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SUBMISSION

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AMA submission to the TGA review into the safety and regulatory oversight of unapproved medicinal cannabis products

Consultation closes 7 October 2025

Via Email: medicinalcannabisreforms@health.gov.au

Introduction

The Australian Medical Association (AMA) welcomes the opportunity to contribute to the Therapeutic Goods Administration's (TGA) review into the safety and regulatory oversight of unapproved medicinal cannabis products. The AMA has consistently advocated for a robust, evidence-based regulatory framework that ensures patient safety, clinical integrity, and responsible prescribing and dispensing practices.

The rapid expansion of medicinal cannabis prescribing — particularly through vertically controlled, direct-to-consumer telehealth models — has exposed significant gaps in the current regulatory framework. These models often bypass traditional safeguards, including in-person assessments, community pharmacy dispensing, and continuity of care. The AMA is concerned that the Special Access Scheme (SAS) and Authorised Prescriber scheme (AP), originally designed for exceptional access, are being exploited as commercial pathways for unapproved products.

The AMA supports reforms that re-balance access and safety, rebuild incentives for sponsors of therapeutic goods to seek Australian Register of Therapeutic Goods (ARTG) registration, and protect the integrity of the SAS and AP schemes from misuse — particularly by vertically controlled, direct-to-consumer telehealth models. Patients and clinicians alike need clear labelling, safety, efficacy, consistent quality signals, and guardrails for high-risk products and cohorts.

Since the opening of this consultation, TGA compliance activity has intensified, with infringement and direction notices issued for the unlawful advertising of prescription-only medicines and the indirect promotion of medicinal cannabis. We support continued, proactive enforcement — especially against indirect and social media advertising, and third-party promotion — given the documented risks of demand creation and fragmentated care.

The AMA's submission draws on shared stakeholder concerns and recent guidance from the Australian Health Practitioner Regulation Agency (Ahpra) and reflects the AMA's commitment to ensuring medicinal cannabis is prescribed and dispensed in the same manner as other Schedule 8

medicines — within a framework of clinical governance, regulatory oversight, and patient-centred care.

Quality and safety requirements

1. **Are the current quality and safety requirements for medicinal cannabis products appropriate and sufficient?**

The AMA does not consider the current quality and safety requirements for unapproved medicinal cannabis products to be appropriate or sufficient. Most products supplied under the SAS and AP pathways are not registered on the ARTG, meaning they have not undergone rigorous pre-market assessment for safety, efficacy, and quality. This situation undermines public confidence and exposes patients to unnecessary risk. The AMA supports a regulatory framework that treats medicinal cannabis with the same caution as other drugs of dependence and calls for stronger enforcement of existing standards such as TGO 93.

The SAS and AP schemes are important and legitimate prescription pathways for situations of exceptional clinical need, but the current scale of unapproved supply means patients and prescribers are navigating products not pre-evaluated by the TGA. The AMA supports reforms that lift baseline safety standards through uniform labelling, packaging, and information requirements, and introduce a time-bound transition to ARTG registration for products supplied at scale.

2. **What changes (if any) would you recommend to the current quality requirements, and why?**

The AMA recommends several changes to strengthen the quality requirements for medicinal cannabis products. All products used beyond exceptional access should be registered on the ARTG, supported by priority evaluation and targeted fee relief to facilitate compliance. In support of this, clear thresholds for prescribing volume or supply should be established to trigger mandatory ARTG registration. Compounded products should be subject to enhanced oversight, including Good Manufacturing Practice (GMP) compliance and mandatory adverse event reporting.

A review for the improved regulation of medicinal cannabis prescribing is long overdue. The AMA therefore recommends Category 5 products with Tetrahydrocannabinol (THC) concentrations exceeding 98 per cent be removed from the market during this review. Uniform labelling and packaging standards should be introduced, aligned with Therapeutic Goods Orders, and should include child-resistant packaging and calibrated dosing aids. We recommend the TGA require sponsors whose products reach defined supply thresholds to progress to ARTG registration within 24–36 months or exit the SAS and AP schemes.

These changes address the risks inherent in large-scale supply of unapproved products and reflect the AMA's consistent position that ARTG registration should be the default for ongoing access. The AMA believes this approach will ensure the SAS and AP pathways return to their intended purpose as exceptional access mechanisms rather than functioning as a de facto market.

