TGA Consultation

Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products

Joint submission

by the

Australian Medicinal Cannabis Association (AMCA)

and the

Medicinal Cannabis Industry Association (MCIA)

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Introduction

We appreciate that the Therapeutic Goods Administration (**TGA**) has afforded medicinal cannabis stakeholders the opportunity to respond to the TGA consultation on *Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products* (**Consultation**).

About AMCA and MCIA

The Australian Medicinal Cannabis Association (**AMCA**) and Medicinal Cannabis Industry Australia (**MCIA**) are the two leading national organisations representing the Australian medicinal cannabis sector. Together, we act for approximately 60% of the licensed medicinal cannabis industry (including domestic cultivators, producers and manufacturers, and importers of medicinal cannabis products), health practitioners and patient advocates. We represent the mutual interests of our members and other stakeholders to build a professional industry based on legitimacy, credibility and recognition for the Australian sector in domestic and international arenas.

AMCA is a not-for-profit association that was established in July 2020 and has approximately 500 individual members. Its membership spans the entire medicinal cannabis sector, from domestic cultivators and producers to health professionals and patient advocates. AMCA's mission is to create a united voice that improves patient access and affordability, supports industry credibility and ensures that Australia's medicinal cannabis framework continues to evolve in a safe and evidence-based manner. Dr Teresa Nicoletti is the current chair of AMCA.

MCIA is a peak industry body for Australia's licensed medicinal cannabis sector established in 2018. It too represents companies across the full supply chain from cultivation, product development, research and export and is working to position Australia as a global leader in medicinal cannabis development. Its current chair is Mr Kristin Viccars.

MCIA aims to build a professional industry based on legitimacy, credibility and recognition for the Australian sector in domestic and international arenas. In 2020, in pursuit of its aims, MCIA established an Industry Code of Conduct,[1] which promotes high standards of integrity across the medicinal cannabis industry so that patients and healthcare professionals can have confidence in their dealings with one another.

Both AMCA and MCIA share a commitment to fostering a sustainable and responsible medicinal cannabis sector that is trusted and valued for its social and economic contribution. This encompasses all activities of medicinal cannabis licence holders across research, cultivation and manufacturing, and interaction with patients, the medical profession and the community. Central to a trusted and valued sector is the facilitation of a regulatory framework that enhances community wellbeing through access to safe, standards-based quality medicinal cannabis products for Australian and International patients. By ensuring that the industry and its products are built on sound science and underpinned by industry processes and standards, patients can have confidence in the sector and its products, services and information.

[1] MCIA Code of Conduct – Medicinal Cannabis Industry Australia.

We note that much of the content of this joint submission was prepared by the Mills Oakley legal team under the instruction of Dr Nicoletti, in her capacity as both a partner at Mills Oakley and the Chair of AMCA, and adopted by AMCA and MCIA. As a result, there is considerable overlap between this joint AMCA and MCIA submission and the submission independently submitted by Mills Oakley.

Overview of joint submission

This joint submission is founded on the premise that patient access to current products must be maintained while this consultation and further review and response steps are conducted in 2025 and 2026.

Ideally, there should be a mechanism available for new and innovative products to be introduced to market to better service patient needs during this time. We are committed to collaborating with all stakeholders to develop a regulatory framework that balances patient access with clinical oversight and regulatory integrity.

MCIA and AMCA believe that any reforms to the medicinal cannabis framework must be built upon established principles of good regulatory practice and align with Australia's national health objectives. The guiding principles for effective regulation include the following attributes:

- Risk-Based and Proportionate: Regulatory oversight must be directly proportional to the potential hazards associated with a product or practice, focusing resources and controls on areas of genuine, evidence-backed risk.
- Transparent: All regulatory determinations and the evidence underpinning them must be clearly communicated to build trust among clinicians, patients, industry and the public.
- Aligned with the National Medicines Policy (**NMP**): Reforms must uphold the four core pillars of the NMP: efficacy, quality, and safety; equitable and affordable access; rational use; and a viable and responsible industry.

Our goal is to therefore work collaboratively with the TGA, industry bodies and other stakeholders to develop a responsive, patient-centred, pragmatic, quality and standards-based regulatory framework that is appropriate for medicinal cannabis. Importantly, we see this as an evolution from where we are now, not a revolution.

While we provide answers below to each of the 22 specific questions posed by the Consultation, we wish to focus on the following **5 key recommendations** which have been developed after extensive consultation between MCIA and AMCA, with MCIA and AMCA members, and with other stakeholders across the industry, including prescribers, pharmacists, providers/sponsors, processors, producers and patient groups:

1. Establish a fee-based Australian Register of Therapeutic Goods (**ARTG**) pathway tailored to medicinal cannabis products, requiring submission of an abbreviated dossier (compared to full AUST R registration) containing comprehensive evidence relating to GMP adherence and product quality assurance, with sponsors accepting continuous post-market pharmacovigilance obligations. Comprehensive safety and efficacy data packages would not be required. Current products in the market could gain transitional registration with a defined window (not less than 3 years) to show full compliance with ARTG requirements.
2. Introduce standardised, responsible labelling formats and dosing advice, potentially using the Australian Medical Terminology (**AMT**) coding system, if appropriate.
3. Facilitate access to medications containing delta-9-tetrahydrocannabinol (**THC**) across a range of potencies, supported by prescriber oversight and strengthened through post-market monitoring to ensure safety and effectiveness.
4. Introduce an evidence registry and a pathway to building the evidence base across Real World, Scientific and Clinical Evidence.

5. Co-Develop with Medical Schools and/or Colleges, and introduce, contemporary health practitioner education. This could start initially with THC products to address higher potency products and or inappropriate behaviours in prescribing/dispensing linked to those products, and then move to the wider cannabidiol (**CBD**) product base.

We expand upon these 5 key recommendations in detail further below. Some of them are addressed in our answers to specific questions raised in the Consultation, while others are ancillary recommendations that support overall reform of the regulatory regime.

Background

In order for our submissions to be placed in the appropriate context, this Background section provides some information about medicinal cannabis, its demand in Australia, and the relationship between cannabis and the law, both within Australia and internationally.

Benefits of medicinal cannabis

Cannabis, derived from the plant *Cannabis sativa*, contains approximately 140 chemical constituents called 'cannabinoids'. The most well-known cannabinoids are cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), with THC being the first cannabinoid to have been isolated for scientific research in 1964 and the key psychoactive constituent.[2] Research throughout the 20th century uncovered the sophisticated endocannabinoid system, which comprises several biochemical receptors throughout the human brain and body, upon which cannabinoids were observed to act and produce a variety of therapeutic and psychoactive effects.[3] Different strains of cannabis contain different quantities and types of cannabinoids and thus different plant strains may offer different therapeutic benefits and/or psychoactive profiles.[4]

Cannabis for therapeutic or medicinal purposes comes in three distinct forms: pharmaceutical preparations, standardised herbal preparations and herbal (non-standardised) cannabis. Pharmaceutical preparations of cannabis contain specific, known quantities of synthetic or naturally derived cannabinoids and have been developed and tested by pharmaceutical companies for approval by national regulatory bodies like the TGA in Australia. Although the therapeutic effects of pharmaceutical preparations are reliable and well-documented, pharmaceutical cannabis preparations are also likely to be more expensive for patients.

Standardised herbal preparations of cannabis are produced in controlled conditions from cultivation (so that the cannabinoid concentration of plants is kept constant) to manufacture (so that the final product strength and composition remains constant).[5] Non-standardised herbal cannabis, as is the case with illicit cannabis, contains unknown quantities and types of cannabinoids and may be contaminated with mould, heavy metals or pesticides.[6] On this basis, non-standardised herbal cannabis is not recommended for medicinal use because of the potential for impurities and inconsistencies in its chemical profile, which may be dangerous for patients.

Pharmaceutical preparations of cannabis are generally designed for oral administration (*e.g.* oils, capsules and tablets),[7] however studies involving medicinal cannabis have investigated

[2] Russo E, 'Taming THC: potential cannabis synergy and phytocannabinoid-terpenoid entourage effects' (2011) *British Journal of Pharmacology* 1344.
[3] Piomelle D and Russo E, 'The cannabis sativa versus cannabis indica debate: an interview with Ethan Russo, MD' (2016) 1(1) *Cannabis and Cannabinoid Research* 44, 45.
[4] *Background on Cannabis and its medicinal use* (10 Feb 2016) Australian Government Department of Health http://www.health.gov.au/internet/ministers/publishing.nsf/Content/5E437BF8715C3EBACA257F540078A07A/$File/Background%20on%20Cannabis%20and%20its%20medicinal%20use.pdf, 1.
[5] Hazekamp A, 'An evaluation of the quality of medicinal grade cannabis in the Netherlands' (2006) 1(1) *Cannabinoids* 1 - 4.
[6] *Ibid,* 7
[7] Sharkey K, Darmani N, Parker L, 'Regulation of nausea and vomiting by cannabinoids and the endocannabinoid system' (2014) 722 *European Journal of Pharmacology* 134, 142; Whiting P, *et al.*, 'Cannabinoids for Medical Use: A Systematic Review and Meta-analysis' (2015) 313(24) *The Journal of the American Medical Association* 2456 - 2459.

administration by oromucosal spray,[8] tincture or ointment or vaporisation.[9] Based on evidence of the adverse effects associated with smoking, smoking of cannabis is not recommended for medicinal use.[10]

There is clinical evidence which shows that THC and CBD can be used in the treatment and/or symptom control of a range of medical conditions, including chronic pain,[11] AIDS/HIV,[12] chemotherapy-induced nausea and vomiting (**CINV**),[13] cancer,[14] diabetic peripheral neuropathy,[15] epilepsy,[16] multiple sclerosis (**MS**)[17] and anxiety and depression.[18] There is also some evidence that THC and CBD may assist in the symptomatic relief of glaucoma,[19] Tourette syndrome[20] and sleep disorders.[21]

Regulation of Cannabis

Australia is a party to three significant international agreements which concern the supply and use of narcotic drugs (including cannabis). Primarily, the *Single Convention on Narcotic Drugs 1961*[22] (**Single Convention**) requires signatories to prevent abuse and diversion of narcotic substances by limiting cultivation, production, manufacturing and other activities (including use and possession), but permits the provision of narcotic substances for medical and scientific purposes, subject to adequate controls, and specifically carves out of its scope of operation cannabis for industrial or horticultural purposes.[23] The Single Convention is implemented into Australian law by a number of instruments at the Commonwealth and state/territory level, primarily, at the former, by the *Narcotic Drugs Act 1967* (**ND Act**).

In addition, Australia is a party to the *Convention on Psychotropic Substances 1971*[24] which describes the obligations of parties to facilitate the use of psychotropic substances for medical and scientific purposes (and to limit their availability for other use(s)), and the United Nations *Convention*

[8] Lynch M and Ware M, 'Cannabinoids for the Treatment of Chronic Non-Cancer Pain: An Updated Systematic Review of Randomized Controlled Trials' (2015) 10(2) *Journal of Neuroimmune Pharmacology* 293 - 295.
[9] M Wallace *et al.*, 'Efficacy of Inhaled Cannabis on Painful Diabetic Neuropathy' (2015) 16(7) *The Journal of* Pain 616 – 625.
[10] Gordon A, Conley J and Gordon J, 'Medical Consequences of Marijuana Use: A Review of Current Literature' (2013) 15 *Current Psychiatry Reports* 419-430; Zhang L, *et al.*, 'Cannabis smoking and lung cancer risk: Pooled analysis in the International Lung Cancer Consortium' (2015) 136(4) *International Journal of Cancer* 893-904
[11] 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, DC: The National Academies Press.
[12] Victorian Law Reform Commission, *Medicinal Cannabis: Report*, Report No 32 (August 2015), 39 and 64.
[13] https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-guidance-documents/guidance-use-medicinal-cannabis-treatment-palliative-care-patients-australia
[14] Whiting et al, above n 7, 2460.
[15] J Croxford and T Yamamura, 'Cannabinoids and the immune system: Potential for the treatment of inflammatory diseases?' (2005) 166(1) *Journal of Neuroimmunology* 3, 12.
[16] tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-guidance-documents/guidance-use-medicinal-cannabis-treatment-epilepsy-paediatric-and-young-adult-patients-australia.
[17] https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-guidance-documents/guidance-use-medicinal-cannabis-treatment-multiple-sclerosis-australia.
[18] Whiting *et al.*, above n 7, 2463.
[19] Jarvinen T, Pate D and Laine K, 'Cannabinoids in the treatment of glaucoma' (2002) 95 *Pharmacology & Therapeutics* 203 - 215.
[20] Whiting *et al.*, above n 7, 2464.
[21] *Ibid*.
[22] *Single Convention on Narcotic Drugs 1961*, opened for signature 30 March 1961, 520 UNTS 204 (entered into force 13 December 1964), as amended by the 1972 Protocol *amending the Single Convention on Narcotic Drugs 1961*.
[23] Ibid, Art 2; and Art 28 for cannabis cultivation specifically.
[24] *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).

Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988,[25] which aims to promote cooperation between parties to address the illicit trafficking of narcotic drugs and psychotropic substances.

The Commonwealth Government is ultimately accountable for ensuring that any national, state or territory scheme for the cultivation, production, manufacture or supply of cannabis and products derived from cannabis is consistent with Australia's international obligations, including where responsibility for regulating aspects of the regime is devolved to the states and territories (as it is in relation to industrial cannabis). As a signatory to the Single Convention, Australia is obliged to regularly provide information to the International Narcotics Control Board (**INCB**), such as annual estimates of harvest areas and yields, amount of raw material and refined products in stock, amounts required for importation and relevant trends in use for medicinal purposes.[26] Failure to meet such international obligations poses certain diplomatic and economic risks, including potential damage to Australia's international reputation (in particular, for its progressive, balanced and comprehensive approach to dealing with the problems posed by the use and misuse of drugs in the community).[27]

Critically, the legal and policy issues that arise in relation to medicinal cannabis can be readily differentiated from those applying to the regulation of cannabis for non-medicinal purposes. The priorities, considerations and challenges which affect decisions in relation to medicinal cannabis differ significantly from those for industrial, recreational or other use.[28]

In our view, any discussion of medicinal cannabis should be underpinned by the International Convention on Economic, Social and Cultural Rights (**ICESCR**), which states that everyone has the right to the highest attainable standard of physical and mental health,[29] and to the Australian Charter of Healthcare Rights, which provides that all Australian patients have the right to receive safe and high quality care in an effective continuum.[30]

Regulation within Australia

Cannabis and cannabis-related activities are tightly controlled in Australia. The cultivation, production, manufacture, import, export, distribution, trade, possession, use and supply of cannabis and cannabis-derived products are, like other narcotic and non-narcotic drugs and their derived products, regulated by several Commonwealth and state/territory laws:[31]

(a) As a starting point, the Criminal Code 1995 (Cth) and separate state and territory crime, drug misuse and/or drug/poison control legislation generally make it illegal to traffic, import, export, manufacture, cultivate or possess cannabis or cannabis products.[32]

[25] *Convention on Psychotropic Substances 1971*, opened for signature 21 February 1971, 1019 UNTS 175 (entered into force 16 August 1976).
[26] Ibid Arts 18-20; Explanatory Memorandum, *Narcotic Drugs Amendment Bill 2016* (Cth), 7
[27] Explanatory Memorandum, *Narcotic Drugs Amendment Bill 2016* (Cth), 6.
[28] For example, see, R Pacula *et al.*, 'Developing public health regulations for marijuana: Lessons from alcohol and tobacco' (2014) 104(6) *American Journal of Public Health* 1021.
[29] International Covenant on Economic, Social and Cultural Rights, opened for signature 16 December 1966, 993 UNTS 3(entered into force 3 January 1976)
[30] ACSQH, Australian Charter of Healthcare Rights (2008) Australian Commission on Safety and Quality in Health Care https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDf.pdf; The University of Sydney Community Placement Program in Partnership and MGC Pharmaceuticals, Medicinal Cannabis in Australia: Science, Regulation & Industry, White Paper (2016).
[31] Ibid, 6.
[32] See, for example, *Drugs, Poisons and Controlled Substances Act 1981* (Vic) and *Therapeutic Goods Act 2010* (Vic); *Controlled Substances Act 1984* (SA); *Drugs of Dependence Act 1989* (ACT) and *Criminal Code Regulation 2005* (ACT); *Misuse of Drugs Act 2001* (TAS) and *Poisons Act 1971* (TAS); *Cannabis Law Reform Act 2010* (WA) and *Misuse of Drugs Act 1981* (WA); *Drug Misuse and Trafficking Act 1985* (NSW); *Drugs Misuse Act* (QLD) and *Police Powers and Responsibility Act 2000* (QLD); and *Misuse of Drugs Act* (NT).

(b) On the other hand, the ND Act permits the cultivation and production of cannabis[33] and the manufacture of drugs comprising or derived from cannabis or its constituent parts,[34] but in so doing it inflexibly observes Australia's obligations under the Single Convention by ensuring those activities are closely controlled.

(c) The *Customs Act 1901* (Cth) addresses the import[35] and export[36] of narcotic substances generally, and the *Customs (Prohibited Imports) Regulations 1956* (Cth) and *Customs (Prohibited Exports) Regulations 1958* (Cth) provide a mechanism for the importation and exportation, respectively, of cannabis for medical and scientific purposes, subject to the appropriate licences and permits.[37]

(d) The *Therapeutic Goods Act 1989* (Cth) (**TG Act**), *Therapeutic Goods Regulations 1990* (Cth) (**TG Regulations**) and other subordinate legislation and guidelines, and complementary state and territory legislation, regulate the availability and supply of medicines and other therapeutic goods in Australia.[38]

(e) The states and territories, through drugs misuse, poisons/drug control and/or hemp specific legislation, license and control the cultivation, production, manufacture, storage, possession and supply of cannabis, including cannabis products scheduled under the *Therapeutic Goods (Poisons Standard - June 2025) Instrument 2025* (**Poisons Standard**) and industrial hemp and its derivative products.[39]

Safety profile of cannabis

The TGA has identified four broad categories of concern regarding unapproved medicinal cannabis products:

(a) Emerging safety concerns with medicinal cannabis products;

(b) Risks associated with certain dosage forms;

(c) Risks associated with high concentrations of medicinal cannabis components; and

(d) Access to medicinal cannabis for vulnerable population groups.

These concerns are well-founded. Unapproved therapeutic goods are not subjected to the same regulatory standards as goods that are registered on the ARTG, particularly with respect to the threshold tests for establishing quality, safety and efficacy, and the requirement for adverse event reporting. Notably, the safety profile of any given medicinal cannabis product varies depending on its composition, and this can be a factor impacting its safe use.

In our view, however, the extent of this risk should be assessed in line with the actual patterns of medicinal cannabis use, and in doing so it is important to materially consider the evidence provided by the TGA in support of its propositions.

Our review of the research articles cited by the TGA indicates that they are not written in the context of the Australian regulatory framework and risk misrepresenting the risks associated with the regulated supply of medicinal cannabis. Identifying these limitations is not intended to discount the concerns raised by the TGA, but to ensure that any policy and legislative decisions that are made subsequent to the consultation process are properly evidence-based.

[33] *Narcotic Drugs Act 1967* (Cth), Ch 2 Pt 2 Div 1-2.
[34] Ibid, Ch 3 Pt 2 Div 1-3.
[35] Ibid, s 49.
[36] Ibid, s 112.
[37] *Customs (Prohibited Imports) Regulations* 1956, r 5.
[38] *Therapeutic Goods Act 1989* (Cth), Pts 3-1 and 3-2.
[39] See, for example, the *Hemp Industry Act 2008* (NSW).

Review of TGA evidence

Research is relied upon to assert that "cannabis use" is linked to an increased risk of coronary heart disease, myocardial infarction and stroke,[40] and cannabis use disorder.[41] However, the articles which are cited do not distinguish between medicinal and recreational cannabis use. Notably, many respondents in these cross-sectional studies cited reside in the United States, where recreational cannabis is widely legal at the state level. The majority of the research that is cited fails to make this distinction. Petrilli *et al.* (2022) relied on six observational studies and, relevantly, five of the six studies were identified as "poor quality" in the risk of bias evaluation. The results of three of the six studies did not account for any confounding variables. Frequency of administration was only accounted for in two of the studies. A webpage is also relied upon to assert that smoking cannabis can harm lung tissue, and cause scarring and damage to small blood vessels.[42] The evidence that smoking causes tissue damage (including damage to blood vessels) is uncontroversial and reliance on this source is somewhat unexpected. A single-author literature review is cited as evidence linking THC-containing products with mental health conditions, including anxiety, depression and suicidal ideation. The studies that are assessed by the author in relation to depression focus either on young girls (children and adolescents) or on adults already diagnosed with depression (*i.e.*, assessing symptoms of depression in those already affected). Anxiety is also assessed in adults with pre-existing depression. The conclusions drawn in relation to suicidal ideation are directed at adolescents and veterans, not the general adult population. The paper does not distinguish between medicinal and recreational use and, consistent with its focus, many of the references relate to the unintentional or recreational exposure of children and adolescents to THC.

Further evidence is relied upon by the TGA to support the proposition that THC is associated with psychosis. A case report by Bradlow *et al.* (2024) details the admission of a young male to a psychiatric unit following an intentional overdose of escitalopram amidst several months of psychosis.[43] The history of the patient is that his family history included a sister with bipolar affective disorder and long-term self-diagnosed anxiety. Further, the patient had been abusing illicit cannabis for eight years via smoking through a water pipe and had only switched to medicinal cannabis eight months prior to the episode, which was also administered through a water pipe. Allegedly, it was only after switching to medicinal cannabis that the patient began to develop symptoms of psychosis (paranoia, auditory hallucinations and delusional jealousy). It is intimated in the paper that this is a consequence of the THC content of the medicinal cannabis; however, notably the paper does not state the THC content of the medicinal cannabis, so whether it was in truth 'high THC' is unknown. It is also notable that, despite allegedly suffering from these symptoms of psychosis for eight months, they were only clinically observed following the intentional overdose of escitalopram. It is relevant that selective serotonin reuptake inhibitors, such as escitalopram, can themselves induce psychotic episodes, particularly in individuals with an underlying vulnerability.

While the Bradlow paper makes much of the fact that the patient's mental health symptoms abated following the cessation of medicinal cannabis, little attention is given to the fact that the patient simultaneously received 15 mg of aripiprazole and 50 mg of quetiapine daily, both being antipsychotics used in the treatment of schizophrenia and bipolar disorder. Further, he was instructed to continue treatment on both medications for six months following discharge from the mental health unit. It therefore cannot be excluded that the abatement of psychotic symptoms was the result of adherence to the prescribed antipsychotic regimen as opposed purely or primarily to cessation of medicinal cannabis.

[40] Jeffers AM, Byers L, Keyhani S, 'Association of Cannabis Use With Cardiovascular Outcomes Among US Adults' (2024) 13(5) *Journal of the American Heart Association* 1-11.
[41] Petrilli K, *et al.,* 'Association of cannabis potency with mental ill health and addiction: a systematic review' (2022) 9 (9) *The Lancet Psychiatry* 736-750.
[42] Centres for Disease Control and Prevention, *Cannabis and Lung Health*, *Cannabis and Public Health* (15 February 2024) https://www.cdc.gov/cannabis/health-effects/lung-health.html.
[43] Bradlow, *et al.* 'High Prescribing: A Case Study of High-Potency Medicinal Cannabis Inducing Psychosis' *Case Reports in Psychiatry,* Volume 2024.

As such, the evidence in the Bradlow paper does not justify attributing causality to the pharmacology of medicinal cannabis *per se*. In our view, the more compelling issue in that case (and more generally) is the siloing of prescribing information and medical history as between the patient's general practitioner and medicinal cannabis prescriber. This event speaks more to concerns regarding unsafe or inappropriate medicinal cannabis prescribing practices, and underscores the need for robust regulatory prescribing safeguards rather than questionable categorical claims about the inherent pharmacological safety profile of medicinal cannabis, particularly when it is based on one study alone. That is not to say that the increased risk of psychosis associated with increasing THC use should be downplayed, but to point out that reliable and unambiguous evidence is required before such risk can be properly understood, quantified/qualified and appropriately managed in clinical settings.

A clinical perspective paper authored by Scott and Scott (2025) has also been relied on by the TGA to highlight the alleged relative inefficacy and disproportionate harms of medicinal cannabis products for patients suffering from chronic non-cancer pain, as against inactive placebo rather than established active substances (*i.e.*, NSAIDs or opioids).[44] This design choice produces results of limited real-world value. Whether medicinal cannabis is better than other available treatments, which have arguably more harmful adverse effects, is significantly more relevant than comparing it to a basal response to chronic pain. The authors also note that adverse events are reported unevenly across studies, making it difficult to determine whether harms are due to the intrinsic pharmacological effects of medicinal cannabis or to poor trial design and selective reporting.

The Scott and Scott paper also erroneously states that a side effect of CBD administration is psychosis, however neither paper proffered in support of this position[45] actually states that CBD administration causes psychosis in patients. Similarly, the paper erroneously states that medicinal cannabis use is associated with the development of other substance abuse disorders, however, once again the paper relied on to support this position[46] does not state this as it does not differentiate between illicit, recreational and medicinal use cohorts, meaning that this conclusion simply cannot be drawn.

Despite these limitations, we do agree with the authors' ultimate position that it is not the intrinsic safety profile of medicinal cannabis, or rather THC, that is of primary concern, but rather the unsafe prescribing practices and lack of effective regulation regarding the circular and vertically integrated nature of many specialist medicinal cannabis clinics presently operating in Australia, which represent the most pressing risk to the public when it comes to medicinal cannabis use.

Finally, the TGA provided a letter to the Editor of *Australasian Psychiatry* authored by Lupke *et al* (2024).[47] We note that of the 67 patients admitted to the early psychosis service during the period reported in the letter (November 2022 to July 2023), six had started using "high concentrate prescribed THC" within three months of presenting. However, we further note that what constitutes "high concentrate" in the authors' view is not stated, and that one of the patients was abusing a medicinal cannabis product not prescribed for them, meaning not only was their use illicit, but also, as the product had not been prescribed to them, they had not undergone a clinical assessment by any practitioner. Further, the authors report that four patients received medicinal cannabis prescriptions following presentations of psychosis which, while plainly poor prescribing practice, does not speak to the innate safety profile or psychosis risk presented by THC. As such, we contest the validity of using this letter as evidence that THC presents a heightened or unacceptable risk of psychosis in patients generally.

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[44] Scott and Scott, 'Medicinal cannabis: is current use clinically justified?' (2025) *Internal Medicine Journal.*
[45] Arnold JC. 'A primer on medicinal cannabis safety and potential adverse effects' (2021) 50 *Australian Journal of General Practice* 345–350, Wang L, *et al.,* 'Medical cannabis or cannabinoids for chronic non-cancer and cancer related pain: a systematic review and meta-analysis of randomised clinical trials' (2021) *BMJ* 373.
[46] Blanco C, *et al.,* 'Cannabis use and risk of psychiatric disorders: prospective evidence from a US national longitudinal study' (2016) 73 *JAMA Psychiatry*, 388–395.
[47] Lupke, *et al.*, 'Impacts of medicinal cannabis on an early psychosis service' (2024) 32(2) *Australasian Psychiatry* 164-166.

That said, as with Scott and Scott above, once again we agree with Lupke ***et al.'s*** overall primary concern that inappropriate prescribing of medicinal cannabis products is occurring where insufficient patient assessment or clinical history review is taking place prior to a patient being prescribed medicinal cannabis.

The unregulated growth of vertically integrated telehealth clinics and a lack of systematic monitoring of prescribing outcomes make it difficult to build a reliable evidence base. Regulators and clinicians are interested in finding more effective and safer agents for treating chronic non-cancer pain where simple analgesics or other drugs are ineffective and not tolerated. However, the current evidence does not reflect the treatment context and risks over-generalising the harms caused by medicinal cannabis. Any regulatory framework should necessarily provide mechanisms to encourage scientific research for the safe and effective use and prescribing of medicinal cannabis. Restricting patient access would therefore be contrary to existing public health policy.

