The Pharmacy Guild of Australia

SUBMISSION

Reviewing the Safety and Regulatory Oversight of Unapproved Medicinal Cannabis Products

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ABOUT THE GUILD

The Pharmacy Guild of Australia (the Guild) is the national peak organisation representing community pharmacy. It supports community pharmacy in its role of delivering quality health outcomes for all Australians. It strives to promote, maintain, and support community pharmacies as the appropriate providers of primary healthcare to the community through optimum therapeutic use of medicines, medicines management and related services. Community pharmacies are the most frequently accessed and most accessible health destination, with over 443 million individual patient visits annually and many pharmacies open after-hours, including on weekends.

Owned by pharmacists, community pharmacies exist in well-distributed and accessible locations, and often operate over extended hours, seven days a week in urban, regional, rural and remote areas. They provide timely, convenient, and affordable access to the quality and safe provision of medicines and healthcare services by pharmacists who are highly skilled and qualified health professionals. In capital cities, 96% of people have access to at least one pharmacy within a 2.5km radius, while in the rest of Australia 74% of people are within 2.5km of a pharmacy.

The Pharmacy Guild of Australia (Guild) welcomes the opportunity to respond to the TGA's consultation. This response seeks to strengthen regulatory oversight of medicinal cannabis products and facilitate the listing of evidence-based products on the Australian Register of Therapeutic Goods (ARTG). It addresses patient and product safety, unlawful promotion, patient choice, and supply chain issues to ensure appropriate use and access for patients with a legitimate therapeutic need.

There is an urgent need for regulatory reform of medicinal cannabis to address issues that have become engrained due to an ineffective regulatory framework, and to ensure quality, safety, efficacy and appropriate clinical governance into the future. The Guild recommends introducing tighter clinical governance, restricting telehealth prescribing, mandating e-prescriptions, regulating clinics, enforcing advertising standards, prohibiting closed-loop supply chains, facilitating ARTG registration, and ensuring coordinated regulatory action.

GUILD RESPONSE TO CONSULTATION

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

No, the existing quality and safety requirements are not adequate. Of concern to the Guild is the low evidence base for the use of medicinal cannabis products for many of the conditions for which it is being prescribed, and the potential harm to patients due to a lack of regulatory requirements to assess the safety of unapproved medicinal cannabis products.

The current Therapeutic Goods Order No. 93 (TGO93) for quality requirements for medicinal cannabis also falls short, particularly in relation to packaging and labelling standards. There have been reports of unregistered medicinal cannabis products being marketed with party-related names, eye-catching packaging and music and food pairings that are inconsistent with the presentation of legitimate therapeutic goods. To ensure these products are treated as serious health interventions, a stricter approach should be adopted - similar to the plain packaging regulations applied to tobacco products. This would mean removing promotional imagery and branding and ensuring that product names and packaging reflect their intended therapeutic use.

Question 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.

Yes, all medicinal cannabis products should be required to be listed on the Australian Register of Therapeutic Goods (ARTG). This would align them with the regulatory standards applied to other therapeutic goods, ensuring rigorous assessment of safety, quality, and efficacy. ARTG registration would also provide healthcare professionals and consumers with greater confidence in the legitimacy and reliability of these products, with the TGA having the ability to undertake comprehensive compliance and pharmacovigilance activities as part of the regulatory framework.

Manufacturers must be required to comply with Good Manufacturing Practice (GMP) standards, and every batch should undergo independent laboratory testing. This is essential to verify cannabinoid content, detect contaminants (e.g., pesticides, heavy metals, microbial impurities), and ensure batch-to-batch consistency.

Importantly, products manufactured from the cannabis plants are likely to have trace amounts of tetrahydrocannabinol (THC) present—even in products marketed as "CBD-only".[i] Manufacturers do not dispute this, yet patients are rarely informed. For individuals with zero tolerance for THC—due to medical, legal, or occupational reasons—this lack of transparency poses a significant risk. Clear labelling and patient education must accompany testing protocols to ensure informed decision-making and safe use.

Further, a robust pharmacovigilance system should be implemented to monitor real-world safety and efficacy. This includes mandatory adverse event reporting, active surveillance programs, and transparent data sharing. Enhanced post-market oversight would allow for early identification of safety signals, inform regulatory decisions, and contribute to continuous improvement in product quality.

