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SUBMISSION TO TGA

To:	Therapeutic Goods Administration
Date:	7 October 2025
Re:	Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products

Executive Summary

1. Indicated Legal welcomes the opportunity to respond to the Therapeutic Goods Administration's (**TGA**) consultation, "***Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products, Version 1.0, August 2025***" (**Consultation**). We represent clients across the medicinal cannabis industry, including cultivators, manufacturers, sponsors, distributors and registered health professionals. Each of these clients have direct engagement with Australian medicinal cannabis rules and regulations, particularly those related quality and safety.

2. The focus of our submission is on the legal and regulatory framework governing the supply of medicinal cannabis products in Australia. We are not in a position to comment on clinical or safety outcomes associated with the use of medicinal cannabis products. Accordingly, we have responded only to the questions relating to the legal and regulatory aspects of the Consultation.

3. Our submission is firmly in support of a pro-access model. However, we consider that there are a number of issues with the current framework and a perceived lack of TGA assessment and enforcement. Accordingly, we advocate for the development of a national regulatory framework tailored specifically to medicinal cannabis. The framework should implement the following regulatory priorities:

    a. A dedicated ARTG registration pathway for medicinal cannabis products, focusing primarily on establishing product safety, while adopting a more flexible evidentiary threshold for efficacy.

    b. Enforcement of product quality standards, including GMP compliance and greater batch-level consistency.

    c. An emphasis on prescriber education, clinical guidance, and real-world evidence collection to support safe and appropriate use.

4. Our submission also makes a number of comments regarding some observed deficiencies and unintended outcomes associated with the current framework.

Context & Legal Framework

5. The Consultation provides an overview of the legislative and regulatory framework that has enabled Australian patients to access medicinal cannabis products via the Special Access Scheme Category B (**SAS B**) and Authorised Prescriber (**AP**) pathways.

6. It is evident that the volume of prescriptions for medicinal cannabis has increased significantly since the inception of the scheme. This sharp rise in demand was not anticipated by key regulatory bodies.

7. We submit that the substantial growth in prescribing activity should not be interpreted as a failure of the regulatory framework. Rather, it demonstrates that medicinal cannabis is meeting a significant and previously unmet clinical need within the Australian health system.

8. Although we agree with the Consultation's assessment that the SAS B and AP pathways were not originally designed to support widespread prescribing of medicinal cannabis, we strongly caution against responding to this with restrictive measures. Limiting access would risk undermining the health outcomes of thousands of patients.

9. It is essential that the TGA's evaluation of the medicinal cannabis framework does not occur in isolation but is considered against the broader harms posed by the illicit cannabis market. Restricting medicinal cannabis access does not suppress cannabis consumption. It pushes patients into unregulated, unsafe, and criminal supply chains. Australia's longstanding *National Drug Strategy (2017–2026)* mandates a harm minimisation approach that integrates supply reduction, demand reduction, and harm reduction through coordinated action between health and law enforcement agencies.[1] Empirical evidence and position statements underscore that shifting cannabis consumption away from the black market toward a regulated supply pathway can significantly reduce risks associated with contamination, unpredictable potency, and criminal activity, while redirecting public funds from illicit economies into regulated health systems.[2]

10. Australia's experience with an expanding medicinal cannabis market is not unique but is consistent with international patterns. In several jurisdictions, including the United States, Canada, Germany and Portugal, medicinal cannabis schemes initially introduced under narrow, restrictive conditions have expanded rapidly in response to patient demand and prescriber supply. This is typically followed by regulatory concerns regarding misuse. In most instances, the eventual legalisation of adult-use (recreational) cannabis followed. In such cases, the medicinal market typically contracts and stabilises at a level consistent with the regulator's original expectations.

11. The Australian trajectory appears to be following a similar path. However, it is

[1] Department of Health, *National Drug Strategy 2017-2016* (National Framework No 11814, June 2017), 6.
[2] Health Canada, *Legislative Review of the Cannabis Act: Final Report of the Expert Panel* (Final Report, Health Canada, March 2024) 7, 29; Canadian Centre on Substance Use and Addiction, *Public Safety and Cannabis: Taking Stock of Knowledge Since Legalization* (Report, April 2022) 16; Lauren Dryburgh et al, "Cannabis Contaminants: Sources, Distribution, Human Toxicity and Pharmacologic Effects" (2018) 84(11) *British Journal of Clinical Pharmacology,* 2468 – 2476; Benedikt Fischer, Tessa Robinson and Hans-Jörg Albrecht, "Key Crime- and Public Safety-Related Results of Non-Medical Cannabis Legalization Policy in Canada" (2025) *Journal of Criminological Research, Policy and Practice,* 11(3), 273-286.

uncertain, perhaps unlikely, that an adult-use market will be established within the foreseeable future. Accordingly, Australia must implement a national regulatory framework to appropriately and responsibility administer a medicinal cannabis scheme which supports a large number of patients.

