Medicinal Cannabis Council Australia

MCCA supports sensible regulatory requirements to ensure proportionate and evidence-based oversight of unapproved medicinal cannabis products

Here is a summary of our October 2025 submission to the Therapeutic Goods Administration's (TGAs) consultation on the Safety and Regulatory Oversight of Unapproved Medicinal Cannabis Products. Our submission supports balanced regulatory reform that strengthens quality standards, pharmacovigilance, prescriber education and clinical governance while preserving patient access.

MCCA's five key recommendations

1. Establish a dedicated medicinal cannabis pathway within the Australian Register of Therapeutic Goods (ARTG), focused on product quality, GMP compliance and pharmacovigilance obligations, rather than requiring full pharmaceutical registration.
2. Introduce standardised product labelling, dosing guidance and patient information.
3. Maintain access to THC-containing products across a range of potencies under appropriate medical supervision rather than imposing arbitrary potency limits.
4. Create a national evidence registry to support collection of real-world, clinical and pharmacovigilance data.
5. Develop contemporary education programs for healthcare professionals to improve prescribing practices and patient safety.

Supporting evidence-based and proportionate reform

Any reforms must be evidence-based, proportionate to risk, transparent and aligned with the National Medicines Policy. While acknowledging legitimate concerns regarding patient safety, adverse events and inappropriate prescribing, the submission contends that much of the evidence relied upon by the TGA is derived from recreational cannabis populations, illicit cannabis use, smoking-related harms or overseas jurisdictions with significantly different regulatory frameworks. As such, caution should be exercised when applying these findings to Australia's regulated medicinal cannabis market.

The MCCA acknowledges that medicinal cannabis is not risk-free and issues such as dependence, cannabis use disorder, psychosis risk in susceptible individuals and adverse effects associated with THC require ongoing monitoring. Our Submission argues these risks should be assessed relative to existing therapies commonly used for chronic pain, anxiety and sleep disorders, including opioids and benzodiazepines, which often carry greater risks of dependence, overdose and serious adverse events.

Getting the regulatory oversight of prescribing and clinical governance right

A key issue facing the sector and the government is how to get the prescribing and a clinical governance operating environment right to support patient access to quality medicinal cannabis products. The MCCA acknowledges concerns raised by stakeholders about telehealth-health only prescribing services, inadequate patient assessments, potential conflicts of interests within the system and limited regulatory oversight of non-clinical clinic operators.

Reducing regulatory burden while preserving appropriate oversight

Our submission highlights concerns regarding the administrative burden of the current Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways, which were not designed to support the scale of medicinal cannabis prescribing now occurring in Australia. Reform is needed.