MONASH University

MONASH MEDICINE NURSING AND HEALTH SCIENCES

MONASH ADDICTION RESEARCH CENTRE

Submission to the Therapeutic Goods Administration's review of the safety and regulatory oversight of unapproved medicinal cannabis products

October 2025

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Re: Therapeutic Goods Administration's review of the safety and regulatory oversight of unapproved medicinal cannabis products

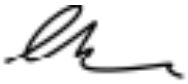
The Monash Addiction Research Centre (MARC) unites world-leading expertise from across Monash University to address the complex challenges of addiction. Harnessing the University's multidisciplinary strengths, MARC develops and tests innovative, scalable approaches to prevention and treatment. Our mission is to deliver national solutions to addiction by integrating insights from basic and social sciences, clinical research, and epidemiology. Through this work, we generate new knowledge, inform government policy, and advance evidence-based practices that improve lives.

MARC welcomes the opportunity to make a submission to the Therapeutic Goods Administrations' review of the safety and regulatory oversight of unapproved medicinal cannabis products. Based on our recently completed Rapid Review and international policy scan on the efficacy and safety considerations with higher delta-9-tetrahydrocannabinol (THC) concentration Category 5 medicinal cannabis products,[1] we make the following evidence-based recommendations:

1. Conduct a detailed evidence review to develop formal definitions of 'high' and 'very high' THC dose across dosage forms to inform clinical practice, including guidance so supplied amounts are consistent with therapeutically appropriate quantities.
2. Prohibit typically nonmedical high THC extract concentrate dose forms (e.g., 'dabs', 'shatter' that contain 75–88% THC).
3. Consider implementing a THC concentration limit ≤ the biological THC limit of the plant.
4. Limit total THC content per dose and package for pastilles.
5. Limit or prohibit non-cannabis flavours and ensure all medicinal cannabis products have plain, child-resistant packaging to reduce their appeal to, and risk of accidental ingestion by, children and young people.
6. Ensure studies measuring the therapeutic effects of THC in Australia collect robust measures of cannabis use disorder to enable an understanding of this safety outcome.
7. Advocate for the National Health and Medical Research Council and the Medical Research Future Fund to prioritise epidemiological research on cannabis use disorder in the context of medicinal use in Australia, to better understand long-term safety outcomes associated with medicinal cannabis.

We also provide the following attached responses to the consultation paper's questions.

Yours sincerely,



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[1] Myfanwy Graham et al, *Efficacy and Safety of Higher THC Potency Category 5 Medicinal Cannabis Products: A Rapid Review and International Policy Scan* (Report, December 2024).

Quality and safety requirements for medicinal cannabis products

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

No. Oral oil-based products for oral or sublingual use were dominant in the Australian medicinal cannabis market in the period immediately following medicinal cannabis legalisation in 2016. But between 2022 and December 2024, there was a shift from oral oil-based products to higher THC concentration Category 5 dried flower (categorised by the TGA as "herb, dried") and inhalation products with almost 200,000 prescription application approvals. Category 5 medicinal cannabis products now account for more than half of all Special Access Scheme Category B (SAS-B) approvals. Based on 2025 data, most (75%) SAS-B prescriptions for medicinal cannabis are for people experiencing chronic pain and anxiety.[2]

This shift in use is concerning because high THC concentration medicinal cannabis use has been associated with increased risk of psychosis and suicide,[3] and while some medicinal cannabis products have an evidence base for their safety and efficacy, our Rapid Review on Category 5 medicinal cannabis products highlights limited, mixed evidence on safety for higher-THC products. There is also no randomised controlled trial research examining efficacy above ~22% THC,[4] despite such products being increasingly prescribed in Australia (most Australian Category 5 products fall between 13–88% THC).[5]

Of particular concern is the absence of an upper THC concentration limit for products accessed via the Australian medicinal cannabis framework and a lack of safety or efficacy data for the medicinal use of concentrated extract products for inhalation up to 88% THC. Indeed, the 2024 National Academies of Sciences, Engineering, and Medicine identified high THC concentration products as a public health issue in legal cannabis markets.[6]

Given these concerns, various policy approaches have been proposed or implemented to limit the use of higher THC concentration products, with the aim of reducing potential public health harms including acute presentations (e.g., psychosis, cannabis hyperemesis syndrome, inadvertent overconsumption)[7] and chronic harms (e.g., cannabis use disorder [CUD]).[8]

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[2] 'Medicinal Cannabis Special Access Scheme Data', *Therapeutic Goods Administration* (Web Page, 1 May 2024) <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-usage-data/medicinal-cannabis-special-access-scheme-data>.

[3] Katie Lupke et al, 'Impacts of Medicinal Cannabis on an Early Psychosis Service' (2024) 32(2) *Australasian Psychiatry* 164.

[4] Graham et al (n 1) 4.

[5] Ibid 34.

[6] National Academies of Sciences, Engineering, and Medicine, *Cannabis Policy Impacts Public Health and Health Equity* (Report, 2024) <https://doi.org/10.17226/27766>.

