Observers at Ministerial Advisory Committees

Consultation document

Medsafe

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Purpose and scope

This consultation document is aimed at pharmaceutical companies, health professional organisations, Medsafe, the Ministry of Health or individuals who are interested or involved in activities affected by any of the four Ministerial Advisory Committees that receive secretarial support from Medsafe.

The purpose of this consultation document is to provide background information on the history and current format of including observers at meetings. The term observers includes Medsafe or Ministry of Health staff, representatives of pharmaceutical companies, health professional organisations, and other interested parties.

Ministerial Advisory Committees

Under section 8 of the Medicines Act 1981 (the Act), the Minister may appoint advisory or technical committees to advise for the purposes of the Act. Four advisory committees have been established, all of which receive secretarial support from Medsafe. Information on each of these committees is provided below.

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 (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.

The composition of the MCC is determined under section 9 of the Act. 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’.

As Committee members cannot be expected to have knowledge in specialist areas it will sometimes be necessary to consult outside experts or specialist bodies. For this reason, the MCC process includes a transparent consultation process. In addition, Medsafe will sometimes seek outside expert advice in order to prepare papers for consideration by the Committee. More information about the MCC is available on the Medsafe website.

Medicines Assessment Advisory Committee (MAAC)

The MAAC is an independent, technical advisory committee established under section 8 of the Act to advise the Minister of Health on the risk-benefit profile of new medicines. The terms of reference of the MAAC are to consider applications for the Minister’s consent that have been referred to the Committee, and to annually review a sample of reports of the

evaluation of applications for the Minister's consent or provisional consent to the distribution of new medicines and provide expert advice to Medsafe and the Minister on the quality of the risk-benefit assessments that have been completed.

The MAAC is scheduled to meet three times a year (usually in March, June and September).

The composition of the Committee is not described in the Act. However, the proposed membership was agreed by the Minister on 2 November 2009 and ideally should comprise up to 12 members including:

- a clinical pharmacologist
- a general practitioner
- an expert in infectious diseases
- an expert in pharmaceutical chemistry and the manufacturing of pharmaceuticals
- an oncologist
- a paediatrician
- a biostatistician
- up to four specialist clinicians (for example from fields such as cardiology, dermatology, geriatrics, neurology, psychiatry and women's health)
- a layperson.

Committee members are appointed for a term of three years and may be reappointed for one further term. A Committee member may be appointed for a third term if they act as Chair. More information about the MAAC is available on the Medsafe website.

Medicines Adverse Reactions Committee (MARC)

The MARC is a technical advisory committee established under section 8 of the Medicines Act 1981 to provide expert advice to the Director-General of Health and Minister of Health on medical and scientific evaluations of medicines safety issues, referred to the Committee by Medsafe. Based on these evaluations, the MARC may recommend strategies to improve the risk-benefit profiles of medicines.

The MARC meets four times a year (usually in March, June, September, and December).

The MARC comprises up to 13 members as follows:

- an epidemiologist
- two general practitioners (one in urban practice, one in rural practice)
- a clinical pharmacologist
- two clinical pharmacists (one hospital based, one community based)
- four specialist clinicians (eg, from fields such as psychiatry, paediatrics, cardiology etc)
- a nurse
- a layperson
- the Director of the New Zealand Pharmacovigilance Centre.

Members are appointed for a three year term, which may be renewed once for a further three years.

Medsafe may obtain further expert advice from other specialists where such expertise is not available within the Committee. More information about the MARC is available on the Medsafe website.

Medicines Review Committee (MRC)

The MRC is an appeals committee established under section 8 of the Act to consider appeals relating to decisions relating to licensing and approvals under the Act.

The MRC meets on an as required basis.

The composition of the MRC is determined under section 10 of the Act. The MRC comprises five members appointed by the Minister, of whom one shall be appointed by the Minister as Chair, and includes:

- one person with wide experience in the practice of medicine
- one person with wide experience in the practice of pharmacy
- one person with wide experience in the pharmaceutical manufacturing industry
- one person with wide experience in a form of chemistry other than pharmaceutical chemistry
- one person with wide experience in the practice of natural therapy to act as a member of the Committee whenever any matter relating to the practice of natural therapy is before the Committee.

Current processes regarding observers at Ministerial Committee meetings

Medicines Classification Committee

At the 45th meeting on 12 April 2011, the MCC considered the potential for observers to attend MCC meetings, following a request from the New Zealand Self-Medication Industry Association (NZSMI). A recommendation was made to pilot applicants of reclassification applications being able to observe over the next four meetings.

