

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 or individuals who are considering applying to change the legal classification of a medicine in 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 New Zealand to help ensure an easy to understand and transparent process.

Definitions

Applicants	Pharmaceutical companies, health professional organisations, Medsafe or individuals who are applying to change the legal classification of a medicine in New Zealand
MCC	Medicines Classification Committee
INN	International Non-proprietary Name

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 used by a registered member of another specified health profession when permitted in the First Schedule to the Medicines Regulations 1984 or amendments.
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. Medicines not listed in the classification schedules are deemed to be unclassified, and are referred to as general sale medicines. These medicines may be sold from any outlet.

To avoid confusion, the full term should be used when referring to a medicine's classification. Avoid using acronyms (PM, RM, POM).

Medicines are generally classified according to their active ingredients. The INN is the name of choice. If the medicine has more than one active ingredient, the active with the most restrictive classification determines the classification of the medicine. The First Schedule to the Medicines Regulations 1984 is a list of active ingredients grouped under their respective classifications.

Classification changes occur approximately every six months. Updates may occur either through an amendment to the Medicines Regulations 1984 or through

publication of a notice in the *New Zealand Gazette*. Amendments are usually published in June each year. For the latest amendment see the Current Amendment to the Classification Schedule on the Medsafe website at www.medsafe.govt.nz/profs/class/amendment.asp.

When checking a classification, refer to the latest amendment to the Medicines Regulations 1984 and any subsequent updates published in the *New Zealand Gazette*. Alternatively, check the classification on the Classification Database on the Medsafe website at www.medsafe.govt.nz/profs/class/classintro.asp.

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 Regulations 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 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 regarding the classification of medicines as prescription medicines, restricted medicines or pharmacy-only medicines.

The MCC recommends the classification of active ingredients where these have not previously been scheduled. Most new active substances are initially classified as prescription medicines. The MCC considers and reports to the Minister on any matter concerning the classification of medicines and access to medicines by health professionals and the public.

The MCC will also consider applications for the reclassification of medicines. The reclassification of prescription medicines to non-prescription medicines is sometimes referred to as switching.

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

The MCC comprises two nominees from each of the New Zealand Medical Association and the Pharmaceutical Society of New Zealand and two members of 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 members retain their appointments 'during the pleasure of the Minister'.

Before making a submission for reclassification

Applicants are encouraged to make a risk-benefit assessment of the medicine, proposed for reclassification, before making a submission to the MCC.

A useful tool for conducting a risk-benefit assessment is shown below.