In the consultation, two research articles were referenced in support of the negative impact on cardiac, respiratory and neurological systems[48,49] of the use of unapproved medicinal cannabis products containing high potencies of THC. However, neither of the articles distinguish between medicinal and recreational cannabis use, and while increased THC use is undoubtedly associated with the potential for increased harms, they key point is that those harms can largely be mitigated by facilitating a scheme that provides for access to high-quality products under a regulatory framework that mitigates risk through a range of regulatory measures that facilitate the responsible use of medicinal cannabis under the clinical oversight of a prescriber.

Chetty *et al.* (2021) conducted a literature review which was primarily focused on the cardiovascular system. However, there are significant limitations in the papers assessed, notably, that most studies were published at a time when cannabis use was illegal and concomitant tobacco use was "very prevalent" and likely a confounding factor.[50] There was significant variability in the routes of administration, dose rates and whether the cannabis used was synthetic, further confounding the findings. Any conclusions drawn in relation to the respiratory system must be limited to the ingestion of cannabis by smoking, rather than the constituent cannabinoids themselves. It is unclear why the TGA has sought to rely on this review when it has clearly stated that it does not support smoking as a route of administration. Marconi *et al.* (2016) assessed outcomes related to psychosis and schizophrenia, not "neurological systems" as stated. While the meta-analysis found a positive dose-dependent association between the extent of cannabis use and the risk of psychosis, the authors clearly stated that a causal link cannot be unequivocally established.[51]

Several articles were advanced in support of the risks associated with certain dosage forms, particularly the administration of medicinal cannabis with vaping devices. Broadly, the articles that were cited do not have relevance for the purposes which the TGA is seeking to rely on them. Two research articles were cited for the proposition that the use of battery-operated vaping devices has been linked to adverse events.[52,53]

Bonner *et al.* (2021) does not assess the physical dangers associated with the use of vaping devices to administer medicinal cannabis.[54] It is possible that the footnote was placed incorrectly and was instead intended to support the TGA's concerns regarding "E-cigarette or Vaping Product Use-Associated Lung Injury" (**EVALI**) in the context of medicinal cannabis administration. However, even in that case, this paper does not provide strong evidence that vaporisation of dried cannabis

[48] Chetty K, Lavoie A, Deghani P, 'A literature review of cannabis and myocardial infarction: What clinicians may not be aware of' (2021) 3(1) *CJC Open* 12—21. doi: 10.1016/j.cjco.2020.09.001.
[49] Marconi A, Di Forti M, Lewis CM, *et al.*, 'Meta-analysis of the association between the level of cannabis use and risk of psychosis' (2016) 42(5) *Schizophr Bull* 1262—-1269.
[50] above at n 48.
[51] above at n 49.
[52] MacCallum C, Lo L, Boivin M, '"Is medicinal cannabis safe for my patients?" A practical review of cannabis safety considerations' (2021) 7(89) *European Journal of Internal Medicine*, 10-18.
[53] Bonner E, *et al.,* 'The chemistry and toxicology of vaping' (2021) 9 Pharmacology & Therapeutics 225.
[54] ibid.

flower increases the risk of EVALI. In fact, a subsequent paper cited in the Consultation states that *"There is no strong evidence that vaporization with dried cannabis flower increases the risk of EVALI"*.[55] Similarly, MacCallum *et al.* (2021) does not assess the physical dangers associated with the use of vaping devices to administer medicinal cannabis. Medicinal cannabis is not the focus of the paper. While the paper does support the proposition that the use of medicinal cannabis vaporisers may be associated with the incidence of EVALI, this association is limited to the use of THC-containing e-liquids (and not flower).

A National Industrial Chemicals Notification Assessment Scheme (**NICNAS**) paper[56] is cited as further evidence for the dangers associated with the use of vaping devices. Specifically, the concern relates to the potential for metals from heating coils to transfer into emissions, leading to user metal exposure. However, the paper focuses exclusively on e-liquid–based vaporisers *per se* and does not present emissions data for cannabis devices specifically. It is also unclear whether these concerns about e-liquid devices extend to dried flower vaporisers, which typically use different heating mechanisms and, if so, the extent of the concern. Reliance on this paper risks conflating distinct product categories and misrepresenting the evidence base, potentially misleading regulatory decision-making for medicinal cannabis products.

A further claim is made in reliance on MacCallum *et al.* (2021) that there is limited evidence to support the safety and efficacy of other dosage forms such as sprays, suppositories, topicals and edibles.[57] However, this representation is made as an unsupported assertion, as there are no references cited nor is evidence provided which explains how the authors arrived at this position. Indeed, nabiximols (Sativex®) is a registered pharmaceutical oro-mucosal spray, undermining this argument. The Consultation relies on a paper by the Royal Australian College of General Practitioners in relation to medicinal cannabis and driving. The evidence relied upon relates to the rapid and transient peak in blood and oral fluid THC concentrations when smoking or vaporising cannabis (as opposed to oral ingestion of cannabis). This is referenced immediately preceding the statement that *"the dosage form can play a significant impact the risks* [sic] *associated with safety with regards to THC".* Plainly, the intended reference is that the rapid and transient presence of THC in the blood and oral fluid affects its safety profile. However, in the context of the original paper from which this representation is drawn, the statement refers to the unreliability of using THC levels in blood or oral fluid to assess impairment, particularly in the context of roadside drug testing. Put simply, the representation is unrelated to the purpose for which the TGA seeks to rely on it in the consultation paper.

Research is relied upon to discuss the potential impacts of cannabis exposure in both paediatric patients and women during pregnancy. There is a reference to a literature review on marijuana use in children, namely, accidental or recreational exposure to cannabis.[58] The overall tenor of the paper is that cannabis should never be supplied to children or adolescents, a position that is at odds with the indication for Epidyolex (adjunctive therapy of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome for patients 2 years of age and older) in Australia. As such, the prospect of medicinal cannabis use is entirely unexplored, except for a passing reference noting that medicinal cannabis can be prescribed in the USA as part of broader legalisation efforts. Another paper is referred to in support of the assertion that cannabis use can disrupt foetal brain development, and that it is linked to lower birth weight, a higher risk of preterm birth and can negatively affect neonatal outcomes. This paper does not differentiate between medicinal and recreational cannabis use.

We reiterate that we do not seek to undermine the TGA's concerns regarding patient safety and public health in relation to unapproved medicinal cannabis products. However, we repeat that any

[55] above at n 52.
[56] Non-nicotine liquids for e-cigarette devices in Australia. National Industrial Chemicals Notification and Assessment Scheme. Department of Health. 2 October 2019.
[57] above at n 53.
[58] Stoner MJ, Dietrich A, Lam SH, 'Marijuana use in children: An update focusing on paediatric tetrahydrocannabinol and cannabidiol use' 2022 3(4) *Journal of the American College of Emergency Physicians Open*, 12770.

regulatory reform must be supported by robust evidence demonstrating a substantiated problem or clear need for change. The reliance on generalised assertions risks perpetuating the longstanding stigma associated with medicinal cannabis and yielding reforms that are neither evidence-based nor proportionate.

Comparative Safety Profile

If the view of the TGA is that medicinal cannabis should only be used when commercially available (ARTG-registered) treatments have failed, its risk:benefit profile should be proportionately assessed against the medicines that it is intended to supplant.

The most common indications for which medicinal cannabis is prescribed in adults under the Special Access Scheme B pathway (**SAS-B**) are chronic pain and anxiety disorders. The regulation and prescription of medicinal cannabis as an unapproved therapeutic good means that should only be prescribed where conventional therapies have been tried and found to be unsuitable or ineffective. This positioning requires that, in addition to considerations about whether to prescribe medicinal cannabis to treat certain medical conditions, its safety profile be understood relative to other well-established medicines, particularly the prescription of opioids for chronic pain management and benzodiazepines for anxiety and sleep disorders. Both classes of medicines carry significant risks associated with their continued use, including the risk of fatal overdose.

In addition to fatal overdose, opioid therapy has other serious or moderately concerning potential adverse effects including addiction, misuse, constipation, nausea, pruritus, dizziness, drowsiness, respiratory depression and opioid-induced hyperalgesia.[59] However, opioids also have clear benefits in treating chronic and postoperative pain, relevantly due to their rapid onset and limited impact on organ function. Medicinal cannabis has emerged as an alternative or adjunct therapy to opioids in the treatment of pain. When examined against the unfavourable effects of opioid therapy for the treatment of chronic pain, medicinal cannabis overall has a relatively safer profile.

Cannabinoids have shown efficacy in treating specific chronic pain subtypes such as neuropathic, fibromyalgia and geriatric pain.[60] The overall data regarding the treatment of musculoskeletal pain and as an adjunct in cancer pain trends towards a positive effect, but the results are not as conclusive. At the higher doses that are required to relieve moderate to severe cancer pain, opioids often have significant side effects. As the TGA is well aware, medicinal cannabis is not an infallible drug which does not have any side effects. Regular cannabis use, in the same way as opioids, can lead to dependence or addiction. Prolonged use may lead to serious side effects including predisposing younger individuals to altered brain development and poorer education outcomes. Notwithstanding the potential for misuse, the side effects of cannabinoids are generally relatively mild in comparison with opioids.[61] This is not always at the expense of efficacy either—data collected in recent surveys has demonstrated overwhelming rates of reduced prescription drug and opioid consumption after using medicinal cannabis.[62]

The TGA has relied upon Scott & Scott (2025) who cite three studies that purport to show increased opioid use among individuals using medicinal cannabis.[63] With respect, we take a different view and, as outlined below, consider that the three studies do not provide a reliable basis for the conclusion advanced. Campbell *et al.* (2018) found that most participants reported that cannabis had no effect on their use of opioid medication. However, 30% of participants at the 4-year follow-up reported that

[59] Bedson *et al.*, 'Risk of adverse events in patients prescribed long-term opioids: A cohort study in the UK Clinical Practice Research Datalink' 2019 23(5) *European Journal of Pain* 908-922.
[60] Ang *et al.*, 'Cannabinoids as a Potential Alternative to Opioids in the Management of Various Pain Subtypes: Benefits, Limitations, and Risks' 2023 12(2) *Pain and therapy* 355-375.
[61] Ibid.
[62] Kvamme SL, Pedersen MM, Rømer Thomsen K, *et al.*, 'Exploring the use of cannabis as a substitute for prescription drugs in a convenience sample' (2021) 18(1) *Harm Reduction Journal* 72. Reiman A, Welty M, Solomon P, 'Cannabis as a substitute for opioid-based pain medication: patient self-report' 92017) 2(1) *Cannabis Cannabinoid Research* 160–6.
[63] Scott and Scott, above n 44.

they sometimes or regularly reduced their opioid medication when using cannabis.[64] Olfson *et al.* (2017) has two main limitations. It relies on data that were collected in 2007 at a time when the social and legal context of cannabis use was very different.[65] The research also claims that it was unable to distinguish recreational from medical marijuana use, however, it is extremely probable that the data collected were predominantly, if not entirely, from illegal recreational use. Lastly, Caputi & Humphreys (2018) does not report on opioid use as distinct from prescription drug use.[66] The conclusion drawn, namely that medicinal cannabis patients are more likely to seek out prescription drugs, seems unsurprising given that many of those patients suffer from serious long-term health conditions.

Medicinal cannabis is presently most appropriately used in carefully selected cases where conventional therapies have been ineffective or have resulted in undesirable side effects. In doing so, the proposed reforms, particularly to the Special Access Scheme (**SAS**) and Authorised Prescriber Scheme (**APS**), risk reducing access for those patients who stand to benefit in these cases. This places disproportionate barriers on legitimate therapeutic use, undermining the last-line role that medicinal cannabis is already confined to under the regulatory framework.

Concerns have also been raised about the prevalence of cannabis abuse and dependence, collectively referred to as *Cannabis Use Disorder* (**CUD**). Recent Australian research, including the largest study to date by Mills *et al.* 2025)[67] has shown that while rates of CUD are lower among individuals prescribed medicinal cannabis compared with those using illicitly sourced cannabis for therapeutic purposes, dependence rates in prescribed users remain substantial – typically in the range of 10–20%. This underscores that, while medical oversight and standardised dosing may mitigate some risks, CUD remains an important clinical and regulatory consideration in medicinal cannabis prescribing.

Available research further suggests that the diagnostic criteria for CUD, as currently defined in the *DSM-5*, may not fully distinguish between appropriate therapeutic use and problematic use in a prescribed setting.[68] Specifically, the *DSM-5* criteria include tolerance and withdrawal as indicators of disorder, whereas for *Opioid Use Disorder* (**OUD**), these criteria are excluded where the medicine is used as prescribed under medical supervision. However, this exclusion would only apply to *prescription cannabis use disorder* where the patient is strictly adhering to prescribed medical use. Analysis of Australian CAMS22 data shows that, even after excluding patients reporting any non-medical use or smoking of flower (rather than vaping), the prevalence of CUD among prescribed users decreased only modestly – from approximately 41% to 37% f – indicating that dependence symptoms remain relatively common even within the medically supervised cohort.

While frequency of use has been cited as a diagnostic indicator of CUD, its application in the medicinal context warrants caution. Frequent or daily use may reflect treatment adherence rather than misuse. Nonetheless, when assessed using current criteria, the persistence of clinically significant symptoms in a proportion of prescribed users suggests that physical dependence and withdrawal are genuine therapeutic risks that warrant ongoing monitoring rather than dismissal.

Interpretation of CUD rates across studies is also constrained by variability in study design and population characteristics. Much of the international literature originates from jurisdictions such as the United States, where recreational cannabis is legal and patients often report overlapping

[64] Campbell, *et al.*, 'Effect of cannabis use in people with chronic non-cancer pain prescribed opioids: findings from a 4-year prospective cohort study' (2018) 3(7) *The Lancet Public Health* 341-350.
[65] Olfson, *et al.*, 'Cannabis Use and Risk of Prescription Opioid Use Disorder in the United States' (2017) 175(1) *American Journal of Psychiatry* 47-53.
[66] Caputi and Humphreys, 'Medical Marijuana Users are More Likely to Use Prescription Drugs Medically and Nonmedically' 2018 12(4) *Journal of Addiction Medicine* 295-299.
[67] Mills L, Arnold JC, Macgregor IS and Lintzeris L, Factors associated with cannabis use disorder among Australians using prescribed and illicitly-sourced medical cannabis, *Drug and Alcohol Depend Rep.,* 16 (2025) 100362.
[68] Sagar, *et al.*, 'Assessing Cannabis Use Disorder in Medical Cannabis Patients: Interim Analyses from an Observational, Longitudinal Study' 2021 4(2) *Cannabis* 47-59.

medicinal and non-medicinal motives. In Australia, CAMS data indicate that most medicinal cannabis users also report some level of non-medical use, which can confound CUD prevalence estimates. Moreover, self-reported medicinal use may underestimate rather than inflate dependence rates, as social desirability and recall bias can lead to under-reporting of problematic use patterns.

A further limitation of the evidence base is the scarcity of long-term, prospective cohort studies examining CUD incidence in Australian patients prescribed medicinal cannabis under current regulatory conditions. The available evidence nonetheless indicates that the risk of developing problematic use patterns is influenced by both the *THC content* and the *mode of administration* of the prescribed product. High-THC formulations (typically 20–30% THC), which are common in some prescribed flower and oil products, are more strongly associated with dependence and adverse neurobiological outcomes than low-THC or CBD-dominant products. By contrast, illicit cannabis in Australia typically contains lower THC levels (<20%). These findings support the need for careful clinical oversight and may justify consideration of general potency caps or other controls to minimise dependence risk (while providing for use of higher doses in clinically justified circumstances – subject to more robust regulatory oversight.

Finally, useful parallels can be drawn with benzodiazepines prescribed for anxiety and sleep disorders. Despite their clear therapeutic utility, benzodiazepines have a very high capacity for misuse and related overdose deaths have increased concurrently with rising rates of prescribing.[69] Studies have shown that concurrent use with medicinal cannabis can reduce benzodiazepine use.[70] Patients have discontinued pre-existing benzodiazepine therapy over only 2 months of medicinal cannabis therapy.[71] Although the overall clinical importance of medicinal cannabis as a ”benzodiazepine sparing” treatment is unclear, the comparative safety profile is self-evident.

Taken together, these comparisons demonstrate that medicinal cannabis, while not risk-free, presents a markedly safer profile than opioids or benzodiazepines when prescribed under appropriate medical oversight. Evidence suggests that for some patients, it may reduce reliance on more harmful medications without introducing comparable risks of fatal overdose or severe dependency. Relying on evidence in jurisdictions with established recreational cannabis markets that make no distinction between recreational and medicinal cannabis participants risks misrepresenting, and perhaps overstating, the risks posed by medicinal cannabis. Rather than zeroing in on the existing stakeholder concerns regarding regulatory oversight in emerging clinical settings, the proposed reforms ostensibly reinforce the stigma associated with cannabis use. The evidence relied upon by the TGA does not represent the true picture and perpetuates the stigma.

Stakeholder concerns under the extant therapeutic goods regime

SAS/APS scheme

The current regulatory pathways under which medicinal cannabis may be accessed are registration in the ARTG, the SAS, APS and the clinical trial notification and exemption schemes. As there are currently only two registered medicinal cannabis products (Epidyolex and Sativex), the SAS and APS are heavily relied upon by prescribers who wish to prescribe medicinal cannabis to their patients. However, these schemes are extremely limiting and were not designed to facilitate the prescription of medicinal cannabis under what has become a *de facto* commercial scheme.

The SAS was introduced to facilitate the supply of therapeutic goods to individual patients on a case-by-case basis. The expectation is that a health practitioner will have considered the unsuitability of any therapeutic goods that are entered in the ARTG and can be sourced in Australia before submitting an SAS application. This expectation has remained unchanged since the inception of the SAS.

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[69] Votaw *et al.*, ’The epidemiology of benzodiazepine misuse: A systematic review’ (2019) 200 *Drug and Alcohol Dependence* 95-114.
[70] Pottie K, Thompson W, Davies S, *et al.*, ‘Deprescribing benzodiazepine receptor agonists: evidence-based clinical practice guideline.‘ *(*2018) 64(5) *Canadian Family Physician* 339–51.
[71] Purcell C, Davis A, Moolman N, *et al.*, ‘Reduction of benzodiazepine use in patients prescribed medical Cannabis’ (2019) 4(3) *Cannabis and Cannabinoid Research* 214–8.

As a result, many practitioners have expressed their concern about the suitability of the pathway. At a high level, the attitude of the TGA is that medicinal cannabis should only be accessed by medical practitioners as a last-line therapy. However, evidence has clearly demonstrated its efficacy as an adjunct treatment and, in some cases, a viable alternative treatment option.

An SAS approval provides a single approval to a health practitioner for a specific category medicinal cannabis product for a specific patient. The inflexibility of the approval process means that if a patient does not derive sufficient benefit from a specific product, the health practitioner must submit another SAS application if the patient requires another medicine that is in a separate and distinct category from the original product for which an application was submitted.

Medical practitioners therefore bear the onus of preparing SAS applications which require a clinical justification to be submitted to the TGA in each case, including that all other ARTG-entered treatment options have been tried and have either failed or been ineffective. The requirement to submit repeated SAS applications is disproportionate to the potential risks, particularly where a medical practitioner is simply seeking to adjust the strength of a product during a treatment plan.

Like the SAS, an authorisation for an Authorised Prescriber (**AP**) is granted in respect of a single category of product. The supply of a medicine under an AP authorisation must be only to specified patients under the Authorised Prescriber's immediate care. The authorisation is similarly restrictive in that if an AP wants to administer the same product to a different class of patients or for a different indication, then another AP application is required. In addition, the AP is a burdensome pathway in practice because it requires a submission to be made to a Human Research Ethics Committee (HREC) or a specialist committee to become an Authorised Prescriber in the first place.

Closed loop models

A closed-loop medicinal cannabis model refers to a supply framework where all stages of the cannabis supply chain (*i.e.,* supplier, clinic and pharmacy) are vertically integrated. Some common examples of concerning industry practice are clinics forcing patients to obtain prescribed medication from a specific pharmacy with whom the clinic has an agreement or pressuring health practitioners to prescribe specific medicinal cannabis products. This has led to the creation of a product formulary model of prescribing where, in some circumstances, medicinal cannabis products are selected by clinics on the basis that they will receive financial remuneration from a supplier if they prescribe the product.

Stakeholders have expressed concern over the potential structural conflicts of interest that are attached to some closed-loop models. The absence of any integration with other healthcare providers has the potential to compromise patient care by reducing what medicinal cannabis products they can access and where they can access them. Financial arrangements between clinics, suppliers and dispensaries can, if not appropriately managed, also conflict with professional duties of healthcare practitioners to provide health services, short circuiting the normal checks and balances that exist when a therapeutic good is prescribed and dispensed to a patient. As a result, patients may feel pressured into particular treatment pathways, rather than being able to exercise genuine choice over products and pharmacies. Because treatment is siloed within vertically integrated clinics, patients' regular general practitioners may be excluded from the treatment process, resulting in reduced oversight over the patient's health.

It should be emphasised, however, that there are cogent reasons why clinics create product formularies that are not profit driven. With approximately 1700 SKUs currently on the Australian market, it is not feasible for prescribers to be across all of the medicinal cannabis variants potentially available. This being the case, clinic operators evaluate and select a suite of medicinal cannabis products, from numerous sponsors, that broadly cover the range of different products, by THC and CBD composition, strength and dosage form that their prescriber are likely to prescribe, This does not restrict the prescriber from prescribing any other medicinal cannabis product, and is intended to facilitate clinical decision-making by introducing products to the product formulary which have been thoroughly assessed, independent of the sponsor, for quality and consistency.

For-profit focus and inappropriate prescribing

There has been a noticeable shift towards the corporatisation of care of patients in the medicinal cannabis sector. Recent years have seen a rapid increase in the number of telehealth-only medicinal cannabis clinics which are, in many cases, designed to prioritise financial gain over patient care.

Clinics should have robust treatment suitability protocols that consider a patient's medical history, prior treatments, risk factors, and indications and contraindications. However, it is not uncommon for clinical practice to involve brief consultations which result in clinics taking inadequate or incomplete patient history. Brief initial consultations are particularly concerning because it greatly reduces the ability of the prescriber to facilitate a decision that is in the best interests of the patient. In some cases, clinics are prescribing to a patient without a real-time direct consultation. Instead, an asynchronous prescribing model is used where the patient completes a questionnaire and a non-prescriber (*i.e.*, a nurse) devises a treatment plan. A prescription is then issued by the prescriber.

A for-profit focus has resulted in several business practices that highlight the potential conflicts of interest inherent in closed-loop models. One example is the practice of 'white labelling', where a manufacturer of medicinal cannabis products enters into an agreement with a clinic or doctor to label the products with the branding of the healthcare facility. Under these agreements, doctors are inclined to prescribe their own products for reasons driven by profit, rather than products which have the most appropriate therapeutic benefits for the patient.

Inappropriate prescribing is also targeted at individuals using non-compliant advertising which encourages unnecessary use of health services. Such practices are potentially misleading, for example, in offering free consultations when the price of the consultation is absorbed in the cost of the product. This is particularly a problem with closed-loop models due to the lack of regulatory oversight and in-built conflicts of interest that result in patients being overcharged for medication which is already ineligible for subsidies under the PBS.

Little regulatory scope to prevent clinic operator misconduct

In many medicinal cannabis clinics, the clinic operator is not a registered healthcare practitioner. While health practitioners are personally bound by professional codes of conduct, there is no equivalent professional framework that regulates how non-practitioner operators run their clinics. In the event of misconduct, regulators can sanction healthcare practitioners, however a non-clinician operator faces fewer direct consequences. Non-clinician operators are also inclined to design financial structures that drive inappropriate prescribing and are more likely to favour vertically integrated models that maximise profit.

Many medicinal cannabis sector stakeholders have called for clearer oversight mechanisms for vertically integrated cannabis clinics. Irrespective of whether clinic operators are healthcare practitioners or not, many stakeholders support introducing greater disclosure obligations and potentially extended healthcare practice regulation to cover non-clinical operators. Currently, the Health Practitioner Regulation National Law and Australian Consumer Law have minimal scope in effectively regulating non-healthcare practitioner clinical operators.

Conclusion

Restricting access to medicinal cannabis risks creating disproportionate harm by limiting access for patients with genuine therapeutic need. The available evidence does not suggest medicinal cannabis is harmful itself, but rather that adequate clinical and regulatory oversight is necessary to ensure it is *prescribed* safely. The most pressing industry concerns stem from structural barriers to access and conflicts of interest where non-practitioner clinic operators exert financial pressure over prescribers and patients. In some manner, the proposed reforms are misaligned. They would burden patients and prescribers acting responsibly, while leaving the regulatory gaps that enable clinic misconduct untouched.

Key Recommendations

Recommendation 1: Establish a fee-based ARTG entry pathway tailored to medicinal cannabis products, requiring submission of an abbreviated dossier (compared to full registration) containing comprehensive evidence relating to GMP adherence and product quality assurance, with sponsors accepting continuous post-market pharmacovigilance obligations.

Overview:

This proposed ARTG entry pathway would introduce a new ARTG category specifically for medicinal cannabis products, and would involve abbreviated registration dossier requirements focusing on Module 1 (country specific product information) and Module 3 (quality), without the need for the compilation and assessment of comprehensive efficacy or safety data packages (although sponsors could be required to provide relevant adverse event data which they may possess in respect of supply of the product on an unapproved basis prior to registration).

MCIA and AMCA members and many other key stakeholders believe that this new ARTG pathway is fundamental to achieving the goals of the review to address "the safety risks associated with the use of certain unapproved medicinal cannabis products" and the "questions [that] are being raised about the appropriateness of the current regulatory oversight of these products".[72]

There are 130+ medicinal cannabis businesses operating in Australia this year. This number represents a nearly 10% increase from the previous year, with double-digit annual growth since 2020.

A new ARTG pathway should include GMP standards and compliance, and sponsor pharmacovigilance accountabilities. These requirements will provide TGA oversight and assurance of product quality, standardisation, compliance and the tracking and reporting of Adverse Events while reducing the regulatory burden on practitioners. This framework should provide a rigorous yet proportionate fit for medicinal cannabis. A fee-based or cost-recovery system should ensure the resources needed for a sustainable pathway.

Currently, MCIA members must abide by the MCIA Code of Conduct updated in February 2025. When a new formal registration pathway is established, sponsor adherence to the Medicines Australia Code of Conduct (V20) should be considered in collaboration with Medicines Australia.[73]

Acknowledging that a new registration scheme would not require evaluation of safety or efficacy, consideration could be given to complementing the ARTG entry scheme by introducing a prescriber notification requirement similar to the Special Access Scheme C (SAS-C) pathway, pursuant to which prescribers would periodically notify the TGA of prescriptions written for products in the new ARTG category rather than seeking individual approvals. Incorporating a prescriber notification mechanism – yielding, in effect, a hybrid registration-notification model – would facilitate continued TGA oversight of the patterns of use of medicinal cannabis products in Australia while significantly reducing administrative complexity and load for practitioners.

Upon implementation of the new ARTG entry scheme, pharmacovigilance responsibilities will shift primarily to the sponsor, with prescribers to report adverse events to the sponsor and the sponsor to manage reporting to regulators and other relevant parties (*e.g.,* manufacturers/suppliers).

Consideration could be given to a "sunset clause" triggering a formal review in the 5th year of the administration of the new pathway ensuring Industry has a "line of sight" to guide investment decisions across the growing, processing, manufacturing and evidence choices it will need to make on commercial, governance and compliance factors over a stable regulatory framework for at least five years.

[72] Final---Consultation-Paper---Medicinal-Cannabis-Review---August-2025.Pdf.
[73] Medicines Australia Code of Conduct Edition 20 adopted at AGM – Medicines Australia; Introduction – Code of Conduct.

Pathway to new ARTG model:

We propose that the new ARTG pathway be introduced after a 3-year window to allow sponsors time to generate stability and other quality data that will be necessary to support the application dossier.

