



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



Guidance document

Medsafe
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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), 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 stipulated in section 9 of the Medicines Act 1981. The MCC comprises of at least seven suitably qualified members. Members may include those with a public health/health policy background, practicing general practitioners, practicing pharmacists, nurses, allied health professionals, and consumer representatives. Members are appointed for a three-year term and may be reappointed for one further term of office.

The MCC meets three times per year, in April, July, and November. 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' or 'down-scheduling'. The reclassification process may also be used to 'upschedule' a medicine (e.g. 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.

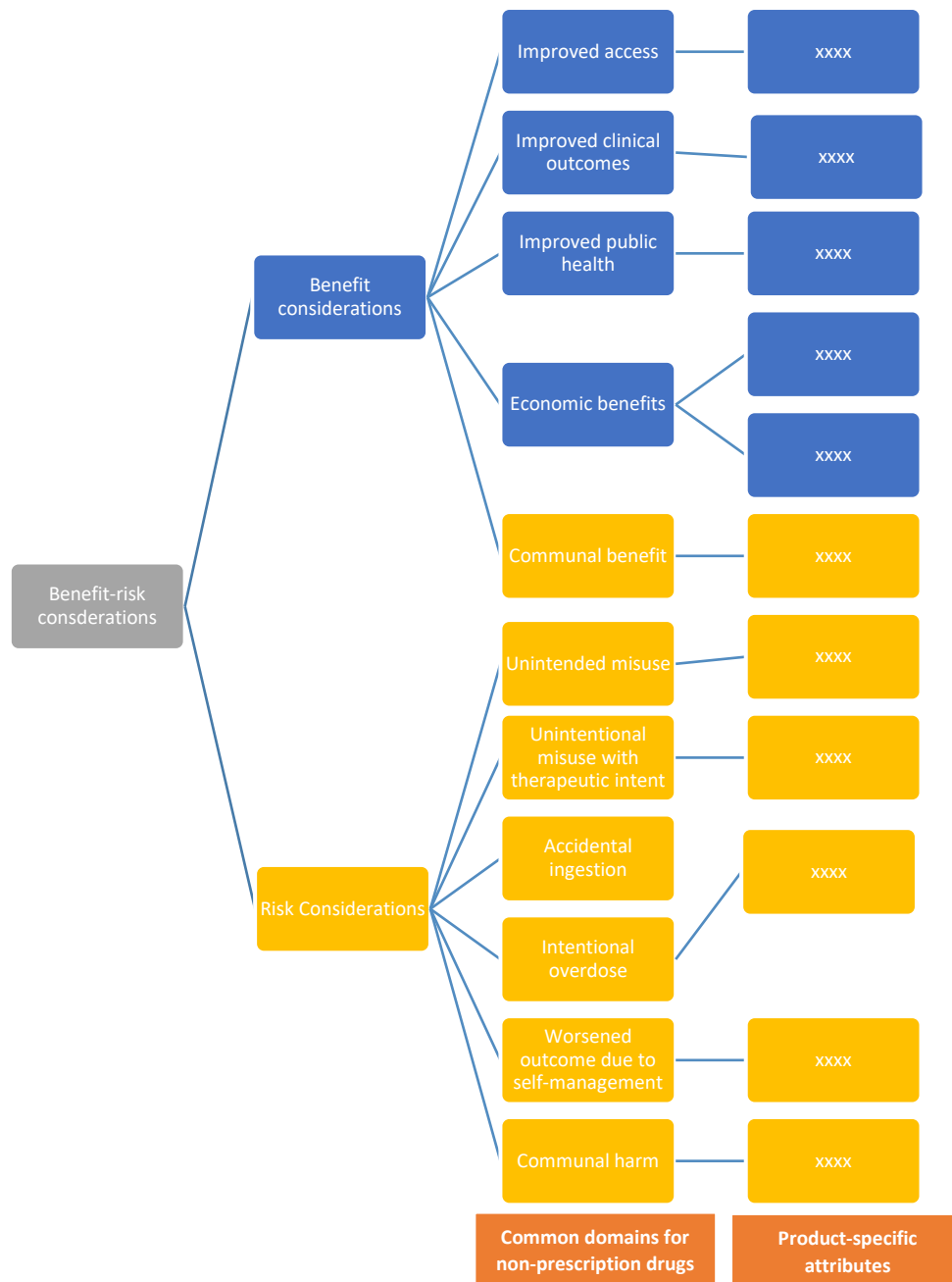


Figure 1 Benefit-risk considerations. Adapted from the Value-tree framework of benefits and risks for non-prescription drugs (Brass EP, Lofstedt R and Renn O. 2011. Improving the Decision-Making Process for Non-prescription Drugs: A Framework for Benefit-Risk Assessment. *Clinical Pharmacology & Therapeutics* 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 the MCC is robust and includes consultation and objection periods, it can take at least six months from the date a reclassification submission is lodged for a final decision by the Minister's Delegate (Group Manager, Medsafe) to be made, 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

