Submission by the Australian Nursing and Midwifery Federation

ANMF Submission to the Therapeutic Goods Association on reviewing the safety and regulatory oversight of unapproved medicinal cannabis products

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Introduction

1. The Australian Nursing and Midwifery Federation (ANMF) is Australia's largest national union and professional nursing and midwifery organisation. In collaboration with the ANMF's eight state and territory branches, we represent the professional, industrial and political interests of more than 322,000 nurses, midwives and care-workers across the country.

2. Our members work in the public and private health, aged care and disability sectors across a wide variety of urban, rural and remote locations. We work with them to improve their ability to deliver safe and best practice care in each and every one of these settings, fulfil their professional goals and achieve a healthy work/life balance.

3. Our strong and growing membership and integrated role as both a trade union and professional organisation provides us with a complete understanding of all aspects of the nursing and midwifery professions and see us uniquely placed to defend and advance our professions.

4. Through our work with members, we aim to strengthen the contribution of nursing and midwifery to improving Australia's health and aged care systems, and the health of our national and global communities.

5. The ANMF thanks the Therapeutic Goods Association (TGA) for the opportunity to provide feedback on reviewing the safety and regulatory oversight of unapproved medicinal cannabis products.

Overview

6. The ANMF is supportive of medicinal cannabis in Australia, provided that the cultivation, manufacture, prescribing, dispensing, and administration of medicinal cannabis are safely and appropriately regulated. This will ensure that approved medicinal cannabis products are accessible and affordable, and that access for evidence-based therapeutic purposes is supported and available where a person, in consultation with their treating health practitioner(s), experiences some benefit from, or has their symptoms alleviated by, medicinal cannabis.

7. The ANMF recognises the clinical benefits of medicinal cannabis for conditions such as epilepsy, inflammation, anxiety, pain, chemotherapy-induced nausea, muscle spasticity, and appetite stimulation.[1,2] The use of medicinal cannabis should be underpinned by robust clinical evidence and ongoing evaluation to determine the risks and benefits. Governments should support large-scale, high-quality clinical trials to examine the benefits and risks of medicinal cannabis in managing health conditions and symptoms to advance the evidence base for its use.

8. A key mechanism for improving the quality and safety of medicinal cannabis is to improve prescribing practices by ensuring that the health workforce is aware of its appropriate use in the treatment and management of medical conditions. This should be supported through the establishment of accessible, high quality professional development opportunities for nurse practitioners, nurses, and midwives, to inform them on the legislation of their state or territory governing of medicinal cannabis. In addition, nurses and midwives (not just those with prescribing rights), should receive education on the endocannabinoid system, the types of products they may encounter when caring for people prescribed medicinal cannabis,

[1] Australian Government Department of Health Therapeutic Goods Administration. Guidance for the use of medicinal cannabis in Australia: Overview, 2017. Viewed May 2024. Available at: https://www.tga.gov.au/resources/resource/guidance/guidance-use-medicinal-cannabis-australia-overview
[2] Purdue, J. Medicinal Cannabis Seminar, Newcastle, 19 October 2018 Report. New South Wales Nurses and Midwives Association, 2018.

modes of administration, requirements for storage and management, and relevant health service policies.[3] This will ensure they are well equipped to inform health consumers about the appropriate use of medicinal cannabis and are able to effectively refer those who may benefit to a medical or nurse practitioner to discuss prescription options.[4]

Quality and safety requirements for medicinal cannabis products

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

9. Noting that TGO 93 does not specify quality standards for devices used to deliver medicinal cannabis substances, this represents a significant gap in ensuring the quality and safety of medicinal cannabis use. In particular, concerns are valid regarding the accuracy of dosage administration through devices such as vaporisers and inhalers. If such devices are not subject to controls, regulations, and quality assurances, these represent risks for overdosage and potential associated harms. Further, as outlined later in this submission, the use of these devices can be associated with substantial risks of harm and should therefore be subject to strict regulation by the TGA.

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.

10. The ANMF recommends several changes to strengthen the current quality requirements for medicinal cannabis products to ensure consistency, safety, and confidence in the therapeutic use of these products. Recommended changes include; batch to batch variability limits, stricter quality control around percentage variation, mandatory testing of imported products by TGA approved/accredited laboratories, increased audits and reduced reliance on manufacturer declarations, and support for full registration of more products with the TGA. Together, these changes would strengthen quality assurance, address current regulatory

[3] Kurtzman ET, Greene J, Begley R, Drenkard KN. "We want what's best for patients." nurse leaders' attitudes about medical cannabis: A qualitative study. Int J Nurs Stud Adv. 2022 Jan 30;4:100065. doi: 10.1016/j.ijnsa.2022.100065.
[4] Scott RJ, Scott IA. Medicinal cannabis: is current use clinically justified? Intern Med J. 2025 Sep;55(9):1433-1444. doi: 10.1111/imj.70094. Epub 2025 Jun 3.

gaps, and ensure that patients, prescribers, and the broader community can have confidence in the safety, consistency, and therapeutic value of medicinal cannabis products supplied in Australia.[5]

11. The introduction of batch-to-batch variability limits is a desirable change. Current requirements allow for variability in cannabinoid content, however further tightening of these would ensure greater therapeutic consistency. While challenging due to the nature of medicinal cannabis, patients and prescribers would benefit from greater confidence that a product will deliver the same effect across batches. Establishing more stringent batch-to-batch variability limits would reduce risks associated with unpredictable dosing, particularly in products containing high concentrations of THC where even small variations can have potentially significantly impacts upon safety and clinical outcomes.

