National Aboriginal and Torres Strait Islander Ageing and Aged Care Council

Submission

Reviewing the safety and regulatory oversight of unapproved medicinal cannabis product

October 2025

NATSIAACC

Contents

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Acknowledgement of Country

NATSIAACC acknowledges the Traditional Owners of the lands and waters on which we work, live and gather, as well as Country throughout Australia, and their enduring connections to land, sea and community. NATSIAACC acknowledges that these lands and waters were never ceded, and we acknowledge the sovereignty and self-determination of the Traditional Owners.

NATSIAACC pays its deepest respects to Elders past and present and recognise the continued cultural and spiritual connection to Country and/or Island Home, community, culture and knowledge.

NATSIAACC thanks them for their wisdom and courage, and for sharing their ways of knowing, being and doing – teachings that guide us to cherish and protect our Elders and Older People.

This always was and always will be Aboriginal Land.

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National Aboriginal and Torres Strait Islander Ageing and Aged Care Council

About

The National Aboriginal and Torres Strait Islander Ageing and Aged Care Council (NATSIAACC) is the national peak body for Aboriginal and Torres Strait Islander ageing and aged care. NATSIAACC works to ensure that Aboriginal and Torres Strait Islander Elders and Older People can access support and care that is culturally safe, trauma aware and healing-informed, and recognises the importance of their personal connections to community, Country and/or Island Home.

NATSIAACC is building a membership base of:

- Aboriginal and Torres Strait Islander community-controlled providers of ageing and aged care, and
- Entities with an interest in culturally appropriate ageing and aged care services.

NATSIAACC's founding Directors are all leaders in Aboriginal and Torres Strait Islander ageing and aged care provision.

Our Vision

All Aboriginal and Torres Strait Islander people are thriving, healthy, strong, with ongoing cultural connections in their older years.

Our Purpose

NATSIAACC supports Aboriginal and Torres Strait Islander older peoples, their families, and communities to identify, engage in, advocate for, and lead systemic reform to embed culturally safe practices across the aged care and ageing sector.

With thanks

NATSIAACC thanks its members, stakeholders, and other peak bodies for their valuable contributions to this submission and for generously giving their time to support older Aboriginal and Torres Strait Islander people.

Funding

NATSIAACC is funded by the Commonwealth Department of Health, Disability and Ageing (the Department). NATSIAACC has been in operation since 2022. In the context of the current aged care reforms and the need for extensive advocacy, input, and leadership in the sector, it will be necessary to provide additional funding to support NATSIAACC to provide the input and engagement required to ensure that the reforms deliver much needed support to Aboriginal and Torres Strait Islander Elders and Older People.

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NATSIAACC Recommendations

Embedding Cultural Safety and Governance

- To embed NATSIAACC's Cultural Safety Definition into the framework.
- To embed cultural safety and trauma-informed care as central requirements to address ongoing inequities, systemic racism, and workforce shortages that put Elders and Older Peoples' health and wellbeing at risk.
- To simplify the framework using plain language, practical tools, and culturally relevant examples while allowing flexibility for local adaptation across urban, rural, remote, and community-controlled settings.
- To embed Aboriginal and Torres Strait Islander governance, self-determination, and accountability mechanisms across all frameworks to ensure that care systems reflect community priorities and uphold the voices of Elders and Older People.

Quality and Safety Requirements

- To strengthen labelling and device safety standards; mandate regular medication reviews for Elders and Older People prescribed cannabis.

Emerging safety concerns for medicinal cannabis products

- To create culturally safe reporting pathways via ACCHOs and ensure regulatory changes do not inadvertently fuel illicit markets.

Dosage Forms and Routes of Administration

- To restrict smoking and vaping forms for Aboriginal and Torres Strait Islanders Elders and Older People and strengthen regulation of devices.

Concentration of Medicinal Cannabis Components

- To cap THC concentration in unapproved products to 15–20%, aligned with international safety benchmarks.

Population groups

- To mandate comprehensive screening protocols for Elders before prescribing medicinal cannabis, with culturally safe communication and family-inclusive consent processes.

Address the current issues with medicinal cannabis products

- To establish an Aboriginal and Torres Strait Islander advisory mechanism within the TGA's regulatory reform process.