[7] André Champagne et al, 'Surveillance From the High Ground: Sentinel Surveillance of Injuries and Poisonings Associated With Cannabis' (2020) 40(5-6) *Health Promotion and Chronic Disease Prevention in Canada* 184; Andrew Monte et al, 'Acute Illness Associated With Cannabis Use, by Route of Exposure: An Observational Study' (2019) 170(8) *Annals of Internal Medicine* 531; Rachel Wightman et al, 'Cannabinoid Hyperemesis Syndrome: Clinical Trajectories and Patterns of Use Three Months Following a Visit to the Emergency Department' (2024) 31(5) *Academic Emergency Medicine* 463.

[8] Danielle Dawson et al, 'The Prevalence of Cannabis Use Disorders in People Who Use Medicinal Cannabis: A Systematic Review and Meta-Analysis' (2024) 257 (April) *Drug and Alcohol Dependence* 1.

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

No. While the quality of medicinal cannabis products is important, much of the harms arising from medicinal cannabis use are related to uncertainty around safety and efficacy, particularly with respect to products that result in higher THC exposure. For this reason, our submission is focussed on these issues.

It is worth noting that patients with complex chronic health conditions or who are immunocompromised can be particularly susceptible to health harms arising from product contamination.[9] This risk could be mitigated by ensuring regulatory compliance monitoring also includes regular auditing of product composition, quality, and accuracy of labelling across all dosage forms.

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.

No. Current labelling requirements are complex and may not be helping consumers understand the product they are using and the potential harms. Some of these gaps in understanding may be filled by requiring standard dosing units on labels, as well as greater investment in education about medicinal cannabis products for prescribers, patients, and carers.

Improvements to existing requirements could also include: standardisation of the active ingredient composition information, plain product packaging with health warning labels,[10] and ensuring that when medicinal cannabis products are white labelled / repackaged or extemporaneously compounded, they are done so in child-resistant packaging. Investment in compliance with labelling requirements can also support this.

A systematic review of cannabis health warning labels concluded that "health warnings on cannabis packaging are an important strategy to communicate risk to consumers. Mandating warnings increased notice, recall, and health knowledge. Warnings with pictures and describing specific risks were most effective, as was showing warnings without product branding."[11]

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?

There are a range of options for improving medicinal cannabis product labels, including:

- Standardised cannabinoid content measures per unit dose and per pack (THC, CBD, other cannabinoids; mg/mL or, w/w % for inhaled/solid forms).
- Clear dosing guidance (starting dose, titration steps, maximum daily dose) tailored by dosage form and route of administration (inhaled vs oral).

[9] Laura Dryburgh et al, 'Cannabis Contaminants: Sources, Distribution, Human Toxicity and Pharmacologic Effects' (2018) 84(11) *British Journal of Clinical Pharmacology* 2468, 2471.
[10] Seema Mutti-Packer, Brianne Collyer and David Hodgins, 'Perceptions of Plain Packaging and Health Warning Labels For Cannabis Among Young Adults: Findings From an Experimental Study' (2018) 18(1361) *BMC Public Health* 1.
[11] Zachary Massey, David Hammond and Brett Froeliger, 'A Systematic Review of Cannabis Health Warning Research' (2024) 37 (January) *Preventative Medicine Reports* 1.

- Health warnings akin to tobacco packaging could be considered (e.g., psychosis risk with high THC concentration/frequent use and CUD potential) .[12] Additional health warnings for vulnerable populations could focus on people at risk of adverse mental health effects, or who are pregnant or lactating, as well as youth and young people.
- While a 'Keep out of reach of children' warning is currently required, it is unclear how compliant industry is with this requirement.

While medicinal cannabis products included on the Australian Register of Therapeutic Goods must comply with TGO 91 and TGO 92, which mandate warning labels, unapproved medicinal cannabis products only need to comply with TGO 93 which does not mandate warning labels, although it is still considered best practice to comply with TGO 91 and 92.[13]

Emerging safety concerns for medicinal cannabis products

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.

Our Rapid Review identified 15 studies (maximum THC concentration 22%) from around the world that examined products consistent with TGA Category 5 medicinal cannabis products, and found the following safety risks:

- Dizziness, euphoria, anxiety, cough, and nausea are common mild to moderate adverse effects.[14]
- There is a 25% prevalence of CUD among therapeutic users, and the risk is higher with frequent, high-quantity, inhaled use, younger age, and mental health comorbidity.[15]
- Earlier onset[16] and increased odds of psychosis is associated with daily use of high-potency cannabis (defined as >10% THC, noting that a large number of products in Australia provide much higher concentrations).[17] Our analysis of voluntary adverse events reported to the TGA between July 1st, 2022 and May 31st, 2025 associated with Category 5 THC containing medicinal cannabis products show an uptick in psychiatric disorders (n=230) including anxiety (n = 4/230; 20.4%), psychotic disorder (n = 15/230; 6.5%), and suicidal ideation (n = 5/230; 2.17%).[18]

