PENINGTON INSTITUTE

Penington Institute submission

TGA consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products

October 2025

Drugs and the community

Like it or not, drugs are a part of every society.

It would be naive to think otherwise. And cruel to ignore It.

And, while we don't encourage drug use, there are other things that we will always encourage.

Understanding. Openness. Empathy. Communication.

Our default, as a society, has been to pour scorn on those who "use drugs" and judge them harshly by seeing their problems as self-inflicted.

Human beings are complex, and so is this issue. The reasons people use drugs, including alcohol and pharmaceuticals, are countless.

Risky behaviours are part of being human. We need to understand that, not condemn it.

Judging is easy. Helping is a bit more of a challenge. So, how do we rise to that challenge?

At Penington Institute, we believe in approaching drug use in a safe, considerate and practical way. We seek solutions, not scapegoats. We strive for positive outcomes, not negative stereotypes. We follow evidence and data, but we temper it with compassion and empathy, to create change for the better.

Our focus is on making individuals and families safer and healthier.

Our goal is simple: to help communities and frontline services reduce harm and to make public policy work for the people, not against them.

We won't ever give up on that goal, or the people it exists to serve. It is too easy to judge people who use drugs.

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Executive Summary

Penington Institute appreciates the opportunity to provide a submission to the Therapeutic Goods Administration (TGA) consultation reviewing the safety and regulatory oversight of unapproved medicinal cannabis products.

It is imperative that the TGA take steps to support confidence in medicinal cannabis products and the access pathways for patients. It is equally essential that the TGA consider key contextual features about cannabis in Australia. These features include the demonstrated therapeutic benefits of medicinal cannabis, the lack of clear evidence linking medicinal cannabis to public health harms, and the reality of a parallel illicit market that offers no safety protections and is available to any patient who loses access to prescribed medicinal cannabis.

This submission begins by offering broad perspective on cannabis in Australia, including why the medicinal cannabis framework was created and the rise in associated regulatory concerns. The next section discusses patient safety issues and proposes improvements to patient outcomes data collection to more accurately assess clinical benefits and potential harms attributable to medicinal cannabis products. The next section focusses on product regulations and observes that several regulatory objectives identified by the TGA could be resolved through implementation of a formal product assessment and approval process. The final section considers patient access, highlighting the ongoing unmet need for clinical education and training and recommending the creation of a new system designed to meet medicinal cannabis' unique regulatory requirements rather than repeated adjustments to the current access approval framework.

Each section provides recommendations for TGA consideration as the review process continues, as follows:

1. TGA reforms should include formal analysis of the risks associated with the displacement of medicinal cannabis patients into the illicit market.
2. The TGA should prioritise improvements to patient outcomes data collection and analysis.
3. The TGA should assess and approve products prior to market entry on a cost recovery basis.
4. the TGA should facilitate the development of clinical guidelines and accredited training for healthcare professionals.
5. The TGA should develop a new, purpose-built framework to regulate patient access to medicinal cannabis products.

Overall, Penington Institute agrees that the current review offers a crucial opportunity to improve confidence in the medicinal cannabis regime. In line with the TGA's request for "principles that could be considered when developing regulatory options to address the current issues with medicinal cannabis products," this submission emphasises two basic principles:

- Reforms must be evidence-based and risk-based.
- Reforms must consider overall net health and social impacts.

Given the lack of comprehensive data on health harms linked to prescribed medicinal cannabis, the TGA should proceed cautiously in implementing reforms that could curtail patient access and potentially displace current patients into the unregulated, unsafe illicit market.

Consultation context

Penington Institute concurs with the premise of the TGA's consultation paper: concerns regarding patient safety, the potential for adverse effects, poor quality medical care, and limited regulatory oversight of unapproved medicinal cannabis products warrant appropriate scrutiny. A carefully undertaken review can strengthen confidence in the quality and safety of medicinal cannabis products and make access pathways more effective for prescribers and patients. However, preserving benefits for patients and minimising health risks from cannabis products requires a holistic understanding of Australia's overall approach to cannabis regulation. This context is important when determining the process, pace, and range of potential reforms.

Medicinal cannabis's deep roots

Cannabis has a long and well-documented history of therapeutic use, with records of its application in the management of a wide range of health conditions dating back thousands of years. In Australia, cannabis use for both medical and non-medical purposes has been common and consistent for decades.[1] Cannabis criminalisation throughout the twentieth century did little to stem its widespread use, reflecting both expanding cultural acceptance and the perception of therapeutic value by many Australians who self-medicated in the absence of legally available alternatives.

The establishment of a legal medicinal cannabis regime in Australia in 2016 followed years of sustained campaigning by patients, their families, and advocates.[2] These efforts were particularly focused on ensuring legal and regulated access to cannabis for people living with conditions such as severe paediatric epilepsy, cancer-related symptoms, and chronic pain. Despite limited clinical evidence, patients were using illicit cannabis for medical purposes and experiencing benefits. Sussan Ley, speaking as Minister for Health in 2016, exemplified this understanding while speaking in support of the Coalition government's bill to legalise medicinal cannabis, stating, "first and foremost it is about the patient. The relief that can be provided from these products for certain types of pediatric epilepsy and end-stage chemotherapy associated with cancer is quite well known. But when I speak to the researchers they also talk about relief from pain […] other drugs just cannot help or provide too many unpleasant side effects."[3]

The legalisation of medicinal cannabis and subsequent reforms to patient access processes represent acknowledgement of the therapeutic potential of cannabis and the right of patients to pursue treatment options that can meaningfully improve health and wellbeing, even in the absence of the systematic evidence generally associated with prescribed medications.

In research conducted just prior to the legalisation of medicinal cannabis, the Australian Institute of Health and Welfare (AIHW) National Drug Strategy Household Survey 2016 (NDSHS) found that 85% of Australians supported a change in legislation permitting access to cannabis for medical purposes.

[1] Australian Institute of Health and Welfare. 2024. *National Drug Strategy Household Survey 2022-23*. Canberra: AIHW. Table 5.
[2] Freckelton, Ian. 2016. "Medicinal cannabis law reform in Australia." *Journal of Law and Medicine*, 23(3).
[3] Parliament of Australia, *Parliamentary Debates,* House of Representatives, 10 February 2016.