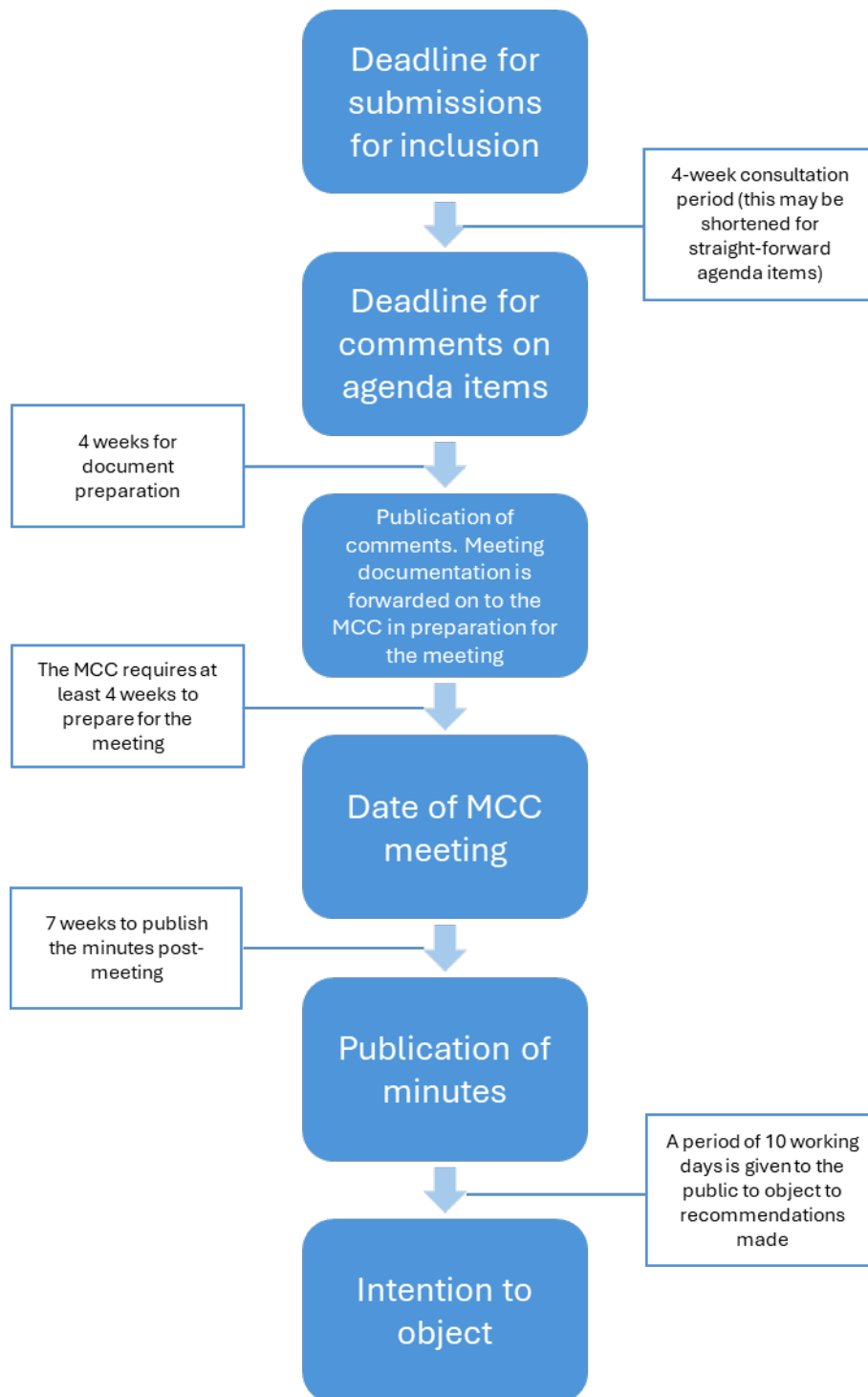


Figure 2 Timeline for reclassification applications and consultations.

Reclassification Phases

The phases of the classification process are outlined below.

Phase One: Application

Meetings are held three times per year, in April, July, and November. Submissions for reclassification may be made at any time. For inclusion of submissions to a specific meeting, submissions must meet fixed annual deadlines:

- April meeting: submissions required by last Friday in January, 5pm NZST
- July meeting: submissions required by last Friday in April, 5pm NZST
- November meeting: submissions required by last Friday in August, 5pm NZST

Exact meeting dates and submission deadlines can be found on the [MCC Dates and Deadlines](#) webpage. You can [subscribe](#) to receive regular emails about medicines classification, including deadlines for submissions for the next meeting, meeting dates, consultation dates, objection dates, and notification of classification changes.

