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

Version 1.0, August 2025

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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Information about this consultation

Purpose and Scope

The purpose of this consultation paper is to gather information on stakeholders' experiences, observations and knowledge of the use of unapproved medicinal cannabis products, including medicinal cannabis medicines and medicinal cannabis devices. The Therapeutic Goods Administration (TGA) is conducting this consultation in response to growing safety concerns, which appear to correlate with the rapid growth in the number and type of unapproved medicinal cannabis products being accessed in Australia. Information obtained will inform regulatory reform options to ensure appropriate regulatory oversight and market controls are in place, providing assurance of the product quality and safe use of these products.

State and territory health departments, peak medical bodies, industry stakeholders and community members have raised concerns about safety risks associated with the use of certain unapproved medicinal cannabis products, especially in the context of rapidly increasing use. These concerns include a reported increase in patients presenting to health services with a range of mental health issues including psychosis and dependency following the use of medicinal cannabis products.

The TGA shares these concerns and supports the call for regulatory change. The unapproved pathways used by prescribers to access medicinal cannabis products, traditionally used as exceptional access mechanisms for unapproved goods, are no longer appropriate due to the high volume of patients accessing an ever-increasing range of products. These products have not undergone any regulatory review or evaluation of their quality, safety, efficacy or performance. Further, the ready access provided via these pathways has reduced or removed the incentive to collect the robust safety, efficacy and performance data necessary for the evaluation and registration of a medicinal cannabis product on the Australian Register of Therapeutic Goods (ARTG).

In Australia, access to medicinal cannabis products is governed through complex arrangements. Legal access to unapproved medicinal cannabis products is facilitated by the TGA, while the practitioners who prescribe and dispense unapproved medicinal cannabis are regulated by the Australian Health Practitioner Regulation Agency (Ahpra), the Medical, Pharmacy, Nursing and Midwifery Boards of Australia, and relevant state and territory legislation.

3 main issues have been raised:

1. Whether there is appropriate regulatory oversight of unapproved medicinal cannabis products being accessed via the unapproved pathways, the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme. These schemes were initially designed to provide access to experimental products often used in clinical trials or for medicines and medical devices not entered on the ARTG but approved overseas, for exceptional circumstances and at the discretion of a health practitioner.
2. The safety risks associated with unapproved medicinal cannabis products, particularly those products containing delta-9-tetrahydrocannabinol (THC), noting there are large numbers of Australian patients accessing and using these products.
3. The growing number of 'product-specific' telehealth services prescribing unapproved medicinal cannabis products (and other medicines), through vertically integrated direct-to-consumer business models.

Given the TGA's role as the regulator of therapeutic goods, the scope of this consultation will focus only on issues 1 and 2.

Through this consultation, the TGA will consider:

- safety concerns with the use of 'high' potency THC medicinal cannabis products
- the low levels of evidence for certain indications and long-term medicinal cannabis use
- concerns about product quality, including labelling requirements
- the appropriate use of medicinal cannabis products in vulnerable population groups, including young people and pregnant women.

The TGA is not intending to remove access to medicinal cannabis products. Rather, we aim to ensure that products being supplied are of appropriate quality, there is confidence in the level of safety, efficacy and performance, and further evidence is being generated to support legitimate use as a therapeutic good. If safety signals with certain unapproved medicinal cannabis products are identified through this consultation, the TGA will take prompt and appropriate regulatory actions to provide greater assurance of the safety of medicinal cannabis products.

Consultation Process

We welcome your responses and feedback to the specific questions posed in this consultation, along with any additional information you consider relevant to inform the regulatory controls on the quality, safety, efficacy or performance of medicinal cannabis products. Unless marked confidential, submissions will be published on the TGA's website. The TGA will consider the feedback provided to inform options for future amendments to a regulatory framework for medicinal cannabis products. Further consultation with stakeholders will be undertaken for any proposed reforms.

How to Provide Feedback

Feedback can be provided using the online submission form at TGA Consultation Hub (tga.gov.au). If you have any questions about the submission or the process, please email MedicinalCannabisReforms@health.gov.au

Submissions are due by **5pm on Tuesday 7 October 2025**

Background

Access to medicinal cannabis products

In 2015, the Standard for the Uniform Scheduling of Medicines and Poisons (the Poisons Standard) was amended through the down-scheduling of cannabidiol (CBD) from Prohibited Substance (Schedule 9) to Prescription-only medicine (Schedule 4). This followed advocacy for access to medicinal cannabis products for specific clinical situations where all other therapy options had been exhausted, specifically for epilepsy and seizure management in children, for palliative care, and for symptoms of rare disease.

In 2016, further legislative changes were introduced to increase access to medicinal cannabis products by reclassifying cannabis and its cannabinoids (excluding CBD) to Controlled drugs (Schedule 8) in the Poisons Standard. This change resulted in access being available to other cannabinoids found in cannabis, including THC. A maximum upper limit allowable for THC was not established at this time.