Subsequent research reinforces that Australians expect governments to enable access to these products so patients can affordably obtain them "at any stage of [their] treatment".[4]

Industry growth

The broadening of access pathways and increasing demand for prescribed cannabis products spurred the development of a rapidly growing industry. While patient access was initially very limited, by 2020 approvals began to increase significantly.[5] TGA data shows that the volume[6] of medicinal cannabis products used by patients roughly doubled from 2022 to 2023,[7] and doubled again from 2023 to 2024.[8]

The sector's growth has outpaced regulatory monitoring capacity, as highlighted by a spate of media stories about allegedly unethical prescribing and distribution practices. Meanwhile, regulatory oversight is divided. Action has been taken in certain areas, such as the TGA pursuing companies for unlawful advertising of medicinal cannabis products[9] and investigations of alleged breaches by individual healthcare workers by the Australian Health Practitioner Regulation Agency (Ahpra)[10] and state health boards.[11] Other areas, such as the operation of high-volume, vertically integrated medicinal cannabis supply models,[12] have fallen into a regulatory grey zone that has hindered effective oversight.

The intensifying focus on industry practices has not been complemented by the collection of robust evidence regarding product safety and patient wellbeing. Attention to health harms has been driven largely by anecdotal reports rather than detailed, comprehensive data. Regulators should be aware of potential stigma toward medicinal cannabis due to its association with the unregulated illicit market and non-medical use, especially when deciding what reforms will best serve patients.

Achieving sensible reform

Penington Institute believes that questions about medicinal cannabis cannot be neatly cleaved from Australia's broader cannabis policy confusion. The burden of disease attributable to cannabis is lower than that of many other illicit drugs, as well as alcohol and tobacco.[13] NDSHS data show that Australians express less concern about cannabis compared to various other substances, there is overwhelming support for removing criminal penalties for using cannabis, and more Australians

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[4] Gething, Katrina, Paul Scuffham and Richard Norman et al. 2025. "Australian public preferences for the provision of medicinal cannabis: A discrete choice experiment." *Pharmacoeconomics and Policy,* 1(2).
[5] MacPhail, Sara, Miguel A. Bedoya-Perez and Rhys Cohen et al. 2022. "Medicinal Cannabis Prescribing in Australia: An Analysis of Trends Over the First Five Years." *Frontiers in Pharmacology* 13.
[6] Measured in the number of units sold.
[7] Penington Institute. 2024. *Cannabis in Australia 2024.* Melbourne: Penington Institute.
[8] Rhys Cohen. 2025. "Market update: insights from unit sales data." Presentation at *ACannabis 2025,* August 12, 2025.
[9] TGA. 2025. Dispensed Pty Ltd issued infringement notices and directed to cease alleged unlawful advertising of medicinal cannabis.
[10] Elise Worthington and Celina Edmonds. 2025. "AHPRA takes action against more than 50 practitioners in medicinal cannabis crackdown." *ABC News* July 9, 2025.
[11] Penington Institute. 2024. *Cannabis in Australia 2024.* Melbourne: Penington Institute.
[12] Penington Institute. 2024. *Cannabis in Australia 2024.* Melbourne: Penington Institute.
[13] Australian Institute of Health and Welfare. 2024. *Australian Burden of Disease Study 2024*. Canberra: AIHW. Table S8; Australian Institute of Health and Welfare. 2025. *Alcohol, tobacco & other drugs in Australia*. Canberra: AIHW.

support than oppose legalising and regulating cannabis for non-medical purposes[14] – leaving existing punitive, restrictionist cannabis policies ever more out of step with community expectations.

Many of the current challenges facing the medicinal cannabis framework could be resolved by legalising and regulating cannabis for adult personal use. Establishing a strictly regulated adult-use market would reduce demand for unapproved medicinal cannabis products and relieve pressure on the medical framework, which should be reserved for patients requiring clinical oversight. Legalisation and careful regulation would also create a clearer distinction between medical and non-medical cannabis use, recognising that these are different contexts that require different regulatory responses.

Nonetheless, in the absence of such reforms, the medicinal cannabis framework can and should be improved to ensure people and communities are adequately protected and supported. There are many possible approaches to reforming the medicinal cannabis system, ranging from incremental adjustments to broader structural changes. Any reforms should be guided by these clear and consistent principles:

- Reforms must be grounded in evidence and be proportionate to the risks associated with cannabis use. All medications and intoxicating substances carry some level of risk that can be managed but never eliminated, which requires policy responses to be proportionate and pragmatic.
- Reforms must consider overall net health and social impacts. This includes considering how reforms intended to improve patient safety could lead to more people accessing illicit, unregulated cannabis without any clinical supervision, exposing them to considerably greater health, safety, and legal risks.

By applying these principles throughout the TGA review process, policymakers can ensure that changes to the medicinal cannabis framework are both effective and sustainable, creating a system that meets patient needs while protecting individual and public health.

[14] Australian Institute of Health and Welfare. 2023. *National Drug Strategy Household Survey 2022–2023*. Canberra: AIHW. Tables 11.5, 11.23, 11.31.

Patient safety

The TGA consultation paper notes increasing clinical concern regarding the use of prescribed medicinal cannabis products, which may cause psychiatric and physical harms, especially when used in high doses by members of vulnerable populations. According to the paper, these concerns "appear to correlate" with the rise of access to unregistered medicinal cannabis products.

Amid an ongoing deficit of clear, systematic data about linkages between medicinal cannabis and health harms, these concerns have been largely based on anecdotal data. Such data are useful and valid forms of evidence, and cannabis can cause harms, especially among vulnerable populations. Just as the experiences of patients who report cannabis's therapeutic benefits should be respected,[15] so too should the observations of healthcare professionals who have reported increases in cannabis-related harms following medicinal cannabis legalisation. However, both the principle of grounding reforms in clear evidence and the principle of ensuring net health benefits suggest a need for more comprehensive evidence to guide substantive policy reforms.

Evidence for the increased use of cannabis for medical purposes

The number of Australians accessing prescribed medicinal cannabis has increased rapidly in recent years, but available data do not clarify whether this has increased the total number of Australians who use cannabis. Data from the NDSHS do indicate, however, that a substantial number of people who currently use prescribed medicinal cannabis had previously been using illicit cannabis for medical purposes.