In the interim period, to ease the TGA administration and prescriber burden associated with the SAS-B and APS approvals, it is suggested to utilise the SAS-C pathway in parallel to moving towards the ARTG entry pathway.

Given the vast majority of current medicinal cannabis products are S8, we would recommend that most or all S8 products be included on the SAS-C at the outset. Alternatively, if was considered necessary, interim use of the SAS-C mechanism could involve a staged approach with, for example, an immediate transition to current S4 medicinal cannabis products being added to and accessed via SAS-C, with the view to subsequently add to the scope of the SAS-C regime the oral dose forms that are in the AP Established History of Use (**EHOU**) lists,[74] followed by some or all of the remaining S8 products after that. This recognises the differentiation of risk already attributed to these two sub-categories of medicinal cannabis products. Accessing those products via SAS-C would, in time, be replaced by the ARTG entry / prescriber notification procedure for which we advocate above.

Please see our responses to Consultation questions 19 and 20 below for further discussion of the rationale for the proposed model.

Short-term actions:

- *On-shore testing of imported products*

  Some countries, such as the UK and Germany, require imported finished medicinal cannabis products to undergo onshore potency and microbiological testing upon arrival to ensure patient safety. Additionally, testing methods vary widely between countries, so an onshore test would provide the healthcare practitioner and patient with certainty that these imported products meet the same quality specifications as Australian-made products.

  Standardised release for supply requirements for medicinal cannabis products that included onshore testing could be used to implement this practice.

- *Introduction of SAS C pathway*

  Most or all current medicinal cannabis products to be added to the SAS. Alternatively, if a staged approach is required, initial addition of S4 products at this point.

Short to mid-term actions:

- *Addition of further products to SAS C pathway*

  If the staged approach is undertaken, addition of EHOU products to SAS C program, and potentially most or all remaining S8 products as well.

Mid-term actions:

- *Introduction of ARTG pathway*

  As described above, this would be an abbreviated dossier-based assessment providing a rigorous yet proportionate fit for medicinal cannabis. Listing in the ARTG (AUST L) is not suggested because that category is designed for low-risk medicines and cannabis is in Poison Standard (SUSMP) in Schedules 3, 4 & 8.

  Full registration (AUST R) is not proposed, given the challenges generating evidence that would meet the strictures of this category (as discussed in answer to Consultation questions

[74] https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners/lists-products-established-history-use/authorised-prescriber-established-history-use-lists#medicinal-cannabis-products.

19 and 20 below). That is not to say, however, that individual cannabinoid products with robust data could not obtain full registration in the future.

Under the new ARTG category we are proposing, products would be entered in the ARTG as medicines but would not be able to be advertised to consumers due to S4/S8 scheduling, similar to registered prescription medicines.

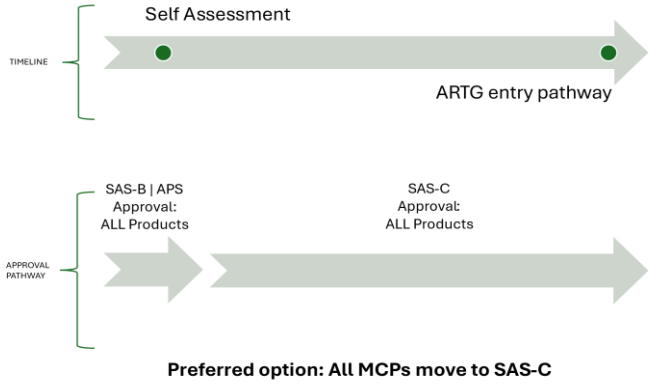
In moving to a new pathway for Medicinal Cannabis, ensuring patient access is maintained is critical. If use of the SAS-C in the interim period is not adopted, consideration should be given to 'grandfathering' all items currently on the market (through SAS-B or AP) into the new pathway with a 2-year transition to comply with the new criteria for the pathway or lose the transitional registration. This timeframe should be realistic for most sponsors, while ensuring patient continuity for those who are stabilised on their current medication.

Timeline overview:

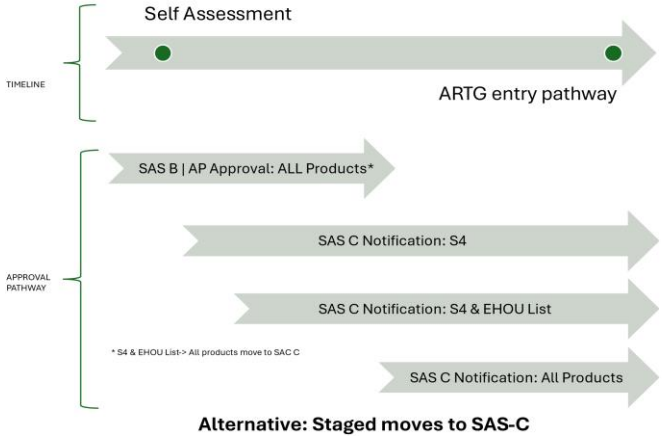
As the specific pathway is introduced for medicinal cannabis products to be entered in the ARTG, increased sponsor accountability should be a pre-qualification to be able to apply for entry. This should include:

- opening a TGA Business account;
- certifying (with independent validation) that they can exercise their responsibility/liability for 'release' of product; and
- demonstrating a financial /insured capacity to handle potential pharmacovigilance and litigation issues.

The following diagrams show the two alternative timelines proposed above:



Preferred option: All MCPs move to SAS-C



Alternative: Staged moves to SAS-C

Recommendation 2: Introduce standardised, responsible labelling formats and dosing advice, potentially using the Australian Medical Terminology (AMT) coding system if applicable.

Overview:

Clear product labelling is fundamental to ensuring the safe and appropriate use of medicinal cannabis. We recommend the TGA introduce standardised, medicinal cannabis-specific labelling requirements to help both health practitioners and patients understand product contents and how to use the medicine. Labelling must be accessible and user-friendly, presented in plain language with legible fonts. The labelling requirements should accommodate varying levels of health literacy among patients.

Currently, *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (Cth) (**TGO 93**) provides basic labelling information for medicinal cannabis but omits many safety and usability features mandated under *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (Cth) (**TGO 91**), *Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines* (Cth) (**TGO 92**), *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (**TGO 110**) and the Poisons Standard. Incorporating items such as (but not limited to) signal headings, advisory statements, layout and legibility controls, allergen/excipient declarations, dispensing-label space, and barcode/traceability requirements would align TGO 93 with the broader regulatory framework for scheduled medicines.

Additionally, many sponsors are utilising the label as post-marketing 'advertising'. Standardising at least the Main Label for medicinal cannabis products will limit the impact labels will play in influencing consumers (patients) in any unnecessary use of an unapproved medicine.

Standardising the format and required information on medicinal cannabis labels improves patient safety, supports prescribers and pharmacists, strengthens regulatory compliance, and builds market transparency.

There is a critical importance of ensuring that label requirements for medicinal cannabis are explicitly linked to standardised Consumer Medicines Information (**CMI**) and Product Information (**PI**) documents within the TGA regulatory framework. A harmonised approach strengthens patient safety, improves clinical decision-making, and supports compliance across the supply chain. Introducing the requirements for standardised information leaflets (CMI/PI), similar to what is required for vaping goods,[75] will standardise the information available to patients (including specific warnings) and improve the safe supply of these medicines.

The Australian medicinal cannabis industry should consider the feasibility of adopting the National Clinical Terminology Service (**NCTS**)[76] and the Australian Medical Terminology (**AMT**)[77] as the core product coding standards for all stages of the supply chain, from sponsor product development and TGO 93 label generation to electronic prescribing and dispensing.

The above approach ensures:

- regulatory compliance (alignment with TGA labelling and scheduling);
- operational efficiency (seamless e-prescribing and dispensing);
- patient safety (decision support); and
- strategic readiness (Pharmaceutical Benefits Scheme (**PBS**), data analytics, and export potential).

[75] TGO 110.
[76] NCTS Digital Health Developer Portal <https://www.healthterminologies.gov.au/>.
[77] https://www.healthterminologies.gov.au/understanding-clinical-terminology-landing/the-amt-focusing-on-medicines/.

Global Alignment and Mutual Recognition:

AMCA and MCIA recommend that updates to TGO 93 and associated labelling requirements for medicinal cannabis be explicitly aligned with international best practice.

In particular:

- New Zealand – the Medicinal Cannabis Agency's Minimum Quality Standard (MQS) requires cannabinoid content tolerances, batch ID, expiry date, manufacturer details and mandatory warnings.
- Israel and Poland – both operate EU-GMP–based systems, with pharmacopeial standards driving labelling consistency for imported and domestically manufactured products.

TGO 93 lacks requirements in terms of prominence rules and per-dose expression standardisation (e.g., mg per capsule/actuation). Its other weaknesses include allowing the following practices:

- No requirements for information leaflets/CMI/PI;
- No standardised medicinal cannabis-specific Warning Statement;
- The information in CMI is not standardised, many sponsors do not use the TGA CMI template, and not all products have CMI's;
- Many 'herb, dried (for vaporisation)' medicinal cannabis products change cultivar from batch to batch without altering the SKU. The product remains aligned to the active ingredient concentration/ratio.

Please see our responses to Consultation questions 2, 3, 4 and 23 below for further discussion of these matters.

Short-term actions:

- Consider updates to TGO 93:
  - Reinforcing that the SUSMP must be adhered to for prescription medicines, including (but not limited to) the fonts, font sizes, placement of signal words and legibility (contrast).
  - Restricting the use of 'cartoon' images or other promotional, inappropriate imagery.
- Include elements of TGO 91 in TGO 93:
  - Section 10 – Qualifications and special requirements:
    - (12) Very small containers (not including injections).
    - (14) Strip, blister and dial dispenser packs.
  - Section 11 – How information is to be expressed:
    - Mandate all unapproved medicinal cannabis products align with the Black Triangle Scheme (including visibility on labels and leaflet/CMI)
    - Require the TGA Business Services Client Identification Number to be stated on the label.
- Mandate the requirement for product leaflet/CMI/QR codes
  - Development with stakeholders of standard warning statements for each dosage form.
  - Requirement for the leaflet to be included with the product attached to the packaging or digital links to this information (QR code being preferred method for environmental reasons), in line with TGO 110 Part 5.

- Include requirements for preparation of medicines, where applicable. i.e., Herb, dried (for inhalation) in line with TGO 92 section 8(1)(m).
- Include specific warnings for 'higher risk' products such as high THC products.
- Include similar requirements to those in TGO 110 Part 4 - Containers, 14 Containers of therapeutic vaping substances
    - It is not suggested to limit to the grey scale (4 shades). Due to the large number of products on the market, this could lead to challenges in pharmacies with product identification. However, aspects of the label design, such as limiting it to certain colour palettes, should be considered in consultation with all stakeholders.
- Generate standard templates for CMI (and then PI) for each dosage form and include specific warning statements for 'high-risk' products (based on THC concentration). Information to be standardised, including but not limited to:
    - What should I know before I use [medicine name]?
        - Standardised warnings about unapproved medicines
    - What if I am taking other medicines?
        - Standardised medicine warnings, including drug-to-drug interactions
    - How do I use this medicine?
        - Standardised instructions for preparation of concentrates and dried herb for vaporisation.
    - Are there any side effects?
        - Standardised side effects based on dosage form and active ingredient concentrations

Mid-term actions:

- MCIA, AMCA and other peak bodies to form a working collaboration with leading institutions to explore use of NCTS & AMT to establish consistent naming for medicinal cannabis products and the process for introduction of consistent naming for new medicinal cannabis active ingredients.
    - Create a working group with the National Clinical Terminology Service (NTCS) and Australian Medicines Terminology (AMT) and relevant leading institutions.
- If appropriate, incorporate these requirements as part of the new ARTG entry pathway for medicinal cannabis.
- Update TGO 93 to include a requirement for 'herb, dried (for vaporisation)' product SKUs to be consistent with the cultivar being supplied. Generate and apply details in a similar way to Listed Medicines by detailing Permitted Changes and a Variation Table. These permitted changes and variations table would need to be generated via an expert working group, noting these would be distinctly different to the AUST-L & AUST-L(A).

Recommendation 3: Maintain access to THC medications across a range of potencies, supported by prescriber oversight and strengthened through post-market monitoring to ensure safety and effectiveness.

Overview:

While we recognise the TGA's concern about the prescription of products with a higher concentration of THC, we do not support the introduction of a strict potency cap for THC concentration in medicinal cannabis products above which products are absolutely prohibited. There is no universal "safe" upper limit for THC use. Rather, the available evidence supports the use of clinical vigilance thresholds based on product type. Potency restrictions do not seem to have succeeded when introduced overseas and may have inadvertently driven patients to illicit markets and products of unknown quality and safety, actually exacerbating potential issues. This recommendation reflects the need for a patient-centred, evidence-informed and internationally aligned approach to regulating THC potency in medicinal cannabis products.

Much of the evidence commonly cited is limited, as it derives from studies of frequent, high-potency recreational cannabis use[78], rather than examining psychiatric risk within the context of medicinal use prescribed under a regulated clinical framework.[79] [80] Regulatory oversight must be directly proportional to the potential hazards associated with a product or practice, focusing resources and controls on areas of genuine, evidence-backed risk. The risks associated with clinically supervised medicinal cannabis use are not commensurate with unsupervised recreational use of cannabis.

Although we do not believe that there should be an absolute prohibition on high potency products, we consider it appropriate for there to be additional regulatory controls (additional prescriber justification or regulator approval) that apply to the prescribing of dried flower products and oral liquid products which have potency higher than 30% / 30 mg/mL THC. AMCA also considers it appropriate for those additional regulatory controls to apply also to the prescribing of liquid products intended for inhalation / use in vape cartridges, whereas MCIA recommends that such products not be made subject to that further layer of oversight due to the desire to empower doctors for limited acute indications to prescribe liquid products responsibly when requiring rapid onset and / or fast acting relief where a higher potency is deemed necessary.

In addition to potency controls, AMCA and MCIA propose that there be a maximum 20 mg THC dosage per unit for all solid oral forms.

The TGA may be considering imposing maximum limits on pack sizes, especially for high-potency or high-dose products. AMCA and MCIA do not believe that it would be appropriate to place a maximum limit on pack sizes that is less than the equivalent of a month's supply for a reasonable proportion of the patients for whom a given product would be suitable. Pack sizes should be at the discretion of the sponsor/manufacturer, having regard to prescribing patterns/preferences and to commercial and other factors, such as stability considerations. The key consideration is what constitutes appropriate prescribing, and in that regard both AMCA and MCIA support standard prescriptions being written for a month's supply for the relevant patient (with allowance for practitioners to write prescriptions for shorter timeframes where appropriate (e.g., for cautious introduction and/or titration purposes). That said, it would not be appropriate for sponsors to supply pack sizes of high-potency / high-dose products of more than 1 month's supply, even for the highest dosage users.

Our responses to Consultation questions 6, 9, 10 and 22 contain detailed discussion of this issue, but we draw attention to the following matters in particular.

[78] Di Forti et al., 2019; Murray et al., 2017.
[79] https://www.health.qld.gov.au/__data/assets/pdf_file/0026/1453436/med-cannabis-qld-action-plan.pdf.
[80] https://www.ama.com.au/sites/default/files/2025-07/AMA_Media_Release_AMA_welcomes_updated_guidance_on_medicinal_cannabis_prescribing.pdf .

Global Alignment and Mutual Recognition:

AMCA and MCIA note that international best practice does not rely on potency caps. Jurisdictions such as the EU, New Zealand, Israel, and Poland regulate potency indirectly through GMP, pharmacopeial standards, and prescriber frameworks. By following this model, Australia can align with trusted markets, enable future mutual recognition of testing/labelling standards, and avoid the unintended consequences of potency caps seen in Canada and proposed in the US.

Risk Context:

AMCA and MCIA acknowledge the importance of protecting children and young adults from potential neurodevelopmental risks associated with high-potency THC exposure. Brain development continues until approximately age 25, and some studies suggest increased vulnerability to psychosis in individuals with genetic predisposition or existing mental health conditions. However, the evidence linking high-potency THC cannabis use to psychosis is not conclusive and often oversimplified. Key limitations in the literature include:

- failure to control for genetic and environmental factors.
- lack of differentiation between recreational and medically supervised use.
- confounding variables such as tobacco use, urban living, and poly-substance misuse.

Patients with severe or co-morbidities—including chronic pain, PTSD, neurological disorders, and mental health conditions—often require higher doses of THC to achieve therapeutic benefit. These patients may experience:

- reduced treatment burden through fewer daily doses.
- improved compliance due to simplified regimens.
- lower stigma by avoiding frequent public dosing.
- greater societal participation through more effective symptom control.

Evidence from Canadian veterans and complex care patients supports the need for higher THC concentrations to manage symptoms effectively. Forcing these patients to consume larger volumes of lower-potency products increases cost, complexity, and stigma, and may reduce adherence to treatment[81].

It is at the prescriber/patient interface that detailed discussion as to the patient's need, prior use, other drug use and polypharmacy should be undertaken, and prescriptions recommended to “avoid unnecessary risks, especially for patients with prior psychiatric history or cardiovascular risk. Clinical frameworks prioritise safety and individualised dosing, with evidence suggesting reduced acute harm in tightly regulated prescription markets compared to non-regulated or recreational sources”.[82] Given that we are strongly recommending a new ARTG pathway for Medicinal Cannabis, we believe that this and the enhanced prescribing guidelines outlined in Recommendation 5 (introduce contemporary Prescriber education) should minimise risk and potential harms from higher potency THC products.

Real-Time Prescription Monitoring systems:

Currently, each state and territory has a Real-Time Prescription Monitoring (**RTPM**) system with varying degrees of integration with one another and with medical and dispensing software; this results in the lack of a ‘single’ touch integration of data to inform the prescribing or dispensing action. The consequence of this is either significantly more time spent logging into and checking multiple RTPM systems (and potentially not having access to all systems) or checking the status of prescribing or dispensing events and the patient's home state/territory. Both options have significant vulnerabilities and can and do lead to prescribing or dispensing occurring without a complete medication history.

[81] https://jmvfh.utpjournals.press/doi/pdf/10.3138/jmvfh-2022-0080.
[82] PEN-Cannabis-Regulation-Paper-July-2024.pdf.

The RTPM system consists of two components:

1. A National Data Exchange (**NDE**), which captures information from state and territory regulatory systems, prescribing and dispensing software, and a range of external data sources.
2. Regulatory systems within each state or territory, which manage the authorities or permits for controlled medicines in each state and territory.

A fully integrated 'one-touch' RTPM system would serve as one layer of risk mitigation in the prescribing of THC medicinal cannabis products.

International Experience:

Canada:

- Quebec's 30% THC cap on dried flower led to a resurgence of illicit market activity, with First Nation stores and illegal producers supplying high-potency products.
- Legal producers responded by clustering products just below the cap (e.g. 29% THC), undermining the intent of the policy.
- The 2024 Legislative Review of the Canadian Cannabis Act83 concluded that THC potency caps were ineffective and often counterproductive, recommending education and packaging controls instead.
- Canadian regulators found that:
    - child-resistant packaging and label warnings were more effective tools for managing public health risks.
    - education campaigns helped shift consumer behaviour, with the average age of cannabis initiation rising from 18.9 to 20.7 years between 2018 and 2024.

United States:

- In the United States, the legal status of cannabis differs significantly between the federal and state levels. At the federal level, cannabis remains classified as a Schedule I controlled substance under the Controlled Substances Act.
- Noting the complex legal environment, any potency cap information from the United States is of limited value. However, Lezli Engelking, president of the Foundation of Cannabis Unified Standards (FOCUS), founded FOCUS to address quality, consistency, and safety in the cannabis industry—none of which, she says, will be helped by setting THC limits.'[84]

Germany:

- Medical cannabis is supplied on prescription under the 2024 Medizinal-Cannabisgesetz. Products are controlled via medicines-law licences (manufacturing/wholesale/import) and must meet pharmacopeial quality (e.g., the German Pharmacopoeia/DAB cannabis flower monograph, revised for THC/CBD assay from 1 Oct 2024) and EU-GMP; there is no blanket THC potency cap in the medical framework. Risk is managed through quality standards, pharmacy supply, and prescriber oversight. [85,86,87,88]
- During debates over Germany's 2024 Cannabis Act, proposals for THC potency limits, especially for younger adults, were discussed in leaked drafts and expert commentary (e.g.,

[83] Legislative Review of the Cannabis Act: Final Report of the Expert Panel - Canada.ca.
[84] https://www.greenstate.com/perspective/thc-potency-caps/.
[85] BfArM. "Medizinisches Cannabis / MedCanG" – medical cannabis regulated under Medizinal-Cannabisgesetz (2024).
[86] EDQM. *Ph. Eur. Cannabis flower monograph (3028), Suppl. 11.5* (adopted 2023, in force 2024).
[87] Revised DAB Cannabis Monograph - GMP Navigator.
[88] Library of Congress note on CanG/MedCanG.

10 % THC for ages 18–21).[89] Ultimately, no explicit potency cap for medical cannabis appears in the enacted law, which retains physician oversight under MedCanG.[90] Such a compromise, applied here, would allow the Australian government to increase protection for children and young adults but would also allow doctors the freedom to prescribe the best treatment for their patients.

Poland:

- Medical cannabis is treated as a pharmaceutical raw material for extemporaneous preparation. Import/repackaging requires a manufacturing authorisation and compliance with GMP; authorities emphasise quality control and pharmacy compounding rather than any universal potency limit[91,92]

France:

- Under the ANSM pilot (now transitioning toward a permanent framework), medical cannabis is tightly regulated: initial prescriptions must be hospital-based in reference centres, restricted to indications/situations where efficacy is presumed, and subject to mandatory prescriber training. General practitioners can later continue prescriptions after patient stabilisation under agreement.[93,94,95,96] Access remains under strict clinical control and transition rules (no new patient inclusion post-cut off, transitional coverage).[97] The framework emphasises product quality, safety, oversight, and regulation, rather than imposing a THC potency cap on medical cannabis. [98,99]

New Zealand:

- Under the Medicinal Cannabis Scheme, all medicinal cannabis products intended for supply must comply with the Minimum Quality Standard (MQS) set out in the *Misuse of Drugs (Medicinal Cannabis) Regulations 2019*. This framework requires that every product meet strict quality assurance criteria, including:
    - Cannabinoid content tolerances – the actual cannabinoid content must be verified within defined assay ranges, with validated test methods (typically ±10% of the labelled claim).
    - Pharmaceutical quality controls – limits on microbial contamination, residual solvents, heavy metals, and pesticides, with methods aligned to European Pharmacopoeia standards.
    - Labelling accuracy and mandatory information – product name, cannabinoid content, batch/lot ID, expiry, storage conditions, and the statement “MEDICINAL CANNABIS PRODUCT” on the principal display panel.
    - GMP manufacturing and traceability – all products must be manufactured in GMP-compliant facilities, and sponsors must ensure batch traceability and quality certification prior to supply.

[89] The Hanway company: A cap on high-potency is far from low-risk.
[90] Chambers Global Practice Guide: Medical Cannabis & Cannabinoid Regulation 2025 – Germany.
[91] Chambers Global Practice Guide: *Medical Cannabis & Cannabinoid Regulation 2025 – Poland* (pharmaceutical raw material; GMP; compounding).
[92] CMS Expert Guide: *Cannabis Law and Legislation in Poland* (raw material authorisation; manufacturing/import rules).
[93] ANSM. *Dossier thématique: Cannabis à usage médical* (programme framework & oversight).
[94] Chambers Global Practice Guide: Medical Cannabis & Cannabinoid Regulation 2025 – France.
[95] Chambers Global Practice Guide: Medical Cannabis & Cannabinoid Regulation 2023 – France.
[96] Notification of the texts governing the use of medical cannabis to the European Commission: a new step for access to treatment in France – 2025.
[97] France: 28 March 2025 - Directorate for Legal and Administrative Information (Prime Minister) Therapeutic cannabis.
[98] ANSM. “Professionnels de santé: formation, prescription, dispensation” – mandatory training for pilot prescribers/dispensers. Updated Apr 25, 2025.
[99] GMP-Compliance/ECA summary of the French pilot structure (supporting context).

- Importantly, New Zealand does not impose blanket potency caps on THC or CBD for medicinal cannabis. Instead, risk is managed through the MQS quality framework, labelling accuracy, prescriber oversight, and pharmacovigilance. Products that meet MQS are deemed of suitable quality for prescribing, but they remain *unapproved medicines* unless separately assessed and consented under the Medicines Act. This approach aligns New Zealand more closely with EU-style systems that emphasise standardisation, GMP and testing, rather than an arbitrary cannabinoid ceiling.[100] [101] [102] [103]

Short/mid/long-term actions:

Rather than imposing arbitrary potency caps, AMCA and MCIA recommends:

- *Full national integration of Real Time Prescription Monitoring (RTPM) systems – 'one touch' national medication checks:*

  Integrating the Real-Time Prescription Monitoring (RTPM) systems of all states and territories as a further harm minimisation mechanism. This provides information to doctors/nurse practitioners (prescribers) and pharmacists (dispensers) about a patient's history and use of controlled medicines when they are considering prescribing or dispensing these medicines.

- *Implementation of Recommendation 1:*

  We recommend that the new ARTG pathway for Medicinal Cannabis include relevant and proportionate safeguards to address any perceived issues regarding the risk and effects of varying potency products, while maintaining the flexibility for prescribing varying potency products on a patient needs basis.

- *Implementation of Recommendation 2:*

  We believe there are other methods to reduce perceived or actual risk with varying potency products, such as standardised labelling and dosage, use of the AMT, child-resistant packaging, child safety warnings on THC pastilles and polypharmacy / mental health advisories on high potency THC flower prescription.

- *The strengthening of potency testing standards:*

  We recommend mandatory onshore release for supply potency testing to ensure that all products are initially tested in TGA-accredited laboratories (rather than GMP equivalent overseas laboratories). This will provide additional assurance regarding the stated claims of the active ingredients, specifically THC, and thereby offer clinical confidence in the products being prescribed. Post market surveillance and randomised testing could ensure standards and potency remain consistent after the initial launch period.

[100] Ministry of Health / Medsafe. "Medicinal cannabis products that meet the Minimum Quality Standard (MQS)" (ongoing list; MQS requirements).
[101] Ministry of Health. *Guideline on the Regulation of Medicinal Cannabis in New Zealand – Guidance for new product application* (v3, Apr 2025).
[102] NZ Legislation – Misuse of Drugs (Medicinal Cannabis) Regulations 2019.
[103] NZ Ministry of Health – Guidance for new product applications (Key changes 2024 update).

Recommendation 4: Introduce a shared evidence registry and a pathway to building the evidence base across real world, scientific and clinical evidence.

Overview:

The proposed ARTG entry pathway (Recommendation 1) is designed to enable continued market access for medicinal cannabis products through submission of a dossier focused on GMP compliance, product quality assurance, and pharmacovigilance, without requiring safety or efficacy evidence modules. To complement this, the introduction of a shared evidence registry provides a universal mechanism for systematically collecting, consolidating, and analysing real-world, scientific, and clinical evidence across all products in the market. Together, these measures ensure that patient access is not hindered by evidentiary barriers, while still establishing a structured and transparent framework for building the national evidence base over time. This integrated approach balances patient access, product quality, and the progressive development of high-quality data to inform future regulatory and clinical decision-making.

There is a basic body of evidence regarding the impact of Medicinal Cannabis, supported by widely shared observational stories of the difference it has made for patients, particularly linked to improved sleep, reduced anxiety and relief from chronic pain.[104,105,106]

Expanding the totality of the evidence base for medicinal cannabis in the short to mid-term is a high priority to be supported by any new Medicinal Cannabis ARTG pathway.

Industry is keen to form a collaboration with regulators and key stakeholders to identify an action plan that can rapidly, professionally and ethically create a contemporary benchmark of the relevant evidence base and agree and create the mechanisms by which to harness Real World Data (**RWD**) for Real World Evidence (**RWE**).