Together, these reforms would better support pharmacists in their clinical role, improve therapeutic outcomes for patients, and ensure safe, equitable access to medicinal cannabis for Australians with a legitimate therapeutic need.

Question 3. Noting the current labelling requirements outlined in TGO 93, do you consider these to be adequate to allow prescribers and consumers

sufficient information to properly identify the goods and know how to use and store them safely? If not, please describe which changes are required.

No, the current labelling framework for medicinal cannabis products is inadequate and poses significant challenges for safe and effective prescribing and dispensing. Some products feature excessively long names - up to 200 characters - which hampers clear identification and complicates tracking through Real-Time Prescription Monitoring (RTPM) systems. To address this, product names should be standardised to ensure consistency, readability, and seamless integration with digital health platforms.

In addition, many labels lack essential information regarding cannabinoid composition, dosage instructions, and regulatory classification. This lack of clarity creates confusion among prescribers, pharmacists, and patients, potentially leading to inappropriate use or errors. To mitigate these risks, it is imperative to implement stricter standards for both product naming conventions and labelling requirements.

The Guild understands some products being marketed have names such as ‘Joker Juice’, ‘Gelato Sherbert’ or ‘Black Cherry Punch’, none of which imply a health-related product. These standards should explicitly prohibit names or branding that suggest frivolous or recreational use, thereby reinforcing the therapeutic intent of these products and supporting safe clinical practice.

Question 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?

To ensure the safe and effective use of medicinal cannabis, product labels must provide clear, comprehensive, and clinically relevant information. This includes a detailed breakdown of active cannabinoids such as THC, CBD, and others, expressed in both milligrams and percentages; inclusion of terpenes; and information on the type of cannabis strains i.e. indica, sativa or hybrid. Labels should also specify the dosage form (e.g., oil, capsule, flower) and route of administration (e.g., oral, inhalation), which are essential for guiding appropriate use. Clear dosage instructions and titration guidance are critical for patient comprehension and minimising adverse effects, while storage instructions and expiry dates help maintain product integrity.

Equally important is the inclusion of regulatory information. Labels should clearly state the product’s regulatory status—for example, “Unregistered Product”—to assist pharmacists in dispensing and counselling, and to help patients understand the nature of the product they are using. Indicating whether the product is listed on the Australian Register of Therapeutic Goods (ARTG) or accessed via Special Access Scheme (SAS) or Authorised Prescriber (AP) pathways further supports transparency.

Safety warnings should be prominently displayed, especially for vulnerable populations such as children, pregnant or breastfeeding women. Together, these labelling requirements will enhance clarity, reduce confusion, and promote safe and informed use of medicinal cannabis across the healthcare system.

In additional to labelling information, feedback from our members is that Product Information and Consumer Medicines Information for these products is extremely difficult to access due to the number of companies, suppliers and contacts that are involved. The TGA should facilitate easy access to this information to support safe use.

Question 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.

Unapproved medicinal cannabis products present significant safety concerns in Australia. These products bypass the rigorous evaluation process of the TGA, resulting in inconsistent quality, unpredictable dosing, and limited oversight. Between July 2022 and June 2025, the TGA received over 600 adverse event

reports linked to these products, including serious psychiatric effects such as psychosis, suicidal ideation, schizophrenia, bipolar disorder, and even homicidal ideation.[ii] Despite the volume of reports, most products have not been investigated, leaving patients vulnerable. The lack of standardisation in THC concentration and formulation further increases the risk, particularly for vulnerable populations such as children, the elderly, pregnant women, breastfeeding women and individuals with mental health conditions.

Strengthening Prescriber Accountability

To mitigate these risks, it is essential to strengthen the regulatory framework around prescribers. All Authorised Prescribers (APs) should be required to obtain approval or endorsement from a Human Research Ethics Committee (HREC) or relevant specialist college before receiving TGA authorisation to prescribe medicinal cannabis. Furthermore, AP and Special Access Scheme (SAS) approvals should be restricted to conditions supported by a robust evidence base or covered by clinical guidance documents. This ensures that prescribing practices are grounded in sound clinical reasoning and evidence-based medicine.

Regulating Supply Chains and Product Quality

The supply of medicinal cannabis products must be tightly regulated to ensure safety and quality. Overseas suppliers should face stricter controls, or supply should be limited to domestic manufacturers who meet Australian standards. All companies supplying medicinal cannabis must be mandated to provide the TGA with evidence of compliance with the required quality and safety standards prior to product distribution. This will help prevent the circulation of substandard or unsafe products and reinforce public trust in the medicinal cannabis framework.

