MEDSAFE

New Zealand Medicines and Medical Devices Safety Authority

How to change the legal classification of a medicine in New Zealand

Guidance document

Medsafe
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Contents

Purpose and scope

This guidance document is aimed at pharmaceutical companies, health professional organisations, Medsafe, Ministry of Health (Manatū Hauora), Health New Zealand (Te Whatu Ora), Māori Health Authority (Te Aka Whai Ora), or individuals/ groups who are considering applying to change the legal classification of a medicine in Aotearoa New Zealand.
The purpose of this guidance document is to provide general advice on the process for changing the legal classification of a medicine in Aotearoa New Zealand to help ensure the process is easy to understand and transparent.
Please note that the medicine classification process is separate to the medicine approval process.

Background and legislative context

The Medicines Act 1981 defines three classification categories for medicines:

1. **Prescription medicine** – prescription medicines may be supplied only on the prescription of an authorised prescriber (as defined in the Medicines Act 1981). They may also be sold or used, in some instances, by a registered member of another specified health profession when permitted by their classification.
2. **Restricted medicine** (also referred to as pharmacist only medicine) – restricted medicines may be sold without a prescription, but the sale must be made by a registered pharmacist, in a pharmacy, and details of the sale must be recorded.
3. **Pharmacy-only medicine** (also referred to as pharmacy medicine) – pharmacy-only medicines may only be sold in a community or hospital pharmacy, or a shop in an isolated area that is licensed to sell that particular medicine. The sale may be made by any salesperson.

Medicines in each of these classification categories are listed in the First Schedule to the Medicines Regulations 1984 and amendments. The First Schedule to the Medicines Regulations 1984 is a list of medicines grouped under their respective classifications. Medicines not listed in the First Schedule are deemed to be unclassified and are referred to as general sale medicines. These medicines may be sold from any outlet.

The Medicines Classification Database published on the Medsafe website is a record of current medicine classifications and general sale medicines.

The term 'over the counter' (OTC) medicines refers to medicines that can be supplied without a prescription, or, in other words are classified as restricted or pharmacy-only medicines or are available for general sale.

Medicines are generally classified according to their active ingredients. The international non-proprietary name (INN) is the name of choice. If the medicine has more than one active ingredient, the active ingredient with the most restrictive classification determines the classification of the medicine.

Controlled Drugs

Narcotics and certain psychotropic agents are regulated under the Misuse of Drugs Act 1975 as controlled drugs. The Misuse of Drugs Act 1975 defines three classes of controlled drugs. These are Class A, Class B (further subdivided into Parts I, II & III) and Class C (further subdivided into Parts I to VII). The controlled drugs in each class are listed in the Schedules to the Misuse of Drugs Act 1975.

The Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977 contain the requirements for the manufacture, sale, supply, prescribing and labelling of controlled drugs. Controlled drugs that are also medicines are required to meet the requirements of both the Misuse of Drugs legislation and the Medicines legislation. Where there is any inconsistency between the two sets of legislation, the Misuse of Drugs legislation takes precedence over the Medicines legislation.

Medicines Classification Committee

The Medicines Classification Committee (MCC) is a Ministerial advisory committee, established under section 8 of the Medicines Act 1981, whose terms of reference are to make recommendations to the Minister of Health (the Minister) or their delegate (Group Manager, Medsafe) regarding the classification of medicines as prescription medicines, restricted medicines or pharmacy-only medicines.

The composition of the MCC is determined in section 9 of the Medicines Act 1981. The MCC comprises of two members nominated by each of the New Zealand Medical Association and the Pharmaceutical Society of New Zealand and two members who are current employees at the Ministry of Health, one of whom is to be appointed as chairperson. Nominees are appointed for a three-year term and may be reappointed for one further term of office. Ministry of Health members retain their appointments 'during the pleasure of the Minister'.

The MCC meets twice a year, usually in April and October. Secretariat support is provided by Medsafe.

Classification of New Medicines

The MCC recommends the classification of medicines where these have not previously been scheduled. Most new active pharmaceutical ingredients are initially classified as prescription medicines. The MCC considers and reports to the Minister or their delegate on any matter concerning the classification of medicines and access to medicines by health professionals and the public. The MCC also considers new medicines that are classified by the Therapeutic Goods Administration (TGA) of Australia, in view of harmonisation.