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Executive Summary

The National Aboriginal and Torres Strait Islander Ageing and Aged Care Council (NATSIAACC) welcomes the opportunity to contribute and provide feedback on the Therapeutic Goods Administration's (TGA) consultation regarding the safety and regulation of unapproved medicinal cannabis products. As the national peak body for Aboriginal and Torres Strait Islander Ageing and Aged Care, NATSIAACC advocates for reforms that embed cultural safety, respect, self-determination, and support community-led service delivery.

Our vision is to ensure that all Aboriginal and Torres Strait Islander Elders and Older People can access culturally safe, trauma-aware, healing-informed care that is grounded in their connection to culture, community and Country and/or Island Home.

NATSIAACC's policy and advocacy work is guided by *Our Care, Our Way, Our Future*, our five-year strategic plan which prioritises eight key areas to transform aged care for our people. These priorities include expanding community-led services, growing the Aboriginal and Torres Strait Islander aged care provider and workforce base, embedding trusted community-based navigators, and strengthening culturally appropriate assessment services.

Aboriginal and Torres Strait Islander Elders and Older People are among the most vulnerable populations in Australia's health and aged care systems. They experience a disproportionate burden of chronic disease, pain, and palliative care needs, and are more likely to experience inequitable access to healthcare services. The perspectives of Elders and Older People are critical in this discussion because many are prescribed or considering medicinal cannabis for chronic pain, sleep disturbance, and palliative care. There is limited culturally safe information available to Aboriginal and Torres Strait Islander Elders and Older People about medicinal cannabis. Risks of misuse or harm may be heightened due to health inequities, comorbidities, and systemic barriers to care. Decision-making about medicinal cannabis must consider cultural safety, ensuring that care respects identity, connection to Country and/or Island Home, and holistic views of health.

Our submission draws upon NATSIAACC member engagements, including our submissions. Our members have consistently called for cultural safety as not an optional overlay, but as a fundamental requirement for safe, effective and ethical health regulation and emphasised on:

- the growing likelihood of uptake of medicinal cannabis among older cohorts (including both prescribed and illicit forms),
- the critical importance of managing polypharmacy risks,
- the need for culturally safe prescribing and communication, and
- concerns about equity, cost, stigma, and justice impacts.

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Opportunities for inclusion

Unsafe prescribing practices, poor labelling, and lack of monitoring directly impact aged care reform outcomes. For example, under the forthcoming Support at Home program, Elders and Older People may rely on multiple providers to manage medications. Without culturally safe regulatory safeguards, Elders and Older People risk polypharmacy complications and disengagement from care. Similarly, in residential aged care, where GP access is limited, medicinal cannabis use could be unsupervised, compounding clinical and safety risks. Embedding cultural safety in TGA regulation will therefore support both aged care standards implementation and the Closing the Gap health equity agenda.

Aboriginal and Torres Strait Islander Elders and Older People experience higher rates of chronic disease, pain, and mental health conditions, yet face systemic barriers to safe, effective, and culturally appropriate healthcare. This places them at unique risk when engaging with medicinal cannabis, whether prescribed or accessed outside the regulated market.

Cultural safety must underpin regulation of medicinal cannabis. Without it, Aboriginal and Torres Strait Islander Elders and Older People may disengage from formal healthcare, turning to the black market. Prescribing practices risk overlooking trauma histories, experiences of racism, and barriers to mainstream healthcare. Information about cannabis will remain inaccessible for communities who need plain-language, visual, and culturally adapted resources.

Informed consent is compromised when product labelling and clinical information are inaccessible, overly technical, or not adapted to Aboriginal and Torres Strait Islander languages or worldviews. Trust in health systems is undermined by historical trauma and medical racism, leading to reluctance to disclose cannabis use or adverse reactions[1]. Health inequities are deepened if Elders and Older People are prescribed unsafe or inappropriate forms (e.g., high-THC inhalants) without culturally appropriate education on risks.

Aged Care Providers stressed that for some Aboriginal and Torres Strait Islander Elders and Older People, choosing cannabis (prescribed or illicit) may represent an alternative to mainstream medicine, precisely because of past negative experiences in hospitals and clinics. Regulatory systems must acknowledge this context and avoid further marginalisation.

