Pharmaceutical Society of Australia

Consultation: Proposed amendments to the Poisons Standard – Joint ACMS-ACCS meeting #25, June 2020

MAY 2020

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission on proposed amendments to the Poisons Standard being referred for scheduling advice to the Joint ACMS-ACCS meeting (#25) in June 2020. PSA's comments relate to the two cannabidiol items (2.2 and 2.5).

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 32,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Recommendations

Cannabidiol

Private applicant proposal (agenda item 2.2) – PSA does not support this proposal which would result in cannabidiol preparations with cannabidiol as 98 per cent or greater of total cannabinoid content and 0.2 per cent or less of tetrahydrocannabinol content being exempt from scheduling. This is based on PSA's significant concerns around safety implications for patients and carers, as well as the broader public.

Delegate-initiated proposal (agenda item 2.5) – PSA considers that the proposal to create a new Schedule 3 entry for cannabidiol under the specified conditions should have additional Appendix M controls included. Further, PSA does not support the inclusion of cannabidiol in Appendix H.

Comments on proposed amendments to cannabidiol

Cannabidiol (CBD) is currently included in the Poisons Standard through the:

- cannabis entry
    - which has a cross reference to cannabis sativa, hemp, hemp seed oil and tetrahydrocannabinols
    - in Schedule 9 and in Schedule 8
    - in Appendix D, Item 1, and in Appendix K
- cannabidiol entry
    - which has a cross reference to nabiximols, cannabis and tetrahydrocannabinols
    - in Schedule 4.

Agenda item 2.2

PSA's comments

- PSA understands this is a proposal submitted by a private applicant. From PSA's perspective, the overall purpose of the proposal (to exempt certain CBD preparations from scheduling) was clear, however many aspects of the reasons or rationale reportedly given were not easy to follow and somewhat unclear.
- It is stated that CBD should be regulated as a complementary medicine "given its clear evidence of benefits, good safety profile and low risk". PSA would contend that there is still limited availability of evidence of efficacy of cannabis and cannabinoids. Clinical trials are being conducted in Australia for different indications. However, evidence on the safety and efficacy of cannabis and cannabinoids for medicinal use is still limited, particularly around use for different clinical conditions or symptoms and in different patient groups, hence the risk profile of individual substances has yet to be comprehensively established.
- Given the previous dot point, it is also not clear whether CBD would be considered to be a suitable or eligible ingredient under the regulatory pathway for registered complementary medicines. PSA understands that the threshold or requirement for a substance to be regulated as a complementary medicine is that the indications are minor, self-limiting conditions.
- It is reportedly suggested that "concerns about potential drug-CBD interactions can be handled effectively through limiting the amount of CBD able to be sold in a month's supply and the inclusion of appropriate warning labels". PSA has concerns about this suggestion as follows. Firstly, if a person's regular medicine has the potential to interact with CBD, it follows that those two substances should not be supplied or used together. While limiting the amount of one substance might, in some cases, reduce the risk posed by a potential interaction, it is important that known risks of harm are appropriately managed as the outcome of a drug interaction is likely to pose undesirable and possibly significant consequences for the patient. There must be involvement of a pharmacist or prescriber in making these types of decisions. Secondly, there would be no mechanism to easily or effectively track the supply of CBD preparations if they are

unscheduled and therefore it would be impossible to limit the amount supplied to an individual within any given period.

- PSA notes an amendment to the Schedule 4 entry of CBD is proposed to explicitly include synthetic and semi-synthetic formulations. Based on the wording of this proposal, PSA is concerned that consideration may not have been given to the possibility that synthetic CBD may contain the psychoactive (+) CBD enantiomer if it is a racemic mixture.

Summary

It appears that the intention of the proposed amendment is primarily to expand access to CBD preparations for therapeutic use for patients. This may, in part, be consistent with the current policy approach and reforms around medicinal cannabis availability and use in Australia. However, there would be significant safety concerns for patients, carers and the public if these preparations were to be unscheduled. Therefore, PSA does not support these proposed amendments.