12. While Therapeutic Goods Order (TGO) 93 sets minimum standards, we recommend exploring the introduction of stricter thresholds on the percentage variation of active cannabinoids. This would reduce the risk of products deviating from their stated potency and improve reliability for prescribers when tailoring treatment to patient needs. Clearer and stricter limits would also align medicinal cannabis with the quality assurance standards applied to other therapeutic goods.

13. Despite current good manufacturing practice (GMP) requirements, concerns persist about the consistency and reliability of imported unapproved medicinal cannabis products. Requiring independent verification through testing in TGA-approved laboratories would ensure that imported products meet agreed Australian quality and safety standards before reaching patients. This would also help to address perceptions of regulatory inequity between domestic and international manufacturers.

14. Current surveillance relies heavily on sponsor declarations and risk-based TGA testing.

[5] de Souza, M.R., Henriques, A.T. & Limberger, R.P. Medical cannabis regulation: an overview of models around the world with emphasis on the Brazilian scenario. J Cannabis Res 4, 33 (2022). https://doi.org/10.1186/s42238-022-00142-z

Increasing the frequency and scope of independent TGA audits would provide stronger assurance of compliance and product integrity. Introducing penalties for non-compliance would serve as a deterrent to poor manufacturing or reporting practices and help maintain a level playing field across suppliers.

15. Currently, over 99% of medicinal cannabis products accessed in Australia are unapproved and have not undergone TGA evaluation for quality, safety, or efficacy. We strongly support measures to incentivise and facilitate sponsors to transition products, particularly those containing THC, through full TGA registration with accompanying clinical trials. This would generate much-needed clinical evidence on efficacy and safety, reduce reliance on unapproved pathways, and improve community and prescriber confidence in medicinal cannabis as a therapeutic good.

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.

16. The labelling requirements set out in TGO 93 appear to be largely adequate to ensure that prescribers and consumers are well informed about the contents of their medicinal cannabis products. Noting that labels must also comply with TGO 91, warning labels for medicinal cannabis products, such as those for products containing THC, and risks such as drowsiness and neurodevelopmental harms, must be clearly and prominently displayed. Further, where appropriate, labels must specify the product's Schedule and sufficient detail to ensure that consumers and prescribers understand their legal obligations regarding the possession and distribution of these products.

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?

17. Noting that not all labelling requirements under TGO 93 apply to medicinal cannabis that has been extemporaneously compounded, the current labelling standards appear insufficient to fully inform consumers of the product contents. It is recommended that additional

information be included on the label, such as the source of the compounds, including the cannabis plant species and plant part used. Further, details like pharmacist's name and contact details, storage instructions, date of synthesis, and use-by date should also be clearly displayed to ensure safe and informed use.

Emerging safety concerns for medicinal cannabis products

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.

18. The ANMF notes concerns regarding the responsibilities placed on authorised prescribers (including medical practitioners and nurse practitioners) for the prescription of unapproved medicinal cannabis products. While prescribers must be subject to appropriate oversight to minimise risks of overprescribing and ensure patient safety, the current framework disproportionately places accountability for the use of an 'unapproved' therapeutic goods and adverse reactions, on the individual practitioner. This regulatory arrangement may create unintended disincentives for prescribers to engage with medicinal cannabis prescribing, limiting timely patient access to these treatment options.

19. Responsibility for therapeutic safety should be shared across the system, with clearer delineation between the obligations of prescribers, regulators, and manufacturers. It is recommended that shared accountability mechanisms be introduced to ensure adverse event monitoring and product safety are responsibilities jointly managed by prescribers, regulators, and manufacturers. This should be supported by education, clinical guidelines, and decision-support tools to assist practitioners in evidence-based and safe prescribing and improve knowledge about the regulatory status and responsibility in prescribing unapproved products.

20. The ANMF supports a regulatory approach that maintains rigorous safety and quality oversight while not creating unnecessary barriers for patients with legitimate therapeutic need or unduly resulting in punitive outcomes for practitioners where responsibilities lie elsewhere, such as manufactures.

Dosage forms and routes of administration

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.

21. There are known safety risks associated with certain dosage forms of medicinal cannabis products that warrant stronger mitigation measures.[6] Inhaled products, oral/edible dosage forms, and high-potency THC preparations each present unique safety risks. These risks can be mitigated through a combination of tighter quality controls (including excipient restrictions and contaminant testing), improved labelling and product information, clinical prescribing safeguards for vulnerable populations, and potentially the introduction of upper potency limits for THC. These measures would reduce preventable patient harms, increase clinician confidence in prescribing, and support safer and more clinically appropriate use of medicinal cannabis.