Therefore, regulation must embed Aboriginal and Torres Strait Islander governance, culturally safe education materials, and family-inclusive approaches to ensure medicinal cannabis is accessed safely.

Embedding Cultural Safety and Governance

NATSIAACC was commissioned by the Department of Health, Disability and Ageing to define "Cultural Safety in Aged Care" following extensive consultation with communities, Elders, Older People, organisations, and aged care providers. The definition states:

"Cultural safety in aged care for older Aboriginal and Torres Strait Islander people, is understanding one's own culture and the impact that your culture, thinking, and actions may have on the culture of others

[1] Dudgeon, P., Milroy, J., & Walker, R. (2014). Working together: Aboriginal and Torres Strait Islander mental health and wellbeing principles and practice. Commonwealth of Australia

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through ongoing critical self-reflection. Gaining such truthful insight about oneself is critical for ensuring access to a culturally safe, respectful, responsive and racism free aged care system providing for the optimal safety, autonomy, dignity, and absolute wellbeing of Aboriginal and/or Torres Strait Islander Elders and older people, and their families. Only the Aboriginal and/or Torres Strait Islander person who is the recipient of a service or interaction can determine whether it is culturally safe.

Aged care service providers and workers must take responsibility for building trust and relationships with Aboriginal and/or Torres Strait Islander service users, and their families, and for creating a new aged care system which centres on their living experience, cultural, and ageing needs, as determined by Aboriginal and/or Torres Strait Islander service users themselves. The implementation of a trauma aware, healing informed approach to professional practice, and facilitating a greater understanding and respect for individual and collective cultures, histories, knowledges, traditions, stories, and values of Aboriginal and/or Torres Strait Islander service users, and their families, will greatly support the delivery of a quality and culturally safe aged care system. Aged care service providers must also firmly commit to continuously measure and improve structures and behaviours necessary for cultural safety and quality support to remain embedded in the Australian aged care system."

Following this definition, true cultural safety involves:

- Embedding Aboriginal and Torres Strait Islander governance and leadership across all levels of aged care design, delivery, and evaluation.
- Supporting and uplifting cultural identity, self-determination, and community-led decision-making.
- Employing and empowering an Aboriginal and Torres Strait Islander workforce.
- Ensuring services are responsive to cultural determinants of health, including kinship, spirituality, and cultural practices.
- Actively addressing institutional and interpersonal racism in aged care systems and services.

Cultural safety is essential for delivering equitable, high-quality aged care. It must be continuously reflected upon, measured through the voices and experiences of Elders and Older People, and upheld through strong accountability frameworks.

Central to cultural safety is recognising that only Aboriginal and Torres Strait Islander Elders and Older People themselves can determine whether care is culturally safe in practice. Regulatory oversight must therefore embed mechanisms for Elders and Older Peoples' voices to be heard directly and consistently, such as mandatory inclusion of Elders and Older Peoples lived experience surveys, interviews, and co-assessments as part of compliance audits. Embedding Elders and Older People as co-determiners of cultural safety ensures accountability to those most impacted and grounds the regulatory system in cultural authority rather than external judgement alone.

To operationalise cultural safety, Elders must not only be consulted but embedded as co-assessors of regulatory safety. This can be achieved by:

- Introducing Elders and Older Peoples' lived experience surveys as mandatory in TGA compliance audits.
- Funding Elder co-assessment panels to review safety reporting and consent materials for cultural relevance.
- Embedding family-inclusive consent processes, recognising the kinship obligations that guide Aboriginal and Torres Strait Islander decision-making.

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Embedding cultural safety into cannabis regulation aligns with the Closing the Gap Priority Reforms:

- Priority Reform One (Formal Partnerships and Shared Decision-Making): Establishing an Aboriginal and Torres Strait Islander advisory mechanism within TGA ensures governance reflects Elders and Older Peoples voices.
- Priority Reform Two (Building the Community-Controlled Sector): Creating reporting pathways via ACCHOs strengthens the Aboriginal Community Controlled Health sector and ensures accessible, trusted systems.
- Priority Reform Three (Transforming Government Organisations): Mandating cultural safety requirements across TGA frameworks ensures systemic racism and inequities are directly addressed.