Additional scheduling changes were made in 2021 with the introduction of low dose CBD - no more than 150 mg/day – as a Pharmacist-only medicine (Schedule 3). This provided an avenue for patients

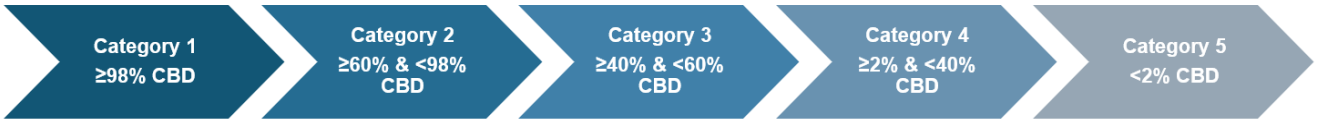
to access certain CBD products without the requirement for a prescription. To date, no complete application for a CBD product that meets the Schedule 3 registration requirements has been submitted or evaluated by the TGA.

When access to medicinal cannabis products was first introduced in Australia, it was expected that a relatively small number of health practitioners would prescribe it to patients with specific clinical needs, and that there would only be a small number of products supplied.

Given the lack of data to support the registration of medicinal cannabis products at the time, the only available mechanism for prescribers and their patients to gain access was via the SAS and AP scheme. It was anticipated that allowing access via SAS/AP scheme would also facilitate the gathering of clinical data and evidence to support products to be Registered on the ARTG.

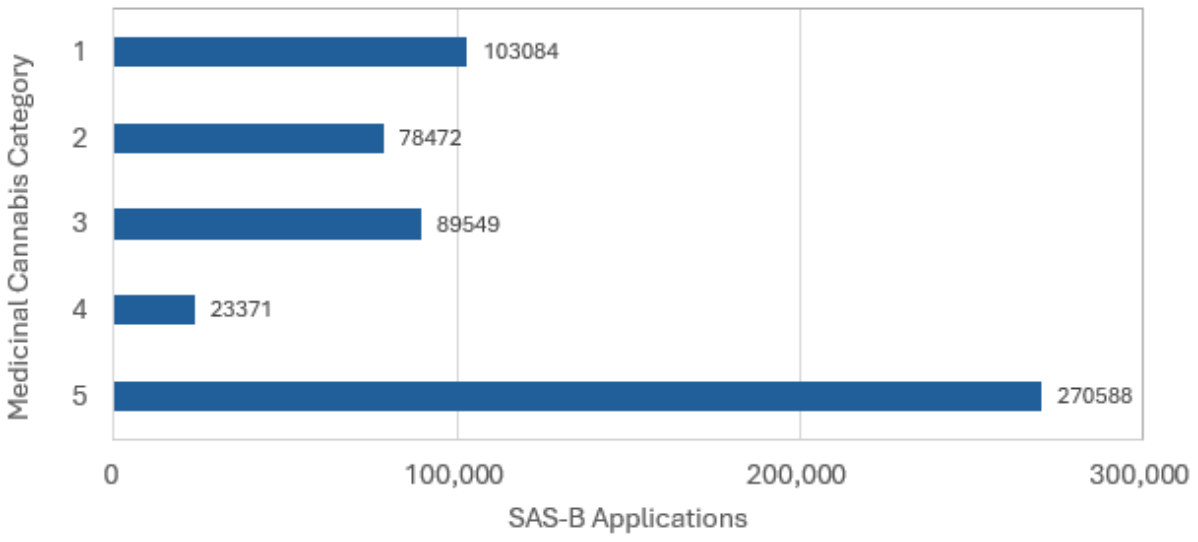
To date, only 2 medicinal cannabis medicines have been Registered on the ARTG - Epidyolex (CBD) to treat certain epileptic conditions, and Sativex (nabiximols) to treat certain symptoms associated with multiple sclerosis. Four devices have been approved for supply for use with medicinal cannabis. All other medicinal cannabis products prescribed are 'unapproved'.

In 2021, changes were made to reduce the administrative burden on prescribers of unapproved medicinal cannabis products. Submissions under the SAS and AP scheme were changed so they could be made based on active ingredient instead of trade name. To further assist, products were 'categorised' based on the proportion of CBD content compared with the total cannabinoid content to align with the Poisons Standard. The categories were not intended to differentiate products based on their relative psychoactivity or THC content. The result was the establishment of 5 categories for unapproved medicinal cannabis, defined by ranges of CBD content. It should be noted although a large proportion of Category 5 products do contain high levels of THC, there are products in this group that have high concentrations of other cannabinoids other than THC.



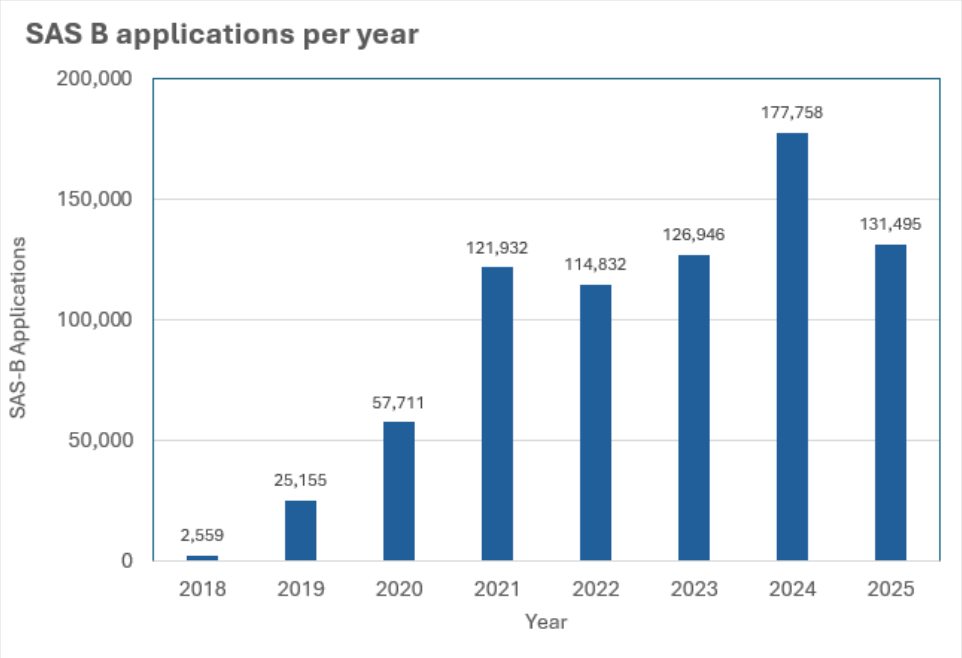
As illustrated in Figure 1 below, as at 31 July 2025, the most commonly accessed medicinal cannabis products fell within Category 5, which represents nearly half of all applications.