3. **Are the current labelling requirements adequate for prescribers and consumers to identify and safely use/store products? If not, what changes are needed?**

The AMA considers the current labelling requirements for unapproved medicinal cannabis products to be inadequate for ensuring safe prescribing and patient use. Labelling is inconsistent and often lacks

critical information, such as cannabinoid concentrations, dosage forms, and regulatory status. This creates risks of dosing errors, inappropriate prescribing, and patient confusion.

To address these issues, the AMA recommends that labels clearly display THC and CBD content in milligrams and percentages per dose and per pack, include dosing instructions and storage requirements, and indicate ARTG registration status using plain language (e.g., "Registered" versus "Unapproved"). Labels should also carry prominent warnings for driving impairment, psychosis and dependence, pregnancy and breastfeeding, and cardiac risk. In addition, the TGA could consider including QR code links to a TGA-hosted page with up-to-date safety information and brand-agnostic substitution guidance for continuity of therapy. These measures will shift labels beyond compliance to clinical usability and protect patient safety.

4. **What additional information should be included on product labels to improve understanding and safe use?**

Medicinal cannabis product labels should include:

- exact concentrations of THC, CBD, and other cannabinoids
- ARTG registration status
- warnings for vulnerable populations (e.g., children, pregnant women, patients with mental health conditions)
- dosage form and route of administration
- a QR code linking to product safety data, prescribing guidance, and adverse event reporting mechanisms.

These enhancements would support safe prescribing and informed patient use. Further details may include:

- cannabinoid content per dose/per pack (THC/CBD in mg and percentage)
- dose units and calibrated device if relevant
- icon-based warnings for driving, psychosis, pregnancy/breastfeeding, child-safety, and cardiac cautions
- batch/CoA reference
- a QR code to the TGA safety page for current guidance and substitutions.

This combination supports safe prescribing and dispensing, reduces confusion during brand substitution, and enables dynamic safety updates without constant re-printing.

Emerging safety concerns

5. **What safety risks have you identified or are concerned about with unapproved medicinal cannabis products? Please provide supporting data or evidence.**

The AMA is concerned about multiple safety risks associated with unapproved medicinal cannabis products. Our members working in emergency departments around Australia have reported increased demand for resources at public hospitals to manage presentations related to the use of high-THC concentration medicinal cannabis products, as well as cases of cannabis-induced psychosis, dependence, and cognitive impairment. Alarmingly, doctors are seeing medicinal cannabis use in people who have pre-existing psychotic conditions. Of particular note are the increasing numbers of people presenting with a condition called cannabis hyperemesis syndrome after taking medicinal

cannabis. While the TGA has recorded more than 400 adverse events attributed to medicinal cannabis, the sector considers this a gross underestimation. The AMA is greatly concerned with the reported increase of cannabis-induced psychosis presenting to early psychosis youth treatment programs. A recent study examining data from the NSW Poisons Information Centre also found the number of cannabis poisonings reported in Australia increased significantly during 2014–24 — particularly exposures of children and adolescents.[1]

The potential for drug interactions with medicinal cannabis is often under-estimated. For example, one common component, cannabidiol, interacts with a range of commonly used medicines. These include epilepsy medicines, antidepressants, opioids, and blood thinners. International evidence reinforces these concerns: high-potency cannabis and frequent use are associated with increased risk of psychosis and cannabis use disorder (Di Forti et al., *Lancet Psychiatry*; Hines et al., *JAMA Psychiatry*). Ahpra's 2025 guidance also highlights unsafe business models and emergency department presentations linked to high-risk prescribing practices.

Additionally, medicinal cannabis has been associated with impaired driving and accidental paediatric exposure, and cardiovascular events in vulnerable populations. Inhaled and vaped products present additional risks, including rapid systemic THC delivery, dose variability, and device-related harms such as e-cigarette or vaping product use-associated lung injury (EVALI). These risks are compounded by prescribing models that bypass traditional safeguards, such as vertically integrated telehealth services, which often lack comprehensive patient assessment and continuity of care.

Dosage forms and routes of administration

6.

a) Are there safety risks associated with certain dosage forms that require mitigation? If yes, what measures would you suggest?

