Consumer Healthcare Products Australia

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25 May 2020
The Secretary
Scheduling Secretariat
GPO Box 9848
Canberra ACT 2601

Email to: medicines.scheduling@health.gov.au

Dear Sir or Madam,

Notice inviting public submissions under regulation 42ZCZK of the *Therapeutic Goods Regulations* 1990. Proposed Amendments to the Poisons Standard to be considered at the joint ACMS/ACCS Meeting, June 2020

We refer to the notice inviting public comment under Regulation 42ZCZK of the *Therapeutic Goods Regulations* and would like to provide the following comments on the scheduling proposals referred to the June 2020 of the ACMS/ACCS.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI). Our key priorities for the industry include **improving health literacy**, **growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

CHP Australia appreciates the opportunity to provide public comment in relation to the ACMS/ACCS agenda. Please find enclosed, under cover of this letter, CHP Australia's comments in relation to the cannabidiol scheduling proposal (agenda item 2.5). The comments submitted below address matters raised in s.52E of the *Therapeutic Goods Act 1989*.

As an industry representative, CHP Australia is a key stakeholder in scheduling matters and we are keen to provide further input as required. We look forward to the Delegate's interim decisions and greater detail on the final scheduling proposals.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steve Scarff
Regulatory and Legal Director

2.5 Cannabidiol

To create a Schedule 3 entry for 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.

Introduction

CHP Australia supports the proposal to create a Schedule 3 entry for cannabidiol.

CHP Australia Comments

History of use

Cannabidiol is currently a Schedule 4 substance and therefore only available in Australia with a prescription. As the delegate notes in the re-scheduling proposal:

> "The access controls on CBD in Australia are notably more restrictive than comparable regulators. CBD is available as an over the counter product (for products without medicinal claims) in the UK and some US states."

Risks

The TGA's report *Safety of low dose cannabidiol* (Version 1.0, April 2020) establishes that CBD has an acceptable safety and tolerability profile at the proposed dose.

Benefits / Purpose

CBD has been reported to be effective in the treatment of a broad range of health conditions including anxiety, depression, epilepsy, chronic pain, insomnia, muscle spasticity.

As the delegate notes in the re-scheduling proposal:

> "The consumer can identify the ailments or symptoms that may be treated by the medicine…"

Dosage, formulation, labelling, packaging and presentation of a substance

There are no cannabidiol products available in Australia without a prescription and any product launched as a result of this re-scheduling will have to be registered with the TGA before it can be supplied.

As part of this registration process (as for any new OTC product), the TGA must approve the dosage, the formulation, the indications, the packaging, the presentation, the label claims and the label warning statements before any supply can occur.

Potential for abuse of a substance

The TGA's report *Safety of low dose cannabidiol* (Version 1.0, April 2020) acknowledges that cannabidiol has a low affinity for the CB1 and CB2 receptors, and thus does not exhibit psychoactive effects.

The potential for abuse/misuse therefore appears low.

Appendix H

CHP Australia supports the inclusion of cannabidiol in Appendix H

There is already a great deal of information (and misinformation) accessible by consumers in relation to cannabis and cannabidiol products, inclusion of cannabidiol in Appendix H will ensure that sponsors can provide reliable information about the products to consumers.

The labelling of any cannabidiol product will be approved by the TGA before supply can occur and a CMI document will be available from pharmacists in order to assist consumers.

Appendix M

CHP Australia would not oppose the inclusion of cannabidiol in Appendix M.

Scheduling factors

The AHMAC *Scheduling Policy Framework*[1] sets out the following scheduling factors for Pharmacist Only Medicines (Schedule 3):

1. **The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.** The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use. Consumer consultation with a pharmacist is necessary to reinforce and/or expand on aspects of the safe use of the medicine.

2. **The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at supratherapeutic doses. Where risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist-consumer consultation.**

3. **The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.**

4. **Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber.** The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

5. **The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.** Pharmacist-consumer consultation is required to detect the risk of masking a serious disease or compromising medical management of a disease, and to deal with it appropriately.

In our view, the proposed new Schedule 3 entry for cannabidiol clearly meets the requisite scheduling factors.

Conclusion

For the reasons outlined above (and in accordance with the delegate-initiated proposal) CHP Australia supports the creation of a Schedule 3 entry for cannabidiol.

[1] https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals