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AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – March 2021

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The following feedback applies to the scheduling proposals referred to the Advisory Committee on Medicines Scheduling (ACMS #33) and joint ACMS/Advisory Committee on Chemicals Scheduling (ACCS) meetings (ACMS-ACCS #27), March 2021.

Appendix H entry for metoclopramide, chloramphenicol, and prochlorperazine

The AMA continues to be opposed to relaxing the regulation around medicines advertising for Schedule 3 products. Direct to consumer advertising of medicines may increase use, but not necessarily effective or rational use in line with quality use of medicines principles. While advertising may potentially increase awareness of certain health conditions and medicines, its primary purpose is to increase demand and sales for the advertiser's product. Advertising to the public is about profits, not improving patient care.

Metoclopramide

The AMA does not believe the applicant has provided sufficient evidence that would override the decisions of the TGA's *Consultation to add substances to Appendix H of the Poisons Standard*[1]. It was decided that there would not be an Appendix H entry for metoclopramide because of its sedative properties, increased pressure on pharmacists to prescribe off label, and the potential for misuse. The AMA believes these reasons not to include metoclopramide in Appendix H are still legitimate.

The AMA has additional concerns regarding metoclopramide plus paracetamol as a Schedule 3 drug. AMA members anecdotally report patients supplied with this combination for conditions other than migraine. AMA members also believe it would be safer to have single ingredient products to minimise the risk of medication misadventure. Further, AMA members report not recommending metoclopramide plus paracetamol products for people aged 12-17 due to the risk of dystonic reactions[2].

[1] Therapeutic Goods Administration (2018) *Outcomes of the consultation to add substances to Appendix H of the Poisons Standard.*
[2] NPS MedicineWise (2001) *The management of acute dystonic reactions.*

As triptan products have recently been downscheduled to Schedule 3, the ACMS may wish to consider upscheduling metoclopramide plus paracetamol products to Schedule 4. Metoclopramide plus paracetamol products are not first line treatments for migraine[3].

Chloramphenicol

Australia has made a commitment as part of the National Medicines Policy to reduce the inappropriate use of antibiotics. Only health practitioners should be providing advice and/or suggesting the use of antibiotics. A patient is not able to identify the difference between viral or allergic conjunctivitis with bacterial conjunctivitis. Advertising chloramphenicol direct to the public will only increase inappropriate demand from patients seeking a quick fix. Given the risks of contributing to antimicrobial resistance, it should not be added to Appendix H.

Prochlorperazine

The AMA believes that there has not been sufficient new evidence provided by the applicant to justify overriding the decision of the 2018 consultation to not refer prochlorperazine to the Delegate for inclusion in Appendix H. The reason not to include was due to a 'negative impact on public health due to potential misuse, abuse, or diversion.'

Processed Aconitum carmichaelii

The AMA opposes the proposal to increase the quantity of toxins identified in processed *Aconitum carmichaelii*. The AMA opposes relying on the "international organisation" standards to control safe levels of toxins found in Aconitum spp, as suggested by the applicant. The applicant summary does not provide evidence that supports an increase on the limits on toxins in Aconitum spp.

The AMA notes that there is potential for aconite poisoning if the product is not processed properly or is taken in high doses[4]. Poisoning can lead to death due to cardiac failure and arrhythmia[5]. The AMA warns against assuming that a product is safe based on a lack of data around adverse events, particularly for complementary medicines that can be bought off the shelf and without supervision from a medical practitioner.

There is limited efficacy evidence regarding most complementary medicines and some have the potential to cause adverse reactions or interact with conventional medicines. Unproven complementary medicines and therapies can also pose a risk to patient health either directly through misuse or indirectly if a patient defers seeking medical advice.

[3] Therapeutic Guidelines (2021) *Acute treatment for migraine with nonopioid analgesics and antiemetics* and *migraine in children*.
[4] Chan, TY. (2009) *Aconite poisoning*. Clin Toxicol (Phila)
[5] Byard, R et al (2017) *What risks do herbal products pose to the Australian community?* Medical J Aust

Kambo

The AMA supports the proposal to include a new Schedule 9 entry for Kambo. The AMA considers kambo to be a significant health risk for those who use it. In addition to its harmful effects both intended and adverse, the act of blistering the skin and applying kambo to the burnt area risks other health concerns such as infection. There is also a risk that using kambo would prevent a patient from seeing a medical practitioner for their medical condition and delay diagnosis.

Kambo should be regulated under the Poisons Standard as it appears to be used as a therapeutic product by 'kambo practitioners'[6]. There is currently insufficient evidence for its intended therapeutic effects.

Nitrous oxide

The AMA supports the proposal to include a Schedule 10 entry for nitrous oxide to deter misuse and abuse. The AMA notes the several significant adverse effects of nitrous oxide, including sudden death and heart attack[7], and the reported increasing misuse over time.

Hemp seed oil

The AMA does not oppose the proposal to exempt hemp seed oil (for oral consumption when compliant with the Food and Standards Code) from the Poisons Standard. The AMA notes the Food Standards Australian and New Zealand's Food Standards Code to permit the sale of low-tetrahydrocannabinol hemp seed foods[8]. The AMA also notes that hemp has low levels of cannabidiol and therefore does not have a therapeutic effect[9].

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[6] Lavoipierre, A (2018) *Tree frog poison being used as an alternative medicine.*
[7] Alcohol and Drug Foundation (2020) *Nitrous Oxide.*
[8] Food Standards Australia and New Zealand (2017) *Hemp seeds as food.*
[9] Ibid.