Reclassification of Medicines

The MCC also considers applications for the reclassification of medicines. The reclassification of prescription medicines to non-prescription medicines is sometimes referred to as switching. The reclassification process may also be used to 'upschedule' a medicine (eg, a switch from non-prescription to prescription medicine).

Before making an application for reclassification

Applicants are encouraged to make a benefit-risk assessment of the medicine, proposed for reclassification, before making an application to the MCC. A useful tool for conducting a benefit-risk assessment is shown below.

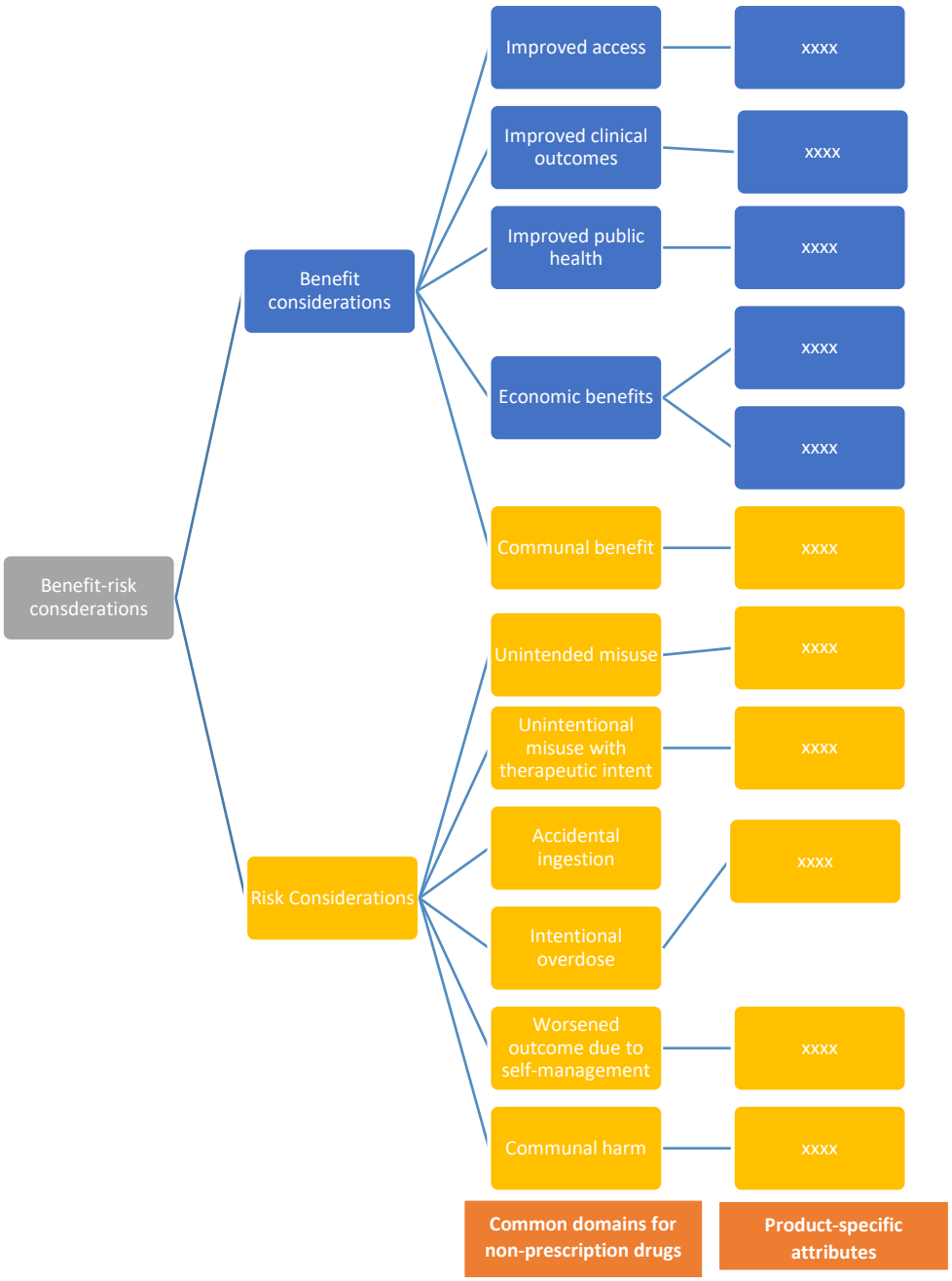

Figure 1 Benefit-risk considerations. Adapted from the Value-tree framework of benefits and risks for non-prescription drugs (Brass EP, Lofstedt R and Renn O. 2011. Improving the Decision-Making Process for Non-prescription Drugs: A Framework for Benefit-Risk Assessment. *Clinical Pharmacology & Therapeutics* 90(6): 791-803.)

Assessment using this framework will allow applicants to evaluate potential risks to their reclassification proposal and include in their application factors to mitigate this risk.

Medsafe does not usually meet with applicants in advance of any reclassification application however, Medsafe can provide advice in some instances.

If the reclassification application is successful

Because MCC meetings are held twice per year, it would typically take at least six months from the date a reclassification application is lodged until a final decision by the Minister's Delegate (Group Manager, Medsafe) and a resulting classification change notified in the *New Zealand Gazette*. The Medicines Regulations 1984 allow for a phase-in to allow time for sponsors to implement and update labelling required as a result of the classification change. It is possible for implementation of classification decisions to be deferred for longer periods when justified, for example to enable a smooth transition in the market. Request for an extended implementation period should be submitted through application, comments, or objection processes.

