ACMS MEETING #49

18 March 2026

DISCUSSION PAPER

Findings from the consultation on the safety and regulatory oversight of unapproved medicinal cannabis products

Purpose

The purpose of this discussion is to provide an overview on the findings from the recent consultation – *Reviewing the Safety and Regulatory Oversight of Unapproved Medicinal Cannabis Products*.

Background

Current scheduling

Cannabis including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared are currently listed as a Controlled drug (Schedule 8) or Prohibited substance (Schedule 9) unless specifically captured by other entries in the Poisons Standard and with certain exceptions for hemp fibre or hemp seed oil (Attachment A).

Cannabidiol (CBD) in oral, oromucosal and sublingual preparations included in the Australian Register of Therapeutic Goods (ARTG) is listed as Pharmacist-only medicine (Schedule 3) subject to restrictions on CBD, tetrahydrocannabinol (THC) and other cannabinoid content (Attachment A). Additional restrictions on dosage, packaging and age also apply. CBD in preparations for therapeutic use or analytical and scientific research is a Prescription only (Schedule 4) medicine with restrictions on CBD and other cannabinoid content.

THC, the primary psychoactive compound in cannabis, and its alkyl homologues are listed in Schedule 9 or in Schedule 8 when extracted from cannabis for human therapeutic use (Attachment A).

All the 3 substances are included in clause 1, Appendix D (available for human use only from or on the prescription or order of an authorised medical practitioner) and Appendix K (Human medicines required to be labelled with a sedation warning). These entries also cross reference each other, other cannabinoids or specific extracts of *Cannabis sativa* plants (nabiximols) or specific synthetic cannabinoid preparations (dronabinol, nabilone; Attachment A).

Scheduling history

Cannabis was placed in the Poisons Standard in January 1955 as a drug of addiction “required by International Conventions to be subject to special measures of control” regarding manufacture and supply (then Schedule 8). Later, in November 1986, it was included in Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons as a prohibited substance. THC was included in Schedule 9 and CBD was captured under the entry for cannabis (cannabis, cannabis oil and cannabis resin and extracts or tinctures of cannabis). In May 1998, hemp seed oil and products for external use

when containing 50 mg/kg or less of THC were exempted from the Schedule 9 entry for THC. Since then, the scheduling of cannabis, cannabidiol (CBD) and THC have been considered on several occasions. The defining changes are described below with the detailed history available in Attachment B.

In 2015, cannabidiol (CBD) was listed in Schedule 4 in the Poisons Standard to allow access to medicinal cannabis products for specific clinical situations (epilepsy and seizure management in children, palliative care and symptoms of rare disease), where all other therapy options have been exhausted.

In 2016, further changes were made to improve access to medicinal cannabis products by creating Schedule 8 entries for cannabis and THC. The Schedule 9 entries for cannabis and THC were amended. The total cannabinoid and THC contents in hemp seed oil were considered, and a limit was set at 50 mg/kg and 20 mg/kg for it to be exempted from the cannabis and THC entries, respectively.

In 2018, the CBD Schedule 4 entry was amended for clarity on the minimum 98% CBD content in the preparations and the natural origin of any other cannabinoids present in the preparations. Scheduling changes were made again in 2021 to create a Pharmacist-only medicine (Schedule 3) entry for CBD to allow access to medicinal cannabis products without the need for a prescription. Additional restrictions were placed on dose (maximum recommended daily dose of 150 mg), supply (maximum 30 days), age (only for adults 18 years or over), form (either plant derived or only the negative enantiomer of CBD, if synthetic), packaging (blister or strip or container with a child-resistant closure) and advertising.

Registration status of medicinal cannabis products in Australia

There are only 2 medicinal cannabis medicines that have been Registered on the Australian Register of Therapeutic Goods (ARTG). Four medical devices have also been approved. All other medicinal cannabis products are ‘unapproved’ which makes up 99% of products currently prescribed to Australian patients. Unapproved medicinal cannabis can be accessed under the Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme when a practitioner considers there is a clinical need, and after all other suitable ARTG products have been considered or trialled. Unapproved goods are not evaluated by the TGA for quality, safety or efficacy.

Consultation – Review on the safety and regulatory oversight of unapproved medicinal cannabis

Purpose

Stakeholders have raised several concerns with the TGA about medicinal cannabis products including:

- the safety risks associated with unapproved medicinal cannabis products, particularly for products containing THC, noting there are large numbers of Australian patients accessing and using these products.
- appropriateness of regulatory oversight of unapproved medicinal cannabis products being accessed via the unapproved pathways, the SAS and AP scheme. These schemes are designed to provide access to experimental products often used in clinical trials or for medicines and medical devices not entered on the ARTG, for exceptional circumstances and at the discretion of a health practitioner.
- the growing number of ‘product-specific’ telehealth services prescribing unapproved medicinal cannabis products (and other medicines), through vertically integrated direct-to-consumer business models.

To address the first 2 issues which fall under TGA’s remit, a public consultation (Attachment C) was conducted to gather information from stakeholders on their experiences, observations and knowledge on the use of unapproved medicinal cannabis products. Other areas of the Department of Health, Disability and Ageing are considering issues concerning telehealth clinics.

The TGA committed to introducing mitigation steps if safety risks were identified through the consultation to minimise patient harm. Further, information from this consultation, is intended to inform any necessary regulatory reform options for medicinal cannabis products.

Consultation outcomes

The TGA received 790 submissions to the consultation from a range of stakeholders including consumers, industry, medical colleges, health professionals, advocacy groups, peak bodies, state and territory health departments and other government bodies.

We heard many concerns from the range of stakeholders including:

- need for greater enforcement of quality standards
- calls to strengthen packaging and labelling requirements
- safety concerns with certain dosage forms and routes of administration
- consideration of limits for THC concentrations
- safety of CBD and cannabinoids
- concerns over the use of medicinal cannabis products in certain at-risk population groups.

Many submissions to the consultation raised safety concerns around the concentration of THC accessed under the current access pathways, stating high potency THC products can increase the risks of developing psychosis and cannabis use disorder.

