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## **MCIA welcomes decision for down scheduled CBD with increased maximum dose of 150mg/day**

Medicinal Cannabis Industry Australia (MCIA) welcomes the Therapeutic Goods Administration (TGA) announcement of its final decision regarding down-scheduling of low-dose CBD, including the significant change to the maximum dose which has been increased to 150mg/day.

MCIA had recommended changes to the interim decision, and in particular the low daily dose, to ensure that there is an effective pathway for S3 CBD products. A report commissioned by MCIA supported a higher dose based on safety and efficacy, and hence, ability to meet the evidentiary requirements for the proposed registration pathway. MCIA is pleased that TGA's further consideration of this information, along with other public submissions, and the advice of the Joint Committee of the Advisory Committees for Medicines Scheduling and Chemicals Scheduling at its November 2020 meeting, has led to a lifting of the daily dose.

MCIA will continue to work with TGA with a view to lifting the dose to 300 mg as this is the threshold at which higher quality evidence accumulates around CBD efficacy, in the absence of significant safety concerns. However, the announcement of 150mg will provide industry with flexibility to develop products for the S3 registered pathway.

“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, “The work of MCIA shows the value that our industry organisation plays in providing a collective view, informed by rigorous and well researched evidence.”

The decision allows low-dose CBD-containing products, up to a maximum of 150 mg/day, for use in adults that have been approved by the TGA, to be supplied over-the-counter accompanied by the advice of a pharmacist, without a prescription.

While noting that products will be required to be approved by the TGA and included on the Australian Register of Therapeutic Goods (ARTG), along with a number of other restrictions, the decision will provide a pathway for industry to develop products for this market.

“Nonetheless, if fewer consumers seek out illicit CBD products which have unknown content and quality, then this move ultimately promotes greater safety for patients, which has to be the priority.”, said Mr Crock.

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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](http://www.mcia.org.au)