Figure 1 – Number of SAS B applications accessed for each unapproved medicinal cannabis category



As shown in Figure 2, there has been significant growth in SAS B approvals to access unapproved medicinal cannabis, increasing from 57,711 in 2020, to 177,762 in 2024.

Figure 2 - Number of SAS B approvals for unapproved medicinal cannabis products, 2018 – 31 July 2025



Over 99% of medicinal cannabis products being prescribed to patients in Australia are unapproved, and have therefore not undergone any pre-market assessment by the TGA to establish their quality, safety, efficacy or performance. Based on sponsor reporting to the TGA, there are over 1,000 unapproved medicinal cannabis products supplied in Australia.

The breadth of indications for the use of unapproved medicinal cannabis products has also grown significantly. Figures 3 and 4 show the most commonly prescribed indications for adults and children.

Figure 3 - Most common indications for medicinal cannabis prescribed for in adults

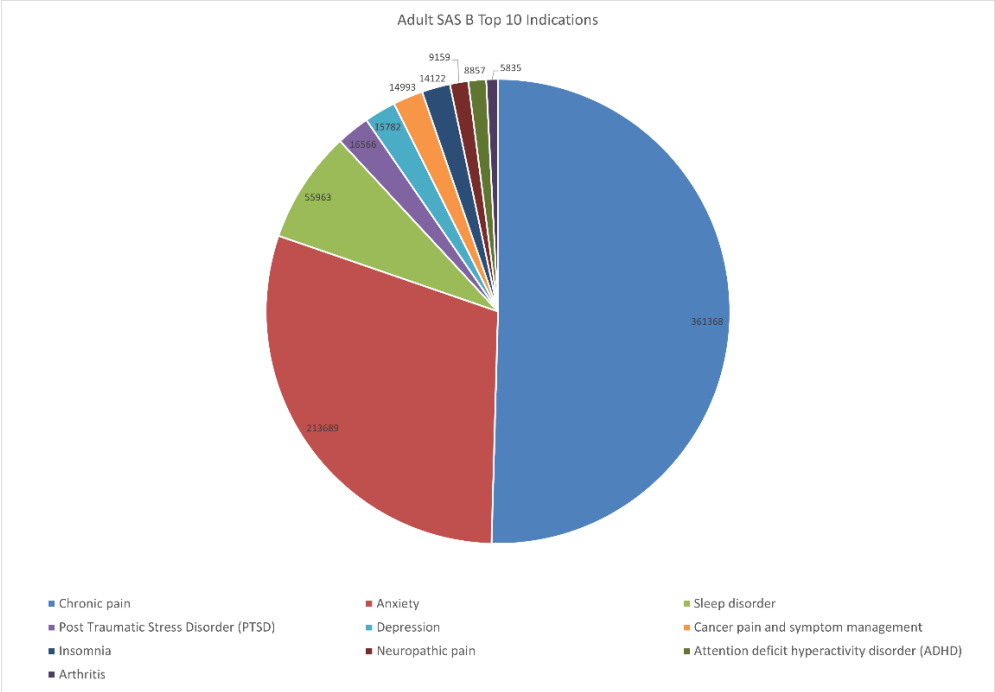
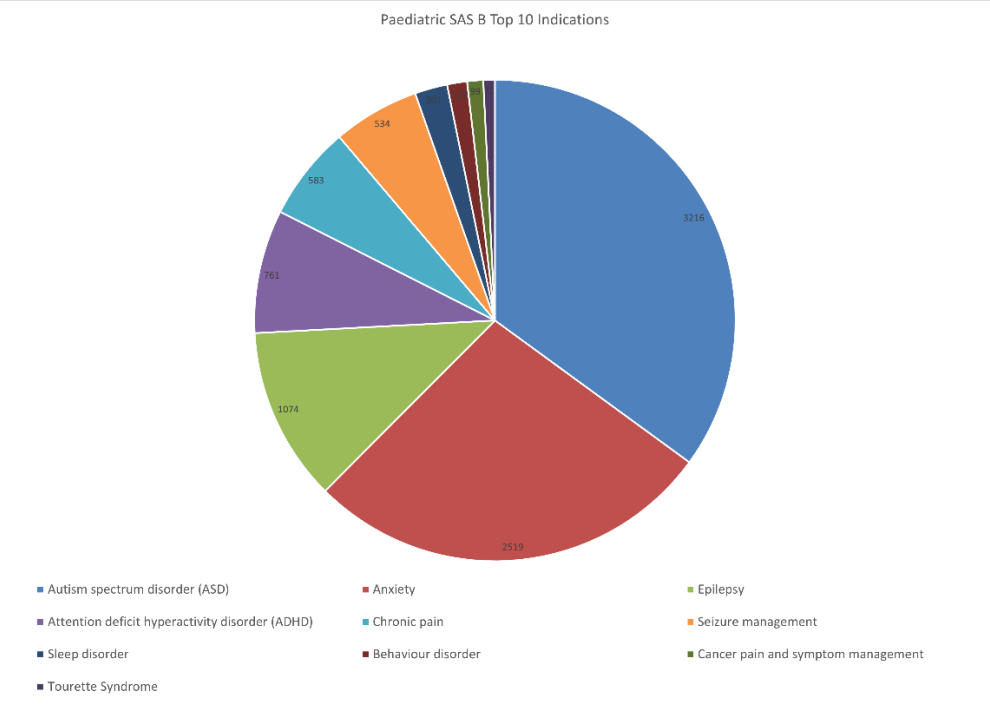