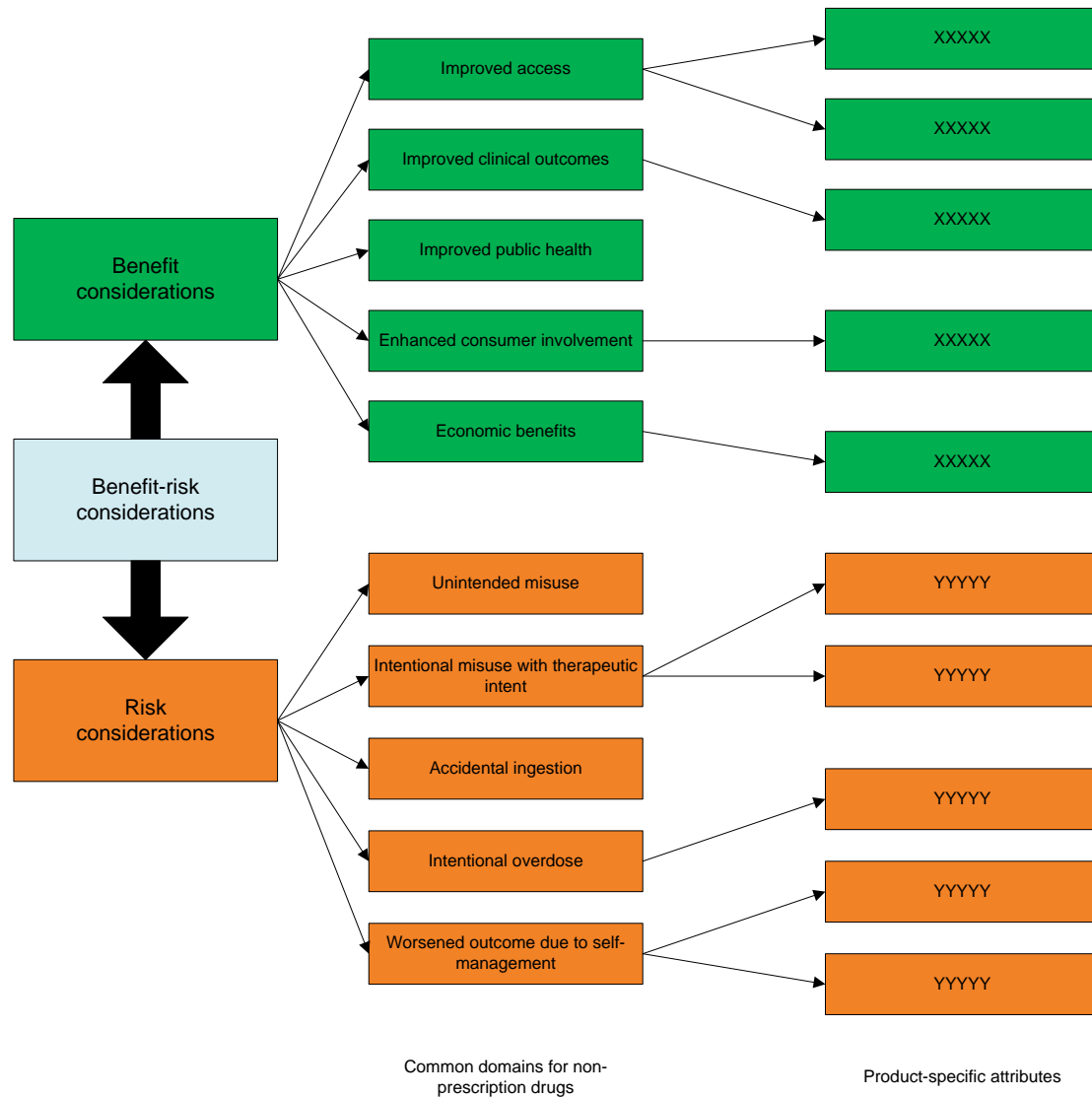


Figure 1 Value-tree framework of benefits and risks for non-prescription drugs (Brass EP, Lofstedt R and Renn O. 2011. Improving the Decision-Making Process for Non-prescription Drugs: A Framework for Benefit-Risk Assessment. *Clinical Pharmacology & Therapeutics* 90(6): 791-803.)

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

Medsafe is unable to meet with applicants in advance of any reclassification submission. Meeting with applicants would pose a significant resource issue for Medsafe and could be considered a conflict of interest for the Ministry of Health members of the MCC.

Should the reclassification submission be successful

It takes approximately six months from the date a reclassification submission is lodged until the resulting classification change is notified in the *New Zealand Gazette*. A maximum of six further months is allowed in the legislation for companies to amend labelling to reflect classification changes.

There are nine phases in the classification process, as outlined below.

Phase 1: Submission

Closing dates for submissions to the MCC are the end of January and the end of July each year.

While applications usually come from sponsor companies, anybody may make a submission to the MCC. Individuals or groups making submissions are advised to liaise with the pharmaceutical companies who market the medicines for which a change of classification is sought.

A submission for the reclassification of a medicine should include:

Part A

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine.
2. Proprietary name(s).
3. Name of the company / organisation / individual requesting a reclassification.
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. Labelling or draft labelling for the proposed new presentation(s).
12. Proposed warning statements if applicable.
13. Other products containing the same active ingredient(s) and which would be affected by the proposed change.

Part B

Reasons for requesting classification change including benefit-risk analysis.