Reclassification process

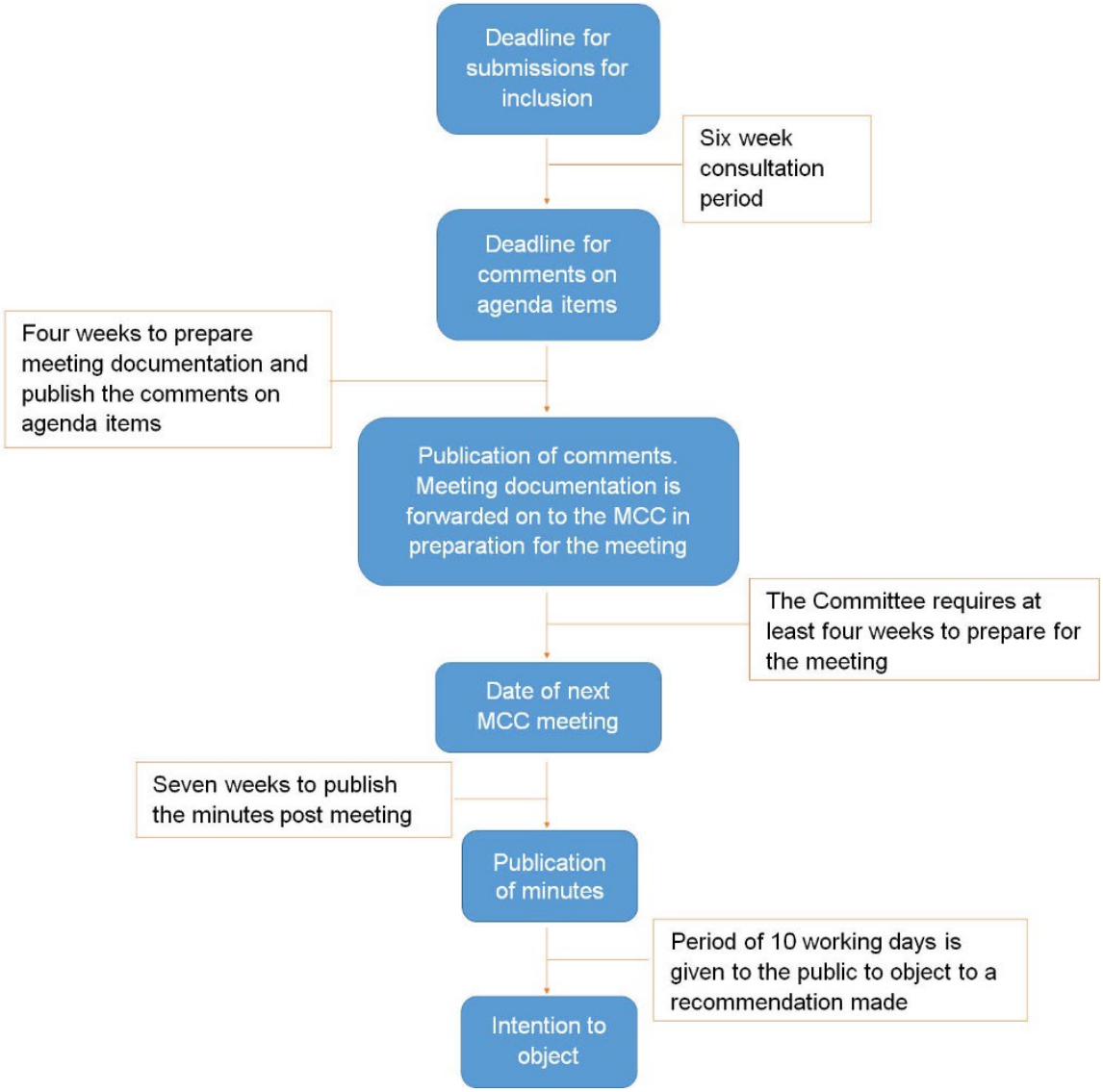

Figure 2 Timeline for reclassification applications and consultations.

Reclassification Phases

The phases of the classification process are outlined below.

Phase One: Application

Applications may be submitted from any interested individuals or groups (including pharmaceutical companies and government agencies/ departments). Those making applications are advised to liaise with the pharmaceutical companies who market the medicines for which a change of classification is sought.

An application for the reclassification of a medicine should include the information found in the classification submission template **(Appendix A).**

Medsafe reviews applications and may make recommendations to the MCC on specifics such as the classification wording.

Submission format

An electronic copy should be submitted via email in a comment-enabled PDF format to the MCC Secretariat (committees@health.govt.nz) If the file size exceeds that which can be sent by email, alternative modes of submission may be arranged by contacting the MCC Secretariat.

Submission deadlines

Closing dates for applications to the MCC are usually scheduled for the end of January and the end of July each year. More information can be found on the MCC Dates and Deadlines page on the Medsafe website.

Complete applications must be received by 5pm NZST on the final day outlined on the Dates and Deadlines page on the Medsafe website. Because of the need for a full consultation period, late applications may not be accepted.

Publication of submissions

All applications are published on Medsafe's website as a link from the agenda under

Agenda Items.
Applications may include supporting documents or appendices such as training materials and screening tools. The applicant should prepare these materials with the expectation that the information will be made publicly available. You may specifically request that some information is not released but only to the extent permissible under the Official Information Act 1982 (OIA) and other relevant laws and requirements.

