Appendix 1

Reclassification of a Medicine for consideration by the Medicine Classification Committee

This form should be completed in conjunction with the directions in the guidance: How to change the legal classification of a medicine in New Zealand.

Once completed, this application should be sent to committees@moh.govt.nz by the deadline indicated on the Dates and Deadlines page on the Medsafe website.

By submitting this form, you are confirming that all information is true and accurate, and understand that this information and any appendices and/or supporting information that is not considered commercially confidential under the Official Information Act 1982 criteria will be published on the Medsafe website.

Part A

1. International Non-proprietary Name of the medicine.

2. Proprietary name(s).

3. Name and contact details of the company / organisation / individual requesting a reclassification.

   Note: Contact details will be removed from the form prior to publication on the Medsafe website.

4. Dose form(s) and strength(s) for which a change is sought.

5. Pack size and other qualifications.

6. Indications for which change is sought.

7. Present classification of the medicine.

8. Classification sought.

9. Classification status in other countries (especially Australia, UK, USA, Canada).

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute.

11. Local data or special considerations relating to New Zealand (if applicable).

12. Labelling or draft labelling for the proposed new presentation(s).

13. Proposed warning statements (if applicable).

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

Part B

1. Indications and dose
   - *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*
   - *What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?*
   - *What is the treatment population for the indication (age; gender etc.)?*
   - *What is the dose and dose frequency of the medicine for this indication?*

2. Presentation
   - *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*
   - *What is the proposed pack size for reclassification?*
   - *What is the proposed packaging for the reclassified medicine? Does it include child resistant containers for liquids; a dosing device etc?*
   - *What disposal considerations need to be made for the medicine?*
   - *What storage considerations need to be made for the medicine?*
   - *How practical and easy to use is the proposed presentation?*

3. Efficacy/benefits
   - *What is the evidence for efficacy and the degree of efficacy for the proposed indication(s)?*
   - *To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?*
   - *What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?*
   - *What is the evidence that improved access is beneficial?*
   - *What is the evidence of improved consumer involvement in their health?*
   - *What are the benefits from a consumer viewpoint?*

4. Contraindications and precautions
   - *What are the contraindications for the medicine and how easy are they to identify and prevent?*
   - *What are the precautions for this medicine and how easy are these to understand?*
   - *Does the medicine have a low therapeutic index?*
   - *What class effects need to be considered and what are the risks?*
   - *What are the risks of the medicine being used in an OTC environment?*
   - *What other drug interactions need to be considered?*
   - *What food and/or drink interactions need to be considered?*
   - *Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?*

- *Are there any special populations where exposure to the medicine needs to be restricted?*

5. Undesirable effects
   - *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*
   - *What are the risks and consequences of known undesirable effects?*
   - *Are there any significant safety concerns for the medicine under review?*
   - *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*
   - *Are there any withdrawal effects following cessation of use of the medicine?*

6. Overdose
   - *Is there a potential for overdose of the medicine?*
   - *What are the consequences of overdose of the medicine?*
   - *Are there any reports of overdose of the medicine?*

7. Medication errors and abuse/misuse potential
   - *Would reclassification affect the risk of unnecessary use?*
   - *Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*
   - *What are the reported medication errors post-market?*
   - *What are the reported cases of abuse/misuse/accidental overdose?*
   - *How would reclassification affect import considerations?*
   - *What is the addiction potential of the medicine?*

8. Communal harm and / or benefit
   - *What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates)?*
   - *What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity as a result of improved access to a communicable disease vaccine)?*

9. Integrated benefit-risk statement
   - *A summary of the reclassification benefits*
   - *A summary of the reclassification risk of harm*
   - *A summary of the need for the medicine at the classification proposed*
   - *Precedent – how are other medicines in the same class classified?*

10. Risk mitigating strategies
    - *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required eg, healthcare professional education; integration of care; consumer information to be provided etc?*
    - *What is the evidence that these proposed risk mitigation strategies would be effective?*

- *What post-market surveillance activities would be carried out?*
- *Is the proposed reclassification supported by professional bodies?*