Figure 4 - Most common indications for medicinal cannabis prescribed for in children



Current framework for supply of unapproved products

The SAS and AP scheme allow practitioners to lawfully access unapproved goods, including medicinal cannabis products. This should only be in circumstances where the prescriber considers there is a specific clinical need for that product, and after all other suitable products on the ARTG have considered or trialled.

There is often an assumption by patients and prescribers that a product accessed via the SAS or AP scheme has been evaluated and 'approved' by the TGA. Unapproved products do not undergo an assessment by the TGA for safety, quality, efficacy or performance. However, unapproved goods must meet applicable TGA product standards. They can only be supplied where there is a valid SAS or AP authorisation in place, and supply data and adverse events must be reported to the TGA. To facilitate rapid product access when clinically required, the unapproved goods regulatory requirements do not impose the same level of regulatory requirements as for products on the ARTG.

In contrast, a product that is on the ARTG provides the highest assurance of community confidence in the safety, quality, efficacy and performance of that therapeutic good for Australian patients. Registered medicines and included medical devices undergo a pre-market evaluation by the TGA. This involves the sponsor providing the TGA with detailed information about their products in support of an application for entry, including information on the manufacturers, manufacturing standards and processes, dosage form, strength, route of administration, and safety and efficacy or performance based on non-clinical and clinical data and information relating to the product's proposed indications. This allows for the product's benefit/risk balance and safety profile to be fully assessed and understood by the TGA.

Also, a product on the ARTG has a 'product owner' or 'sponsor'. Sponsors are responsible for ensuring that safety, quality and efficacy or performance are appropriately maintained while the product is on the ARTG and supplied in Australia. The product sponsor is required to monitor the use of its products and report any adverse events or side effects to the TGA, once they become aware of

them. These responsibilities, among others, are outlined within the *Therapeutic Goods Act 1989* (the Act), with the sponsor being required to abide by all relevant aspects of the Act and its regulations.

Conversely, the sponsor of an unapproved therapeutic good is not subject to the same regulatory requirements as outlined above. For example, sponsors of unapproved goods are not automatically required to provide samples at the TGA's request, and they are not required to report adverse events associated with their product unless they are also the prescriber.

Quality standards for medicinal cannabis products

Unapproved medicinal cannabis products imported into, supplied in or manufactured in Australia must comply with the standard for medicines - the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* or with the Essential Principles for medical devices.

TGO 93, created in 2017, is a standard that specifies the minimum quality requirements for medicinal cannabis medicines, such as:

- variation in cannabinoid content and levels of active ingredients
- contaminations such as pesticides, microbial contamination, mycotoxins and those arising from the manufacturing process
- adulteration with plants and with synthetic psychoactive compounds
- fortification with dronabinol
- misidentification of the plant material

Conformance with TGO 93 is intended to provide assurance to practitioners that medicinal cannabis products meet appropriate standards of quality.

The TGA conducts surveillance testing to monitor the quality of medicinal cannabis substances against the requirements of TGO 93. Rather than testing all available unapproved medicinal cannabis medicines supplied to the Australian market, the TGA applies a risk-based approach to determine which products are tested.

In March 2022, TGO 93 was amended to include additional requirements for manufacturing, packaging and labelling with the aim of enhancing the safety and quality of all medicinal cannabis medicines supplied in Australia.

The Australian medicinal cannabis industry has raised concerns, citing a perceived disparity in the regulatory burden on domestic medicine manufacturers compared to manufacturers of imported product. In 2023, changes to the quality standard made it mandatory for both domestic and overseas manufactures of medicinal cannabis medicines to meet Good Manufacturing Practice (GMP) requirements. While the requirement for GMP manufacturing is equivalent, there is still a perception of unequal regulatory burden for domestic medicine manufacturers as sponsors of overseas manufactured medicines maintain responsibility for assessing compliance. Although this quality standard is in place, there are challenges in the unapproved goods regulatory framework that allows the TGA to take effective action for some circumstances.