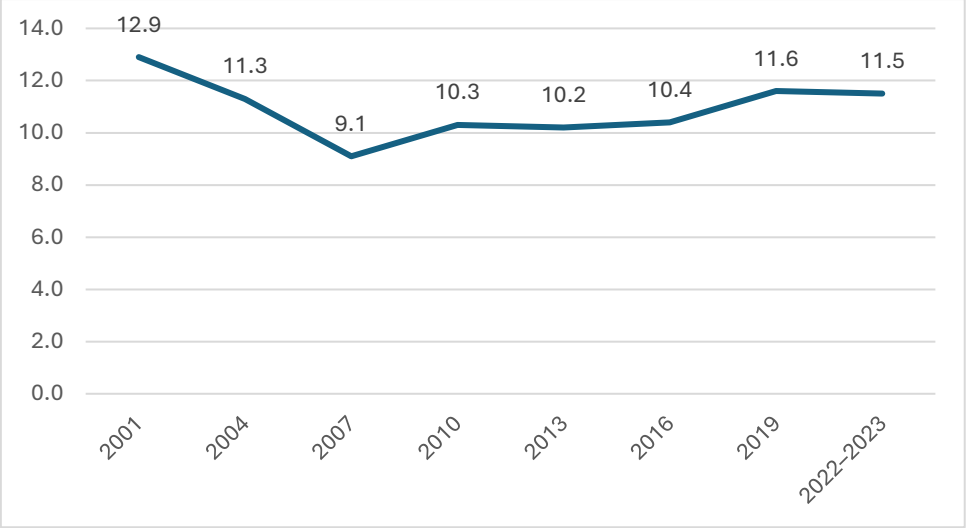
As Figure 1 shows, rates of cannabis use in the community have remained fairly stable for at least 20 years. In 2022-23, 11.5% of Australians used cannabis in the past 12 months, compared to 11.6% in 2019, 10.4% in 2016, and 12.9% in 2001.[16] However, among people who use cannabis, the proportion of people who use cannabis daily increased from 14.4% in 2019 to 18% in 2022-23.[17]

[15] Arkell, Thomas R., Luke A. Downey, and Amie C. Hayley, et al. 2023. "Assessment of Medical Cannabis and Health-Related Quality of Life." *JAMA Network Open* 6(5); Tait, Margaret-Ann, Daniel S.J. Costa, and Rachel Campbell, et al. 2023. "Health-related quality of life in patients accessing medicinal cannabis in Australia: The QUEST initiative results of a 3-month follow-up observational study." *PLOS ONE* 18(9).

[16] Australian Institute of Health and Welfare. 2024. *National Drug Strategy Household Survey 2022-23*. Canberra: AIHW. Table 5.50.

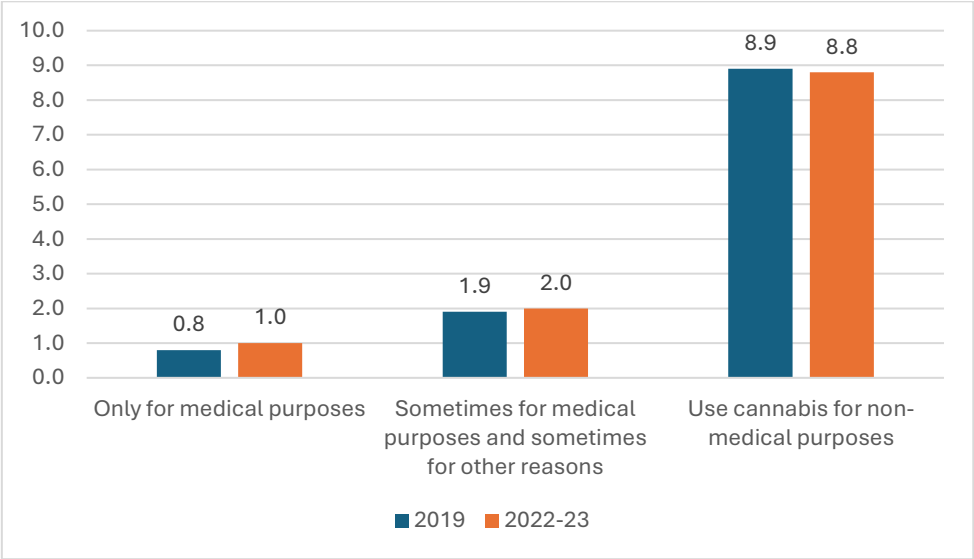
[17] Australian Institute of Health and Welfare. 2024. *National Drug Strategy Household Survey 2022-23*. Canberra: AIHW. Table 5.33.

Figure 1: Recent use of cannabis among Australians aged 14+, percent, 2001 to 2022-23



In 2019, the AIHW began asking people about their use of cannabis for medical purposes. That year, 2.7% of Australians reported using cannabis for medical purposes at least some of the time, and 0.8% of Australians used cannabis exclusively for medical purposes in the past 12 months.[18] As Figure 2 indicates, there were only small increases in these figures by 2022-23.

Figure 2: Purpose of cannabis use by Australians aged 14+, percent, 2019 to 2022-23

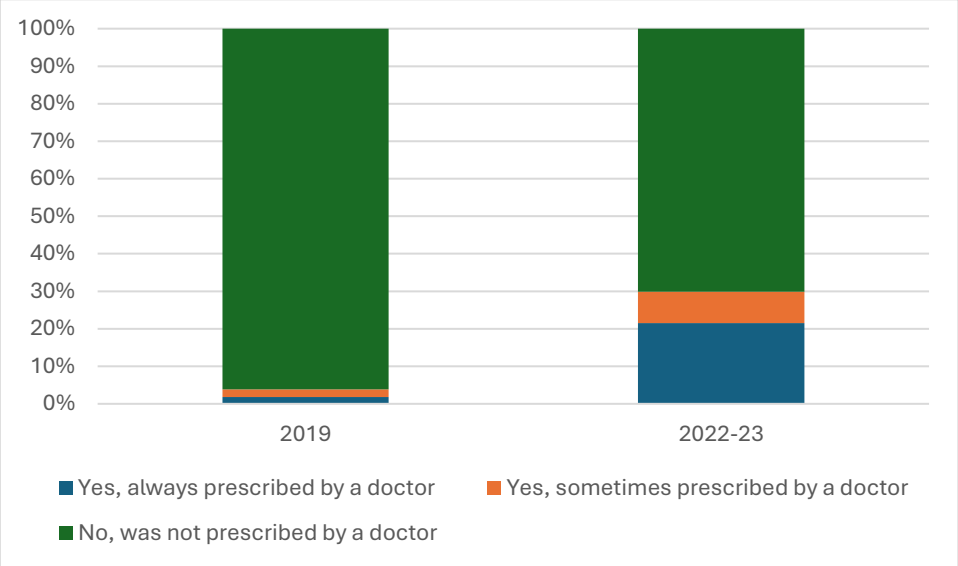


Strikingly, as illustrated in Figure 3, among Australians reporting cannabis use for medical purposes, the proportion who were able to access prescribed and regulated medicinal cannabis products via a healthcare professional rose substantially in this period. Just 3.9% of recent medicinal cannabis users reported their cannabis was always or sometimes prescribed by a doctor in 2019, a number that

[18] Australian Institute of Health and Welfare. 2024. *National Drug Strategy Household Survey 2022-23*. Canberra: AIHW. Table 8.1.

jumped to 29.9% by 2022-23, with 21.5% always being prescribed and 8.4% sometimes being prescribed.[19]

Figure 3: Cannabis prescription status among Australians aged 14+ who report recent cannabis use, 2019 to 2022-23



The sharp rise in prescribed use suggests that many people who use cannabis for medical purposes are replacing unregulated, criminally sourced cannabis with quality-assured products administered under medical supervision. This is likely to be a net benefit to the health and safety of people who use cannabis and the broader community, as recent Australian research has found that people prescribed medicinal cannabis are less likely to consume cannabis via smoking or to experience adverse effects.[20] Conversely, should access to regulated medicinal cannabis be interrupted, it is likely that most affected people would be able to easily migrate back to the illicit market and revert to using unregulated cannabis for medical purposes, exposing them to unnecessary risks.