[12] Jane Allen et al, *Report and Recommendations of the High Potency Cannabis Think Tank to the State of California* (Report, 30 October 2024) 22, 24 <https://www.gettingitrightfromthestart.org/wp-content/uploads/2024/10/California-High-Potency- Cannabis-Think-Tank-Report-10-30-24.pdf>.
[13] Paul Crossley, 'Medicinal Cannabis Reforms Labelling Refresher', *Therapeutic Goods Administration* (Presentation, 1 February 2023) 8 <https://www.tga.gov.au/sites/default/files/2023-02/medicinal-cannabis-reforms-complying-therapeutic-goods -standard-medicinal-cannabis-tgo-93-order-2017.pdf#page=4.00>.
[14] Timna Naftali et al, 'Cannabis is Associated With Clinical But Not Endoscopic Remission in Ulcerative Colitis: A Randomized Controlled Trial' (2021) 16(2) *PLoS One* e0246871.
[15] Dawson et al (n 8).
[16] Marta Di Forti et al, 'Daily Use, Especially of High-Potency Cannabis, Drives the Earlier Onset of Psychosis in Cannabis Users' (2014) 40(6) *Schizophrenia Bulletin* 1509.
[17] Marta Di Forti et al, 'The Contribution of Cannabis Use to Variation in the Incidence of Psychotic Disorder Across Europe (EU-GEI): A Multicentre Case-Control Study' (2019) 6(5) *The Lancet Psychiatry* 427; Marta Di Forti et al, 'Proportion of Patients in South London With First-Episode Psychosis Attributable to Use of High Potency Cannabis: A Case-Control Study' (2015) 2(3) *The Lancet Psychiatry* 233.
[18] Myfanwy Graham, Calvert Tisdale and Suzanne Nielsen, 'Adverse Event Reports With Higher THC Medicinal Cannabis' (2025), in preparation for submission and available on request.

- Cyclical nausea, vomiting, and abdominal pain resulting from long-term heavy cannabis use (cannabis hyperemesis syndrome) has been noted in acute care settings.[19]
- Safety concerns due to unintentional paediatric ingestion of edibles have also been raised.[20]

Current prescribing patterns do not align with the existing evidence base. Although medicinal cannabis is often prescribed to treat chronic pain, anxiety, and sleep disorders, research on the ability of these products to safely and effectively treat these conditions is limited.[21]

Medicinal cannabis is not usually prescribed as a first line treatment for any health condition. But due to current access arrangements, patients are bypassing treatment hierarchies and pharmacological and non-pharmacological treatments with better evidence than medicinal cannabis. Australia's medicinal cannabis program was originally intended to enable access to quality controlled products for conditions where alternative options had been exhausted (i.e., treatment resistant health conditions such as rare childhood forms of epilepsy and palliative care contexts). Based on TGA approvals data, it is clear this is not consistent with current practice.

In addition, there are important evidence gaps concerning safety and longer-term use of medicinal cannabis products. As noted above, a recent systematic review suggests up to one in four people using medicinal cannabis develop CUD, with higher rates associated with higher doses and inhaled use.[22] Yet, few clinical studies of THC use validated measures of CUD to capture this safety concern.

In addition, few epidemiological studies have documented the doses of prescribed medicinal cannabis being used in the community or the outcomes of CUD in the population to properly characterise these safety concerns. Harms arising from medicinal cannabis can also rarely be distinguished from the harms of nonmedical use. These remain important safety evidence gaps, particularly given the increasing use of higher concentration THC products and unknown doses taken in the community, preventing a proper understanding of the likely extent and consequences of current use patterns on outcomes that will impact health systems, including treatment demands for CUD and other related-harms (e.g., increasing emergency department attendances).

[19] Champagne et al (n 7); Monte et al (n 7), Wightman et al (n 7).
[20] Daniel Myran et al, 'Edible Cannabis Legalization and Unintentional Poisonings in Children' (2022) 387(8) *The New England Journal of Medicine* 757; George Wang et al, 'Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015' (2016) 170(9) *JAMA Pediatrics* e160971; Marit Tweet, Antonia Nemanich and Michael Wahl, 'Pediatric Edible Cannabis Exposures and Acute Toxicity: 2017-2021' (2023) 151(2) *Pediatrics* e2022057761.
[21] Li Wang 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) 373 (March) *The BMJ* 1; Maximus Berger, Paul Amminger and Iain McGregor, 'Medicinal Cannabis For The Treatment of Anxiety Disorders' (2022) 51(8) *Australian Journal of General Practice* 586; Kathleen Maddison, Christopher Kosky and Jennifer Walsh, 'Is There a Place for Medicinal Cannabis in Treating Patients With Sleep Disorders? What We Know So Far' (2022) 14 (May) *Nature and Science of Sleep* 957.
[22] Dawson et al (n 8).

Dosage forms and routes of administration

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.

Yes: extract – concentrated; herb, dried (for vaporisation); pastille. Patients who use THC concentrates experience more CUD symptoms compared to those who do not use concentrates.[23] Compared to patients who only use flower products, people who use concentrates are also more likely to report psychotic-like experiences and negative emotional and cognitive effects.[24]

American poison centre data reported greater toxicity with concentrated resins and liquids compared to other cannabis products. Concentrated products, particularly ingestible dose forms, were also most likely to lead to intubation.[25] Edible products also pose the risk of accidental ingestion by children,[26] mitigation measures for which include product packaging that is child-resistant, does not appeal to children, and includes enhanced warnings.