Real World Evidence[107,108] could play a significant role in building the evidence base behind medicinal cannabis in both the short-term and then into the mid-term.

Best practice for RWE in medicinal cannabis involves longitudinal data collection from patients under medical care, using patient-reported outcomes (**PROs**), and integrating data from non-interventional studies, registries, de-identified electronic medical records (**EMR**), and insurance claims to comprehensively assess safety and effectiveness.[109]

For example, in the United Kingdom, a database has been implemented in a uniform way that allows for analysis and purposeful use.[110]

Numerous studies have been published using the data in this database, already demonstrating the value of such a program.

Turning Real-World Data into Real World Evidence includes projects and programs such as:

- **Longitudinal follow-up:** Studies should track patients over extended periods while they are under medical supervision. This approach helps identify both benefits and risks, providing insights that short-term randomised controlled trials (**RCTs**) may not identify.[111]

[104] Is a Low Dosage of Medical Cannabis Effective for Treating Pain Related to Fibromyalgia? A Pilot Study and Systematic Review - Society of Cannabis Clinicians.
[105] NatMed Pro.
[106] PAIN.
[107] Real World Evidence in Medical Cannabis Research | Therapeutic Innovation & Regulatory Science.
[108] Tang M, Pearson SA, Simes RJ, Chua BH. Harnessing Real-World Evidence to Advance Cancer Research. *Curr Oncol.* 2023 Feb 2;30(2):1844-1859. doi: 10.3390/curroncol30020143. PMID: 36826104; PMCID: PMC9955401. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC9955401/.
[109] The value of real world evidence: The case of medical cannabis - PMC.
[110] UK Medical Cannabis Registry | Prescribing Medical Cannabis.
[111] Frontiers | The value of real world evidence: The case of medical cannabis.

- **Use of patient-reported outcomes (PROs):** PROs capture quality of life, functional improvement, and symptom relief in ways that standard clinical measures may overlook. [112]
- **Broad patient inclusion:** Real world studies should include patients with co-morbid conditions and diverse demographics, increasing ecological validity and representing typical clinical populations better than restrictive RCT's.
- **Product diversity tracking:** RWE should account for the variety of medicinal cannabis formulations and dosing regimens actually used by patients, including concurrent use of multiple products.
- **Utilisation of electronic medical records and registries:** These sources support post-marketing safety surveillance, long-term pharmacovigilance, and the identification of rare effects.[113] Ongoing secure extraction and analysis of structured de-identified EMR data could be used to build evidence for prescribing practices, as well as to generate continuing and robust post-marketing safety data.

Several leading universities and institutions in Australia are actively researching medicinal cannabis, with a focus on clinical, pharmacological, agricultural, and health policy aspects. These organisations are at the forefront of both basic and applied research, in partnership with government bodies and industry.[114]

These include, but are not limited to:

- **University of Sydney**: The Lambert Initiative for Cannabinoid Therapeutics is a premier research centre investigating the development of safe and effective cannabinoid medicines for multiple conditions.[115]
- **University of Newcastle**: Hosts the Australian Centre for Cannabinoid Clinical and Research Excellence (ACRE), the first federally funded centre of its kind, alongside other projects on evidence-based frameworks for medicinal cannabis use.[116]
- **Swinburne University of Technology**: Conducts trials on the effects of medical cannabis, including a world-first driving safety trial, and research via the Medicinal Cannabis Research Collaboration.24
- **Curtin University**: Leads the QUEST Global study in partnership with industry, focusing on how medicinal cannabis impacts quality of life and healthcare costs for chronic disease patients.[117]
- **NICM Health Research Institute, Western Sydney University**: Runs multidisciplinary clinical trials examining medicinal cannabis for endometriosis and gynaecological health, involving numerous academic partners across the country.[118]
- **RMIT University**: Home to CannaHub, a partnership focused on cannabinoid medicines, delivery systems, and translational research in conjunction with local and international groups. [119]

Collaborating and Supporting Institutions include:

- **Agriculture Victoria Research**: Recognized for cannabis plant genomics and technical research, supporting industry and government needs.[120]

[112] Evidence on PROMs | Australian Commission on Safety and Quality in Health Care.
[113] Real World Evidence in Medical Cannabis Research - PMC.
[114] Medicinal Cannabis.
[115] Home.
[116] The Australian Centre for Cannabinoid Clinical and Research Excellence / Research / Drug Repurposing & Medicines Research / Institutes and centres / Research / The University of Newcastle, Australia.
[117] Global medicinal cannabis study launches next phase in Australia | Curtin University.
[118] NICM HRI | Medicinal Cannabis and Endometriosis.
[119] CannaHub - RMIT University.
[120] Medicinal cannabis | Crops and horticulture | Agriculture Victoria.

- **University of Melbourne**: Engaged in medicinal cannabis policy and clinical research initiatives, including contributions to prescriber education.[121]
- **National Drug and Alcohol Research Centre (NDARC), UNSW Sydney**: Conducts the Cannabis as Medicine Survey and investigates patterns and impacts of medicinal cannabis use nationally.[122]
- **Deakin University, Macquarie University, University of Tasmania, UNSW Sydney, the Medical Research Institute of New Zealand, and Royal Hospital for Women in Randwick**: Also participate in specific clinical trials through multi-centre collaborations led by the NICM Health Research Institute. [123]

Recognising the growing interest in medical cannabis and its potential to address global health disparities, recent summits organised by the Global Health Catalyst (GHC) brought together stakeholders worldwide. These summits, spearheaded by institutions such as Harvard, Johns Hopkins, and the University of Pennsylvania, aimed to foster knowledge sharing, strategic discussions, and collaboration in translating evidence-based research into clinical practice. These institutions' focus is to maximise the benefits, minimise risks, and reduce disparities in access to safe and effective Medicinal Cannabis. The summits identified four core areas (Care, Outreach, Research, and Education) for advancing global health collaborations in this field.[124]

Short-term actions:

- Implementation of digital tools to enhance, standardise and streamline information available to prescribers to assist in clinical decision making.
    - To further support prescribers, AMCA and MCIA recommends the development of digital tools such as:
        - dosage calculators;
        - product database (Recommendation 1, including products that are in SAS-C and then in a new ARTG category for medicinal cannabis products);
        - clinical decision aids.
    - These tools should be integrated with existing *prescribing platforms and updated regularly to reflect new evidence and product availability.*

Mid-term actions:

- Longitudinal data collection from patients under medical care, using patient-reported outcomes (PROs), and integrating data from non-interventional studies, registries, de-identified electronic medical records (EMR), and insurance claims to comprehensively assess safety and effectiveness.
    - Robust, privacy-focused platforms—exemplified by initiatives such as the University of Melbourne's PATRON system—demonstrate the feasibility of conducting large-scale, multi-site analyses of electronic medical record (EMR) data.[125] These infrastructures are capable of integrating with medical practice software, pooling de-identified information across diverse clinical settings, and linking with complementary datasets such as PBS, MBS, and hospital admission records. This interoperability creates opportunities for comprehensive evaluation of medication adherence, clinical efficacy, dosing/treatment plans, adverse event detection, cost-effectiveness, and broader population health outcomes.

[121] Confusing for doctors, inequitable for patients: why Australia's medicinal cannabis system needs urgent reform | InSight+.
[122] Australia's burgeoning love of medical cannabis: Findings from the biennial Cannabis as Medicine Surveys.
[123] NICM HRI | Medicinal Cannabis and Endometriosis.
[124] From farm to bedside: Potential of medical cannabis in global health.
[125] Manski-Nankervis et al., 2024; University of Melbourne, 2024.

- When enhanced by advanced analytic tools, RWE repositories can fulfil two complementary functions: providing retrospective assessments of safety and effectiveness and delivering real-time clinical decision support to prescribers. Such capabilities enhance the early identification of emerging safety concerns, including risks related to dependence, neurodevelopment, or use during pregnancy, as well as evidentiary support for products included on the ARTG via the proposed Australian Medicines pathway.

- Consideration could be given to establish a Centre of Excellence for Medicinal Cannabis research, science, evidence, treatment and prescribing.[126,127]
  - As a future industry with substantial impact on community-wide patient health and Quality of Life, strong rural and regional wellness and economic impacts and high export possibilities, co-investment between Industry, the Research and Innovation sector, and the Government could create a world-leading centre of excellence in Medicinal Cannabis.
  - An arm of the centre could maintain a centralised database on academics and researchers in this field, as well as current education and information for the industry and its stakeholders. This would have both local and international impact and be an opportunity for services exports.
  - In collaboration with key medical stakeholder groups, it could co-create contemporary education resources on the Human Endocannabinoid system as part of the medical school curriculum. This would have both local and international impact and be an opportunity for services exports.[128]

[126] ARC Centres of Excellence | Australian Research Council.
[127] Centres of Research Excellence | NHMRC.
[128] The endocannabinoid system: Essential and mysterious - Harvard Health.

Recommendation 5: Develop and introduce improved health practitioner education and guidelines.

Overview:

We support the co-development of health practitioner prescribing guidelines and education about medicinal cannabis in partnership with clinical schools, colleges, regulators, professional bodies and patient advocacy groups. The initial focus should be guidance and education about high-potency THC products before broadening to other medicinal cannabis products, including CBD. Evidence-based education programs will ensure prescribers have access to relevant, up-to-date knowledge and adopt best practice prescribing, ultimately improving patient outcomes.

We see a significant opportunity to work in collaboration with regulators (such as the TGA and AHPRA), professional organisations (such as AMA and RACGP), medical schools, Medical, Nursing, Midwifery & Pharmacy Boards, state and territory health ministries, and patient advocacy bodies, to review and update medicinal cannabis prescribing guidelines,[129] building on the recent AHPRA guidelines released in July 2025,[130] Pharmacy Board Guidance released in September 2025,[131] and the updated guidelines released by RACGP in September 2025.[132]

In addition, we advocate for stronger health practitioner education, particularly aimed at general practitioners, to help health practitioners prescribe confidently and safely. Educating general practitioners should reduce reliance on medicinal cannabis-specific clinics and embed treatment within mainstream primary care, leading to better patient outcomes. We specifically support the development of a basic course on the human endocannabinoid system.[133]

<u>Global alignment</u>

Prescriber training or structured guidance is incorporated into several international medical cannabis frameworks:

- France's ANSM pilot requires mandatory training for participating doctors and pharmacists.
- Germany (BfArM) treats cannabis as a prescription medicine and provides official guidance to physicians.
- New Zealand issues prescribing tools under the Medicinal Cannabis Scheme;
- Israel operates a specialist-led licensing system.

Adopting comparable education and guidance in Australia would align with international best practices and support the future recognition of training standards by trusted regulators.[134,135,136,137]

The enabling of more GPs to prescribe confidently and safely by using proposed improved guidelines should reduce reliance on cannabis-specific clinics and embed treatment within mainstream primary care, leading to better patient outcomes.

Short-term actions:

- Industry can draft 'above brand' education for review/endorsement by RACGP and for ultimate delivery by RACGP, including business practice education, Ministerial consultation group with representatives from all regulators.

[129] Appendix-Medicinal-use-of-cannabis-products.pdf.
[130] https://www.ahpra.gov.au/News/2025-07-09-Medicinal-cannabis-guidance.aspx.
[131] https://www.pharmacyboard.gov.au/News/2025-09-23-Medicinal-cannabis-guidance.aspx.
[132] Deprescribing.
[133] Review of the Endocannabinoid System - PMC.
[134] France ANSM:Health professionals: training, prescription, dispensing.
[135] Germany Bfarm: Notes for Physicians.
[136] New Zealand MCA: A guide to prescribing medicinal cannabis.
[137] Israel Ministry of Health: Medical Care with Cannabis.

- Industry could further assist in the short-term distribution of any revised guidelines from the working group/s above, while continuing to engage on the further development of policies through the mid-term with the Regulator and the patient advocacy bodies.

This revised program should reflect the CPD style of training and education, ensuring that prescribers can build their knowledge consistently. These initiatives should be designed in alignment with CPD requirements under AHPRA, RACGP and AMA frameworks, and developed with potential for international reciprocity so that Australian prescriber training can be recognised by trusted overseas regulators and vice versa.

The Centre of Excellence proposed under Recommendation 4 could serve as a platform to house and continually update these prescriber courses, ensuring they remain internationally benchmarked and mutually recognised.

Mid Term:

- AMCA and MCIA recommend a national curriculum for medicinal cannabis prescribing and dispensing aligned with AHPRA'S National Prescribing Competencies Framework. Including but not limited to:
    - The development of an introductory course on the human endocannabinoid system[138] and cannabinoid pharmacology could be a short-term program that bridges the gap between current prescriber knowledge and what is deemed adequate.
    - The development of an extensive course on the human endocannabinoid system[139] and cannabinoid pharmacology could be a mid-term program that aims to bridge the gap between current prescriber knowledge and what is deemed best practice.
    - The development of clinical modules focusing on epidemiology and specialties of treatment, such as pain medicine, palliative care, psychiatry (mental health: anxiety, depression, sleep disorders), oncology, gastroenterology, rheumatology or neurology.
- These courses should include modules such as evidence-based clinical indications (accompanied by graded levels of supporting evidence for each condition), risk-benefit assessments, contraindications and precautions, drug-to-drug interactions, considerations for vulnerable patient cohorts and safety profile/potential side effects, regulatory and legislative requirements at both federal and state/territory levels. Key areas to be addressed include informed consent, development of coordinated care plans with all healthcare providers involved, shared decision-making, principles of safe prescribing and dispensing, ongoing monitoring and clearly defined exit strategies.
- These courses could provide a platform to capture and continuously develop best practices in understanding and prescribing relevant medicinal cannabis products for specific conditions, in an iterative format, if designed as such from the outset.
- These are the current courses currently available on the ECS*:

Institution/Provider	Course Focus	Delivery Mode
Medihuanna	Cannabis Science and Pharmacology, ECS detailed study	Online
University of Sydney (Lambert)	Cannabinoid therapeutics, ECS research	Research & Education
Planteducation	Accredited medical cannabis courses with ECS modules	Online

[138] Review of the Endocannabinoid System - PMC.
[139] Review of the Endocannabinoid System - PMC.

Institution/Provider	Course Focus	Delivery Mode
ANZCCP	Cannabinoid medicine principles including ECS	Online
University of Newcastle (ACRE)	Clinical cannabinoid research and ECS education	Mixed
Western Sydney University (NICM)	ECS in clinical trials and chronic disease research	Mixed

* Perplexity Review 250928

Consultation Submission – Response to Questions

Quality and safety requirements of medicinal cannabis products

1. Do you consider the current quality and safety requirements to be appropriate and sufficient for medicinal cannabis products?

The current quality and safety requirements set out in the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* (**TGO 93**), supported by the *Therapeutic Goods (Poisons Standard - June 2025) Instrument 2025* (**Poisons Standard**), provide a credible minimum standard for quality and safety.

TGO 93 provides a rigorous framework that ensures medicinal cannabis products meet the minimum standards for quality, manufacture, labelling and ingredient identification. This framework ensures that medicinal cannabis aligns with the broader quality and safety requirements that apply to other therapeutic goods, while still recognising the unique characteristics of plant-derived products. TGO 93 ensures high standards of manufacturing quality by requiring compliance with Good Manufacturing Practice (**GMP**). Importantly, it recognises GMP certification from multiple jurisdictions, including the EU, US, Canada, South Africa, New Zealand, and Israel. Where no recognised certification is available, the TGA retains the authority to conduct its own inspections, which provides an additional safeguard to ensure manufacturing quality compliance. This dual approach gives confidence that both domestic and imported products meet equivalent quality expectations.

The requirements under TGO 93 include limits for contaminants such as aflatoxins, ochratoxin A, heavy metals, pesticides, total ash and foreign matter, mandating assay limits with clear tolerance bands depending on dosage form (*e.g.,* 80-120% for herbal forms; 90-110% for tablets, capsules or other dosage forms). TGO 93 incorporates validated pharmaceutical and herbal monographs from the European Pharmacopoeia, ensuring global microbiological quality standards.

Despite requiring manufacturers and sponsors to demonstrate robust quality controls, TGO 93 also ensures flexibility by not imposing rigid and unnecessary pharmaceutical-grade requirements that could restrict patient access.

However, TGO 93 could be enhanced to further improve the quality and safety of medicinal cannabis products. It does not fully account for the unique risks associated with certain dosage forms of medicinal cannabis, such as medicinal cannabis flower intended for inhalation. For this route of administration, although TGO 93 provides a pathway for controlling bioburden to some extent, in terms of the requirement for irradiation, it does not impose a mandatory inhalation-specific microbiological specification. This leaves open the possibility that dried herbal material could contain residual fungal spores or other microorganisms that, while acceptable in oral products, pose a heightened risk of harm when inhaled, especially for immunocompromised patients.

Similarly, there is variability in the analytical methods used by different laboratories for measuring cannabinoids, terpenes, residual solvents and contaminants, such that the absence of harmonised, validated methods means that Certificates of Analysis (COAs) from different sources may not be directly comparable. This may undermine both prescriber confidence and the reliability of regulatory oversight.

While TGO 93 establishes a necessary foundation, further refinements, addressed in our response to Question 2 below, may provide further safeguards ensuring the quality and safety medicinal cannabis supplied in Australia.

Imported products present another vulnerability. Although overseas manufacturers must hold GMP evidence, batch release is based on documentary review of COAs rather than confirmatory testing in Australia. This reliance on desk-based assurances may be appropriate for well-established suppliers with a long track record of compliance, but it creates risk when products are sourced from new

facilities or where analytical methods have changed. On balance, we recommend mandatory onshore (*i.e.* in Australia) release for supply testing to ensure that all products are initially tested in TGA-accredited laboratories, rather than relying solely on GMP equivalent overseas laboratories.

Related to this is the issue of stability. Unlike most conventional pharmaceuticals, medicinal cannabis products may be subject to dynamic chemical change over time, particularly the decarboxylation of acidic cannabinoids in herbal material and the oxidation or precipitation of compounds in oil formulations. There is no cannabis-specific guidance aligned with ICH principles that prescribe real-time, accelerated or in-use stability studies. As a result, label statements about storage conditions and expiry often lack a robust evidence base and do not reflect the compositional complexity of medicinal cannabis.

Another area where the current requirements are insufficient is in the provision of warnings and safe use statements on labels. Although the scheduling framework and Appendix K sedation warning offer some protection, in practice many labels understate or inconsistently present critical risks such as impairment of driving ability, interaction with other sedating medicines, or contraindications in pregnancy and breastfeeding. For inhaled products, there is also no requirement to specify which vaporiser devices and temperature ranges have been validated for use with a given product, even though these factors directly influence both dosing consistency and the generation of degradation byproducts.

Finally, the boundaries between GMP-controlled manufacture and extemporaneous compounding are not clearly drawn. Although extemporaneous compounding of medicinal cannabis products was prohibited under Item 6 of Schedule 5 of the *Therapeutic Goods Regulations 1990* because of concerns about increasing manufacture of medicinal cannabis products that were not manufactured to GMP standards, compounding is still ostensibly being permitted as long as there is an AP or SAS approval in place for the product to be compounded. What that means is that the prohibition under Item 6 of Schedule 5 of the TG Regs has not had its intended effect, which was to significantly curb compounding.

2. Are there any changes you would recommend to the current quality requirements for medicinal cannabis products? If yes, please describe why changes are required

As outlined in our response to Question 1 above, TGO 93 already provides a comprehensive framework for regulating the safety and quality of medicinal cannabis products, including robust GMP manufacturing obligations. The changes we propose are intended to complement the current approach so that it more effectively addresses residual areas of risk. The aim is to strengthen consistency between domestic and international manufacturers and enhance transparency between manufacturers and the TGA.

Verification of evidence

Currently, sponsors are required to retain evidence demonstrating compliance with TGO 93 (*i.e.*, Certificates of Analysis, validation data and test results) until the expiry of the batch. However, this evidence only needs to be presented to the TGA upon request. While this system reduces administrative burden, it also creates a compliance and enforcement gap, where products can reach prescribers and patients before any evidence has been independently verified. Introducing a mandatory pre-release verification step would close this gap without imposing a full pre-market approval regime. Under such a model, sponsors of nominated higher-risk products or dosage forms would be required to upload Certificates of Analysis and other key batch documentation to the TGA before release. The TGA could choose to impose a risk-based proportionate approach where only certain categories of products are prioritised, meaning that not every batch of product would require such verification *e.g.,* restricted only to inhalation products, high-THC potency products, products from new manufacturers (especially from overseas).

Reduced and rotational testing

TGO 93 permits reduced, or rotational, testing of cannabis plant used in the manufacture of a medicinal cannabis product if it is justified on GMP grounds. For example, a manufacturer may be able to justify not conducting pesticide testing if no pesticides are used in the cultivation of the plant. Minimum frequencies should be imposed so that reduced testing does not erode baseline protection against heavy metals and pesticides. Additionally, manufacturers should revert to full testing after any deviation so as to reduce the risk of compromising cannabis plant quality.

Inclusion of medicinal cannabis vaping device safety standards

TGO 93 does not currently include provisions specific to the safety and quality of medicinal cannabis vaping devices. While it establishes requirements for assay, contaminants, microbiological quality and labelling for medicinal cannabis products generally, it does not address the unique risks posed by inhalation delivery systems. By contrast, the Standard for Nicotine Vaping Products (TGO 110) was developed to manage the distinct hazards of therapeutic vapes, incorporating requirements around excipient safety, emissions testing and child-resistant packaging. At present, medicinal cannabis vapes are only covered under TGO 93 to the extent that they must comply with cannabinoid content and purity requirements, with inhalation-specific risks addressed only indirectly through TGO 100 (microbiological standards) or pharmacopeial monographs for excipients.

To address this gap, TGO 93 should be expanded to incorporate a dedicated standard or annex specifically for medicinal cannabis vapes. This framework could include, at a minimum, a positive list of acceptable diluents and excipients to provide clarity on what additives are permitted, as well as requirements for explicit emissions and device safety testing (*e.g.,* controls on coil temperature to prevent combustion or harmful by-products). Establishing a parallel standard to TGO 110 would close current quality gaps across therapeutic vaping products, whether nicotine or cannabis based. Importantly, it would also enhance post-market confidence by assuring prescribers and patients that medicinal cannabis vapes are subject to the same rigorous safety expectations as other inhaled therapies.

Product Labelling

Generally, the existing quality requirements for medicinal cannabis products in Australia (*i.e.* TGO 93) are comprehensive in maintaining the quality of medicinal cannabis products. However, an area for improvement is product labelling. In particular, the introduction of plain or standardised labelling requirements could help distinguish medicinal cannabis products from illicit goods or any potential future recreational products. This approach would reduce the risk of misleading branding that risks blurring the distinction between medicinal and use of cannabis. The potential for labelling improvements is discussed in our response to Question 3 below.

3.	***Noting the current labelling requirements outlined in TGO 93, do you consider these to be adequate to allow prescribers and consumers sufficient information to properly identify the goods and know how to use and store them safely? If not, please describe which changes are required.***

The current labelling requirements for medicinal cannabis products in TGO 93 are largely well-suited to the product category but they are somewhat inadequate in a number of respects and would benefit from a number of improvements, including standardisation.

In terms of what they presently achieve, the current labelling requirements ensure that products can be properly identified, and that basic safety information is available for both prescribers and patients. At their core, these requirements mirror those imposed on other Schedule 8 and Schedule 4 medicines: products must display their name, dosage form, active ingredient concentrations, batch and expiry details, storage instructions and sponsor/manufacturer information. They must also carry any mandatory cautionary statements required by their scheduling status. Prescribers can

confidently identify the product they are authorising, and pharmacists can dispense with traceability assured through batch number and expiry date information. For plant-based products, additional information such as the plant species, plant part, type of preparation and weight of the plant material is also required.

The suitability of this framework is reinforced by the context in which medicinal cannabis is accessed in Australia. These are not consumer goods sold in open retail environments, as in other external jurisdictions. They are prescription medicines accessed through the SAS or APS, dispensed by pharmacists pursuant to a prescription from prescribers who are expected to provide appropriate clinical information to their patients. The label is therefore one part of broader clinical oversight, instruction and education, and not the sole or primary source of patient instruction. For these reasons, the present labelling requirements are fit for purpose to a reasonable extent.

However, there is considerable scope for further improvements to enhance safety. While TGO 93 ensures that key information is present, there are several areas where the practical realities of medicinal cannabis product use indicate that improvements can be made. The first relates to dosing clarity. At present, concentrations are expressed in the conventional pharmaceutical manner, such as mg/mL for oils or mg/g for flower. While this is technically accurate and suitable for prescribers, many patients struggle to translate these figures into practical use. For example, an oil labelled “25 mg/mL THC” requires the patient to calculate how much THC is in the 0.1 mL they are instructed to draw into their oral dropper (or, for example, how much of a 10 mL bottle they are required to draw into their dropper if the dose is 1 mg or 2 mg THC per day). Prescribers often write instructions that simplify this arithmetic, but confusion still arises in practice. For this reason, such information is perhaps best tabulated in a consumer medicines information document that is provided to the patient when the medicine is dispensed. Regardless, requiring that labels express cannabinoid content both as concentration and as the amount per typical discrete unit (*i.e.*, per capsule or per activation of a dispensing device) would bridge the gap between pharmaceutical accuracy and patient usability.

A second area of concern is the signalling of THC-related impairment. Unlike opioids or benzodiazepines, which, as registered goods routinely carry strong impairment warnings, THC-bearing medicinal cannabis products sometimes rely only on the mandatory drowsiness statement required under the Poisons Standard. Yet, as THC’s potential impairment profile is distinctive and well documented, it would therefore be sensible to mandate a clear, THC-specific warning on the principal display panel of any product containing more than a threshold amount of THC (such as a THC dominant product). A statement such as “Contains THC – may cause impairment.” would be proportionate and consistent with the approach taken in relation to other impairing medicines. This small adjustment would give patients a reminder of the risk of impairment at the point of administration that may not otherwise be at the front of their mind when taking the product.

Product differentiation also presents an emerging challenge. Many manufacturers supply multiple formulations under a common brand, differing only in cannabinoid profile. While the technical labelling under TGO 93 distinguishes them, it risks the heightened possibility for patients, or even pharmacists, to confuse a CBD-dominant variant with a THC-dominant one, particularly when their names are similar. A standardised requirement to display the THC:CBD ratio prominently on the front panel would mitigate this risk. For example, a product could be clearly labelled “THC:CBD 20:1” or “THC:CBD: [next most abundant cannabinoid] 3:3:10” for other cannabinoid dominant products. Such ratio cues are already used informally on some labels and standardising this practice would reduce the likelihood of errors occurring.

Another issue is transparency around natural variability. Plant-derived products will inevitably show some degree of batch-to-batch variation in cannabinoid content. While TGO 93 requires actual content to be stated, patients are not necessarily told that a small degree of variation is acceptable. This can erode trust, or in rare exceptional circumstances lead to dose-related issues, when a repeat prescription shows slightly different numbers to a batch of a given medicinal cannabis product. Canada addresses this by requiring labels to state “total THC” and “total CBD” with an acknowledged variance range. Australia could adopt a similar approach, requiring labels to reflect

permitted variance ranges (*i.e.*, "Potency may vary within ±10% of label claim") or embedding that information in a QR code linking to the relevant batch certificate of analysis. This would appropriately inform prescribers and patients that variability is expected and controlled, rather than a sign of quality issues.

Storage instructions under TGO 93 are also generally sufficient but could be refined for certain dosage forms. Oils and extracts often have stability limits once opened, yet few labels specify a "use within X days of opening" instruction. Including such information would prevent patients from unknowingly using degraded products. For dried flower, clearer statements could be given about appropriate storage, such as avoiding high temperatures, refrigeration or freezing unless directed, to reduce the risk of microbial contamination (yeasts or bacteria) or loss of potency. Pictorial representations could be considered for implementation, particularly to assist older patients or those with limited English proficiency.