Feedback on what stakeholders consider to be a ‘safe’ upper limit of THC ranged significantly across the submissions from views that there is no ‘safe’ amount of THC, through to those who consider THC to be safe at any concentration. A large proportion of submissions also suggested ‘safe’ THC concentrations, which were also wide-ranging – from 10% to 100%.

Many stakeholders also raised safety risks across many of the dosage forms, but most concerns related to dried herb (used for smoking or vaping) and concentrated extracts (for vaping). Inhalation was the route of administration of greatest concern.

The consultation also sought views from stakeholders on what they considered were potential amendments that could be made via scheduling for cannabis and its cannabinoids that could address safety concerns. From the consultation submissions:

- some stakeholders called for consideration to be given to down-scheduling CBD due to it being generally well tolerated although there was recognition of its potential for contraindications and interactions.
- there were suggestions for other cannabinoids (e.g. CBN (cannabinol), CBG (cannabigerol) and THCV (tetrahydrocannabivarin) to have their own entry in the Poisons Standard.
- submissions called for limits on THC content, recognising that the limit may vary depending on the dosage form.
- some stakeholders suggested introducing restrictions to specialists-only prescribing for certain at-risk population groups, and for high THC containing products.

Next steps in consultation process

The TGA continues to analyse and consider much needed and supported longer term regulatory reforms. Some short- and medium-term actions have been identified to reduce any potential harms to patients.

The TGA will undertake a range of communication activities to raise awareness with consumers and patients about the unapproved status of most medicinal cannabis products and to highlight that these products have not been assessed for safety, quality and efficacy.

Prescribers will also be reminded of their responsibilities and obligations when prescribing unapproved goods, including medicinal cannabis products.

The TGA is currently preparing a safety assessment report, which will include:

- a summary of all adverse event reports received by the TGA for unapproved medicinal cannabis products
- a targeted review of the published medical literature
- a comparison with comparable overseas jurisdictions and contrast with approved medicinal cannabis products included in the ARTG.

Due to the status of nearly all medicinal cannabis products as unapproved therapeutic goods, there will be inherent limitations to the report due to the lack of baseline clinical data concerning efficacy and safety for unapproved products. This will preclude establishing a full safety profile for specific products, a risk-benefit analysis and consideration of regulatory options as would be standard for a safety signal investigation process.

Further, there are limitations to adverse event reports made to the TGA, and under-reporting represents an additional known limitation. To date a safety signal has not been flagged for any unapproved medicinal cannabis product as part of routine analysis of adverse event reports, and the safety assessment report is distinct to a signal investigation typically undertaken by the TGA.

However, this report will complement the public consultation and reform work underway and may be used to inform other reform options.

The options may include a review of the current scheduling of cannabis, CBD and THC to consider whether they are still appropriate.

Attachments

Attachment A: Current scheduling of cannabis, cannabidiol and tetrahydrocannabinol

Attachment B: Scheduling history of cannabis, cannabidiol and tetrahydrocannabinol

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

Attachment A: Scheduling of cannabis, cannabidiol and tetrahydrocannabinol

CANNABIS

Schedule 9

CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except:**

a) when separately specified in these Schedules; or
b) processed hemp fibre containing 0.1% or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or
c) hemp seed oil containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

Schedule 8

CANNABIS (including seeds, extracts, resins and the plant, and any part of the plant) when prepared or packed for human therapeutic use, when:

a) cultivated or produced, or in products manufactured, in accordance with the *Narcotic Drugs Act 1967*; and/or
b) for use in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
c) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or
d) in therapeutic goods supplied in accordance with the Act;

except:

e) when it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the Therapeutic *Goods Regulations 1990*[1] applies; or
f) when separately specified in the NABIXIMOLS entry in this Schedule; or
g) when captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or

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[1] Schedule 5A applies to therapeutic goods exempt from operation of Parts 3-2 (registered and listed therapeutic goods) and 3-2A (biologicals) of the *Therapeutic Goods Act, 1989* subject to conditions. Item 4, 8, 10, 11 or 12 applies to therapeutic goods imported into Australia by differnt groups of persons (see below). Additional restrictions apply.

- Item 4 applies to therapeutic goods that are imported by a member of a group of persons visiting Australia to participate in a national or an international sporting event and the good is for the treatment of a member or members of that group
- Item 8 applies to therapeutic goods imported by a member of a group of persons who are members of the military forces of another country, visiting Australia for military training and the good is for the treatment of a member or members of the visiting group
- Item 10 applies to therapeutic goods imported into Australia by a medical practitioner or a member of a medical team accompanying a person to Australia who has a critical illness and is under the direct care and supervision of the practitioner or team and the good is for the treatment of the person who has the critical illness
- Item 11 applies to therapeutic goods imported into Australia by a member of a group of persons that must include a person who is the Head of State or Head of Government of a foreign country and senior Government officials of that country, who are visiting Australia on official business and the good is for use in the treatment of a member or members of the visiting group.
- Item 12 applies to therapeutic goods that are part of the medical supplies of a ship (including a yacht or other marine vessel) or aircraft visiting Australia and the good is for the treatment of a passenger or a member of the crew travelling on the ship or aircraft

h) hemp seed oil[2] containing 75 mg/kg or less of cannabidiol and 10 mg/kg or less of tetrahydrocannabinols.

Appendix D, clause 1 (Poisons available for human use only from or on the prescription or order of an authorised medical practitioner)

CANNABIS for human use

Appendix K, clause 1 (Human medicines required to be labelled with a sedation warning)

CANNABIS **except** cannabidiol when included in Schedule 3 or 4

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cross reference: CANNABIS SATIVA, HEMP, HEMP SEED OIL, TETRAHYDROCANNABINOLS

Schedule 9
Schedule 8
Appendix D, clause 1
Appendix K, clause 1

CANNABIDIOL

Schedule 4

CANNABIDIOL in preparations for therapeutic use or analytical and scientific research where:

a) cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and
b) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation;

except when:

c) included in Schedule 3; or
d) in hemp seed oil at a concentration of 75 mg/kg or less.