THC limits per "edible" dose (e.g. "serving size") and total quantity per package have also been proposed.[27] Connecticut and Vermont have a dose limit of 5 mg THC per dose unit, while Massachusetts limits THC to 5.5 mg per dose unit. A 10 mg THC limit per dose unit is also in place in several other U.S. states,[28] while in Canada there is a maximum of 10 mg THC per package for edible dose forms.[29]

The safety profile of a high THC concentration product may be different for an individual with previous frequent use who may have developed tolerance versus a cannabis naïve patient. Limiting the dose and/or package quantity for edible dose forms is particularly important for cannabis naïve consumers, as the delayed effect of edibles may lead to repeated administration and potentially undesirable effects.[30]

There are international precedents for consideration of a THC concentration limit. A Californian think tank recently recommended a 25% THC limit for cannabis flower products.[31] Some states in the USA (Vermont, Connecticut and Mississippi) impose a 30% THC concentration limit for flower products

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[23] Cinnamon Bidwell et al, 'Exploring Cannabis Concentrates on the Legal Market: User Profiles, Product Strength, and Health-Related Outcomes' (2018) 17(8) *Addictive Behaviors Reports* 102.
[24] Gary Chan et al, 'User Characteristics and Effect Profile of Butane Hash Oil: An Extremely High-Potency Cannabis Concentrate' (2017) 178 (September) *Drug and Alcohol Dependence* 32.
[25] Matthew Noble, Katrina Hedberg and Robert Hendrickson, 'Acute Cannabis Toxicity' (2019) 57(8) *Clinical Toxicology* 735.
[26] Myran et al (n 20); Wang et al (n 20); Tweet, Nemanich and Wahl (n 20).
[27] Jane Allen et al, *Report and Recommendations of the High Potency Cannabis Think Tank to the State of California* (Report, 30 October 2024) 22, 24 <https://www.gettingitrightfromthestart.org/wp-content/uploads/2024/10/California-High-Potency- Cannabis-Think-Tank-Report-10-30-24.pdf>; Cannabis Regulators Association, *Best Practices and Guidance for Regulating Cannabinoids For Safety* (Information Sheet, 2024) <https://static1.squarespace.com/static/5f7e577e23ad7c718c269776/t/663c038804aa7e058ab49a72/1715209097353/Best+Practices+in+Minimum+Requirements+for+Regulating+Cannabinoids-FINAL+5.5.24.pdf>.
[28] The Network for Public Health Law, *THC Limits For Adult-Use Cannabis Products* (Fact Sheet, 2022) <https://www.networkforphl.org/wp-content/uploads/2022/11/THC-limits-for-Adult-Use-Cannabis-Products.pdf>.
[29] Government of Canada, *Edible Cannabis, Cannabis Extracts, Cannabis Topicals* (Final Regulations, 14 June 2019) <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/resources/regulations-edible-cannabis-extracts-topicals.Html>.
[30] Samantha Goodman and David Hammond, 'THC Labeling on Cannabis Products: An Experimental Study of Approaches For Labeling THC Servings on Cannabis Edibles' (2022) 4(17) *Journal of Cannabis Research* 1.
[31] Jane Allen et al, *Report and Recommendations of the High Potency Cannabis Think Tank to the State of California* (Report, 30 October 2024) 22, 24 <https://www.gettingitrightfromthestart.org/wp-content/uploads/2024/10/California-High-Potency- Cannabis-Think-Tank-Report-10-30-24.pdf>.

and a 60% THC concentration limit for concentrates.[32] Montana has a 35% THC concentration limit for flower unless an individual is a registered medical card holder.[33] Alabama limits THC content to 3% for products intended for *paediatric* medical use.[34]

In Québec, Canada, the THC concentration limit for cannabis is 30%.[35] Following provisions for nonmedical use in Germany, age-based THC concentration limits of 10% are in place for 18-to-20-year-olds due to neurodevelopmental considerations.[36] Pharmacy supplied cannabis in Uruguay is limited to 20% THC.[37] And in the Netherlands' established medical market, the higher end of THC concentration is ~22%.[38]

Unlike North America, THC concentration limits per dose (e.g., 5–10 mg) and package (e.g., 10 mg, 100 mg) have not been set for medicinal cannabis pastille products in Australia. Prescriptions for these "edibles" have risen sharply, from 763 approvals in 2023 to 23,420 by July 2025.[39] Current products can contain 5–30 mg THC per pastille and up to 1200 mg THC per package,[40] with limited availability of lower-dose options suitable for titration. This poses risks including accidental paediatric ingestion and severe poisoning,[41] redosing due to delayed onset of effects,[42] and adverse outcomes in cannabis-naïve individuals.[43]

We currently lack an understanding of what is a 'high' or 'very high' THC dose, whereas we have this understanding for opioids, with prescription monitoring systems using flags for 50–100mg and 100mg+ daily oral morphine equivalents. A similar approach for cannabinoids might help to raise awareness of where people are taking doses higher than what is supported by the existing evidence. Doses could be categorised (e.g. 'high' and 'very high' with corresponding THC ranges) by dosage form (due to pharmacokinetic differences), with a requirement for warning labels and

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[32] 'Frequently Asked Questions', *Vermont Cannabis Control Board* (Web Page, 2025) <https://ccb.vermont.gov/FAQ>; 'Overview Of High Potency Cannabis and THC Concentrate Product Legislative Enactments Through 2023', *National Conference of State Legislatures* (Web Page, 3 January 2024) <https://www.ncsl.org/health/overview-of-high-potency-cannabis -and-thc-concentrate-product-legislative-enactments-through-2023>.