Route of administration is another area where additional emphasis would be valuable. Some patients have mistakenly assumed oral oils could be used in a vaping device, or conversely have ingested medicinal cannabis product e-liquid preparations intended for vaping. Mandating unambiguous route of administration statements on the labels of products such as "ORAL USE ONLY" or "FOR INHALATION ONLY", would reduce this risk.

Excipient and allergen information, while technically present, is not always salient. For example, the use of MCT oil or sesame oil as a carrier can be important for patients with sensitivities. Registered or listed medicines often carry mandatory warnings on the label or in the PI addressing known allergen concerns.

In considering these proposed changes, it is important to emphasise proportionality. The current labelling requirements have broadly been demonstrated to be both safe and effective, and the changes proposed here are not intended to suggest the present labelling requirements under TGO 93 are unsafe. They build on a framework that is already fit for purpose by adding to clarity, usability, and patient-centred reinforcement. The current labelling requirements under TGO 93 can be considered adequate to allow prescribers and patients to properly identify medicinal cannabis products and to store and use them safely. Nonetheless, there are several refinements that would enhance safety and usability: clearer discreet dose labelling, explicit THC impairment warnings, prominent ratio labelling, transparency about batch variability, stronger storage and route of administration statements and improved excipient and allergen warnings. These proposed changes do not amount to fundamental changes, but rather iterative regulatory improvements that would further strengthen patient safety.

4. What information would you like to see on medicinal cannabis product labels to help better understand what is in them and to ensure their safe use?

The current labelling framework for medicinal cannabis, established under TGO 93, provides a baseline of information but is insufficient to ensure safe, consistent and rational use of these products in clinical practice. Medicinal cannabis is not a conventional pharmaceutical product. Its risk profile varies significantly by route of administration, THC concentration, excipient composition and batch-to-batch variability. Accordingly, labelling requirements must be strengthened and harmonised with the broader regulatory framework for scheduled medicines.

At present, TGO 93 omits a number of important safety and usability features that are mandated under other orders and standards, such as TGO 91, TGO 92, TGO 110, and the Poisons Standard. Incorporating provisions on signal headings, advisory statements, legibility controls, allergen and excipient declarations, dedicated dispensing-label space and barcode/traceability requirements would align medicinal cannabis labelling with the established regime for other therapeutic goods. This would prevent the current regulatory fragmentation in which medicinal cannabis operates outside the safety norms applied to comparable prescription-only medicines.

Moreover, many sponsors are currently using labels as *de facto* post-marketing advertising, which risks influencing patient behaviour inappropriately, particularly given that medicinal cannabis products are unapproved medicines. Standardisation of the main label, including placement, font size, warning statements and clarifying permitted and prohibited content to remove or reduce promotional elements, would ensure that the medicine label functions strictly as a safety and compliance tool rather than a marketing device.

Dosing clarity

Labels presently state cannabinoid concentrations in either mg/mL or mg/g, as required by TGO 93, but do not consistently present the amount of THC and CBD per practical dose increment (*e.g.,* per 0.1 mL increment in oils, per capsule or pastille in solids, per actuation for metered sprays and per typical inhalation for dried flower). Including the amount of THC and CBD per practical dose increment on the label would be consistent with international best practice and help mitigate dosing errors, particularly for vulnerable or unsophisticated consumers.

Impairment and dose route specific warnings

All THC-containing products should include an unambiguous impairment warning, beyond that it may cause drowsiness as required by the Poisons Standard. Route-specific warnings are also critical: inhaled products should highlight rapid onset and relative short effect duration, while oral products should emphasise delayed onset (up to two hours) and relative long effect duration. These requirements are likely to reduce dosing behaviour resulting in acute intoxication or other dosing-based adverse events.

Excipients, quality, and allergen declarations

Labels should include excipient declarations in a dedicated “Contains” statement, particularly for common carriers such as ethanol, MCT oil or sesame oil, which have clinical relevance to certain patients. This aligns with requirements in other TGOs and strengthens informed clinical decision-making.

Batch reporting; variability, stability, and storage

Labels should state tested cannabinoid content together with an accepted tolerance of variance (*e.g.*, ±10%). Explicit storage instructions should be included, such as “Use within X weeks of opening”, “Mix well”, or “Keep container closed when not in use”, depending on dosage form. This provides patients with clear instructions for maintaining stability and quality.

Standardisation and harmonisation with Consumer medicines information and Product information

It is essential that labelling requirements be explicitly linked to mandatory provision of Consumer Medicines Information (**CMI**) and Product Information (**PI**). A harmonised approach, as is already required for nicotine vaping goods, ensures that prescribers and patients access consistent safety information across supply chains. Standardised CMI/PI should include adverse event warnings, interactions and pregnancy and breastfeeding warnings, and would align medicinal cannabis with the obligations imposed on other therapeutic goods.

Label integration with the National Clinical Terminology Service

Consideration should be given as to the merits and feasibility of the Australian medicinal cannabis sector adopting National Clinical Terminology Service (**NCTS**) and Australian Medicines Terminology (**AMT**) as coding standards throughout the supply chain, from product development and TGO 93 label generation to electronic prescribing and dispensing. This could enhance regulatory compliance and operational efficiency, support clinical decision-making and position the sector for possible future PBS (or other reimbursement) integration and international export. QR codes on labels could provide direct access to batch certificates of analysis, CMIs/PIs, and adverse event reporting systems, improving traceability and pharmacovigilance.

Strengthening medicinal cannabis labelling requirements is a sensible regulatory reform strategy that aligns with the broader principle of developing a more rounded regulatory ecosystem for medicinal cannabis products. Incorporating provisions from existing TGOs, standardising label

content and layout, mandating with the provision of CMIs/PIs and embedding coding and traceability standards will improve patient safety, support prescribers and pharmacists, reduce inappropriate advertising and ensure that medicinal cannabis products are more fully integrated within the established regulatory framework for therapeutic goods.

5.	***In general, what are the safety risks you have identified or are concerned about with unapproved medicinal cannabis products? If possible, please provide data or other forms of evidence to support those views.***

While there is no verified evidence of causal harm from appropriately prescribed medicinal cannabis, particularly in supervised clinical settings, the unapproved status of all but two of the medicinal cannabis products supplied in Australia introduces uncertainties that weigh into patient risk. The principal safety risks associated with unapproved medicinal cannabis products in Australia stem from variability in product quality, inconsistent labelling, unregulated or poorly tested delivery devices, and a lack of comprehensive post-market surveillance.

Addressing these concerns through improved regulatory oversight, enhanced labelling requirements and robust monitoring systems would reduce risks and ensure that medicinal cannabis can be used safely and effectively in clinical practice.

Below we outline the primary safety concerns that we believe need to be considered.

Concentration of THC

The concentration of THC in medicinal cannabis products is one of the most significant safety concerns, particularly noting that medicinal cannabis products are unapproved therapeutic goods (apart from Sativex and Epidyolex) and have not undergone pre-market assessment of quality, safety and efficacy.

High-THC products, particularly those exceeding 30% THC by weight (common in dried flower and concentrated oils), carry a higher risk of acute adverse effects. THC's pharmacological profile, which is characterised by rapid onset when inhaled, can lead to heightened risks such as intoxication, anxiety, psychosis, cardiovascular stress (including tachycardia and elevated blood pressure), and cognitive impairment. This is especially relevant for individuals with underlying vulnerabilities or who are unaccustomed to its psychoactive effects. For instance, an unregulated, high-potency product might deliver a far greater dose of THC than the patient's clinical needs, exacerbating these risks.

In contrast, lower-potency products and more controlled delivery mechanisms, such as those with consistent oral dosing, may reduce these acute risks. Nonetheless, the key safety consideration is not just the concentration of THC itself, but how it is dispensed to patients and over what duration. Much like opioids, it is the total daily dose and duration of use that most significantly impacts harm.

The experience with opioids and benzodiazepines provides an instructive parallel. In Australia and internationally, regulators have increasingly recognised that certain high-dose or high-potency formulations carry disproportionate risk and are not supported for routine use. This recognition has driven the introduction of *abuse-deterrent* opioid formulations and restrictions on high-dose products, led notably by the FDA's post-Purdue reforms.

Similarly, prescribing controls and product restrictions have been applied to high-risk benzodiazepines. For example, alprazolam is subject to additional prescribing safeguards, while some fluorinated benzodiazepines are prohibited altogether. The withdrawal of temazepam gel capsules and other abuse-prone formulations has further contributed to harm reduction. These precedents underscore the importance of product-specific controls for high-risk formulations – an approach that may be equally relevant to high-THC medicinal cannabis products.

Mode of Delivery and Device Safety

The route of administration also plays a crucial role in the safety profile of medicinal cannabis. For example, vaporised cannabis provides rapid absorption via the lungs, leading to immediate pharmacodynamic effects. While vaporisers can be effective for rapid symptom relief, they come with potential risks stemming from variability in delivered doses and bioavailability across different devices. A dried flower vaporiser, for example, operates differently from a vaporiser that uses a liquid carrier substance, and each device can deliver a different concentration of cannabinoids, complicating dosage control. Additionally, the delivery devices themselves may present safety risks if they are not adequately tested or regulated. For example, unapproved vaporisers may lack child-resistant features or safeguards against accidental discharge, increasing the risk of misuse or injury. Reports of device malfunctions, including fires, explosions and burns caused by battery failures or faulty designs, underline the importance of ensuring that these devices comply with similar standards to those applying to medical devices. It is worth noting that several medicinal cannabis vaporisers are already included in the ARTG, ensuring that they meet Australian regulatory standards, which should reduce the risk of such incidents, if they are indeed used, which again depends on the route of administration of the prescribed medicinal cannabis.

Product Quality and Variability

Another concern with unapproved medicinal cannabis products is the lack of formal regulatory oversight that ensures consistency in product quality. Unlike approved pharmaceuticals, which undergo stringent testing for quality, safety and efficacy, unapproved medicinal cannabis products are evaluated primarily for manufacturing quality (*viz* GMP compliance) rather than their therapeutic benefit. The precise cannabinoid content of a product, its excipients and formulation may vary significantly between batches. Such variability poses a tangible safety risk, as patients may receive a dose that is significantly different from what is stated on the label, potentially leading to adverse effects or inadequate therapeutic outcomes. While products are required to meet certain labelling standards under TGO 93 – such as active ingredient content, batch number and expiry date – there are often gaps in key information, including instructions on proper administration, specific device usage and guidance on dosing per therapeutic unit. For example, unapproved medicinal cannabis oils or tinctures may not provide adequate information on how to adjust doses according to the concentration of THC, which could result in dosing errors, particularly for patients managing complex medical conditions or polypharmacy. Enhanced labelling practices, including device-specific instructions, more information about cannabinoid and terpene profiles and stability data, would go a long way towards mitigating the risks and improving patient safety.

Vulnerable Populations

The risks associated with high-THC cannabis are amplified in certain vulnerable populations. For example, adolescents and young adults, individuals with a history of psychotic illness or a family history of schizophrenia, those with substance use disorders (including alcohol, opioids or stimulants), patients with serious cardiovascular or cerebrovascular conditions, and those with hepatic impairment or on interacting medications, are at greater risk of experiencing adverse effects from THC. THC has been shown to interact with the brain's reward system and may exacerbate existing conditions, particularly in individuals who are predisposed to psychiatric disorders. As such, prescribers should exercise heightened caution when considering high-potency THC products for these populations. A careful case-by-case clinical assessment is necessary to ensure that THC products are used safely and appropriately.

CBD has fewer safety concerns than THC-containing products – however, it still presents some safety issues for certain patient groups. The initiation and use of CBD needs greater caution in patients with hepatic impairment (and indeed baseline liver function tests should be performed in patients with clinical evidence of hepatic impairment) and in patients using other medications known to impact upon, and be impacted by, CBD metabolism via the CYP450 hepatic enzyme system. CBD can inhibit the metabolism of other medications (notably benzodiazepines and certain opioids such as methadone), thereby increasing their plasma concentrations and potentially causing clinical toxicity of other medications (*e.g.,* oversedation with benzodiazepines or methadone).

Post-Market Surveillance and Reporting

Another important limitation with unapproved medicinal cannabis products is the lack of comprehensive post-market surveillance. Unlike approved therapeutic goods, which are subject to post-market monitoring requirements for quality, safety and efficacy, unapproved medicinal cannabis products lack systematic oversight. Although prescribers are required to report serious adverse events to the TGA within 15 calendar days, there is a general perception that adverse events are underreported which, if it is true, would give an incomplete understanding of real-world outcomes. This gap in surveillance impedes the detection of emerging safety signals or product-specific risks. While international studies have generally found that adverse events with medicinal cannabis are mild and dose-dependent, such as transient dizziness or gastrointestinal discomfort, there is still a need for more robust post-market monitoring, including the requirement for mandatory reporting of serious adverse events. Strengthening these systems would provide more reliable evidence to inform future safety management and regulatory decision-making.

Regulatory Gaps and Recommendations

Although there is an absence of comprehensive regulation in relation to unapproved medicinal cannabis products which may increase the safety risks, these safety risks can be mitigated through enhanced regulatory oversight. Standardising labelling requirements to include clear dosing instructions, excipient details and stability information could reduce the risk of dosing errors. In addition, implementing audited safety and performance standards for delivery devices and ensuring that they meet rigorous acceptable standards would reduce the risk of device-related injuries. Further, implementing mandatory post-market surveillance and serious adverse event reporting requirements would allow the TGA to identify and address any emerging safety concerns that arise. These measures would assist in ensuring that medicinal cannabis products are used safely, supporting their role as a therapeutic option while minimising the risks associated with their unapproved regulatory status.

Dosage forms and routes of administration

6. The following dosage forms are being prescribed for unapproved medicinal cannabis medicines for the following routes of administration – detailed descriptions of each dosage form can be viewed on the TGA's Code Table:

Dosage form	***Associated route of administration***
Capsule	*Oral*
Extract – concentrated	*Inhalation*
Granules	*Oromucosal*
Herb, dried (for vaporisation)	*Vaporisation*
Herb, dried (oral)	*Oral*
Inhalation	*Inhalation*
Inhalation, pressurised	*Inhalation*
Lozenge	*Oral*
Oral liquid	*Oral*
Pastille	*Oral*
Patch, dermal	*Topical*
Pessary	*Vaginal*
Powder	*Oral*
Spray, solution	*Oral*
Suppository	*Rectal*
Tablet	*Oral*
Tablet, chewable	*Oral*
Topical	*Topical*
Wafer	*Sublingual*

By way of preliminary comment, before dealing with each of questions 6(a), 6(b) and 6(c) specifically, we note that medicinal cannabis encompasses a diverse range of dosage forms, each presenting distinct safety considerations that must be carefully evaluated in clinical practice. Among these, inhaled cannabis products, particularly dried flower with high THC potency exceeding 25 to 30 percent by weight, warrant special attention due to their rapid pharmacokinetic profile. Inhalation leads to rapid absorption of THC through the pulmonary alveoli, resulting in peak plasma concentrations within minutes and a short duration of action. This rapid onset and offset pharmacodynamics increase the risk of acute adverse events. Moreover, the swift pharmacological effects may increase the risk of dose escalation, misuse and diversion, as observed clinically where patients using inhaled cannabis frequently request increases in dose, product strength or quantity compared to those using oral formulations.

This contrasts with an oral THC oil where onset may be delayed by one to two hours due to first-pass hepatic metabolism, producing more gradual and sustained effects. This difference highlights the importance of assessing oral and inhaled products as pharmacologically distinct entities, rather than attempting to compare THC content on a milligram-per-milligram basis. Applying "mg THC equivalent" calculations across routes ignores fundamental differences in absorption, metabolism and potential psychoactive effects, which could lead to inappropriate dosing and underestimation of risk.

The variability of hepatic metabolism of oral THC represents another critical consideration. THC undergoes extensive first-pass metabolism. Interindividual differences in hepatic enzyme activity, which may be influenced by genetic polymorphisms, hepatic function and concurrent medications, can result in wide variability in pharmacodynamic response. For instance, patients with enhanced hepatic metabolism may experience stronger or prolonged effects at lower doses, whereas others

may require substantially higher doses to achieve therapeutic benefit. This variability is independent of tolerance or misuse but can lead to misinterpretation by clinicians unfamiliar with these pharmacokinetic nuances, potentially resulting in unjustified labels of medication misuse or inappropriate dose escalation. A pragmatic clinical example includes a patient with hepatic impairment who requires dose adjustments and close monitoring, not for reasons of addiction but due to altered metabolism.

Solid oral formulations such as pastilles or gummies may present practical advantages, especially for older adults or patients with neurological or coordination impairments who struggle with measuring oils or capsules. The ability to cut pastilles into smaller doses enables fine-tuning of THC intake, a dosing flexibility not possible with fixed-dose capsules. However, these formulations carry a potential risk of accidental ingestion by children due to their palatable taste and resemblance to confectionery. This underscores the need for robust regulatory measures such as per-unit THC limits, which are commonly capped at 10 mg THC per edible unit in Canada, and mandatory child-resistant packaging, plain labelling and clear storage instructions to mitigate risk.

Vaporisation devices, including portable vaporisers and pressurised inhalers, must meet stringent quality and safety standards. Several vaporisers are included in the ARTG and therefore comply with the essential principles demonstrating safety and performance. Where possible, clinicians should preferentially ‘prescribe’ ARTG-included vaporisation devices to safeguard patient use and reduce device-related harm. Proper patient education on device maintenance, cleaning and correct usage is essential to prevent malfunction, reduce respiratory irritation and promote treatment adherence. Long-term inhalation effects are incompletely understood but warrant ongoing monitoring given the potential for respiratory effects.

Topical and transdermal medicinal cannabis products offer alternative routes for localised symptom management, particularly in chronic pain and inflammatory conditions. These formulations typically avoid systemic psychoactive effects but their efficacy varies considerably, with limited high-quality clinical evidence supporting their use. Transdermal patches provide controlled release but absorption can be influenced by skin condition, temperature and moisture, introducing variability in plasma concentrations. Patients should be counselled on correct application sites, the potential for skin irritation, and the need for vigilance in reporting adverse reactions.

Specialised dosage forms such as suppositories and pessaries represent alternatives for patients unable to use oral or inhaled routes. These mucosal routes offer both local and systemic absorption but have sparse clinical efficacy and safety data. Patient acceptance and comfort may limit their use, necessitating comprehensive education on administration techniques and potential effects. Clinicians should carefully monitor for adverse events and adjust therapy accordingly.

Fundamental to all dosage forms is the issue of product quality and consistency. Unlike registered pharmaceuticals, all but two of the medicinal cannabis products available in Australia have not undergone rigorous pre-market evaluation. From a quality perspective, batch-to-batch variability in cannabinoid content, unidentified or variable excipients, and lack of standardised manufacturing processes introduce unpredictability in dosing and potential safety hazards. Clinicians should prioritise products manufactured under GMP conditions supported by certificates of analysis verifying consistent cannabinoid concentrations, purity and absence of contaminants. Detailed labelling including cannabinoid profiles, excipients, storage conditions and expiration dates is essential for safe prescribing and patient use.

The regulatory framework should explicitly differentiate oral and inhaled products due to their distinct risk profiles. Blanket application of “mg THC equivalents” risks inappropriate dosing and risk assessments. Higher potency inhaled products above 30–40% THC, while sometimes available in illicit or unregulated markets, may be less justifiable clinically and should prompt heightened caution, particularly in vulnerable populations. A practical mitigation strategy could include establishing additional requirements for prescriber approval to prescribe high-potency THC-containing medicinal cannabis products and evidence of clinical competence in prescribing such products, encompassing training in mental health and substance use disorders to support safe clinical decision-making.

Risk mitigation also extends beyond product and prescriber factors to encompass dispensing practices. Regulation should focus on total THC dispensed rather than cannabinoid ratios, with pack sizes and dispensing intervals aligned with typical daily doses to prevent accumulation and misuse. Mandatory real-time prescription monitoring should support early identification of aberrant prescribing or patient behaviour, reducing diversion and harm.

Finally, child-resistant packaging and clear storage instructions should be mandatory for all THC-containing medicinal cannabis products to prevent accidental paediatric exposures..

Ultimately, the clinical use of medicinal cannabis requires a deep understanding of the pharmacological and safety profiles of diverse dosage forms. Inhaled cannabis presents higher risks due to its rapid onset and greater abuse potential, oral products require individualised dosing strategies due to metabolic variability, and solid oral dosage forms necessitate robust packaging to protect vulnerable populations. Device safety, product quality, regulatory oversight, prescriber education and patient counselling collectively comprise essential components of a comprehensive risk mitigation framework. Through these measures, clinicians can optimise therapeutic benefit while minimising adverse effects, misuse and societal harm, ensuring medicinal cannabis is used safely and effectively across diverse patient populations and dosage forms.

6(a)	***Do you consider there to be safety risks associated with certain dosage forms of medicinal cannabis products that may require mitigation measures? If yes, please provide evidence to support your response. Please also provide any potential mitigation measures that could be considered.***

While the diversity of medicinal cannabis dosage forms enhances therapeutic flexibility, it also introduces specific and varying safety risks that ought to be addressed through targeted regulation and clinical safeguards. By recognising the unique pharmacological and safety profiles of each route of administration, particularly inhaled and solid oral forms, the TGA can look at implementing evidence-informed mitigation measures that support safe, effective and responsible prescribing of medicinal cannabis.

Certain dosage forms pose distinct safety risks that warrant targeted mitigation measures. Among individuals using non-prescribed cannabis, including those with cannabis use disorder or those combining recreational use with prescribed treatment, the predominant route of administration is by inhalation. This real-world situation is mirrored in clinical prescribing, wherein patients using inhaled cannabis are significantly more likely to request increases in dose, product strength or quantity than those using oral formulations. This pattern strongly suggests that inhaled forms of THC carry a greater risk of dose escalation, misuse and diversion. Importantly, this does not imply that inhaled cannabis lacks therapeutic value; rather, it highlights the need for proportionate safeguards around its use. It is also important to note that Australian evidence[140] confirms that whilst there is a stronger association of CUD with inhaled rather than oral products, CUD has been observed with both dosage forms, although inhaled medicinal cannabis carries greater risks than oral forms of medicinal cannabis.

These observations are entirely consistent with established pharmacological principles. Substances with rapid onset and short duration of action, such as injected opioids or short-acting benzodiazepines, tend to carry higher abuse liability than their slower-onset counterparts.[141]The same principle applies to medicinal cannabis: oral and inhaled forms of THC cannot be safely compared on a milligram-to-milligram basis because of differences in pharmacokinetics, metabolism

[140] Mills L, Arnold JC, Macgregor IS and Lintzeris L, Factors associated with cannabis use disorder among Australians using prescribed and illicitly-sourced medical cannabis, *Drug and Alcohol Depend Rep.,* 16 (2025) 100362.

[141] Cooper and Abrams, 'Considering abuse liability and neurocognitive effects of cannabis and cannabis-derived products when assessing analgesic efficacy: A comprehensive review of randomized-controlled studies' (2019) 45(6) *American Journal of Alcohol and Drug Abuse* 580-595.

and subjective effects. Inhaled products (*e.g.,* vaporised flower or vape cartridges) result in a sharp and immediate rise in plasma THC concentrations, which increases their reinforcing potential and risk for problematic use.

By contrast, oral THC has a slower onset and longer duration, meaning that oral forms are less prone to misuse but vary in absorption, especially with food intake, lipid content and hepatic enzyme differences. However, the safety concern with oral products arises from the limited ability to titrate dose against clinical effect (as can be easily done with rapid-onset inhaled products). This creates the safety concern that patients may take an oral dose, wait 1-2 hours, and then take further doses because they feel the medication is not working – only to have a delayed onset of effect – with the risk of serious side effects. Each route has its own safety concerns.

Some patients exhibit unusually rapid hepatic metabolism and reduced clinical benefit from standard oral dosing. In such cases, higher doses may be required to achieve a therapeutic effect. These patients are sometimes incorrectly assumed to be misusing their medication, and prescribers are unfairly accused of over-prescribing, when in fact they are managing pharmacokinetic variability responsibly. This underscores the importance of understanding that dose escalation when using oral THC is not inherently indicative of dependence or misuse, and that clinical judgement must be informed by an appreciation of inter-patient variability in metabolism.

Among inhaled products, there is a clear rationale for distinguishing dry-herb vaporisation from liquid vape cartridges. While dry-herb vaporisation avoids many of the excipient risks associated with liquid-based cartridges, it still delivers THC rapidly and at high peak concentrations. General potency caps for dried flower – such as a benchmark of 30% THC by weight – are therefore a reasonable safety measure, consistent with Canadian norms for non-medical use to mitigate the potential association between high-potency exposure and risks of cannabis use disorder, psychosis and other mental health harms. However, higher potency THC should still remain accessible as higher doses may be justified in certain circumstances (*e.g.,* in palliative care, although perhaps subject to more stringent prescriber justification and regulatory approval requirements.

For liquid vape cartridges, additional hazards arise not just from THC content but from excipients and device-specific risks. The EVALI (e-cigarette or vaping product use-associated lung injury) outbreak in the US between 2019–2020, attributed to vitamin E acetate in some illicit THC cartridges, illustrates how excipient selection can lead to acute pulmonary injury. While Australia's medicinal cannabis supply chain is more regulated, the event reinforces the need for strict excipient controls, emissions testing and device quality standards, including a prohibition on additives like vitamin E acetate and monitoring for carbonyls and heavy metals in emissions.

Solid oral dosage forms, especially pastilles or gummies, warrant particular attention due to their potential for accidental paediatric ingestion. These formats, which resemble confectionery in taste and appearance, have been linked to sharp increases in unintentional paediatric exposures in jurisdictions such as North America following their introduction.[142] While serious physical harm in children is rare, THC exposure can result in psychological distress, somnolence and, in some cases, psychosis. For this reason, robust mitigation measures are essential, including child-resistant packaging, plain labelling, explicit storage instructions (*e.g.,* "keep out of reach of children") and per-unit THC content limits. A cap of 20 mg THC per unit would provide an effective threshold to delineate lower-risk products. Solid oral products containing more than 20 mg per unit should be subject to tighter controls, given their increased risk of diversion and unsupervised ingestion. Nevertheless, pastilles have legitimate therapeutic applications: they are particularly useful in older adults or patients with visual, neurological, or motor impairments who may struggle with oils or other dosing forms. The ability to split pastilles into smaller doses also enables flexible and precise titration not possible with capsules. Clinicians experienced in the prescribing of low-dose THC pastilles regard them to be both effective and safe when prescribed with care.

[142] Coret and Rowan-Legg, 'Unintentional cannabis exposures in children pre- and post-legalization: A retrospective review from a Canadian paediatric hospital' (2022) 57(5) *Paediatrics & Child Health* 265-271.

Other dosage forms such as oromucosal sprays offer more predictable unit dosing than oral oils, but patients should still be counselled on their slower onset compared with inhaled forms, to avoid "dose stacking" during titration. Transdermal patches provide consistent cannabinoid release over time but may cause skin irritation, and absorption rates can vary based on application site, skin condition and external factors such as heat or moisture. Suppositories, pessaries, and wafers offer non-traditional routes of administration with limited evidence of efficacy, and while they may be appropriate for some patients with swallowing difficulties or specific local indications, patient acceptability and consistency of absorption remain concerns. Topical preparations typically involve minimal systemic exposure and are more low risk, but they can cause local irritation or allergic responses, and therefore require proper dermatological labelling and education around application technique.

One unambiguous conclusion is that smoking cannabis should not be considered a medically appropriate route of administration. Combustion generates toxic by-products – including carbon monoxide, tar, and fine particulates – that are associated with respiratory symptoms such as chronic bronchitis and airway inflammation. Even if some patients report subjective relief, the harm profile of smoking makes it unacceptable in a therapeutic context, particularly given the availability of non-combustion alternatives like vaporisation.

Across all dosage forms, the key safety metric should be **total THC and total CBD exposure**, accounting for both concentration and the quantity dispensed over a given interval, rather than THC:CBD ratios. Evidence does not support consistent attenuation of THC's acute effects by CBD at concentrations typically used, meaning that ratios may provide false reassurance. Likewise, dose-route equivalence tables should be avoided, as they obscure the significant differences in pharmacokinetics and clinical effects between oral and inhaled THC. Instead, products should be assessed independently based on route-specific risks, and regulatory controls tailored accordingly.