Of note, TGO 93 does not apply to devices for medicinal cannabis use. Unapproved medicinal cannabis devices are not held to the same quality requirements as those that have been approved by the TGA for supply in Australia.

Current concerns with unapproved medicinal cannabis products

Emerging safety concerns with medicinal cannabis products

There is limited information on the safety profile of unapproved medicinal cannabis products, as these products have not been assessed by the TGA for safety, quality, efficacy or performance. However, there is growing concerns about the safe use of medicinal cannabis products among the medical community. Research from 2024 linked daily cannabis use to an increased risk of coronary heart disease, myocardial infarction and stroke.[1,2] Smoking cannabis can harm lung tissues, and cause scarring and damage to small blood vessels, and this is not a route of administration that is supported by the TGA.[3] Cannabis use can also result in cannabis use disorder, through its addictive and euphoric actions.[4] There is also an increased risk of psychosis and other adverse events associated with products containing high concentrations of THC.

A search of entries in the TGA Adverse Event Management System (AEMS) internal database between 2016 to 31 July 2025 returned 1,101 cases associated with the use of medicinal cannabis products. Of these, 24% were reported by the submitter as a 'serious individual case safety report (ICSR)'.[5] Although adverse events associated with medicinal cannabis products are required to be reported to the TGA, it is highly likely that there is considerable under reporting due to the potential stigma associated with use, concerns over losing access, prescribers and patients not being clear on which adverse events may potentially be associated with medicinal cannabis product use, and a lack of effective regulatory controls.

As most prescribed medicinal cannabis products are unapproved, there is a lack of evidence on safety risks associated with the wide array of ways in which these products are currently being used. Product safety can be influenced by variation in particular plant parts, routes of administration, frequency and duration of use, dosage forms, concentrations of cannabinoids, and differences in population groups.

Risks with certain dosage forms

Currently, the SAS & AP Online system includes 19 different dosage forms that can be selected when accessing an unapproved medicinal cannabis product, as shown in Figure 5 below. No ongoing clinical assessment is undertaken to determine any risks that these medicinal cannabis dosage forms may present. They are selected at the discretion of the prescriber at the time of application, and should

[1] Jeffers AM., Byers L., Keyhani, S. Association of Cannabis Use With Cardiovascular Outcomes Among US Adults. Journal of the American Heart Association 13 (5): 1-11.

[2] Association of Cannabis Use With Cardiovascular Outcomes Among US Adults | Journal of the American Heart Association

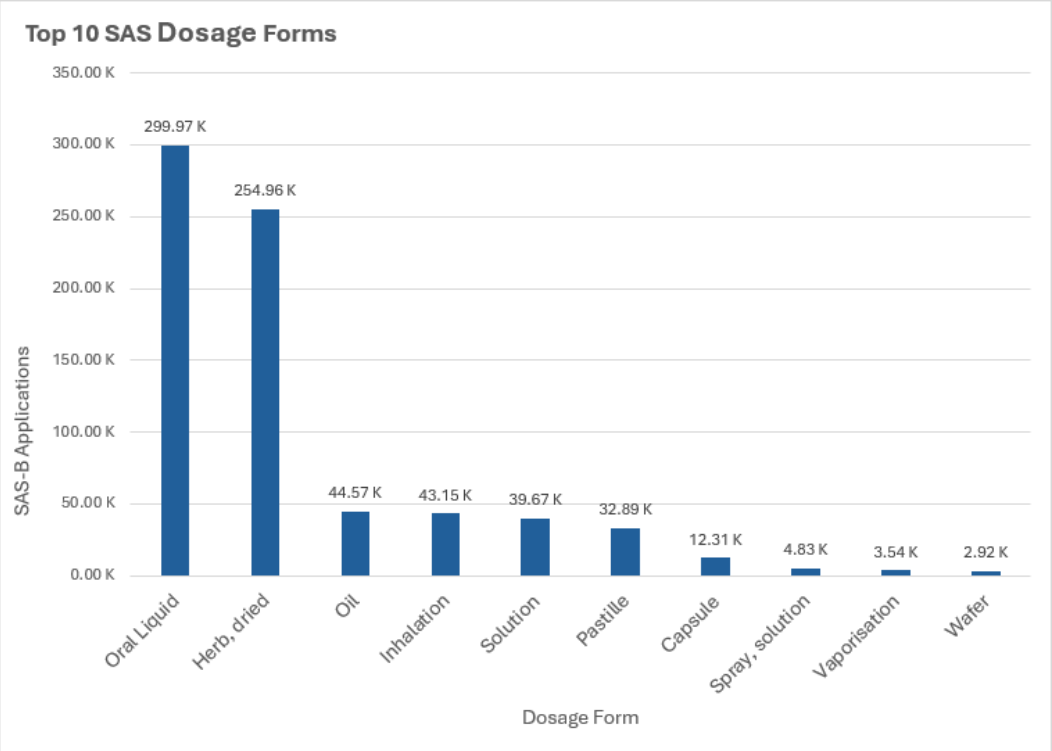
[3] www.cdc.gov/cannabis/health-effects/lung-health.html Accessed 20 January 2025.

