

17 July 2026

Office of Drug Control
Department of Health, Disability and Ageing

By email: ODC.Consultation@health.gov.au

Dear Consultation Team,

Re: Remaking of the Narcotic Drugs Regulation 2016 and Narcotic Drugs (Licence Charges) Regulation 2016

Cannabis Council Australia welcomes the opportunity to provide feedback on the remaking of the Narcotic Drugs Regulation 2016 and the Narcotic Drugs (Licence Charges) Regulation 2016. CCA supports a robust national framework for medicinal cannabis cultivation, production, manufacture and supply that supports lawful access for medical and scientific purposes while preventing diversion and misuse.

CCA is providing high-level sector feedback rather than a detailed technical submission on each provision. The sunseting process presents a timely opportunity to review whether the regulatory framework is operating clearly, proportionately and efficiently in practice, taking into consideration its impact on safety, quality and diversion controls across the whole supply chain, and whether the framework supports the viability of a still-maturing Australian cultivation and manufacturing sector.

Our feedback focuses primarily on regulatory processes and guidance information.

Regulatory process and associated guidance

CCA has received consistent feedback that ODC licensing and permit processes can be complex, time-consuming and difficult to navigate. The most commonly identified concerns relate to timeliness, communication, continuity of case management and inconsistent regulatory expectations.

Stakeholders have reported that applications may move between officers without clear continuity of responsibility, resulting in repeated requests to businesses for information, differing interpretations of requirements and avoidable delays. This creates uncertainty for regulated entities and may impose substantial costs where businesses must maintain facilities, personnel and compliance systems while awaiting decisions.

Stakeholders have also questioned whether some requirements are imposed at the most appropriate stage of the process. For example, applicants may be expected to provide detailed standard operating procedures and risk-management documentation before facilities and business operations are sufficiently established. These documents will necessarily evolve as a business becomes operational, but subsequent changes can trigger further approval processes, additional costs and delays.

CCA recommends that the Department and ODC review licensing and permit processes to consider whether:

- requirements are clear, proportionate and imposed at the appropriate stage;

- routine or lower-risk amendments can be managed through streamlined or risk-based processes;
- applicants have consistent points of contact and greater continuity of case management;
- regulatory requests and decision-making are applied consistently across officers and inspection teams; and
- administrative systems, standardised processes and appropriate automation could reduce duplication and improve efficiency.

CCA also recommends ODC review its regulations with the aim of publishing clearer information on:

- what is required at licence stage compared with permit stage;
- expectations for risk management plans and standard operating procedures given they are required earlier than may be practicable;
- when changes to operational documents require notification, variation or further approval;
- common reasons for delays or requests for further information; and
- how applicants can demonstrate compliance without unnecessary duplication.

Clearer guidance and more consistent case management would benefit both industry and the regulator by improving application quality, reducing rework and supporting timely and consistent decision-making.

Supply chain visibility

CCA has received feedback that the regulatory obligations applying to imported medicinal cannabis may not provide the same level of supply-chain visibility as those applying to domestically cultivated and produced product, particularly once imported product enters Australia and moves through different supply pathways and jurisdictional systems.

The concern is not simply that imported and domestic products are subject to different regulatory pathways. Rather, stakeholders have questioned whether those differences are risk-based, transparent and sufficient to support comparable visibility and accountability across the whole supply chain.

The sunseting process provides an opportunity for the Department and ODC to review whether the respective regulatory frameworks apply proportionate and consistent scrutiny to domestic and imported medicinal cannabis products. This should include consideration of product tracking, record-keeping and reporting requirements, while avoiding unnecessary duplication or regulatory burden.

Fees, charges and regulatory performance

CCA recognises that the medicinal cannabis licence and permit scheme operates within a cost recovery framework. However, stakeholder feedback indicates that the costs of regulation are not limited to formal fees and charges. Delayed decisions, repeated information requests, changing regulatory expectations and the need to obtain further approvals for routine operational changes can impose significant additional costs on regulated entities.

Stakeholders have observed that the level of fees and charges applying to cultivation and production licence holders may not be matched by sufficiently timely, consistent and transparent regulatory services. There would be value in the Department reviewing whether the allocation of

regulatory costs remains equitable and proportionate across different categories of regulated activity, including cultivation, manufacture, importation and wholesale supply.

CCA also proposes the Department and ODC publish clearer regulatory service information, including:

- indicative assessment and decision-making timeframes;
- communication and case-management expectations;
- performance against published service standards;
- the circumstances in which additional fees or charges may arise; and
- avenues for escalating applications that have experienced significant delay.

This would improve transparency and accountability and help demonstrate that cost recovery supports a capable, efficient and appropriately resourced regulatory system.

Conclusion

CCA supports a strong national framework for medicinal cannabis regulation. The framework must support lawful access to medicinal cannabis for medical and scientific purposes, prevent diversion and maintain public confidence.

The sunseting process provides an opportunity to ensure the framework continues to meet these objectives while operating clearly, proportionately and efficiently in practice. Further targeted consultation with directly regulated entities will help ensure the remade instruments support a workable, well-administered and sustainable Australian medicinal cannabis sector.

Thank you for the opportunity to provide feedback. To organise a meeting, or if you have any questions regarding this submission, please contact me via office@cannabiscouncil.org.au.

Yours sincerely,



Lisa Penlington
Chief Executive Officer
Cannabis Council Australia