|  |
| --- |
| **Medsafe consultation submission**  |

|  |  |
| --- | --- |
|

|  |
| --- |
| **Update to Medicines Classification Committee Processes** |

 |
| 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 the Official Information Act 1982 criteria](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)) | [ ]  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.**

|  |
| --- |
| **I am, or I represent, an organisation that is based in:** |
| [ ]  New Zealand [ ]  Australia [ ]  Other (*please specify*):       |

|  |
| --- |
| I am, or I represent, a: *(tick all that apply)* |
| [ ]  Importer | [ ]  Manufacturer | [ ]  Supplier | [ ]  Sponsor |
| [ ]  Government organisation | [ ]  Researcher | [ ]  Professional body | [ ]  Industry organisation |
| [ ]  Consumer organisation | [ ]  Member of the public | [ ]  Institution (eg, University, hospital) |
| [ ]  Regulatory affairs consultant | [ ]  Laboratory professional |  |  |
| [ ]  Health professional – *please indicate type of practice*:       |
| [ ]  Other - *please specify*:       |

**Please return this form to:**

**Email:** committees@moh.govt.nz including “MCC Process Consultation” in the subject line

**Or Post:** MCC Secretary

 Medsafe

 PO Box 5013

 Wellington 6145

**Medsafe is seeking comments on the following:**

|  |
| --- |
| 1. Reference lists for all applications will be made publicly available.
* Do you have any comments on this clarification?

      |
| 1. Supporting documents and/or appendices for applications will be made publicly available, and will only be treated as confidential when the applicant specifically requests this, and only to the extent permissible under the Official Information Act 1982.
* Do you have any comments on this proposal?

      |
| 1. Reclassification applications will now be received electronically via email (file size permitting). Alternatively, applications can be provided with a hard copy of the cover letter along with the application on a CD.
* Do you have any comments on this change?

      |
| 1. Feedback provided on applications will be made publicly available, and will only be treated as confidential when it is specifically requested, and only to the extent permissible under the Official Information Act 1982.
* Do you have any comments on this clarification?

      |
| 1. The proposed criteria for valid objections are:
* The MCC did not consider all the safety issues correctly (for example a new safety concern may have been identified since the start of the consultation)
* The MCC did not consider all the benefits, or
* There was a breach in the appropriate process.

Financial or commercial reasons are not acceptable grounds for objection. * Do you have any comments on these criteria?

      |
| 1. The determination of whether an objection is valid could be made by:
* Medsafe Group Manager on advice from the MCC Secretariat
* MCC Chair
* MCC committee via teleconference
* Director General of Health on advice from the MCC secretariat.

Given the short timelines involved it is noted that the first option is likely to be the quickest and avoids any perception of conflict of interest which would accompany a determination made by the MCC or the chair of the MCC.* Do you have any comments on these options?

      |
| 1. It is proposed that the supporting data for valid objections will be published on the Medsafe website as per the normal submission process.
* Do you have any comments on this proposal?

      |
| 1. Ten days are allowed for objections to be lodged and the supporting data must be available for the next MCC consultation phase.
* Do you have any comments on these timings?

      |
| 1. A maximum of three individuals representing the applicant are able to observe the opening discussion of the agenda item for which they submitted the reclassification proposal. Applicants may also have the opportunity to answer any queries posed by the MCC, which may have arisen following the receipt of comments on the application, and provide explanations which would help make a final recommendation. However, applicants are not able to provide any new data or information that was not included in the original application, in the interests of transparency. Observers are not able to be present for the final recommendation made by the MCC.

- Do you have any comments on the format for observers?      |
| 1. An update and amendment to the current Decision Criteria has been proposed, and a set of parameters developed.

- Do you have any comments on this change?     - Do you have any comments on these parameters?      |
| 1. Do you have any further comments on the MCC process?

      |

Please include additional pages if necessary.