If an applicant considers that material provided in the application should not be made publicly available, the applicant must request redaction of information with reference to the relevant sections under the OIA. Medsafe will review the proposed redactions and confirm prior to publication.

Evidence-based submissions

All claims made in an application should be supported by researched data. References lists must be made available for publication to allow for meaningful, transparent consultation. An executive summary may also be included.

Medicines available without a prescription should show substantial safety in use in the prevention or management of the condition or symptom under consideration and either:

- be for conditions or symptoms that can be diagnosed and managed with the assistance of a pharmacist or other specified appropriate health care professional, or
- be easily self-diagnosed and self-managed by a consumer.

Proposals for pharmacists' supply

The Pharmacy Council and the Pharmaceutical Society of New Zealand (PSNZ) have created a framework (PDF, 270 KB, 8 pages) to evaluate whether medicines proposed for restricted classification or pharmacist supply without prescription (e.g. 'prescription except when' classifications) are within pharmacists' current scope of practice or whether additional training or materials are required. (You can access the framework here: https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf). It is anticipated that reclassifications would typically be within pharmacist scope, however, there may be some additional refreshing of knowledge as part of pharmacists' ongoing competence that is recommended.

Both the Pharmacy Council and PSNZ review the MCC agenda and, where appropriate, provide Medsafe advice as to whether additional training or materials are required for pharmacists should the classification of a medicine be changed.

Although the aforementioned framework is not mandatory for the purposes of the MCC; applicants are encouraged to consult both the Pharmacy Council and PSNZ should they wish to put forward a submission that would enable pharmacist supply of a medicine without prescription.

