |
| 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)* | | 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.**

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| **I am, or I represent, an organisation that is based in:** |
| New Zealand  Australia  Australia and New Zealand |

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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*: | | | |

**Medsafe is seeking comments on:**

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| *The proposed Early Warning System webpages eg*  - Does the content describe the Early Warning System in sufficient detail?  - Is the content understandable?  - Was the layout of information within the webpages and within the Medsafe website easy to follow?  - Are there any changes you would like to suggest? |
| *The presentation of the hypothetical examples eg*  - Did the types of information covered in the monitoring communications meet your expectations?  - Did the types of information covered in the alert communications meet your expectations?  - Did you find the level of detail in the monitoring communications and the alert communications suitable?  - Did you find the information you were interested in?  - Are there any changes you would like to suggest? |
| *The proposed communication channels eg*  - Do you agree with the proposed channels to be used for communicating monitoring communications?  - Do you agree with the proposed channels to be used for communicating alert communications?  - Are there alternative communications channels Medsafe should use when issuing monitoring communications and/or alert communications? |
| *Additional Comments* |

For medicine sponsors and medical device suppliers please provide contact details if you wish to be informed of communications by Medsafe (this information will remain confidential):

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| Organisation name:  Contact person:  Email address:  Direct dial number: |