The purpose for having observers at meetings was that context would be given to statements in the published Committee minutes, thereby giving greater clarity and transparency.

Following this recommendation, Medsafe developed a proposal, which was agreed out-of-session by the Committee and signed off by the Minister's Delegate:

- only those who have made an application for reclassification may observe a meeting
- a maximum of three individuals involved in a specific application may observe
- observers may only observe the discussion around their application
- discussion around an application will only start after each observer has handed a completed and signed Statement of Confidentiality to the Secretary
- observers cannot participate in the reclassification discussion unless invited by the Committee to provide explanations or additional information during the meeting
- observers will be asked to leave the meeting room after the application has been discussed, but before the Committee makes the final recommendation on the reclassification application - a final recommendation will be made autonomously and in private to avoid any conflict of interests or interferences

- the observers attending a specific agenda item would need to be confirmed at least two weeks before a meeting date.

At the 49th meeting on 30 April 2013, there was a review of the pilot.

The Committee reviewed the pilot using the feedback from the companies involved. A survey was sent to those who had observed a meeting and also those who were invited but did not attend. A total of 13 out of 16 recipients responded to the survey. The survey results were published as a link from the agenda to encourage comments from interested parties during the consultation period.

Two pre-meeting comments were received during the consultation period.

One stated it would be interested in hearing the feedback from the observers. This information was already publicly available as a link from the agenda on the Medsafe website (www.medsafe.govt.nz/profs/class/Agen49Feedback.pdf).

The other expressed concern that only those who submit a proposal can be observers. Companies who could be affected by a reclassification proposal would like the opportunity to observe, or present a verbal application, so that questions concerning an objection can be asked by Committee members. The benefit being the Committee would be able to hear and clarify any objections to a proposal before a recommendation is made.

In reviewing the pilot and discussing whether observing should continue, the Committee made the following comments:

- members became more confident in the process with experience
- it was useful to be able to ask the observers questions and get immediate feedback to clarify parts of a application that were unclear
- an industry representative, or companies that could be affected by a reclassification proposal, would not be able to answer questions on the data presented in the application
- there was not enough time for verbal presentations at a meeting – all of the data should be included in the application with the observers only present to clarify and answer any questions
- constructive discussion by the Committee was not restricted because observers left before a final recommendation was made

The Committee agreed that observers may continue to attend meetings under the following guidelines:

- only those who have made an application for reclassification may observe a meeting
- a maximum of three individuals involved in a specific application may observe a meeting
- observers may only observe the initial discussion around their application (ie, when considered under agenda item six)
- discussion around an application will only start after each observer has handed a completed and signed Statement of Confidentiality form to the Secretary
- observers cannot participate in the reclassification discussion unless invited by the Committee to provide explanations or additional information during the meeting
- observers will be asked to leave the meeting room after the application has been discussed, but before the Committee makes the final recommendation on the reclassification application (the Committee will make the final recommendation autonomously and in private to avoid any conflict of interests or interferences).

At the 57th meeting on 1 November 2016, feedback was sought on proposed updates to MCC processes via the guidance document 'How to change the legal classification of a medicine in New Zealand'.

Feedback on the observer process included: Completely open meetings to allow all interested parties to attend, or a completely closed meeting to allow for uninfluenced recommendations to be made. Some comments also supported the ability to supply new information at the meeting, as new information may arise in the time between application and the meeting date, whereas others supported the opportunity to review and comment on any new information.

At the 58th meeting on 16 May 2017, feedback was again sought on proposed updates to MCC processes via the guidance document 'How to change the legal classification of a medicine in New Zealand'.

Feedback on the observer process included: It was reiterated that no new information should be presented by observers at the meeting they attend as there was insufficient time for Committee members to assimilate the new information and it was not a transparent process for any interested parties. It was agreed that it was useful for observers to answer questions, however observers did not necessarily need to be present to answer questions and a teleconference could suffice.

Medicines Assessment Advisory Committee

At the 96th meeting on 26 March 2013, the MAAC considered the potential for observers to attend MAAC meetings, following the pilot initiated by the MCC.

