Therapeutic Goods Administration

Consultation on the proposed amendments to the Poisons Standard referred to the June 2020 Joint ACMS-ACCS in relation to Item 2.5 Cannabidiol

Submission of the Australasian College of Dermatologists

May 2020

About the Australasian College of Dermatologists

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. As the national peak membership organisation, the College represents over 550 specialist dermatologist Fellows (FACD) and 100 trainees across the country.

The College is the leading authority in Australia for dermatology, providing information, advocacy and advice to individuals, communities, government and other health stakeholders on dermatological practice.

ACD Response

The Therapeutic Goods Administration (TGA) has called for public submissions on a delegate initiated proposal to amend the scheduling of cannabidiol (item 2.5) that will be referred to the June 2020 Joint Advisory Committee on Medicines Scheduling and Advisory Committee on Chemical Scheduling meeting (Joint ACMS-ACCS #25).

The ACD welcomes the opportunity to put forward this submission. The ACD has concerns about the proposed amendments to create a new Schedule 3 (Pharmacist Only Medicine) entry for cannabidiol (CBD) at doses up to 60 mg/day or less for the following reasons:

- The rationale for this proposed new Schedule 3 entry is based on the TGA's *Review of safety of low dose cannabidiol* which largely refers to its possible clinical utility when used via the oral route in the management of some conditions. It is unclear whether the proposed scheduling refers to oral preparations only or would also include topical preparations.
- It should be noted that cannabidiol is garnering increasing attention in the public and media as a fashionable ingredient in skincare products. It is being marketed to overseas consumers, and reported in the Australian media, as being anti-inflammatory, analgesic, hydrating, moisturising and wrinkle-reducing. Other claims include its effectiveness in combating skin ageing, acne, eczema, psoriasis and pruritus. While the body of literature on cannabidiol is

growing including for use in dermatology, current data is limited regarding its safety and efficacy.[1]

- As with any new skincare product, there is the risk that people will expend significant time and money on these as yet unproven treatments at the expense of seeking professional advice and evidence-based treatments for their dermatological conditions. Making these products 'Pharmacist only' could lead consumers to believe a greater of body of evidence exists for these products than is actually the case.
- Down-scheduling may risk reducing the ability for prescribers to build the evidence for its clinical efficacy or to monitor the potential irritant effects of topical application i.e. whether these can cause contact dermatitis.
- Indeed, there is little information on the irritant effects of topical cannabidiol. The TGA's 2017 Guidance on Use of Medicinal Cannabis in Australia states that "THC is not generally well absorbed through the skin. CBD and CBN are 10 times more permeable than THC and are more likely to be used in topical preparations, although at least one transdermal THC product is in development. The time of onset and duration of action are unknown. There have been some reports of rash and itching, where the skin has come into contact with cannabis products". It is important that the incidence of adverse effects can be monitored.
- In the event the Committee does determine to recommend a down-scheduling of low dose cannabidiol to Schedule 3, it will be important that resources and education are available to pharmacists to support consumers in their decision-making. This includes advice on the extent of the evidence-base for cannabidiol products, information on alternative therapies for which there is greater evidence of effectiveness, and the importance of consumers seeking timely medical advice for accurate diagnosis and effective management of skin conditions.

Appendix:

Proposed amendments to the scheduling of Cannabidiol (Item 2.5) referred for scheduling advice to the June 2020 meeting of the Joint ACMS-ACCS

[1] The growing trend of cannabidiol in skincare products, NikitaJhawar BS, Elizabeth Schoenberg BA, Jordan V.Wang MD, MBE, MBA, Nazanin Saedi MD, Clinics in Dermatology. Volume 37, Issue 3, May–June 2019, Pages 279-281
https://doi.org/10.1016/j.clindermatol.2018.11.002

Appendix: Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS #25

Proposed scheduling

Cannabis

Schedule 8 - Amend Entry

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

a. cultivated or produced, or in products manufactured[2], in accordance with the *Narcotic Drugs Act 1967*; and/or
b. for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
c. imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the *Therapeutic Goods Act 1989*; and/or
d. in therapeutic goods supplied in accordance with the *Therapeutic Goods Act 1989*,

except when:

i. it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or
ii. separately specified in the NABIXIMOLS entry in this Schedule; or
iii. captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3.

Appendix D, Item 1 (Poisons available only from or on the prescription or order of an authorised medical practitioner)

CANNABIS for human use.

Appendix K

CANNABIS **except** cannabidiol when included in Schedule 4

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CANNABIS
cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

Schedule 9
Schedule 8
Appendix D, Item 1
Appendix K

Cannabidiol

Schedule 4 - Amend Entry

CANNABIDIOL in preparations for therapeutic use where:

a. cannabidiol comprises 98 per cent or more of the total cannabinoid content of the preparation; and
b. 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;

except when included in Schedule 3.

Schedule 3 - New Entry

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.

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