22. There is clear evidence of acute lung injuries linked to inhaled cannabis products, particularly those containing additives such as Vitamin E acetate.[7,8] These harms have been reported internationally, and the TGA consultation paper also highlights the risks of E-cigarette or Vaping Products Use-Associated Lung Injury (EVALI) and chemical exposure from heating devices. Inhalation also carries the potential risk of inaccurate dosing due to rapid absorption rates.[9] Mitigation measures could include stricter controls over excipients and solvents in inhaled products, mandatory testing for contaminants, and strengthened product warnings

[6] MacCallum CA, Lo LA, Boivin M. "Is medical cannabis safe for my patients?" A practical review of cannabis safety considerations. Eur J Intern Med. 2021 Jul;89:10-18. doi: 10.1016/j.ejim.2021.05.002.
[7] Marrocco A, Singh D, Christiani DC, Demokritou P. E-cigarette vaping associated acute lung injury (EVALI): state of science and future research needs. Crit Rev Toxicol. 2022 Mar;52(3):188-220. doi: 10.1080/10408444.2022.2082918.
[8] Meehan-Atrash J, Rahman I. Cannabis Vaping: Existing and Emerging Modalities, Chemistry, and Pulmonary Toxicology. Chem Res Toxicol. 2021 Oct 18;34(10):2169-2179. doi: 10.1021/acs.chemrestox.1c00290.
[9] Bidwell LC, Karoly HC, Torres MO, Master A, Bryan AD, Hutchison KE. A naturalistic study of orally administered vs. inhaled legal market cannabis: cannabinoids exposure, intoxication, and impairment. Psychopharmacology (Berl). 2022 Feb;239(2):385-397. doi: 10.1007/s00213-021-06007-2.

regarding respiratory harms.

23. While oral dosage forms of medicinal cannabis avoid risks to the respiratory system, they can also be associated with high variability in absorption and bioavailability. The delayed and unpredictable onset of effect can lead to unintentional repeat dosing, which can increase the risk of adverse events.[10] Clearer labelling requirements around expected onset times, maximum recommended single doses, and warnings regarding delayed effects could be potentially effective mitigation measures.

24. The consultation paper identifies increasing clinical concern with high THC-containing products and their association with mental health harms such as anxiety, depression, psychosis and suicidal ideation. Evidence suggests that daily users of high-potency THC products could face higher risk of developing psychosis, particularly in adolescents or individuals with a genetic or family predisposition.[11,12] In addition, high-potency THC can induce acute anxiety, panic attacks and paranoia, and impair short-term memory function.[13,14] Longer-term use has been linked with persistent cognitive deficits. Mitigation measures could include consideration of an upper limit on THC concentrations across dosage forms, stricter age-related restrictions for high-THC products, clearer warning statements regarding mental health risks, and stronger clinical justification requirements for prescribing high-potency THC products to younger patients or those with a family history of psychosis.

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[10] Schlienz NJ, Spindle TR, Cone EJ, Herrmann ES, Bigelow GE, Mitchell JM, Flegel R, LoDico C, Vandrey R. Pharmacodynamic dose effects of oral cannabis ingestion in healthy adults who infrequently use cannabis. Drug Alcohol Depend. 2020 Jun 1;211:107969. doi: 10.1016/j.drugalcdep.2020.107969.
[11] Urits I, Gress K, Charipova K, Li N, Berger AA, Cornett EM, Hasoon J, Kassem H, Kaye AD, Viswanath O. Cannabis Use and its Association with Psychological Disorders. Psychopharmacol Bull. 2020 May 19;50(2):56-67.
[12] Young-Wolff KC, Chi FW, Campbell CI, Does MB, Brown QL, Alexeeff SE, Ansley D, Wang X, Lapham GT. Association of psychiatric and substance use disorders with cannabis use and cannabis use disorder during early pregnancy in northern California. Addiction. 2024 Nov;119(11):1987-1997. doi: 10.1111/add.16622. Epub 2024 Jul 31.
[13] Lowe DJE, Sasiadek JD, Coles AS, George TP. Cannabis and mental illness: a review. Eur Arch Psychiatry Clin Neurosci. 2019 Feb;269(1):107-120. doi: 10.1007/s00406-018-0970-7.
[14] Botsford SL, Yang S, George TP. Cannabis and Cannabinoids in Mood and Anxiety Disorders: Impact on Illness Onset and Course, and Assessment of Therapeutic Potential. Am J Addict. 2020 Jan;29(1):9-26. doi: 10.1111/ajad.12963.

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.

25. Certain dosage forms and prescribing practices for medicinal cannabis products can present potentially modifiable safety risks,[15] and should be subject to stricter prescribing safeguards. Edible medicinal cannabis products that mimic confectionery should be reviewed for safety as these may pose an unacceptable risk to children. In addition, highly potent inhalable and high-THC products should be subject to stricter controls, including limiting their prescription to specialist prescribers and introducing explicit safeguards around their use. These measures must be considered to reduce preventable harms and better align medicinal cannabis with the safety expectations placed on other therapeutic goods in Australia.

26. There is growing international evidence that edible cannabis products resembling confectionery (such as gummies, chocolates, or lollies) have been associated with rising rates of accidental paediatric ingestion and subsequent hospital presentations. These forms of medicinal cannabis are easily mistaken for regular food items, making them particularly unsafe in households with children. The TGA Consultation Paper highlights concerns about vulnerable population groups, including children, where exposure to THC-containing products may disrupt brain development and lead to significant adverse health outcomes. We recommend considering either prohibiting edible dosage forms that mimic confectionery items or the adoption of stringent packaging, labelling, and design requirements to reduce risk of accidental ingestion.

27. The consultation paper acknowledges the risks associated with inhalation dosage forms, including E-cigarette or EVALI, inaccurate dosing, and exposure to harmful chemicals from devices. These risks are amplified with high-THC inhalable products, where rapid absorption and high concentrations increase the likelihood of potential acute intoxication, dependency, and mental health harms. The introduction of stricter prescribing guidelines and controls

[15] Mick G, Douek P. Clinical Benefits and Safety of Medical Cannabis Products: A Narrative Review on Natural Extracts. Pain Ther. 2024 Oct;13(5):1063-1094. doi: 10.1007/s40122-024-00643-0.

around highly potent inhalable products, including consideration of potency caps and mandatory contaminant testing for solvents and additives should be considered.