[33] 'Purchasing Power', *Montana Department of Revenue* (Web Page, 2025) <https://revenuefiles.mt.gov/cannabis/safety-awareness/purchasing-power>.

[34] 'Overview Of High Potency Cannabis and THC Concentrate Product Legislative Enactments Through 2023', *National Conference of State Legislatures* (Web Page, 3 January 2024) <https://www.ncsl.org/health/overview-of-high-potency- cannabis-and-thc-concentrate-product-legislative-enactments-through-2023>.

[35] 'The Cannabis Regulation Act', *Québec Government* (Web Page, 8 January 2025) <https://www.quebec.ca/en/health/advice- and-prevention/alcohol-drugs-gambling/recognizing-drugs-and-their-effects/cannabis/regulating-cannabis-in-quebec/cannabis-regulation-act>.

[36] Jakob Manthey, Jürgen Rehm and Uwe Vertheina, 'Germany's Cannabis Act: A Catalyst for European Drug Policy Reform?' (2024) 42 (July) *The Lancet Regional Health Europe* 1.

[37] 'Uruguay: Epsilon, a Cannabis Variety with a Higher Psychoactive Effect, Enters the Market', *Agenzia Nova* (online, 16 October 2024) <https://www.agenzianova.com/en/news/Uruguay-enters-the-market-with-Epsilon%2C-a-cannabis-variety-with -a-greater-psychoactive-effect/>; Elizabeth Bratton, 'Uruguayan Pharmacies to Offer Cannabis With Higher THC Levels', *Latin America Reports* (online, 24 October 2024) <https://latinamericareports.com/uruguayan-pharmacies-to-offer-cannabis-with- higher-thc-levels/9971/>.

[38] 'Types of Medicinal Cannabis', *Dutch Ministry of Health, Welfare and Support* (Web Page, 2025) <https://english.cannabisbureau.nl/medicinal-cannabis/types-of-medicinal-cannabis>.

[39] 'SAS B Applications Dashboard', *Therapeutic Goods Administration* (Web Page, 1 May 2024) <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-usage-data/medicinal-cannabis-special-access-scheme-data>.

[40] 'SAS B Applications Dashboard', *Therapeutic Goods Administration* (Web Page, 1 May 2024) <https://www.tga.gov.au/products/unapproved-therapeutic-goods/medicinal-cannabis-hub/medicinal-cannabis-access-pathways-and-usage-data/medicinal-cannabis-special-access-scheme-data>.

[41] Lesley Pepin et al. Toxic Tetrahydrocannabinol (THC) Dose in Pediatric Cannabis Edible Ingestions (2023) 152(3) *Pediatrics* 1; Myran et al (n 18); Wang et al (n 18); Neta Cohen et al, 'Severe Outcomes Following Pediatric Cannabis Intoxication: A Prospective Cohort Study of an International Toxicology Surveillance Registry' (2023) 61(8) *Clinical Toxicology* 591.

[42] Goodman and Hammond (n 30).

[43] Cesar Leos-Toro et al, 'Cannabis Labelling and Consumer Understanding of THC Levels and Serving Sizes' (2020) 208 (March) *Drug and Alcohol Dependence* 1; David Hammond, 'Communicating THC Levels and 'Dose' to Consumers: Implications For Product Labelling and Packaging of Cannabis Products in Regulated Markets' (2021) 91 (May) *International Journal of Drug Policy* 1.

documentation that this risk has been discussed by prescribers with the patient. This would require a detailed evidence review to recommend those ranges and develop guidance on recommended upper limits for therapeutic daily doses of THC. This may help patients and prescribers understand what is considered a 'high' therapeutic dose or where dosage falls outside the limits for where the evidence supports therapeutic use.

A range of other policy options could be considered in Australia to improve medicinal cannabis regulation and limit exposure to potentially harmful concentrations of THC:

- Restricting or prohibiting the availability and addition of concentrates to dried herb products to increase THC concentrations above the biological ceiling threshold found in the plant, which would result in removing or greatly restricting the use of highly concentrated extract dose forms (e.g., 75–88% THC extracts) from the market.
- For products administered via inhalation, a THC concentration limit of around 22% could be applied, based on the upper limit used in RCT evaluations of therapeutic applications.[44] If this is implemented, ensuring adequate public notice of THC concentration limits for inhalation would allow patients to transition to other dosage forms by titrating doses to reduce the potential for withdrawal.
- For pastilles, one approach is to set clear THC limits per unit and package, such as capping edible products at 5–10 mg THC per dose. This could be combined with packaging and dispensing safeguards, including child-resistant or single-dose unit packaging, reduced package quantities, regulated dispensing intervals, and plain packaging without branding features that appeal to young people.[45] Such measures would align product availability with safe therapeutic use, reduce the likelihood of accidental paediatric exposure, and help prevent appeal to young people and excessive or repeated dosing in adults.
- THC supply limits used in the some parts of the US, Quebec, Uruguay and Germany[46] could help to inform Australia's medicinal cannabis framework. While current guidance urges caution and gradual dosing, clearer limits on quantities and intervals may help prevent misuse. Lessons from opioid prescribing show the risks of dose escalation, but also that any limits must be supported by further research and balance potential unintended consequences for patients already on higher doses.[47]

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.

