New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

12 January 2018

Product Regulation
Medsafe
PO Box 5013
Wellington 6140

By email: committees@moh.govt.nz

Observers at Ministerial Advisory Committee Meetings

Dear Sir / Madam

Thank you for inviting the New Zealand Medical Association (NZMA) to provide feedback on the above consultation.[1] The NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders.

1. We note that Medsafe is consulting on the process for observers at the following four Ministerial Advisory Committees that receive secretarial support from Medsafe: Medicines Classification Committee (MCC), Medicines Assessment Advisory Committee (MAAC), Medicines Adverse Reactions Committee (MARC), Medicine Review Committee (MRC).

MCC

2. We understand that the MCC first considered the potential for observers to attend meetings in 2011, following a request from the New Zealand Self-Medication Industry Association. The original purpose for having observers was that context would be given to statements in the published Committee minutes, thereby giving greater clarity and transparency.

3. Following a review of a pilot observer process, we note the MCC 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)

[1] http://www.medsafe.govt.nz/consultations/Observers/1b-Consultation-Document-Observers-at-Ministerial-Advisory-Committees.pdf

Level 13, 39 The Terrace, PO Box 156, Wellington 6140 | Tel: (04) 472 4741 | Fax: (04) 471 0838 | Email: nzma@nzma.org.nz | www.nzma.org.nz

- 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).

3. We note that Medsafe is currently consulting on the following 3 options regarding observers at the MCC: i) no change (with observers representing the applicant still attending); ii observers representing applicants no longer allowed to attend; iii) observers representing the applicant continue to attend, and other observers are also allowed to attend at the same time. We are aware that feedback on the observer process to date includes the belief that no new information should be presented by observers at the meeting they attend, and that it is useful for observer to answer questions. However, observers do not need to be present to answer questions as they could do so via teleconference.

5. The NZMA has reservations about the attendance of observers representing the applicant. Although applications for reclassification can come from any interested parties, in practice (and historically) most applications have been made by industry. The only kind of observers allowed are those "representing the applicant". MCC meetings are not open to the public, the media or other interested parties. This means observer representation is asymmetric and favours the applicant over other interested parties.

6. We note that, in addition to the opportunity to answer queries posed by the MCC (which may have arisen following the receipt of comments on the application) observers may also provide explanations that could help make a final recommendation. We are concerned that the presence of up to 3 observers could potentially create some indirect influence on proceedings and may provide information to applicants that could only empower them in pursuing their commercial agenda, despite the checks and balances in the existing process. Given the possibility of these unintended consequences, we favour option two, ie, observers representing applicants no longer attend. We also seek further information on the rationale for including observers in the first place. If observers are retained, we believe it is important to ensure that no new information is introduced, and anything observers say or provide is open to full scrutiny.

MAAC

7. We favour option two, ie, observers representing sponsor no longer allowed to attend, for the same reasons identified in paragraphs 5-6. We note that there has been a tendency for observers at MAAC meetings to provide additional information at meetings that was not provided to Medsafe during the evaluation process, potentially affecting the integrity of the committee process. These are further grounds to support option two.

MARC

8. We favour proposal six (no change), ie, observers from the Ministry continue to attend as needed. Academic experts and other observers such as medical trainees are invited to attend as required.

MRC

9. We favour proposal nine (no change), ie observers do not attend MRC meetings.

10. While membership of the MRC is set in the Medicines Act and so out of scope for this consultation, we are very concerned to note that membership of the MRC includes 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. The use of credible evidence to inform and base decisions about healthcare is a core value of the NZMA. It is our view that natural therapy, currently unregulated under the HPCA Act in New Zealand, is the antithesis of evidence-based medicine. We do not believe that representation from natural therapy should be afforded a place on the MRC alongside representation from medicine and pharmacy. As the Therapeutic Products Bill currently being drafted will replace the Medicines Act, we wish to flag this issue and ask officials to ensure this aberration is rectified in the drafting of the new Bill.

We hope that our feedback has been helpful and look forward to learning the outcome of this consultation.

Yours sincerely

Dr Kate Baddock
NZMA Chair