Certain dosage forms, particularly inhaled and vaped products, carry heightened safety risks due to their potential for misuse, youth appeal, and unpredictable dosing. These forms enable rapid THC absorption, which increases the likelihood of acute psychoactive effects, dependence, and psychiatric harms. To mitigate these risks, the AMA recommends inhaled and vaped products should not be considered first-line therapy and should require specialist endorsement or robust clinical justification for initiation. Prescribers should implement scheduled reviews and provide explicit counselling on pulmonary and dependency risks. Labels should include prominent warnings, and all products should be supplied in child-resistant packaging. These measures align with Ahpra's safe prescribing expectations and international harm-reduction principles.

[1] https://onlinelibrary.wiley.com/doi/10.5694/mja2.52586

b) Are there any dosage forms that should not be permitted due to safety risks? Please provide evidence.

The AMA recommends prohibiting the use of vaping devices that are not registered on the ARTG, ultra-high THC concentrates in extract or oil form, and unregulated compounded products with unclear cannabinoid ratios. These forms present unacceptable risks due to their potency, rapid systemic absorption, and lack of standardisation. Observational data and clinical experience indicate high-THC inhaled products are associated with increased risk of psychosis, dependence, and driving impairment. Where prohibition is not immediately feasible, these products should be subject to the highest level of regulatory control and restricted to exceptional circumstances under specialist oversight.

c) Are there safety risks with specific dosage forms being prescribed for certain routes of administration? If yes, please provide evidence.

Concentrated high-THC liquids intended for inhalation, or devices enabling rapid pulmonary absorption, pose disproportionate risks compared to orally titrated products. Combining high potency with inhalation magnifies acute psychoactive effects and dependence potential, consistent with observational data and Ahpra's harm signals. The AMA recommends prioritising oral or oromucosal routes for routine use and restricting high-risk combinations to exceptional circumstances with specialist oversight and clear monitoring plans.

Concentration of medicinal cannabis components

7. Does CBD at specific concentrations pose safety risks for patients or population groups?

The AMA considers cannabidiol (CBD) generally well tolerated; however, risks emerge at higher doses and in specific populations, particularly due to dose-related transaminase elevations and drug–to-drug interactions. Australian product information for ARTG-registered CBD (Epidyolex) documents ALT/AST elevations — with higher risk when combined with valproate — and recommends baseline and periodic liver-function monitoring, which is pertinent when CBD is used at moderate–high doses or alongside hepatically active co-medications. The US label similarly emphasises hepatocellular injury, somnolence, and the need for monitoring, reinforcing a cautious approach in polypharmacy, hepatic impairment, paediatrics, and during pregnancy or breastfeeding. In line with Ahpra's guidance to apply Schedule-8-level diligence to medicinal cannabis (thorough assessment, clear therapeutic justification, coordination of care), prescribers should prefer ARTG-registered CBD where suitable, and if unapproved CBD is used via SAS/AP, incorporate explicit monitoring plans and clear patient counselling. The TGA consultation's focus on risks with high concentrations of cannabis components further supports adopting these safeguards in product labelling and clinical protocols.

8. Do you have evidence of harm from inhaling or vaping high-THC products?

There is credible evidence of harm associated with inhaled/vaped high-THC products, spanning psychiatric, driving, and pulmonary risks. Observational and case–control studies link high-potency cannabis and frequent use with an elevated risk of psychotic disorders and earlier onset of psychosis, which is particularly concerning when high THC is delivered rapidly via the pulmonary route. In addition, the CDC's investigation of e-cigarette or vaping product use-associated lung injury (EVALI) identified THC-containing products — especially those from informal sources — and vitamin E acetate as strongly linked to thousands of ED presentations and dozens of deaths in 2019–20, underscoring

route-specific hazards. Consistent with Ahpra's 2025 guidance highlighting unsafe models and patient harm, the AMA supports tighter controls for inhaled/vaped cannabis products — including non-first-line status, stronger warnings, scheduled reviews — and calls for ARTG-level assessment of devices where inhalation remains under consideration, to minimise dose variability and device-related risks. The TGA consultation's emphasis on emerging safety concerns and dosage form-specific risks provides the policy context for implementing these route-specific mitigations.

9. Should there be a 'safe' upper limit for THC use? If yes, what should it be?

The AMA does not propose a single universal "safe" upper limit for THC across all patients and indications, because risk varies by potency, total daily dose, frequency, route of administration, and patient vulnerability (e.g., psychosis risk, cardiovascular disease, safety-critical occupations). A risk-proportionate approach is preferable:

- treat higher absolute THC content and inhaled routes as higher risk
- make high-THC products clearly non-first-line
- require specialist co-management and scheduled reviews at higher potency/dose bands
- suspend Category 5 (>98% THC) products from SAS/AP pending ARTG-level evidence.