Yes: extract – concentrated; herb, dried (for vaporisation). High THC potency cannabis flower use is associated with heavier consumption and risk for CUD among young adults.[48] Inhaled extract

[44] Graham et al (n 1) 4.
[45] Samantha Goodman, Cesar Leos-Toro and David Hammond, 'The Impact of Plain Packaging and Health Warnings on Consumer Appeal of Cannabis Products' (2019) 205 (December) *Drug and Alcohol Dependence* 1; Mutti-Packer, Collyer and Hodgins (n 10); Michael Cooper and Yuyan Shi, 'Packaging of Cannabis Edibles, Health Warning Recall, and Perceptions Among Young Adults' (2025) 8(4) *JAMA Network Open* 1; Leos-Toro et al (n 43).
[46] 'The Cannabis Regulation Act', *Québec Government* (Web Page, 8 January 2025) <https://www.quebec.ca/en/health/advice -and-prevention/alcohol-drugs-gambling/recognizing-drugs-and-their-effects/cannabis/regulating-cannabis-in-quebec/cannabis-regulation-act>; Manthey, Rehm and Vertheina (n 36); Magdalena Cerdá and Beau Kilmer, 'Uruguay's Middle-Ground Approach to Cannabis Legalization' (2017) 42 (April) *International Journal of Drug Policy* 118; Rosalie Liccardo Pacula et al, 'Current U.S. State Cannabis Sales Limits Allow Large Doses for Use or Diversion' (2021) 60(5) *American Journal of Preventive Medicine* 701.
[47] Amy Seitz et al, 'Evaluating Opioid Analgesic Prescribing Limits: A Narrative Review' (2022) 31(6) *Pharmacoepidemiology & Drug Safety* 605.
[48] Michael Dunbar et al, 'High Potency Cannabis Flower Use is Associated With Heavier Consumption and Risk For CUD Among Young Adults in California, United States' (2025) *Addiction* (advance).

concentrates (e.g. 75% and 88% THC) and products where THC concentrates have been added to increase THC concentrations above what would normally occur in the plant should not be permitted, except where other dose forms cannot be used such as in palliative care and when the acute relief of the vaporised route of administration is needed. Harms between various inhaled routes of administration (e.g. vaporised, e-cigarette/vape, smoked) need to be differentiated. We are not recommending that all vaporised herb products be removed, but do recommend that: 1) there is a cap on the THC concentration of such products (i.e. removal of high concentration products), 2) there is differentiation between different inhaled dose-forms, and 3) restrictions be placed to limit the use of these products only to instances where other products are not appropriate.

Finally, butane hash oil is associated with an increased risk of depression, anxiety, and substance use disorder diagnosis over a person's lifespan.[49] These kinds of typically nonmedical, high THC concentrate dose forms including butane hash oil, should not be permitted.

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.

Yes: extract – concentrated; herb, dried (for vaporisation); pastille. The potential for high THC concentration products to deliver a larger dose via rapid delivery by inhalation may increase the risk of adverse events and health effects. Patients may self titrate their dose, which decreases the potential for these adverse events, though some evidence suggests any reduction in dose does not fully offset the increased amount of THC consumed with higher concentration products.[50]

See response to Question 6(a) for comments regarding safety risks with products such as pastilles.

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?

Yes. Although CBD products are considered relatively safe when taken on their own at a low dose,[51] they are not without side effects,[52] and consideration must be given to the way CBD products interact with other medications a patient may be taking.[53] This remains a salient point in Australia, despite the decline in CBD compared to THC containing products, considering the down-scheduling of CBD to Schedule 3. With telehealth clinics and the postal provision of CBD products, as well as these drugs being often acquired through clinics that are separate to the rest of a patient's medical care, this reduces the opportunity for interactions to be detected and for patients to be counselled about what to look out for.

[49] Gary Chan et al, 'User Characteristics and Effect Profile of Butane Hash Oil: An Extremely High-Potency Cannabis Concentrate' (2017) 178 (September) *Drug and Alcohol Dependence* 32.
[50] Graham et al (n 1) 56.
[51] Therapeutic Goods Administration, *Safety of Low Dose Cannabidiol* (Report, No 1, April 2020) 4 <https://www.tga.gov.au/sites/default/files/review-safety-low-dose-cannabidiol.pdf>.
[52] Myfanwy Graham et al, 'A Provisional Evaluation of Australia's Medical Cannabis Program' (2023) 122 (December) *International Journal of Drug Policy* 1.
[53] Myfanwy Graham et al, 'Cannabidiol Drug Interaction Considerations For Prescribers and Pharmacists' (2022) 15(12) *Expert Review of Clinical Pharmacology* 1383.

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

Unsure. See response to Question 5 for an overview of the harms of high THC containing products. There is a lack of, and need for, high quality data on the safety risks of inhaling or vaporising high THC-containing products. Currently we rely on incomplete and ad hoc adverse event reports which cannot provide an adequate understanding of the harms.