Recommendation 1: TGA reforms should include formal analysis of the risks associated with the displacement of medicinal cannabis patients into the illicit market

TGA reforms must ensure that patients are not unintentionally relegated to accessing illicit, unregulated cannabis. As part of a risk-based approach, any proposed TGA reforms should include analysis of the potential for patient migration into the illicit market and the health risks this entails, including exposure to unregulated, untested products and disengagement from clinical care and oversight.

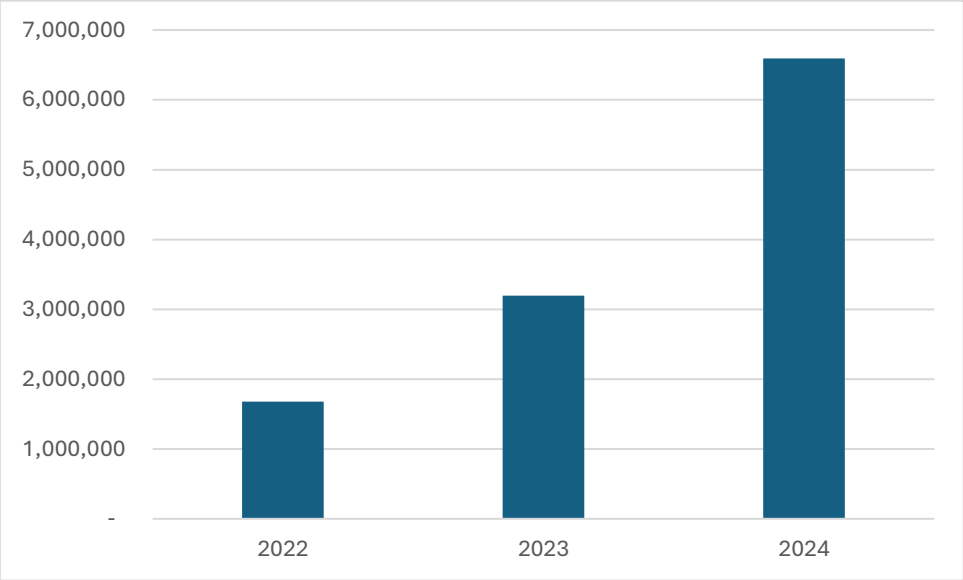
Evidence for increased health harms from medicinal cannabis use

The volume of medicinal cannabis products accessed by Australian patients accelerated following the November 2021 patient access reforms developed and implemented by the TGA.[21] As Figure 4

[19] Australian Institute of Health and Welfare. 2024. *National Drug Strategy Household Survey 2022-23*. Canberra: AIHW. Table 8.3.
[20] Mills, Llewellyn, Jonathan C. Arnold, and Anastasia Suraev et al. 2024. "Medical cannabis use in Australia seven years after legalisation: findings from the online Cannabis as Medicine Survey 2022–2023 (CAMS-22)." Harm Reduction Journal 21(104).
[21] NPS MedicineWise. 'Unapproved' medicinal cannabis: changes to prescribing pathway.

demonstrates, the volume of medicinal cannabis products sold to patients reached 1.68 million units in 2022, 3.20 million units in 2023, and 6.59 million units in 2024.[22]

Figure 4: Medicinal cannabis units sold, 2022 to 2024



Given cannabis's potential to produce acute and chronic health harms, it is likely that some patients have experienced negative outcomes. If increased access to prescribed medicinal cannabis is an important contributor to cannabinoid-related harms, we would expect to see indicative evidence of an increase in such harms over this period. However, there is very little publicly available, systematic data that offer clear understanding of medicinal cannabis's role in the prevalence, nature, and trajectory of cannabinoid-related harms – and the visible data does not reveal any evident causal connection between medicinal cannabis access and reported harms.

Hospitalisation data

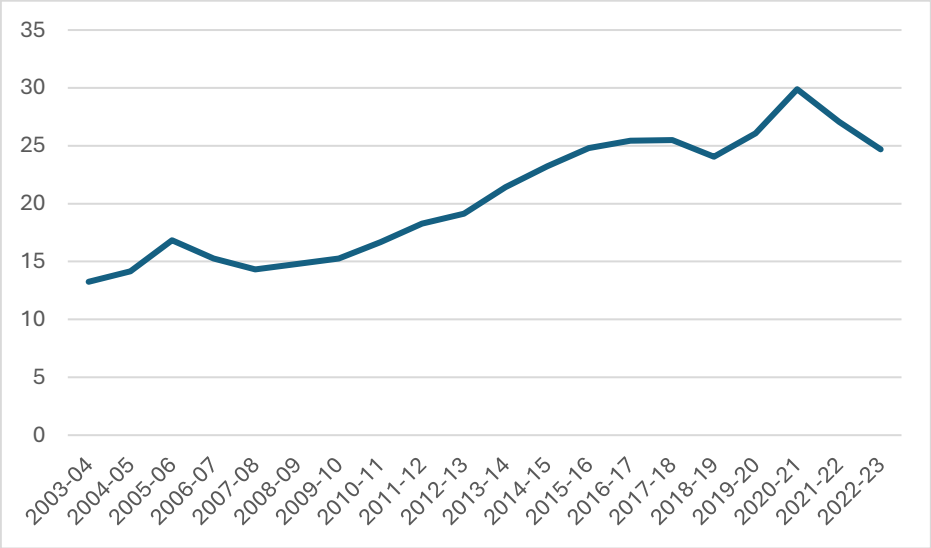
The TGA consultation paper highlights AIHW data showing an all-time peak in the population-weighted rate of cannabis-related hospitalisations in 2019-20, implying a correlation between increased access to medicinal cannabis and rising hospitalisations. This is the sole data point provided in the consultation paper to illustrate population-level health harms. However, the hospitalisation data do not distinguish between prescribed and illicit cannabis use, or between the use of botanical cannabis products and highly risky synthetic cannabinoid receptor agonists (SCRAs). This lack of granularity makes it challenging to infer the specific contribution of prescribed medicinal cannabis use on hospitalisation rates.