The AMA calls for graduated controls (e.g., more stringent frameworks at higher THC bands), which will address risks with high concentrations without undermining legitimate, exceptional access. In those cases where the TGA prefers numeric guardrails, the AMA supports a targeted expert process to set route-specific thresholds (with lower caps for inhaled forms). However, these should be anchored in clinical data and real-world harms, and accompanied by clear label warnings and post-market pharmacovigilance.

10. Are there safety concerns with other cannabinoids? Please provide evidence.

Beyond THC and CBD, evidence for many minor cannabinoids (e.g., CBG, CBN, CBC) is limited in real-world therapeutic use, including uncertainties around pharmacodynamics, interactions, neuropsychiatric effects, and special populations (adolescents, pregnancy/breastfeeding). Given this uncertainty — and the consultation's explicit focus on risks with high concentrations of medicinal cannabis components — the AMA recommends precautionary labelling (declaring all cannabinoid contents), prescriber justification for non-THC/CBD products in SAS/AP submissions, and structured outcome monitoring with a low threshold for cessation if harms emerge. We may also support adopting an evidence-first, ARTG-oriented approach for novel or concentrated minor cannabinoids, with clear warnings where evidence is sparse.

11. Are there dosage form and route combinations that present unacceptable safety risks? If yes, which ones?

The following dosage form and route combinations present unacceptable safety risks due to their association with rapid systemic THC delivery, unpredictable dosing, and increased risk of psychiatric and pulmonary harm, as evidenced by international studies and the e-cigarette, or vaping, product use-associated lung injury (EVALI) outbreak:

- ultra-high THC concentrates delivered by inhalation or vaping
- THC liquids used in non-ARTG-registered vaping devices
- unstandardised compounded cannabis products administered via pulmonary routes.

These risks are especially pronounced in vulnerable groups, such as children and pregnant or breastfeeding women. The AMA therefore supports restricting these combinations, prioritising oral or oromucosal routes with defined cannabinoid content and lower THC concentrations, and reserving higher-risk forms for exceptional, specialist-managed circumstances only. This aligns with Ahpra's guidance and the TGA's consultation focus on managing risks by dosage form and concentration.

Vulnerable population groups

12. Is the current restriction requiring paediatric specialist support for THC products in patients under 18 appropriate and sufficient?

The AMA supports the current requirement for paediatric specialist involvement when prescribing THC-containing medicinal cannabis products to patients under 18 years of age. This safeguard is appropriate given the neurodevelopmental vulnerability of children and adolescents, as well as the limited evidence base for efficacy and safety in this population. However, further measures are warranted to strengthen clinical oversight. These should include structured review intervals, explicit informed consent covering neurocognitive risks, and mandatory communication with the child's usual general practitioner to ensure coordination of care and deprescribing plans.

13. What additional risk mitigation measures should be applied for paediatric patients?

The AMA recommends several additional risk mitigation measures for paediatric patients prescribed medicinal cannabis. These include mandatory adverse event reporting, prohibition of prescribing via direct-to-consumer telehealth models, and referral to paediatric specialists for all THC-containing products. Prescribers should be required to document treatment goals, measurable outcomes, and time-limited trials with clear stop rules. Inhaled and vaped products should be restricted, and ARTG-registered options should be prioritised where available. Prescribers should also attest to discussing non-pharmacological alternatives and to reviewing school and functional outcomes before continuation of therapy.

14. Do you have concerns about specific product types being prescribed to paediatric patients (e.g. dosage forms, concentrations)?

The AMA is concerned about the prescribing of high-THC products, vaping, and compounded formulations to paediatric patients. These products lack sufficient evidence for safety and efficacy in children and pose heightened risks to developing brains. The AMA recommends that, where medicinal cannabis is considered, oral or oromucosal forms with defined cannabinoid content and lower THC concentrations should be preferred, under specialist oversight and with explicit review and exit plans.