28. High-potency THC products have been linked with an increased risk of psychosis in daily users, particularly in adolescents, and those with a family predisposition, acute anxiety, paranoia, and cognitive impairment.[16] Given these risks, it is not appropriate for high-THC products to be prescribed without specialised prescriber oversight. Limiting prescribing of high-THC products to appropriately qualified specialist prescribers with a working knowledge of the patient's history, presentation, medications, and conditions (e.g., nurse practitioners, general practitioners, and specialists) rather than those with little to no prior contact with or knowledge of the patient (as with some virtual and telehealth practices) should be considered. Further, requiring prescribers to provide a detailed clinical justification when applying under the Special Access Scheme (SAS) or Authorised Prescriber (AP) schemes should also be considered.

29. The TGA has noted the absence of an upper limit for THC concentrations in unapproved products, with some preparations exceeding 80% THC. This creates significant safety risks, particularly among younger populations or those with existing vulnerabilities. Introduction of more stringent prescribing safeguards for high-THC products, limits on maximum allowable THC concentrations for unapproved products, mandatory patient counselling on mental health risks, and clearer labelling and warning statements to highlight the absence of TGA evaluation of efficacy and long-term safety should be considered.

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.

30. There can be significant safety risks associated with certain dosage forms of medicinal cannabis products that require more stringent mitigation measures. Inhaled products, including vaporised dried herb and oils, carry notable risks. Published evidence has linked

[16] Hall W, Degenhardt L. Cannabis use and the risk of developing a psychotic disorder. World Psychiatry. 2008;7(2):68-71. doi: 10.1002/j.2051-5545.2008.tb00158.x.

inhaled cannabis products containing additives such as Vitamin E acetate with acute lung injuries and as the Consultation Paper highlights, risks of EVALI and chemical exposure from heating devices, can occur. As explained above, inhalation also has a high risk of inaccurate dosing due to rapid absorption rates.[17] These risks could be mitigated through stricter controls over excipients and solvents, mandatory contaminant testing, and strengthened product warnings regarding respiratory harms.

31. Oral products and edibles also present safety concerns. Although oral dosage forms avoid risks to the respiratory system, they are associated with variable absorption and bioavailability. The delayed and unpredictable onset of effect can lead to unintentional repeat dosing, increasing the risk of acute intoxication. This could be addressed by improving labelling to provide clearer information on expected onset times, maximum recommended single doses, and warnings regarding delayed effects.

32. High-potency THC products also carry a distinct set of risks. Evidence indicates that daily users of high-THC products face a higher risk of psychosis, particularly in adolescents or individuals with a family history of mental illness. High-THC products can also induce acute anxiety, paranoia, and panic attacks, impair short-term memory, and are associated with long-term cognitive deficits. These risks could be reduced by introducing an upper limit on THC concentrations, stricter age-based restrictions, mandatory warnings about mental health risks, tighter clinical justification requirements for high-THC prescribing, and greater education for prescribers.

33. Some dosage forms should be reviewed due to the potential for disproportionate risks. Cannabis edibles designed to resemble lollies or chocolates present a clear risk of accidental paediatric ingestion if accessed by children. International data show rising hospital presentations linked to such products, and the TGA consultation paper already highlights concerns around exposure to THC in children and its negative impact on brain development.

[17] Usmani, O.S., Lavorini, F., Marshall, J. *et al.* Critical inhaler errors in asthma and COPD: a systematic review of impact on health outcomes. *Respir Res* **19**, 10 (2018). https://doi.org/10.1186/s12931-017-0710-y

To minimise this risk, such products should be subject to more stringent packaging and labelling requirements.

34. Highly potent inhalable products also raise concern as they carry compounded risks of acute intoxication, dependency, and respiratory harm.[18] The consultation paper notes that inhaled cannabis produces rapid and high systemic THC peaks. These products should be subject to stricter prescribing guidelines and controls, including potency caps, contaminant testing, and enhanced product warnings. Given the established mental health and cognitive risks, prescription of high-THC containing products requires careful oversight and knowledge of the patient and medication with clear and reasonable clinical justification required under the SAS or AP schemes. Safeguards should also include mandatory patient counselling on mental health risks, consideration of family psychiatric history, and clearer labelling.

35. Safety risks are also known to be associated with certain dosage forms when prescribed for specific routes of administration. Sublingual sprays, for example, result in faster systemic absorption than solid oral dosage forms.[19] While rapid onset may be beneficial in some contexts, dosing errors and adverse events can be more likely without careful patient education. Products with higher THC concentrations, especially when delivered through such routes also pose a potential risk of impairing cognitive and psychomotor function. This can increase the likelihood of driving accidents, workplace incidents, and other safety-critical harms. Smoking or vaporising cannabis produces rapid and transient THC peaks, which can intensify these effects. There is also evidence that high, single doses of THC can precipitate transient hallucinations, delusions, or psychotic-like symptoms even in otherwise healthy individuals, particularly when delivered through rapid-onset routes such as inhalation or sublingual delivery. In addition, THC-containing products can cause sedation and dizziness,

[18] Matheson J, Le Foll B. Cannabis Legalization and Acute Harm From High Potency Cannabis Products: A Narrative Review and Recommendations for Public Health. Front Psychiatry. 2020 Sep 23;11:591979. doi: 10.3389/fpsyt.2020.591979.
[19] Bahraminejad S, Almoazen H. Sublingual and Buccal Delivery: A Historical and Scientific Prescriptive. Pharmaceutics. 2025 Aug 20;17(8):1073. doi: 10.3390/pharmaceutics17081073.

which in some populations (e.g., older people) could amplify the risk of falls.