Observing hospitalisation data at additional time points raises further doubt about the strength of the data linking medicinal cannabis access to increased harms. More recent data depicted in Figure 5 shows that cannabis-related hospitalisations actually peaked in 2020-2021, not 2019-20, and

[22] Rhys Cohen. 2025. "Market update: insights from unit sales data." Presentation at *ACannabis 2025,* August 12, 2025.

subsequently declined. As of 2022-23, the rate was lower than in 2015-16, before the legalisation of medicinal cannabis.[23]

Figure 5: Cannabinoid-related hospitalisations, age-adjusted rate per 100,000, 2003-04 to 2022-23



The visible long-term rise in cannabinoid-related hospitalisation rates requires attention, but the most recent trends do not correlate with trends in access to prescribed medicinal cannabis. Indeed, cannabinoid-related hospitalisation rates doubled from 2003-04 to 2015-16 – before medicinal cannabis was legalised – and declined in the post-2021 period even as medicinal cannabis prescribing rates rose sharply.[24]

Adverse event data

The TGA consultation paper also highlights a significant increase in the number of reported medicinal cannabis-related adverse events (AE), which broadly correlates with the increase in the volume of medicinal cannabis units sold over time. This is unsurprising, as all prescribed psychoactive substances pose some risk. Moreover, people using illicit cannabis for medical reasons would be far less likely to report an AE to the TGA or their treating physician than someone who is being prescribed medicinal cannabis by a doctor.

According to recent media reports, in 2022-23 55 AEs were reported to the TGA, growing to 246 in 2023-24 and 314 in 2024-25. Most AEs involved symptoms such as anxiety, headache, and nausea, although more serious symptoms such as psychosis and hallucinations have also been reported.[25] A very small number of AEs contain "suspected associations" between the use of liquid vape medicinal cannabis products and the onset of some kind of respiratory symptom.[26] However, no verified reports have confirmed that these products are causing e-cigarette and vaping-associated lung injury (EVALI), as suggested in the TGA consultation paper. Evidence from overseas demonstrates that

[23] Chrzanowska, Agata, Nicola Man, and Rachel Sutherland, et al. 2025. *Trends in drug-related hospitalisation in Australia, 2003-2023*. Sydney: NDARC.
[24] Chrzanowska, Agata, Nicola Man, and Rachel Sutherland, et al. 2025. *Trends in drug-related hospitalisation in Australia, 2003-2023*. Sydney: NDARC.
[25] Matilda Marozzi. 2025. "TGA yet to investigate the safety of most medicinal cannabis products." *ABC News* September 10, 2025.
[26] Therapeutic Goods Administration. *FOI 26-1890*. Canberra: TGA.

cannabis-related EVALI cases are predominantly caused by excipients used in illicit, unregulated cannabis vapes,[27] a risk that can be mitigated through regulated access to quality-controlled products.

Unfortunately, AE data is incomplete and unreliable. Reports only reflect the suspected involvement of medicinal cannabis, based on observations which can be made by any member of the community, and reports are not investigated or verified by the TGA. This means AE data can be overinclusive, erroneously ascribing some AEs to the use of medicinal cannabis products, and underinclusive, as many AEs likely continue to go unreported.

Psychiatric data

One of the key health concerns raised in the TGA consultation paper is a reported increase in Australians being prescribed medicinal cannabis and subsequently developing symptoms of psychosis.

The association between cannabis use and psychotic illnesses has been extensively studied, but there is little scientific consensus. The best evidence suggests that while cannabis on its own is unlikely to cause schizophrenia or similar conditions, it may contribute to the onset of latent psychotic disorders, particularly if used heavily from a young age, and for people with genetic risk factors.[28]

The involvement of medicinal cannabis in cases of psychosis was prominently articulated in a 2023 publication by clinicians at an early psychosis service in Queensland, who reported an increase in the number of patients who had been prescribed medicinal cannabis prior to presenting at the service.[29] Other stakeholders and researchers, including Ahpra,[30] the Royal Australian and New Zealand College of Psychiatrists QLD branch,[31] and health science academics[32] have subsequently cited concerns about prescribed medicinal cannabis leading to the onset of psychosis.

Rates of cannabinoid-related psychosis resulting in hospitalisation have increased in recent years. As Figure 6 indicates, the largest increase in hospitalisation rates for psychotic disorder occurred between 2009 and 2017, before medicinal cannabis became accessible. A second spike occurred between 2018-2019 and 2020-2021, when use of prescribed medicinal cannabis was starting to rise. However, as with overall cannabinoid-related hospitalisations, the 2021-2023 period in which access to prescribed medicinal cannabis products increased exponentially correlated with a modest *decline* in cannabinoid-related hospitalisation rates for psychotic disorder.[33]

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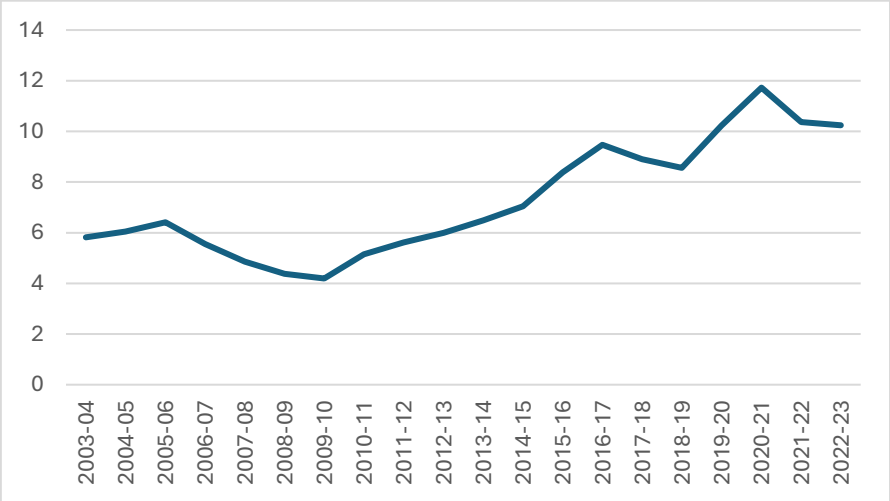
[27] Marracco, Antonella, Dilpreet Singh, and David C. Christiani, et al. 2023. "E-Cigarette Vaping Associated Acute Lung Injury (EVALI): State of science and future research needs." *Critical Reviews in Toxicology* 52(3).
[28] Volkow, Nora D., James M. Swanson, and A. Eden Evins, et al. 2016. "Effects of Cannabis Use on Human Behavior, Including Cognition, Motivation, and Psychosis: A Review." *JAMA Psychiatry* 73(3).
[29] Lupke, Katie, Amy Gerard, and Brendan Murdoch, et al. 2023. "Impacts of medicinal cannabis on an early psychosis service." *Australasian Psychiatry* 32(2).
[30] Ahpra. 2025. Guidance on medicinal cannabis prescribing targets unsafe practice.
[31] Janelle Miles and Elise Worthington. 2024. "Doctors warn of significant increase in people hospitalised with psychosis after being prescribed medicinal cannabis." *ABC News* July 21, 2024.
[32] Rose Cairns and Nicholas Buckley. 2025. "Medicinal cannabis concerns include psychosis and child poisonings. We're not the only ones worried." *The Conversation* September 12, 2025.
[33] Chrzanowska, Agata, Nicola Man, and Rachel Sutherland, et al. 2025. *Trends in drug-related hospitalisation in Australia, 2003-2023*. Sydney: NDARC.

