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AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – March 2020

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The AMA thanks the Therapeutic Goods Administration (TGA) for the opportunity to comment on the *Proposed amendments to the Poisons standard* consultation. The following feedback applies to the scheduling proposals referred to the Advisory Committee on Medicines Scheduling (ACMS #29) and joint ACMS/ Advisory Committee on Chemicals Scheduling (ACCS) meetings (ACMS-ACCS #24), March 2020.

The AMA does not support the down-scheduling of medicines unless there is strong evidence it is safe to do so, and there is demonstrated patient benefit and safety in dispensing the medication by this method.

Regulation through the My Health Record

The AMA's view is that if additional supply requirements or controls are required in order for pharmacists to safely dispense a medicine, then it is – by definition – unsafe and inappropriate to down-schedule that medicine.

The AMA understands that the scheduling changes for rizatriptan, melatonin, and adapalene, include an obligation for pharmacists to enter the details of the supply of these medicines into the patient's My Health Record. My Health Record includes a Medicines view that lists PBS Medicines prescribed and dispensed but healthcare providers are not obligated to use it with every patient or for every encounter. An individual's My Health Record may not include a record of every interaction the patient has had with the health system or an up-to-date status of their health. One in ten Australians do not have a My Health Record[1].

The My Health Record was never designed to replicate the full clinical notes curated by the patient's treating medical practitioner and is an inappropriate tool to be used by non-clinician pharmacists to inform clinical judgements about the appropriateness and risks of administering medicines to individual patients. The My Health Record is also consumer facing and patient controlled. Privacy, security and consent aspects of the My Health Record permit patients to set record access codes to limit access to selected healthcare providers, control access to specific documents, remove documents or delete their entire record. Consequently, the AMA opposes reliance on pharmacy uploads to the patient's My Health Record to support down-scheduling

[1] Australian Digital Health Agency (2019) *9 out of 10 Australians have a My Health Record.*

medicines that without the My Health Record would otherwise be considered unsafe to supply over the counter. Decisions to down-schedule medicines should be decided on clinical merit.

Further, the Committee needs to consider how such an obligation would be enforced and monitored given the privacy and security nature of patient's My Health Record.

Referring to down-scheduling generally, the AMA reiterates its concern that there is, in effect, no compliance or enforcement mechanisms except through a complaint being brought to the Pharmacy Board or the relevant State/Territory government agency. Without any monitoring or reporting mechanisms in place it is likely that non-compliance will only come to the attention of these bodies when a patient suffers an adverse event.

Ranitidine

The AMA supports an increase in ranitidine pack sizes available under Schedules 2 and 4. However, the AMA encourages pharmacists to enquire into the reasons why ranitidine is being used if the symptoms are recurring to reduce the risk of serious morbidities, and to refer the patient on to their medical practitioner if symptoms persist.

Selective serotonin reuptake inhibitors (SSRIs)

The AMA supports the introduction of a Schedule 4 entry as the Poisons Standard does not currently contain a group entry for SSRIs. The AMA agrees that SSRIs require regulation to ensure that their prescription remains under the discretion of medical practitioners into the future. Patients with mental illness require a level of care higher than a pharmacist's scope of practice. Depression and anxiety disorders must be diagnosed by the patient's medical practitioner or psychologist before prescription medication is considered to ensure the treatment aligns with the patient's condition and circumstances.

Fexofenadine

The AMA does not oppose the proposal to increase the availability of fexofenadine. The AMA considers the changes proposed to be low-risk.

Flurbiprofen

The AMA does not oppose the proposal to unschedule low dose flurbiprofen, provided that the warning statements remain.

Ondansetron

The AMA does not support the proposal to down-schedule ondansetron. The warnings of an association between the use of ondansetron and abnormal heart rhythms[2] indicates that this is a risky medication for the general public to be able to access. Medical practitioners know a patient's medical history, including cardiac risk, and use their expertise to determine whether ondansetron is an appropriate treatment for their patient.

