

31 August 2018

Medicines Classification Committee Secretary
By email: committees@moh.govt.nz

Agenda for the 61st meeting of the Medicines Classification Committee

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide comment to the Medicines Classification Committee (MCC) regarding three items on the agenda for the 61st meeting scheduled for 2 November 2018.

Items 5.3 and 6.1 (reclassification of melatonin)

We note that the 61st meeting of the MCC will consider two separate agenda items regarding the reclassification of melatonin. Item 5.3 relates to the proposed reclassification of oral melatonin in doses of 3mg or less from prescription medicine to restricted medicine. Item 6.1 relates to the proposed reclassification from prescription medicine to prescription except when provided at a strength of 2mg prolonged release to people who meet clinical and eligibility criteria when sold by a pharmacist who has completed an approved training programme.

We are supportive of a regulatory framework that supports better access to melatonin (including taking into account cost to patients) while ensuring appropriate use (particular concerns relate to the long-term use of melatonin and of parents medicating children) and safeguarding standards of safety, efficacy and quality (including good manufacturing process).

A reclassification from prescription medicine to prescription except when provided at a strength of 2mg prolonged release to people who meet clinical and eligibility criteria when sold by a pharmacist who has completed an approved training programme should address concerns about inappropriate use and may also improve access for some patients. However, the cost of a pharmacist consultation is likely to represent a significant barrier for many people.

While a reclassification of melatonin from prescription to restricted medicine could be expected to improve access and cost (no pharmacist / GP consultation fee), it could widen inappropriate use even though it provides for some monitoring of patterns of purchase. Furthermore, our understanding is that if a medicine is changed to restricted (pharmacist-only) status, it would potentially allow importation of unregulated melatonin from overseas with all the attendant concerns about poor quality and lack of oversight.

We recommend that the committee balance all these factors when determining which regulatory option is best for melatonin.

Item 6.2 Dextromethorphan, opium tincture, squill oxymel and pholcodine reclassification

We support the reclassification of the above opioid (and opioid-like) cough medicines from general sale and pharmacy-only medicines to restricted medicines. This measure harmonises the regulation of opioid derivatives and is an important step towards reducing the well-known potential for abuse of these medicines.

We hope our feedback is helpful.

Yours sincerely

A handwritten signature in blue ink that reads "K. Baddock". The signature is written in a cursive style with a large initial 'K' and a decorative flourish at the end.

Dr Kate Baddock
NZMA Chair