This section should be supported by the following:

1. A statement of the benefits to both the consumer and to the public expected from the proposed change.
2. Potential risk of harm to the consumer as a result of the proposed change, and factors to mitigate this risk.
3. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated.
4. Relevant comparative data for like compounds.
5. Local data or special considerations relating to New Zealand.
6. Interactions with other medicines.
7. Contraindications and precautions.
8. Possible resistance.
9. Adverse events - nature, frequency, etc.
10. Potential for abuse or misuse.

All claims made in a submission should be supported by researched data. Only key papers need to be supplied. References are adequate for other material. An executive summary may also be included.

The MCC does not make recommendations to the Minister on moral or ethical matters, or on financial matters other than in terms of access for consumer convenience.

One electronic copy of each submission is required including any supporting data or references. The electronic copy should be submitted on a CD (in either Microsoft Word format or comment enabled PDF format). Copies of submissions are circulated to MCC members electronically and this format enables comments to be included during the review process.

All submissions are published on Medsafe's website as a link from the agenda under Agenda Items at www.medsafe.govt.nz/profs/class/clasagencon.asp. Any reports written for the MCC by Medsafe may also be published. All references cited that are of critical relevance to the argument must be made publicly available to fully inform the consultation process.

Submissions may contain commercially sensitive information such as training materials and screening tools, which can be withheld from publication. In such cases, the commercially sensitive information should be included as an appendix to the submission and clearly marked as confidential. Justification for confidentiality must also be provided. If the information withheld is critical to the management of the risks associated with a medicine, the main submission should note that this information has been provided to the Committee and withheld for confidentiality purposes.

In addition to the electronic copy, one hard copy of each submission is also required. As submissions need to be filed in hard copy at Medsafe, it is preferable that they are presented in a secure fashion.

Submissions should be addressed to the MCC Secretary at:
Medsafe
PO Box 5013
Wellington 6145

All other communications on classification matters should be addressed to the MCC Secretary at committees@moh.govt.nz.

Because of the need for a full consultation period, late submissions cannot usually be accepted.

Submissions are sometimes allocated to Medsafe evaluators for independent review. The resulting reports are peer reviewed to ensure that they reflect Medsafe's view rather than that of an individual evaluator. The reports may involve extensive literature searches as well as assessment of the material submitted.

Phase 2: Public consultation

After the closing date for submissions for each meeting, the agenda for the next meeting is published on the Medsafe website at www.medsafe.govt.nz/profs/class/clasagencon.asp. Links to company submissions

are provided. Any Medsafe reports may also be provided when these have been completed.

The consultation period provides an opportunity for interested parties to comment on the proposed agenda items. Comments should be supplied to the MCC Secretary electronically (if more than five pages long, one hard copy should also be provided). A completed cover sheet must be included with the comments. The template is available at www.medsafe.govt.nz/profs/class/ClassificationSubmissionsForReclassification.asp. Comments on agenda items are published on the Medsafe website under Agenda Items at www.medsafe.govt.nz/profs/class/clasagencon.asp. Commercially sensitive and personal information will be withheld from publication upon request.

Pharmaceutical companies and other interested bodies are expected to watch the Medsafe website to check whether any of their products are likely to be affected by a proposed change. Medsafe sends a weekly email with a list of changes to the Medsafe website.

Approximately six weeks is available for the preparation of comments. Closing dates are provided on the Medsafe website in Dates and Deadlines at www.medsafe.govt.nz/profs/class/dates.asp.

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

Submissions, 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 may not be accepted.

Phase 3: Meeting and MCC recommendations

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

Applicants are given the opportunity to observe a meeting. If present at the meeting, applicants (maximum of three) are able to observe the discussion around their reclassification proposal. The meeting in general is held under the Chatham House Rule (www.chathamhouse.org.uk/about/chathamhouserule/). Applicants may also have the opportunity to answer any queries posed by the MCC and provide explanations which would help make a final recommendation. However, applicants are not able to be present for the final recommendation made by the MCC.

The MCC uses the following principle when considering a medicine for suitability for non-prescription sale: Medicines which may be available without prescription shall be able to either:

- a. show substantial safety in use in the prevention or management of the condition or symptom under consideration
- b. be for conditions or symptoms that can be diagnosed and managed by a pharmacist
- c. be easily self-diagnosed and self-managed by a patient.