36. High-potency inhalable medicinal cannabis, sublingual sprays, and high-THC preparations should be subject to stricter prescribing safeguards and enhanced regulatory oversight. Introducing dosage form restrictions, potency limits, clear prescribing requirements, and improved labelling and clinician and patient education would reduce preventable harms and better align medicinal cannabis regulation with the safety expectations applied to other therapeutic goods in Australia.

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?

37. While CBD is generally well tolerated, at higher concentrations it can cause elevated liver enzymes and result in clinically important drug interactions. High-dose CBD has been associated with transaminase elevations requiring monitoring and sometimes treatment cessation.[20] In addition, CBD is a known inhibitor of CYP3A4 and CYP2C19, which can increase plasma levels of medicines such as warfarin, antidepressants, certain antiepileptics and immunosuppressants.[21,22,23] These risks are particularly relevant for vulnerable patients or those on multiple medications. To mitigate them, prescribers should conduct baseline and follow-up liver function testing for higher-dose CBD regimens, screen for potential drug interactions, and adjust or monitor co-medications as required.[24,25] Stronger product

[20] Florian J, Salcedo P, Burkhart K, et al. Cannabidiol and Liver Enzyme Level Elevations in Healthy Adults: A Randomized Clinical Trial. JAMA Intern Med. 2025;185(9):1070–1078. doi:10.1001/jamainternmed.2025.2366.
[21] Balachandran P, Elsohly M, Hill KP. Cannabidiol Interactions with Medications, Illicit Substances, and Alcohol: a Comprehensive Review. J Gen Intern Med. 2021 Jul;36(7):2074-2084. doi: 10.1007/s11606-020-06504-8.
[22] Antoniou T, Bodkin J, Ho JM. Drug interactions with cannabinoids. CMAJ. 2020 Mar 2;192(9):E206. doi: 10.1503/cmaj.191097.
[23] Vázquez M, Guevara N, Maldonado C, Guido PC, Schaiquevich P. Potential Pharmacokinetic Drug-Drug Interactions between Cannabinoids and Drugs Used for Chronic Pain. Biomed Res Int. 2020 Aug 13;2020:3902740. doi: 10.1155/2020/3902740.
[24] Eadie L, Lo LA, Boivin M, Deol JK, MacCallum CA. Clinical guidance for cannabidiol-associated hepatotoxicity: A narrative review. J Gastroenterol Hepatol. 2024 Dec;39(12):2522-2532. doi: 10.1111/jgh.16730.
[25] Lo LA, Christiansen A, Eadie L, Strickland JC, Kim DD, Boivin M, Barr AM, MacCallum CA. Cannabidiol-associated hepatotoxicity: A systematic review and meta-analysis. J Intern Med. 2023 Jun;293(6):724-752. doi: 10.1111/joim.13627.

labelling and prescriber education and guidance would also help ensure safer use.

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.

38. As set out in the submission to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024*, the ANMF highlights the significant risks and lack of clinical evidence supporting the therapeutic benefits of vaping. While noting that vaping cannabis generally provides higher absorption efficiency and greater bioavailability of THC compared to smoking,[26] and may avoid some harmful combustion byproducts,[27] vaping has been linked to lung injury (EVALI),[28] and may expose users to volatile organic compounds, carbonyls, heavy metals, and carcinogens, all of which can damage lung tissue and impair respiratory health.[29] Despite therapeutic benefits, vaping clearly still presents significant risks to patients. While absorption rates and bioavailability may be important considerations for some patient groups, where possible, the TGA and prescribers should strongly recommend safer alternatives and ensure that health care professionals and consumers are well informed and educated regarding the potential risks associated with inhaling or vaping high THC-containing products.

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

39. Clinical and toxicology evidence indicates dose-related thresholds for acute harms and for

[26] Spindle TR, Cone EJ, Schlienz NJ, Mitchell JM, Bigelow GE, Flegel R, Hayes E, Vandrey R. Acute Effects of Smoked and Vaporized Cannabis in Healthy Adults Who Infrequently Use Cannabis: A Crossover Trial. JAMA Netw Open. 2018 Nov 2;1(7):e184841. doi: 10.1001/jamanetworkopen.2018.4841. Erratum in: JAMA Netw Open. 2018 Dec 7;1(8):e187241. doi: 10.1001/jamanetworkopen.2018.7241.
[27] Chaiton M, Dubray J, Kundu A, Schwartz R. Perceived Impact of COVID on Smoking, Vaping, Alcohol and Cannabis Use Among Youth and Youth Adults in Canada. Can J Psychiatry. 2022 May;67(5):407-409. doi: 10.1177/07067437211042132.
[28] Smith ML, Gotway MB, Crotty Alexander LE, Hariri LP. Vaping-related lung injury. Virchows Arch. 2021 Jan;478(1):81-88. doi: 10.1007/s00428-020-02943-0.
[29] Chadi N, Minato C, Stanwick R. Cannabis vaping: Understanding the health risks of a rapidly emerging trend. Paediatr Child Health. 2020 Jun;25(Suppl 1):S16-S20. doi: 10.1093/pch/pxaa016.

dependence that should be considered and inform conservative prescribing limits and safeguards.