It is not within the MCC remit to design training programmes; however, they can recommend that additional training is required in the classification conditions. For example, the classification of levonorgestrel allows for pharmacist supply of the levonorgestrel emergency contraceptive pill (ECP) and selected oral contraceptives (SOCs) provided certain conditions are met and the pharmacist has completed an approved training programme.

Phase Two: Public consultation

After the closing date for applications for each meeting, the agenda for the next meeting is published on the Medsafe website under Agenda Items. Links to applications are provided. Any Medsafe reports may also be provided when these have been completed.

Pharmaceutical companies and other interested bodies should monitor the Medsafe website to check whether any of their products are likely to be affected by a proposed change. Medsafe sends out regular emails with a list of changes to the Medsafe website, which can be subscribed here.

The consultation period provides an opportunity for interested parties to comment on the proposed agenda items. Comments and feedback, including any supporting data or references, should be submitted electronically via email with a completed cover sheet to the MCC Secretariat (committees@health.govt.nz).

Publication of comments

Comments on agenda items are published on the Medsafe website under Agenda

Items. As with the submission of proposals for reclassification, comments should be agenda items should prepared with the expectation that the information will be made publicly available. Should information be proposed for redaction it must be in line with the OIA.

Consultation period

Approximately six weeks is available for the preparation of comments. Closing dates are provided on the Medsafe website under Dates and Deadlines.

During this period, Medsafe may also seek independent advice from experts or specialist organisations.

Applications, comments on agenda items and Medsafe reports are sent to MCC members three to four weeks before the date of a meeting. As MCC members need this time to prepare for meetings, late comments on agenda items cannot be accepted.

Phase Three: Meeting and MCC recommendations

The MCC meets every six months, around April and October of each year to make recommendations to the Minister of Health.

Opportunity for the MCC to raise questions with the applicant

Applicants are not able to provide any new information that was not included in the original application, in the interests of transparency. The meeting in general is held under the Chatham House Rule.

The meetings are not open to the public, media or other interested parties.

What is considered?
For each proposed medicine reclassification the MCC considers the parameters listed in the submission (e.g. Appendix A) along with the benefit/risk considerations (e.g. figure 1) and any other relevant information for that medicine.

What is not considered?

The MCC makes recommendations based on ensuring the safe and equitable access to medicines for all New Zealanders. Factors such as the potential impact of a reclassification on the cost of a medicine are not considered by the MCC.

Harmonisation with Australia

The MCC also reviews recent classification changes in Australia, with a view to harmonising classification where appropriate.

Requests for Information

The MCC may in some instances make a recommendation that the applicant, or Medsafe, should provide further information to clarify certain points or to address the MCC's concerns regarding their application. The applicant will be informed of the questions by Medsafe, and will be able to provide a revised submission for the next meeting, which will be consulted on.

Recommendations
Following a meeting, minutes summarising the discussion and the recommendations are drafted, peer reviewed and sent to MCC members for comment.

Phase Four: Noting of the MCC's recommendations by the Minister's Delegate

The ratified minutes are forwarded to the Minister's Delegate together with a memo from Medsafe.
The Minister's Delegate notes the recommendations made by the MCC, but does not exercise a regulatory power at this time.

Phase Five: Publication of the minutes and MCC recommendations

Once the recommendations have been noted by the Minister's delegate, the full minutes of the meeting are published on the Medsafe website under Meeting Minutes.

Phase Six: Objection to an MCC recommendation

Notice of intention to object to a recommendation for reclassification, and a summary of the grounds for that objection (including reference to any supporting data to be provided), must be lodged with the MCC Secretariat by the date given on the Dates and Deadlines page for inclusion on the agenda for the next meeting. Approximately ten working days, following publication of the minutes, are allowed.

Supporting data for an objection need not be lodged at this time but should be submitted electronically to the MCC Secretariat (committees@health.govt.nz) by the closing date published on the Dates and Deadlines page.

Phase Six is an opportunity to object to the recommendation made by the MCC, not to the initial proposal. The determination of whether an objection is valid will be made by the Medsafe Group Manager on advice from the Secretariat of the MCC.

