The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC25-002166

Dr Nick Yim
President
AMA Queensland
c/o [redacted]

Dear Dr Yim

Thank you for your correspondence of 31 January 2025 to the Minister for Health and Aged Care, the Hon Mark Butler MP, cosigned by Dr Chris Owen, President of the Pharmacy Guild of Australia Queensland, Dr Cath Hester, Chair of the Royal Australian College of General Practitioners Queensland, and Professor Brett Emmerson AM, Chair of the Royal Australian and New Zealand College of Psychiatrists Queensland, regarding the rapid rise in the prescribing of unapproved medicinal cannabis products and associated adverse events.

I note that you met with Professor Robyn Langham, Chief Medical Adviser, on 29 January 2025. I encourage you to continue to collaborate with the Therapeutic Goods Administration (TGA) who are actively reviewing the medicinal cannabis framework through the Medicinal Cannabis Expert Working Group (MCEWG) and considering mechanisms by which regulatory safety risk controls can be integrated into the current patient access framework to ensure patient safety.

The TGA has a responsibility to safeguard and enhance the health of the Australian community. The TGA achieves this by regulating the advertising, manufacturing, import, export and supply of therapeutic goods, in line with the *Therapeutic Goods Act 1989* (TG Act).

As you are aware, the majority of medicinal cannabis medicines accessed in Australia are unapproved and have not undergone assessment by the TGA for safety, quality and efficacy. The TG Act has provisions to allow the use of unapproved medicines by a registered health practitioner for a patient under certain circumstances.

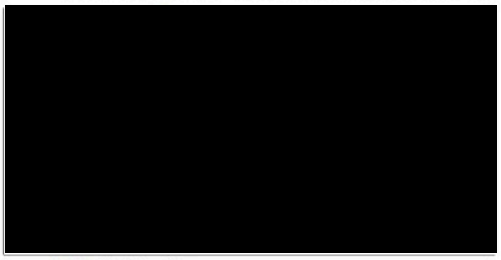
The Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme are established pathways that enable registered healthcare practitioners to access unapproved therapeutic goods for patients under their care. It is important to note that the use of an unapproved therapeutic good for a patient is a clinical decision made at the discretion of the registered healthcare practitioner (a medical practitioner or pharmacist) who is responsible for obtaining informed consent from their patient or patient's guardian. Informed consent takes into account the risks and benefits of that treatment verses other available treatments or no treatments at all, based on the individual circumstances.

While the TGA facilitates access to unapproved medicinal cannabis products, the Department of Health and Aged Care does not regulate the prescribing practice of health practitioners. As you are aware, the medical profession is regulated by the Medical Board of Australia (MBA) which is supported in its role by the Australian Health Practitioner Regulation Agency (Ahpra). These bodies are established independently of government under the Health Practitioner Regulation National Law 2009 as enacted in each state and territory.

I note that Ahpra has recently established a Rapid Regulatory Response Unit to proactively investigate matters to inform regulatory responses to emerging issues involving health practitioners. I understand medicinal cannabis is a focus area for the Unit, and the TGA is actively supporting this work.

The TGA is committed to a continued, collaborative approach and appreciates your advice and involvement. The TGA continues to explore possible solutions relating to safety concerns of medicinal cannabis.

Thank you for writing on this matter.



Mark Butler

28/5/2025