

AusCann Supports Final TGA Decision for Over-the-Counter CBD

Key Highlights

- The TGA finalised its decision to amend the classification of CBD to include a new pharmacy-only listing (Schedule 3)
- AusCann is developing compliant CBD-only products based on its Neuvis® delivery platform

16 December 2020 - AusCann Group Holdings Limited (ASX: AC8) ('AusCann' or 'the Company') supports the final decision of the Therapeutic Goods Administration (TGA) to amend the current classification of cannabidiol (CBD) to include a Schedule 3 entry, removing the need for a doctor's prescription. The decision comes into effect on 1 February 2021.

The TGA's final decision aligned with the interim decision. Further, AusCann is pleased to note that the TGA has taken into account the advice from the Advisory Committees on Medicines and Chemicals Scheduling, and public submissions in reaching its final decision. Importantly, key points of AusCann's submissions have been reflected in the TGA's final decision, including an increase in the daily dose limit to 150mg per day versus the previous recommendation of 60mg per day. Based on scientific literature and clinical data, AusCann believes that a dose of 150mg CBD per day is safe and effective.

AusCann is developing CBD-only products at multiple dose levels using the Company's Neuvis® delivery platform. These products now have the potential to be developed and registered as pharmacy-only medicines in accordance with this TGA decision.

Mr Nick Woolf, AusCann's CEO, commented: "We are pleased that Australian policy is being driven by rigorous scientific review and is responsive to clinical evidence. The TGA decision is a positive outcome for the industry. We are well advanced in developing compliant CBD-only products that could be registered as over-the-counter medicines. These products are presented in a hard-shell capsule and offer enhanced drug absorption. This aligns with our R&D strategy to develop meaningful pharmaceuticals to address unmet medical needs."

ENDS

This ASX announcement was authorised for release by the Board of AusCann.

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ABOUT AUSCANN

AusCann Group Holdings Limited (ASX:AC8) is an Australian-based pharmaceutical company focused on the development, production, and distribution of cannabinoid-based medicines within Australia and internationally. AusCann transforms the way medicinal cannabis is dispensed today by making standardised, controlled dose products, providing educational support to healthcare professionals and generating clinical evidence that is accessible to patients, physicians and healthcare providers. AusCann is developing a pipeline of proprietary differentiated cannabinoid-based pharmaceutical products. The Company's first product was successfully launched in Australia in 2020 and is available under special access provisions for medicines.