Addressing Systemic Issues in Service Delivery

The rise of niche online clinics has introduced new risks to patient care. These clinics often operate with limited oversight, bypassing regular care providers and relying on scripted questionnaires and single-product prescribing. Reports have criticised these models for poor professionalism, inadequate patient care, and unsafe prescribing practices. Unlawful promotion, reduced patient choice, and problematic supply arrangements are prevalent. Regulatory fragmentation and lack of coordination between agencies have hampered effective enforcement, allowing these unsafe models to persist.

Protecting Patient Choice and Ensuring Transparency

Many of the medicinal cannabis vertically integrated clinics operate a closed loop arrangement where the prescriber will send the prescription to a preferred dispensary, often owned by the same organisation, for dispensing and supply. If a patient prefers to have the prescription sent to their regular pharmacy a surcharge is applied and paid by the patient. Also, there are number of cases where there is channelling of prescriptions to in-house dispensaries or partnership pharmacies without patients being made fully aware of their options. Often barriers to patients being able to use their preferred pharmacy are imposed e.g. costs to release prescriptions or paperwork (e.g. TGA prescribing approvals). To uphold patient autonomy and improve transparency, the Guild recommends e-prescriptions should be mandated for medicinal cannabis. Prescriptions must not be sent directly to preferred suppliers, as this bypasses the patient's ability to choose their provider. A centralised database of TGA approvals should be made accessible to health professionals, and regulations should require that TGA paperwork be transferable to a patient's preferred provider at no additional cost. These measures will ensure continuity of care, protect patient rights, and promote informed decision-making.

Unethical Advertising and Promotion Practices

There is growing concern over aggressive and unlawful marketing practices employed by some medicinal cannabis clinics. A recent study found that 47% of the 54 clinics investigated were classified as having committed 'high-level breaches' of the TGA advertising requirements.[iii]

These breaches included tactics such as offering same-day or after-hours product delivery, bypassing the need for a GP referral, providing discounted consultation fees, and deploying targeted advertising campaigns on social media platforms[iv]. Such practices undermine professional standards and patient safety. To address this, TGA must implement stronger oversight of medicinal cannabis clinics, actively monitor for breaches of advertising and professional conduct, and enforce penalties where appropriate.

This should include the publication of deidentified breach reports and referral of individual clinician violations to the relevant regulatory bodies for review and disciplinary action.

We understand that there are cannabis clinics that promote medicinal cannabis to patients via emails and SMS messages asking if they require further prescriptions or supply of medicinal cannabis. We have received a report from a member that one of their pharmacy's patients who had one supply of medicinal cannabis and experienced a psychotic episode, was being constantly sent SMS messages from a clinic to obtain a new prescription. Promotion of a Schedule 8 substance is inappropriate and in breach of the Therapeutic Good Advertising laws, yet companies continue to use these tactics with seemingly no consequences.

Medicinal cannabis prescriptions by telehealth and vertically integrated Clinics

There is increase in the number of vertically integrated cannabis clinics. The Guild has significant concerns with regards to these clinics. The majority of these clinics do not provide face-to-face consultations. The patient registers their interest in receiving a medicinal cannabis product online and is then consulted by a nurse, who then refers the patient to a doctor. A prescription for medicinal cannabis is nearly always provided. Patients using these clinics "learn" the right answers to provide in order to obtain the prescription.

In many cases, a patient's general practitioner (GP) remains unaware that medicinal cannabis has been prescribed or supplied. To ensure continuity of care and uphold clinical standards, communication should be established between the prescribing clinician and the patient's regular healthcare team. This collaborative approach supports informed decision-making and promotes safer, more coordinated treatment.

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

Yes. Inhaled/vaporised forms pose respiratory risks and rapid THC absorption. Dried herbs can have significant batch variation in concentration of active ingredients as well as contaminants. Restrict use to ARTG-listed products with clinical justification.

Question 6b: 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.