Schedule 3

CANNABIDIOL in oral, oromucosal and sublingual preparations included in the Register when:

a) the cannabidiol is either plant derived or, when synthetic, only contains the (-)-CBD enantiomer; and
b) the cannabidiol comprises 98% or more of the total cannabinoid content of the preparation; and
c) any cannabinoids, other than cannabidiol, must be only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the preparation and of which tetrahydrocannabinol (THC) can only comprise 1% of the total cannabinoid content; and
d) the maximum recommended daily dose is 150 mg or less of cannabidiol; and

[2] **Hemp seed oil** means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.

e) packed in blister or strip packaging or in a container fitted with a child-resistant closure; and
f) in packs containing not more than 30 days' supply; and
g) for persons aged 18 years and over.

Appendix F, clause 4 (Poisons that must be labelled with warning statements and safety directions)

CANNABIDIOL when included in Schedule 3

Do not use if pregnant or likely to become pregnant.

Do not use if breastfeeding or planning to breastfeed.

Index

CANNABIDIOL

cross reference: NABIXIMOLS, CANNABIS, TETRAHYDROCANNABINOLS

Schedule 4

Schedule 3

Appendix F, clause 4

TETRAHYDROCANNABINOLS

Schedule 8

TETRAHYDROCANNABINOLS when extracted from cannabis for human therapeutic use, when:

a) included in products manufactured in accordance with the *Narcotic Drugs Act 1967*; and/or
b) imported as therapeutic goods, or for use in therapeutic goods, for supply, in accordance with the Act; and/or
c) in therapeutic goods supplied in accordance with the Act;

except when:

d) it is in a product to which item 4, 8, 10, 11 or 12 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies; or
e) separately specified in the NABIXIMOLS entry in this Schedule; or
f) captured by the CANNABIDIOL entry in Schedule 4 or Schedule 3; or
g) in hemp seed oil at a concentration of 10 mg/kg or less.

Schedule 9

TETRAHYDROCANNABINOLS and their alkyl homologues, **except**:

a) when included in Schedule 4 or Schedule 8; or
b) processed hemp fibre containing 0.1% or less of tetrahydrocannabinols, and hemp fibre products manufactured from such fibre; or
c) in hemp seed oil at a concentration of 10 mg/kg or less.

Appendix D, clause 1 (Human medicines required to be labelled with a sedation warning)

TETRAHYDROCANNABINOLS for human use

Appendix K, clause 1 (Human medicines required to be labelled with a sedation warning)

TETRAHYDROCANNABINOLS except cannabidiol when included in Schedule 3 or 4

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TETRAHYDROCANNABINOLS

Cross reference: CANNABIS, HEMP SEED OIL, NABIXIMOLS

Schedule 9

Schedule 8

Appendix D, clause 1

Appendix K, clause 1

Other relevant entries[3]

NABIXIMOLS

Schedule 8

NABIXIMOLS (botanical extract of Cannabis sativa which includes the following cannabinoids: tetrahydrocannabinols, cannabidiol, cannabinol, cannabigerol, cannabichromene, cannabidiolic acid, tetrahydrocannabinolic acids, tetrahydrocannabivarol, and cannabidivarol, where tetrahydrocannabinols and cannabidiol (in approximately equal proportions) comprise not less than 90% of the total cannabinoid content) in a buccal spray for human therapeutic use.

DRONABINOL

Schedule 8

DRONABINOL (delta-9-tetrahydrocannabinol) when prepared and packed for therapeutic use.

NABILONE

Schedule 8

NABILONE.

[3] CANNABICHROMENE, CANNABIDIOLIC ACID, CANNABIDIVAROL, CANNABINOIDS, CANNABINOL, HEMP SEED OIL and TETRAHYDROCANNABIDIVAROL are not listed separately, but cross refer NABIXIMOLS, TETRAHYDROCANNABINOLS, CANNABIS.

Attachment B: Scheduling history of cannabis, cannabidiol and tetrahydrocannabinol

Cannabis was placed in the Poisons Standard in January 1955 as a drug of addiction "required by International Conventions to be subject to special measures of control" regarding manufacture and supply (then Schedule 8). Later, in November 1986, it was included in Schedule 9 of the Standard for the Uniform Scheduling of Drugs and Poisons as a prohibited substance. THC was included in Schedule 9 and cannabidiol (CBD) was captured under the entry for cannabis (CANNABIS, CANNABIS OIL AND CANNABIS RESIN AND EXTRACTS OR TINCTURES OF CANNABIS). In May 1998, hemp seed oil and products for external use when containing 50 mg/kg or less of THC were exempted from the Schedule 9 entry for THC.

In February 2009, the scheduling of THC and CBD were considered in relation to access to a medicine, Sativex containing both THC and CBD. An exemption and corresponding Schedule 8 entry specific to the formulation were proposed to allow access to Sativex while prohibiting any inappropriate access to cannabis-type substances. Subsequently, a Schedule 8 entry was created for NABIXIMOL (an approved non-proprietary name for a specific extract of *C. sativa* similar to Sativex) in buccal spray for human therapeutic use.

In November 2014, the Advisory Committee of Medicines Scheduling (ACMS) considered the scheduling of CBD and for specific clinical situations (epilepsy and seizure management in children, palliative care and symptoms of rare disease), where all other therapy options have been exhausted. The ACMS recommended that therapeutic use of CBD, including extracts of *C. sativa*, and including preparations of up to 2% of cannabinoids be listed as Prescription only (Schedule 4) medicine. The reasons included:

- the conditions that CBD treats (the therapeutic use) require diagnosis, management and monitoring under an appropriate medical practitioner.
- CBD has a safety profile which is consistent with a Schedule 4 listing.
- there is low risk of misuse or abuse as cannabidiol does not possess psychoactive properties.

The recommendations were adopted and a new entry was created for CBD.

