ASA response regarding the TGA delegate of the Secretary's interim decision to down-schedule modified release melatonin formulations from Schedule 3 of the Poisons Standard, with restrictions on age and pack size and a proposed date of effect (1 October 2020)

The Australasian Sleep Association (ASA) is the peak scientific body in Australia representing clinicians, scientists and researchers in the broad area of Sleep. Our vision is the provision of world standard research, education and training, and establishment of clinical standards to ensure clinical best practice in sleep medicine resulting in an informed community with healthy sleep practices.

Sleep Disorders are one of the major health concerns in Australia. It is estimated that 22.4% of the Australian population have a sleep disorder, including insomnia and obstructive sleep apnoea (OSA). The total health system costs per year attributable to sleep disorders and their effects is $1.86 Billion AUD[1].

Unfortunately the ASA was not specifically consulted or asked to make a submission regarding the plan for modified release melatonin to be down-scheduled. We have only this week been made aware of this and the planned effect date of 1st October 2020.

The ASA believes that this plan to down-schedule modified release melatonin could be harmful to patients with sleep problems. There are very few properly designed trials to evaluate the use of melatonin as a hypnotic agent. Most of the studies regarding melatonin utilize its effect as a chronobiotic, to regulate circadian rhythms and not its hypnotic effect. There are studies suggesting harm in certain groups such as diabetics, pregnant/lactating women, adolescent females, those with autoimmune disorders and epileptics. There is minimal data on the appropriate dosage to be used, or the safety of long-term melatonin use. There are ongoing concerns about potential effects of melatonin on the reproductive system, based on effects observed in rodents, sheep and primates[2]. In the Australian setting previous research suggests that melatonin is frequently used without supporting evidence, especially in children[3].

It is our opinion that, given the extent of sleep disorders in the community and the real likelihood that patients with sleep problems could "self-medicate" with melatonin, this decision should be reviewed urgently by the TGA with consultation from relevant professional bodies, such as the ASA and the Royal Australasian College of Physicians. We strongly recommend that melatonin should only be prescribed by general practitioners and specialists who understand the implications of prescription of these drugs and who can organise appropriate follow up of the patient and further investigations if symptomatic improvement does not occur. This may involve consultation with an appropriate sleep physician with appropriate investigations (blood tests, polysomnography, wrist actigraphy, vigilance testing) or referral to other health care providers, including behavioural sleep medicine providers. The timing, dose and

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formulation of melatonin needs to be carefully prescribed in order to maximise benefits and minimise potential harm. These important steps can only be assessed and supervised by general practitioners or specialists.

It is therefore the firm view of the Australasian Sleep Association that melatonin formulations should remain classified as Schedule 4, in the relevant Poisons Standard.

Yours sincerely

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1. Asleep on the job. Costs of Inadequate Sleep in Australia. Sleep Health Foundation; Delolitte; 2017
2. Kennaway DJ, Potential safety issues in the use of the hormone melatonin in paediatrics. J Paediatr Child Health. 2015 Jun;51(6):584-9. doi: 10.1111/jpc.12840. Epub 2015 Feb 3.
3. Nikles J, Lo V, Giam JA, Saini B. Exploring melatonin prescribing among customers of compounding pharmacies in Australia. *Med J Aust*. 2012;196(6):384-385. doi:10.5694/mja12.10145