40. Multiple clinical reports and experimental studies show that single doses in the 20–30 mg THC range are associated with severe intoxication in some users — acute anxiety, panic, marked tachycardia, vomiting and transient psychotic-like symptoms.[30] The risk of these acute events depends on route (inhalation and sublingual produce higher peak levels), user tolerance, age and co-morbidities. The TGA paper emphasises the particular hazards of rapid-onset routes that create high peak THC concentrations.

41. Sustained daily exposure to higher THC doses carries a materially increased risk of dependence.[31] Evidence summarised in the consultation paper and the broader literature indicates substantially increased dependence risk (and associated harms) with prolonged use at higher doses; higher doses can have a significant dependence risk, particularly with sustained long-term use and among younger users. As there is no single internationally or regulatorily agreed “safe” upper limit, regulators should not rely on an absolute figure alone. The absence of an established limit in current scheduling means the TGA should consider policy options (e.g., maximum concentration limits, dose caps, or scheduling amendments) rather than assume safety at any high dose.

42. As inhalation and sublingual routes generate higher and faster THC peaks, stricter limits or clinician requirements could be considered for prescribing medicinal cannabis by these routes (for example, lower dose caps, specialist prescribing only, mandatory counselling on acute effects). The safety and appropriateness of prescribing for certain vulnerable groups including adolescents, pregnant/breastfeeding people, and those with a personal/family history of psychosis should be carefully considered and stricter access controls or preclusion

[30] Schmid Y, Scholz I, Mueller L, Exadaktylos AK, Ceschi A, Liechti ME, Liakoni E. Emergency department presentations related to acute toxicity following recreational use of cannabis products in Switzerland. Drug Alcohol Depend. 2020 Jan 1;206:107726. doi: 10.1016/j.drugalcdep.2019.107726.

[31] Hoch, E., Volkow, N.D., Friemel, C.M.*et al.*Cannabis, cannabinoids and health: a review of evidence on risks and medical benefits. *Eur Arch Psychiatry Clin Neurosci*. 275, 281–292 (2025). https://doi.org/10.1007/s00406-024-01880-2.

from high-THC prescribing should be considered.

43. Introduction of mandatory treatment plans and careful monitoring requirements for patients prescribed THC (including mental health review, documentation of family psychiatric history, and review of intoxication/functional impairment), and limiting routine prescribing of high doses with clear audit and adverse-event reporting requirements should be considered.

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

44. As there is relatively little evidence in relation to certain cannabinoids (i.e. CBG, CBN, CBC and THCV), more high-quality clinical trials need to occur to determine their safety profile. As noted above, due to the fact that many cannabinoids can interact with other medicines including antidepressants and anticoagulants, further research is required here also.

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.

45. Edibles with delayed onset and combusted/smoked cannabis may present unacceptable or high risks to patients in some settings. Edibles because of their pattern of delayed absorption and repeat dosing leading to severe intoxication (and paediatric accidental ingestion), and smoking because of direct respiratory harm and high peak THC exposure. Regulatory action (greater care around high-risk formats, strict packaging/label rules, route-specific prescribing limits and patient counselling) could be considered as justified and proportionate to reduce preventable harm.

46. Edibles (especially those resembling confectionery) pose a particular risk because of their delayed and highly variable onset. Such delays can lead patients to re-dose thinking the first dose “didn’t work,” which can produce unexpectedly large cumulative exposure and precipitate severe sedation, vomiting, acute intoxication and psychotic-like symptoms. Evidence from international reports also links confectionery-style edibles with rising rates of accidental paediatric ingestion and hospital presentations; for this reason, such edible

formats are particularly unsafe in household settings with children.[32,33]

47. Smoking cannabis is another route of medication administration which might have unacceptable public-health risks. Smoking cannabis can harm lung tissues, cause scarring and damage to small blood vessels, and is associated with respiratory symptoms; prolonged smoking can contribute to chronic respiratory disease (including chronic cough, exacerbation of asthma and the potential for COPD-like effects).[34] These respiratory harms — together with the rapid and high THC peaks produced by smoking — increase both short-term and long-term patient risk.

Population groups

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 medicinal specialist. Do you consider this current restriction to paediatric patients appropriate and sufficient? If not, please provide an explanation to support your response.

48. The current restriction is both appropriate and necessary to protect children and adolescents from avoidable harms while still allowing carefully supervised access where there is a compelling clinical need. We support the current restriction requiring a letter of support from a paediatrician or relevant medical specialist for patients under the age of 18 accessing medicinal cannabis products through the SAS or AP scheme. This safeguard is appropriate, as it ensures careful oversight in a group particularly vulnerable to the adverse effects of cannabis on neurodevelopment.

49. Specialist involvement also provides an important check to ensure that any prescribing is clinically justified, that potential drug interactions are carefully reviewed, and that alternative

[32] Zwiebel H, Greenky D, Goldman RD. Accidental cannabis ingestion in young children. Can Fam Physician. 2025 Mar;71(3):161-163. doi: 10.46747/cfp.7103161.
[33] Hammig B, Jones C, Haldeman S. Pediatric Poisonings Associated With Ingestion of Marijuana Products. J Emerg Med. 2023 Feb;64(2):181-185. doi: 10.1016/j.jemermed.2022.12.025.
[34] Ribeiro LI, Ind PW. Effect of cannabis smoking on lung function and respiratory symptoms: a structured literature review. NPJ Prim Care Respir Med. 2016 Oct 20;26:16071. doi: 10.1038/npjpcrm.2016.71.

evidence-based therapies have been considered. Given the complexity of managing comorbidities and polypharmacy in paediatric populations, requiring oversight from a paediatrician or other relevant specialist offers an essential layer of safety.

