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, the Ministry of Health 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 the process is easy to understand and transparent.

Definitions

Applicants	Pharmaceutical companies, health professional organisations, Medsafe, the Ministry of Health or individuals who are applying to change the legal classification of a medicine in New Zealand
INN	International Non-proprietary Name
MCC	Medicines Classification Committee
OIA	Official Information Act 1982
OTC	Over the Counter

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.
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.

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.

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 (MCC)

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 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).

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

The composition of the MCC is determined in The Medicines Act 1981. 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 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.

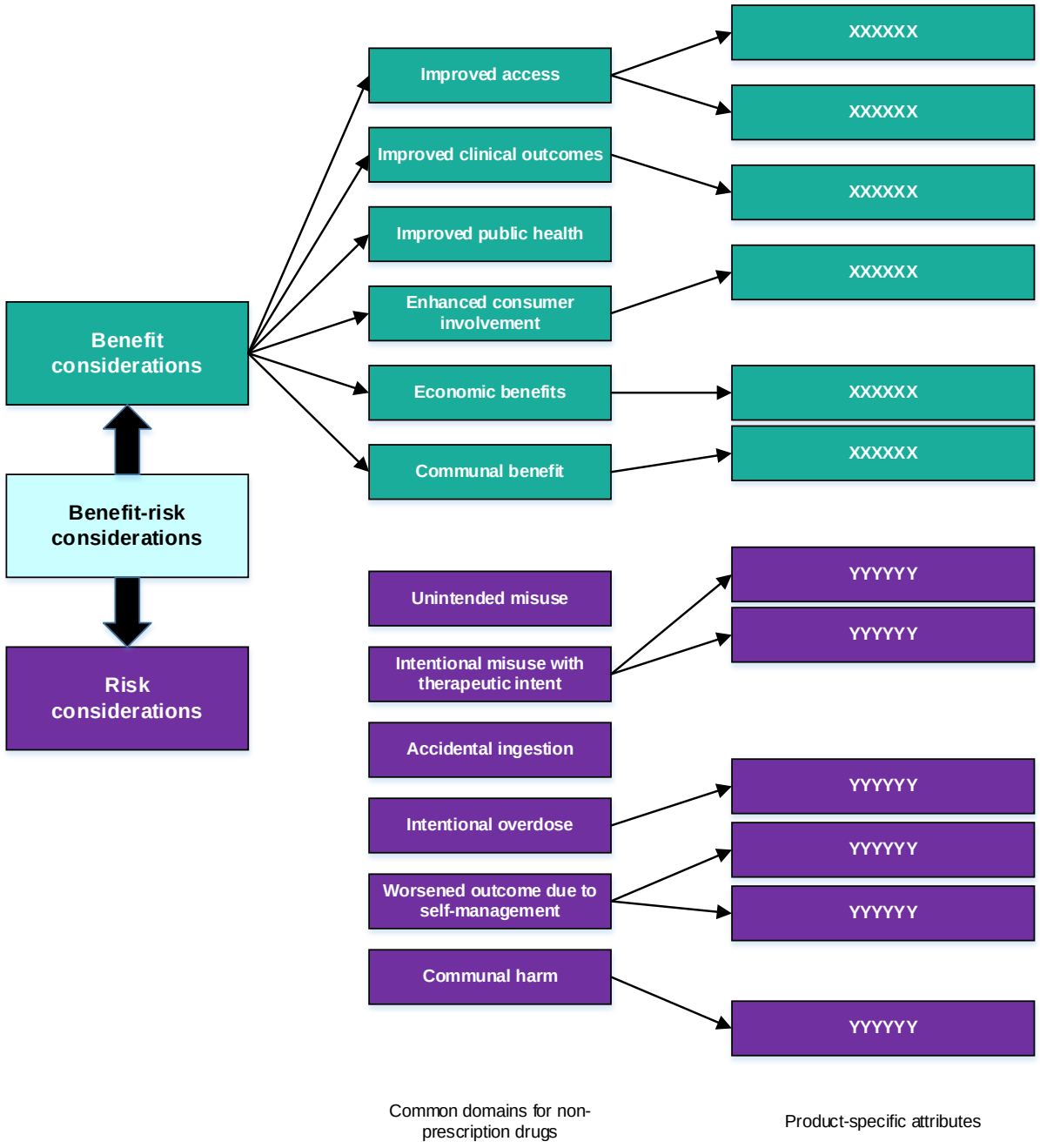

Figure 1 Adapted from the Value-tree framework of benefits and risks for non-prescription drugs (Brass EP, Lofstedt R and Renn O. 2011. Improving the Decision-Making Process for Non-prescription Drugs: A Framework for Benefit-Risk Assessment. *Clinical Pharmacology & Therapeutics* 90(6): 791-803.)