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

[5] Serious individual case safety reports (ICSR) are defined as an adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a birth defect. NOTE: Serious ICSR is determined by the submitter and therefore includes self-reporting/assessment by consumers.

be based on the patient's clinical need. As at 31 July 2025, the 3 most common dosage forms prescribed were oral liquid, dried herb and oil.[6]

Figure 5 - Dosage forms of unapproved medicinal cannabis prescribed under SAS B approvals



While inhalation of medicinal cannabis using a device has generally been thought to be safer than smoking, it has been linked to harm such as E-Cigarette, or Vaping Products Use-Associated Lung Injury (EVALI). One of the clinical advantages to this dosage form is that it takes effect within 5-10 minutes compared to one hour when taken orally.[7] This can be clinically beneficial for patients needing rapid onset therapeutic effect, such as for patients that are in palliative care.

The use of battery-operated vaping devices has been linked to adverse events including thermal runaway, explosions, burns, projectile injuries, overheating, spillage malfunction or accidental activation. [8,9]

Chemical exposure from vaping devices is linked to chemical composition, power output and the temperature of the heated coil. An increase in the relative power supplied to a device can increase coil temperature, increasing the production of free radicals, carbonyl compounds, benzene and metals. A particular concern with vaping devices is the potential for metal from the heating coil creating emissions, leading to metal exposure during its use.[10]

Dried herb or oils accessed through vaping and inhalation are known to have a rapid absorption rate. It also comes with a risk of inaccurate dosing of medicinal cannabis to the patient. The use of oral

[6] dashboard-data.health.gov.au/single/?appid=1066afbe-2b37-427d-8c47-2caa5082cccc&sheet=088f611b-10de-4d72-be68-ccf8d12c54e9&select=clearall

[7] Caroline A. MacCallum, Ethan B. Russo Practical considerations in medical cannabis administration and dosing European Journal of Internal Medicine Volume 49, March 2018, Pages 12-19

[8] MacCallum C, Lo L, Boivin M "Is medicinal cannabis safe for my patients?" A practical review of cannabis safety considerations. Eur J Intern Med. 2021 Jul:89:10 - 18

[9] Bonner E, et al The chemistry and toxicology of vaping. Pharmacol Ther. 2021 Sep;225:107837. doi: 10.1016/j.pharmthera.2021.107837. Epub 2021 Mar 19. PMID: 33753133; PMCID: PMC8263470.

[10] Non-nicotine liquids for e-cigarette devices in Australia: chemistry and health concerns. National Industrial Chemicals Notification and Assessment Scheme. Department of Health. 2 October 2019.

dosage forms, usually liquid, may avoid effects on the respiratory system and supports accurate dosing. There is limited evidence to support the safety and efficacy of other dosage forms such as sprays, suppositories, topicals and edibles.[11]

The dosage form can play a significant impact on the risks associated with safety with regards to THC. *"Smoking or vaporising cannabis produces a rapid and transient peak in blood and oral fluid THC concentrations. When taken orally, cannabis is absorbed more slowly through the gastrointestinal tract, producing far lower blood THC concentrations*".[12]

Risks with high concentrations of medicinal cannabis components

The cannabis plant contains hundreds of bioactive molecules, most of which are yet to be characterised. The 2 most well-known are THC and CBD.[13] While CBD is considered generally safe and non-intoxicating, it can interact with some medications and should be used with caution in patients with certain conditions.[14]

There is increasing clinical concern with the risks associated with the use of high potency THC-containing unapproved medicinal cannabis products. There is very limited clinical evidence to support the safe and therapeutic use of medicinal cannabis products that contain THC. There are safety signals that link THC-containing products with mental health conditions such as anxiety, depression, psychosis and suicidal ideation.[15] It may also negatively impact cardiac, respiratory and neurological systems.[16,17] In 2019-20, Australia recorded its highest ever rate of cannabinoid-related hospitalisations, with 92% of cases diagnosed with mental and behavioural disorders.[18] Interpretation is limited by the fact that recreational and medical cannabis product use was not separated.

When scheduling amendments were made to allow access to cannabis and other cannabinoids, a maximum upper limit for THC was not established. There is therefore no maximum THC concentration limit for medicinal cannabis products. The concentrations of THC found in unapproved medicinal cannabis products supplied in Australia can vary considerably and can be much higher (>35%) than the amount found naturally in a cannabis plant.

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[11] MacCallum CA, Lo LA, Boivin M. Is Medical cannabis safe for my patients? A practical review of cannabis safety considerations. European Journal of Internal Medicine. July 2021; V89: 10-18

[12] Thomas R Arkell, Danielle McCartney, Iain S McGregor Volume 50, Issue 6, June 2021 **Medical cannabis and driving** doi: 10.31128/AJGP-02-21-5840 www1.racgp.org.au/ajgp/2021/june/medical-cannabis-and-driving#:~:text=Smoking%20or%20vaporising%20cannabis%20produces,the%20amount%20of%20cannabis%20consumed

[13] Arnold JC, Nation T, McGregor IS. Prescribing medicinal cannabis. Aust Prescr 2020;43(5):152–59. doi: 10.18773/austprescr.2020.052

[14] Epidyolex Product Information https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent=&id=CP-2025-PI-01094-1&d=20250707172310101 (accessed 7 July 2025) www1.racgp.org.au/ajgp/2021/june/a-primer-on-medicinal-cannabis-safety-and-potentia

[15] Stuyt E. The Problem with the Current High Potency THC Marijuana from the Perspective of an Addiction Psychiatrist Mo Med. 2018 Nov-Dec;115(6):482–486.

