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Dear Jessica,

Agenda for the 61st meeting of the Medicines Classification Committee

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the Agenda for the 61st meeting of the Medicines Classification Committee.

Introduction to general practice and the College

General practice is the medical specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent of New Zealand's specialist workforce and their professional body, The Royal New Zealand College of General Practitioners (the College), is the largest medical college in the country. The College provides training and ongoing professional development for GPs and rural hospital generalists and sets standards for general practice. The College has a commitment to embed the three principles (participation, partnership and protection) of Te Tiriti o Waitangi (Treaty of Waitangi) across its work, and to achieving health equity in New Zealand.

Health equity is the absence of avoidable or remediable differences in health outcomes and access to health services among groups of people, whether those groups are defined socially, economically, demographically, or geographically (WHO). To achieve health equity, we advocate for:

- A greater focus on the social determinants of health (including labour, welfare, education, housing, and the environment).
- Funding and support to sustain the development of a GP workforce of sufficient capacity to meet population need for access to quality primary medical care, particularly in rural and high need areas.
- Sustained focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Improved integration of primary, community, and secondary care health and social services which ensures the provision of high-quality services.
- Universally accessible free primary health care for children and low-income families, because health inequities begin early and compound over the life course.
- A review of the funding model for primary care to ensure that resourcing is allocated equitably across diverse populations with differing needs.

Submission

The College wishes to comment on the following three agenda items.

- 5.3 Melatonin - proposed reclassification from prescription medicine to a restricted medicine
- 6.1 Melatonin prolonged release 2 mg tablets – proposed reclassification from prescription medicine to prescription except when classification
- 6.2 Cough medicines

The two agenda items concerning Melatonin will be considered together

Agenda items 5.3 and 6.1

The College supports increasing access to melatonin. The issue before the Committee is which of the two proposed regulatory classifications will best achieve this. The NZMA submission on this topic outlines the issue well and we have included it below with their permission.

> 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[1].

In addition to supporting the NZMA stance we would like to make the following points.

The proposal outlined under agenda item 6.1 (a prescription except classification) would see pharmacists undertaking additional training in sleep disorders, including training to advise on non-pharmacological management. It will also lead to the increased availability of educational material for patients. This will benefit patients and a further benefit will be that some patients with secondary insomnia who would not otherwise consult a doctor will be identified by the pharmacist and encouraged to seek assistance.

[1] http://www.nzma.org.nz/__data/assets/pdf_file/0004/84784/NZMA-Submission-on-agenda-of-61st-meeting-of-the-Medicines-Classification-Committee.pdf

As mentioned in the NZMA submission the prescription-except option (item 6.1) would continue the restriction on the purchase of melatonin from overseas. If melatonin instead became a restricted medicine, the combination of the ease with which unregulated melatonin could then be purchased from overseas, and the frequency of sleep problems in children will probably lead to the inappropriate use of melatonin in children. A prescription-except classification as proposed in item 6.1 would retain the prohibition on purchase from overseas, while increasing access to melatonin for those indications for which Circadin is licenced and for which there is evidence of safety and effectiveness.

The proposal under item 6.1 would not enable pharmacists to supply Melatonin for the unapproved indications for which some people use melatonin currently, for example to manage jet lag. The only legal mechanism for supply for an unapproved indication is under section 25 of the Medicines Act. Unlike pharmacists GPs can prescribe medicines for unapproved indications under section 25. The GP must however take the responsibility for the safety of prescribing for such off-label use. [2]

The fact that an application has not been made to add such indications, suggests that the evidence of safety and effectiveness to support such an application is not available. If evidence for additional indications becomes available and these are added to the license this would open a pathway that could lead to appropriately trained pharmacists being able to supply melatonin in such circumstances.

Finally, we received feedback from members who would be keen to see PHARMAC fund 2mg slow release melatonin as an alternative to the funded but addictive hypnotics such as benzodiazepines and zopiclone.

Agenda item 6.2 Dextromethorphan, opium tincture, squill oxymel and pholcodine – proposed reclassification from general sale and pharmacy only medicines to restricted medicines

The College supports this Medsafe initiated reclassification proposal as it will decrease the ease with which these medications can be abused. Although cough medicines are popular with patients a 2014 Cochrane review found no good evidence for or against the effectiveness of OTC medications in acute cough[3]. Removing them from the open shelves of pharmacies to where they can only be purchased after discussion with the pharmacist will enable the pharmacist to suggest alternative management of cough where appropriate.

We hope you find our submission helpful. Should you require any further information or clarification please contact the College's policy team at policy@rnzcgp.org.nz.

Yours sincerely

Michael Thorn
General Manager – Strategic Policy

[2] https://bpac.org.nz/BPJ/2013/March/unapproved-medicines.aspx

[3] https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001831.pub5/abstract