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AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – June 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), June 2020. It includes feedback for the additional proposal for a Schedule 3 entry for cannabidiol.

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.

Oxymetazoline

The AMA does not oppose the proposed changes to oxymetazoline, where nasal preparations with 0.05% or less oxymetazoline will be unscheduled.

Eletriptan

The AMA supports increased access to eletriptan for patients experiencing migraines, as it supported increased access to rizatriptan, zolmitriptan and sumatriptan in its previous submissions[1,2]. 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.

[1] Australian Medical Association (2019) *AMA submission to the Therapeutic Goods Administration – proposed amendments to the Poisons Standard (November 2019 meetings).*
[2] Australian Medical Association (2020) *AMA submission to the Therapeutic Goods Administration – proposed amendments to the Poisons Standard (March 2020 proposals)*

Clotrimazole

The AMA does not oppose the proposed changes to clotrimazole, where clotrimazole for vaginal use with 1% or less will be available as a Pharmacy Medicine.

Sildenafil

In 2017[3] and 2018[4] the AMA lodged submissions opposing the proposal to down-schedule sildenafil. No new, publicly available, information appears to have been provided to substantiate or justify another application, following the TGA's rejection of the previous application. The AMA remains opposed to the proposal to down-schedule sildenafil.

Erectile dysfunction (ED) is a complex medical condition, not a simple health issue.

ED is a marker of the state of the blood vessels in other parts of the cardiovascular system and should be thoroughly investigated before phosphodiesterase inhibitors are prescribed. This is best investigated by the patient's usual medical practitioner in a consultation where this issue can be teased out and, if appropriate, alternatives discussed.

ED may also be caused by many other prescription medicines.

It is also crucially important to explore whether there are psychological causes of ED which can be a very significant reason for presentation.

The above issues cannot be addressed by a pharmacist. Only medical practitioners are trained to make a complete diagnosis, monitor the ongoing use of medicines and to understand the risks and benefits inherent in prescribing, based on the individual's full medical circumstance. This is also why a pharmacist confirming that the patient has previously been prescribed sildenafil as a treatment for ED is not an appropriate requirement of the Schedule 3 entry. Further, the requirement is not clear on how the pharmacist would confirm this, nor how recent the prescription by a medical practitioner should be. A patient may have developed a cardiovascular or other condition since sildenafil was originally prescribed.

It has been argued before that men will be more likely to seek help with ED problems if they can access medicines over the counter at a pharmacy, rather than make an appointment with their general practitioner. However, accessing these medicines from a pharmacist does not avoid initiating a conversation about ED issues. Conversations with men regarding ED can be very difficult to initiate where there is not a well-developed therapeutic relationship between doctor and patient. It is most unlikely that a pharmacist delivered checklist (as in previous down-scheduling applications) will facilitate the confidence and trust and emotional security to entertain such a delicate discussion.

Once ED issues are broached, a consultation with a general practitioner will ensure that a full health assessment is undertaken, risk factors are identified and holistic advice is provided. A medical practitioner consultation to obtain a prescription of sildenafil also provides an

[3] Australian Medical Association (2017) *AMA submission on TGA proposal to down-schedule Vardenafil and Sildenafil.*

[4] Australian Medical Association (2018) *AMA submission to the TGA on codeine and sildenafil scheduling proposal.*

opportunity to screen for diabetes mellitus and sexually transmissible infections, as well as undertake unrelated but important health prevention activities. The AMA believes a Schedule 3 entry for sildenafil would significantly diminish the patient safety that is currently provided by the work of medical practitioners.

The Advisory Committee on Medicines Scheduling (ACMS) will also be well aware that sildenafil is known to have serious adverse interactions with a range of other medicines. While theoretically a pharmacist may know about a patient's usual medicines, a patient's regular general practitioner will also know the full range of medicines currently prescribed, why those particular medicines were prescribed, and be able to discuss safe alternative approaches knowing the full medical history of the patient. A pharmacist identifying a potential adverse drug interaction will, in any event, have to refer the patient to their general practitioner.

ACMS will also be aware of the potential, and serious, adverse reactions associated with use of sildenafil, and the significant range of contraindications.