15. Should access be restricted or risk mitigation applied for pregnant or breastfeeding women?

The AMA strongly supports restricting access to THC-containing medicinal cannabis products for pregnant or breastfeeding women, given the risks to foetal development and neonatal outcomes. Prescribing in these circumstances should require specialist consultation and clear labelling warnings. SAS/AP applications should require prescribers to attest that safer alternatives have been considered and that risks to foetal and neonatal development have been discussed with the patient. High-THC and inhaled routes should be avoided in this population.

16. Should restrictions or mitigation be applied to other vulnerable groups (e.g. mental health, addiction history)?

The AMA recommends enhanced screening and risk mitigation for patients with a history of mental health conditions, addiction, significant cardiovascular disease, or those in safety-critical occupations. Prescribing THC-containing products for anxiety should be prohibited unless supported by robust evidence. Enhanced controls should include non-first-line status, lower-THC preferences, specialist co-management, and scheduled reviews with an exit plan. Coordination with other treating practitioners is essential to ensure safe and appropriate use. Ahpra's guidance offers a practical template for embedding these controls in SAS/AP workflows.

Treatment resistance must not be asserted unless: (i) guideline-concordant therapies have been trialled to dose and duration; (ii) a clinician with expertise in the target condition has assessed or reviewed management; and (iii) an exit plan is defined. For paediatric, perinatal, or psychiatric indications, specialist co-management and scheduled reviews should be required.

Regulatory reform options

17. What elements or principles should be considered when developing regulatory options to address current issues?

The AMA recommends that regulatory options be anchored in the following principles:

- proportionality to risk, with tighter controls for higher THC content and inhaled/vaped dosage forms
- an evidence-first pathway that returns routine supply to ARTG registration, keeping SAS/AP for exceptional clinical need rather than a de-facto market
- co-regulation and data sharing, with the TGA focusing on product regulation and Ahpra/National Boards on practitioner conduct, enabled by clear legal mechanisms for information sharing
- transparency and clinical usability, including plain-English labels that disclose ARTG status and clinically actionable information
- equity and continuity of care, ensuring prescribing is coordinated with the patient's usual GP and that vulnerable groups receive enhanced safeguards.

These principles accord with the AMA's prior submissions to the TGA and respond to this consultation's emphasis on quality, dosage-form risk, and access settings.

<u>Operational safeguards for safe access within SAS/AP</u>

Further, to realign the SAS/AP with their intended role while preserving access for exceptional clinical need, the AMA suggests the TGA, in collaboration with Ahpra and ACSQHC, consider:

(i) a time-limited "registration-in-progress" pathway with enforceable milestones and sunset dates for continued unapproved supply

(ii) per-patient dispensing limits for high-THC products (e.g., weekly caps and maximum pack sizes) and controlled repeat intervals

(iii) Authorised Prescriber eligibility calibrated to risk (for higher-risk products/indications, require relevant specialist registration and explicit review intervals)

(iv) mandatory notification to a patient's usual GP for all SAS/AP approvals to support continuity of care.

Further to the above, SAS/AP consent forms and guidance should explicitly authorise prescribers and dispensers to notify the patient's usual GP — and other treating practitioners, as appropriate — of medicinal cannabis prescriptions and dispensing, to improve safety and continuity of care. We recommend a privacy "safe harbour" or legislative instrument to give practitioners assurance that such coordination does not breach confidentiality when conducted in good faith and within defined parameters.

These measures complement our recommendation to suspend Category 5 (>98% THC) products during the review and restore ARTG registration as the default for routine supply.

The AMA supports standardised clinical labelling (THC and CBD in mg per dose and per pack, with per-unit clarity across forms) and strengthened pharmacovigilance, including better use of real-world data under robust privacy and ethics governance. We do not support an alternative "declared products" market as a destination state. Any such construct, if adopted, should be time-limited and transitional, with enforceable milestones toward full ARTG registration and sunset clauses to prevent "evergreen" unapproved supply.

18. Would you support restricting or preventing access to most or all unapproved medicinal cannabis products via the SAS and AP scheme?

The AMA does not support a blanket prevention of access because SAS/AP must remain available for exceptional clinical need. However, as stated elsewhere, the AMA supports significantly restricting access to ensure products used at scale transition to ARTG registration within fixed timeframes, that high-risk categories are curtailed (e.g., suspending Category 5 products with > 98% THC pending evidence), and that inhaled or vaped high-THC forms are treated as non-first-line options with strengthened controls. This approach restores SAS/AP to their intended role while protecting patients and prescribers from the risks associated with large-scale unapproved supply.

