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AMA Submission to the Therapeutic Goods Administration – Proposed amendments to the Poisons Standard – November 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 #32) and joint ACMS/Advisory Committee on Chemicals Scheduling (ACCS) meetings (ACMS-ACCS #26), November 2020.

The AMA does not support the downscheduling 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.

Amygdalin and hydrocyanic acid

The AMA opposes the downscheduling of amygdalin and hydrocyanic acid from S10 to S4 for use in traditional Chinese medicine. 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[1]. 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 [2,3]. Therefore, the AMA considers this downscheduling proposal a public health safety risk.

Cannabidiol

The AMA opposes the proposal to include synthetic or semi-synthetic copy of the CBD molecule with 2 per cent or less of impurities into the S4 entry.

[1] Milazzo, S., Horneber, M., Ernst, E. (2015) *Laetrile treatment for cancer.* Cochrane Library.
[2] Ibid.
[3] 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.

Research states that synthetic CBD has not been used in clinical trials and more research into their mechanism of action is needed to develop synthetic CBD-based drug therapies[4,5].Synthetic CBD is 'likely' to be psychoactive and has different pharmacological activity to plant derived CBD[6]. However, the AMA believes more research is required to include synthetic or semi-synthetic CBD in the S4 entry.

Further, while the amendments add that impurities of two per cent or less of the total synthetic CBD product are appropriate, the applicant does not provide information on the impurities that might be present in synthetic CBD. The AMA asks the ACMS to consider what evidence has been used to determine whether two per cent or less is a safe threshold for impurities and how potential impurities interact with the human body.

Bilastine

The AMA does not oppose the proposal for Bilastine, where new S2, S4, and Appendix F, Part 3 entries will be included in the Poisons Standard.

Budesonide and formoterol

The AMA opposes the downscheduling of budesonide and formoterol. Asthma management regimens prescribed using this combination are complex and are typically specifically tailored for individual asthmatics[7]. Allowing pharmacists to prescribe this combination would undermine this tailoring process and interfere with the regimes developed by the patient's medical practitioner. Potential side effects from long term use and the maximal daily recommended doses for different products[8] warrant the monitoring and support of a medical practitioner. Pharmacists will not be able to confirm with certainty whether the patient has a medical diagnosis of asthma, while a medical practitioner is trained to do this.

Psilocybin and MDMA

The AMA opposes the downscheduling of psilocybin and N, α-Dimethyl-3,4-(methylenedioxy) phenylethylamine (MDMA). The AMA understands that the treatment of certain medical conditions with MDMA and psilocybin is an emerging field and research has reported positive outcomes with minimal risk to the patient.

However, more high-quality research using larger scale studies are needed before it can be used more widely by medical practitioners. High quality studies would determine the safety and efficacy of using these drugs for mental illness. Currently, long-term side effects are not known.

[4] Morales, P., Reggio, P., Jagerovic, N. (2017) *An overview on medicinal chemistry of synthetic and natural derivatives on cannabidiol.* Front Pharmacology.
[5] Chesney E, McGuire P, Freeman TP, Strang J, Englund A. (2020) *Lack of evidence for the effectiveness or safety of over-the-counter cannabidiol products*. Therapeutic Advances in Psychopharmacology.
[6] Therapeutic Goods Administration (2020) *Safety of low dose cannabidiol.*
[7] NPS MedicineWise (2020) *Budesonide with formoterol for mild asthma: New PBS listings*
[8] AstraZeneca (2019) *Symbicort rapihaler: consumer medicine information.*

For example, the potential to develop psychosis, Hallucinogen Persisting Perception Disorder has not yet been investigated[9]. While MDMA and psilocybin have been considered 'breakthrough therapies' in the US, transition to a prescription medicine is still subject to Phase 3 trials. This shows that these therapies are not ready for use outside of clinical trials.

Trials generally exclude people with personal or family history of psychosis, mania, violence, suicide attempts requiring hospitalisation, current drug or alcohol use disorders, as they have a higher risk of developing a psychotic disorder[10].

The AMA supports best practice advice for medications that are evidence-based from high quality studies specific to the health condition being treated.

The AMA appreciates the barriers to research as raised by the applicant. However, these barriers should be addressed outside of the Poisons Standard Framework. The AMA believes that the need to reduce research barriers does not warrant making psilocybin and MDMA more readily available to practising medical practitioners as it would through down-scheduling. For example, a review of the barriers to MDMA and psilocybin through the Special Access Scheme or the Authorised Prescriber Scheme might be more appropriate. Through this, appropriate and safe research conditions should be maintained. Approved trials should be undertaken only by medical practitioners with the appropriate psychiatric and psychotherapy training to ensure risks and side effects are managed. Trials should be overseen by institutional research ethics committees.

Azelaic acid

The AMA opposes the proposal, in its current wording, to delete the S2 entry and include an S5 entry for azelaic acid.

The AMA does not in principle oppose making azelaic acid more available for human therapeutic or cosmetic use. However, is concerned that the current proposal wording may hinder availability of existing products. Currently there are two products available that medical practitioners may recommend to their patients containing 20% azelaic acid under S2[11]. It is unclear whether the deletion of the S2 entry would mean these products would be included under S4 or S5. There are issues with both options.

The AMA does not believe that the currently available 20% azelaic acid products warrant prescription as use of this product is generally safe with the occasional risk of irritation. Rescheduling to S4 would in practice increase the number of prescriptions doctors would have to fill unnecessarily, causing greater administrative burden.

The alternative S5 entry for these products may essentially create cost to the manufacturers through relabelling their product, creating risk that these products may be taken off the market. AMA members would not support a decision that means these products would no longer be

[9] Royal Australian & New Zealand College of Psychiatrists (2020) *Clinical memorandum: therapeutic use of psychedelic substances*.
[10] Ibid.
[11] Therapeutic Goods Administration (2020) *ARTG search – azelaic acid*.

available to their patients. The AMA asks the ACMS-ACCS to ensure current access to 20% azelaic acid products is not hindered by this proposal.

September 2020

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