During a meeting the MCC considers the following criteria when reviewing a medicine for reclassification for non-prescription sale. The list is not ranked in any

order of importance. The criteria may vary in importance according to the medicine being considered for reclassification. In some cases one criterion alone may be sufficient to outweigh all others in determining whether or not a medicine should be reclassified.

- **Patient access**

Accessibility of the medicine. Accessibility includes time and location factors. Would improved access increase uptake of appropriate treatments (eg, emergency contraception) or contribute to unnecessary medication use.

- **Accuracy**

The ability of a consumer and / or healthcare professional to accurately identify a disease or condition, including the understanding of the symptoms and the possibility for alternate conditions or diagnosis. The ability of a consumer to understand how the medicine they are purchasing should be used, particularly when in addition to other healthcare products that the consumer may be using. Accuracy includes a consideration of the consequences of an incorrect understanding or diagnosis (eg, the failure to seek or receive appropriate treatment).

- **Efficacy**

The ability of a medicine to produce a desired therapeutic effect (and therefore avoid harm associated with suboptimal therapy and / or an inappropriate risk-benefit balance).

- **Precedent**

The availability of medicines with a similar therapeutic purpose.

- **Therapeutic index**

The margin between therapeutic and toxic effects.

- **Toxicity**

The potential of a medicine to produce adverse effects, taking into consideration the seriousness and frequency of such effects. Safety of the medicine when used inappropriately (eg, when not indicated, inappropriate dosage, inappropriate duration of treatment, against warnings).

- **Abuse potential**

The use of a medicine for gratification-producing effects not required for therapy.

- **Inappropriate use**

Factors relevant to the minor ailment or symptom for which the medicine is indicated, including the suitability of the condition for self-monitoring and the likelihood of misdiagnosis. Risk of diversion of treatment to inappropriate patients (eg, children, those with contraindications).

- **Precautions**

Factors relevant to the medicine under consideration such as contraindications, side-effects and interactions with other medicines. Taking into consideration the ability to mitigate these with labelling, patient information, etc.

- **Communal harm and / or benefit**

The possibility of community harm and / or benefit resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria or increased immunisation rates).

The potential impact of a reclassification on the cost of a medicine is not a factor considered by the MCC when reviewing a medicine for reclassification for non-prescription sale.

The MCC will also consider the classification of the medicine in Australia. Since the early 2000s, New Zealand and Australia have been working towards the harmonisation of classification decisions in both countries.

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

Ministerial powers in relation to classification have been delegated to the Chief Medical Officer, Clinical Leadership, Protection and Regulation Business Unit, who acts as the Minister's Delegate. The agreed minutes are forwarded to the Minister's Delegate together with a report from Medsafe. If Medsafe does not agree with any recommendation made by the MCC, Medsafe's view will be included in this report together with a justification for that view.

Phase 4: Noting of the MCC's recommendations by the Minister's Delegate

The Minister's Delegate notes the recommendations made by the MCC. The Minister's Delegate will either support the recommendations made by the Committee or accept the alternative advice provided by Medsafe, but does not exercise a regulatory power at this time.

The minutes are returned to Medsafe for further action.

Phase 5: Publication of the minutes and MCC recommendations

During the period between a meeting and noting of the recommendations made at that meeting, it is not normal practice to make the MCC's recommendations known.

As soon as the recommendations have been noted by the Minister's delegate, the full minutes of the meeting are published on the Medsafe website at <http://www.medsafe.govt.nz/profs/class/minutes.asp>.

If the Minister's Delegate supports the advice of Medsafe, rather than the MCC, the reasons for this will be published on the Medsafe website.

Those who have made applications to the MCC receive an email explaining the outcome before the minutes are published.

A period of four weeks' advance notice is provided before changes are put into effect by a notice in the *New Zealand Gazette*. This allows lead-in time for preparation of new labelling and for pharmacists to prepare for marketing under the new classification. Time is also allowed to lodge objections.

