Submission to the Therapeutic Goods Administration

Consultation: Reviewing the Safety and Regulatory Oversight of Unapproved Medicinal Cannabis Products

Submitted by: Novachem
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Introduction

Novachem welcomes the opportunity to provide feedback to the Therapeutic Goods Administration (TGA) on its consultation paper reviewing the safety and regulatory oversight of unapproved medicinal cannabis products. As a sponsor of medical products with a long-standing commitment to compliance, quality management, and patient safety, Novachem fully supports the TGA's initiative to strengthen regulatory oversight and address the significant concerns raised by the current framework.

Novachem's Position and Ideology

Novachem's philosophy is grounded in the principles of patient safety, compliance, and accountability. We believe that sponsors must bear direct responsibility for the quality and safety of products supplied to the Australian market. We support robust, enforceable regulation and advocate for transparent product labelling, strict quality standards, and appropriate regulatory oversight. We recognise the therapeutic potential of cannabinoids but stress the need for a cautious, evidence-informed approach to ensure that access is balanced with safety.

At the core of this, we advocate for a product registration regime to be introduced, similar to the New Zealand product registration framework which requires that products meet a "minimum quality standard". Compliance with this standard should be required to be evidenced (by way of provision of a Certificate of Analysis / Certificate of Conformance from a validated testing laboratory or service) for every batch of product released, and the records of this should be publicly available. This register should be known as the Australian Register of Cannabinoid Therapeutic Goods (ARCTG), and each product should be given a registration number (AUST C) similar to the existing AUST R and AUST L ids for registered and complimentary medicines. Along with product registration, labelling changes should be required to ensure information is available to practitioners and patients alike and sufficient warnings should be provided on the label.

We believe that practitioners who complete specified training covering prescribing of cannabinoid medicines should be registered in a CAP (Cannabis Approved Prescriber) program. This program should be similar to the current AP pathway for prescribers, with two changes.

1. that completion of CAP program will allow the prescribing of any cannabinoid medicine registered on the ARCTG (not be restricted to dose form and category)
2. that prescribing nurse practitioners who have completed appropriate training should also be permitted to prescribe cannabinoid medicines.

Novachem believes that the current system is unwieldy, and encourages a large number of products which may have some questionable levels of validated provenance or quality to be provided to market. The use of SAS-B pathways for medicinal cannabis has always been unfit for purpose, so a new scheme and approach is required which addresses all areas of product quality, safety and efficacy.

Section 1: Purpose, Scope & Background

Novachem supports the TGA's recognition that the SAS/AP pathways, designed for exceptional circumstances, are no longer appropriate as the primary route of supply for medicinal cannabis products. The current framework creates risks for patient safety, undermines incentives for ARTG registration, and allows products to enter the market without adequate oversight. Novachem supports reforms that place sponsor accountability at the centre of regulation and ensure patient safety is prioritised. Labelling must comply with TGO 91, remain generic, and exclude overt branding. Sponsors must be held fully accountable for product compliance, and the TGA must enforce these obligations.

Section 2: Quality Standards

Q1 - Do you consider the current quality and safety requirements to be appropriate and sufficient for medicinal cannabis products?

Response: Current requirements under TGO 93 are insufficient and lag behind international standards. Novachem recommends adopting requirements equivalent to at least EP 3028[1], with tighter controls on heavy metals, trimming, and ±10% label claim accuracy. Additional quality standards such as ASTM standards being developed by the D37 Committee on Cannabis[2] should also be considered. Submission of evidence of compliance with these new quality and safety guidelines should be mandatory for each batch of product released in the

[1] European Pharmacopoeia, Monograph 3028 – Cannabis flower: EDQM link
[2] ASTM International, Committee D37 on Cannabis: ASTM D37 info\

market, and these should be readily available on a centralised register of products, similar to New Zealand[3].

Q2 - Are there any changes you would recommend to the current quality requirements for medicinal cannabis products?