Products like suppositories, pessaries, and dermal patches lack sufficient safety data and should be restricted until further evidence is available.[v] These forms present unique pharmacokinetic challenges. Suppositories and pessaries, which are administered rectally or vaginally, bypass first-pass hepatic metabolism. While this route can enhance bioavailability for some drugs, in the case of cannabinoids, it may lead to unpredictable absorption rates, variable therapeutic effects, and increased risk of adverse outcomes due to inconsistent dosing.[vi] Similarly, dermal patches, although promising for sustained release, currently lack comprehensive data on skin permeability, systemic absorption, and long-term safety when used with cannabis-derived compounds. The variability in cannabinoid concentrations and the absence of standardized formulations further complicate their safe use.[vii]

Until these dosage forms are supported by rigorous clinical trials and pharmacological studies, it is prudent to limit their availability to protect patient safety and ensure therapeutic consistency.

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

Yes. For example, dried herb for oral use is inappropriate due to unpredictable dosing and potential misuse.[viii]

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

Yes, while generally well tolerated, high doses of CBD may cause liver toxicity, drug interactions, and reproductive risks. Vulnerable populations (e.g., children, pregnant women) require caution. A recent publication in Australian Journal of General Practice recommends therapeutic daily doses of CBD are between 50 mg and 1500 mg.[ix] This reference is used by some regulatory agencies for risk management and investigation.

Currently, the TGA guidelines include dose recommendations for managing cancer pain and epilepsy. There should be clear national evidence-based guidance that outlines suitable doses for common indications to support safe and appropriate use.

Question 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.

Yes, there are well-documented safety concerns associated with inhaling or vaping high-THC cannabis products. One of the primary issues is the unpredictable pharmacokinetics of inhaled THC, which can vary significantly depending on the method and depth of inhalation, the device used, and individual patient factors. Unlike oral or sublingual administration, inhalation leads to rapid absorption through the lungs, resulting in a faster onset of action, higher peak plasma concentrations, and shorter duration of effect. These variations can make dosing difficult to control and increase the risk of adverse outcomes.[x]

From a pharmacological perspective, inhaled THC is metabolised differently compared to other routes of administration, leading to inconsistent therapeutic effects and heightened potential for harm. High-THC inhaled products have been associated with a range of psychiatric and behavioural risks, including acute anxiety, paranoia, psychosis, and the development or exacerbation of cannabis use disorder. These risks are particularly pronounced in individuals with a personal or family history of mental health conditions, adolescents, and those using cannabis frequently or in high doses.[xi]

Emerging evidence from clinical and observational studies supports these concerns. For example, research published in *The Lancet Psychiatry* and other peer-reviewed journals has linked high-potency cannabis use - especially via inhalation - to increased rates of psychotic episodes and hospitalisations. Additionally, vaping-related lung injuries (EVALI) reported internationally, though more commonly associated with illicit products, underscore the need for strict regulation of inhaled cannabis formulations.[xii]

Given these risks, high-dose and inhaled or vaped THC products should be subject to tighter regulatory controls or prohibited. We recommend that the Category 5 group should be prohibited, and the Category 4 group reassessed to see if prohibition is not justified. For all categories with any THC content, their use

should be restricted to conditions with strong clinical justification or specialist prescribing. Public health messaging should also highlight the potential harms of these products, particularly for vulnerable populations.

Question 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.

There is no universally accepted "safe" upper limit. A recent publication in Australian Journal of General Practice recommends therapeutic daily doses of THC are between 5 mg and 20 mg.[xiii] In managing chronic pain, THC daily dose up to 60mg may be used (Sydney Addiction Seminars- Medicinal cannabis in 2021).[xiv] These references are used by some regulatory agencies for risk management and investigation. However, products exceeding 10–15 mg THC per dose may pose significant risks, especially for naïve users or vulnerable groups.[xv] Therefore, there should be a clear national guidance that outlines suitable doses for common indications.

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

Unsure, not enough known at this stage- there are potential safety concerns with certain cannabinoids, although the evidence base remains limited and evolving. One of the key complexities lies in the entourage effect, which refers to the synergistic interaction between cannabinoids (such as THC, CBD, CBG) and other plant compounds like terpenes and flavonoids. While this effect is often cited as enhancing therapeutic outcomes, it also introduces variability and unpredictability in clinical responses.[xvi]

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

Yes, certain combinations of dosage forms and routes of administration for medicinal cannabis do present unacceptable safety risks, particularly when not used as intended or without appropriate clinical guidance.

While cannabis flower remains one of the most commonly prescribed forms of medicinal cannabis in Australia, there is growing concern over the method of administration. Anecdotal and clinical observations suggest that many patients do not use Therapeutic Goods Administration (TGA)-approved vaporisation devices for medicinal cannabis. Instead, a significant proportion may inhale cannabis flower through combustion methods such as smoking.