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 specific components, such as the classification statement 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.

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 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 regularly comment on 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 to [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 on agenda items should be 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 4 weeks is available for the preparation of comments, depending on the size of the agenda. The consultation period may be shortened for straight-forward agenda items. 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 three times per year, in April, July, and November, 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.

The MCC make recommendations based on their professional experience and judgement, and based on the information provided to them at the meeting. The MCC does not undertake extensive research on agenda items, such as systematic literature reviews for example, to gather further information – this must be provided by the submitter.

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 presented to them;
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.

The final decision on classification of medicines is by the Minister's delegate.

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 (i.e. the publication of the gazette notice) 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, 47KB, 8 Pages)

Submission for Medicine Reclassification

Purpose

Use this form to request a change to the legal classification of a medicine in New Zealand for consideration by the Medicines Classification Committee (MCC).

Before you start

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

Submitting

Please prepare concise, well-referenced answers to the questions in this form. Complete the form as per the instructions provided with each question, and complete the mandatory field declaration at the start of this form. Once completed, please email this form and any appendices to the MCC Secretariat (committees@health.govt.nz) by the [published submission deadline](#).

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

Mandatory Field Declaration

I confirm that the mandatory fields (indicated next to each question by *****) are completed.

Please note: submissions with incomplete mandatory fields before the submission deadline will not be accepted.

Submission Overview*

Please provide a concise summary of the proposal and background context. Include the current access situation, what change is sought, and why the change is needed.

Part A - Administrative Information & Proposed Classification

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

Do you wish to have personal names and contact details removed prior to publication?

Yes No

If yes, please clearly mark the fields you wish to be redacted.

2. International non-proprietary (INN) name of the substance*

Please see the World Health Organization site on International Non-proprietary Names for more information: <https://www.who.int/teams/health-product-and-policy-standards/inn>

3. Current classification of the substance*

The current classification of a substance can be found on the Medsafe website:

<https://www.medsafe.govt.nz/profs/class/classintro.asp>

If the substance is not yet classified in New Zealand, please state this.

4. Proposed classification*

Please provide the proposed classification statement for the substance. If your proposed classification statement refers to healthcare professionals, or imposes conditions on supply to certain healthcare professionals, consultation with relevant professional bodies may be beneficial. If relevant, please outline any consultation undertaken and their outcome.

You may also wish to explain what you want the classification to achieve (e.g. to enable supply of these medicines by a pharmacist).

5. International classification*

Please provide the classification status of the substance in other countries (particularly Australia, UK, USA, and Canada). If seeking alignment with other jurisdiction(s), please provide any justification for harmonisation with these countries. The following resources may be helpful:

- Australia: [The Poisons Standard](#)
- United Kingdom: [The Prescription Only Medicines \(Human Use\) Order 1997](#)
- Canada: the [Prescription Drug List](#) and the [Natural Health Products Ingredients Database](#)

6. New Zealand product details

Please provide the following information:

- List the approved medicines that contain the substance. Products can be searched on the Medsafe website: <https://www.medsafe.govt.nz/regulatory/dbsearch.asp>
- State the dose form(s), strength(s), route(s) of administration, and/or pack size(s) of medicines containing the substance that are approved in New Zealand. Does this submission only apply to certain dose forms, strengths, and/or pack sizes?

7. Related substances in the same class

How are other medicines in the same class of the substance classified? Does the proposed reclassification of the substance align with those of the same class, or does it deviate?

8. Warning statements

Do you propose any additional warning statements to be included on products to manage any risk associated with the proposed reclassification? Please see the Label Statements Database on

the Medsafe website for examples of warning statements:

<https://www.medsafe.govt.nz/regulatory/labelling.asp>

Part B - Benefit/Risk Assessment

MEDICINE DETAILS

9. Approved indications*

What are the approved indications for medicines containing this substance in New Zealand? Does this submission only apply to certain indications? Do these indications only apply to certain doses/strengths? Please provide details.