Response: All products—imported or locally manufactured—must meet identical quality standards, validated at registration through independent batch testing (e.g. 1st, 3rd, 6th, 10th, then every 10th batch) and ongoing Continuous Process Verification (CPV) in line with PIC/S compliance requirements[4]. Surveillance testing in Australia should be mandatory, and actively followed up by TGA. Submission of compliance with any new quality regime must be required for every batch of product in the market.

Any products which may be available as compounded material must ensure that the API for that compounding meets all product quality controls of finished goods, and that any non plant based or liquid based API meets GMP production requirements.

Q3 - Noting the current labelling requirements outlined in TGO 93, do you consider these to be adequate?

Response: No. Labelling must also comply with TGO 91[5], ensuring generic, standardised labels with no overt branding. Additional labelling advice regarding the Unapproved nature of cannabinoid medications (Black Triangle Scheme)[6], warnings for pregnant or breastfeeding mothers should also be considered / included, and a link to a centralised registry database where patients and practitioners can look up the registered ID and download all relevant product information and batch analysis, validation and conformance certificates.

[3] NZ Ministry of Health – Minimum Quality Standard for Medicinal Cannabis Products: NZ Medicinal Cannabis Standards
[4] PIC/S Annex requirements https://www.tga.gov.au/sites/default/files/2024-03/pe-009-16-gmp-guide-annexes.pdf
[5] TGO 91 Labelling: https://www.legislation.gov.au/F2016L01285/2023-04-30/2023-04-30/text/original/pdf
[6] Black Triangle Scheme: https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/report-adverse-events-medicines-and-biologicals/black-triangle-scheme

Fig. 1 – possible pregnant / breastfeeding warning logo

Q4 - What information would you like to see on medicinal cannabis product labels?

Response: Labels should include cannabinoid profile (mg/mL and % w/w on dried basis), expiry, storage, batch number, GMP certification, sponsor details, contraindications, and a Black Triangle Scheme warning to ensure enhanced monitoring, warnings for breastfeeding or pregnant women and an ID tied to the product registration (AUST C, linked to ARCTG).

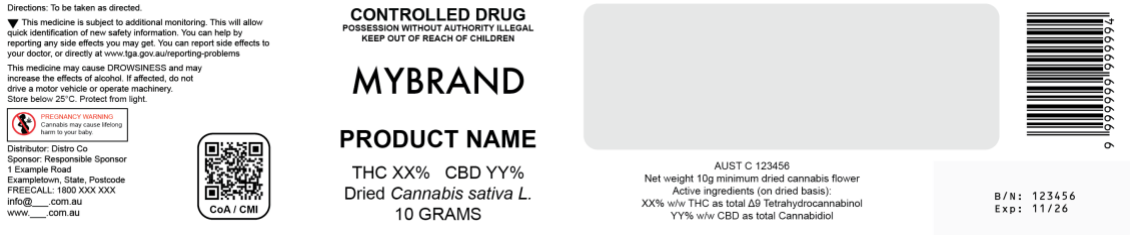

Fig. 2 – example generic label

Section 3: Safety Concerns

Q5 - In general, what are the safety risks you have identified or are concerned about with unapproved medicinal cannabis products?

Response: The highest risks are overuse and Cannabis Use Disorder, particularly with high-THC formulations. Flavourants and colourants make products attractive to children[7][8] and should be prohibited, except minimal neutral adjuvants. Risks also include psychiatric and cardiovascular harms, inaccurate dosing, and variable bioavailability linked to dose form inconsistency and lack of approved devices for inhalation. Evidence includes:

- An acute trial where inhaled cannabis (25 mg THC) caused significantly more adverse effects and cardiovascular responses compared to lower dose inhalation.[9]
- Meta-analyses showing cannabis use is associated with increased risk of cardiovascular disease death.[10]
- Pharmacokinetic studies showing oral, oil, powder, inhalation, and transdermal dosage forms yield very different Cmax/Tmax and bioavailability.[11]