This practice poses substantial risks to respiratory health. Combustion releases harmful byproducts including tar, carbon monoxide, and carcinogens, which can contribute to long-term pulmonary complications such as chronic bronchitis, airway inflammation, and reduced lung function. These risks are well-established in the broader context of smoked substances and are particularly concerning given the therapeutic intent of medicinal cannabis.

The absence of standardised delivery mechanisms, issues obtaining TGA approval through the Special Access Scheme for unapproved devices (e.g., 510 battery), and limited patient education around safe inhalation practices further compounds the issue. Without clear guidance and regulation, patients may unknowingly adopt harmful consumption methods that undermine the safety and efficacy of their treatment.[xvii]

Edible cannabis products present a distinct set of safety challenges that require careful consideration in clinical practice. Due to their delayed onset of action—typically ranging from 60 to 120 minutes—patients may mistakenly consume additional doses before the initial effects are felt. This can result in unintentional overdose, leading to excessive intoxication and adverse outcomes such as anxiety, paranoia, impaired cognition, and in severe cases, hospitalisation.

Unlike inhaled or sublingual forms, edibles produce prolonged and often unpredictable effects due to variable gastrointestinal absorption and first-pass metabolism. These pharmacokinetic characteristics are particularly problematic for cannabis-naïve individuals or those with limited understanding of dosing principles.

In many instances, prescribers do not provide comprehensive instructions on how to safely use edible products, leaving pharmacists to fill critical gaps in patient education. This lack of coordinated guidance increases the risk of misuse and undermines the safe integration of medicinal cannabis into therapeutic regimens.[xviii]

To address these concerns, it is essential to implement stricter prescribing protocols, clearer labelling, and mandatory counselling for high-risk dosage forms. Regulatory oversight should also ensure that products are used with approved devices and that patients are fully informed about onset times, dosing intervals, and potential risks associated with each route of administration.

Question 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.

Yes, the current restriction requiring specialist support for paediatric access to medicinal cannabis is appropriate and necessary. THC-containing products pose significant risks to developing brains, including potential impacts on cognition, emotional regulation, and psychiatric health. Adolescents exposed to cannabis are more vulnerable to long-term neurodevelopmental effects.[xix.xx]

Question 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.

- Mandatory specialist oversight for all SAS/AP applications.
- Limit dosage forms to oral liquids or tablets with known pharmacokinetics. This assists with dose titrations and adjustments.

Question 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 Therapeutic Goods Administration Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products or any other pharmaceutical aspects? If yes, please provide an explanation to support your response.

Yes. High-THC products, inhaled forms, and poorly labelled products should be avoided. Only products with evidence and indications for paediatric use (e.g., epilepsy) should be considered.

Question 15. Given the unknown safety impact of medicinal cannabis products on foetal development, do you consider there to be a need to restrict access or should risk mitigation elements be applied for pregnant

or breastfeeding women? If yes, please provide an explanation to support your response.

Yes, access to medicinal cannabis products for pregnant or breastfeeding women should be restricted or carefully managed through specialist oversight and informed consent, given the potential risks to foetal development. Emerging research has identified statistically significant associations between increased cannabinoid exposure and higher rates of congenital anomalies, including cardiovascular, gastrointestinal, and neurological malformations. These findings raise important concerns about the teratogenic potential of cannabinoids and underscore the need for precautionary measures in vulnerable populations.[xxi]

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

Yes. Patients with mental health conditions or addiction history should be subject to stricter prescribing controls, including mandatory psychiatric review. There should be restrictions on approvals for conditions with low evidence base (e.g. anxiety, psychosis, insomnia) to mitigate risks.

Having an expert clinical group (e.g. Council of Australian Therapeutic Advisory Groups or the National Health and Medical Research Council) regularly review and update clinical guidance based on ongoing research would support evidence-based use, particularly in vulnerable populations (this may also facilitate more registration of products). Unapproved medicinal cannabis should only be prescribed by non-specialist prescribers for these evidence-based conditions.

Question 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.

