CMA Policy Position Statement
Proposals to Amend Scheduled Access to Cannabidiol (CBD)

Key Messages:
Over the past 10 years, there has been an increasing demand for access to medicinal cannabis, including cannabidiol ('CBD'), by patients and their families. As the social and political debate has intensified, Commonwealth, state and territory governments passed legislation to facilitate and regulate greater access. However, many patients still struggle to access medicinal cannabis.

Since 2016, Australian governments have together established a tightly regulated medicinal cannabis regime, including CBD, managed by medical practitioners and the state/territory health departments. In 2019, the World Health Organisation ('WHO') made a recommendation that preparations containing predominantly CBD with not more than 0.2% THC should not be placed under international drug control. CBD has a very low risk of abuse or misuse as it is not psychoactive.

A recent Senate Inquiry occurred to better understand and address the current barriers to patient access to medicinal cannabis (including CBD), which reported on the 12 February 2020. Submissions to the Senate Inquiry from affected consumers and representative disease groups overwhelmingly supported **low cost** and **easily available** consumer access to **high-quality CBD products**. The Inquiry recommended that the medicines regulator, the Therapeutic Goods Administration (TGA) consult with the public on reducing barriers. In particular, Senate Recommendations 12 and 13 provided that the TGA conduct broad public consultation on the down-scheduling of CBD as a matter of priority.

Key Policy Positions:
CMA supports down-scheduling of cannabidiol ('CBD') in Australia as a critical measure to reduce community barriers to accessing medicinal cannabis. The level of access **must** meet consumer expectations for Cannabidiol set by the Senate Inquiry into Medicinal Cannabis, whilst taking into consideration community expectations and transparency on safety, quality and efficacy.

Legislatures, governments and regulators should continue to improve the scheme through:

- Reducing barriers to access cannabidiol such that Australians have access to low-dose, low-cost, high-quality, safe CBD products;
- This may be achieved by the down-scheduling of low-dose cannabidiol (CBD) to unscheduled in Australia within strict safety limits;
- Coupling with Minister-led approval of plant-derived CBD as a "Permitted Ingredient" with strict safety controls will enable rapid and low-cost supply under minimised risk;
- A TGA Listed Medicine efficacy monograph (recommended by the Expert MMDR Review), coupled with "N=1" consumer trials will ensure controlled claims with quality monitoring of efficacy, safety, and side-effects; and
- Remain open to further evidence-based policy changes.

Date Adopted: 13 May 2020
Audience: Federal, State and Territory Governments, policymakers and program managers, CMA members, media, consumers.
Related: CMA Submission to proposed amendments to the Poisons Standard (available 22 May 2020).

Beyond Bank Building, Level 1
105 Mawson Drive Mawson ACT 2607
PO Box 450
Mawson ACT 2607
www.cmaustralia.org.au
carl.gibson@cmaustralia.org.au
P +61 2 6260 4022
ACN 169 036 088

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.

Comparison of CMA Submission to existing down-scheduling proposals

	A. Australian Government/TGA	B. Private Applicant	C. CMA Submission
Access	**Pharmacist Only (Schedule 3).**	✓ **Unscheduled**, ready consumer access.	✓ Agree with B – with additional controls on safety, quality.
Regulatory level	'Registered' (AUST R) medicine – TGA pre-approved – must obtain clinical trials proving effectiveness at the 60mg dose before it can be approved.	✓ Eligible to become *either* 'Listed' (AUST L with low level claims) or 'Registered'.	✓ Agree with B.
Cannabinoids	✓ **98% cannabidiol** or more of total cannabinoid content		✓ Agree.
Other content	✓ 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.	Contains less than or equal to 0.2 per cent tetrahydrocannabinol (THC).	✓ Agree with A.
CBD source	✓ Plant derived; or ✓ Synthetic, if it only contains the (-) CBD enantiomer	Whole plant cannabis product or distillate or isolate *(Synthetic or semi-synthetic CBD as prescription only.)*	✓ Agree with A, noting that only plant derived complementary medicines should be eligible to become Listed Medicines.
Maximum daily dose	**60mg** (~1mg/kg/day)	Not specified.	✓ **90mg** (~1mg/kg/day) from: ✓ **undivided preparations,** *or* ✓ **tablets/capsules 30mg or less** Based on ~1mg/kg/day and ABS 2018 data that the typical Australian male weighs **87kg** and the typical female **72kg;** Evidence indicating dose may need adjustment for therapeutic effects or mild side effects.
Pack size	✓ **30 days** supply.	Not specified.	✓ Agree with A.
Age	✓ **Adults** 18 years or **older**	Not specified.	✓ Agree with A.