19. Would you support a time-limited mechanism allowing sponsors to gather evidence to transition products to the ARTG?

The AMA believes this mechanism is necessary to encourage responsible product development by sponsors and legitimise medicinal cannabis medicines found to be safe, effective, and supported by scientifically rigorous medical evidence. We support a time-limited "registration-in-progress" mechanism that enables continued supply while sponsors complete a defined clinical and quality program, including milestones, pharmacovigilance, and enforcement. Upon expiry, the product should either be registered or withdrawn from SAS/AP, with limited extensions permitted only when justified against published milestones. The AMA has consistently advocated for policies on medicinal cannabis to balance patient continuity with evidence-based regulation.

20. What is an appropriate timeframe for sponsors to collect sufficient clinical evidence?

The AMA considers 24–36 months generally appropriate, recognising differences by indication, formulation, and whether pivotal trials or device conformity assessments are required. Milestones should be front-loaded to avoid "evergreen" unapproved supply (e.g., protocol finalised within six months, first patient in by 9–12 months, and pre-specified interim analyses at 18–24 months).

21. What scheduling amendments could address safety concerns for cannabis and cannabinoids?

The AMA recommends scheduling amendments that codify non-first-line status for high-THC medicinal cannabis, tighten controls on inhaled/vaped high-THC dosage forms, and harmonise state/territory controls to reduce diversion while enabling legitimate, supervised access. We suggest reviewing the settings for low-risk CBD in step with the emergence of ARTG-registered options that meet evidence and quality thresholds, while maintaining cautious settings until such evidence is established.

Throughout this paper we distinguish CBD and THC in safety analysis, labelling, scheduling, and risk-mitigation, recognising different pharmacology and risk profiles. Labels and guidance must state THC and CBD content in mg per dose and per pack, not ratios alone. Where warranted by risk, the AMA supports stronger scheduling for ultra-high THC products (e.g., Category 5) pending ARTG-level evidence.

22. What labelling requirements would help prescribers and patients understand product contents and regulatory status?

- Display cannabinoid concentrations.
- ARTG registration status.
- Warnings for vulnerable populations.
- QR code linking to safety data and prescribing guidance.

Further to our response to questions 3 and 4, the AMA recommends that for higher-risk products, labels and conditions of supply should specify maximum pack sizes, prohibit automatic repeats without clinical review, and include prominent icon-based warnings (e.g., driving impairment, psychosis/dependence, pregnancy/breastfeeding, and child safety).

Recommendations

The AMA urges comprehensive reform of the regulatory framework for unapproved medicinal cannabis products to restore clinical governance, protect patient safety, and uphold the integrity of Australia's therapeutic goods system. Central to this is the requirement that products used beyond exceptional access must be registered on the ARTG, ensuring rigorous pre-market assessment for safety, efficacy, and quality. An immediate high THC concentration product freeze and prescribing volume thresholds would promote patient safety while the regulatory arrangements for medicinal cannabis products are reviewed. Products that reach defined levels of use should be required to justify their registration status, with exclusion from the SAS and AP pathways if standards are not met.

The AMA has supported legislative measures to enable data sharing between the TGA, Ahpra, and state and territory regulators, alongside additional resources for Ahpra to investigate high-volume prescribers and enforce compliance with prescribing guidelines. National guidance on stockholding and supply practices, stronger collaboration between regulators, prescribers, and pharmacists, and education campaigns are also essential. The development of a national clinical governance framework, led by the Australian Commission on Safety and Quality in Health Care, would also ensure medicinal cannabis is prescribed and dispensed with the same rigour as other Schedule 8 medicines.

While the regulation of direct-to-consumer (DTC) telehealth models falls outside the scope of this consultation, the AMA reiterates its longstanding concerns about the risks posed by vertically controlled entities that bypass traditional safeguards such as in-person assessments, community pharmacy dispensing, and continuity of care. Excessive prescribing and the proliferation of unapproved products are most safely addressed when medicinal cannabis is brought within Australia's established regulatory frameworks — specifically, when products are listed on the ARTG and subject to robust oversight. Responsible prescribing, even within telehealth contexts, is best supported by clear regulatory standards, transparent labelling, and coordinated care, ensuring patient safety remains paramount and the integrity of the therapeutic goods system is maintained.

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