


Member Alert

Publication of CMA position statement – Down-scheduling of Cannabidiol (CBD)

AUST L(A) Data Protection: The *Therapeutic Goods Amendment (2020 Measures No. 1) Bill 2020*

End of Advertising Pre-approval process

CMA Position Statement on Cannabidiol (CBD)

The Therapeutic Goods Administration (TGA) are currently consulting with interested parties to alter the Poisons Standard to down-Schedule the supply of low-dose (60mg/day) 98% pure Cannabidiol (CBD) to Pharmacist Only - Schedule 3 (AUST R). This is based on a safety review of CBD at lower doses to determine whether 'relaxation of the scheduling status of low dose CBD (e.g. to over the counter access) could be considered during 2020'. The safety review and down-Scheduling proposal were stimulated by Recommendations 12 and 13 of the Senate Inquiry into Medicinal Cannabis (February 2020).

At the same time, a private applicant has made a submission to make 98% pure plant-derived CBD widely available as an unscheduled preparation without any dose restrictions. The two open consultations will result in one final decision as to what form consumer access to CBD will take from early or mid-2021 onwards.

CMA have published a position statement that proposes combining the best aspects of both applications, and applying additional safety and efficacy controls, to ensure that lower-dose, low-cost, high quality CBD could be made widely available with strict controls on safety, quality, claims and advertising. This meets the community demands strongly expressed in the Senate Inquiry whilst adding as many protections as possible. It ensures CBD could come quickly to market by trusted Australian manufacturers and brands, without delays, extensive costs, or delays to research for other kinds of medicinal cannabis preparations.

CMA's position statement, available here, outlines key policy positions which are in alignment with this sentiment and this will inform CMA's submission response. The due date for both cannabidiol consultations is close of business **22 May 2020**.

CMA's "hybrid" position is summarised in the table below:

Step 1 – Proposal for rapid, safe access (hybrid of TGA & Private proposals)

Scheduling Proposal	Comment
• **Unscheduled**	Freely available for consumer and health professional access, with high safety, quality, and efficacy control (Step 2).
• **CBD >98% of cannabinoids** • **Any other cannabinoids <2% and naturally occurring**	• As per World Health Organization (WHO) preparation • As per TGA Safety Review / Scheduling Proposal
• **Adults only**	• As per TGA Safety Review / Scheduling Proposal
• **30 day pack**	• As per TGA Safety Review / Scheduling Proposal
• **1mg/kg/day**	• As per TGA Safety Review / Scheduling Proposal
• **90mg/day maximum**	An average Australian male is 87kg (ABS)
• **Undivided preparations OR tablets/capsules 30mg or less**	Permits dose adjustment for body weight, therapeutic effect or mild side effects.

Step 2 – Government approval rapid, low cost, safe, high quality public access

"Listed Medicine" Approval	Comment
Low cost, competitive access: ★ **Minister-led approval of CBD as a "Permitted Ingredient" [1].**	Minister-led approval of CBD preparations examined by TGA and WHO, for 'Listed Medicines', allows rapid competition by Australian manufacturers. The Australian public would be able to access high quality, low cost CBD products in the very near future.
Safe: ✓ **Clear warnings** ✓ **CBD single-active** ✓ **Plant-derived**	Low dose CBD is thought to be reasonably well-tolerated. Single-active CBD helps monitor safety. Effective warnings decided by public consultation. Drug interactions may be controlled as for other products, *e.g. 'St John's Wort affects the way many prescription medicines work - including oral contraceptives. Consult your doctor.'*
High-Quality: ✓ **GMP Manufacturing** ✓ **Required Conditions** ✓ **TGA Standard for Medicinal Cannabis (TGO 93)**	Australia has an international reputation for high quality complementary medicines such as vitamins and herbs. Australian GMP-licensed manufacturers are highly capable and ready to supply high-quality lower-cost CBD for Australian consumers.
Effective: ✓ **Monograph - TGA-approved claims** ✓ **'N=1 trials' via app for clinical data**	Government decides on specific wording of allowed claims for CBD to help ensure it can become widely and easily available at a low cost in the very near future. "N=1 trials" via a voluntary app can gather efficacy and safety data for Australian researchers.

[1] Section 26BC of the Therapeutic Goods Act 1989 provides the Minister authority to do so, of his or her own initiative.

AUST L(A) Data Protection: Second reading of the *Therapeutic Goods Amendment (2020 Measures No. 1) Bill 2020*

A Second Reading of the Therapeutic Goods Amendment (2020 Measures No. 1) Bill 2020 occurred on 14 May 2020. This bill makes a number of minor and technical amendments to the *Therapeutic Goods Act 1989* (the Act), which governs the regulation of medicines and medical devices in Australia. Importantly, it amends the Act to introduce a data protection regime for assessed listed medicines.

Schedule 9 of the Bill introduces a data protection regime for assessed listed medicines - which are complementary medicines that are listed in the register but are assessed for efficacy before they are given approval for sale and supply to the market. This amendment will provide five years protection for clinical trial information that a sponsor submits in support of an application where that information is not otherwise available. This mirrors the existing regime for innovative prescription medicines.

End of pre-approval process for advertising in specified media

As a result of a recommendation from the Expert Review of Medicines and Medical Devices Regulation that the advertising pre-approval scheme be stopped in favour of more self-regulation, from **1 July 2020** advertisements for medicines appearing in specified media do not need pre-approval from the Therapeutic Goods Administration (TGA). Until 30 June 2020, advertisers must seek pre-approval under the *Therapeutic Goods Regulations 1990* for ads about medicines that will be broadcast or published in 'specified media', which includes:

- magazines
- newspapers
- newsletters
- catalogues
- cinema advertising
- public displays about goods, including posters, billboards and displays in or on public transport.

Although pre-approval will no longer be necessary from 1 July 2020, the regulation of advertising content remains, with the onus on advertisers to ensure that their ads meet the requirements under the therapeutic goods legislation and advertising code.

The mandatory pre-approval scheme will not be replaced by any other statutory vetting scheme. A list of questions and answers around the end of the advertising preapproval scheme is available here. Please see the TGA website for more details.

CMA is continuing to participate in the Independent Review of the Therapeutic Goods Advertising Framework by Ms Rosemary Sinclair, AM. This Review is examining advertising reforms introduced in 2018 for impact, effectiveness, and performance. However, the removal of the pre-approval process for advertising is not being reconsidered as part of this Review.