In March 2016, the ACMS considered a proposal to amend the Poisons Standard to enable appropriate access to medicinal cannabis products by creating Schedule 8 entries for cannabis (plant and flowering tops), cannabis extracts and THC where they are botanically derived from cannabis. Noting the increasing use of cannabis and its extracts, some evidence for some treatment resistant conditions and need for easier access under Schedule 8, new Schedule 8 entries were created for cannabis and THC provided:

a) the substances are grown, manufactured or imported in adherence to the *Narcotic Drugs Act 1967* and/or the *Customs (Prohibited Imports) Regulations 1956*

b) any supply and import of products containing these substances comply with the *Therapeutic Goods Act 1989* and *the Therapeutic Goods Regulations 1990* i.e. products must be listed on the ARTG or have exemption or approval to be legally supplied in Australia.

In November 2016, the appropriateness of the 50 mg/kg limit on total cannabinoids or THC content in hemp seed oil for exemption from the cannabis and THC entries was considered. The limits were amended to a maximum 20 mg/kg of THC and 50 mg/kg of total cannabinoids for hemp seed oil to be exempted from these two entries. The reasons were:

- lower cut-off for THC (5-20 mg/kg) imposed by international jurisdictions on hemp seed oil for food use
- low risk associated with 50 mg/kg of total cannabinoids permitted under the exemption, and further reducing in the toxicity with the lower THC level.
- no evidence of misuse or abuse of the products containing low concentrations of THC or cannabinoids further reduced by limiting the THC content
- Office of Drug control considered products having more than 50 mg/kg total cannabinoids as drugs and would possibly breach Australia's obligations under the Single Convention on Narcotic Drugs 1961 should such products be available.

In 2018, the Schedule 4 entry for CBD was further amended to clarify that CBD must constitute 98% or more of total cannabinoid content of the preparations and any cannabinoids, other than CBD, and must be only those naturally found in cannabis and comprise 2% or less of total cannabinoid content of the preparation. A proposal to further amend the Schedule 4 entry for CBD to require other cannabinoids comprise no more than 1% w/v of the product (rather than 2% of less of other cannabinoids) was rejected. This was based on the possibility of inadvertent down scheduling of certain THC preparations from Schedule 8 to Schedule 4 while the intention behind creating a Schedule 4 entry for CBD was to facilitate scientific investigation without enabling supply of psychotropic cannabinoids. The reference to 2% of other cannabinoids was to allow for unavoidable impurities in the raw material.

In April 2020, a proposal to exempt whole plant cannabis products or distillates or isolates containing at least 98% CBD and up to 0.2% THC from the Schedule 4 cannabis entry was considered. The proposal also sought to amend the Schedule 4 entry for CBD to include synthetic or semi-synthetic CBD and exempt preparations containing up to 0.2% THC. The intention was to regulate such formulations as listed, assessed-listed or registered medicines. The Delegate also initiated a proposal to create a Pharmacist only (Schedule 3) entry for CBD for preparations containing plant derived or synthetic CBD (minus enantiomer only) with restrictions on dose, pack size, and age. Both the proposals were referred to the Joint ACMS-ACCS and in September 2020, based on the committee advice and an external evaluation report, the Delegate made an interim decision:

- not to amend the current Poisons Standard to exclude CBD from scheduling and allow its general sale
- to create a Schedule 3 entry in accordance with specified requirements with additional supply requirements specified in Appendix M to allow it to be provided by a pharmacist.

The external evaluation report found that whilst CBD has low toxicity, adverse events and drug interactions are possible. The committee unanimously agreed that CBD did not meet the criteria for ‘reasonable safety’ as defined in the Scheduling Policy Handbook. Due to uncertainty of adverse effects, the effects of longer-term use and the potential for drug interactions, the Delegate considered that risks cannot be managed with packaging and labelling in the absence of pharmacist advice, and CBD was not exempted from scheduling as proposed.

The Committee and the evaluation report raised concern over the difficulty in assessing risks and benefits of over-the-counter (OTC) use in the absence of a registered product or a specific indication and paucity of evidence of efficacy for many of the indications for which there is public demand. The Delegate considered that an Appendix M entry would ensure that only products approved for a specific indication appropriate under a Schedule 3 listing would be available without a prescription.

Based on findings from the external review the maximum recommended daily dose (RDD) was restricted to 60 mg/day, supply was restricted to 30-days and only for adults 18 years and over. An Appendix F warning was included to manage risks from CBD during pregnancy and lactation and child-resistance packaging was included to manage risks, especially to children from liquid preparations.

The Delegate further referred the scheduling matter to a Joint ACMS-ACCS meeting in November 2020 seeking specific feedback on the Appendix M entry, dose restrictions, age restrictions, advertising restrictions, restrictions on synthetic form (-)-CBD and reference to analytical trials.

Based on recommendations and advice from the Committee, the Delegate finally decided to incorporate the requirement for preparations to be included in the ARTG into the Schedule 3 entry, rather than Appendix M. This was to ensure consistency across Australia as Appendix M was not adopted by all states and territories and would require new regulations to incorporate the requirements of Appendix M or adopt Appendix M by reference.

The maximum RDD was revised from 60 mg/day to 150 mg/day in view of existing evidence of safety at the higher dose, the 60 mg/day dose being potentially sub-therapeutic and the lower average body weight used in safety calculations (60 kg vs 72-87 kg for Australian adults).

Limiting synthetic CBD to the (-)-CBD enantiomer was maintained as the evidence supporting the scheduling of CBD pertained to cannabis-based products containing (-)-CBD and there was limited evidence for (+)-CBD contained in synthetically derived products.

The Delegate also decided to limit THC to 1% of total cannabinoids to keep it well below intoxicating limits and included reference to 'analytical and scientific research' to prevent bench top research and laboratory analysis from being inadvertently captured in Schedule 9.

Advertising restrictions and age restrictions were also maintained, and the decision was implemented on 1 February 2021.