Figure 6: Cannabinoid-related hospitalisations for psychotic disorder, age-adjusted rate per 100,000, 2003-04 to 2022-23



To be clear, healthcare practitioners should always exercise caution if prescribing products containing tetrahydrocannabinol (THC) to people with preexisting mental health vulnerabilities and should avoid prescribing THC to people with a personal or family history of psychosis.[34] However, people vulnerable to psychotic disorders have a higher propensity toward drug use, including cannabis.[35] It is difficult to ascertain whether medicinal cannabis access is increasing the probability of the onset of psychosis, or whether people with mental health vulnerabilities who previously used illicit cannabis are seeking access to prescribed products.

The inability to properly monitor for potential emerging health risks is a cause for concern. However, without a clearer understanding of the health impacts of prescribed medicinal cannabis, substantive policy reforms in this area are at risk of causing unknown and potentially counterproductive outcomes.

Recommendation 2: The TGA should prioritise improvements to patient outcomes data collection and analysis

Systematic evidence regarding both the potential risks and benefits associated with medicinal cannabis products is notably deficient. Patient health and safety should remain the primary consideration, and psychiatric risks in particular require systematic monitoring and accurate reporting so that clinicians, regulators, and patients have access to reliable information. Harms must also be weighed against the well documented clinical benefits experienced by patients[36] to enable a balanced assessment of current policies and potential reforms.

The TGA should work towards strengthening the evidence base by supporting improvements in the collection and analysis of patient outcomes data. One potential method involves the systematic use of real-world evidence through the extraction of de-identified data from electronic medical records.

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[34] Arnold, Jonathan C. 2021. "A primer on medicinal cannabis safety and potential adverse effects." *Australian Journal of General Practice* 50(6).
[35] Australian Institute of Health and Welfare. Mental health and substance use.
[36] National Academies of Sciences, Engineering, and Medicine. 2017. *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research*. Washington: The National Academies Press.

Analysing linked de-identified data is particularly useful for tracking clinical and social outcomes in cohorts that are otherwise hard to reach and study. Penington Institute's work on harm minimisation involving other prescribed and illicit drugs routinely draws on research that harnesses these datasets, especially longitudinal research on health service utilisation[37] and assessment of the effectiveness of clinical treatment options such as opioid pharmacotherapy.[38]

The value of such an approach to address evidence gaps relating specifically to medicinal cannabis has already been identified overseas[39] and has been proposed by other stakeholders in submissions to this consultation.[40] The TGA should also consider how patient safety data collected through proposed enhanced pharmacovigilance requirements for sponsors can be integrated with these observational datasets.

Product regulations

Unlike registered medicines, unapproved medicinal cannabis products are not assessed for quality, safety, or efficacy. Products are expected to comply with quality standards, but currently the TGA does not test all products for compliance, instead testing an unknown number of products selected on the basis of risk.

The challenges regarding regulatory oversight of unapproved medicinal cannabis products are well documented, including a perceived "unequal regulatory burden" that advantages imported products relative to Australian ones;[41] a lack of "adequate cost recovery methods" to fund enforcement;[42] and the absence of a requirement to provide regulators with evidence of compliance before products enter the market.[43] The TGA has broad regulatory and legal powers to investigate products for compliance. How often these powers are used is unknown, but regulators acknowledged that no surveillance tests were performed on imported products in the 12 months to April 2024,[44] suggesting infrequent application.

Registration of medicinal cannabis products on the Australian Register of Therapeutic Goods (ARTG) would mitigate these problems. ARTG registration would ensure products are assessed for quality,

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[37] Jones, Nicola R., Matthew Hickman, and Sarah Larney, et al. 2021. "Hospitalisations for non-fatal overdose among people with a history of opioid dependence in New South Wales, Australia, 2001–2018: Findings from the OATS retrospective cohort study." *Drug and Alcohol Dependence* 218(108354).

[38] Bharat, Chrianna, Sarah Larney, and Sebastiano Barbieri, et al. 2021. "The effect of person, treatment and prescriber characteristics on retention in opioid agonist treatment: a 15-year retrospective cohort study." *Addiction* 116(11).

[39] Schlag, Anne Katrin, Saoirse E. O'Sullivan, and Rayyan R. Zafar, et al. 2021. "Current controversies in medical cannabis: Recent developments in human clinical applications and potential therapeutics." *Neuropharmacology* 191.

[40] Montu Group. 2025. *Response to Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products*. Melbourne: Montu Group.

[41] Therapeutic Goods Administration. *Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products*. Canberra: TGA.

[42] Graham, Myfanwy, Vivian Chiu and Daniel Stjepanovic, et al. 2023. "A provisional evaluation of Australia's medical cannabis program." *International Journal of Drug Policy* 112(104210).

[43] Penington Institute. 2024. *Cannabis in Australia 2024*. Melbourne: Penington Institute.

[44] Tyrone Dalton and Else Kennedy. 2024. "Imported medicinal cannabis sold without testing for Australian standards, industry warns." *ABC News* 9 April 2024.

safety, and efficacy; shift many medico-legal risks and responsibilities from prescribers to product sponsors; and resolve other outstanding issues regarding product consistency, provenance, labelling, and pharmacovigilance.