The MAAC made a recommendation to allow observers to attend meetings, and Medsafe developed a proposal that was agreed out-of-session by the Committee and signed off by the Minister's Delegate:

- only those representing the applicant may observe a MAAC meeting
- a maximum of three individuals involved in a specific application may observe a MAAC meeting
- the Medsafe evaluator may also be present at the meeting to answer questions
- observers may only observe the discussion around their application
- discussion around an application will only start after each observer has handed a completed and signed Statement of Confidentiality form to the Secretary
- observers cannot participate in the discussion unless invited by the MAAC to provide explanations or additional information during the meeting
- it is expected that observers will be able to comment on the risks and benefits of what has been evaluated and address the concerns raised in the evaluation report(s). Observing will not be a marketing opportunity for products or services
- observers will be asked to leave the meeting room after the application has been discussed, but before the MAAC makes the final recommendation on the application. The MAAC will make the final recommendation autonomously and in private to avoid any conflict of interests or interferences
- after an applicant has received the letter that their application has been referred to the MAAC, the Secretary will email the applicant and give them the opportunity to attend and observe the meeting
- if there is a positive response from the email, the Secretary will organise a time that the observers should attend the MAAC meeting in liaison with the Chair

- the pilot will take place over three meetings at which the MAAC has applications to consider.

At the 102nd meeting on 17 November 2015, the MAAC reviewed the pilot for observers and feedback from applicants was considered. Medsafe received feedback from observers who had attended meetings and found that applicants were unclear of their role at the meeting and felt they were inadequately informed of the process of the meeting; that they would have an opportunity for them to speak, and did not prepare themselves for questions regarding the application. It was noted that the letters to the applicants were written in a way to discourage promotion of unapproved medicines to the Committee. The MAAC considered a change in protocol for observers outlining that a 10 minute presentation may be delivered to the Committee and this should focus on the risks and benefits and not include the promotion of unapproved medicines. The decision making process would remain closed to allow for unanimous decision making.

Medicines Adverse Reactions Committee

As a general rule, observers do not attend MARC meetings, with the exception of Medsafe or other Ministry staff.

Invited experts may attend MARC meetings to advise the Committee on pharmacovigilance issues within that person's specialist area. Invitations are issued by the Secretary after consultation with the Chair. Observers, such as medical trainees may also attend MARC meetings. The MARC Secretary will make these known to the Chair for agreement prior to the meeting. Invited experts and observers are required to sign a Statement of Confidentiality. Invited experts must also confirm that their conflicts of interest do not preclude them from participating in the MARC meeting or particular item for which they are invited. Therefore, invited experts will need to complete the conflicts of interest form.

Medicines Review Committee

Observers do not attend MRC meetings.

Proposed processes regarding observers at Ministerial Committee meetings

MCC

Proposal 1: No change

Observers from the Ministry continue to attend as needed. Observers representing the applicant could still attend as outlined above for the current process.

Proposal 2: Observers representing applicants no longer allowed to attend

The process would be transparent, applicants could provide written proposals only. The Committee has a formal process to request further information. There has been a tendency for observers to provide additional information at meetings that was not consulted on, potentially affecting the transparency of the committee process.

Proposal 3: Observers widened

Observers representing the applicant could be allowed to attend and discuss the application with the Committee as at present. Other observers could also be allowed to attend at the same time. This could include observers from other companies, consumers, and healthcare professionals. Given the constraints of time, the number would be restricted and there would be an application process.

MAAC

Proposal 4: No change

Observers from the Ministry continue to attend as needed. Observers representing the sponsor could still attend as outlined above for the current process.

Proposal 5: Observers representing sponsor no longer allowed to attend

There has been a tendency for observers to provide additional information at meetings that was not provided to Medsafe during the evaluation process, potentially affecting the integrity of the committee process.

MARC

Proposal 6: No change

Observers from the Ministry continue to attend as needed. Academic experts and other observers such as medical trainees invited to attend as required.

Proposal 7: No observers other than from the Ministry allowed

Observers from the Ministry continue to attend as needed. Academic experts and other observers such as medical trainees are no longer allowed to attend.

Proposal 8: Allow sponsors to attend for section 36 issues to provide a presentation and answer questions

Sponsors are invited to attend for section 36 issues to provide a presentation and answer questions that may arise during the Committee's discussion.

MRC

Proposal 9: No change

Observers do not attend MRC meetings.

Proposal 10: Applicants for a review allowed to present their case to the Committee

Applicants that request an appeal to a decision made by the MAAC or MCC may observe the discussion regarding their appeal.

Implementation and timeframes

Medsafe proposes to publish this document for consultation following review by each Committee. Consultation would be open for a period of six weeks.

Following consultation, results would be presented to each Committee for review, seeking recommendations. Implementation of changes would take place at the meeting following the recommendation by each Committee.