Quality and safety requirements for medicinal cannabis products: Questions 1 & 2

12. Unapproved medicinal cannabis products imported into, supplied in or manufactured in Australia must comply with the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017* or, in respect of vaporisers for the administration of such medication, with the Essential Principles for medical devices.[3]

Enforcement of TGO 93

13. TGO 93 includes stringent quality requirements relating to cannabinoid content and potential contamination and adulteration of medicinal cannabis products. We are not aware of any medicinal cannabis product being audited by the TGA for compliance with TGO 93. Accordingly, it appears that there is little risk for non-compliance. We consider that enforcement of TGO 93 is an area that could be improved.

Cannabinoid Limits

14. The limits on cannabinoid content may not be appropriate. Under TGO 93, a cannabinoid is an 'active ingredient' if the quantity or proportion of which is greater than or equal to 2% w/w or w/v of the product. For medicinal cannabis products in herbal final form, the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be within 20% of the stated content of that active ingredient (referred to as the **Label Claim**). For other dosage forms, the average content must be within 10% of the Label Claim.

15. For medicinal cannabis products with one main active ingredient (referred to as **Major Cannabinoids**), this is a fairly generous limit. A cannabis flower product with a Label Claim of 25% can have an average tested THC content of between 20-30%.

16. A patient prescribed such a product may therefore find that the next batch of the product is up to 50% stronger than the last batch of product supplied under the same prescription (being the difference between 20% and 30%). The prescriber and the patient would not likely be aware of the possibility of substantial THC content variations between batches, as the batch test results are not ordinarily shared, and the prescriber would rely on the Label Claim.

17. However, for cannabinoids at lower concentrations (referred to as **Minor Cannabinoids**), staying within these limits can be extremely difficult. For a cannabis oil product with a Label Claim of 3% Cannabigerol (**CBG**), each subsequent batch must contain between 2.7% - 3.3% w/v of CBG.

18. Suppliers and manufacturers of medicinal cannabis products are therefore incentivised to keep Minor Cannabinoids under 2% w/w or w/v and to keep Major Cannabinoids high in concentration.

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[3] *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) sch 1 reg 2.1.

Vaporiser Batteries

19. An unintended consequence of recent regulatory changes, specifically those introduced in connection with the nicotine vaping reforms, is the requirement that 510-thread vaporiser batteries now be individually approved through the SAS-B pathway when used in conjunction with prescribed inhalable medicinal cannabis vaporiser cartridges (**Vaporiser Cartridges**). This requirement has arisen not due to safety concerns with Vaporiser Cartridges or the 510-thread batteries, but rather due to the blanket reclassification of vaping devices under the nicotine framework. Accordingly, health practitioners who prescribe Vaporiser Cartridges must now also obtain a separate SAS-B approval for the associated battery device, even though these batteries are interchangeable, low-risk, and essential for the use of a legitimate dosage form.

20. This regulatory position has created unnecessary administrative burden for prescribers and has resulted in a disincentive to prescribe Vaporiser Cartridges altogether. Furthermore, the current approach requires prescribers to provide clinical justification as to why a registered product cannot be used, even though no registered vaporisation device is currently approved for use with Vaporiser Cartridges. This circular logic imposes an unreasonable compliance barrier.

21. **Our Recommendations:**

    a. Implement a robust audit program for compliance with TGO 93 for medicinal cannabis products. Levy fines and penalties for non-compliance. Publish fines and penalties for non-compliance with TGO 93 on the TGA website.

    b. Change the average cannabinoid concentration limits on ‘active ingredients’ to be more permissive for Minor Cannabinoids and more restrictive for Major Cannabinoids. A cascading approach could be used, an example of which is provided below.

