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## IMPROVED ACCESS FOR CRITICALLY ILL PATIENTS

## **Highlights**

- Senator Di Natale's disallowance motion restores the rights of terminally ill patients to access cannabinoid medicines through the TGA's Special Access Scheme Category A.
- AusCann welcomes changes that assist Australian medical practitioners to prescribe cannabinoid medicines to critically ill patients.

**AusCann Group Holdings Ltd** (ASX: AC8 or 'the Company') welcomes changes that increase the ability of Australian medical practitioners to prescribe cannabinoid medicines to critically ill patients.

The Therapeutic Goods Administration (**TGA**) currently has two access pathways in which Australian medical practitioners may prescribe unregistered cannabinoid medicines - the Authorised Prescriber Scheme (**APS**) and the Special Access Scheme (**SAS**) Category B. Both of these pathways require the medicinal practitioner to apply for and wait for approval from the TGA prior to being able to prescribe.

SAS Category A does not require prior approval but is a process where the medical practitioner notifies the TGA they have prescribed the medicines.

Prior to the changes, any unregistered therapeutic goods can potentially be supplied via the SAS Category A process, except for:

- 1. Prohibited substances in Schedule 9 of the Poisons Standard; and
- 2. medicinal cannabis products.

Senator Di Natale's disallowance motion changes the *Therapeutic Goods and Other Legislation Amendment (Narcotic Drugs) Regulation 2016* to enable terminally ill patients to access medicinal cannabis products through the TGA SAS Category A process.

Elaine Darby, Managing Director of AusCann said: "AusCann believes that excluding cannabinoid medicines from this pathway was not necessary given the safety evidence in respect to cannabinoids that has come out of pre-clinical and clinical studies. We are pleased terminally ill patients will now be able to access cannabinoid medicines through the TGA's Special Access Scheme Category A."

Category A patients are defined as 'persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment'.

The medical practitioner completes the relevant Category A form and sends it to the supplier of the product and a copy to the TGA. This provides the supplier, such as AusCann, with the legal authority to supply the product.



In respect to other patient groups AusCann believes that the TGA SAS and APS access schemes provide the necessary checks and balances for the approval of medical practitioners to prescribe unregistered cannabinoid medicines.

## For more information please contact

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## **ABOUT AUSCANN GROUP**

AusCann is an Australian based company that was incorporated in September 2014 with the aim of producing and providing high quality, affordable and clinically validated cannabis medicines to patients. It is bringing together leading expertise and operations across all aspects of the medical cannabis value chain, beginning with cultivation and production, through to manufacture and distribution of products and has built a strong team of experts and partners across the globe. Partners include: TSX listed Canopy Growth Corporation - the largest producer of medicinal cannabis globally; DayaCann - the only licensed medicinal cannabis grower in Chile; and Tasmanian Alkaloids, producer of ~40% of the world's alkaloid raw material.