The AMA does not have confidence that a pharmacist, even supported by additional training, will mitigate the risks to patient safety or ensure dispensing and use that is consistent with quality use of medicines principles. Relying on pharmacists to control the use of low-dose codeine products was unsuccessful in stemming the increase in codeine-related deaths post 2010.

The applicant has not cited evidence to support the claim that increased advertising will encourage patients to visit their medical practitioner for ED issues, especially considering the proposal involves pharmacist prescribing. While some advertisements may raise awareness, there is also evidence that advertising of a medication may instil fear, mislead, or confuse patients, and may lead to inappropriate requests and hinder the doctor-patient relationship[5]. If awareness of ED did increase through advertising, this is not a sufficient reason to promote pharmacist prescribing of sildenafil. The AMA considers the intent behind ED advertising to be more of a promotional opportunity for those who would profit from sildenafil sales, with a focus on the drug more than the condition, its possible underlying causes, or the risks/benefits of taking the medication[5,6].

It should also be noted that pharmacists will gain financially from the dispensing of these medicines; there is an inherent conflict of interest.

Ibuprofen

The AMA opposes the proposed changes to ibuprofen, where higher strength (400mg) tablets would be available as a Pharmacy Medicine. AMA members anecdotally report significant ibuprofen overuse in Australian society. AMA members report that it is common for patients weaning off opioids to overuse ibuprofen to compensate. Potential for overuse may increase if the number of tablets needed to overuse is reduced (i.e. higher dose per tablet), as patients are sometimes more sensitive to the number of tablets they are taking more so than the dose.

[5] See Hall, d., Hones, S., Hoek, J (2010) *Direct to consumer advertising versus disease awareness advertising: consumer perspectives from down under.* Journal of Public Affairs. Vol 11:1.
[6] See Hall, D., Jones, S., and Iverson, D (2009) *Content of analysis of disease awareness advertisements in popular Australian women's magazines.* Medical Journal of Australia. doi: 10.5694/j.1326-5377.2009.tb03355.x

While ibuprofen has a strong safety profile in comparison to other non-steroidal anti-inflammatory drugs, there is evidence to suggest that dose may influence the risk of gastrointestinal adverse events[7]. Ibuprofen use may increase the risk of heart attack and stroke and can result in kidney and liver damage[8]. AMA members report cases of patients experiencing adverse effects in the kidneys that are only identified if tests are completed.

Patients with acute pain can achieve good analgesic outcomes with 200mg tablets with some combinations, such as paracetamol or caffeine[9]. AMA members encourage milder to moderate dosing with 200mg tablets as opposed to higher strength tablets when maximal (or supra-maximal) dosing would be more likely with greater risk of side effects which can be irreversible.

The AMA suggests that the Schedule should remain for 200mg ibuprofen tablets to be available over the counter only.

Cumyl-pegaclone (synthetic cannabinoid and New Psychoactive Substance)

The AMA does not oppose the proposed changes to Cumyl-pegaclone, where it will be classified as Schedule 9 entry.

The synthetic cannabis products cannot be considered safe given that the synthesized psychoactive substances in them have not been rigorously tested, and little is known about their long or short-term health effects, dependence potential or adverse reactions. Psychotic symptoms have been associated with use of some synthetic cannabinoids, as well as signs of addiction and withdrawal symptoms similar to those of cannabis. Adverse outcomes have been reported from the use of Kronic in Australia[10].

Nicotine

The AMA does not oppose the proposed changes to nicotine. The changes clarify that nicotine for human use (other than tobacco for smoking) is only exempt under Schedule 4 when included in oromucosal and transdermal preparations for smoking cessation.

Cannabidiol

The AMA opposes the proposal to make cannabidiol (CBD) products with at least 98% CBD and 0.2% or less of tetrahydrocannabinol (THC) an unscheduled product that is listed, assessed listed, or a registered medicine on the Australian Register of Therapeutic Goods (ARTG). The AMA also opposes the proposal to make a Schedule 3 entry for CBD products with a maximum daily dose of 60mg/day.

