Proposed Amendments to the Poisons Standard (Chemicals)

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

De-scheduling of Cannabis

Metagenics appreciates the opportunity to provide the following submission for the de-scheduling of Cannabis from the current Schedule 4.

With the significant increase in SAS (B) applications for use of cannabis in patients in the past 18 months and the recent Senate enquiry into Cannabis formed after significant consumer sentiment for the increase in availability of cannabis there is an overwhelming increase in consumer support for the wider availability of affordable cannabis for medicinal purposes in Australia and beyond.

According to the Department of Health January 2020 submission to the Senate Community Affairs References Committee for the enquiry into the current barriers to patient access to medicinal cannabis in Australia. Approximately 30,000 approvals to access medicinal cannabis products have been written in Australia in the period to the end of 2019. It is expected that by end 2020 about 70,000 prescriptions are anticipated to have been written in Australia for medicinal cannabis. Furthermore, more than 18,000 patients have been approved to access medicinal cannabis products since 2016. More than 1400 individual medical practitioners, have received approvals to prescribed medicinal cannabis for patients to treat more than 130 different medical conditions.

Significant reviews into the safety of pure CBD (>98% CBD) containing less than 0.2% THC have shown there are medicinal benefits for consumers who may have chronic conditions that have sort relief using CBD with little to no significant adverse reactions.

In an Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies Cannabis, Cannabinoid Res. 2017 Jun 1;2(1):139-154. doi: 10.1089/can.2016.0034. It was found the safety profile of CBD in humans was confirmed, however, the majority of studies were performed for the treatment of epilepsy and psychotic disorders. The most commonly reported side effects were tiredness, diarrhea, and changes of appetite/weight. In comparison with other drugs used for the treatment of these medical conditions, CBD had a better side effect profile.

By mandating specific controls in manufacturing (under the cGMP, testing (TGO93), labeling (appropriate cautionary statements) and licencing of Sponsors through the Listing of medicines the scheduling committee could de-schedule the current Schedule 4 CBD substance to be an unscheduled substance.

Whilst there are two applications supplied to the Scheduling Committee for review, that is the TGA application to de-schedule from S4 to S3 and the other application, a private applicant suggesting no schedule, Metagenics would like the committee to consider a hybrid application similar to Complementary Medicines Australia submission.

This hybrid application would contain some attributes provided by both applicants but also introduce additional requirements for consideration such as;

	A. TGA/Delegate of Secretary applicant	**B.** Private Applicant	**CMA Submission**
Access	**Pharmacist Only (Schedule 3).**	**Unscheduled**, ready consumer access.	**Unscheduled**, ready consumer access with additional controls on therapeutic indications, preparation type, dose and safety restrictions/warnings.
Regulatory level	'Registered' (AUST R) medicine. Full safety, quality, and efficacy pre-approval by TGA. Eligible for more serious therapeutic indications (health claims).	Eligible to become *either* 'Listed' (AUST L) or 'Registered' medicines. 'Listed' only use low-level 'permitted' indications.	✓ Agree with B.
Cannabinoids	**98% cannabidiol** or more of total cannabinoid content	(same as A.)	✓ 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** (based on ~1mg/kg/day)	Not specified.	**90mg** by way of: - **undivided preparations,** *or* - **tablets or capsules each 30mg or less** (permitting differential dosing by bodyweight and use). Based on ~1mg/kg/day and ABS 2018 data that the typical Australian male weighs **87kg** and the typical female **72kg;** Evidence indicating that there is not a 'one size fits all' dose; and to reduce dose if there are side effects.
Pack size	**30 days** supply.	Not specified.	✓ Agree with A.
Age	**Adults** 18 years or older	-	✓ Agree with A.

Metagenics is considered an A1 TGA Licenced manufacturer of Listed and Registered Complementary Medicines. As an A1 medicine manufacturer Metagenics has been able to repeatedly pass TGA audits that follow the PIC/s standard for medicine manufacture. If the committee de-schedule the substance it will allow Metagenics to submit an application to apply to the TGA to allow CBD as a Listable substance and thus allow the use of CBD in Listable medicines. By allowing Listable medicines to utilise this significant therapeutic substance a wider community of people will be able to use and ultimately reduce the burden on the Health budget.

Metagenics hopes the submission provides further evidence to support de-scheduling of the substance to allow greater community access to the CBD material for medicinal purposes whilst also providing the necessary controls to ensure the consumers receive a quality, safe and efficacious substance.

Thank you