Later, in October 2021, Schedule 9 entries for cannabis and THC were again amended to exempt hemp seed oils allowed in foods in Australia from scheduling, when for oral use. This was in line with the changes to the Food Standards Code and imported goods legislations. Sale of low THC hemp foods, including hemp seed oil, was allowed by Food Standards Australia and New Zealand in 2017. This was based on a safety assessment that deemed the oral consumption of hemp seed foods safe for human consumption when they contain no more than 10mg/kg total THC, including its acid precursor delta 9-tetrahydrocannabinolic acid. While a CBD limit in hemp seed oil was not deemed to be necessary to protect public health and safety, a maximum limit of 75 mg/kg was set to ensure enforceability. The *Customs (Prohibited Imports) Regulations* 1956 were also updated in 2018 to support the Food Standards Code amendments.

Since then, two subsequent proposals to amend the scheduling to allow cannabis and THC for animal medicines and to create a Schedule 7 entry for cannabis and THC for use in analytical and scientific research have been rejected.

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.

Contents

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

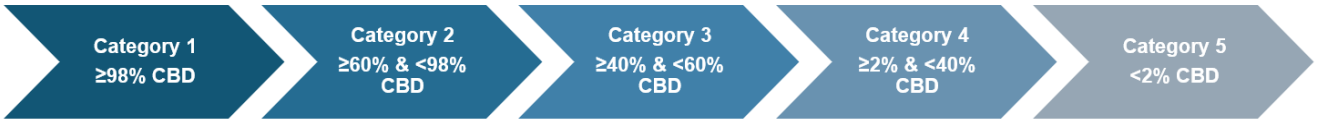
to access certain CBD products without the requirement for a prescription. To date, no complete application for a CBD product that meets the Schedule 3 registration requirements has been submitted or evaluated by the TGA.

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.

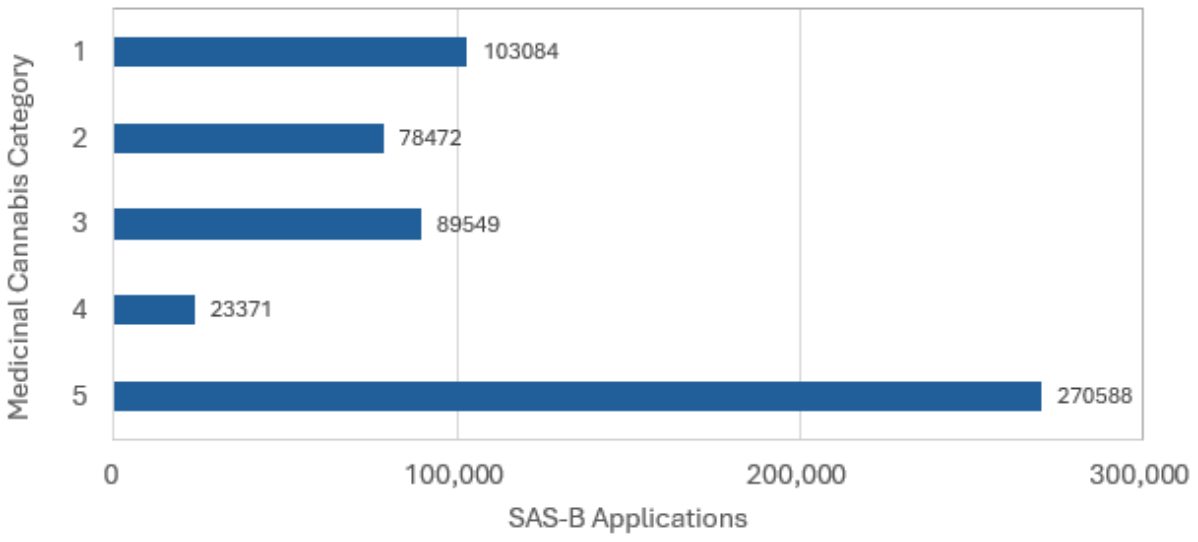
To date, only 2 medicinal cannabis medicines have been Registered on the ARTG - Epidyolex (CBD) to treat certain epileptic conditions, and Sativex (nabiximols) to treat certain symptoms associated with multiple sclerosis. Four devices have been approved for supply for use with medicinal cannabis. All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



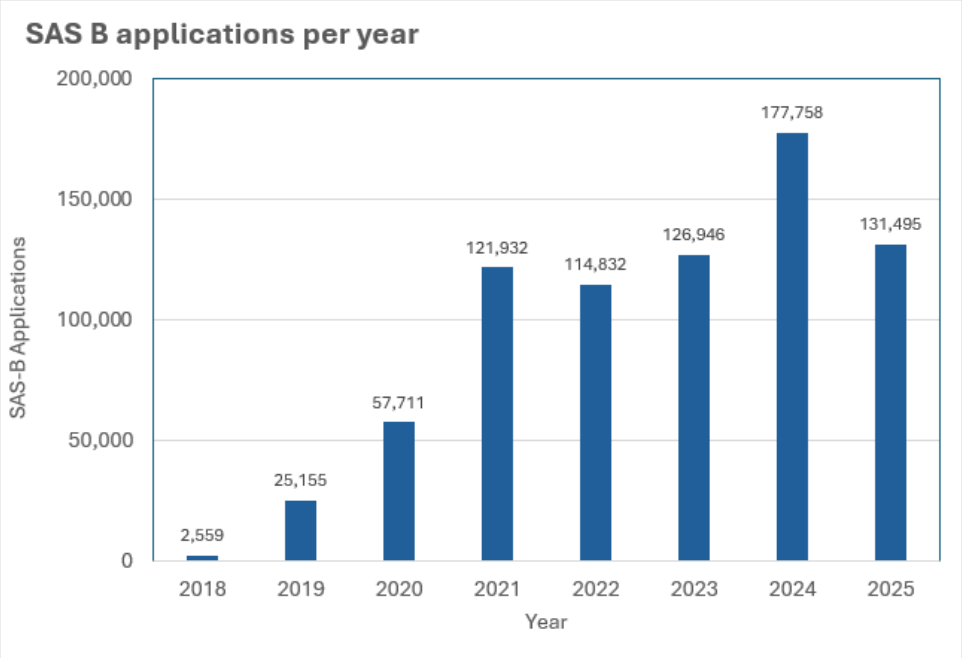
As illustrated in Figure 1 below, as at 31 July 2025, the most commonly accessed medicinal cannabis products fell within Category 5, which represents nearly half of all applications.