Unfortunately, traditional ARTG registration is incompatible with the TGA's stated intention to not remove access to medicinal cannabis products. As the consultation paper notes, sponsors have few commercial incentives to pursue registration. This is not due to particularities of the ARTG – a mere handful of cannabis-based medicines have ever been registered in any country[45] due to the risk, expense, and scientific challenges associated with research and commercialisation of these products.[46] Again, context is relevant: medicinal cannabis companies must compete with established producers of unregulated cannabis, limiting the ability to recoup substantial investment.

Withdrawal of patient access to existing unapproved medicinal cannabis products, even if sponsors were provided time to pursue ARTG registration, would likely lead to a retraction of nearly all currently available products. Continuity of care for hundreds of thousands of patients would be interrupted and many patients would doubtless return to – or seek out for the first time – Australia's affordable and easily accessible criminal cannabis market. In addition to a complete lack of quality assurance and exposure to drugs far riskier than cannabis, illicit market suppliers have a history of targeting sick and vulnerable Australians to sell "fake, poisonous and intoxicating [cannabis] products" when access to legal, regulated products is restricted.[47]

This necessary context reinforces the need for caution and careful analysis before undertaking dramatic reforms. However, Penington Institute agrees that product quality, safety, and regulatory oversight for unapproved medicinal cannabis products must be improved, and effective measures are readily available. The reforms proposed below can address many of the concerns raised by the TGA, ensuring regulatory controls are appropriate and sufficient.

Recommendation 3: The TGA should assess and approve products prior to market entry on a cost recovery basis

Medicinal cannabis products should be subject to an approval process that assesses compliance with quality and safety standards prior to market entry, without requiring sponsors to demonstrate therapeutic efficacy, and all products and sponsors in the market should always be known to the TGA. To improve pharmacovigilance monitoring and reporting, relevant legal and regulatory responsibilities should be transferred from prescribers to product sponsors. Quality standards requirements should be extended to medical devices used to administer medicinal cannabis, and consistent labelling should clearly communicate the regulatory status of these products, specifying they have not been assessed for efficacy. Regulatory oversight would be funded by fees or levies imposed on sponsors. Following an appropriate transition period, it is likely that sponsors would only

[45] De Souza, Maira Ribeiro, Amélia Teresinha Henriques, and Renata Pereira Limberger. 2022. "Medical cannabis regulation: an overview of models around the world with emphasis on the Brazilian scenario." *Journal of Cannabis Research* 4(33).
[46] Namdar, Dvora, Omer Anis, and Patrick Poulin, et al. 2020. "Chronological Review and Rational and Future Prospects of Cannabis-Based Drug Development." *Molecule* 25(20), 4821; Bonn-Miller, Marcel O., Mahmoud A. ElSohly, and Mallory J. E. Loflin, et al. 2018. "Cannabis and cannabinoid drug development: evaluating botanical versus single molecule approaches." *International Review of Psychiatry* 30(3).
[47] Christiane Barro. 2018. "The cannabis oil 'healers' preying on Australia's sick and dying." *The New Daily* October 13, 2018.

seek approval for a small subset of the more than 1,100[48] products currently available, enhancing capacity for regulatory oversight.

Two potentially viable pathways to achieve this outcome include creating a new pathway for registration within the ARTG, and creating a stand-alone assessment and approval process similar to the system used in New Zealand.

Creating a new pathway for ARTG registration has already been proposed in a 2022 internal TGA briefing paper.[49] As noted in the paper, this would enable the TGA to require sponsors to demonstrate that all products meet minimum quality and safety requirements, including Good Manufacturing Practice (GMP) certification, consistent labelling, and enhanced pharmacovigilance obligations. It would not, however, require products to have been evaluated for effectiveness. A version of this proposal has been articulated by other stakeholders during the current consultation process, through the creation of a "declared medicinal cannabis products category".[50]

If ARTG amendments prove impractical, an alternative approach would draw lessons from the system adopted in New Zealand. Instead of creating a new pathway or category for medicinal cannabis products to be approved by Medsafe, New Zealand legislators created a stand-alone framework specifically for medicinal cannabis products. The framework sets out quality and safety standards, requires sponsors to submit products for assessment and approval by the New Zealand Ministry of Health prior to market entry,[51] and sets associated fees.[52] The government then maintains a public list of approved products.

Patient access

Allegations of inappropriate prescribing practices are among the primary drivers of concern about the medicinal cannabis sector. One key way the current consultation and review process can improve health outcomes is by exploring how the TGA can support the development of appropriate prescribing practices, reduce potential risks to patients, and improve patient access processes and oversight.

Supporting practitioners

While the TGA is just one of the agencies responsible for patient safety and care quality, it can play a central role in ensuring that prescribers are well-informed and supported. Enhancing prescriber knowledge and confidence is essential for maintaining patient safety, achieving therapeutic benefits, and fostering public trust in the regulatory framework.

The need to educate and support prescribers was identified at the outset of Australia's medicinal cannabis framework. In 2017 the TGA took the unusual step of developing clinical guidance

[48] Therapeutic Goods Administration. 2025. *FOI 25-0145*. Canberra: TGA.
[49] Therapeutic Goods Administration. 2022. *Briefing Paper: Medicinal cannabis patient access reforms*. Canberra: TGA.
[50] Montu Group. 2025. *Response to Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products*. Melbourne: Montu Group.
[51] New Zealand Ministry of Health. Requirements for the medicinal cannabis minimum quality standard.
[52] New Zealand Ministry of Health. Application fees related to a medicinal cannabis licence.

documents for medicinal cannabis prescribing.[53] At the time, the Australian Advisory Council on the Medicinal Use of Cannabis, a body formed to provide the Assistant Minister for Health and Aged Care with expert advice, noted "a need to ensure that the general community and medical practitioners understand that these documents will be revised and updated with emerging data on safety and efficacy as further medical evidence comes to hand".[54] Despite the steady accumulation of data from studies in overseas jurisdictions, clinical evidence in the guidance documents was last updated in February 2020.

Since then, the need for updated clinical guidance has been frequently identified but rarely addressed, in part because the anticipated arrival of new ARTG-registered medicinal cannabis products – with clearly established treatment protocols for specific indications – has largely failed to materialise. Prescriber education and formal clinical guidelines for medicinal cannabis have been recommended by a 2018 study of Australian general practitioners;[55] the 2020 *Senate Inquiry into barriers to patient access to medicinal cannabis in Australia;*[56] a 2022 study of Australian general practitioners;[57] a 2023 analysis of Australian and international clinical guidance resources;[58] a 2024 study of Australian healthcare practitioners;[59] the 2024 Ahpra roundtable on medicinal cannabis prescribing;[60] and the 2025 Queensland Health *Medicinal Cannabis Action Plan*.[61]

Responsibility for developing clinical guidelines, accreditation of medical training, and regulating the professional conduct of medical practitioners rests primarily with the relevant professional medical bodies and Ahpra rather than the TGA. However, a lack of coordinated action is contributing to the concerns the TGA seeks to address through the current consultation process.

