CANNABIS COUNCIL AUSTRALIA

Commonwealth funding to strengthen safety, quality, and system integrity for medicinal cannabis products

Cannabis Council Australia (CCA) is seeking the Australian Treasury's consideration of funding measures in the 2026–27 Budget that will strengthen safety, quality and system integrity for medicinal cannabis products accessed by patients across Australia.

CCA is the national peak body for medicinal cannabis, representing licensed producers, prescribers and pharmacists. Our purpose is to achieve safe, equitable access to medicinal cannabis for Australians who may benefit — through evidence-based practice, sound clinical governance and nationally consistent standards for the cultivation and manufacture of medicinal cannabis products.

Background

Medicinal cannabis has been legally available in Australia since 2016 under "exceptional access" mechanisms administered by the Therapeutic Goods Administration (TGA). These pathways were designed to facilitate access where clinically appropriate, but were not designed to function as the dominant, high-volume mechanism for a long-term therapeutic market.

Over time, the market has scaled rapidly and is now characterised by a large volume of unapproved products in routine clinical use. There are currently around 1,300 unapproved medicinal cannabis products in the market. Recent stakeholder feedback has raised concerns about inconsistent pre-market assurance, variable product standards and verification, inconsistent product labelling and dose expression, and limited end-to-end monitoring at the scale expected for high-volume therapeutic goods.

CCA supports the TGA's Consultation: *Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products* conducted in 2025 as part of a broader review called by the Minister for Health and Aged Care. The TGA's consultation provides a timely opportunity to implement scalable, enforceable reforms while maintaining continuity of care for current patients.

CCA's broader submission to the TGA consultation focuses on improved cultivation, importation and manufacturing standards, supported by a dedicated medicinal cannabis Australian Register of Therapeutic Goods (ARTG) pathway and strong clinical governance supported by real-world evidence (RWE) and pharmacoepidemiology. This pre-budget submission relates to enhancing the safety, quality, and efficacy of medicinal cannabis products.

Summary of funding request and deliverables

In line with our submission to the TGA consultation, CCA is calling for sufficient Commonwealth funding of the TGA's operations so the TGA can deliver the following activities over the next 36 months:

- Review and uplift Therapeutic Goods Order (TGO) 93 to enhance enforceable safety and quality standards for unapproved medicinal cannabis products (including modernised, standardised label schema and unit-based dose expression).

- Establish a pre-market product compliance and verification regime (including independent verification/testing settings proportionate to risk) to level compliance expectations for sponsors, whether products are domestically manufactured or imported.
- Work with health stakeholders and the sector to design a national mechanism for de-identified RWE and monitoring, integrated with pharmacovigilance, adverse event reporting and pharmacoepidemiology to support evidence development and identify safety signals.
- Establish a fit-for-purpose medicinal cannabis ARTG category and product approval pathway, aligned to the uplifted TGO 93 settings and supported by structured post-market obligations, with a clear transition pathway over time.

CCA anticipates that elements of this program that create ongoing administrative functions for the TGA can progressively transition to cost recovery (for example, listing-related fees, verification and testing, and credential mechanisms) once core capability is established.

Why this matters now
Healthcare that involves medicinal cannabis is becoming increasingly accepted by patients and health practitioners and can be a life-changing therapy for patients who have exhausted other treatment options for complex and often chronic clinical conditions. However, the current access mechanisms were not designed for a high-volume, long-term therapeutic market.

This program of work is intended to lift enforceable product standards and respond to the safety and quality concerns being raised in relation to unapproved medicinal cannabis products supplied at scale. It will provide assurance to governments and the Australian public, and improve the long-term sustainability of the medicinal cannabis sector. It will strengthen confidence across the broader health system by establishing consistent, enforceable product and labelling standards with proportionate compliance oversight across domestic and imported supply, while building a credible pathway to stronger evidence through structured monitoring and pharmacoepidemiology over time.

Implementation and funding approach
This work can be implemented alongside the Commonwealth's current digital medicines safety reforms, including the recently announced requirement for medicines-related information from online prescribers to be available via My Health Record and the staged development of a National Medicines Record.

This funding proposal is designed to leverage existing Commonwealth activity (including the current TGA reform process) and to be scalable over forward estimates. CCA recommends an initial establishment investment, with a clear pathway to cost recovery for ongoing administrative functions once regulatory architecture is in place. This will help ensure core regulatory functions are adequately resourced to support consistent decision-making and compliance oversight.

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