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 is unable to meet with applicants in advance of any reclassification application. 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 application be successful

It takes approximately six months from the date a reclassification application 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.

Reclassification process

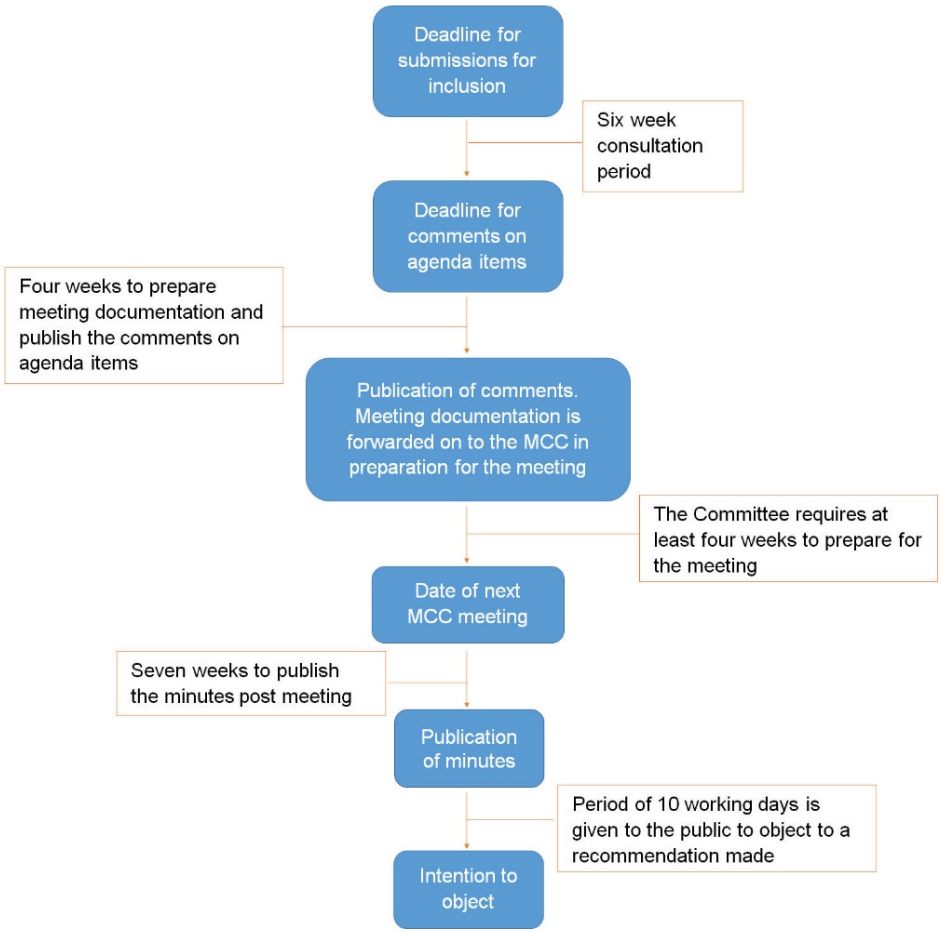

Figure 2 Timeline for reclassification applications and consultations.

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

Phase 1: Application

Closing dates for applications to the MCC are 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.

While applications usually come from sponsor companies, anybody may make an application to the MCC. Individuals or groups 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:

Part A
Administrative details

1. International Non-proprietary 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. 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
Evidence supporting the classification change proposal including benefit-risk analysis.

Parameters (evidence considered)

The MCC uses the following principles when considering a medicine for suitability for non-prescription sale: Medicines available without a prescription should be able to either:

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

During a meeting, the MCC considers the following parameters when reviewing a medicine for reclassification. The list is not ranked in any order of importance. The parameters may vary in importance according to the medicine being considered for reclassification. In some cases one parameter alone may be sufficient to outweigh all others in determining whether or not a medicine should be reclassified. This section should be supported by the following:

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 (ie, 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 for the individual?
- 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? Are these reversible or treatable?
- 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?
- Will 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)?

Communal harm or benefit includes wider community concerns, not just the safety of the medicine under consideration.

9) Integrated benefit-risk statement

- A summary of the reclassification benefits.
- A summary of the reclassification risks 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?

A template form for submitting an application can be found at Appendix 1.