To mitigate risks across dosage forms, several practical measures could be implemented:

(a) **Route-specific regulation:** Inhaled and oral THC products should be treated as distinct risk categories, with no cross-route "mg THC equivalent" conversions.

(b) **Potency caps and controls:** Dried flower products should have an upper potency threshold of ~30% THC, with higher-potency products (>30%) requiring additional prescriber justification and/or regulatory approval. AMCA considers it appropriate that oral liquid products and liquid products intended for inhalation/use in vape cartridges should similarly have an upper potency threshold of 30 mg/mL THC, with higher potency products (>30%) requiring additional prescriber justification and/or regulatory approval. MCIA recommends that oral liquids and liquids for inhalation/vaping not be made subject to that further layer of oversight due to the desire to empower doctors for limited acute indications to prescribe liquid products responsibly when requiring rapid onset and / or fast acting relief where a higher potency is deemed necessary.

(c) **Excipient and emissions control for vape products:** Mandatory excipient transparency, emissions testing and device standards should be implemented to address risks associated with e-liquids and hardware failures.

(d) **Per-unit limits for solid oral forms:** Consideration should be given to capping the potency of tablets, capsules, pastilles and gummies at 20 mg THC per unit of consumption (*i.e.,* per tablet, capsule, pastille or gummy).

(e) **Packaging and labelling:** All THC-containing products should be in child-resistant containers with plain, non-appealing packaging and clear instructions for storage and administration.

(f) **Dispensing and monitoring controls:** Apply limits on total THC dispensed over time, with mandatory real-time prescription monitoring (and frequent follow-up consultations to facilitate responsible prescribing.

(g) **Patient education and warnings:** Provide route-specific safety information (*e.g.,* "rapid onset/short duration" for inhaled, "delayed onset/long duration" for oral), titration guidance and warnings about potential drug–drug interactions.

6(b) Are there any dosage forms of medicinal cannabis products that should not be permitted due to safety risks? If yes, please provide evidence to support your response.

At present, there is no compelling justification to prohibit any specific medicinal cannabis dosage form outright. Instead, a risk-proportionate framework is the most appropriate and effective approach. This model should reflect the distinct pharmacological profiles, safety considerations and clinical utility associated with each route of administration. Rather than categorical bans, which may inadvertently drive patients toward the unregulated illicit market, policy should focus on route-specific safeguards, excipient standards, potency thresholds and total THC exposure limits, all within the structure of regulated prescribing and monitoring.

The pharmacokinetics of different routes of administration vary considerably and have direct implications for safety. Inhaled forms of THC, such as vaporised dried flower or liquid cartridges, result in rapid systemic absorption and high peak plasma concentrations, which increase the risk of intoxication, dose stacking and cannabis use disorder, particularly at higher potencies. These risks are magnified in liquid vape cartridges, where excipients and device quality become central safety concerns. The EVALI outbreak in the United States in 2019–2020, attributed to vitamin E acetate adulteration in illicit vape cartridges, underscored the hazards associated with poorly regulated inhalation products. While Australia's pharmaceutical supply chain already restricts such excipients, this event demonstrates that device and excipient controls, not outright prohibition, are the most effective safety lever. Regulatory mechanisms should require full disclosure and pre-approval of diluents, prohibit oils not proven safe for inhalation, mandate emissions testing (for carbonyls, metals and particulate matter) and ensure vaporisation devices meet strict technical standards.

That said, inhaled cannabis can be a clinically useful route for conditions requiring rapid relief – such as breakthrough pain, chemotherapy-induced nausea, or severe anxiety – and certain patients find it the only effective or tolerable option. These benefits, however, should be balanced against the greater potential for harm, particularly with high-potency products. A pragmatic and proportionate measure would be a potency cap for vaporised flower, for example at or below 30% THC by weight. Similarly, prescribers managing inhaled cannabis – especially at higher strengths or total doses – should be required to demonstrate appropriate clinical expertise, ideally with training in substance use and mental health. Dosing guidelines and total dispensed THC limits, aligned with the management of other Schedule 8 substances, should also apply.

Oral dosage forms – including oils, capsules, pastilles and lozenges – carry a different safety profile. The slower onset of effects due to gastrointestinal absorption and first-pass hepatic metabolism introduces variability in patient response. This can result in delayed intoxication or inadvertent dose stacking if patients are unaware of the pharmacokinetic lag. Nevertheless, these risks are well characterised and largely mitigated through clear labelling, low starting doses, titration protocols and patient education. Solid oral forms that are palatable or resemble confectionery – such as gummies or flavoured pastilles – do pose a legitimate risk of accidental paediatric ingestion. International data from North America have shown increased emergency department presentations and poison centre calls linked to unintentional ingestion of THC-containing edibles by children. The appropriate response, however, is not prohibition, but mitigation through child-resistant packaging, plain labelling, storage warnings and per-unit THC limits. A cap of 20 mg THC per unit would reduce risk without compromising therapeutic access.

Other dosage forms, such as transdermal patches, topical creams, oromucosal sprays, suppositories and pessaries, each present unique challenges, but again none requiring outright prohibition. Topical and transdermal products generally result in minimal systemic exposure and

their primary risks involve local skin reactions, which can be managed through patient education and patch testing. Suppositories and pessaries, while less common, can be beneficial for patients unable to tolerate oral or inhaled administration, such as those with severe nausea, swallowing difficulties or during palliative care. Systemic absorption from these routes can be variable, but this argues for specialist oversight and further data collection, not their removal from the prescribing toolbox. Similarly, oromucosal sprays and oral liquids offer measured dosing and are generally well tolerated when patients are properly counselled on delayed onset and potential interactions.

A universal concern across all dosage forms is the variable quality and limited pre-market evaluation of many medicinal cannabis products in Australia. While TGO 93 provides a solid foundation for minimum quality and labelling standards, significant batch-to-batch variability, unidentified excipients and limited stability data can lead to inconsistent therapeutic outcomes and unpredictable side effects. These risks should be mitigated through rigorous manufacturing standards (GMP), certificate of analysis requirements, batch testing, robust labelling and post-market surveillance systems (some of which is already in place). A transparent and traceable supply chain will always offer better safety than forcing patients into illicit or unregulated channels due to restricted access.

Lastly, it is important to acknowledge that prohibiting a dosage form – even with good intentions – can produce unintended harm. For many patients, especially those with chronic, complex or palliative conditions, a specific dosage form may be the only effective or acceptable option. Removing access could compromise symptom control or drive use of unsafe or unregulated alternatives. A harm-minimisation approach that balances access, quality, clinical oversight and product-specific safety measures is both more ethical and more effective than a prohibitionist stance.

In summary, while certain dosage forms (especially high-potency inhaled products and child-attractive solid orals) carry elevated risks, there is no current justification for banning any dosage form outright. Instead, Australia's regulatory framework could mitigate risk by introducing additional controls on potency, excipients, devices, labelling, packaging, total THC exposure and prescribing practices, tailored to the specific risks of each route. This strategy ensures that therapeutic flexibility is preserved, patients remain within the safety of the regulated system, and public health risks are addressed with precision rather than blunt-force prohibition.

6(c) Do you consider there to be safety risks with certain dosage forms being prescribed for specific routes of administration? If yes, please provide evidence to support your response.

Certain dosage forms of medicinal cannabis do present route-specific safety risks, which require differentiated clinical and regulatory controls rather than broad prohibitions. The safety profile of a given product is highly influenced not just by its cannabinoid content, but by its formulation, route of administration, excipients, device type (where relevant) and patient factors. Understanding these variables is essential to ensuring safe prescribing practices and mitigating harm.

The most clearly established safety risks relate to inhaled products, particularly when used in the form of vaporised liquids (*e.g.,* cartridges or pods) that include carrier substances or excipients. The 2019–2020 EVALI outbreak in North America provides strong evidence of the potential harms associated with poorly evaluated or undisclosed inhaled additives – in this case, vitamin E acetate, which was found in the lung fluid of most affected patients and not in controls. Although Australia's regulated medicinal cannabis market does not typically use the same excipients implicated in EVALI, the event underscores that unknown diluents or excipients – and the thermal degradation products they may produce – can pose serious respiratory risks independent of cannabinoid dose. As a precaution, medicinal cannabis e-liquids should only be permitted when excipients and carriers are fully disclosed, positively assessed for inhalation safety and subjected to emissions testing for carbonyls, metals and other potential toxicants. Oil-based thickeners and substances without demonstrated pulmonary safety should be explicitly prohibited from use.

Even where no harmful excipients are present, inhaled THC – particularly at high concentrations – poses a risk of rapid-onset intoxication, which may result in acute psychological (e.g., anxiety, paranoia, panic) and physiological (*e.g.,* tachycardia, dizziness, hypotension) reactions. These risks are intensified by the steep pharmacokinetic curve associated with inhalation: THC is absorbed into systemic circulation within minutes and reaches peak plasma concentrations rapidly, producing a "rate-of-rise" effect that can lead to reinforcement and problematic use, especially in susceptible individuals. Accordingly, for general prescribing, high-potency inhaled forms, including dry herb vaporised products, should be subject to THC potency caps (*e.g.,* 30% w/w), total dose limitations per dispense and prescribed only under appropriate clinical oversight. For higher potencies, a more rigorous regulatory approval pathway could be introduced that still provides an access pathway for these higher risk products, but with additional regulatory scrutiny that establishes a clinical justification for the higher potency.

The use of combustion (smoking) as a route of administration also carries well-established respiratory harms, including chronic bronchitis and pulmonary function decline, and should be strongly discouraged in medical practice. Safer alternatives, such as regulated vaporisation or oral dosing, are available and provide equivalent symptom relief for many indications, without the additional burden of combustion-related toxins.

By contrast, oral dosage forms (*e.g.,* oils, capsules, tablets, pastilles) carry different but equally important safety concerns, primarily related to their delayed onset of action and longer duration due to first-pass metabolism in the liver. Oral THC is metabolised to 11-hydroxy-THC, a potent active metabolite that contributes to extended psychotropic effects. This delay in effect can lead patients to "stack" doses prematurely, mistakenly believing that the initial dose was insufficient, which can result in prolonged intoxication lasting many hours (and, in some cases, more than a day). Case reports and pharmacokinetic studies have documented such outcomes, particularly with high-dose oral preparations or where patient education has been lacking.

Despite this, oral forms remain clinically valuable and safe when prescribed with appropriate guidance. Dual labelling (in mg/mL and mg per usual dose), patient education around onset and duration and a "start low, go slow" titration protocol are all essential safeguards. The per-unit concentration of THC in solid oral forms should be carefully controlled – especially for products that may be mistaken for confectionery, such as flavoured pastilles or gummies – to reduce the risk of accidental ingestion, particularly by children. Such products should be dispensed in child-resistant packaging, with clear storage and safety warnings.

Other dosage forms such as transdermal patches, topical creams, suppositories and pessaries generally present lower systemic risk, but still warrant attention. For example, transdermal systems, while typically providing localised effects and minimal systemic exposure, can produce variable absorption based on skin integrity, application site and environmental conditions like heat or moisture. Similarly, suppositories and pessaries, although valuable for patients with severe nausea or swallowing difficulties, have unpredictable pharmacokinetics depending on formulation and patient anatomy. These forms should be prescribed cautiously, with clear instructions for administration and close monitoring for efficacy and tolerability, particularly where data on systemic exposure remain limited.

A cross-cutting issue across all dosage forms is the variable quality and incomplete safety data associated with many medicinal cannabis products currently available in Australia. Unlike approved pharmaceuticals, most medicinal cannabis products have not undergone full pre-market evaluation. This creates potential risks from batch inconsistency, unverified excipients, and inadequate labelling. Ensuring GMP compliance, requiring certificates of analysis and supporting post-market surveillance are necessary to protect patient safety across all routes of administration.

While each route of administration carries distinct and predictable safety considerations, these risks can be effectively managed through a combination of route-specific product standards, robust clinical oversight, prescriber education and patient guidance. High-potency inhaled products and high-dose oral THC formulations present the most significant concerns due to their respective pharmacokinetics and systemic exposure profiles, but even these do not warrant outright prohibition

when proper controls are in place. Instead, a differentiated, evidence-based regulatory approach, tailored to the pharmacology and risk profile of each dosage form and its route and potency, is both safer and more consistent with patient-centred care and harm-minimisation principles.

Concentration of medicinal cannabis components

7. CBD is currently considered to be well tolerated and generally safe for most clinical situations. Is there any evidence to suggest that CBD at specific concentrations poses a safety risk for patients generally or for specific population groups?

While CBD is generally considered safe and well-tolerated across a wide range of clinical contexts, there are specific dose-related and population-specific safety risks that must be acknowledged and appropriately managed.

Compared with THC-containing products, CBD carries a superior safety profile: it lacks intoxicating properties, is not associated with abuse or dependence, and does not pose the same medico-legal complexities around scheduling, diversion or roadside drug testing. These attributes make it a more straightforward therapeutic option for prescribers and patients alike. However, CBD is not entirely risk-free, and safety considerations still emerge at higher doses and in vulnerable populations.

The most consistently documented risk associated with CBD is hepatotoxicity, particularly at higher systemic exposures.[143] Pivotal clinical trials supporting the approval of purified CBD (*e.g.,* in Epidyolex) for severe childhood epilepsies demonstrated a dose-dependent increase in liver transaminases, especially when co-administered with valproate, with elevations occurring in up to 17% of patients at 20 mg/kg/day.[144] While most cases resolved with dose reduction or discontinuation, the effect is pharmacologically significant and has led to specific product information requirements for baseline and ongoing liver function monitoring. These findings are not restricted to paediatric epilepsy cohorts: randomised trials in healthy adults have also identified liver enzyme elevations at therapeutically relevant doses, suggesting that this risk reflects a general pharmacodynamic effect of high-dose CBD, rather than an artefact of patient complexity.[145]

Beyond hepatotoxicity, gastrointestinal upset, appetite suppression and weight loss have also been reported more frequently at higher doses. Drug-drug interactions are another key safety consideration. CBD is known to inhibit several cytochrome P450 enzymes, which can lead to elevated plasma levels of co-administered drugs – a particular concern in patients taking clobazam, where increased sedation due to elevated levels of its active metabolite has been observed.[146] This risk is also pertinent in polypharmacy populations, including older adults, transplant recipients and oncology patients on medications with narrow therapeutic indices (*e.g.,* mTOR or calcineurin inhibitors, immunosuppressants used after transplantation and for the treatment of some cancers). For these groups, even moderate doses of CBD may alter drug metabolism and warrant close monitoring.[147]

Certain patient populations require particular caution. In individuals with hepatic impairment, systemic exposure to CBD can increase by up to five-fold, increasing the potential for adverse effects. In pregnant or breastfeeding women, data are lacking and preclinical studies have suggested potential developmental impacts, prompting general recommendations to avoid use

[143] GW Pharmaceuticals, *Australian Product Information – Epidyolex® (cannabidiol) oral solution* (24 November 2023) Therapeutic Goods Administration.
[144] *Ibid*.
[145] Mechula A, *et al.*, 'Adverse Effects of Oral Cannabidiol: An Updated Systematic Review of Randomized Controlled Trials (2020–2022)' (2023) 12(3) *Healthcare* 277.
[146] Klein P, Tolbert D, Gidal BE, 'Drug-drug interactions and pharmacodynamics of concomitant clobazam and cannabidiol or stiripentol in refractory seizures' (2019) 10(99) *Epilepsy & Behavior* 106459.
[147] Leino A, *et al.*, 'Evidence of a Clinically Significant Drug–Drug Interaction between Cannabidiol and Tacrolimus' (2019) 19(10) *American Journal of Transplantation* 2944.

unless clinically essential. Similarly, although CBD is approved for paediatric use in specific indications, long-term safety data in children and adolescents remain limited. As such, dosing in these populations should be conservative and closely monitored.

The route of administration also matters. Oral forms, such as oils, capsules and liquids, are most common and well-studied, but inter-individual variability in absorption and metabolism can lead to unpredictable systemic exposure. Topical and transdermal forms generally carry lower systemic risk, although local reactions such as skin irritation or dermatitis have been reported.[148] Patient education on correct use, dosing and titration is essential to ensure therapeutic benefit while minimising adverse effects.

While it well accepted that CBD is safe for the vast majority of patients, especially at low to moderate doses, its safety is dose- and context-dependent. The evidence clearly supports the use of CBD in clinical practice when prescribed carefully and appropriately, in alignment with patient-specific risk factors. Key risk mitigation strategies include:

- initiating at low doses and titrating gradually;
- monitoring liver function, particularly at higher doses or in patients on hepatically metabolised medications;
- avoiding use in pregnancy or where safety data are lacking;
- reviewing potential drug interactions in polypharmacy populations; and
- ensuring product quality and consistency through regulated supply channels.

When these precautions are implemented, CBD remains a safe, non-intoxicating therapeutic option with a broad therapeutic window and a risk profile that is favourable compared with many other pharmaceuticals. However, recognising and managing the nuanced risks associated with higher doses, hepatic metabolism and vulnerable patient populations is essential to uphold patient safety and ensure evidence-based, responsible prescribing.

8. Concerns have been raised over safety risks associated with high THC-containing products, particularly when inhaled. Do you have information on safety risks or harm associated with vaping high THC-containing products? If yes, please provide evidence to support your response.

There are well-established safety risks associated with the inhalation or vaporisation of high THC-containing medicinal cannabis products, particularly when concentrations exceed clinically necessary thresholds. The primary concern arises from the rapid pharmacokinetic onset of inhaled THC, which results in a faster rate of rise in blood concentration compared to oral forms. This rapid delivery increases the risk of acute psychoactive and physiological reactions such as severe intoxication, anxiety, panic, paranoia, psychosis and cardiovascular effects including tachycardia and orthostatic hypotension. These risks are amplified with higher THC concentrations, as a smaller dose delivers both therapeutic and adverse effects more quickly and with greater intensity, narrowing the margin of safety.

Cannabis products containing more than 25–30% THC by dry flower weight are generally considered potent. Above this threshold, there is less evidence of additional clinical utility, but there is an increase in risk, including a greater likelihood of adverse psychological events and higher diversion potential, as such products are also more desirable in recreational contexts. Accordingly, while high-THC products should not be categorically prohibited – as some clinical scenarios may justify their use – their prescription should be tightly regulated, preferably under a framework of enhanced regulatory oversight and practitioner accountability.

[148] Filipiuc S, *et al.*, 'The Skin and Natural Cannabinoids–Topical and Transdermal Applications' (2023) 16(7) *Pharmaceuticals* 1049.

Inhalation-related risks extend beyond pharmacological effects of THC alone. Liquid vape cartridges, particularly those containing oils or other excipients, introduce additional hazards not found with dried flower products. The 2019–2020 EVALI (E-cigarette or Vaping Use-Associated Lung Injury) outbreak in the US, which was linked to vitamin E acetate in illicit THC vape liquids, demonstrated how unsafe excipients and thermal degradation products can cause severe pulmonary injury, even independently of cannabinoid content. While Australia's regulated medical market is more tightly controlled, this episode underscores the importance of robust excipient controls, emissions testing (for carbonyls and metals) and explicit prohibition of oil-based thickeners in all vaporised cannabis formulations. Dried flower vaporisation, when performed with regulated (ARTG-included) devices, avoids these diluent risks, but careful regulation is still required due to its high bioavailability and rapid systemic uptake.

Another key concern relates to product quality and consistency. The majority of medicinal cannabis products currently prescribed in Australia are unapproved and have not undergone TGA assessment for quality, safety or efficacy. This raises concerns about variable cannabinoid concentrations, batch-to-batch inconsistencies and potential contamination with heavy metals, pesticides or residual solvents. Such variability can lead to unpredictable dosing, reducing therapeutic reliability and increasing the risk of adverse effects, particularly in products with high THC content.

Population-specific risks must also be considered. Individuals with a history of mental health disorders, as well as adolescents and older adults, are more vulnerable to the psychiatric and cognitive side effects of THC, especially when delivered via rapid-onset routes. There is growing concern among professional bodies, including the Royal Australian and New Zealand College of Psychiatrists and the Australian Medical Association, about the over-prescription of high-THC cannabis products and associated increases in cannabis-induced psychosis, including in patients without a prior history of psychiatric illness. The Medical Board of Australia has issued guidance emphasising that medicinal cannabis – especially high-THC variants – should not be a first-line treatment, and should only be considered when conventional therapies have been unsuccessful.[149]

To reduce the risks associated with inhaled high-THC products, a multi-layered regulatory and clinical strategy is warranted. This should include:

- THC concentration thresholds (*e.g.,* 30% by dry flower weight) imposed for ‘general’ prescribing, with higher potencies triggering additional regulatory requirements for approval and subject to greater regulatory scrutiny;
- mandatory excipient disclosure and emissions testing for vaporised liquids;
- prescriber training and certification pathways focused on the inherent risks of high potency THC, including in relation to mental health, and the risk of substance use disorders;
- enhanced clinical oversight, including comprehensive patient assessment, informed consent and routine monitoring;
- for patients with legitimate, refractory conditions, a regulatory mechanism to ensure that access to high-THC products is maintained where clinically justified, subject to additional regulatory controls and oversight; and
- national prescribing standards, to address geographical inconsistencies and prevent over-concentration of prescribers in certain regions.

In summary, while high-THC inhaled products may offer therapeutic benefits in select clinical scenarios, their use is accompanied by material safety risks that must be managed through a combination of product-level controls, practitioner oversight and regulatory safeguards. A prohibitionist approach is neither clinically necessary nor practical, as structured, proportionate regulation can protect patients while preserving access to high-potency products when appropriately

[149] Australian Health Practitioner Regulation Agency (AHPRA) *Medicinal cannabis prescribing* https://www.ahpra.gov.au/Resources/Medicinal-cannabis-prescribing.aspx

indicated. The aim should not be to restrict access indiscriminately, but rather to ensure that access is safe, justified and accountable within a clear and enforceable clinical framework.

9. Do you consider there to be a 'safe' upper limit of THC use? If yes, what is this and please provide evidence to support your response.

There is currently no universally agreed “safe” upper limit of THC use that applies across all patient populations. Instead, the safe and effective use of THC must be understood as highly individualised, influenced by numerous factors including route of administration, prior cannabinoid exposure, comorbidities, age, metabolism, dose formulation and frequency of use. Both clinical experience and emerging evidence indicate that fixed numeric caps are unlikely to be appropriate across the board and may inadvertently restrict access for patients with legitimate therapeutic needs. Instead, thresholds – such as daily dose markers or potency bands – should function as triggers for clinical oversight and justification, not as rigid maximums.

In clinical practice, particularly within Australia’s medicinal cannabis regulatory framework, oral THC dosing varies significantly between individuals. Some patients experience psychoactive effects at doses as low as 0.5–2.5 mg, while others, particularly those with refractory symptoms, chronic pain or palliative care needs, may tolerate and benefit from doses above 40 mg/day.[150] This variability is not always due to tolerance or misuse but reflects differences in metabolism, absorption, and therapeutic response. Based on both clinical observation and registry data, doses in the range of 5 – 20 mg/day are commonly used and generally well tolerated.[151] Doses exceeding this threshold may carry an increased risk of sedation, dizziness, transient tachycardia or cognitive effects, but these are typically mild, self-limiting and manageable through titration and monitoring. Thus, while generally doses above 20 mg/day may be a reasonable threshold for increased clinical vigilance, it should not be viewed as a hard upper limit.

For inhaled THC, the risks are influenced more by potency and route of administration than by absolute dose. Products containing over 25-30% THC by dry weight (flower) or high-potency extracts offer limited additional therapeutic value while increasing the risks of acute intoxication, anxiety, psychosis and diversion, particularly in vulnerable populations. Inhalation also delivers THC more rapidly into systemic circulation, narrowing the therapeutic window and increasing the likelihood of overshooting the intended dose. For these reasons, higher-potency inhaled products should be treated as high-risk products, warranting additional regulatory controls and prescriber training requirements.

Several international jurisdictions provide helpful reference points. For example, Canada limits discrete oral units (*e.g.,* gummies, capsules) to 10 mg THC per unit, with a maximum of 1,000 mg per container. Germany’s approach is more decentralised, with some federal states limiting dried flower to 22% THC, while Uruguay limits state-distributed strains to 20% THC or less. These examples reflect a precautionary public health stance, particularly where cannabis is used outside tightly supervised medical settings. Importantly, however, even these systems allow for clinical discretion and carve-outs for palliative care or other exceptional clinical contexts where higher potency THC products may be necessary.

Australian regulators could consider aligned threshold values, such as:

- 25-30% THC potency caps for dried flower products and prohibiting THC fortification.
- 20 mg THC per discrete unit for oral or vaporised extracts.
- Package size limits (*e.g.,* 1,000 mg per container) to prevent excessive supply, particularly in high-potency formats.

[150] Herbet A, Hardy J ‘Medicinal cannabis use in palliative care’ (2021) 50(6) *Australian Journal of General Practice* 363-368.
[151] Arnold J, *et al.*, ‘Prescribing medicinal cannabis’ (2020) 43(5) *Australian Prescriber* 152 – 159.

Crucially, any such thresholds should be accompanied by clear exemptions for compassionate use, including palliative care, chemotherapy-induced nausea, intractable pain, or treatment-resistant epilepsy, where higher doses may be necessary and the primary clinical objective is symptom relief rather than long-term harm minimisation.

Furthermore, product concentration alone is not an accurate proxy for safety. Clinical outcomes depend more on total milligrams consumed, the formulation used and the context of use, including whether the product is used under medical supervision. For example, a 30 mg/mL THC oil may be appropriate when dispensed in small volumes (e.g. 1–2 mL), particularly for patients with poor gastrointestinal absorption or high therapeutic need. Restricting such options could result in greater pill burden, increased cost and poorer patient adherence, without enhancing safety.

In summary, while there is no universal "safe" upper limit of THC use, the available evidence supports the use of clinical vigilance thresholds, rather than absolute caps, based on product type, route, and daily dose. Thresholds such as 25-30% THC for flower, 20 mg THC per discrete oral unit, and 40–80 mg/day total oral THC can serve as pragmatic markers above which there should be enhanced regulatory oversight, but dosing must remain flexible to accommodate diverse patient needs. The core principles should be individualised dosing, prescriber accountability, regulated supply and context-specific risk–benefit assessments – especially in cases involving vulnerable populations or high-risk products. This approach best balances access, safety and therapeutic utility within a robust clinical governance framework.

10. Do you consider there to be safety concerns with other cannabinoids? If yes, please provide evidence to support your response.

We do not consider there to be "safety concerns" with non-THC cannabinoids in the traditional sense primarily due to their limited and underdeveloped clinical evidence base. Before firm conclusions can be drawn as to the safety profile of other relevant cannabinoids, robust evidence is essential to determine tolerability, potential adverse effects and long-term safety of such cannabinoid use in humans. We have conducted research into several cannabinoids of interest for reason of their similarities to the commonly prescribed CBD and THC variants.

Cannabigerol (CBG)

There has been a dearth of clinical data examining the effect of CBG in humans, with only three published clinical studies to date. The most recent trial by Cuttler *et al.* (2024) employed a gold-standard double blind, placebo controlled, crossover design to assess the acute effects of a single 20 mg oral dose of hemp-derived CBG in healthy cannabis-using adults.[152] The study found that CBG significantly reduced subjective ratings of anxiety and stress, also enhancing verbal memory relative to placebo. The ratings of subjective intoxication and drug-liking were low in both CBG and placebo conditions, indicating that CBG carries a low potential for abuse. Importantly, there were no significant effects of CBG on changes in dry eyes, dry mouth, sleepiness, appetite changes or heart palpitations, suggesting that it is well tolerated and does not elicit acute adverse effects typically associated with THC administration. A prior survey indicated that some respondents experienced mild effects (*viz* dry eyes, dry mouth, sleepiness, increased appetite) after using CBG-dominant cannabis, however, the study suggests these effects may have been due to participants using cannabis products that contained both CBG and THC. Further research is required to determine potential side effects of CBG with higher doses, repeated dosing and over longer periods.