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.

50. A paediatric medicinal cannabis register would be a valuable risk mitigation tool, providing much-needed evidence on safety and efficacy while enhancing protections for young patients. Such a register would enable systematic collection of data on the safety, efficacy, and long-term outcomes of medicinal cannabis use in this vulnerable group. It would provide critical information on neurocognitive development, psychiatric outcomes, and other potential adverse effects associated with early exposure to cannabinoids. Given the limited evidence base for paediatric use and the known risks to the developing brain, longitudinal data collection is essential to better understand both short- and long-term impacts. A register would also create a mechanism for monitoring prescribing practices, ensuring accountability, and identifying emerging safety concerns. This would support clinicians, regulators, and families in making more informed decisions while maintaining appropriate access for children and adolescents with compelling clinical need.

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.

51. High-THC products and concentrates raise substantial risks in paediatric patients. Exposure to high concentrations of THC during adolescence has been consistently linked with adverse effects on neurodevelopment, including impacts on cognition, memory, and executive functioning, as well as an elevated risk of psychiatric outcomes such as anxiety, depression, and psychosis.[35] These risks are magnified in younger patients whose brains are still

[35] Solinas M, Melis M. Developmental exposure to cannabis compromises dopamine system function and behavior. Current Opinion in Behavioral Sciences. 2024 Oct 1;59:101442.

developing and are therefore more vulnerable to long-term harm.[36]

52. We also hold concerns about inhaled products in this population. Inhalation exposes the lungs and other tissues directly to heated particles, solvents, and potential contaminants. This mode of administration is associated with respiratory harms, including airway inflammation, chronic cough, and the risk of longer-term conditions such as asthma exacerbation or chronic obstructive pathology.[37] Given that safer oral alternatives are available (but have their own potential risks – especially edible forms that mimic lollies - also discussed above), the use of inhaled cannabis products in children and adolescents should be carefully considered.

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.

53. The lack of safety evidence combined with clear biological plausibility of harm strongly supports considerations around more careful oversight or restricting access to medicinal cannabis products for pregnant and breastfeeding women,[38] with any use tightly controlled under exceptional circumstances and specialist supervision. Both THC and CBD readily cross the placenta and the blood–brain barrier, meaning that the foetus is exposed during critical stages of neurodevelopment.[39] This creates potential risks for brain development, cognitive function, and longer-term psychiatric outcomes. Given the absence of robust safety data and the potential for lasting harm, prescribing medicinal cannabis products in pregnancy should be restricted to situations of absolute clinical necessity, and only under specialist oversight.

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[36] Zehra A, Burns J, Liu CK, Manza P, Wiers CE, Volkow ND, Wang GJ. Cannabis Addiction and the Brain: a Review. J Neuroimmune Pharmacol. 2018 Dec;13(4):438-452. doi: 10.1007/s11481-018-9782-9.
[37] Preteroti M, Wilson ET, Eidelman DH, Baglole CJ. Modulation of pulmonary immune function by inhaled cannabis products and consequences for lung disease. Respir Res. 2023 Mar 28;24(1):95. doi: 10.1186/s12931-023-02399-1.
[38] Metz TD, Borgelt LM. Marijuana Use in Pregnancy and While Breastfeeding. Obstet Gynecol. 2018 Nov;132(5):1198-1210.
[39] Thompson R, DeJong K, Lo J. Marijuana Use in Pregnancy: A Review. Obstet Gynecol Surv. 2019 Jul;74(7):415-428. doi: 10.1097/OGX.0000000000000685.

54. Similarly, both THC and CBD are known to transfer into breastmilk,[40] exposing infants to cannabinoids during a highly vulnerable period of neurological and physiological development.[41] This raises comparable concerns for neurodevelopmental impacts, as well as for other unknown long-term effects. For this reason, restrictions around prescribing medicinal cannabis products to breastfeeding women should also be considered.

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.

55. Restrictions and additional safeguards should apply to vulnerable groups. As THC is associated with psychosis, schizophrenia, severe anxiety and depression, prescribers should take a full mental health history before initiating treatment. A risk-based prescribing approach is essential to identify individuals with pre-existing psychiatric conditions and minimise the likelihood of exacerbating illness. Given that high-THC products carry a risk of dependence, clinicians should have a strong knowledge of the patient and also complete a comprehensive medical history to assess vulnerability to substance use disorders prior to prescribing. In older adults, high-THC products can worsen cognitive impairment and increase the risk of falls, delirium and drug–drug interactions due to polypharmacy.[42,43] For these reasons, prescribing to vulnerable populations should be carefully restricted, supported by mandatory screening, and guided by a risk–benefit assessment under specialist oversight where appropriate.