10. Contraindications and precautions*

Please address the following, citing key sources where available:

- *Contraindications: what are they and how easy are they to identify and prevent?*
- *Precautions: what are they and how easy are they to understand?*
- *Class effects: what class effects need to be considered, and what are the risks?*
- *Interactions: are there any food/drink/drug interactions?*
- *Therapeutic index: does the medicine have a narrow therapeutic index? What are the risks of the medicine being used in an over-the-counter environment?*
- *Special populations: are there any restrictions when taking the medicine, i.e. driving restrictions or operating machinery? Are there any other special populations where exposure to the medicine needs to be restricted?*

11. Undesirable effects*

Please address the following:

- *Undesirable effects: what are the known adverse effects, their frequencies, and risks/consequences? Do they vary for special populations?*
- *Regulatory status: are there any significant safety concerns for the medicine under review? Have there ever been any withdrawals of the medicine (during a specific time period or in a specific jurisdiction)?*
- *Withdrawal: can withdrawal effects occur following cessation of use?*

BENEFIT CONSIDERATIONS

12. Safe access*

Describe the current access issues and how the proposed classification change would address them. Include:

- *Use history: how many people in New Zealand (and overseas) use this medicine? To what extent is this medicine used for the proposed indication(s) (i.e. duration of use; frequency of use)?*
- *Inappropriate access: what is the evidence that access is currently inappropriate? Are any groups particularly impacted? How would the reclassification improve safe access to the substance?*
- *Practice impact: how would the reclassification impact access/administration by other healthcare professionals (e.g. midwives, paramedics)?*

13. Improved clinical outcomes*

Describe the expected clinical benefits as a result of the proposed reclassification. What is the evidence that the proposed change in access is beneficial for the individual? Is there any benefit of improved consumer involvement in their health? Are there any other benefits, from a consumer viewpoint?

14. Public health benefits

If relevant, outline broader public health benefits resulting from the proposed reclassification. Examples could include (but are not limited to):

- *Greater herd immunity due to improved access to a communicable disease vaccine*
- *Reduced health system pressure due to over-the-counter availability*
- *Support for wider public health goals (e.g. reduce smoking rates)*
- *Prevention of antimicrobial resistance by restricting access to certain medicines*
- *Reduced poisoning incidents by removing over-the-counter availability*
- *Reduce crime or illicit manufacture of certain substances*
- *Limiting environmental impact of certain medicines*

RISK CONSIDERATIONS

15. Medication errors and abuse/misuse potential*

Could the proposed reclassification increase the risk of inappropriate use or medication errors? Please address the following:

- Reports: what are the reported medication errors post-market? What are the reported cases of abuse/misuse/accidental overdose, in New Zealand and overseas?
- Inappropriate use: what is the addiction potential of the medicine? What are the risks of incorrect or inappropriate self-selection, and how are these mitigated? What are the risks associated with self-management? Are there risks of patients using these medicines 'off-label'?

16. Overdose*

Is there a potential for overdose of the medicine? Are there any reports of overdose, and what are the consequences of an overdose? What risks are there of accidental ingestion, for example by children? Does the proposed reclassification increase the risk of overdose?

17. Communal harm

Are there any community-wide harmful consequences that may result from the proposed classification change? Examples could include (but are not limited to):

- Increased risk of antibiotic resistance due to overuse of antibiotics
- Promotion of inappropriate use (e.g. on social media)
- Reduced opportunities for clinical assessment for certain conditions
- Increased use of unapproved substitutes
- Higher healthcare system burden

18. Risk mitigation strategies*

What risk mitigation strategies (if any) are required? Please address the following:

- Strategies: is healthcare professional education, integration of care, provision of consumer information, etc needed? Should the medicine be provided with necessary tools to enable correct dosing (e.g. liquids supplied with a measuring device)? Should

there be limits on pack size, or maximum daily dose? What is the evidence that these proposed risk mitigation strategies would be effective?

- *Data: what post-market surveillance activities would be carried out?*
- *Support: is the proposed reclassification supported by professional bodies, interest groups, or other relevant groups?*

REGULATORY & ECONOMIC IMPACT

19.Regulatory impact

What are potential regulatory impacts (intended or unintended) of reclassification? The following points may be helpful for your discussion:

- *Is it possible that other products will inadvertently be captured by the classification? If so, are there caveats in the classification statement that could manage this?*
- *Are there any other legal restrictions that need to be considered (e.g. Misuse of Drugs Act 1975, Dietary Supplement Regulations 1985)?*
- *Would the proposed reclassification be an incentive for companies to supply (or not supply) certain products in New Zealand?*
- *Please suggest any issues that may need to be considered by Medsafe when drafting a classification statement.*

20.Economic impact

What are potential economic impacts of the proposed change? Does the change relieve any unnecessary burden on the health system? Or could it place unnecessary pressure on the system? Is there likely to be any impact on costs for the consumer?

Summary*

Please provide a summary of the proposal, including:

- *A summary of the need for the substance to be reclassified*
- *An integrated summary of the potential benefits and harms of the proposed reclassification; how do the potential benefits outweigh the potential harm?*

References*

Please provide references for your submission. Submissions should be supported by high-quality, well-referenced evidence from credible and authoritative sources, where available.

Appendices

Please provide any supporting documentation as labelled appendices.