TASMANIAN ALKALOIDS PTY. LTD.
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To: Advisory Committee on Medicines Scheduling (ACMS) and Advisory Committee on Chemicals Scheduling (ACCS)

Consultation submission: Proposed amendments to the Poisons Standard – Joint ACMS/ACCS meetings, June 2020.

Cannabidiol Scheduling

Tasmanian Alkaloids Pty Ltd (TasAlk) is pleased to take part in the proposed scheduling amendments to the Poisons Standard following the procedure outlined in the *Therapeutic Goods Regulations 1990* (the Regulations).

TasAlk is a globally focused innovative research and manufacturing company based in Tasmania, Australia. The company is fully integrated from field and factory to the finished goods, employing highly skilled scientifically and technically qualified employees.

TasAlk has developed and cultivated high-yielding agricultural raw materials for the extraction and purification of high-value plant-derived products for the pharmaceutical industry and includes businesses focused on natural alkaloid and cannabinoid based products.

TasAlk hold Medicinal Cannabis Licences (Research, Cultivation and Manufacturing) issued by the Office of Drug Control (ODC) and a GMP licence to Manufacture Therapeutic goods.

Matters relevant to the submission

Cannabidiol (CBD) has a range of suggested therapeutic effects on several conditions, including Parkinson's disease, Alzheimer's disease, cerebral ischemia, diabetes, rheumatoid arthritis, other inflammatory diseases, nausea and cancer. There has also been a corresponding increase in publications on CBD based on its anti-inflammatory, anti-oxidative and neuroprotective effects (Zuardi, 2008).

The increase in publications has rapidly increased over the last five years leading to a greater understanding of the effects of CBD, including patient response related to dosage. These publications outline some of the potential beneficial effects linked with dosage still waiting to be confirmed by clinical trials.

Taking the additional information available into account, CBD products for therapeutic use provided by TasAlk for Sch. 3 supply would be manufactured in a GMP licensed facility with appropriate dosage, formulation, labelling, consumer information & packaging. This allows the product to be presented in an acceptable format and with the provision of professional advice when accessed by the patient through a pharmacy.

TasAlk support the continued review of CBD and patient accessibility and believe that the down scheduling with appropriate dosage/age restrictions satisfies the risks and benefits of the substance. This also brings Australian access controls closer to other regulators in the UK and Australia for CBD products with medicinal claims.

TasAlk support the changes to the Schedules to enable clearer patient access to CBD products, as the dosage range is consistent with other jurisdictions and Schedule 3 still allows the appropriate professional advice required.

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The proposed changes allow TasAlk to facilitate our ability, through the supply of raw material and formulations to produce a commercial product with improved accessibility. The improved accessibility will lead to an increased understanding of the effects of CBD, improve the options available and allow the parties to gain commercially.

This also aligns with the increased amount of literature and information for CBD currently available, any commercial gains may allow increased funds to be made available for research and clinical trials to confirm these effects.

Regards

John Kearns

Commercial Director