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

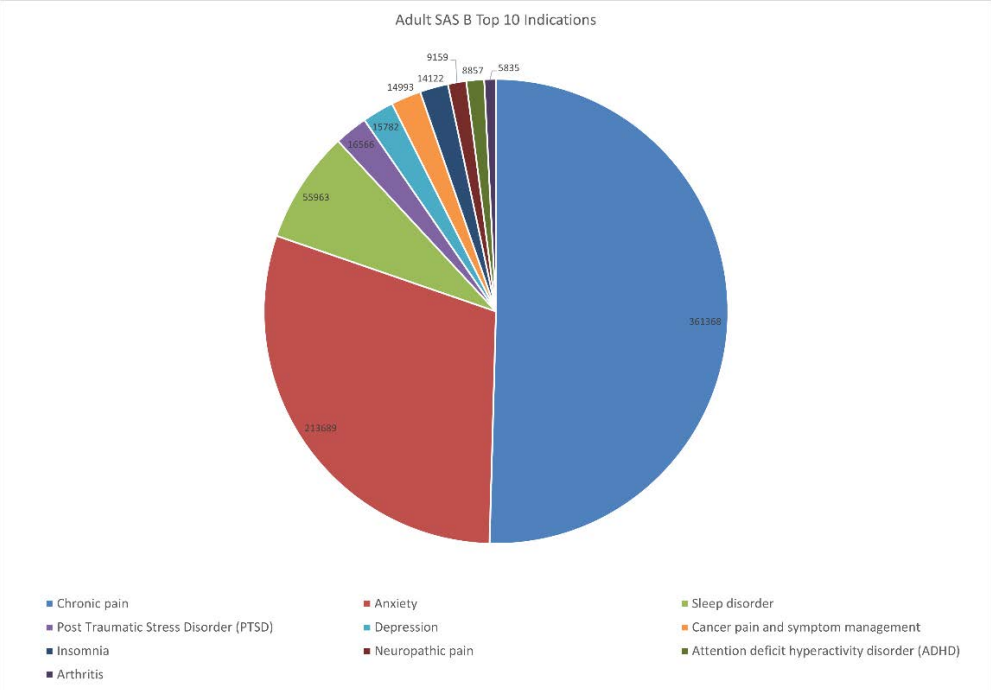
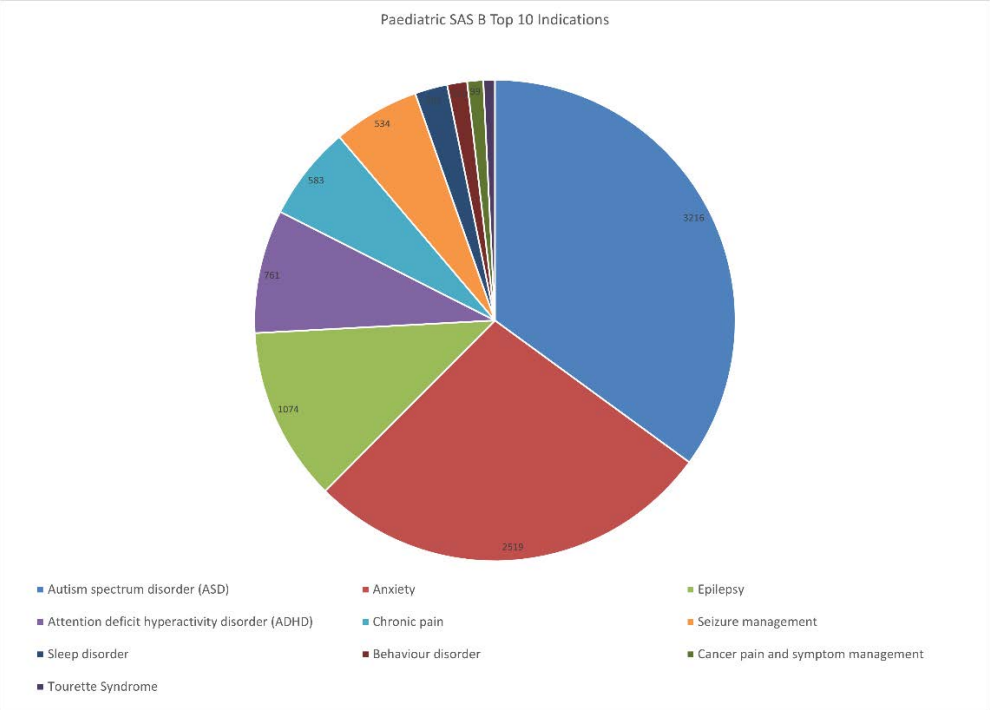


Figure 4 - Most common indications for medicinal cannabis prescribed for in children