Agenda item 2.5

Summary of proposal

PSA understands this is a Delegate-initiated application which seeks to create a new entry in Schedule 3 as follows.

> ***Cannabidiol*** *in preparations for therapeutic use when:*
>
> *a. the cannabidiol is either plant derived, or when synthetic only contains the (-) CBD enantiomer; and*
>
> *b. the maximum recommended daily dose is 60 mg or less of cannabidiol; and*
>
> *c. in packs containing not more than 30 days' supply; and*
>
> *d. cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and*
>
> *e. any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2 per cent or less of the total cannabinoid content of the preparation; and*
>
> *f. for adults aged 18 years and over.*

PSA's comments

- PSA is aware that this proposal takes into account the recently published review report on the **Safety of low dose cannabidiol** (April 2020) including that:
  - cannabidiol presents a good safety and tolerability profile at the low dose range of under 60 mg/day
  - there were potential conditions for low dose cannabidiol that would not require oversight by a medical practitioner

- low dose cannabidiol for plant derived CBD or synthetic CBD which only contains the (-) CBD enantiomer would be suitable for consideration for down scheduling, potentially to Schedule 3, given that the conditions for which it is proposed for use require oversight by a healthcare professional and there remains the potential for drug-drug interactions.

- This followed on from a recommendation of the Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia which **reported** in late March 2020.

- The proposed wording and conditions for a new Schedule 3 entry for CBD are consistent with the published findings of the safety review.

- The proposal to include CBD in Schedule 3 reflects the review's outcome that there is potential clinical utility without medical oversight of low dose, oral CBD. PSA notes, however, that the report mentions that "no clear conclusions can be drawn on efficacy of CBD at low doses" due to a lack of larger phase III and conclusive efficacy trials. Due to limited experience in clinical use, PSA also notes that "the evidence for which conditions it is effective has not been thoroughly characterised". The limited evidence base may raise some concerns for pharmacists with regards to the provision of advice on appropriate use.

- PSA notes the report also states the need to "ensure that a medicine supplied under lower medical oversight" (i.e. a pharmacist, for example) "is not used to substitute medicines in conditions where medical supervision is required (e.g. in the treatment of epilepsy or schizophrenia where medical supervision is required and known drug-drug interactions and pharmacodynamics interactions could lead to patient harm)". Given patients seeking to access CBD may do so to source an alternative therapy or as a 'last resort' option, this may present complex or delicate situations for the pharmacist in ensuring prescribed medical care is not compromised.

- The medical conditions and symptoms for which patients may choose to access CBD are serious health conditions involving medical diagnosis and management. Therefore, PSA would suggest that additional Appendix M controls to support Schedule 3 supply may be warranted. For example, the Appendix M criterion of "Need for formal diagnosis or periodic review of the condition by a medical practitioner" could be employed for CBD. This could mean that the patient's doctor, if appropriate, could initiate treatment with CBD for the patient, and that patient could continue to access CBD as a Pharmacist Only medicine with the pharmacist ensuring the patient is referred to the prescriber for periodic review. This would also help mitigate against the patient inadvertently substituting other prescribed medication with CBD.

- PSA highlights that any moves to compound CBD-containing preparations must be undertaken with caution to ensure standardisation and quality of the products. Compounded products should be formulated with active pharmaceutical ingredients of known source, quality and certainty of potency. Under current processes, a compounding pharmacy has no method to determine or provide evidence for the amounts of CBD content as well as other non-CBD substances including THC, whereas manufactured products (on the ARTG) are subject to rigorous testing and controls including pharmaceutical analysis to confirm the ingredients and the final contents. The natural source of the CBD products creates substantial risk that compounded products would contain varying amounts of active and restricted substances, which warrants further and careful consideration.

- PSA would not support inclusion of CBD in Appendix H given the conditions for which CBD may be used are serious medical conditions.

Summary

PSA believes that the addition of Appendix M controls to the proposed new Schedule 3 entry for CBD is preferable to ensure the use of low dose CBD does not compromise any medical management of the patient's condition. PSA does not support the inclusion of CBD in Appendix H.

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