Australian Traditional-Medicine Society Ltd
PO Box 1027 Meadowbank NSW 2114
Freecall 1800 456 855 Tel +61 2 9809 6800
Fax +61 2 9809 7570 info@atms.com.au
www.atms.com.au ABN 46 002 844 233

Friday 22 May 2020

Therapeutic Goods Administration
Department of Health

Re: Proposed Amendments to the Poisons Standard (Medicines/Chemicals)

Over the past decade, there has been an increasing demand for access to medicinal cannabis, including cannabidiol ('CBD'), by patients and their families. Commonwealth, State and Territory governments passed legislation to facilitate and regulate greater access however despite a record number of approved scripts in 2019 of 25,182, many patients still struggle to access medicinal cannabis.

The Australian regimen to access CBD is tightly regulated and 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% tetrahydrocannabinol (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 reported submissions 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.

The Australian Traditional Medicine Society Ltd (ATMS) supports down-scheduling of CBD to classify it as a listed medicine in Australia as a critical measure to reduce community barriers to accessing medicinal cannabis. This is subject to access meeting consumer expectations for CBD set by the Senate Inquiry and taking into account community expectations on quality and safety.

Purpose

- To classify CBD preparations as a listed medicine would enable the public to access high quality and lower cost CBD products.
- In terms of treatment claims it is recommended that the current requirements that apply to listed medicines apply which includes the use of traditional claims as well as claims supported by Randomised Controlled Trial's and Systematic Reviews. There is a significant body of research being developed in regards to CBD in its use in terms of other types of pain, such as IBS and Endometriosis, as well as in tremors and spasms.

Dosage/Formulation

- It is recommended that the formulation contain greater than 98% of cannabinoids and less than or equal to 0.2 per cent THC.
- The recommended dose of 1mg/kg/day is considered a reasonable level and has shown a low rate of side effects in evidence compiled by the TGA.
- The cap of 60mg a day will result in sub-optimal doses for Australian males who have an average weight of 87kg. It is recommended that the cap is increased to 90mg/day.

Australian Traditional-Medicine Society Ltd
PO Box 1027 Meadowbank NSW 2114
Freecall 1800 456 855 Tel +61 2 9809 6800
Fax +61 2 9809 7570 info@atms.com.au
www.atms.com.au ABN 46 002 844 233

- Dosing formulation should provide the options of CBD in an oil or tablet or capsule to allow for trituration of dosages and also individual consumer preferences.

Risk/Benefits

- The benefit/risk ratio is such that CBD formulations in which 98% or greater of the cannabinoid content is CBD and where the upper limit to THC content is 0.2% (by dry weight), should not be regulated as an unapproved medicine through its inclusion on Schedule 4 of the SUSMP, but instead, regulated as listed, assessed-listed or registered medicines (depending on the level of therapeutic claim) under the Australian Register of Therapeutic Goods (ARTG).
- Given its clear evidence of benefits, good safety profile and low risk, it should be regulated as a complementary medicine in the same way that other plant medicines (herbal medicines) are regulated in Australia.
- Regulation of CBD as a complementary medicine will allow its prescription by other qualified healthcare practitioners such as naturopaths, western herbal medicine practitioners and registered Chinese herbal medicine practitioners, consistent with their scope of practice, and further increase access to patients.
- The potential benefits of removing plant-derived CBD from the Poisons Standard and instead regulating it as other herbal medicines and complementary medicines are regulated (listed, assess-listed or registered on the ARTG) is that this will substantially increase its access and reduce costs to the consumer.
- Concerns about potential drug-CBD interactions can be handled effectively through prescription by a qualified healthcare practitioners. The indicated uses for cannabinoids, such as epilepsy and cancer, are frequently complex cases with a range of medications. An understanding of medications and their interaction is essential to effective use and management.
- Australia's requirement for GMP standards for manufacturing will ensure high quality CBD product is available to consumers.
- Australian researchers are undertaking a range of research projects on the use of CBD and this will expand the local research capacity.

Thank you for the opportunity to provide a submission.

[redacted]