> OMG OZ MEDICANN GROUP

1 November 2023

To: The Australian Senate

Subject: Submission on the Legalisation of Cannabis in Australia

Distinguished Members of the Australian Senate,

We, OZ Medicann Group (OMG), express our gratitude for the opportunity to present our perspective on the potential legalisation of cannabis in Australia. As a prominent Australian medical cannabis, hemp, and CBD therapeutics company, we are firmly committed to innovation, science-driven product development, and the well-being of patients across the globe. In light of our experiences and lessons learned from other jurisdictions, we firmly advocate against the legalisation of cannabis in Australia at this point, substantiated by the following key lessons:

#### 1. Commitment to Science and Research:

The journey of cannabis legalisation in various jurisdictions has highlighted the paramount importance of scientific inquiry. Lessons from other regions have underscored the necessity of investing in research and development to understand the diverse cannabinoids present in cannabis fully. The complexities of the cannabis plant necessitate ongoing, methodical research to unlock its therapeutic potential fully.

## 2. Concerns About the Impact on Research:

In regions where cannabis has been legalised for recreational use, there has been a perceptible shift in the focus of cannabis-related businesses. These entities often prioritise commercialisation and profit-driven motives over research and scientific innovation. The enticement of immediate financial gains in the recreational market can divert resources from vital medical research, which is detrimental to patients and the advancement of cannabis as a medical therapy.

# 3. Confidence in Existing Regulations:

Experience from other jurisdictions has shown that strict regulations and oversight, akin to Australia's current regulatory framework led by the Therapeutic Goods Administration (TGA), play an essential role in safeguarding public health. Stringent regulations are crucial to ensure the quality, safety, and

efficacy of medical cannabis products. This experience validates the effectiveness of our current regulations and emphasizes the importance of maintaining these safeguards.



## 4. Legal Channels for Access:

Evidence from regions with legalised cannabis has demonstrated that legal channels for access, such as through medical professionals, foster a secure environment for patients and consumers. This practice ensures that products meet approved standards and quality criteria. In many of these areas, access to legal cannabis is preferential to the illicit market, resulting in better patient safety and well-being.

### 5. Call for Continued Research:

A crucial lesson from regions that have legalised cannabis is that the therapeutic potential of this plant remains incompletely understood. Ongoing clinical trials and scientific research are vital to unveil its effectiveness in treating various medical conditions. The wealth of compounds within cannabis necessitates continuous scientific exploration to ascertain their specific therapeutic applications and optimal modes of administration.

## 6. TGA's Recognition of USA Companies' GMP Compliance:

At present, the Therapeutic Goods Administration (TGA) does not recognise USA companies as TGA 93 Good Manufacturing Practice (GMP) compliant unless the TGA has conducted an audit themselves, even if the USA facility is FDA approved and has a GMP certification. This recognition challenge significantly impacts the ability of companies to source quality and innovative manufacturing. We propose that there should be a streamlined and internationally recognised process for GMP compliance recognition, enabling efficient access to quality manufacturing facilities worldwide.

In addition to these lessons, we would like to express our thoughts on the possibility of introducing easier but controlled access to everyone who needs cannabis. While we advocate against full legalisation, we believe there is an opportunity to enhance access within a controlled framework:

## 7. Balancing Access and Control:

We propose a controlled approach to expanding access to cannabis for those who genuinely need it for medical purposes. This approach can involve:

### Introducing a nuanced approach:

As the medical cannabis industry continues to evolve and diversify, adapting regulatory frameworks to encompass the unique properties of different product categories, including cannabis topicals, is

essential for public health, consumer safety, and the advancement of the industry as a whole. Such an approach encourages responsible use and supports the wellbeing of individuals seeking relief from various conditions. Cannabis topicals, for example, are applied directly to the skin at specific areas of the body. This localised application means that the active compounds are not distributed throughout the bloodstream, which is in contrast to ingestible forms of Cannabis. As a result, the systemic effects and potential risks associated with ingestion are minimised.



Cannabis topicals come in various formulations, such as creams, balms, lotions, and transdermal patches. Each of these formulations may have specific considerations for regulation, as the choice of formulation can impact the product's absorption, effectiveness, and user experience. Tailoring regulations to account for these differences ensures appropriate oversight.

### • Expanded Medical Access:

Australia can broaden the list of qualifying medical conditions for which patients can access medical cannabis, ensuring that those in need have a straightforward path to treatment.

## • Reducing Bureaucratic Barriers:

Streamlining administrative procedures and reducing paperwork can make it easier for industry participants and patients to source and access cannabis products, all while maintaining strict regulatory controls.

### • Cost Reduction:

Initiatives to reduce the cost of medical cannabis products, in the hands of the patients, such as subsidies or insurance coverage, can ensure that financial limitations do not hinder access to treatment, and the medicine is available to everyone who needs it.

#### Monitoring and Adjusting Regulations:

Regular monitoring and adaptation of regulations ensure a responsive and effective medical cannabis system.

In conclusion, our position remains that the Australian Senate should permit the medical cannabis industry the requisite time and resources to conduct essential research and scientific investigations before considering any form of full legalisation. Our proposal also advocates for a controlled approach to expanding access to medical cannabis, addressing the needs of those who require it while maintaining strict controls.

OMG is committed to advancing the science and understanding of medical cannabis for the betterment of patients, and we believe that this endeavour necessitates the time and resources to unlock its full potential.

We thank the Australian Senate for the opportunity to engage in this important dialogue. OMG remains available for further discussions, additional information, or to address any inquiries on our perspective.

Thank you for your attention to this critical matter.



**Yours Sincerely** 



John Leith Founder and Chairman OZ Medicann Group