NATSIAACC recommends:

- To embed NATSIAACC's Cultural Safety Definition into the framework.
- To embed cultural safety and trauma-informed care as central requirements to address ongoing inequities, systemic racism, and workforce shortages that put Elders and Older peoples' health and wellbeing at risk.
- To simplify the framework using plain language, practical tools, and culturally relevant examples while allowing flexibility for local adaptation across urban, rural, remote, very remote and community-controlled settings.
- To embed Aboriginal and Torres Strait Islander governance, self-determination, and accountability mechanisms across all frameworks to ensure that care systems reflect community priorities and uphold the voices of Elders and Older People.

Quality and Safety Requirements

Current standards (TGO 93) are insufficient for Aboriginal and Torres Strait Islander Elders and Older People. Labels are confusing, overly technical, and not available in accessible or culturally relevant formats. Elders and Older People need plain-language, culturally safe guidance on dosage, storage, side effects, and warnings (e.g., for pregnancy, driving, or mixing with alcohol). Devices (e.g., vaporisers) must be regulated to prevent harm (burns, explosions, toxic emissions). NATSIAACC members highlighted the importance of polypharmacy reviews. Elders and Older People are often on more than five medications, and cannabis can cause unknown interactions if monitoring is not frequent. In residential aged care, where GP access is limited, cannabis could be used unsafely without safeguards.

NATSIAACC recommends:

- To strengthen labelling and device safety standards; mandate regular medication reviews for Elders prescribed cannabis.

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Emerging safety concerns for medicinal cannabis products

Unapproved products expose Elders and Older People to potency variability (THC concentrations ranging up to 88% in extracts). Psychiatric risk, particularly psychosis, anxiety, and cognitive impairment from high-THC products[2]. Under-reporting of adverse events, as stigma and mistrust prevent Elders and Older People from engaging with formal reporting systems. Without safe legal access, Elders and Older People are pushed to illicit markets where potency is higher, and risks are uncontrolled. Members emphasised that when restrictions on THC doses were too strict, people returned to the black market to seek stronger cannabis. This increases risks of unsafe use and criminalisation.

NATSIAACC recommends:

- To create culturally safe reporting pathways via ACCHOs and ACCOs and ensure regulatory changes do not inadvertently fuel illicit markets.

Dosage Forms and Routes of Administration

NATSIAACC members were concerned that Aboriginal and Torres Strait Islanders Elders and Older People in aged care may turn to cannabis for pain relief where GP or pharmacy access is low. Regulation must ensure that oral products (safer for long-term use) are affordable and accessible. Smoking and vaping cannabis present high respiratory and cardiovascular risks, especially for Elders and Older People with chronic disease. Safer alternatives (oral liquids, capsules) should be prioritised. Suppositories, sprays, and novel forms lack evidence and should be restricted until proven safe.

NATSIAACC recommends:

- To restrict smoking and vaping forms for Aboriginal and Torres Strait Islanders Elders and Older People and strengthen regulation of devices.

Concentration of Medicinal Cannabis Components

CBD is generally safe, but dosage should be monitored for drug interactions. CBD is generally well tolerated, though interactions with common medicines (e.g., anticoagulants) require caution[3] High-THC products are a major concern for Elders and Older People. High concentrations increase risks of psychosis,

[2] Petrilli, K., Ofori, S., Hines, L., et al. (2022). Association of cannabis potency with mental ill health and addiction: A systematic review. The Lancet Psychiatry, 9(9), 736–750. https://doi.org/10.1016/S2215-0366(22)00161-4

[3] Arnold, J. C., Nation, T., & McGregor, I. S. (2020). Prescribing medicinal cannabis. Australian Prescriber, 43(5), 152–159.

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falls, impaired cognition, and interactions with cardiovascular medicines[4]. Current absence of an upper THC limit is unsafe. A maximum THC limit must be introduced.
Members cautioned that strict THC limits without considering user histories could drive people back to illicit markets. A balance is needed: products should be regulated but not so restrictive that they discourage legal access. Inhaled high-THC forms (vapes, dried herb) present unacceptable risks for Elders and Older People and should be heavily restricted.