On receipt of a valid objection, the medicine in question will be removed from the *New Zealand Gazette* notice until the matter has been resolved. All valid objections will be published on the Medsafe website.

The proposed criteria for valid objections are:

1. 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);
2. the MCC did not consider all the benefits;
3. there was a breach of the appropriate process.

Financial or commercial reasons are not acceptable grounds for objection.

Companies should contact Medsafe (at medsafeapplications@health.govt.nz) if they are unable to meet the proposed implementation timeframes.

Phase Seven: Final Decision of the Minister's Delegate

After the closing date for objections, the Minister's Delegate will consider the recommendations made by the MCC along with any comments made by Medsafe and valid objections received. The Minister's delegate will then make a final decision regarding the MCC recommendations for that meeting.

Phase Eight: Notification in the *New Zealand Gazette*

The *New Zealand Gazette* is the official Government newspaper and authoritative journal of constitutional record. The Minister of Health (or the Minister's delegate) may classify medicines by notice in the *Gazette* under section 106 of the Medicines Act 1981.

Following the Minister's delegate's final decision any medicines which are to be classified or reclassified will be published in a *Gazette* notice. To the extent that any such *Gazette* notice is inconsistent with any provisions of any regulations included in the First Schedule of the Medicines Regulations 1984 the classification as according to the *Gazette* notice will be regarded as the classification of that medicine. A copy of the *New Zealand Gazette* notice is published on the Medsafe website under 'Recent New Zealand Gazette Notices Relating to Classification'.

The Medicines Classification Database will keep record of the current classifications of medicines in Aotearoa New Zealand and is regularly updated.

Changes will eventually be incorporated into an amendment to the First Schedule to the Medicines Regulations 1984. Amendments to the First Schedule to the Medicines Regulations 1984 are completed approximately every two years.

Phase Nine: Implementation of a reclassification change

When a classification change takes place, a change of labelling may be required. Other changes may also be necessary. Companies need to consult the Guideline on the Regulation of Therapeutic Products in New Zealand to see whether they are required to submit a Self-assessable Change Notification, a Changed Medicine Notification or a New Medicine Application.

Changes to labels/ data sheets may be necessary or new labels/ data sheets may be required.

Regulation 15(4) and (5) of the Medicines Regulations 1984 allows three months from the date of notification of a classification change for stock labelled with the old classification to be replaced at wholesale level and six months for replacement of stock at retail level. However, any existing stock must be sold at the new level of classification from the date on which the change comes into effect.

Appendix A- Submission Template

A downloadable copy of the medicine reclassification submission template can be found **here**. (*Word document 35KB, 7 pages*)

Submission for medicine reclassification for consideration by the Medicines Classification Committee

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

Please also complete an introduction summarising the intention of the submission and provide any relevant background.

Once completed, this application should be sent to the MCC Secretariat (committees@health.govt.nz) by the deadline 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 understanding that this information and any appendices and/ or supporting information that is not considered commercially confidential under the Official Information Act 1982 will be published on the Medsafe website.

Introduction

Please provide background context for the submission

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

2. Proprietary names (if applicable)

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

Contact details can be removed from the form prior to publication of the Medsafe website if requested.

4. Dose form(s) and strength(s) for which a change is sort (if applicable)

5. Pack size, storage conditions and other qualifications (if applicable)

6. Indications for which change is sought (if applicable)

7. Present classification of the medicine

8. Classification sought

9. Classification status in other countries (especially Australia, UK, USA and Canada), and any justification for harmonisation

10. Extent of usage in New Zealand and elsewhere (e.g. sales volume) and dates of the 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) (if applicable)

13. Proposed warning statements (if applicable)

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

Part B- Clinical Context and Implications

15. 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?*

16. Presentation

- *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*
- *What disposal considerations need to be made for the medicine?*
- *How practical and easy to use is the proposed presentation?*

17. Consumer benefits

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

18. 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?*

19. 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?*

20. 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?*

21. Medication errors and abuse/ misuse potential

- *Would reclassification affect the risk of unnecessary use?*
- *Should 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?*

22. Communal harm and/or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., 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 (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?*

23. 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?*

24. Risk mitigating strategies

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., 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?*

Conclusion

A brief summary of the purpose of the submission and any concluding remarks

References

Please provide references for your submission