[40] Josan C, Shiplo S, Fusch G, Raha S, Shea AK. Cannabis use during lactation may alter the composition of human breast milk. Pediatr Res. 2023 Jun;93(7):1959-1968. doi: 10.1038/s41390-022-02315-1.
[41] Castro-Navarro I, McGuire MA, Williams JE, Holdsworth EA, Meehan CL, McGuire MK. Maternal Cannabis Use during Lactation and Potential Effects on Human Milk Composition and Production: A Narrative Review. Adv Nutr. 2024 Apr;15(4):100196. doi: 10.1016/j.advnut.2024.100196.
[42] Abuhasira R, Ron A, Sikorin I, Novack V. Medical Cannabis for Older Patients-Treatment Protocol and Initial Results. J Clin Med. 2019 Nov 1;8(11):1819. doi: 10.3390/jcm8111819.
[43] Wolfe D, Corace K, Butler C, Rice D, Skidmore B, Patel Y, Thayaparan P, Michaud A, Hamel C, Smith A, Garber G, Porath A, Conn D, Willows M, Abramovici H, Thavorn K, Kanji S, Hutton B. Impacts of medical and non-medical cannabis on the health of older adults: Findings from a scoping review of the literature. PLoS One. 2023 Feb 17;18(2):e0281826. doi: 10.1371/journal.pone.0281826.

How do we address the current issues with medicinal cannabis products?

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.

56. As described above, several principles should guide regulatory reform. Tighter controls on batch-to-batch variability for both CBD and THC are needed to ensure dosing consistency and clinical reliability. All products, particularly imports, should undergo independent testing in TGA-approved laboratories to confirm quality and compliance. Enhanced labelling requirements would improve transparency for prescribers and consumers, including clearer information on potency, onset times and potential risks. Prescribing of higher-risk products should require specialist oversight for vulnerable groups, such as paediatric patients, older people (especially those on multiple medications or at risk of falls or cognitive issues) and those with pre-existing mental health conditions, to minimise avoidable harms.

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.

57. The ANMF supports the continued availability of medicinal cannabis products for the therapeutic treatment of symptoms, provided their use is evidence-based and recommended by a person's treating health practitioner(s). While the ANMF acknowledges concerns regarding current regulation in Australia, including over-prescription driven by profit models that risk patient safety, these products must remain accessible to patients with genuine clinical need. To achieve this balance, stronger regulatory measures are required.

58. Such reforms should include enhanced prescriber oversight through mandatory training and certification to improve clinical decision-making and reduce inappropriate prescribing. Robust monitoring and reporting systems to track prescribing patterns and adverse events, ensuring continuous surveillance and safety improvements should also be implemented. In addition, national guidelines covering clinical indications, dosing, and monitoring requirements should be developed to provide a consistent and evidence-informed

framework across Australia. These measures must be supported by high-quality clinical research into the efficacy, safety, and long-term outcomes of medicinal cannabis to continually inform clinical practice and regulatory policy.

59. Specific reforms could also include mandating consultation with a patient's regular healthcare practitioner as part of the prescription process, to introduce safeguards that limit third party online prescribing services that prioritise commercial gain over integrity or patient safety. Certain providers, such as Dispensed, have already been identified as engaging in unethical and harmful practices, underscoring the need for tighter oversight mechanisms.

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.

60. The ANMF would be supportive of a time-limited regulatory mechanism to allow sponsors of unapproved medicinal cannabis products time to gather evidence of efficacy or conformity assessment certification to transition to the ARTG as this would allow sponsors of unapproved products to complete clinical trials and apply for TGA approval

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?

61. It is anticipated that sponsors/companies would require at least 12 to 18 months to complete initial clinical trials for both phase 2 and 3 trials and then up to five years to gain TGA approval.

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

62. Potential amendments would include reinforcement of Schedule 8 (S8) controls for THC containing medicinal cannabis products while keeping low dose CBD products as Schedule 3 with the implementation of stronger prescribing guidelines around dosing.

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?

63. Medicinal cannabis product labelling requires stricter, more transparent requirements to improve prescriber and patient safety and informed use. As described throughout this submission, potential improvements include greater content and dosing transparency, improved dosing instructions, better safety and regulatory transparency, safety warnings including for driving and machinery operation and pregnancy and breastfeeding warnings, and greater transparency around regulatory status. Further, up to date, high-quality education and information for prescribers are critical for the safe and effective use of medicinal cannabis. Since most of these products are unapproved and not on the ARTG, prescribers must have up-to-date knowledge to make informed decisions and manage patient care responsibly.

64. Mandatory inclusion of more accurate cannabinoid content on all labels is crucial. This would provide prescribers and patients with the precise information needed to manage dosing more effectively. In addition to THC and CBD, listing other cannabinoids and terpenes if and when possible would offer a more comprehensive profile, allowing prescribers to make more nuanced treatment decisions.

65. Labels should move beyond generic advice. They should provide clear, step-by-step instructions for the specific product, including starting doses, titration schedules, and methods of administration (e.g., drops for sublingual oils, inhalations for vaporised products). This is vital for patient safety and efficacy, especially for new users unfamiliar with the "start low, go slow" principle of cannabis therapy. Prescribers would need clear information and education to help guide patients in this.

66. Labels must carry prominent, easily understandable safety warnings to mitigate risks. Clear, standardised text warning about the potential for impairment is necessary. This is particularly important for products containing THC, as it is illegal to drive with any trace of THC in your system in many Australian states. Labels should include a strong, unambiguous warning

against use by pregnant or breastfeeding women. This is due to the potential for THC to cross the placenta and enter breast milk, which may affect fetal and infant development.

67. Transparency regarding a product's regulatory status is essential for building patient and prescriber confidence and ensuring ongoing access to medicinal cannabis in Australia. The label should clearly state whether the product is included on the Australian Register of Therapeutic Goods (ARTG). Explicitly stating this status would provide greater clarity, informing patients regarding whether or not the product has been fully evaluated by the TGA for efficacy, safety, and quality.