[7] Medical Journal of Ausrtalia - https://www.mja.com.au/journal/2025/222/3/cannabis-poisonings-australia-following-legalisation-medicinal-cannabis-2014-24
[8] SCHN advise on cannabis safety and children https://www.schn.health.nsw.gov.au/kids-health-hub/alcohol-and-substances/safety/cannabis-marijuana-and-gummies
[9] JAMA Network https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2716990
[10] BMJ Heart: https://heart.bmj.com/content/early/2025/06/10/heartjnl-2024-325429
[11] Journal of Cannabis Research: https://jcannabisresearch.biomedcentral.com/articles/10.1186/s42238-025-00294-8

Use of medicinal cannabis (or any cannabis product) can be problematic for pregnant or breastfeeding women and should be discouraged[12].

Q6 - Do you consider there to be safety risks associated with certain dosage forms?

Response: Yes. Some inhalation products carry significant risks and should be tightly controlled. Products such as pastilles may be attractive to children and so must have child resistant closures (CRCs), and appropriate warnings. Oral dosage forms including capsules, wafers and oils dispensed with a metered syringe provide safer baselines. Dosage forms with limited evidence should only be permitted through registration requiring baseline safety data.

Q7 - Is there any evidence to suggest that CBD at specific concentrations poses a safety risk?

Response: CBD is generally considered safe up in many jurisdictions. According to WHO, "CBD is generally well tolerated with a good safety profile. … To date, there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD."[13] Furthermore, it should be considered for broader access with dosing up to 200 mg/day, with a maximum 50 mg per discrete dose. Overall CBD generally safe at ≤200 mg/day with pharmacist oversight; monitoring and interaction checks. Products under these limits should be considered for Schedule 3, subject to a registration (AUST C) and applicable quality controls.

Q8 - Do you have information on safety risks or harm associated with inhaling or vaping high THC-containing products?

Response: Yes. Vaping of high-THC products increases risks of psychosis, dependency, cardiovascular harm, and lung injury. These should be restricted or prohibited, especially in vulnerable groups. Recent studies have also shown that many vaping products have substantive potential issues with excipients and degradation products[14]. Cases of e-cigarette, or vaping product use associated lung injury (EVALI) have also increased overseas, with Vitamin E Acetate being associated with EVALI in THC containing products[15]. The use of flavourants is also problematic with products such as diacetyl which are commonly used having been linked to pulmonary injuries[16].

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[12] Advice on cannabus use RWH - https://thewomens.r.worldssl.net/images/uploads/fact-sheets/Cannabis-2021.pdf
[13] WHO CBD Report 2018 - https://cdn.who.int/media/docs/default-source/controlled-substances/whocbdreportmay2018-2.pdf
[14] Frontiers in Toxicology June 2025 https://www.frontiersin.org/journals/toxicology/articles/10.3389/ftox.2025.1568207/full
[15] CHEST Journal 2023 - https://journal.chestnet.org/article/S0012-3692%2823%2905146-2/fulltext
[16] Sciencedirect 2021 - https://www.sciencedirect.com/science/article/abs/pii/S0048969721005544

It is however worth noting here that inhalation of vaporised plant material products (flower / or dried herb form) is specifically different to inhalation of vapour cartridge concentrates. Natural plant material which has been produced under GACP and packed and handled in accordance with PIC/S GMP protocols does not have the same level of inhalation harm that concentrates have[17]. Any high THC vaping product available should be limited to direct extraction / resin materials only. Consideration should be given to the banning of the use of flavoured distillates in vape carts across the board.

Q9 - Do you consider there to be a 'safe' upper limit of THC use?

Response: Potentially. A maximum daily intake of 50 mg THC may be appropriate and has been supported clinically[18]. This should also be adjusted for bioavailability and route of administration. Clinical data has suggested that most therapeutic dosing is well below 50 mg[19]. A standardised dose table with metabolism factors should be developed to assist practitioners understand the cannabinoid metabolic pathways and impacts of hepatic metabolism vs pulmonary inhalation.