[16] Chetty K, Lavoie A, Deghani P. A literature review of cannabis and myocardial infarction: What clinicians may not be aware of. CJC Open 2021;3(1):12–21. doi: 10.1016/j.cjco.2020.09.001.

[17] Marconi A, Di Forti M, Lewis CM, Murray RM, Vassos E. Meta-analysis of the association between the level of cannabis use and risk of psychosis. Schizophr Bull 2016;42(5):1262–69

[18] National Drug and Alcohol Research Centre (NDARC): University of New South Wales. Trends in drug-related-hospitalisations in Australia, 2019-20 2022. ndarc.med.unsw.edu.au/resource-analytics/trends-drug-related-hospitalisations-australia1999-2020#cannabinoid-overall-section

Examples of upper THC concentrations of different dose forms include:

- extracts up to 88% w/w THC
- herb dried up to 60% w/w THC
- inhalation products up to 880 mg/mL
- oral liquid up to 50 mg/mL

Consideration of access for vulnerable population groups

Research has indicated that exposure to cannabis in paediatric patients carries potential risks to the developing brain.[19] The TGA therefore expects practitioners to provide evidence from a paediatrician or other relevant medical specialist supporting the use of a medicinal cannabis product if the patient is under the age of 18 years. Although there is demonstrated benefit in using CBD products in children with specific medical conditions such as epilepsy, including the Registered product Epidyolex, there is limited evidence to support THC-containing medicinal cannabis products in this population group.

Medicinal cannabis use is not recommended for women who are pregnant, planning to become pregnant, or breastfeeding. This is largely based on the limited research and the unknown negative impacts of medicinal cannabis use during pregnancy. There is evidence that cannabis use can disrupt foetal brain development, is linked to lower birth weight and higher risk of preterm birth, and can negatively affect neonatal outcomes.[20]

Research also recommends avoiding the use of high THC-containing medicinal cannabis products in patients with angina or a history of myocardial infarction, or to those who have a personal or family history of schizophrenia or psychotic disorders.[21]

Existing regulatory powers

Under the Act, there are powers that underpin the SAS and AP scheme, allowing the TGA to impose conditions on SAS A authorisations, SAS B approvals and AP authorisations to support the safe use of therapeutic goods, including medicinal cannabis products. These conditions apply to the health practitioners to whom the approval or authorisation is given.

The Act also contains a range of criminal offences and civil penalties that address non-compliance, including in relation to the import and supply of therapeutic goods that do not comply with applicable standards, and the breach of conditions by sponsors or practitioners. There is also the option to not grant future SAS B and AP approvals where a product is found to be non-compliant.

However, there would be further benefits from a compliance perspective of products being on the ARTG, including the options of suspension or cancellation from the ARTG for non-compliant products, the imposition of a greater breadth of requirements or conditions imposed on sponsors of

[19] Stoner MJ, Dietrich A, Lam SH, Wall JJ, Sulton C, Rose E. Marijuana use in children: An update focusing on pediatric tetrahydrocannabinol and cannabidiol use. J Am Coll Emerg Physicians Open. 2022 Jul 5;3(4):e12770. doi:10/1002/emp2.12770

[20] figshare.unimelb.edu.au/articles/online_resource/Cannabis_Use_During_Pregnancy_Patterns_and_Potential_Impacts_on_Offspring_and_Maternal_Health_-_Summary_of_Literature/26087770?file=47246797

[21] Volume 50, Issue 6, June 2021 A primer on medicinal cannabis safety and potential adverse effects. Jonathon C Arnold doi: 10.31128/AJGP-02-21-5845 www1.racgp.org.au/ajgp/2021/june/a-primer-on-medicinal-cannabis-safety-and-potentia

goods, and the accurate identification of all goods with market approval in Australia at any point in time and the sponsor of those goods.

There is a strong desire to clarify and enhance enforcement of quality related issues. This would be facilitated by standardisation of labelling requirements to better enable safe prescribing and dispensing through the community, including to support product identification through the Australian Medical Terminology (AMT) coding system.

Legislation for unapproved goods mandates reporting of certain matters to the TGA. Adverse events or defects related to unapproved medicinal cannabis products must be reported to the TGA by health practitioners to assist with identifying potential safety issues. Sponsors and authorised prescribers must also provide reports to the TGA every 6 months on the number of products supplied and patients prescribed unapproved medicinal cannabis products. Limited regulatory powers make it is difficult for the TGA to take effective action on sponsors or prescribers when reporting obligations are not met.

Current challenges in Registering medicinal cannabis products on the ARTG

Medicinal cannabis medicines can be Registered on the ARTG through 2 regulatory pathways. The first is the prescription medicine pathway. Epidyolex and Sativex have been evaluated and approved under this framework. Alternatively oral, oral mucosal and sublingual low dose CBD-only preparations can be Registered on the ARTG as over the counter (OTC) products and can be supplied by a pharmacist without a prescription. To date there are no medicinal cannabis medicines Registered on the ARTG via this OTC pathway.

Medicinal cannabis devices can also be included on the ARTG after consideration or approval by the TGA. Four devices that can be used for medicinal cannabis have been approved for supply in Australia. Of note, none of the devices for medicinal cannabis included on the ARTG can be used for vaping of medicinal cannabis oils.

