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CRICOS Provider No. 00114A

28th August 2020

Re: Proposed amendments to the Poisons Standard (Medicines). Notice under Regulation 42ZCZP of the Therapeutic Goods Regulations 1990 of a call for further submissions on an interim decision to amend the current Poisons Standard in relation to melatonin

Dear Therapeutic Goods Administration,

We are treating Sleep Psychologists at the Insomnia Treatment Program, Adelaide Institute for Sleep Health. Together, we have been treating sleep disorders using Cognitive Behavioural Therapy for over 40 combined years and have over 60 combined years in the research and development of sleep disorder treatments.

Overall, the data on the melatonin as a hypnotic for Insomnia is sparse and the notice to amend accessibility of melatonin to over the counter, could enable patients to "self-medicate" without ever seeing a GP or specialist to effectively treat their sleeping difficulty. Melatonin may be effective for very specific types of insomnia, however, not without direction from professionals regarding the timing and dosage of its use. Per current evidence, the unknowns regarding melatonin and its potentially harmful effects outweigh the reasons for amending the current legislation to enable over the counter purchases.

The Australian Psychology Society, the Australasian Sleep Association and appropriate sleep and health professionals should be further consulted on this prior to reaching a decision.

Kind Regards,

[Redacted signature block]

Psychologists and researchers, Adelaide Institute for Sleep Health

inspiring
achievement