

Medsafe Consultation Submission form



Observers at Ministerial Advisory Committees

| | |
|--|--|
| 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: <i>(Please give reasons and identify specific sections of response if applicable)</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| (Reasons for requesting confidentiality must meet Official Information Act 1982 criteria) | |
| I would like my name to be removed from all documents prior to publication on the Medsafe website. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| I would like for my name not to be included within the list of submissions published 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"/> Other <i>(please specify):</i> | |
| 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> | | | |

Please return this form to:

Email: committees@moh.govt.nz with 'Observers at Ministerial Advisory Committees' in the subject line

Or by post: Product Regulation, Medsafe, PO Box 5013, Wellington 6145

Medsafe is seeking comments on the following proposals for each Committee:

Medicines Classification Committee (MCC)

Proposal 1: No change

Observers from the Ministry continue to attend as needed. Observers representing the applicant could still attend as outlined above for the current process.

Proposal 2: Observers representing applicants no longer allowed to attend

The process would be transparent, applicants could provide written proposals only. The Committee has a formal process to request further information. There has been a tendency for observers to provide additional information at meetings that was not consulted on, potentially affecting the transparency of the committee process.

Proposal 3: Observers widened

Observers representing the applicant could be allowed to attend and discuss the application with the Committee as at present. Other observers could also be allowed to attend at the same time. This could include observers from other companies, consumers, and healthcare professionals. Given the constraints of time, the number would be restricted and there would be an application process.

Medicines Assessment Advisory Committee (MAAC)

Proposal 4: No change

Observers from the Ministry continue to attend as needed. Observers representing the sponsor could still attend as outlined above for the current process.

Proposal 5: Observers representing sponsor no longer allowed to attend

There has been a tendency for observers to provide additional information at meetings that was not provided to Medsafe during the evaluation process, potentially affecting the integrity of the committee process.

Medicines Adverse Reactions Committee (MARC)

Proposal 6: No change

Observers from the Ministry continue to attend as needed. Academic experts and other observers such as medical trainees invited to attend as required.

Proposal 7: No observers other than from the Ministry allowed

Observers from the Ministry continue to attend as needed. Academic experts and other observers such as medical trainees are no longer allowed to attend.

Proposal 8: Allow sponsors to attend for section 36 issues to provide a presentation and answer questions

Sponsors are invited to attend for section 36 issues to provide a presentation and answer questions that may arise during the Committee's discussion.

Medicines Review Committee (MRC)

Proposal 9: No change

Observers do not attend MRC meetings.

Proposal 10: Applicants for a review allowed to present their case to the Committee

Applicants that request an appeal to a decision made by the MAAC or MCC may observe the discussion regarding their appeal.

Are there any other comments you would like to make on Observers at Ministerial Advisory Committees?

Please include additional pages if necessary.