An earlier study by Peters *et al.* (2023) examined the safety and tolerability of a CBD and CBG-based formulation that was designed to support recovery from delayed onset muscle soreness

[152] World Health Organization, *Cannabidiol (CBD) Critical Review Report* (Report, Expert Committee on Drug Dependence, 39th Meeting, 5–7 June 2018).
[152] GW Pharmaceuticals, *Australian Product Information – Epidyolex® (cannabidiol) oral solution* (24 November 2023) Therapeutic Goods Administration.

(**DOMS**).[153] Consistent with prior findings on CBD, the study found a modest reduction in self-reported soreness and discomfort 72 hours post-DOMS. No safety concerns were observed, and no unexpected interactions were identified among the formulation's multiple constituents. However, because the intervention contained several active ingredients, the study was unable to attribute these preliminary effects specifically to CBG.

Cannabinol (CBN)

Similar to CBG, there have been no rigorous clinical trials to date examining the isolated effects of CBN in humans. The CUPID study protocol by Lavender *et al.* (2023) outlines the first randomised, double-blind, placebo-controlled crossover trial designed to evaluate the acute effects of 30 mg and 300 mg doses of CBN on sleep quality, next-day functioning and safety outcomes in individuals with insomnia disorder.[154] As this publication reports only the protocol and not results, it does not provide efficacy or safety data but highlights the current evidence gap. The trial will be an important step in determining the safety, tolerability and potential therapeutic utility of CBN, given that existing claims about its sedative properties remain largely anecdotal and untested in controlled human studies

Cannabichromene (CBC)

CBC remains very understudied in humans, with no completed clinical trials directly evaluating its safety profile to date.

Tetrahydrocannabivarin (THCV)

THCV is a naturally occurring analogue of THC. Abioye *et al.* (2020) highlight that the safety advantage of THCV is that it lacks the psychoactive effects of THC.[155] Unlike its synthetic analogue rimonabant (withdrawn due to psychiatric adverse effects), THCV has not been associated with similar safety concerns in preclinical models.

A two-phase, dose-ranging, placebo-controlled trial by Peters *et al.* (2023) in healthy participants found that THCV had a favourable safety profile, with most adverse events being mild.[156] Lower doses suggested improved sustained attention, while higher doses produced mild THC-like effects. The study indicates that future large human trials are required to pinpoint the dose of THCV where they may be an inflection in the results.

Conclusions regarding Safety Concerns

As discussed above, the primary limitation remains the lack of clinical data directly testing the effects of non-THC cannabinoids in humans. Current evidence is restricted to a small number of early-phase or pilot studies, most with modest sample sizes and short observation periods. For CBG and THCV, the available (albeit limited) clinical trials suggest favourable tolerability at the studied doses and an absence of the acute adverse effects typically associated with THC. By contrast, for CBN and CBC, there is insufficient evidence to reach a conclusion on their safety profiles. No completed trials of isolated CBN or CBC have reported safety outcomes to date, meaning that their risk profiles remain largely unknown. An overarching advantage of emerging cannabinoids such as CBG, CBN, CBC and THCV, compared with THC, is their non-psychoactive profile. Unlike THC, which carries established risks of intoxication, dependence, psychosis and acute impairment (particularly with high concentration THC-bearing products), the limited human studies on these other cannabinoids

[153] Klein P, Tolbert D, Gidal BE, 'Drug-drug interactions and pharmacodynamics of concomitant clobazam and cannabidiol or stiripentol in refractory seizures.' (2019) 10(99) *Epilepsy & Behavior* 106459.
[153] Mechula A, *et al.*, 'Adverse Effects of Oral Cannabidiol: An Updated Systematic Review of Randomized Controlled Trials (2020–2022)' (2023) 12(3) *Healthcare* 277.
[154] Leino AD, *et al.*, 'Evidence of a clinically significant drug-drug interaction between cannabidiol and tacrolimus' (2019) 19(10) *American Journal of Transplantation* 2944-2948.
[155] Abioye, *et al.*,'Δ9-Tetrahydrocannabivarin (THCV): a commentary on potential therapeutic benefit for the management of obesity and diabetes' (2020) 2(1) *Journal of Cannabis Research.*
[156] Peters *et al.*, 'A Two-Phase, Dose-Ranging, Placebo-Controlled Study of the Safety and Preliminary Test of Acute Effects of Oral Δ8-Tetrahydrocannabivarin in Healthy Participants' (2023) 8(1) *Cannabis and Cannabinoid Research* 71 - 82.

suggest they may deliver therapeutic effects without producing the same psychoactive adverse events. While the evidence base is still small and longer-term safety remains to be established, their lack of intoxicating effects positions these cannabinoids as potentially safer alternatives to THC-dominant products in clinical contexts.

11. Do you consider there to be certain dosage forms when combined with certain routes of administration that present unacceptable safety risks? If yes, which combinations and please provide evidence to support your response.

There are certain dosage forms of medicinal cannabis, when combined with specific routes of administration, that can present heightened or potentially unacceptable safety risks, particularly when used inappropriately, without adequate clinical oversight, or in vulnerable populations. While many medicinal cannabis formulations – such as oral oils, capsules and vaporised dried flower – have acceptable safety profiles when used within a regulated prescribing framework, others warrant increased caution due to their pharmacokinetic properties, formulation concerns or the potential for unpredictable or exaggerated effects.

The most notable area of concern is liquid cannabis vaporiser products, especially those administered via pressurised inhalation devices. Unlike dried-flower vaporisation, which is better characterised and has a relatively consistent onset and safety profile, liquid THC vape formulations lack robust safety data and present a range of unresolved issues. These include unknown risks associated with excipients or carrier solvents, such as propylene glycol and vitamin E acetate – substances linked to severe lung injury outbreaks (*e.g.,* EVALI in the U.S.) – as well as poorly defined bioavailability, inconsistent dosing and difficulty in determining safe prescribing thresholds. Given these uncertainties and the absence of long-term inhalation safety data, these products should only be prescribed with strong clinical justification, clear risk–benefit reasoning and close monitoring. Until standardised testing and validated safety frameworks are established, this dosage form–route combination should not be considered suitable for routine medicinal use.

Similarly, combustion (*i.e.,* smoking) of cannabis presents unacceptable safety risks and should not be endorsed as a therapeutic route. Smoking dried cannabis flower exposes patients to harmful combustion byproducts such as tar, carbon monoxide and polycyclic aromatic hydrocarbons, all of which are well-documented contributors to pulmonary, cardiovascular and carcinogenic harm. This contradicts the therapeutic goals of medicinal cannabis and is clinically inappropriate, especially when safer alternatives (*e.g.,* vaporisation, oral administration) are available and effective.

Other dosage form–route combinations also raise concerns, not due to inherent toxicity, but due to variable or poorly understood pharmacokinetics. For example, suppositories – whether rectal or vaginal – may offer a route to bypass first-pass metabolism, but they remain poorly studied, with unpredictable absorption, uncertain dosing guidelines and limited patient acceptability. These factors, combined with potential hygiene issues and mucosal variability, make suppositories a high-risk and investigational route of administration at present, suitable only under defined and carefully controlled circumstances.

Transdermal cannabinoid products such as patches or creams are similarly under-researched, with significant variability in systemic absorption depending on skin condition, temperature and formulation excipients. While topical applications generally pose a low risk of systemic effects and are associated primarily with local skin reactions, transdermal patches intended for systemic delivery carry the potential for dose dumping or unexpected accumulation, particularly when used with absorption enhancers. Without consistent, standardised pharmacokinetic data, their safety profile remains insufficiently defined for widespread use.

By contrast, oral oils, capsules and oromucosal sprays have more predictable and gradual pharmacokinetics, allowing for slower titration, reduced likelihood of acute intoxication and better dose control. However, even these carry risks, such as dose stacking with oral THC due to delayed onset (1–3 hours), especially in naïve users or those with impaired hepatic metabolism.

Nonetheless, with appropriate patient education, titration protocols and prescriber oversight, these routes are considered safe and clinically appropriate. Observational data from Australian medicinal cannabis registries further supports their overall safety profile, particularly when compared to inhaled or high-concentration products.

Finally, inhaled high-THC products, particularly dried flower with THC content above 25-30% or vaporised extracts, are associated with rapid absorption, peak plasma levels within minutes and an elevated risk of dose-dependent adverse effects. These can include acute intoxication, tachycardia, anxiety and transient cognitive or psychomotor impairment, particularly in cannabis-naïve individuals, older adults or those with cardiovascular or psychiatric comorbidities. While these products can be used safely under medical supervision, their rapid onset and narrow therapeutic window necessitate careful titration, clear patient guidance and vigilant monitoring, especially during initiation or when switching formulations.

In summary, while no dosage form is inherently unsafe, certain combinations, such as liquid vaporisers, high-THC inhaled products, suppositories, transdermal patches and injectables, present elevated or poorly characterised risks that must be approached with caution. Clinical safety depends not only on the cannabinoid content but also on the formulation, route, patient context and regulatory controls. A risk-stratified approach, grounded in individualised prescribing, gradual titration and clear safety thresholds, remains essential to maximising therapeutic benefit while minimising harm.

Population groups

12. Due to the concern over its impact on developing brains, access to medicinal cannabis products for paediatric patients (under 18 years of age) accessed via the SAS and AP scheme requires a letter of support from a paediatrician or relevant medical specialist. Do you consider this current restriction to paediatric patients appropriate and sufficient? If not, please provide an explanation to support your response.

The current restriction requiring a letter of support from a paediatrician or relevant medical specialist for access to medicinal cannabis products in patients under 18 years of age is both appropriate and necessary. This measure reflects a precautionary and ethically responsible approach to safeguard paediatric patients, who represent a uniquely vulnerable population due to the ongoing development of their neurological and physiological systems. The requirement ensures that access is only granted following a detailed, individualised risk–benefit assessment performed by a clinician with expertise in paediatric care, including the specific condition being treated and the potential impacts of cannabinoid exposure on the developing brain.

The developing adolescent brain is particularly sensitive to exogenous cannabinoids, especially THC, which interacts with the endocannabinoid system, an essential regulator of neurodevelopment, synaptic plasticity and cognitive function. There is a growing body of both preclinical and clinical evidence that suggests that early exposure to THC may be associated with long-term neurocognitive effects, including impairments in attention, memory, executive functioning and emotional regulation.[157] Moreover, observational studies have linked adolescent cannabis use to an increased risk of psychiatric illness, such as psychosis, depression and anxiety disorders, and a higher likelihood of developing cannabis use disorder later in life.[158] While medicinal cannabis is not equivalent to recreational use and is often administered in controlled doses under medical supervision, these neurodevelopmental and psychiatric risks remain relevant, particularly in children and adolescents with pre-existing vulnerabilities.

[157] Jacbous and Tapert, 'Effects of Cannabis on the Adolescent Brain' (2014) 20(13) *Current Pharmaceutical Design* 2186-2193.
[158] Baral, *et al.*, 'Cannabis Use and Its Impact on Mental Health in Youth in Australia and the United States: A Scoping Review' (2024) 5(1) *Epidemiologia* 106-121.

In this context, the involvement of a paediatrician or relevant specialist serves as an appropriate safeguard. These clinicians are best placed to determine whether the use of medicinal cannabis is clinically justified, particularly when conventional therapies have failed, are contraindicated or are associated with intolerable side effects. Paediatricians can weigh the severity of the condition and how refractory it is, against the potential short- and long-term risks of cannabinoid exposure. Their expertise also enables them to consider drug–drug interactions, appropriate dosing strategies and monitoring plans that may not be as readily implemented by general practitioners unfamiliar with paediatric pharmacology or complex developmental conditions.

The current restriction also promotes consistent clinical governance, helping to mitigate the risk of inappropriate or unmonitored prescribing in this high-risk group. Paediatric patients often present with multiple comorbidities, may be on polypharmacy regimens and require age-appropriate dosing, all of which necessitate specialist oversight. Clinical data from Australian medicinal cannabis registries indicate that while adverse events in paediatric populations are generally mild when CBD-only products are used, they may be more frequent or severe with THC-containing formulations, especially without precise titration and follow-up. Reported side effects can include somnolence, gastrointestinal upset, behavioural changes and cognitive disturbances, which may interfere with daily functioning and developmental progress.

Furthermore, the current framework supports broader public health objectives by facilitating the systematic collection of safety and efficacy data through specialist-led prescribing and follow-up. This structured approach enables ongoing evidence generation, essential for informing future policy decisions and clinical guidelines. It also ensures that families receive adequate education on product administration, secure storage, recognition of adverse effects and appropriate escalation pathways if issues arise – elements that are more likely to be delivered effectively within a specialist setting.

In summary, the requirement for paediatrician or specialist support for patients under 18 is a necessary and proportionate measure that aligns with clinical best practice, the precautionary principle and patient safety imperatives. It strikes an appropriate balance between ensuring access to potentially beneficial therapies for children with serious or refractory conditions, and protecting the developing brain from uncertain or avoidable harm. While ongoing research, including prospective registry and trial data, may inform future refinements to access pathways, the current restriction represents a sound, evidence-informed approach to medicinal cannabis prescribing in the paediatric population.

13. Are there any additional risk mitigation elements you consider should be applied to support medicinal cannabis use in paediatric patients? If yes, please provide an explanation to support your response.

While the current requirement for paediatric specialist involvement represents an important and appropriate safeguard, additional structured risk mitigation strategies could be implemented to further support the safe and effective use of medicinal cannabis in paediatric patients. Given the heightened vulnerability of children and adolescents, including ongoing brain development, evolving metabolic capacity, and the presence of complex comorbidities, it is essential that medicinal cannabis prescribing in this population is conducted within a well-defined, evidence-informed clinical governance framework. However, these measures should be targeted and proportionate, enhancing safety without imposing overly restrictive or blanket prohibitions that may limit access for children with severe, refractory or palliative conditions.

The most impactful safeguards are those that strengthen clinical structure, oversight and data quality, while preserving the clinician's ability to make individualised decisions depending on the clinical context. Central to this is the use of standardised, gradual titration protocols, particularly for THC-containing products. Slow and cautious dose escalation under specialist supervision reduces the likelihood of dose-dependent adverse effects such as sedation, cognitive impairment, behavioural changes or psychoactive responses, while allowing time to assess therapeutic benefit

and individual tolerability. This is especially critical for naïve patients or those with neurodevelopmental or mental health vulnerabilities.

Ongoing clinical and laboratory monitoring is also important. Structured follow-up should include assessments of growth, sleep, cognition, mood, school functioning and neurobehavioural development, alongside targeted blood tests such as liver function monitoring for patients receiving CBD or polypharmacy regimens. For children with epilepsy, specific attention must be paid to potential interactions with anticonvulsants, including clobazam and stiripentol, due to CYP450 enzyme modulation. Establishing a shared care plan, with clearly defined roles for specialists, GPs and pharmacists, can help ensure coordinated monitoring, timely dose adjustments and appropriate escalation in response to emerging concerns.

Caregiver education is another essential pillar of risk mitigation. Parents or guardians should receive clear, accessible information about dosing techniques, safe storage, recognition of adverse effects and emergency procedures in the event of overdose or unintentional exposure. Where possible, adolescent patients themselves should also be engaged in the informed consent process. Enhancing both consent and assent procedures ensures families are active, informed participants in the treatment journey, which supports adherence and safety at home.

The quality and consistency of the product itself also plays a crucial role in risk reduction. Only high-quality, pharmaceutically manufactured products with standardised cannabinoid content and clear dosing instructions should be used in paediatric settings. Products should be supplied in child-resistant packaging and include accurate, calibrated dosing devices (*e.g.,* syringes), particularly for oral liquids. These features help prevent dosing errors and accidental ingestion, and ensure reproducibility of treatment outcomes.

In addition, prescribers should document a clear diagnostic rationale for the use of THC-containing products outside of palliative care, and undertake baseline mental health screening, with periodic reassessment to identify potential early signs of neuropsychiatric harm. This includes monitoring for changes in mood, anxiety, cognition or social functioning. The presence of such monitoring mechanisms allows for a low threshold to discontinue therapy if risks begin to outweigh benefits.

To complement clinical efforts, enhanced pharmacovigilance and data collection should be embedded into practice. A lightweight, opt-in national paediatric registry, collecting de-identified, diagnosis-specific outcomes, would facilitate real-world learning about which regimens are effective, for whom, and under what conditions harm is most likely. This approach builds the evidence base over time and can guide future updates to clinical guidance without imposing additional regulatory burdens.

In summary, the most effective risk mitigation for paediatric medicinal cannabis use involves reinforcing and formalising clinical best practices – slow titration, structured monitoring, specialist-led shared care, product quality controls, caregiver education and data capture – rather than introducing blanket restrictions. These strategies raise the safety baseline while preserving access for children who may benefit, and ensure that prescribing decisions are evidence-informed, ethically sound and tailored to the needs of this highly vulnerable population.

14.	***Do you have concerns with specific types of medicinal cannabis products being prescribed to paediatric patients, including different dosage forms, concentration of certain components or any other pharmaceutical aspects? If yes, please provide an explanation to support your response.***

Yes, there are specific concerns regarding certain types, routes and concentrations of medicinal cannabis products being prescribed to paediatric patients. These concerns reflect the unique physiological, developmental and behavioural vulnerabilities of children and adolescents, and underscore the importance of cautious product selection, appropriate dosing strategies and comprehensive risk mitigation in this group.

As a guiding principle, oral formulations – particularly oils and liquids – should remain the default route for paediatric patients where a cannabinoid trial is clinically justified. Oral products allow for controlled dosing, gradual titration (typically in mg/kg) and more predictable pharmacokinetics compared to inhaled or topical forms. They also allow clinicians to select products with known cannabinoid concentrations and excipient profiles, which supports safer prescribing and monitoring. However, even oral forms present risks, especially when they contain high concentrations of THC. In such cases, delayed but prolonged psychoactive effects can occur, increasing the risk of over-sedation, cognitive or behavioural changes, and misjudged repeat dosing. Precise measurement is essential but can be difficult in younger or cognitively impaired children, making clear dosing instructions and caregiver training essential components of safe use.

Inhaled products, including vaporised liquids or dry-herb vaporisers, are generally inappropriate for routine paediatric use. They deliver cannabinoids rapidly into systemic circulation, making dose titration highly unpredictable and increasing the risk of acute psychoactive or neurocognitive effects, transient cardiovascular responses and behavioural disturbances. The variability introduced by different devices, breath-hold techniques and heating mechanisms complicates accurate dose delivery. Furthermore, the thermal degradation of excipients (*e.g.,* PEG, PG) in vape liquids poses additional toxicological concerns. These products should be restricted to exceptional circumstances, such as end-of-life care where rapid onset is essential, and only with documented specialist justification and detailed caregiver guidance. The behavioural signal that "medical vaping" sends to adolescents, particularly in the context of rising youth nicotine use, is another public health concern.

Smoked cannabis is unequivocally inappropriate for children due to the respiratory risks and toxicant exposure it entails and should not be permitted under any circumstances.

Edible formulations, such as pastilles, introduce their own set of risks. While they can offer palatability and ease of administration, particularly for children who cannot tolerate oils or capsules, they must be approached with heightened caution, especially when they contain THC. There is a significant risk of accidental or unsupervised ingestion, particularly if the product resembles confectionery. Variability in chewing or dissolution can affect cannabinoid absorption and pharmacokinetics, potentially leading to inconsistent or excessive dosing. For these reasons, pastilles should be used only when clinically necessary and must include robust safeguards: TGO 93–compliant child-resistant packaging, non-confectionery appearance and caregiver education on locked storage and consistent administration.

Topical and transdermal products, while often perceived as low-risk due to limited systemic absorption, should be used cautiously. For localised conditions such as dermatological issues, they may be acceptable if the product has clear composition, microbiological quality and appropriate packaging. However, for systemic conditions like epilepsy or spasticity, these forms are not appropriate substitutes for oral therapies due to variable absorption and lack of evidence for systemic efficacy. Similarly, suppository formulations can result in inconsistent bioavailability and may present practical administration challenges without proper caregiver training.

Across all dosage forms, product concentration and cannabinoid profile are critical considerations. While CBD-dominant products are generally better tolerated and associated with fewer psychoactive effects, THC-containing products, particularly those with high potency or high THC-to-CBD ratios, may carry significant neurodevelopmental risks. These include impacts on mood, cognition, behaviour and executive function, especially in children with underlying psychiatric or neurological vulnerabilities. Any consideration of THC in paediatric patients should involve baseline mental health assessment, the lowest effective dose and regular follow-up focused on mood, sleep, school performance and cognitive function, with a low threshold for discontinuation if adverse effects arise.

Finally, product labelling and pharmaceutical quality are essential safety features. Products should clearly display both mg/mL and total cannabinoid content, list THC and CBD separately, include a full excipient list and carry prominent storage warnings (*e.g.,* “keep out of reach of children”). Caregivers should be provided with clear administration instructions, ideally within the context of a shared care plan involving pharmacists, specialists and general practitioners.

In summary, oral CBD-dominant products are the least problematic and most appropriate starting point for paediatric patients when medicinal cannabis therapy is deemed necessary and/or appropriate. Other formulations, particularly inhaled products, high-THC oils and edible pastilles, require significant caution, clear justification and robust safeguards to mitigate the risks of dose variability, psychoactive effects and accidental ingestion. Ultimately, all product types used in children must be treated with the same clinical seriousness and oversight as any high-risk or unregistered Schedule 8 medicine, with specialist-led prescribing, detailed monitoring and informed caregiver participation forming the foundation of safe and ethical care.

15. Given the unknown safety impact of medicinal cannabis products on pregnant or breastfeeding women, do you consider there to be a need to restrict access or should risk mitigation elements be applied for this patient population? If yes, please provide an explanation to support your response.

Yes, there should be restrictions on access to medicinal cannabis products for pregnant and breastfeeding women, and where access is considered under exceptional circumstances, it must be subject to robust risk mitigation strategies. The current evidence base – although limited, heterogeneous and often confounded, indicates enough potential risk to justify a precautionary, safety-first approach. It goes without saying that the developing foetus and neonate are particularly vulnerable to exogenous substances due to rapid organogenesis, active neurodevelopment and immature metabolic systems. Both THC and CBD cross the placenta, and THC concentrates in breast milk, persisting for weeks, with studies reporting milk-to-plasma ratios >4 and prolonged infant exposure. These pharmacokinetic properties underscore the need for stringent safeguards.

Emerging research – much of it Australian or locally relevant – suggests adverse maternal and child outcomes associated with cannabis exposure during pregnancy or breastfeeding. A large Australian cohort study (Curtin University) found that maternal cannabis use disorder was associated with a tripled risk of disruptive behaviour disorders in offspring. Other studies have reported increased rates of preterm birth, low birth weight and longer-term neurocognitive and behavioural impacts.[159] Although much of this research relates to recreational use, the pharmacological mechanisms involved in medicinal products, particularly those containing THC, remain biologically relevant, and there is no current evidence base establishing the safety of these products in the perinatal context.

In light of these findings, routine prescribing of medicinal cannabis during pregnancy and breastfeeding should not occur. Instead, access should be restricted to rare and clinically compelling scenarios, such as severe refractory epilepsy or palliative care in late pregnancy, where the benefit to maternal health clearly outweighs potential risks to the foetus or infant. In such circumstances, prescribing should be undertaken only with multidisciplinary specialist oversight, including obstetric/maternal-foetal medicine, the treating specialist and paediatrics or neonatology. Informed consent must be formally documented and include counselling on the current limitations of the evidence base, potential neurodevelopmental risks and milk transfer kinetics for breastfeeding mothers.

THC-containing products should be contraindicated in pregnancy and breastfeeding due to the potential for psychoactive and neurotoxic effects, and any exception must follow an explicit risk–benefit analysis supported by specialist endorsement. CBD-only products, while considered to have a more favourable safety profile, should still be approached with caution. Unless there are exceptional circumstances, only registered CBD products (e.g., Epidyolex) with a known safety and pharmacokinetic profile should be considered, and only under neurologist and obstetric co-management. For unregistered CBD products, an even higher threshold of clinical justification should be put in place, including documented failure of conventional treatments and acknowledgment of unknowns in long-term safety.

[159] Tadesse A, *et al.*, 'Maternal cannabis use disorder and offspring behavioural outcomes: findings from a linked data cohort study' (2025) *Psychiatry Research* 346.

Additional risk-mitigation measures are essential and include:

- clear labelling and product warnings, such as “Not recommended during pregnancy or breastfeeding—seek specialist advice”, incorporated into the Consumer Medicines Information and mandated under TGO 93 updates.
- contraception counselling for individuals of reproductive potential prescribed cannabinoids, to reduce inadvertent foetal exposure.
- shared care documentation among prescribers, obstetric/maternal-foetal medicine, and paediatric/lactation teams.
- scheduled reviews during pregnancy trimesters and post-partum periods to reassess necessity, dosing and potential transition away from cannabinoids where appropriate.
- absolute avoidance of combustible or inhaled cannabis in pregnancy and breastfeeding, due to the risk of pulmonary toxins, excipient-related lung injury and rapid cannabinoid absorption with peak systemic concentrations.

To improve the evidence base and support future guidance, Australia should also establish a voluntary perinatal medicinal cannabis registry capturing data on indication, formulation, dose, trimester, breastfeeding status and maternal-infant outcomes. This would align with the country’s translational research strengths and support more informed policy over time.

In summary, a “restricted access plus safeguards” model is both ethically and clinically warranted. It balances compassion for rare, high-need maternal health scenarios with the imperative to minimise the risks to unborn and breastfeeding infants, whose exposure is involuntary and potentially long-lasting. Until higher-quality, prospective data confirms safety, particularly for THC, the responsible course is to restrict use to exceptional circumstances, prohibit high-risk product types, apply stringent oversight and mandate clear product warnings and documentation.

16. Should restrictions or risk mitigation steps be applied to other vulnerable population groups? If yes, please provide and explanation to support your response.

Yes, targeted restrictions and risk mitigation strategies should be applied to specific vulnerable population groups when prescribing medicinal cannabis, particularly those with a history of mental illness, substance use disorders, developmental vulnerability and cardiovascular or hepatic comorbidities. However, these measures must be proportionate, clinically informed, and avoid blanket prohibitions. A nuanced framework that balances therapeutic need with potential risk is essential to support safe, equitable and patient-centred care.

People with mental health conditions such as schizophrenia, bipolar disorder, major depression or severe anxiety may be more susceptible to the psychoactive and neuropsychiatric effects of THC. Evidence from observational studies, neuroimaging and clinical cohorts shows that THC may precipitate or exacerbate psychosis, mood instability or cognitive dysfunction in predisposed individuals. Even though much of these data come from recreational use, the pharmacological properties of THC are relevant regardless of context. Therefore, cannabis should not be automatically ruled out for individuals with mental health histories – some of whom may also experience therapeutic benefits – but prescribing must proceed with caution. Structured psychiatric assessment, specialist input and close monitoring for emerging psychiatric symptoms should be required, especially when THC-containing products are involved. For these patients, CBD-dominant or ARTG-listed products should be prioritised, and informed consent should include a clear explanation of potential risks and unknowns.

Similarly, individuals with a history of substance use disorder (SUD), including dependence on opioids, alcohol or stimulants, represent another group at heightened risk. Although cannabis use disorder appears less common in medical contexts, these individuals may have greater vulnerability

to misuse, escalation or substitution patterns. Careful assessment of use history, readiness for treatment, behavioural risks and social context is essential. Where medicinal cannabis is considered appropriate, prescribers should favour low-THC, non-inhaled formulations (*e.g.,* oral oils or capsules), which have a slower onset and lower abuse potential. Integration with addiction services, behavioural monitoring and treatment agreements can help reduce misuse risk while allowing access in select, carefully managed cases.

