

# Medsafe consultation submission



Joint Medsafe and TGA project: Trans-Tasman early warning system of safety concerns for medicines and medical devices	
<b>Name and designation</b>	
<b>Company/organisation name and address</b>	
<b>Contact phone number and email address</b>	
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No

**It would help in the analysis of stakeholder comments if you provide the information requested below.**

I am, or I represent, an organisation that is based in:	
<input type="checkbox"/> New Zealand	<input type="checkbox"/> Australia <input type="checkbox"/> Australia and New Zealand
I am, or I represent, a: <i>(tick all that apply)</i>	
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Sponsor
<input type="checkbox"/> Government	<input type="checkbox"/> Researcher <input type="checkbox"/> Professional body <input type="checkbox"/> Industry organisation
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Member of the public <input type="checkbox"/> Institution (e.g. university, hospital)
<input type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional
<input type="checkbox"/> Health professional – <i>please indicate type of practice:</i>	
<input type="checkbox"/> Other - <i>please specify:</i>	

**Medsafe is seeking comments on:**

*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):

Organisation name:

Contact person:

Email address:

Direct dial number: