20 May 2020

Submission to the Therapeutic Goods Administration (TGA)

Consultation:

Proposed amendments to the Poisons Standard Medicines/Chemicals – ACMS and Joint ACMS-ACCS meetings June 2020

Althea Company Pty Ltd | ABN 82 618 177 192

A. Level 37, 360 Elizabeth Street, Melbourne, 3000, Victoria, Australia

E. info@althea.life

P. 1300 70 20 20

W. althea.life

1. About Althea Company Pty Ltd

Althea welcomes the opportunity to make this submission to the Therapeutic Goods Administration (TGA) in relation to the proposed amendments to the scheduling of cannabidiol (CBD).

Althea is an Australian licensed producer, supplier and exporter of medicinal cannabis and is a wholly owned subsidiary of an entity listed on the Australian Securities Exchange. Althea also offers a range of education, access and management services to support eligible patients and healthcare professionals in navigating medicinal cannabis treatment pathways. Althea currently operates within highly regulated medicinal cannabis markets including Australia, United Kingdom and Germany, with plans to expand into emerging markets throughout Asia and Europe.

Since May 2018, Althea has supplied its range of medicinal cannabis products to more than 6,000 Australian patients via the TGA's Special Access Scheme and Authorised Prescriber pathways, prescribed by approximately 534 Australian healthcare professionals.

2. Proposed Scheduling Amendments

The TGA is undertaking consultation for both a delegate-initiated proposal and a private submission to amend the scheduling of cannabidiol (CBD) and is seeking feedback on the proposed scheduling.

Althea is supportive of delegate initiated proposal to amend the scheduling for CBD which will support patient access to CBD products that deliver therapeutic benefit in a safe manner by creating a new Schedule 3 (Pharmacist Only Medicine) for CBD at doses up to 60 mg/day or less. The delegate-initiated proposal is set out below. Althea's comments are set out in Section 3.

Proposed scheduling

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.

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.

3. Feedback on Proposed Scheduling

There are key matters that need to be addressed so that any changes to scheduling are clear, consistent, and actually help patients in accessing safe, efficacious and quality CBD products.

Key Matter #1 - Consistency re CBD product supply

The following criteria is taken from the Schedule 8 definition for CANNABIS:

a. *cultivated or produced, or in products manufactured, 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 from a country with a national framework for the production of medicinal cannabis, 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,*

Althea believes that these criteria provide a level of rigour which should be applied equally to the Schedule 3 entry for cannabidiol.

Althea's interpretation of subsection (a) and (b) of the above is that only Office of Drug Control (ODC) licence holders for medicinal cannabis cultivation and medicinal cannabis manufacture, in Australia, would be able to produce a medicinal cannabis product. Althea would expect the same licensure to be applicable to CBD products registered and sold under Schedule 3.

Subsection (c) of the above should be amended for the purposes of the rescheduling of CBD to ensure that imported products meet the same cultivation, processing and manufacture standards as Australian grown and manufactured medicinal cannabis products. This means that products should only be imported from countries that have a national (federal) medicinal cannabis legislative framework comparable to that of the ODC in Australia. Further, approval based on adherence to the national framework(s) must be granted by the national governments of both the importing and exporting countries before shipment can occur. CBD products which are food grade/nutritional products should not be permissible for import as they do not meet the stricter pharmaceutical regulatory requirements.

Key Matter #2 - Products derived from cannabis plants

Synthetic or semi-synthetic cannabinoids should not be permissible. Medicinal cannabis contains hundreds of identified potent phytotherapeutic agents which contribute to superior efficacy which a synthetic molecule would not contain. Studies demonstrate therapeutic activity exists beyond the isolated THC and CBD fraction. Further, the wording 'any other synthetic or semi-synthetic cannabinoid' is far too broad, as there is insufficient safety data to allow the unregulated addition of synthetic or semi-synthetic compounds.

This would also contravene the TGA's TGO93 which states that any cannabinoid must be manufactured from the cannabis plant only and additions would cause adulteration.

As such, Althea recommends that the new entry for Schedule 3 should read as follows:

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.

4. Conclusion

Althea is supportive of the down scheduling of CBD and the prospect of registered Schedule 3 Pharmacist Only (Medicine) CBD products being available to patients across Australia. By enforcing the same rigorous criteria for the legal cultivation, processing and manufacture of other (scheduled) medicinal cannabis products, Schedule 3 CBD products sold in Australia will avoid the quality issues and false claims typical of hemp suppliers operating and causing safety concerns in countries including the US, UK and France. Cannabidiol is an active pharmaceutical ingredient and as such, CBD products should be controlled as a medicine / therapeutic good.

Althea does not support the private applicant submission regarding the scheduling of CBD.

We would be happy to discuss the content of our submission with the TGA/Committee.

Yours sincerely,

[redacted]

Patty Holmes
Chief Operating Officer

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