       For products in herbal final form:

       - Active ingredients between 2% and 5% w/w must be within 100% of the Label Claim.
       - Active ingredients between 5% and 10% w/w must be within 50% of the Label Claim.
       - Active ingredients between 10% and 20% w/w must be within 25% of the Label Claim.
       - Active ingredients between 20% and 35% w/w must be within 10% of the Label Claim.
       - Active ingredients above 35% w/w must be within 5% of the Label Claim.

    c. Urgently review the regulatory treatment of vaporiser batteries for medicinal cannabis and consider issuing guidance that exempts low-risk, reusable 510-thread batteries from separate SAS-B approval, where they are used solely to administer legally prescribed medicinal cannabis formulations.

Concentration of medicinal cannabis components - Questions 8 & 9

22. If any limits on THC concentration were imposed, we advocate for the limits to be applied to the maximum number of milligrams of THC to be administered per day and not as a maximum THC percentage of a medication.

23. Imposing a maximum THC percentage limit on cannabis products may result in a greater amount of lower strength cannabis products being prescribed by health practitioners and consumed by patients. It may also remove access to concentrated products such as Vaporiser Cartridges. This may incentivise patients to access higher strength cannabis or concentrated products via the black market. Such an outcome should be avoided, in the absence of clear safety signals being observed regarding a particular dosage form.

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

Question 17: Specific feedback, elements or principles to be considered

24. We advocate for the following principles to be considered when developing regulatory options for medicinal cannabis:

    a. *Incentivise Evidence Gathering* - Regulation should incentivise market participants to conduct trials and gather evidence.

    b. *Supporting Appropriate Access* - Regulation should support appropriate patient access to medicinal cannabis treatment.

    c. *Disincentivise Black Market* - Regulation should disincentivise patients from accessing cannabis through the black market.

    d. *Enforcing Standards* - Regulation should uphold and enforce high standards of quality, safety and transparency.

    e. *Patient and Prescriber Education* - Regulation should focus on patient and prescriber education, particularly regarding the potential risks of use and misuse of medicinal cannabis.

25. We propose these principles be applied in support of the regulatory priorities outlined in paragraph 3 of this submission.

Creation of a Dedicated ARTG Registration Pathway for Medicinal Cannabis Products

Incentivise Evidence Gathering

a. We consider that the current registration pathway is inappropriate for most medicinal cannabis products. Very few medicinal cannabis products contain a single active molecule. Instead, these products, particularly those in herbal form, may contain hundreds of molecules. Evidence suggests that cannabinoid molecules combine to create the overall therapeutic effect. This phenomenon is referred to as “The Entourage Effect”.[4]

[4] André et al, “The Entourage Effect in Cannabis Medicinal Products: A Comprehensive Review” (2024) 17(11) *Pharmaceuticals* 1543, 2.

b. Under the current ARTG pathway, it is unclear how efficacy trials could be conducted on these medicinal cannabis products when there are a large numbers of molecules playing a role in the therapeutic outcomes. This has led to a reluctance to conduct lengthy and expensive clinical trials on medicinal cannabis products. It is also unclear whether batch consistency issues will prevent medicinal cannabis products from being registered under the current framework.

c. To encourage ARTG registration, a new cannabis-specific ARTG pathway should be established which focuses on demonstrating product safety and quality, while allowing for a flexible evidentiary threshold for efficacy.

d. Examples of similar registration schemes can be found in international jurisdictions. *Directive 2004/24/EC of the European Parliament and of the Council* allows certain herbal products to be registered without the need for traditional efficacy testing. Instead, the application needs to demonstrate a long history of traditional use and provide bibliographic or expert evidence of efficacy and safety.[5]

Supporting Appropriate Access

e. A cannabis-specific registration model with a flexible efficacy threshold lowers entry barriers for sponsors, while still encouraging data development. Allowing provisional registration based on safety and real-world evidence incentivises phased clinical trial investment.

Disincentivise Black Market

f. When patients have access to registered cannabis medicines, they may be less likely to turn to illicit sources.

Enforcing Standards

g. A registration pathway will enhance pre-and-post-market regulatory obligations on sponsors, which should mirror obligations for sponsors of ARTG registered products.

h. ARTG registration inherently requires minimum quality standards and product characterisation. A dedicated pathway can further tailor these requirements to cannabis-specific risks (e.g. THC variability or delivery format).

Patient and Prescriber Education

i. ARTG listing enables more reliable guidance to be provided to prescribers and patients. Registered products can be linked to official prescribing information, which forms the basis for clinician training and pharmacist counselling.

Enforcement of Product Quality Standards Including GMP Compliance and Batch-Level Consistency

[5] *Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use* [2004] OJ L 136/85.