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

No. As with all medicines, they are never completely 'safe' and severe reactions can occur in vulnerable patient populations, even at lower levels of use. In Australia, there are currently no upper limits of use or daily dose THC limits (see response to Question 6(a) for more detail). The total doses taken (based on quantities consumed) as well as the high concentrations taken, go well beyond what has been tested in clinical trials, which means there is no evidence to support this kind of use. Where there is evidence to support safety and efficacy for specific conditions and within specific populations, upper limits should be consistent with research evidence, and great care should be taken when going outside these bounds.

As noted earlier, no randomised controlled trial research examining the efficacy of medicinal cannabis products (consistent with the Australian regulatory framework) above ~22% THC currently exists.[54] A recent systematic review highlighted the need for prospective studies on the therapeutic, cardiorespiratory, pre- and peri-natal, and cancer outcomes of high-potency cannabis. It also found a relatively consistent link between higher-potency cannabis and indicators of harmful use, though the overall quality and certainty of the evidence remain low.[55] While this systematic review and a separate scoping[56] and systematic review[57] have examined higher-THC products, their relevance to the Australian context is limited as product composition often differs from, or cannot be verified against, Category 5 products.

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

Yes. There are a range of synthetic cannabinoid receptor agonists with concerning safety profiles. Additional cannabinoids should not be added to what can be prescribed without adequate safety data.[58]

[54] Graham et al (n 1) 4.
[55] Stephanie Lake et al, 'High-Potency Cannabis Use and Health: A Systematic Review of Observational and Experimental Studies' (2025) 182(7) *American Journal of Psychiatry* 616.
[56] Lisa Bero et al, 'Health Effects of High-Concentration Cannabis Products: Scoping Review and Evidence Map' (2023) 113(12) *American Journal of Psychiatry* 1332.
[57] Thanitsara Rittiphairoj et al, 'High-Concentration Delta-9-Tetrahydrocannabinol Cannabis Products and Mental Health Outcomes: A Systematic Review' (2025) (August) *Annals of Internal Medicine* 1.
[58] Ayman Alzu'bi et al, 'The Synthetic Cannabinoids Menace: A Review of Health Risks and Toxicity' (2024) 29(49) *European Journal of Medical Research* 1 <https://doi.org/10.1186/s40001-023-01443-6>.

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.

Yes. The answer to this question is addressed in our responses to questions 6(a), (b) and (c).

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.

No. Some parts of the brain, particularly those involved in self-control and complex reasoning, continue maturing up until 25 years of age, and there is a higher risk of CUD when cannabinoids are used at a younger age.[59] As such, additional measures to avoid both unintentional ingestion by paediatric populations, and the appeal of and harms related to higher THC concentration products to youth and young people are advisable.

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.

Yes. While nonmedical use was legalised in Canada in 2018, people must be 19 years of age or older in most Canadian provinces to buy or consume cannabis, with the exception of Alberta (18 years) and Québec (21 years).[60] Canada also has plain and child-proof packaging with warning labels.[61]

Cannabis flowers were legalised for medical use in Germany in 2017, with legalisation for nonmedical use following in 2024. The current model involves home cultivation or collective cultivation through cannabis clubs, with no access for under 18s. For 18-to-20- year-olds, THC potency and monthly quantity limits apply. Regardless of age, all product packaging in Germany is required to include cannabinoid composition information, health warnings and a neutral appearance.[62]

In Australia, further measures should be implemented to protect paediatric patients. For instance, although most products use child-resistant packaging, flower-based and e-cigarette products remain exempt. Applying the existing TGA standards for nicotine e-cigarettes (which cover permitted flavours and excipients, plain packaging, product naming, labelling, design, and technical standards) to medicinal cannabis e-cigarettes/vapes and other dosage forms could help reduce their appeal to young people if diverted or accidentally accessed. In addition, while advertising restrictions are already in place, more resources are needed to strengthen compliance monitoring. This could

[59] Jad Hamaoui et al, 'Age of Onset of Cannabis Use and Substance Use Problems: A Systematic Review of Prospective Studies' (2025) 163 (April) *Addictive Behaviors* 1.
[60] 'Authorized Cannabis Retailers in the Provinces and Territories', *Government of Canada* (Web Page, 26 October 2022) <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/provinces-territories.html>.
[61] Ibid.
[62] Manthey, Rehm and Vertheina (n 36).

include audits of product composition and quality, e-cigarette devices, packaging (both plain and child-resistant), health claims, and labelling across all dosage forms.

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 very limited indications where use in paediatric populations can be supported by evidence, for example in the treatment of rare treatment resistant epilepsies. In general, higher THC content products and inhaled forms of medicinal cannabis should be avoided in paediatric patients.

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

Yes. The American College of Obstetricians and Gynecologists recommends that women who are pregnant, contemplating pregnancy, or lactating should not use cannabis. This is because of potential negative effects on neurodevelopment, as well as maternal and foetal exposure to the adverse effects of smoking[63] and THC.[64]

Evidence from the US indicates some women perceive medicinal cannabis to be 'natural' and safer than pharmaceutical drugs in pregnancy and may not be accessing safer, tested treatments for symptoms like morning sickness.[65] Prescribers should endeavour to have non-stigmatising conversations with patients to help them understand the potential risks of medicinal cannabis and the evidence-based alternatives available.