Phase 6: 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 Secretary by the date given on the Medsafe website (at www.medsafe.govt.nz/profs/class/dates.asp) 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 (if more than five pages long, one hard copy should also be provided) by the closing date published on the Medsafe website. This date usually coincides with the closing date for comments on agenda items for the next meeting.

Phase 6 is an opportunity to object to the recommendation made by the MCC rather than to the initial proposal. If Medsafe considers that an objection has been made on valid grounds, the medicine in question will be removed from the *New Zealand Gazette* notice until the matter has been resolved.

Objections to recommendations on the classification of medicines should be made only on safety issues and should contain new safety data not available to the MCC at the time the recommendation was made. Financial or commercial reasons are not acceptable grounds for objection.

Medsafe will consider the evidence submitted in support of an objection and will decide whether or not the matter should be referred back to the MCC. Normally objections will be referred back to the MCC only when there is substantial new safety evidence to support the objection.

All objections that are valid will be made available to the original applicant prior to review by the MCC. The original applicant will be given the opportunity to provide information to the MCC to address the objection.

Phase 7: Confirmation by the Minister's Delegate

After the closing date for objections, the Minister's Delegate signs a notice prepared by Medsafe for publication in the *New Zealand Gazette*. This notice implements the recommendations for a change of classification which have been accepted earlier and which have not been the subject of a valid objection.

Phase 8: Notification in the *New Zealand Gazette*

Approximately four weeks after the recommendations of a meeting have been published on the Medsafe website, classification changes are published in the *New*

Zealand Gazette. Classification changes take effect from the date of publication of the *New Zealand Gazette*.

The Classification Database on the Medsafe website (at www.medsafe.govt.nz/profs/class/classintro.asp) is updated. A copy of the *New Zealand Gazette* notice is published on the Medsafe website (at <http://www.medsafe.govt.nz/profs/class/recent.asp>). Changes are subsequently incorporated into an amendment to the First Schedule to the Medicines Regulations 1984.

Phase 9: 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* (at www.medsafe.govt.nz/regulatory/guidelines.asp) 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.

Section 16(2) and (3) 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.

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

General policies

From time to time the MCC makes general policy statements which are intended for long-term application. The following policy statements have been made since 1990:

- Presentation of submissions (6 July 2009)

Presentation of submissions to the MCC should be as one electronic copy on CD (in either MS Word format or comment enabled PDF format) and as one hard copy.

Electronic copies should contain the full text of the submission including any supporting data and references. Please note, supporting data and references will not be published on the Medsafe website. Commercially sensitive material should be identified and may be withheld from public release. The nature of the commercially sensitive material should be declared in the application together with the relevant section of the Official Information Act 1982 that you propose to use to justify withholding the data from release.

Hard copies should be presented in a secure fashion.

Submissions which do not meet these requirements will not be considered by the MCC.

Comments and objections to the MCC should be provided in electronic form. If more than five pages long, one hard copy should also be provided.

- Scope of Committee Recommendations (25 May 2000)

The MCC should make recommendations only about those medicines which it has been asked to consider and which have undergone consultation, not other medicines in the same therapeutic group.

The MCC should make recommendations only on the classification status sought in a submission and not recommend an alternative classification. It may, however, indicate its willingness to consider a classification change other than that sought initially.

- Requirements for Reclassifying NSAIA's to General Sale (20 May 1998)

Before any non-steroidal anti-inflammatory agent (NSAIA) will be considered for general sale availability the MCC will require both utilisation data to show that it is safe in a general sale environment, and also post-marketing surveillance data from its use in a general sale environment.

Note: It was recognised that these requirements will prevent New Zealand from taking an initiative in making NSAIA's available as general sale medicines as this sort of information can be obtained only after a medicine has been marketed at that level over a number of years in another country.

- Use of Prescription Medicines by Optometrists (25 November 1993)

Any classification changes concerning access by optometrists to prescription medicines used in the eye should be made only after consultation with both the New Zealand Society of Optometrists and the Ophthalmological Society of New Zealand.