

21 May 2020

To: medicines.scheduling@health.gov.au

Subject: 'Proposed Amendments to the Poisons Standard (Medicines/Chemicals)'

In accordance with section 52E of the *Therapeutic Goods Act 1989*, the Faculty of Pain Medicine (FPM) of the Australian and New Zealand College of Anaesthetists (ANZCA) submits this response to the proposed rescheduling of **cannabidiol** (CBD) to Schedule 3 (Pharmacist Only Medicine).

FPM is the teaching academy responsible for the education, training and continued professional development of specialist pain medicine physicians. As part of our Strategic Plan, we seek to position FPM as the trusted source of expertise in addressing the societal impact of the problem of pain. Specifically, we welcome engagement with key policy makers to shape their decisions towards optimal outcomes for people experiencing pain.

The question of the role of cannabinoids in the management of patients with pain is germane to both the educational and societal roles of FPM. In the current context, we make reference to our position on medicinal cannabis expressed in [PM-10: Statement on "Medicinal Cannabis" with particular reference to its use in the management of patients with chronic non-cancer pain.](#)

PM-10 notes in particular:

6. *At the present time, the scientific evidence for the efficacy of cannabinoids in the management of people with chronic non-cancer pain is insufficient to justify endorsement of their clinical use.*
7. *FPM recognises the difficulties inherent in performing trials of any medications in patients with chronic non-cancer pain. Nonetheless FPM believes that if pragmatic trials of cannabinoids are considered to be necessary they should be conducted on a coordinated national basis.*

PM-10 also endorses the recommendations made in the TGA document [Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia.](#)

The current proposal is to create a new Schedule 3 (Pharmacist Only Medicine) entry for cannabidiol (CBD) at doses up to 60 mg/day or less.

FPM OPPOSES this proposal. The following is the basis for the FPM's position.

1. Application

Among the reasons put forward by the Applicant is noted:

"Given its clear evidence of benefits, good safety profile and low risk, it should be regulated as a complementary medicine in the same way that other plant medicines (herbal medicines) are regulated in Australia."

As will be shown below, "clear evidence of benefits" is a gross overstatement.

2. Efficacy considerations

In its report, *Safety of low dose cannabidiol*, the TGA observed that, "... CBD has not been widely used in clinical practice and the evidence for which conditions it is effective has not been thoroughly characterised..." (p. 7).

This report presented its review of efficacy in dose-stratification tranches:

- (a) High dose range (10-15mg/kg/day)
 - "Treatment of **refractory epilepsy** is the most studied condition with dosages of 10 mg/kg/day to 20 mg/kg/day being successfully utilised predominantly in children and young adults, with the occasional use of a very high dose of 50 mg/kg day.
 - "Studies in **schizophrenia, bipolar disorder, Huntington's disease** at what would be considered a high dose also have mixed results in terms of efficacy outcomes."
- (b) Medium dose range (1-10mg/kg/day)
 - "Studies pertaining to the management of symptoms associated with **Parkinson's disease** consist of both controlled trials and case studies in dose ranges of 1.25 to 7 mg/kg/day.
 - "A dose of 5 mg/kg/day has been used in **graft-vs-host disease** and **cannabis dependence**."
- (c) Low dose range (<1mg/kg/day)
 - "**anxiety and insomnia secondary to post-traumatic stress disorder**"
 - "...utilised locally (*sic*) and systemically in **chronic pain of different aetiologies**": "chronic refractory pain or defects of neurological function and pain related to systemic sclerosis skin ulcers"

However there is no discussion in any detail of the efficacy of CBD in the conditions mentioned.

In particular, the *only* reference to the use in pain is #9: Notcutt W et al, *Initial experiences with medicinal extracts of cannabis for chronic pain: results from 34 'N of 1' studies*. *Anaesthesia* 2004; 59:440-452.

This is despite the extensive bibliography on cannabinoids in pain, as can be found in FPM professional document PM-10 and especially in the definitive systematic review and meta-analysis of cannabis and cannabinoids in the treatment of people with chronic non- cancer pain [Stockings E, et al., *Pain* 2018; 159:1932-1954]. It is recognised that most literature in this area refers to THC alone or THC/CBD combinations, in which any analgesic activity is attributed to the THC component.

3. Safety considerations

The TGA report is understandably concerned more with the safety of CBD, concluding that

"At low doses, CBD appears to have an acceptable safety and tolerability profile, although it was evident that there is a high potential for drug-drug interactions when used concomitantly with many other commonly prescribed drugs that are metabolised via CYP pathways. Currently there is insufficient evidence as to whether these would not occur with the use of low dose CBD."(p. 13).

That CBD may have an "acceptable" safety profile is no compensation for its very limited therapeutic efficacy. Furthermore, its "high potential for drug-drug interactions" is particularly relevant in the management of pain where, regrettably, polypharmacy is not uncommon.

4. Summary

In summary, there is no substantive support for CBD as an analgesic agent.

We contend, therefore, that chronic pain would not be one of the “potential conditions for low dose cannabidiol that would not require oversight by a medical practitioner” (TGA report, pages 4 and 13). Taken together with the high probability of adverse drug interactions in the pain management context, this lack of efficacy argues strongly against facilitating access to an unproven remedy by down-scheduling of CBD.

Altering the scheduling of CBD products to Schedule 3 will allow a more liberal advertising policy for product sponsors. FPM believes that given the current deficiencies in OTC product regulation; highlighted in [*Auditor-General Report No. 3 of 2011–12*](#), this would further add to the misinformation and misleading claims promoted by the product sponsors, who continue to claim efficacy where no clear evidence exists, and downplay risks which are well-documented, as outlined above.

The faculty welcomes ongoing consultation on these recommendations.

Yours sincerely



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