NATSIAACC recommends:

- To cap THC concentration in unapproved products to 15–20%, aligned with international safety benchmarks.

Population groups

Paediatric restrictions are appropriate and should remain. For Elders and Older People, additional screening for comorbidities (cardiac disease, psychosis, history of substance use) is needed. Pregnant and breastfeeding women require culturally safe warnings due to evidence of foetal neurodevelopmental risks[5]. Elders and Older People with dementia are at particular risk from misuse or inappropriate prescribing, and safeguards must be applied.

Cultural safety requires family-inclusive discussions, respecting kinship structures in decision-making. Members noted that cannabis is often sought as an alternative to mainstream medicine due to racism or negative experiences in the health system. Regulation must not create more barriers, which would push Elders and Older People towards illicit supply and expose them to criminal justice risks — a critical issue given already high incarceration rates among Aboriginal and Torres Strait Islander people.

NATSIAACC recommends:

- To mandate comprehensive screening protocols for Elders and Older People before prescribing medicinal cannabis, with culturally safe communication and family-inclusive consent processes.

Address the current issues with medicinal cannabis products

NATSIAACC supports shifting accountability from prescribers to sponsors, as with alcohol labelling. However, safeguards are needed to prevent sponsors leaving the regulated market for illicit supply if requirements are too strict. Sponsors should ensure safe formulations, warnings and monitoring. Time-limited approvals are required to encourage ARTG registration, allowing safe access while evidence is

[4] Stuyt, E. (2018). The problem with high potency THC marijuana from the perspective of an addiction psychiatrist. Missouri Medicine, 115(6), 482–486.
[5] Stoner, M. J., Dietrich, A., Lam, S. H., et al. (2022). Marijuana use in children: An update focusing on pediatric THC and CBD use. Journal of the American College of Emergency Physicians Open, 3(4), e12770. https://doi.org/10.1002/emp2.12770

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gathered. Labelling must include plain warnings (e.g., pregnancy risks, driving impairment, polypharmacy risks). Stronger labelling transparency is needed, including statements that clarify whether a product is ARTG-registered or unapproved.

Regulatory reform must embed Aboriginal and Torres Strait Islander Elders and Older People governance and invest in an evidence base on Aboriginal and Torres Strait Islander Elders and Older People' use of cannabis, which is currently absent.

NATSIAACC members highlighted the lack of recognition of Aboriginal and Torres Strait Islander people in TGA processes and advisory structures. This absence undermines cultural safety and risks Elders and Older people being "afterthoughts" in regulation.

NATSIAACC recommends:

- To establish an Aboriginal and Torres Strait Islander advisory mechanism within the TGA's regulatory reform process.

Conclusion

Medicinal cannabis represents both an opportunity and a risk for Aboriginal and Torres Strait Islander Elders and Older People. While it has the potential to relieve pain, support palliative care, and provide alternatives for those failed by mainstream health systems, the current reliance on unapproved products leaves Aboriginal and Torres Strait Islander Elders and Older People vulnerable to inconsistent quality, unsafe potency, and limited monitoring of interactions with existing medications.

For regulation to be meaningful, it must extend beyond technical standards and embed cultural safety, equity, and accountability. Elders and Older People have emphasised the importance of plain-language information, trusted prescribing through Aboriginal Community Controlled Health Organisations, and safeguards against polypharmacy risks. At the same time, regulatory changes must avoid pushing people towards illicit markets, where health and justice risks are far greater.

NATSIAACC urges the TGA to ensure that Aboriginal and Torres Strait Islander voices are no longer absent from decision-making. Embedding Aboriginal and Torres Strait Islander governance, funding culturally led research, and creating accessible reporting and education systems are essential steps toward ensuring safety, trust, and equity.

Ultimately, regulation must protect vulnerable populations without creating new barriers. A balanced, culturally grounded framework will not only improve the safe use of medicinal cannabis but also contribute to restoring trust in healthcare systems for Aboriginal and Torres Strait Islander Elders and older people.

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