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MCIA pursues better patient access for down scheduled CBD

In responding to the Therapeutic Goods Administration's (TGA) interim decision in relation to cannabidiol (CBD) to down-schedule CBD medicines to S3, or pharmacist-only, medicines at appropriate dosage levels, Medicinal Cannabis Industry Australia (MCIA) has recommended further change to the proposed scheduling to ensure that there is an effective pathway for S3 CBD products.

Medicinal cannabis has an important role to play in improving health outcomes. MCIA supports down-scheduling of CBD to S3, which has the potential to provide patients with improved access to a safe low dose cannabis product for medical use.

While the interim decision by TGA to down schedule CBD is a step in the right direction, the proposal has limitations in terms of delivering the desired patient access, and will restrict the ability for industry to bring products to market in a timely manner.

The aim of the down-scheduling proposal is to deliver improved access and benefit for patients to CBD. However, a report commissioned by MCIA found that the proposed daily dose of 60 mg will make it difficult for products to achieve registration, due to the difficulty of meeting the evidentiary requirements for efficacy. Thus, down-scheduling as outlined in the interim decision will not achieve the desired outcome of patient access to low dose CBD products, leaving patients to continue to access products through the illicit market.

MCIA encourages a review of the dose limitation based on dose and body mass calculations drawn upon by the TGA in their safety review, and also on the safety data which supports higher dose rates. The MCIA Report found that 300 mg oral dose of CBD is the threshold at which higher quality evidence accumulates around CBD efficacy, in the absence of significant safety concerns. In proposing a higher dose, it is recognised that this is within the S3 framework where the product would only apply to conditions that do not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

MCIA advocates that CBD be down-scheduled to S3, with a higher maximum daily dose, which provides the opportunity for products to be able to meet registration requirements for efficacy, thereby delivering real outcomes for patients.

"Down-scheduling of CBD will benefit patients by allowing them to move from the illicit market and providing easier and more affordable access to high quality products", said Mr Peter Crock, MCIA Chair, "Our submission proposes an approach to the down-scheduling of CBD that balances benefits and risk. We strongly encourage review of the daily dose cap. This regulatory clarity will deliver better safety, quality, and efficacy outcomes for patients and the community".

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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. More information is available at: www.mcia.org.au