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

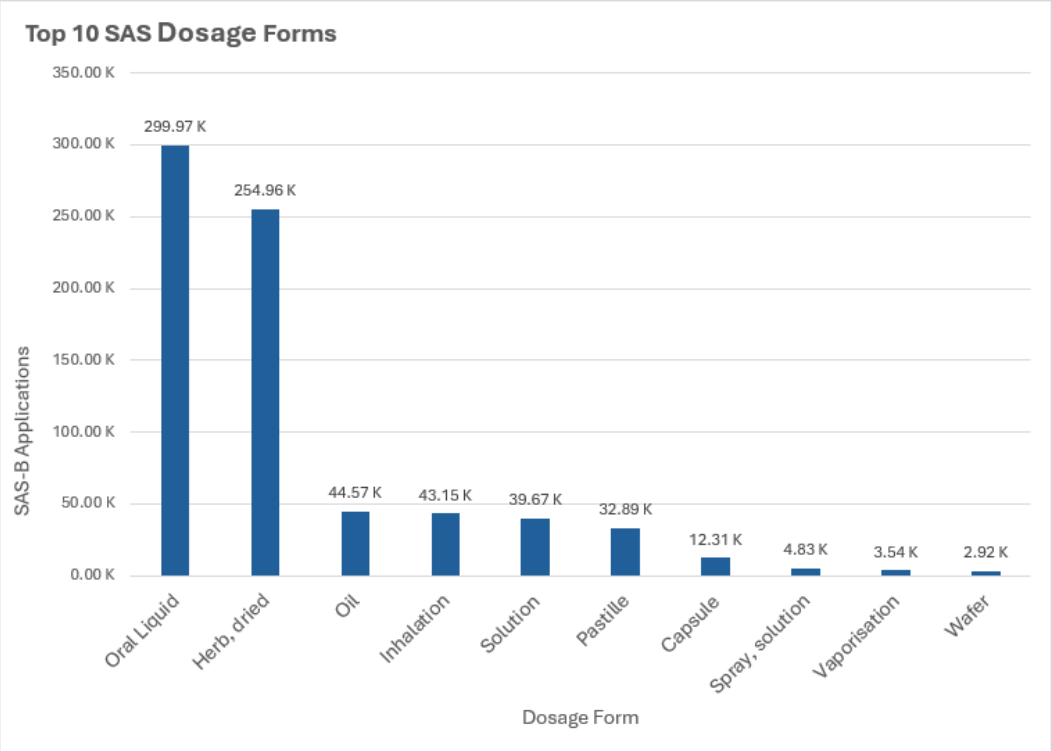
[3] www.cdc.gov/cannabis/health-effects/lung-health.html Accessed 20 January 2025.

[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

Therapeutic Goods Administration

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Reference/Publication #

Medicinal Cannabis Regulatory Reforms

Consultation Findings & Next Steps

s22
Director
Medicinal Cannabis Regulatory Reforms Section

Review of unapproved medicinal cannabis products

Why did we consult?

Multiple stakeholders raised concerns about:

1. **Safety risks with THC-containing unapproved medicinal cannabis products**
2. **Large number of patients prescribed medicinal cannabis via the unapproved therapeutic goods pathways (SAS and AP scheme)**
3. Growing 'product specific' telehealth and direct-to-consumer businesses prescribing through vertically integrated business models.

TGA is addressing the **first 2 issues**

Submissions Received

Gathered input on knowledge, experiences and observations on unapproved medicinal cannabis products in Australia

Stakeholders	Submissions
Consumers/patients	606
Healthcare professionals	74
Industry/Sponsors	61
Peak body organisations	12
Academics	12
Advocacy groups	11
Commonwealth and/or state and territory departments	9
Medical Colleges	5
Total	**790**

What we heard…

Unapproved status of medicinal cannabis products

- Consumers/patients are unaware that most medicinal cannabis products are **unapproved** and **not assessed** by the TGA for quality, safety or efficacy.

- Access pathways via SAS/AP are no longer fit for purpose.
  - product volume
  - insufficient oversight
  - intent of these access mechanisms not appropriate for medicinal cannabis products.

What we heard…

Safety

THC concentration limits

- Some did not support setting an upper limit for THC, as ‘safe’ concentrations vary depending on patient group, clinical situation and dosage form.
- Other stakeholders proposed varying ‘safe’ upper limits for THC concentrations.
- Many submissions noted that high potency THC products can increase risks of developing psychosis and cannabis use disorder.

CBD and other cannabinoids

- Most stakeholders consider CBD to be well tolerated although some submissions highlighted the potential for contraindications and interactions.
- Although CBD was viewed as having a more favourable safety profile compared to THC, stakeholders emphasised the limited availability of high-quality safety and efficacy data.
- Many also noted the current lack of evidence for the use of other cannabinoids.

What we heard…

Safety concerns with certain dosage forms/routes of administration

- Stakeholders raised safety risks across all dosage forms, but most concerns related to dried herb (smoking/vaping) and concentrated extracts (for vaping).
- Many highlighted accidental ingestion risk by children of pastilles/gummies due to similar appearance to confectionary and snack food.
- Safety concerns were raised with inhalation (vaping and smoking) of medicinal cannabis as a route of administration.

What we heard

Product quality and labelling

Greater enforcement of quality standards & labelling requirements:

- Strong support from stakeholders to medicinal cannabis products where the quality has been assured.
- Strong support from industry for consistent application and enforcement of quality standards for both domestic and imported products.
- Calls to establish device-specific quality standards.
- Stakeholders would like to introduce:
  - plain packaging
  - standardisation of THC/CBD descriptors
  - mandatory warning statements
  - transparency of registration status,
  - Product information documents
  - child-resistant closures
  - restrictions to inappropriate brand names.

What we heard…

At risk population groups

Paediatric patients

- Strong support for restricting access to THC-containing products, particularly those for inhalation.
- Support for specialist oversight, with calls to consider increasing the age limit from 18 to 25 years due to brain development.

Use in pregnancy or breastfeeding

- Calls to prohibit or restrict access to medicinal cannabis products for those who are pregnant or breastfeeding due to lack of safety evidence.

Other at-risk groups

- Strong caution was recommended for use in patients with a history of mental health conditions, addiction/substance use disorder, cardiovascular issues, the elderly or cognitive impairment.

What we heard…

Scheduling:

CBD and other cannabinoids

- Some calls for consideration to down-schedule CBD.
- Suggestions for other cannabinoids to have their own entry in the Poisons Standard e.g. CBN (cannabinol), CBG (cannabigerol) and THCV (tetrahydrocannabivarin).

THC

- Strong calls to include limits on THC potency, recognising there are differences based on dosage forms.
- Introduction of restrictions to specialists-only prescribing for certain patient population groups and for high THC concentration products.