Recommendation 4: the TGA should facilitate the development of clinical guidelines and accredited training for healthcare professionals

The TGA should take proactive steps to engage with professional medical bodies and other regulatory agencies to better understand the obstacles that have prevented the development of clinical guidelines and accredited education programs. Where feasible, the TGA should assist in identifying solutions and facilitating collaboration between stakeholders to address these barriers.

Supporting the education and training of healthcare practitioners is a practical and evidence-based way to address patient safety issues the TGA has expressed concern about, such as instances of

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[53] TGA. Medicinal cannabis - guidance documents.
[54] Office of Drug Control. 2018. *The Australian Advisory Council on the Medicinal Use of Cannabis (AACMC), Communique #4*. Canberra: ODC.
[55] Karanges, Emily A., Anastasia Suraev, and Natalie Elias, et al. 2018. "Knowledge and attitudes of Australian general practitioners towards medicinal cannabis: a cross-sectional survey." *BMJ Open* 8(7).
[56] Senate Standing Committee on Community Affairs. 2020. *Current barriers to patient access to medicinal cannabis in Australia*. Canberra: Parliament of Australia.
[57] Bawa, Zeeta, Danielle McCartney, and Ramesh Manocha, et al. 2022. "Knowledge, experiences, and attitudes of Australian General Practitioners towards medicinal cannabis: a 2021–2022 survey." *BMJ Primary Care* 23(330).
[58] Graham, Myfanwy, Elianne Renaud, and Catherine J. Lucas, et al. 2023. "Medicinal Cannabis Guidance and Resources for Health Professionals to Inform Clinical Decision Making." *Clinical Therapeutics* 45(6).
[59] Dobson, Olivia, Michaela Barber, and Myfanwy Graham, et al. 2024. "'The wild west of medicine': A qualitative investigation of the factors influencing Australian health-care practitioners' delivery of medicinal cannabis." *Drug and Alcohol Review* 43(5).
[60] Ahpra. 2024. Regulators come together as one million Australians turn to medicinal cannabis treatments.
[61] Queensland Health. 2025. *Medicinal cannabis in Queensland Action plan (2025-2026).* Brisbane: QLD Health.

poor-quality medical care, the use of emerging dose formats, and products with higher THC concentrations. Supporting prescribers is likely to result in more consistent and safe clinical practice, more systematic adverse event reporting, and better health outcomes for patients. In contrast, relying on blunt regulatory measures such as blanket restrictions on product potency or formats risks inadvertently limiting treatment options for patients with legitimate clinical needs for higher doses of THC.

Approval processes

The SAS and AP pathways were established to allow exceptional, limited access to medicines and medical devices not currently registered on the ARTG and were not intended to provide large-scale or routine access to unregistered medicines. The mismatch between the schemes' intention and their subsequent evolution creates two key challenges. First, the schemes impose a considerable and growing regulatory and administrative burden on both prescribers and the TGA. Second, the schemes do not properly enable the TGA to oversee, monitor, or report on the extent and nature of access in a comprehensive and efficient manner.

Medicinal cannabis has already been the catalyst for two substantial reforms to the SAS and AP pathways, implemented in 2018 and 2021, respectively.[62] Overall, these reforms successfully achieved their stated aim of expanding access to medicinal cannabis through reduction of administrative barriers. However, these measures have also highlighted the inherent limitations of continually adjusting the SAS and AP frameworks to accommodate what is effectively routine access to unapproved products. Further adjustments to the pathways may be helpful, but the more sustainable solution would be to develop a dedicated patient access framework designed specifically for medicinal cannabis.

Recommendation 5: The TGA should develop a new, purpose-built framework to regulate patient access to medicinal cannabis products

Developing a new framework, instead of further amending the SAS and AP, would enable the TGA to pursue many of the objectives and opportunities identified in the consultation paper. For example:

- A dedicated framework could be structured to ensure that the TGA has access to accurate, comprehensive, and timely data about patient numbers, demographics, conditions treated, and products prescribed.
- The current medicinal cannabis product categorisation system could be reviewed and potentially replaced with a risk-based classification model that takes into account both THC content and route of administration. This would support the TGA to differentiate between lower- and higher-risk prescribing more clearly, potentially enabling notification-only requirements for lower-risk prescribed products and indications while retaining or fortifying safeguards and oversight for higher-risk prescribing.
- The prescribing practices of individual healthcare practitioners could be systematically collected and shared with relevant government and regulatory bodies. This would enable the identification of patterns that may present safety or quality concerns, thereby supporting appropriate interventions and contributing to better patient outcomes.

[62] MacPhail, Sara, Miguel A. Bedoya-Perez and Rhys Cohen et al. 2022. "Medicinal Cannabis Prescribing in Australia: An Analysis of Trends Over the First Five Years." *Frontiers in Pharmacology* 13.

The creation of a reimagined framework would be a significant undertaking requiring legislative and regulatory amendments. While the specifics of a proposed framework would need to be carefully developed and considered in consultation with patients, prescribers, regulators, and community representatives, the potential benefits would be considerable.

Conclusion

Penington Institute is committed to supporting patient access to medicinal cannabis through a safe, affordable, and reliable framework that improves health outcomes and protects patients from the risks associated with both the illicit market and inadequate oversight of regulated products.

The legalisation of medicinal cannabis in Australia was a laudable policy reform intended to alleviate suffering and improve health and wellbeing. Governments must now ensure that the medicinal cannabis framework continues to achieve those outcomes in a sustainable way that satisfies community expectations. We commend the TGA for engaging in a thorough and transparent process to find solutions to this significant regulatory challenge.

As described in this submission, consideration of medicinal cannabis within the broader social context of cannabis is essential to ensure that any proposed reforms do not make patients worse off, particularly by driving them into Australia's vigorous unregulated illicit cannabis market. It is imperative that the TGA take the time to properly evaluate the evidence underpinning any proposed reforms and, if necessary, gather additional data before adopting steps that could affect care provision for many thousands of Australians.

Implementing the recommendations proposed in this submission will directly address many of the concerns described in the TGA consultation paper, including issues with product quality and safety and the operation of the patient access approval framework. More broadly, adherence to both the principles and recommendations will promote a review process that fosters better understanding of the clinical benefits and risks posed by the use of prescribed medicinal cannabis, a higher standard of care, and improved patient outcomes.

Penington Institute remains eager to contribute to the development of policies that effectively balance these difficult questions and produce better results for Australians through safer, healthier communities.