Update to Medicines Classification Committee Processes

Consultation document

Medsafe

August 2016

Contents

Purpose and scope

The purpose of this consultation document is to propose changes to the running of the Medicines Classification Committee. These changes are envisaged to improve the transparency of the Committee processes and provide better information to the Committee to maintain the quality of decision making.

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 substance)	International Non-proprietary Name (ie, the name of the active
OIA	Official Information Act 1982

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 (unscheduled substances are suitable for general sale). 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, for example, change from non-prescription to prescription.

The MCC meets twice a year, usually in April and October. Secretarial 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'.

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 http://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 http://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.

The current application process is outlined in the guidance document *How to change the legal classification of a medicine in New Zealand*.

Proposed Changes to the Application Process

Publication of reference lists

Applications should be supported by researched data. Only key papers need to be supplied to the Committee. These will not be published on the Medsafe website. It is proposed that the full reference list must be made available for publication in the interest of public good and to allow for meaningful, transparent consultation.

Publication of additional information

Applications may include supporting documents or appendices such as training materials and screening tools. Currently these are not always published, which means that they are not consulted upon, reducing the transparency of the process.

It is proposed that the applicant should prepare these materials with the expectation that the information will be made publically available in the public's interest, unless it is specifically requested that it is not, and then 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 publically 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.

Format of applications

From the 58th MCC onwards, one electronic copy of each application will be 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. If the total file size of the attachments exceeds 200MB, then the applicant should notify the MCC Secretary that a CD will be provided. A hard copy of a cover letter should be provided along with two electronic copies of the application on separate CDs, and sent to:

MCC Secretary

Medsafe

PO Box 5013

Wellington 6145.

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

Agenda Items.

Complete applications must be received by 5pm 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.

Proposed Changes to the Consultation Process

Publication of comments on applications

Feedback received by Medsafe on agenda items is subject to the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should prepare their comments with the expectation that the information will be made publically available, in the interest of public good.

Medsafe will not treat any part of a comment or feedback as confidential unless it is specifically requested that it is, and then only to the extent permissible under the OIA and other relevant laws and requirements. It is proposed that if a commenter would like Medsafe to withhold any commercially sensitive, confidential proprietary, or personal information included in their feedback, this must be clearly stated, and they must identify the relevant sections that they would like withheld. Medsafe will give due consideration to any such request.

This aligns the rights of the applicant with those providing comments on the applications.

Format of comments

From the 58th MCC meeting, comments and feedback, including any supporting data or references should be submitted electronically via email with a completed cover sheet template to committees@moh.govt.nz.

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

Items.

Approximately six weeks is available for the preparation of comments. 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.

Proposed Changes to the Objection Process
The MCC recommendations are published seven weeks after the meeting. Any interested party then has the right to object to any recommendation within 10 calendar days of the minutes being published.

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 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 by the closing date published on the Medsafe website. This date will coincide with the closing date for applications for the next meeting.

This process 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 could be made by the:

- Medsafe Group Manager on advice from the MCC Secretariat
- MCC Chair
- MCC committee via teleconference
- Director General of Health on advice from the MCC secretariat.

Given the short timelines involved it is noted that the first option is likely to be the quickest and avoids any perception of conflict of interest which would accompany a determination made by the MCC or the chair 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.

It is proposed that 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, or
- there was a breach in 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.

Clarification of the Rules and Obligations for Meeting Observers
Who can attend a MCC 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 reclassification proposal. The meetings are not open to the public, media, or other interested parties.

What is the role of observers?

The meeting in general is held under the Chatham House Rule. Applicants 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.

Proposed Changes to the Decision Parameters

The decision criteria considered by the Committee, the risk-benefit assessments that applicants are encouraged to consider, and the information that should be included in an application is all currently outlined in the guidance document *How to change the legal classification of a medicine in New Zealand*.

At the 55th MCC meeting, it was proposed that the criteria referred to when considering a medicine classification should be reviewed.

It is proposed that the parameters considered by the Committee, and included in applications should be clearly aligned so that a comprehensive risk-benefit assessment can take place.

These are the proposed parameters for consideration of a reclassification. In some cases, one parameter alone may be sufficient to outweigh all others in determining whether or not a medicine should be reclassified:

Parameters

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.

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.

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?

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?

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 medicines use for the proposed indication(s) ie, number of users; number of countries used in?
- What is the evidence that improved access is beneficial?
- What is the evidence of improved consumer involvement in their health?
- What is the evidence of a benefit to the community and the health system?
- What are the benefits from a consumer viewpoint?

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?

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?

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?

Medication errors and abuse/misuse potential

- Would reclassification affect the risk of unnecessary use?
- Is the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?

- What are the reported medication errors post-market?
- What are the reported cases of abuse/misuse/accidental overdose?
- How would reclassification affect import considerations?
- What is the addiction potential of the medicine?

Applications should include the following:

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?

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?

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.

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.