While there is a slowly growing body of evidence regarding the therapeutic use of cannabinoids, it is still experimental, in some cases conflicting and far from decisive or reassuring.

[7] Varrassi, G. et al. (2020*) Ibuprofen Safety at the Golden Anniversary: Are all NSAIDs the Same? A Narrative Review*. Advances in Therapy. Vol 37, 61–82.
[8] Alcohol and Drug Foundation (2020) *Ibuprofen.*
[9] Moore, R. et al (2015) *Non-prescription (OTC) oral analgesics for acute pain – an overview of Cochrane reviews.*
[10] Australian Medical Association (2014) *Cannabis use and health.*

The AMA's position statement on *Cannabis use and health*[11] acknowledges that cannabis has constituents that may have potential therapeutic uses:

- Appropriate clinical trials of potentially therapeutic cannabinoid formulations should be conducted to determine their safety and efficacy compared to existing medicines, and whether their long-term use for medical purposes has adverse effects.
- Therapeutic cannabinoids that are deemed safe and effective should be made available to patients for whom existing medications are not as effective.
- Smoking or ingesting a crude plant product is a risky way to deliver cannabinoids for medical purposes. Other appropriate ways of delivering cannabinoids for medical purposes should be developed.
- Any promotion of the medical use of cannabinoids will require extensive education of the public and the profession on the risks of the non-medical use of cannabis.

Use of medicinal cannabis should remain largely restricted to clinical trials and in the hands of a small group of approved prescribers, largely in the palliative care of paediatric settings for palliative control of chronic pain and management of intractable epilepsy in children. Many medical practitioners are ambivalent about medicinal cannabis, potentially due to the view that anecdotal evidence and public opinion have deemed it safe and even preferable without the appropriate scientific evidence to support it[12]. The AMA is concerned that down-scheduling CBD products sends the wrong message to the public. There is a risk of normalising the concept that cannabis is a good therapeutic product without established evidence to support it and potentially dissuades use of products with a genuine evidence-based for benefit. Prescription-only CBD will ensure that it is used only for evidence-based indications.

The AMA understands that the TGA has recently published a review of CBD, concluding that there is a "good safety and tolerability profile at the low dose range of under 60mg/day"[13]. While this may be the case, the TGA also highlights that evidence for the efficacy of CBD on medical conditions have not been well established, and currently CBD is not widely used in clinical practice. The review also highlights the issues with drug-drug interactions and the risk that patients may substitute their regular medications (e.g. for epilepsy or schizophrenia) for low dose CBD. Further, there is limited evidence for CBD use in children and this needs to be considered.

The AMA would especially oppose any scheduling of CBD use that would only be subject to post-market reviews. The AMA has previously raised its concerns to the TGA regarding the high rate of non-compliance for listed medicines.

While the AMA supported a review of regulatory barriers for prescribing and the TGA has established that low dose CBD is safe, the AMA does not believe that CBD use is at the stage where it should be freely available as a therapeutic, complementary substance, or as a Schedule 3 medicine. Patients should consult a medical practitioner if they are experiencing medical conditions that may be alleviated from medicinal cannabis use. The high potential for drug-drug interactions require monitoring by a medical practitioner. Finally, efficacy for specific medical conditions need to be established.

[11] Australian Medical Association (2014) *Cannabis use and health*.
[12] Australian Medical Association (2020) *AMA submission to senate inquiry into the current barriers to patient access to medicinal cannabis in Australia*.
[13] Therapeutic Goods Administration (2020) *Safety of low dose cannabidiol.*

Methylisothiazolinone and methylchloroisothiazolinone

The AMA does not oppose the proposal for Methylisothiazolinone and methylchloroisothiazolinone; to amend Schedule 6 to include warnings that repeated exposure may cause sensitisation, and to exclude applications not indented for use on skin for products containing 0.05% or less of isothiazolinones.

Isothiazolinones

The AMA does not oppose to the proposal for isothiazolinones; to include a new Schedule 6 entry – to include a warning that repeated exposure may cause sensitisation, and to include isothiazolinones not elsewhere specified in the Schedule with the exception of applications not indented for use on skin for products containing 0.05% or less of isothiazolinones.

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