20 May 2020

Advisory Committee on Medicines Scheduling (ACMS)
Therapeutic Goods Administration

By email: medicines.scheduling@health.gov.au

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

Medicinal Cannabis Industry Australia (MCIA) welcomes the opportunity to make this submission to the Therapeutic Goods Administration (TGA) in relation to proposed amendments to the scheduling for cannabidiol.

Background

The Therapeutic Goods Administration (TGA) is undertaking consultation for both a delegate-initiated proposal and a private submission to amend the scheduling for cannabidiol.

Down scheduling CBD

MCIA is supportive of changes to the schedules that will enable patient access to CBD products that deliver therapeutic benefit in a safe manner.

MCIA welcomes a down-scheduling of CBD in light of increasing evidence of its safety profile, however, has some reservations in relation to the detail of the specific proposal. MCIA does not support the de-scheduling of CBD.

In relation to the proposed changes, MCIA supports a schedule 3 – Pharmacist Only medication registration option for low dose CBD products as the TGA registration process would then ensure that efficacy, safety, and quality are pre-assessed.

We would, however, note that the capping of daily dose is an unusual inclusion in a Poisons Schedule entry and further is far lower than doses within the literature from which the safety profile is drawn.

Further it is unclear to us how patient access will be enabled under the proposed changes given that CBD is not on the Permissible Ingredients List, and product registration would be improbable given lack of demonstrated clinical utility at the levels stated. We would envisage little likelihood that it would be feasible for companies to bring such products to market through this pathway.

Consistency for imported products

Regardless of schedule, MCIA believes that all imported medicinal cannabis products should meet the same cultivation, production and manufacture standards as Australian grown and manufactured products. This means that products should only be imported from countries that have a national medicinal cannabis legislative framework. Further, approval based on adherence to the national framework(s) must be granted by the national governments of both the importing and exporting countries before shipment can occur. Products that are food grade/nutritional products should not be permissible for import into Australia as they do not meet the stricter pharmaceutical regulatory requirements.

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About MCIA

MCIA is the peak industry organisation for Australia's licensed medicinal cannabis industry. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing and interaction with patients, the medical profession and communities.

MCIA's focus is on building an industry that enhances wellbeing through facilitating access to quality Australian medicinal cannabis products for Australian and global patients.

MCIA provides stewardship for an economically sustainable and socially responsible industry that is trusted and valued by patients, the medical community and governments. The Australian industry and its products are built on sound science and underpinned by industry processes and standards that ensure patients, the medical community and governments have confidence in the sector and its products.

We would be happy to discuss the limitations of the down schedule proposal with the TGA/Committee with a view to developing a model that would enable improved patient access to low dose CBD products that deliver therapeutic benefit in a safe manner.

Yours sincerely