Those applications proposing a reclassification to either restricted or pharmacy-only medicine should use the Pharmacy Council's process for medicines reclassification at Appendix 2.

All claims made in an application should be supported by researched data. Key papers must be supplied to the Committee. These papers will not be published on the Medsafe website. References are adequate for other material, and the reference list must be made available for publication to allow for meaningful, transparent consultation. 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.

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

One electronic copy of each application is required including any supporting data or references. The electronic copy should be submitted via email in comment-enabled PDF format to committees@moh.govt.nz. Copies of applications are circulated to MCC members electronically and this format enables comments to be included during the review process.

If the total file size of the attachments exceeds 200MB, then the applicant should notify the MCC Secretary that a CD will be provided. The CD should be sent to the:

MCC Secretary
Medsafe
PO Box 5013
Wellington 6145.

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 cannot be accepted.

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, they must clearly state this in the application and identify the relevant sections under the OIA that the applicant considers justify its exclusion. Medsafe will then give due consideration to any such request. Medsafe reviews applications and may make recommendations to the MCC on specifics such as the classification wording.

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

Phase 2: 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.

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 committees@moh.govt.nz.

Comments on agenda items are published on the Medsafe website under Agenda Items. Anyone commenting on agenda items should prepare their feedback 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 OIA and other relevant laws and requirements. If the person commenting considers that material provided in their feedback should not be made publicly available, they must clearly state this

in the application and identify the relevant sections under the OIA that the applicant considers justify its exclusion. Medsafe will then give due consideration to any such request. Personal information will be withheld from publication upon request.

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

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 3: Meeting and MCC recommendations

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

Observers[1]
Applicants are given the opportunity to observe a meeting. If present at the meeting, up to a maximum of three individuals representing the applicant are able to observe the opening discussion of the agenda item for which they submitted the application.

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

The meeting in general is held under the Chatham House Rule. Observers may also have the opportunity to answer any queries posed by the MCC, which may have arisen following the receipt of comments on the application, and provide explanations which would help make a final recommendation. However, applicants are not able to provide any new data or information that was not included in the original application, in the interests of transparency. Observers are not able to be present for the final recommendation made by the MCC.

What is considered?
During a meeting, the MCC considers the parameters listed in Phase 1 when reviewing a medicine for reclassification.

What is not considered?
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.

Harmonisation with Australia
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.

[1] Observers at Ministerial Advisory Committees is being consulted on at the same time as this Guidance document – refer to http://www.medsafe.govt.nz/consultations/current.asp

Requests for Information
The MCC may in some instances make a recommendation that the applicant 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.

Ministerial powers in relation to classification have been delegated to the Group Manager, Medsafe, 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 under Meeting Minutes.

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 prior to the minutes being 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 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 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 committtees@moh.govt.nz by the closing date published on the Dates and Deadlines page. This date will coincide with the closing date for applications for the next meeting.

Phase 6 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 MCC Secretariat.

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:

- the MCC did not consider all the safety issues correctly (for example a new safety concern may have been identified since the start of the consultation)
- the MCC did not consider all the benefits
- there was a breach of the appropriate process.

Financial or commercial reasons are not acceptable grounds for objection.

Once the supporting data for a valid objection has been received, the objection will be provided to the applicant (if applicable) and the MCC. The objection will be published to allow for consultation with the public. The application, objection and further applications will then be considered at the next MCC meeting.

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 is updated. A copy of the *New Zealand Gazette* notice is published on the Medsafe website under Recent New Zealand Gazette Notices Relating to Classification. 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 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 applications (QQ June 2017***)***

  Presentation of applications to the MCC should be as one electronic copy (in comment enabled PDF format) and emailed to committees@moh.govt.nz.

  Electronic copies should contain the full text of the application including any supporting data and references. Only key papers need to be supplied to the Committee. These papers will not be published on the Medsafe website. References are adequate for other material, and the reference list must be made available for publication to allow for meaningful, transparent consultation. An executive summary may also be included.

  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 in the public's interest, unless it is specifically requested that it is not, and then only to the extent permissible under the OIA and other relevant laws and requirements. If an applicant considers that material provided in the application should not be made publicly available, they must clearly state this in the application and identify the relevant sections under the OIA that the applicant considers justify its exclusion. Medsafe will then give due consideration to any such request.

  Applications which do not meet these requirements will not be considered by the MCC, and if the applicant cannot submit an application that meets these requirements before the deadline, they will be required to resubmit for the subsequent meeting.

- 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 an application 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 NSAIAs 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 NSAIAs 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.