What we heard…

Transition to the Australian Register of Therapeutic Goods (ARTG)

Strong support for regulatory reform

- Wide calls for changes to the regulatory framework for medicinal cannabis products.

Transitional mechanism

- General support for a transitional mechanism to allow evidence to be gathered.
- Varying views on length of time needed (6 months to 5+ years).
- Those who were not supportive raised concerns about continuity of access to medicinal cannabis products if SAS/AP pathways closed or restricted.

Evidence requirements

- Calls to consider adapting efficacy data requirements for medicinal cannabis i.e. increased weighting of evidence provided through traditional use, real world evidence etc.
- Some raised concerns about cost impacts on industry to conduct clinical trials noting there is a lack of exclusivity/IP protection.

Regulatory principles identified through the consultation:

The Special Access Scheme (SAS) and Authorised Prescriber (AP) schemes:

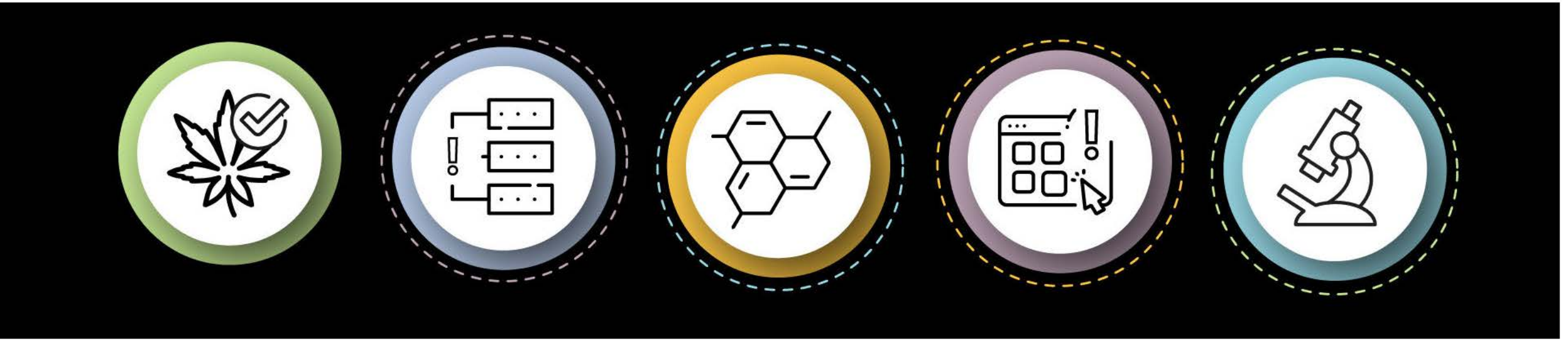
- Are no longer fit for purpose.
- The current regulatory framework is not proportionate to the risks posed by products.

Effective legislative powers are needed to take regulatory action and ensure compliance, while maintaining access:

- Consumers/patients cautioned against over regulation, leading to accessing illicit cannabis.
- Significant support for regulatory obligations to be the responsibility of product sponsors.
- Many want to establish a national registry within Australia for medicinal cannabis.
- Strong support for pharmacovigilance frameworks to be established for medicinal cannabis with close monitoring of adverse events.
- Alignment with, or take ‘lessons learned’ from, international medicinal cannabis frameworks.

Next Steps

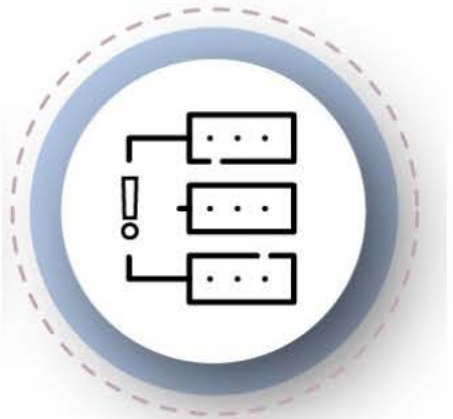
While we continue to analyse and consider much needed and supported longer term regulatory reforms, we have identified actions to be undertaken in the short to medium term to reduce potential harm to patients.



Short term - Public Awareness

Communications activities to raise awareness

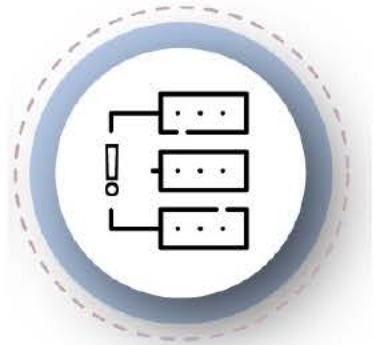
- Increase awareness of the lack of regulatory assessment of unapproved products.
- Raise awareness with patients as well as prescribers that the TGA does not assess the safety, quality or efficacy of unapproved medicines, including medicinal cannabis.



Medium term - Risk mitigation

Consider Current Scheduling Arrangements

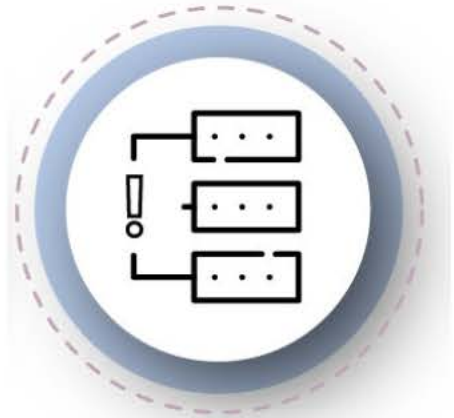
- Scheduling decisions involve a risk-benefit consideration to set controls over the availability of a substance to protect public health and safety.
- Consider initiating a review of current entries in the Poisons Standard for cannabis, CBD and THC in recognition of potential safety risks, particularly in relation to acute psychosis, to determine if the entries are still appropriate.



Long term - Regulatory reform

Regulatory reform options

- Regulatory reform options to be co-developed with stakeholders to ensure there is appropriate oversight.
- Recommendations from this work will then be considered by Government.



Questions?

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