

Oz Medicann Group celebrates TGA's landmark decision to legalise low-dose CBD as an over-the-counter Pharmacist Only Medicine

Sydney Based Medicinal Cannabis Company Oz Medicann Group (OMG) welcomes the decision by the Therapeutic Goods Administration (TGA) to legalise low-dose CBD as a pharmacist only medicine. Under the new arrangement patients will now have access to safe, high quality and affordable medicines after an initial consultation with their pharmacists. Furthermore, OMG embraces the TGA's decision to upgrade the initial recommended dose from 60mg per day to 150mg per day. OMG founder and CEO John Leith, says "At OMG we see the decision as a win for patients and a game changer for the industry. It's exciting news for both patients and consumers who have been reluctant to source CBD through the current prescription-based system".

The decision opens the door for the sale of low-dose CBD products (with 2% or less other cannabinoids, but only <1% THC) that demonstrate efficacy and benefits that meet the TGA's requirements for a registered pharmaceutical product. Once CBD products are registered by the TGA they will be available to adults over the age of 18. The recommended daily dose of up to 150mg per day means that consumers will be able to purchase up to 4,500mg of CBD in a 30-day supply.

Patient Access

The decision to re-schedule low-dose CBD products from the current Schedule 4 to a Schedule 3 pharmacy only medicine opens the market for companies like OMG to develop and produce new safe, effective and affordable quality products. These will benefit patients and those suffering from long term illnesses as well as offering a natural alternative medicine as part of their treatment plan.

When Leith was asked how OMG would respond in the market to the re-scheduling he said "that OMG's mission is to provide better patient access through affordable solutions and we are excited about the decision. I believe OMG with our focus on research we will be well placed to enter the market with a number of low-dose CBD products. We have been preparing for this decision over the past months by developing products for the Schedule 4 Special Access Scheme that can be easily adjusted to meet the Schedule 3 requirements."

Research

In the first half of 2021 OMG will launch its first range of Schedule 4 products and will commence the process of registration for their low-dose preparations. Additionally, OMG with partner with the National Institute of Complimentary Medicine (NICM) to launch the first Australian research project focused on CBD as a treatment for the complications associated with Type II Diabetes. It's a disease which is in epidemic proportions globally and impacts one person every 5 minutes in Australia. OMG is well placed to understand the complications of Diabetes and through their Hemp Oz Business is continuing to

research and produce Hemp based health and wellness products which are 'Inspired by Nature and Backed by Science'. In independent early-stage trials Hemp Oz Products have been proven to reduce the symptoms associated with Type II Diabetes.

While the TGA's decision allows for implementation to commence in February 2021 patients and consumers should be aware that in order for a product to be registered, suppliers need to demonstrate that they meet the TGA requirements. This can take some time and therefore consumers should not expect to see products on shelves until the end of 2021. OMG is well positioned to meet this timeline as their products are produced in GMP certified facilities and are well on the way to meeting the TGA requirements for pharmacy only medicines. OMG anticipates that their first product will be available towards the end of 2021

OMG are now well placed to initiate supply once OMG's products are registered. Over the past twelve months OMG, through their Hemp Oz Health and Wellness Company have built considerable relationships with independent pharmacies and pharmacy groups with established distribution channels throughout Australia.

For more information and the full TGA announcement go to:

<https://www.tga.gov.au/media-release/over-counter-access-low-dose-cannabidiol>