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

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Introduction

The following submission refers to the proposed amendments to the Poisons Standard to be considered by the Advisory Committee on Medicines Scheduling (ACMS) #34 meeting, June 2021. The AMA has provided a separate submission to the proposals relating to oral contraceptives, to be considered at the same meeting.

Amygdalin and hydrocyanic acid

The AMA continues to oppose the unscheduling of amygdalin and hydrocyanic acid. The applicant's comparison to the levels of cyanide/hydrocyanic acid in food is not appropriate as the intention is to use these products as a therapeutic good through traditional Chinese medicine (TCM). As such, their presence on the Schedule remains appropriate. TCM products should go through the same process as other medicines to become registered on the Australian Register of Therapeutic Goods to be appropriately assessed for safety, quality, and efficacy, and be monitored.

The AMA's position remains the same as was submitted to the November 2020 proposed amendment to the Poison Standard[1]. Amygdalin is referred to as an alternative to cancer therapy. However, there is no reliable evidence that it has a therapeutic effect on cancer patients[2]. There are also serious risks of cyanide poisoning by taking amygdalin orally as amygdalin metabolites can convert to hydrocyanic acid and accumulate in the body [3,4]. Therefore, the AMA considers this proposal a public health safety risk.

[1] Australian Medical Association (2020) *AMA submission to the Therapeutic Goods Administration – proposed amendments to the Poisons Standard – November 2020.*
[2] Milazzo, S., Horneber, M., Ernst, E. (2015) *Laetrile treatment for cancer.* Cochrane Library.
[3] Ibid.
[4] Shi, J, Chen, Q, Xu, M, et al. (2019) *Recent updates and future perspectives about amygdalin as a potential anticancer agent: A review.* Cancer Med. 8: 3004– 3011.

The AMA also note's the Delegate's interim[5] and final decision[6] not to amend the Poisons Standard for amygdalin and hydrocyanic acid as proposed in November 2020. The ACMS found that there was a high risk of cyanide toxicity with high variability and limited evidence of benefit. The AMA supports the Delegate's comments around the risks of exposure by children if these products are provided at a general sale level. The AMA would also add that it may delay patients seeking evidence-based care by a registered medical practitioner if they believe these TCM products would provide a therapeutic benefit for their condition.

Bufexamac

The AMA supports the proposal to amend the Schedule 4 entry for bufexamac so that preparations for dermal use containing five per cent or less of bufexamac, and suppositories, are no longer available for general sale. The AMA supports that all bufexamac products should be covered under Schedule 4 due to the TGA's recent investigation that determined unacceptable safety and effectiveness issues, including the risk of serious skin reactions[7].

Ibuprofen

The AMA opposes the proposal to include higher dose ibuprofen in Schedule 2, where 600mg modified release tablets would be available as a Pharmacy Medicine.

The AMA's concerns remain the same as those outlined in its submission for the June 2020 proposal to include a 400mg tablet as a Pharmacy Medicine[8].

The AMA is not convinced there is a clinical need for 600mg modified release tablets and on that basis does not believe it should be widely available to the public.

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[9]. Ibuprofen use may increase the risk of heart attack and stroke and can result in kidney and liver damage[10]. 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[11]. AMA members encourage milder to moderate dosing with 200mg tablets as opposed to higher strength tablets when maximal (or supra-

[5] Therapeutic Goods Administration (2021) *Notice of interim decisions on proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, November 2020.*
[6] Ibid.
[7] Therapeutic Goods Administration (2020) *Bufexamac – safety advisory – risk of serious skin reactions.*
[8] Australian Medical Association (2020) *AMA submission to the Therapeutic Goods Administration - proposed amendments to the Poisons Standard – June 2020*
[9] 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.
[10] Alcohol and Drug Foundation (2020) *Ibuprofen.*
[11] Moore, R. et al (2015) *Non-prescription (OTC) oral analgesics for acute pain – an overview of Cochrane reviews.*

maximal) dosing would more likely come with greater risk of side effects which can be irreversible.

The AMA notes that the ACMS and the Delegate consider that clinical experience with modified release products is limited and that the safety profile is vastly different to immediate release formulations. The interim decision did not recommend modified release ibuprofen tablets for downscheduling[12]. The AMA supports these as reasons to not downschedule modified release 600mg tablets as in this proposal.

The AMA is also concerned that public awareness/health literacy around the difference between immediate and modified release tablets is too low and will cause confusion if it is available under Schedule 2, without patient education and advice from a medical practitioner. Patient confusion may also be experienced if the number of products available increases further.

The AMA suggests that Schedule 2 should remain for 200mg ibuprofen tablets.

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[12] Therapeutic Goods Administration (2020) *Notice of interim decisions on proposed amendments to the Poisons Standard – ACM and Joint ACMS-ACCS meetings, June 2022 3.5 Ibuprofen.*