16. Should restrictions or risk mitigation steps be applied to other vulnerable population groups, such as those with a history of mental health conditions, addiction etc? If yes, please provide an explanation to support your response.

Yes. Additional safeguards should be applied, including screening, lower starting strengths/doses, closer review, and ensuring other approved medicines are used before unapproved products are recommended (i.e. all existing evidence-based options have been exhausted) for patients with mental health conditions including substance use disorders, and/or a family history of mental health conditions including schizophrenia, given associations between high-potency / frequent use and CUD / psychosis.[66] However, these safeguards should be applied in ways that do not stigmatise or create equity issues for these patient groups.

[63] American College of Obstetricians & Gynecologists' Committee on Clinical Consensus–Obstetrics, *Cannabis Use During Pregnancy and Lactation* (ACOG Clinical Consensus, No 10, October 2025) <https://www.acog.org/clinical/clinical-guidance/ clinical-consensus/articles/2025/10/cannabis-use-during-pregnancy-and-lactation>.

[64] 'What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding', *U.S. Food & Drug Administration* (Web Page, 16 October 2019) <https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about -using-cannabis-including-cbd-when-pregnant-or-breastfeeding>.

[65] Judy Chang et al, Beliefs and Attitudes Regarding Prenatal Marijuana Use: Perspectives of Pregnant Women Who Report Use' (2019) 196 (March) *Drug and Alcohol Dependence* 14.

[66] Di Forti et al (n 16); Dunbar et al (n 48).

How do we address 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 outlined in this paper? If yes, please provide an explanation to support your response.

Yes. A balanced regulatory framework for cannabis should focus on keeping exposure within evidence-supported ranges (e.g., by setting concentration limits for THC according to product form and capping the amount of THC permitted per unit and per pack). Particular attention ought to be paid to higher-risk products (e.g., prohibiting non-medical-style concentrates and requiring prominent health warnings).

It is critical to consider the manner in which medicinal cannabis is prescribed to reduce fragmentation of care and risks of undetected drug interactions or clinical contraindications. Effective control of therapeutically appropriate quantities and robust monitoring is essential (e.g., the introduction of THC-based dispensing limits and improved integration of high concentration cannabis products into prescription drug monitoring programmes so that risky patterns of use can be more readily identified).

Further research is needed to inform therapeutically appropriate quantities and dosing intervals across all dosage forms and cannabinoid composition.

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.

Yes. There is a real patient need being addressed through medicinal cannabis products, and we support their continued availability through the SAS and Authorised Prescriber schemes. However, given evidence gaps above ~22% THC,[67] a risk-based approach is preferable, with access for lower-THC products maintained and tighter controls enforced on high-THC products and certain forms (concentrates) until better data becomes available.

The high volume of approvals of medicinal cannabis and the demographics represented by those using higher concentration products do not appear to align with where more limited clinical need for medicinal cannabis is expected. There currently seems to be poor alignment with supply and clinical need, based on the limited number of clinical indications where medicinal cannabis is expected to provide therapeutic benefits, and the common use in conditions where other treatment approaches are considered first line. There is limited data to determine the proportion of products currently being accessed for which there is reasonable evidence of effectiveness and safety in Australia.

[67] Graham et al (n 1) 4.

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.

Yes. A mechanism is needed that would support a process whereby medicinal cannabis products become approved with known doses for specific indications. This would, however, require a considerable amount of time to be established, and detailed consultation would be needed to ensure there are not unintended consequences, such as preventing product availability where there is evidence of a clinical need, as well as allowing sufficient time to develop reasonable dose, safety, and effectiveness data.

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 product?

+ 5 years.

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

Scheduling is a relatively blunt instrument and is not generally used as a mechanism to improve clinical practice. The current scheduling (Schedule 8) of THC-containing medicinal cannabis appears appropriate and should not be amended.

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?

Implementation should involve clear and consistent measures to support safe and informed use. Product information ought to include a canonical cannabinoid panel specifying THC and CBD content per dose and per pack. Route-specific dosing instructions are also crucial, emphasising start-low, go-slow titration alongside a clearly stated maximum daily dose. In addition, health warnings should be displayed prominently, covering risks such as psychosis, CUD, impairment, and the need to keep products out of children's reach.

To assist prescribers and patients understanding of what is contained in a product, labelling approaches need to be combined with health professional and public health education approaches. The Royal Australian and New Zealand College of Psychiatrists clinical memorandum on the therapeutic use of medicinal cannabis products also calls for training of potential prescribers that emphasises medicinal cannabis as a treatment of last resort for specific conditions for which there is a limited evidence base for its efficacy.[68]

[68] The Royal Australian and New Zealand College of Psychiatrists, *Therapeutic Use of Medicinal Cannabis Products* (Clinical Memorandum, March 2024) <https://www.ranzcp.org/getmedia/233218fd-068d-4846-875e-3bf319bb5d0a/cm-therapeutic-use- of-medicinal-cannabis-products.pdf>.