Some options to consider include:

- Tighter restrictions on overseas suppliers
    - Office of Drug Control must enforce regulations to prevent stockpiling
- All companies must provide TGA with evidence of compliance with Australian quality and safety standards
- Prohibition to prescribing Category 5 unapproved medicinal cannabis as these have the highest potential to cause harm, including risks of addiction, misuse and abuse. There is also little robust evidence, if any, to support the use of high-THC medicinal cannabis. Another option is to prohibit all categories that are not CBD dominant.
- Time dependent dispensing volume limits per patient (e.g. a reduction from 90 grams to 30 grams per week)
- Under the AP pathway, all authorised prescribers should have an endorsement or approval from a human research ethics committee (HREC) or specialist college. Currently authorised prescribers using the ‘Established history of use’ pathway are exempt. More bodies could be allowed to provide such an endorsement.
- Cap the number of prescriptions that any one prescriber can issue per month under the SAS/AP pathways
- Introduce stronger penalties for regulatory breaches (including advertising breaches), with criminal penalties for serious breaches such as repeat offenders
- Implement charges for companies of unregistered medicinal cannabis products to support the necessary coding for unapproved medicinal cannabis products to be included on prescribing and dispensing software for use via the National Prescription Delivery Service.

- Introduce regulations that restrict unwarranted reminders to renew or refill prescriptions for medicinal cannabis and ensure patients always have the option to opt out and subscriptions supply services where prescriptions for medicinal cannabis are automatically filled, and products delivered to the patient without request.

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

Yes. These pathways should be reserved for exceptional cases for patients to access medicines not marketed in Australia. Companies should be encouraged to invest in the research to gather the necessary evidence base to list products on the ARTG. The arrangements put in place for prescribing unapproved medicinal cannabis has set up an alternative process to listing on the Australian Register of Therapeutic Goods (ARTG) and does not incentivise companies to research and register their products. Routine prescribing of unapproved products undermines regulatory intent and patient safety.

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

Yes, introducing a transitional mechanism could incentivise sponsors to generate and submit evidence for currently unapproved medicinal cannabis products. To ensure accountability, this pathway should be subject to strict regulatory oversight and a defined timeframe—ideally a maximum of two years. After this period, products must either obtain ARTG listing or be removed from prescribing and supply channels. This approach supports regulatory integrity while promoting timely compliance. Safeguards should also be in place to prevent misuse, such as rebranding the same unapproved product under a different name. These provisions should apply only to existing products and not to new entries, which must follow the standard ARTG application process. A provisional ARTG listing could be considered for current products that demonstrate safety within the two-year window, with an additional period allowed to establish efficacy before full registration.

Question 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?

Given that arrangements for access to unapproved medicinal cannabis products have been in place since 2017, we believe a limit of 2 years is appropriate. Companies should never have considered the unapproved pathway process as a permanent option for supplying medicinal cannabis.

Question 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.

Regulation via an appendix in the Poisons Standard that:

- all prescriptions for unapproved medicinal cannabis must only be by an electronic prescription and accompanied by relevant approvals or authorities (this would ensure patient choice in provider is retained)
- all initial patient assessments for medicinal cannabis must be done in-person between the prescriber and the patient; and,
    - the patient must have demonstrated failure to achieve an adequate response to 2 or more conventional treatments prior to prescribing, and
    - Multiple doctors must sign off on the patient's treatment plan

- telehealth prescribing of medicinal cannabis is restricted to:
  - a person's regular General Practitioner with an established clinical relationship (or GP from the same clinic); or
  - a specialist on referral from a person's regular GP; or
  - another GP, only after discussion between the person's regular GP to ascertain appropriateness of treatment.

In addition, consideration could be given to amending the Schedule 8 entry for Tetrahydrocannabinols (THC) with a maximum concentration limit.

Question 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?

Display cannabinoid profile clearly: Product labels should clearly present the cannabinoid profile, detailing exact concentrations of THC, CBD, and other active compounds. This information is vital for accurate dosing, informed therapeutic decisions, and minimising potential adverse effects. Transparent labelling also enables healthcare professionals to personalise treatment and ensures consistency across product batches.

Add warnings for vulnerable groups: Products should carry clear warnings for populations at higher risk of harm, such as children, adolescents, pregnant or breastfeeding individuals, and those with a history of psychiatric conditions. These warnings should be prominently displayed and based on current clinical evidence.

Include QR code linking to product safety data and regulatory status: A QR code on the packaging should link directly to up-to-date product information, including safety data sheets, manufacturing standards, batch testing results, and regulatory documentation. This digital access empowers prescribers and patients to verify product quality and compliance in real time.

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