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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** |

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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)*      | [ ]  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: |