Incentivise Evidence Gathering

a. Quality-controlled environments provide a stable foundation for conducting clinical trials.

b. Clinical trials require predictable batch consistency to draw valid conclusions, reinforcing the importance of strong manufacturing controls.

Supporting Appropriate Access

c. Consistent batch specifications and quality allow prescribers to confidently identify and recommend appropriate products, improving patient uptake and therapeutic outcomes.

Disincentivise Black Market

d. Products that consistently meet GMP and batch specifications become preferred over illicit alternatives that vary in potency and content.

Enforcing Standards

e. To ensure patient safety and build confidence in the legal market, it is critical that all medicinal cannabis products, whether registered or unregistered, comply with consistent and enforceable quality standards.

f. Mandatory GMP, expanded TGO 93 standards (including for devices), and batch-level testing provide concrete regulatory mechanisms to support safety.

g. The inclusion of delivery devices like vaporisers under quality standards reduces safety risks from poorly manufactured hardware.

Patient and Prescriber Education

h. When product quality is assured, educational materials (e.g. dosing charts and titration schedules) become more accurate and useful.

Emphasis on Prescriber Education, Clinical Guidance, and Real-World Evidence Collection.

Incentivise Evidence Gathering

a. Real-world data collection can feed back into regulatory approvals, giving sponsors a path to registration through observational data. A product widely prescribed under the AP pathway with positive real-world outcomes could later be registered based on post-market data.

Supporting Appropriate Access

b. General Practitioners who currently do not prescribe medicinal cannabis may consider cannabis medication as a treatment option after completing an accredited training module. This may benefit patients currently utilising telehealth services who would prefer in-person medical consultations.

Disincentivise Black Market

c. When prescribers can confidently prescribe legal products, patients may

be less likely to self-medicate or source cannabis illicitly. A patient who learns that black market THC products may exacerbate anxiety may be more likely to pursue regulated treatment.

Enforcing Standards

d. Clear national standards can help General Practitioners navigate cannabinoid selection and avoid misuse.

Patient and Prescriber Education

e. Prescribers need clear, practical, and evidence-based information to guide appropriate prescribing and use of medicinal cannabis. Likewise, structured data collection is vital to monitor safety, efficacy, and long-term outcomes.

f. Education ensures prescribers are aware of potential adverse effects and contraindications. Training modules could flag risks of prescribing high-THC formulations to adolescents or patients with a history of psychosis.

Questions 18 – 20: Restricting Access and Timing of Transition

26. We do not support restricting or preventing access to unapproved medicinal cannabis products via the SAS B and AP pathways without a robust and complete replacement scheme being implemented that seamlessly allows patient access to be maintained. Restricting access would deny the thousands of patients currently using the products of therapeutic benefits and create major disruptions to continuity of care. It would also incentivise patients to source their cannabis products from the black market.

27. If a dedicated ARTG pathway is established for medicinal cannabis, a gradual phasing out of access to medicinal cannabis products via the SAS B and AP pathways may be appropriate. At the same time, incentives should be created to encourage participants to utilise the new registration pathway. Such incentives could include providing fee waivers or subsidies for clinical studies underpinned by public health objectives (e.g. opioid harm reduction) or establishing a national real-world experience repository that enables pooled data collection from prescribers and sponsors.

28. The appropriate length of time for this transition depends on the reasonable time required to gather evidence and register the medicinal cannabis products under the new dedicated ARTG pathway. Under the current ARTG registration pathway, registration can take many years, mostly as a result of the need to recruit a large number of Phase 2 and 3 clinical trial participants.[6] We advocate for the new ARTG registration pathway to be expedited. This will allow a faster transition away from the current SAS B and AP pathways.

[6] CT:IQ GREET Project, *Clinical Trial Site Recruitment Guide* (2025) https://ctiq.com.au/wp-content/uploads/GREET-Guide-FINAL-2025.pdf; Clinical Trials Alliance, *Scoping Review: Exploring Technologies to Improve Recruitment (Australia)* (2022) https://clinicaltrialsalliance.org.au/wp-content/uploads/2023/01/ACTA-Scoping-review_Exploring-technologies-to-improve-recruitment_v1.2.pdf.

We welcome further engagement and are available to contribute to the co-design of regulatory frameworks that uphold both public health and patient rights.

Respectfully submitted,

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On behalf of Indicated Legal