Several factors contribute to a lack of medicinal cannabis products transitioning to the ARTG. The first is that the SAS and AP scheme provide a pathway to supply products without the requirement to undergo a pre-market assessment process that incurs fees and charges, and requires sponsors to demonstrate evidence of safety, quality and efficacy or performance. Registration/inclusion on the ARTG also brings on-going post-market obligations. There is little incentive for companies to conduct expensive clinical trials for their product for the purpose of collecting such data to have their product Registered/Included on the ARTG.

Industry has also raised concerns about the absence of an ‘exclusivity’ provision for products that are able to be Registered/Included on the ARTG. As an example, a sponsor may go through the clinical trial and registration process and successfully have their product entered onto the ARTG. However, similar medicinal cannabis products may be able to be supplied under the SAS or AP scheme as unapproved goods with some slight variations. Based on this, consideration is needed on whether there should be removal or significant restrictions of access via the unapproved pathways for these products.

We are seeking your input to inform future regulatory reform

The TGA supports the need for regulatory change and the establishment of an appropriate legislative framework for medicinal cannabis products. We are seeking stakeholder input on key aspects to help our considerations.

Quality and safety requirements for medicinal cannabis products

Quality standards are in place for therapeutic goods to ensure they are safe, effective and of consistent quality. Such standards cover various aspects including the manufacturing standards, ingredient composition and labelling requirements.

Currently, unapproved medicinal cannabis medicines imported into and supplied or manufactured in Australia must conform with TGO 93. This standard covers all aspects of medicinal cannabis production, including the cannabis plant, ingredients and manufacturing processes. It sets out specific quality standards, including testing for various contaminants and ensuring the product meets the stated content of active ingredients.

TGO 93 does not contain information on the required quality standards for devices intended for use in delivering the medicinal cannabis substance which is a potential safety gap.

Stakeholders have recently reported concern over conflicting and inconsistent information on medicinal cannabis product labels, making product selection difficult and posing potential safety issues for patients. There is also inherent variability in the content of herbal preparations, which appears to be causing challenges in defining active ingredients and identifying the correct TGA categorisation for their medicinal cannabis products.

Questions

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

Emerging safety concerns for medicinal cannabis products

As previously outlined, there are growing concerns over the safety risks associated with use of medicinal cannabis products, particularly with respect to the use of ‘high concentration’ THC-containing products. There is currently no upper limit for THC concentrations for use in medicines. Further, there may be vulnerable population groups that are at risk from using certain medicinal cannabis products and dosage forms.

There are no safety requirements in place for unapproved devices used for medicinal cannabis, such as child-safe mechanisms or those to prevent accidental discharge of a vaping device. In addition, there have been an increase in cases of fires, explosions, and burns from the batteries of vaping devices.

A range of regulatory mitigations can be implemented to address safety risks with therapeutic goods, such as scheduling changes and labelling or product warnings. To help inform appropriate future regulatory options, we are seeking information on the safety risks that are relevant to medicinal cannabis products.

If safety issues are identified through this consultation, the TGA may need to take more immediate regulatory action to ensure product safety.

Questions:

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.

Dosage forms and routes of administration

Questions:

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

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

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.

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.

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.

Concentration of medicinal cannabis components

Questions:

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

Population groups

The TGA developed guidance in 2017 reflecting the research on medicinal cannabis products available at that time. While not intended to be a clinical guideline, the guidance documents provided advice and explanations about appropriate clinical use of medicinal cannabis products to support health practitioners at the time. This guidance material includes contraindications and suggested considerations to mitigate specific risks to vulnerable groups.

More recently, the TGA implemented requirements for accessing THC-containing products for patients under the age of 18 years. Due to limited research on the efficacy and safety of THC-containing medicinal cannabis products, the Australian Advisory Council on the Medicinal Use of Cannabis recommended that all SAS B and AP paediatric applications for products containing THC be submitted by a paediatrician or relevant medical specialists, or from a medical practitioner who can provide a letter of support from a relevant medical specialist.

Questions:

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.
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.
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.

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.
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.

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

Regulatory options will be developed using feedback from this consultation. To assist with this, we are seeking views on elements or principles that we may want to consider during the development of such options.

Key elements and principles could include:

- Transferring the responsibility of the regulatory and legal requirements to the sponsor of the product rather than the prescriber, as is the case currently under the SAS and AP scheme.
    - This approach sets clear and appropriate responsibilities in monitoring the safety, efficacy or performance of the product while it is marketed in Australia.
- Consideration of appropriate regulatory oversight of these products to ensure they meet appropriate quality standards and are safe.
- Developing a framework to incentivise sponsors to gather evidence to support safety and efficacy.
    - This approach could consider a transitional mechanism to allow continued access to medicinal cannabis products that are safe, while sponsors collect evidence to support full Registration of their product on the ARTG.
- Greater transparency of the level of regulatory oversight of these products for prescribers and consumers.
    - This approach could require warning statements advising of the level of assessment that has, or has not, been undertaken for that product.
- Additional scheduling amendments which could be prescriptive for a range of aspects to ensure safety.
- Changes to the SAS and AP scheme framework for access to medicinal cannabis products.

Questions

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.
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.

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

Version history

Version	Description of change	Author	Effective date
V1.0	Original consultation paper	International Regulatory Branch	August 2025

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Reference/Publication #