[2] Food and Drug Administration (2012) *FDA drug safety communication: updated information on 32 mg intravenous ondansetron (Zofran) dose and pre-mixed ondansetron products.*

Rizatriptan

The AMA supports increased access to rizatriptan for patients experiencing migraines, as it supported increased access to zolmitriptan and sumatriptan in its previous submission[3]. However, there should be safeguards to ensure that access to this medication does not delay more urgent care. For example, symptoms similar to those of a migraine may actually be the result of a brain tumour. There needs to be increased pharmacist education around how to accurately and confidently diagnose a migraine. Further, new Schedule entries should specify a certain number of times a patient can purchase this medication until it is recommended to consult a medical practitioner.

Melatonin

The AMA supports the down-scheduling of melatonin. AMA members agree that melatonin offers a safer alternative to benzodiazepines or sedating anti-depressants for sleep conditions. Often individuals may use over the counter antihistamines to treat insomnia, despite limited evidence that it is effective[4]. Alternatively, Australians are purchasing stronger melatonin products from overseas suppliers and this can create a safety risk if the country of origin does not have the same or better standards or regulation as Australia. The AMA would also support increased access to melatonin products available by prescription to reduce the safety risks that come with overseas-bought products.

Dosage and labelling requirements will be important for this change. For example, it must be communicated to patients that there is limited evidence for the long-term efficacy of melatonin use and sleep hygiene practices should be considered before melatonin is used[5].

Adapalene

The AMA does not support the down-scheduling of adapelene. The AMA supports the Australasian College of Dermatologists' (ACDs') submission[6] to this consultation and shares its concerns regarding the adverse health effects that may occur if adapalene were down-scheduled, as summarised below.

Adapalene can be highly irritating to the skin and requires monitoring and instruction on its use by a medical practitioner. Adapalene may cause birth defects and therefore there is a risk of an increase in congenital deformity if adapalene products are Schedule 3. The AMA is also concerned that adapalene may be misused as a cosmetic anti-ageing product instead of an acne treatment.

There are conditions, such as papular rosacea, that have similar symptoms to acne and require a medical diagnosis and different treatment to acne. The AMA reiterates the ACD's point that pharmacists are not trained to distinguish between these conditions and the condition could be aggravated if adapalene is used.

[3] Australian Medical Association (2019) *AMA submission to the Therapeutic Goods Administration – proposed amendments to the Poisons Standard (November 2019 meetings).*

[4] Grima et al (2019) *Insomnia management*. Australian Journal of General Practice. 48:4.

[5] Janjua, I., & Goldman, R. D. (2016). *Sleep-related melatonin use in healthy children. Canadian family physician Medecin de famille canadien, 62(*4), 315–317.

[6] The Australasian College of Dermatologists (2019) *Consultation on the proposed amendments to the Poisons Standard referred to the Advisory Committee on Medicines Scheduling (AACMS #29): adapalene.*

Adapalene is a continuing therapy for many patients experiencing acne, and therefore the cost over time can be significant. The AMA asks the ACMS to consider the financial effects of losing adapalene on the Pharmaceutical Benefits Schedule (PBS) under these changes.

Nicotine

The AMA vehemently opposes the proposal to amend the Schedule 7 listing for nicotine to increase the availability of nicotine for heated tobacco products (HTPs) instead of combustible cigarettes. The claim made by the applicant that HTPs are a better alternative to combustible smoking is incorrect. There is currently no reliable evidence to suggest that HTPs are less 'risky' than combustible cigarettes, or that they are effective cessation aids[7]. There are also concerns that chemicals within HTPs may be associated with health effects, with more than 20 harmful/potentially harmful chemicals identified in higher quantities than cigarette smoke[8]. The highly addictive quality of nicotine makes it difficult for smokers to quit. The tobacco industry does not consider their customer's health a priority.

Pentobarbital

The AMA supports the proposal to make pentobarbital Schedule 8 only, to remove it as a potential mechanism for suicide. However, the Australian Government must recognise and act on the fact that a significant proportion of the Australian population experiences mental illness in their lifetime[9], and Australia's suicide rates are too high[10]. Mental health and psychiatric care services are significantly underfunded compared to physical health services. Increasing access to these services, and investing in preventative care, is essential to prevent suicide.

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[7] World Health Organization (2019) *Tobacco*.
[8] Ibid.
[9] Australian Institute of Health and Welfare (2019) *Mental health services in Australia.*
[10] Australian Bureau of Statistics (2019) *Causes of Death, Australia, 2018: Intentional self-harm, key characteristics.*