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AMA Submission to the Therapeutic Goods Administration – interim decision on amendments to the Poisons Standard – cannabidiol

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The AMA thanks the TGA for the opportunity to provide feedback on the interim decision for the proposed amendments to cannabidiol (CBD) in the Poisons Standard.

The AMA urges the Delegate of the Secretary to reconsider the interim decision to down-schedule CBD to Schedule 3. The AMA notes that this interim decision was not supported by the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS). The AMA agrees with the ACMS-ACCS recommendation that there is insufficient evidence to relax the access controls on CBD and is surprised that the interim decision goes against this advice. Medicines should only be down-scheduled if 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. This is not the case for CBD.

Medical practitioners have only been prescribing CBD products for a few years, the evidence is still emerging, more education around its use is required, and the AMA does not consider pharmacists to have more education than medical practitioners in advising patients on when it would be appropriate to use CBD products. Among general practitioners, confusion remains about which specific conditions CBD products should be prescribed for, as the evidence base for different conditions varies. While the TGA has guidance documents for CBD prescriptions in relation to chronic pain, palliative care, epilepsy, spasticity from multiple sclerosis, and chemotherapy-induced nausea and vomiting, approvals have also been granted for conditions where there is less evidence that CBD is effective – including autism and insomnia. As the Australian Prescriber recently noted, "TGA assessments under SAS-B appear to give the benefit of the doubt with regard to evidence"[1]. The AMA maintains that medical practitioners require more guidance on the process and reasons for prescribing CBD and is concerned that pharmacist only provision will encounter a similar, if not exacerbated, level of uncertainty from pharmacists.

Prescribing by a medical practitioner provides checks and balances to ensure the medication is suitable for the patient and allows development of a treatment plan and monitoring. It is best practice for a medical practitioner to discuss the risks and benefits of CBD, conduct a regular review, and for dosing titration[2] to occur. However, this will be less likely to occur if products do not require a consultation from a medical practitioner. Medical practitioners will not be able to monitor their patient's CBD use if it is down-scheduled. There is a risk that patient conditions that

[1] Arnold, JC., Nation, T., McGregor, I (2020) *Prescribing medicinal cannabis*. NPS MedicineWise.
[2] *Ibid.*

are associated with CBD use (e.g. anxiety, psychosis, chronic non-cancer pain, and epilepsy) will go unchecked and cause further harm to the patient. Additionally, as emphasised in the AMA's earlier submission, CBD products carry a significant risk of interacting negatively with other prescribed medicines, necessitating oversight by a doctor. Medical practitioners must be able to determine whether there are other medications more suitable for their patient's condition before prescribing CBD.

The AMA urges the Delegate to reconsider the AMA's original submission, as copied below, and the valid points made by the ACMS-ACCS in their recommendation not to down-schedule CBD.

Original AMA submission on the decision to down-schedule CBD

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.

The AMA's position statement on *Cannabis use and health*[3] 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 or 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[4]. 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.

[3] Australian Medical Association (2014) *Cannabis use and health*.
[4] Australian Medical Association (2020) *AMA submission to senate inquiry into the current barriers to patient access to medicinal cannabis in Australia*.

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"[5]. 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.

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[5] Therapeutic Goods Administration (2020) *Safety of low dose cannabidiol.*