Adolescents and young adults require special consideration due to ongoing brain development and strong evidence linking early THC exposure with cognitive and psychosocial harms. Access for individuals under 18 should be restricted to cases with strong clinical justification (*e.g.,* paediatric epilepsy) and only under specialist paediatric oversight. High-THC products and combustible or vaporised forms should be strictly avoided in this group.

Other vulnerable populations include individuals with serious cardiovascular disease, such as recent myocardial infarction, arrhythmias or poorly controlled hypertension. Emerging evidence suggests a possible link between cannabis (particularly THC) and increased risk of major adverse cardiovascular events.[160] While causality remains under investigation, caution is warranted. THC-containing products should only be considered in such patients under cardiologist guidance, and only when therapeutic need is compelling and alternatives are unsuitable.

Those with hepatic impairment or on hepatotoxic or interacting medications may also face higher risk from CBD, which is known to elevate liver transaminases in a dose-dependent manner. In such cases, prescribers should obtain baseline and follow-up liver function tests (LFTs), titrate doses conservatively and seek input from hepatology or clinical pharmacology where appropriate.

To implement these safeguards effectively, several practical and scalable mitigation measures could be adopted across clinical settings:

- Structured screening at the point of prescribing, including documented histories of psychiatric illness, SUD, cardiovascular or hepatic disease, and other relevant risk factors.
- Product selection controls, favouring CBD-dominant or ARTG-registered products in high-risk groups, and avoiding high-THC or inhaled products where risk is substantial.
- Specialist oversight, particularly from psychiatrists, paediatricians, addiction specialists, cardiologists or hepatologists, depending on the identified risk profile.
- Conservative dosing, beginning at the lowest effective dose with slow titration and clear stopping rules if adverse effects or clinical deterioration emerge.
- Ongoing monitoring tailored to patient risk, including mental state reviews, cognitive or behavioural assessments, LFTs and cardiovascular observations.
- Patient and caregiver education, with accessible materials explaining dosing, risks, early warning signs and the importance of adherence and follow-up.
- Shared care arrangements between prescribers, GPs and pharmacists to ensure continuity, communication and accountability in long-term treatment.

Finally, the establishment of structured data collection systems, such as clinical registries for high-risk patient groups, can generate much-needed real-world evidence to inform ongoing clinical guidance and regulatory refinement. These registries should capture outcomes related to efficacy, adverse events, misuse potential, and long-term safety in vulnerable cohorts.

In summary, the application of restrictions and tailored risk mitigation strategies is both necessary and ethically appropriate when considering medicinal cannabis for vulnerable populations. Such an approach allows prescribers to exercise clinical judgement, protects patients who are more likely to experience serious adverse effects, and maintains access to care where benefits outweigh risks. A

[160] Theerasuwipakorn N, *et al.,* 'Cannabis and adverse cardiovascular events: A systematic review and meta-analysis of observational studies' (2023) 10 *Toxicology Reports* 537–543.

balanced, risk-based model supports public health objectives without undermining therapeutic potential for those most in need.

Addressing the current issues with medicinal cannabis products

17. Do you have specific feedback on elements or principles that could be considered when developing regulatory options to address the current issues with medicinal cannabis products? If yes, please provide an explanation to support your response.

When developing regulatory options to address current issues with medicinal cannabis products, several foundational principles and practical elements must guide the creation of a balanced framework that preserves patient access while ensuring safety, quality and clinical appropriateness. Foremost among these is the recognition that clinical decisions about patient suitability and cannabinoid delivery methods must remain the responsibility of treating clinicians, grounded in individual patient context rather than prescriptive regulatory mandates. Regulators should instead focus on establishing and maintaining clear standards for product quality, safety and consistency, thereby empowering prescribers with a reliable and diverse range of medicinal cannabis options.

The current regulatory environment, dominated by the Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways, has proven unsustainable given the exponential growth in prescribing volumes, expected to reach millions annually. These schemes were originally designed as temporary, limited-access solutions and now lack the scalability or robustness to provide meaningful regulatory oversight. Consequently, the system places disproportionate burdens on prescribers to ensure product safety and monitor patient outcomes, without sufficient regulatory or sponsor support. Addressing this imbalance requires a fundamental shift in accountability, assigning primary responsibility for product quality, consistency and pharmacovigilance to sponsors, as they are best positioned to implement rigorous quality assurance, batch testing and ongoing compliance with Good Manufacturing Practice (GMP) standards, which are essential to safeguarding patients and instilling confidence among clinicians.

Given the sheer volume of products and prescriptions, the regulatory framework should evolve toward a more streamlined, risk-based model, whereby prescribers can access products with demonstrated quality and safety histories under simplified reporting requirements. Such a model would maintain necessary pharmacovigilance through shared responsibility between sponsors and prescribers, with sponsors actively managing product quality and safety data submission to regulators, while prescribers monitor clinical outcomes and report adverse events. This approach would substantially reduce bureaucratic complexity and administrative burden on clinicians, allowing them to focus on individualised patient care.

Simultaneously, regulatory reform should incentivise sponsors to generate and submit evidence supporting the quality and, to the extent known through real-world use, safety of their products. Tailored dossier requirements, such as a simplified or medicinal cannabis-specific Module 3, and no requirement to submit comprehensive Module 4 or Module 5 data, would significantly improve feasibility for sponsors, recognising the unique challenges posed by cannabinoids and the absence of intellectual property protections.

Other regulatory options could incorporate prescriptive scheduling and legal controls tailored to product characteristics and patient populations, including concentration limits, formulation types and route of administration restrictions. Such measures could help protect vulnerable groups (e.g., children, pregnant women or those with comorbidities) by mandating specialist oversight or enhanced monitoring where appropriate.

Finally, the reform process must prioritise continuity of patient access, avoiding abrupt disruptions to existing therapies while transitioning to a more sustainable regulatory environment. Abrupt removal of current access pathways without viable alternatives would risk harming patients who rely on medicinal cannabis after having exhausted conventional treatments.

In summary, an effective regulatory framework for medicinal cannabis should rest on clearly delineated sponsor responsibility for product quality and pharmacovigilance; robust but streamlined regulatory oversight; incentives to build a stronger evidence base; transparency in product status and risks; tailored scheduling provisions to enhance safety; and simplified access pathways that support clinicians and protect patients. By integrating these elements, Australia can ensure a system that upholds both public health and patient needs, fostering confidence, encouraging research and enabling responsible clinical use of medicinal cannabis products.

18. Would you support restricting or preventing access to most or all unapproved medicinal cannabis products via the SAS and AP scheme? If yes, please provide an explanation to support your response.

We do not support broadly restricting or preventing access to most or all unapproved medicinal cannabis products via the Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways without careful consideration of the impacts on patients, clinicians, and the emerging industry. Medicinal cannabis has provided life-changing benefits to many Australians who have exhausted conventional treatment options, and these regulated pathways offer crucial legal, clinically supervised access to these therapies. Abruptly limiting access risks penalising legitimate patients who responsibly seek care through medical channels, potentially driving them towards unregulated, illicit markets where product quality and safety cannot be assured.

At the same time, the current landscape – in which approximately 1,600 unapproved products exist with only two products registered in the ARTG – raises valid concerns around variability in product quality, cannabinoid concentration, labelling accuracy and therapeutic consistency. This variability can pose safety risks, especially in vulnerable populations such as children, elderly patients or those with complex health conditions, where careful dosing and monitoring are essential. Addressing these risks requires a balanced approach that improves quality and safety without undermining patient access.

Rather than wholesale restriction, a more effective strategy is to maintain controlled access via the SAS/AP frameworks while implementing targeted reforms to enhance oversight and patient safety. For example, strengthening prescriber education and guidance, mandating adverse event reporting, incrementally raising product quality standards – including clearer dosing information and labelling requirements – and stratifying regulatory controls based on product risk profiles can all help manage concerns around inappropriate prescribing or diversion. These measures would support safe, evidence-informed prescribing while preserving the flexibility clinicians need to tailor treatments to individual patients.

From an industry perspective, restricting access to unapproved products would destabilise the growing domestic medicinal cannabis sector, threatening jobs, investment in quality compliance and Australia's capacity to produce high-quality products. It could also reduce incentives for sponsors to invest in incremental product development or clinical research by shrinking the market. Importantly, expecting all cannabis products to undergo full ARTG registration is impractical given the diversity of formulations, the complex nature of botanical medicines, and the lack of intellectual property protections that make registration financially challenging and impractical. Instead, regulatory incentives such as tailored registration pathways with alternative dossier requirements could encourage sponsors toward implementation of more robust regulatory systems while maintaining patient access during this transition.

Introducing a unique pathway to entry of medicinal cannabis products in the ARTG, in a category distinct from listed and other registered medicines, would be a well-balanced and viable long-term solution. Entry in this new category specific to medicinal cannabis products could be achieved by abbreviated dossier requirements, with sponsors being required to establish a TGA Business account, submit robust evidence of GMP/quality systems, and agree to undertake pharmacovigilance responsibilities akin to those applicable to 'regular' medicines that are listed and

registered in the ARTG. Comprehensive safety and efficacy modules would not be required to be submitted and assessed, leaving decisions as to safety and efficacy to the prescribing clinicians who will be required to have regard to the known evidence base (which they should be assumed to be across).

If desirable and appropriate, this new ARTG entry scheme could be coupled with a prescriber notification mechanism akin to the SAS Category C notification system, where prescribers periodically notify (rather than seek individual approvals) their use of products that have obtained the ARTG designation. This would streamline access and reduce administrative burden. This hybrid approach would yield a clear allocation of responsibility, whereby sponsors would bear accountability for product quality, consistency and pharmacovigilance, while prescribers would focus on clinical decision-making (including assuring safety and efficacy) and patient monitoring. Such a model would align regulatory responsibility more appropriately and enhance overall system transparency and safety.

Ultimately, any move toward restricting access to unapproved medicinal cannabis products must be carefully planned with transitional arrangements that preserve continuity of care. Patients with significant clinical need, particularly those with treatment-refractory conditions, should have priority access through structured pathways involving specialist oversight, risk mitigation strategies, and ongoing safety monitoring. Transparency about product regulatory status should be enhanced to support informed decision-making by clinicians and patients alike.

In summary, significantly restricting or preventing access to unapproved medicinal cannabis products through the SAS and AP schemes without a suitable alternative framework would be counterproductive—, disadvantaging patients, failing to deter misuse and destabilising the domestic industry. A balanced regulatory approach that maintains access while improving quality, safety, oversight and incentives for evidence generation best serves public health interests. By integrating these principles, Australia can foster a sustainable, clinically credible medicinal cannabis sector that protects patients, supports prescribers and aligns with international best practice.

19. Would you support a time-limited regulatory mechanism that could allow sponsors of unapproved medicinal cannabis products time to gather evidence of efficacy or conformity assessment certification to transition to the ARTG? If yes, please provide an explanation to support your response.

We do not support any general requirement that sponsors of medicinal cannabis must obtain full registration in the ARTG, even where it would be subject to a broadly framed, time-limited regulatory mechanism to give sponsors of unapproved medicinal cannabis products a runway to transition to registration of their products. On balance, such an approach would not be likely to address the real drivers of non-registration and would very likely lead to reduced access in the ARTG, potentially harming patients. A more effective and proportionate path is to tighten and resource existing controls (SAS/AP oversight, product quality floors, pharmacovigilance and prescriber education) and to create a hybrid ARTG-approval/entry scheme that is achievable and commercially viable.

There are three linked practical realities that make a time-limited “transition window” a poor policy choice. First, the fundamental commercial incentives for full ARTG registration of medicinal cannabis products are weak. Cannabis botanicals and most finished formulations are difficult to protect by patent in any meaningful way, and therefore exclusivity and IP protection are limited. Academic reviews of intellectual property trends in medicinal cannabis show that while there are patents around processes and novel formulations, sponsors cannot easily rely on exclusivity to recoup the very large costs of ARTG dossiers and clinical trials. In that economic environment, providing a temporary regulatory reprieve does little to change the underlying calculus that currently discourages registration. Sponsors are unlikely to invest in large, expensive trials if the market will shortly be open to competitors marketing substantially similar or virtually identical formulations.

Second, a transition window risks entrenching a two-tier market in which provisional entrants exploit looser requirements to capture market share while deferring the costly work of ARTG registration. This is not hypothetical. Australia's SAS/AP system is already the primary pathway for medicinal cannabis supply and has seen explosive growth – recent TGA dashboards and industry reporting show very large increases in SAS approvals and a booming market in unapproved products. Creating a time-limited alternative would give a veneer of legitimacy to a market that is already functioning as a *de-facto* commercial market, making it politically and commercially harder later to compel sponsors to meet full ARTG standards. In other regulated contexts, conditional or managed access schemes have worked where clear clinical unmet need and strong IP/economic incentives exist (*e.g.*, orphan or breakthrough drugs). Medicinal cannabis is different: the combination of broad demand, product homogeneity and weak exclusivity favours entrenchment, not conversion to ARTG registration under the usual framework for registered prescription medicines.

Third, a time-limited mechanism would impose significant operational and enforcement burdens on regulators and clinicians at a time when the sector already strains existing resources and systems. Conditional approval schemes only work where there is capacity and political will to enforce milestone reporting, to suspend or remove non-compliant products and to require expensive post-market studies. The European and UK conditional pathways succeed because sponsors are typically single pharmaceutical companies with existing regulatory experience and because there is a commercial model that supports post-market evidence generation. In Australia's medicinal cannabis market, a proliferation of small sponsors, many lacking clinical trials experience, would likely struggle to meet the onerous registration obligations. The TGA would face an expanded compliance workload without clear assurance of better evidence or safer products as an outcome.

A time-limited mechanism will also do little to address the real bottlenecks that slow ARTG registration. ARTG registration requires robust dossiers, long-running stability data, clinical evidence and process validation, none of which are short or cheap to assemble. If the government genuinely wants more ARTG registrations, it should address those barriers directly: provide targeted funding for pivotal clinical studies, or create an abbreviated ARTG entry pathway that is at least achievable, such as requiring only Module 1 (country-specific) and Module 3 of the CTD to be submitted for ARTG approval purposes. The TGA could also explore limited forms of data exclusivity for genuinely innovative formulations.

A blanket transition window in the context of requiring full ARTG registration is a blunt instrument that is not forward-looking and risks wasting a legislative opportunity to genuinely reform the medicinal cannabis access pathways by creating an access pathway that is fit for purpose. The SAS/AP schemes are no longer fit for purpose and they were never intended to administer the sheer scale of medicinal cannabis products that we are seeing today. Practical experience also warns against relying on conditional approvals to build evidence. Expedited or conditional approvals can perversely shift the emphasis from rigorous pre-approval trials to weaker post-market commitments that are often delayed, underpowered or poorly enforced. Empirical analyses of conditional regulatory pathways highlight this risk: without strong enforcement and credible penalties, post-market commitments may not be completed, leaving regulators to manage uncertainty indefinitely.[161] Australia's medicinal cannabis sector reflects similar trends. There has been rapid growth in prescribing via the SAS-B and AP pathways in settings with a very limited gold-standard evidence base and many suppliers competing under minimal differentiation. However, counterbalancing the absence of gold-standard evidence is the increasing body of real-world evidence, which has been accumulating in Australia since legalisation since 2016. With some 7 million prescriptions now being issued annually in Australia, the SAS-B and AP pathways are not fit for purpose because of the unmanageable administrative burden they place on the TGA to review and assess applications for approval based on sound clinical justifications.

A viable way forward in the circumstances is to consider the option proposed in our response to Question 18 – the creation of a medicinal cannabis product category in the ARTG that implements

[161] U.S. Department of Health and Human Services, Office of Inspector General (2022), *Delays in confirmatory trials for drug applications granted FDA's Accelerated Approval raise concerns* (OEI-01-21-00401).

an ARTG approval pathway that is achievable for this class of products, whether or not combined with a prescriber notification mechanism for products in this category. Rather than pushing for an unrealistic standard of registration in the ARTG, a more constructive scheme would be to introduce realistic dossier requirements with standards that are specific to medicinal cannabis products. These targeted pathways avoid the systemic risks of a broad transition program and align incentives with tangible evidence generation. Such a framework would mandate greater shared responsibility over the safety and quality of medicinal cannabis products between the prescriber and the sponsor of the products.

For these reasons, policymakers should reject a sweeping, time-limited transition mechanism and instead focus on practical reforms: raise and enforce quality floors for all products supplied via SAS/AP, improve prescriber education and monitoring, require mandatory pharmacovigilance or registries for medicinal cannabis prescribing and invest in clinical trials where public health need justifies it. That combination will better protect patients, encourage genuine safety improvement where commercially and clinically feasible and avoid the regulatory and safety pitfalls that a broad transition window is likely to create.

20. What do you consider to be an appropriate length of time to allow sponsors to gather sufficient clinical evidence to support their medicinal cannabis medicine?

As noted above, we do not consider it an appropriate or sufficient policy lever to require sponsors to generate dossiers and migrate unapproved medicinal cannabis products onto the ARTG, whatever the length of time that may be given. The limiting problems are structural and economic, weak intellectual property protection for most medicinal cannabis products, the high and uncertain costs of clinical development, and the fragmented commercial landscape of medicinal cannabis sponsors, not the calendar time it takes to run studies. A regulatory clock that ignores those realities will impose heavy regulatory burdens that are unachievable. Policy should instead target the root causes: tangible incentives, pragmatic regulatory reliance, strict quality floors for products in the supply chain and regulatory pathways that sponsors can embrace and work towards achieving.

The real reason most medicinal cannabis products remain unregistered is not that sponsors haven't been given enough months or years to run trials; it is that the economics of registering plant-derived cannabis medicines often do not justify the costs. Clinical development – even limited, pivotal programmes – is expensive and resource-intensive. Recent analyses of trial costs show that the median cost of clinical trials supporting registration approvals is measured in the millions to tens of millions of dollars per trial, and total development costs once preclinical work, manufacturing and regulatory workstreams are included are substantially higher. Even smaller trials that would support complementary medicine-type approvals would cost in the order of $500,000 to conduct. Inevitably, the up-front capital required, plus the ongoing risk of failure, will be a deterrent for sponsors unless there are credible revenue protections or other financial incentives.

Intellectual property realities compound the problem. Most medicinal cannabis products are botanicals or straightforward formulations whose active composition cannot be meaningfully protected by composition-of-matter patents in the way novel small molecules or biologics can. While patents do exist around cultivation methods, extraction processes or certain novel formulations, these are narrow and easily designed around; they do not create the long-term exclusivity that justifies multi-year, multi-million-dollar clinical programmes for most companies. Academic reviews of medicinal cannabis patenting show that where protection is weak or transactional barriers exist (*e.g.,* plant breeders' rights, Nagoya Protocol entanglements), commercial incentives to undertake full registration are low. In short, granting more calendar time to assemble evidence does not create new exclusivity or improve the return on investment that sponsors require.

Practical experience confirms that registration succeeds where commercial incentives exist. Epidyolex (pharmaceutical-grade cannabidiol) reached ARTG status because it was developed by a large, well-funded sponsor with an established clinical development engine and regulatory strategy

(including orphan-type designations and international approvals), not because regulators merely allowed more time to assemble data for generic, commodity oils. That example shows registration is attainable, but typically only for sponsors who can protect value or who are prepared to make large strategic investments. The difference is funding model and commercial exclusivity, not simply time.

If the policy objective is genuinely to increase ARTG registrations for medicinal cannabis products, the obvious levers are not more calendar time but structural incentives and targeted regulatory reform. Concrete, evidence-based options include:

(a) pragmatic reliance pathways that allow abbreviated dossiers that demonstrate robust quality standards with adherence to GMP/PICS;

(b) financial incentives for pivotal trials, grants, matched funding or public-private co-funding for trials that address nationally important indications;

(c) narrowly targeted data-protection measures or exclusivity for genuinely novel formulations that complete post-market commitments; and

(d) a strict “quality floor” for any product available under SAS/AP (GMP certification, batch CoAs, standard labelling and child-resistant packaging).

However, we submit that a more feasible approach which avoids the commercial uncertainty and complexity associated with a push towards the standard model of ARTG registration should be preferred. Incentivising the registration of medicinal cannabis products via a separate novel ARTG category (perhaps with SAS-C-equivalent notification) by permitting abbreviated dossiers and incentivising greater sponsorship involvement in quality assurance would produce a more favourable result. The former risks compromising patient access for those who genuinely rely on medicinal cannabis therapies and is driven by an illusory time factor. The latter will facilitate greater regulatory oversight by the TGA while avoiding the obstacles which make ARTG registration an impractical solution.

In summary, there is no single “appropriate length of time” that will reliably drive the transition of most unapproved medicinal cannabis products to ARTG registration. Time is not the binding constraint; commercial incentives, IP structure, standards of evidence and regulatory capacity are. Policy should therefore focus on changing the economics and regulatory architecture rather than on setting an arbitrary calendar for dossier assembly. That is the pragmatic route to more high-quality medicinal cannabis therapies for Australian patients.

21. What are some potential amendments that could be made via scheduling for cannabis and its cannabinoids that could address safety concerns? Please provide detail.

At present, all THC-bearing medicinal cannabis products are Schedule 8 substances (Controlled Drugs). This approach is routed in historical and politically motivated stigmatisation of cannabis and, as such, it imposes unnecessary administrative and medico-legal burdens on prescribers that may be disproportionate to the actual risk profile of many medicinal cannabis products. In particular, equating THC with opioids within the Schedule 8 framework is difficult to justify. Unlike opioids, THC does not carry a meaningful risk of lethal overdose, and while there are risks of dependence and misuse, these are lower than opioids and more broadly comparable to benzodiazepines, the majority of which are managed under Schedule 4. The current scheduling regime therefore risks creating barriers to patient access without delivering commensurate safety benefits.

A more balanced and evidence-based approach would be to adopt a staged down-scheduling model that reflects the actual risk profiles of different dosage forms and concentrations of medicinal cannabis. Oral preparations, particularly those at lower concentrations, could appropriately be managed under Schedule 4. This would significantly reduce unnecessary administrative barriers for

prescribers and improve timely patient access, while maintaining safeguards through prescription-only controls and pharmacy oversight.

By contrast, inhaled products should remain within Schedule 8, given their rapid onset of effect, higher risk of diversion, and greater potential for problematic use. Within this framework, stratification by concentration or potency thresholds would serve as an additional safeguard. Products that fall below clearly defined limits, for instance, lower-potency oral liquids or capsules, could reasonably be treated as Schedule 4 substances, whereas higher-potency formulations or inhaled products would continue to require the stricter regulatory controls of Schedule 8. This tiered approach would create a regulatory environment that is proportionate to risk, reduces burdens on clinicians and patients in lower-risk scenarios, and preserves the necessary checks and balances where safety concerns are more pronounced.

Related to scheduling concerns is the TGA's medicinal cannabis categorisation pathway, which currently places products into Categories 1–5 based on the ratio of CBD to "THC" (meaning THC and other cannabinoids). While this framework has provided a degree of structure, it does not adequately align with the real determinants of clinical risk.

The only category that is both appropriate and effective is Category 1, which applies to CBD-only products. This distinction is logical, as CBD-only formulations carry negligible risk of misuse or dependence and are generally well tolerated across a wide range of patient populations. However, the approach taken for Categories 2–5, which rely on the proportion of CBD relative to THC, is problematic. The CBD: "THC" ratio is not a reliable indicator of misuse or dependence liability, nor does it accurately reflect the physiological and psychological risks associated with high THC exposure. While CBD may have some modulatory or protective effects, these cannot be relied upon in any consistent or clinically meaningful way to mitigate the risks of products with higher THC concentrations.

Further, the current categorisation system is deficient in that products are categorised only by the ratio of CBD to THC. While theoretically this delineates medicinal cannabis products along a spectrum (corresponding with Categories 1–5) of perceived psychoactive effect, there is a concerning oversight in this system. Specifically, the system prescribes that any other cannabinoid is deemed to be "THC-equivalent" for the purposes of categorisation.

While this has always plainly been a regulatory oversight, it is becoming more objectively problematic as minor cannabinoids such as CBN and CBG are being more thoroughly studied and "minor cannabinoid" products are being separately formulated and becoming more readily available to prescribers as alternative, non-psychoactive products. As a consequence of the categorisation rules, a product that is CBG-dominant would be deemed a Category 5 product (THC medicinal cannabis product), as all cannabinoids other than CBD are deemed to be "THC-equivalent" for the purposes of categorisation, even where the product may contain no THC whatsoever.

This is clearly a regulatory deficiency that requires addressing, as it is confusing to sponsors, prescribers and patients, and does not support safe and effective supply or prescribing.

Otherwise, the true determinants of risk are twofold. First, the concentration of THC, whether expressed as mg/mL in liquids, mg/unit in solids or percentage weight in dried flower, is the most reliable predictor of acute intoxication risk, diversion potential and the likelihood of dependence. Second, the total amount of THC dispensed per prescription interval is critical. Large-volume pack sizes of high-potency products present far greater safety risks than smaller, tightly controlled quantities, regardless of the CBD:THC ratio.

As such, we propose replacing the current ratio-based categorisation system with a THC-exposure framework that better reflects clinical realities. Under this model:

(a) Category A (low risk): Products without significant THC, equivalent to current Category 1 (CBD-only products).

(b) Category B (standard THC products): Products containing THC but below defined thresholds, such as oral liquids ≤30 mg/mL, solid oral units ≤20 mg per unit, and dried flower ≤30% THC by weight.

(c) Category C (high-potency THC products): Products exceeding these thresholds. These would remain available but subject to additional regulatory oversight, such as requiring an explicit clinical justification, SAS approval or specialist prescriber endorsement.

This THC-exposure framework should be integrated with scheduling decisions to create a risk-proportionate regulatory system. Low-concentration oral products (Category B) may be most appropriate as Schedule 4, reflecting their lower risk profile and making them more accessible to patients. By contrast, high-potency inhaled products (Category C) should remain Schedule 8, with additional approval requirements to ensure prescribing is limited to circumstances where clinical benefit outweighs risk. Borderline cases, such as unusually strong oral products or low-concentration inhaled formulations, could be assigned on the basis of both concentration thresholds and route of administration.

Such an integrated approach would reduce inappropriate barriers for low-risk products while ensuring stronger safeguards remain in place for those formulations that present heightened risks of intoxication, misuse or diversion. This model would also bring Australia's regulatory system into closer alignment with international best practice, while preserving clinical flexibility for prescribers and maintaining strong protections for public health.

22. Please provide your feedback on certain labelling requirements that could be implemented to assist prescribers and patients understanding of what is contained in a product, and what would provide greater transparency on a product's regulatory status?

Effective labelling is a fundamental component of the safe and appropriate use of medicinal cannabis products. Clear, comprehensive and accurate labelling supports prescribers in clinical decision-making and enables patients to understand the contents and safe use of their medicines. Furthermore, transparent labelling regarding a product's regulatory status fosters confidence in both healthcare providers and consumers.

We recommend that the following labelling requirements be mandated for medicinal cannabis products to assist prescribers and patients in understanding what is contained in a product:

As outlined in our substantive response to question 3, our view is that labelling should include precise quantitative information on key cannabinoids (*i.e.*, THC, CBD), expressed in milligrams per dose/unit and total container volume or weight. This should also reflect cannabinoid ratios where relevant, to guide appropriate prescribing. The dosage form (*i.e.*, oil, vaporiser cartridge, dried herb) and intended route of administration must be clearly indicated to prevent misuse or confusion. Further, relevant warnings addressing potential risks, such as effects on driving, use in pregnancy and breastfeeding and contraindications, should be clearly visible.

For product integrity and traceability, batch or lot numbers and expiry dates should continue to be mandatory on all products. This information is important for product recall processes and ensuring patients do not use products beyond their shelf life.

The presentation of this information is equally important. Labelling must be accessible and user-friendly, presented in plain language with legible fonts and formatting should accommodate varying levels of health literacy among patients. This ensures that critical details about product contents and regulatory status can be easily understood and facilitates communication between prescribers and patients about the products they are prescribing.

Implementing these labelling requirements will materially enhance the safety of medicinal cannabis use by supporting clinical decision-making and patient education.

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