Additionally, some individuals are hypersensitive to THC and potentially other cannabinoids. The traditional "Start Low and Go Slow" prescribing advice widely adopted should continue to be the basis of prescribing advice for cannabis naïve patients in particular.

Q10 - Do you consider there to be safety concerns with other cannabinoids?

Response: Yes. Psychoactive cannabinoids, including CBN, should be subject to caution. Non-psychoactive cannabinoids (CBD, CBG) are lower risk but should still be monitored. Studies on minor cannabinoids are limited, however a summary of current understandings are below[20] [21].

Cannabinoid	Psychoactivity Profile	Notes
Δ9-THC	Strongly psychoactive	Main CB1 partial agonist; primary intoxicant.
Δ8-THC	Moderately psychoactive	Milder, less potent than Δ9-THC.
THCV	Dose-dependent	Low doses: CB1 antagonist (non-psychoactive, may counter THC). High doses: CB1 agonist (psychoactive, shorter acting).

[17] PICS Annex 7 – Herbal products https://picscheme.org/docview/3890/PICS-Guide-to-GMP-Annexes-Annex-7-2021
[18] ANZCCP Dosing Guidelines https://anzccp.org/wp-content/uploads/2025/03/Draft-General-Guidance-for-Prescribing-V1.pdf
[19] Sciencedirect Systematic Review of Medical Cannabinoids Dosing in Human (2022) https://www.sciencedirect.com/science/article/abs/pii/S0149291822003496
[20] Frontiers in Pharmacology 2021 - https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2021.777804/full
[21] MDPI Pharmacology of minor cannabinoids 2022 - https://www.mdpi.com/2813-2564/1/1/2

Cannabinoid	Psychoactivity Profile	Notes
CBN (Cannabinol)	Mildly psychoactive	Degradation product of THC; weak CB1 agonist; sedative at higher doses.
CBC (Cannabichromene)	Non-psychoactive	Weak/no CB1 agonism; studied mainly for anti-inflammatory and analgesic effects.
CBD (Cannabidiol)	Non-psychoactive	Negative allosteric modulator of CB1; can reduce THC psychoactivity.
CBG (Cannabigerol)	Non-psychoactive	Very low CB1 affinity; interacts with CB2 and TRP channels.
CBDV (Cannabidivarin)	Non-psychoactive	No CB1 activity; anticonvulsant potential.
Δ9-THCP	Highly psychoactive	~30× CB1 binding affinity vs Δ9-THC; limited human data but likely very intoxicating.
Varin derivatives (THCVA, CBDVA, CBGVA)	THCVA: potentially psychoactive at high doses. CBDVA & CBGVA: non-psychoactive	Structurally shorter side-chain versions; THCV-like properties.
Degradation products (e.g. THC → CBN)	Mild psychoactivity	CBN is the main degradation product; others less well-studied.

Q11 - Do you consider there to be certain dosage forms when combined with routes of administration that present unacceptable risks?

Response: Yes. Vaping particularly of high-THC oils with excipients / flavourings, present substantive risks compared with plant material vaporisation, oral or topical routes. In addition, the use of flavourings likely to attract children in dose forms such as pastilles also present high risk.

Section 4: Vulnerable Populations

Q12 - Do you consider the current restriction to paediatric patients appropriate and sufficient?

Response: Yes. The current restrictions are appropriate and should be maintained. Any prescribing of THC for patients under 18 years of age should be strictly limited and only approved by a specialist paediatric physician with appropriate expertise.

There is emerging evidence that specific cannabinoids may provide benefit in certain severe paediatric conditions. For example, purified cannabidiol (CBD) has demonstrated efficacy in reducing seizure frequency in treatment-resistant epilepsies such as Dravet syndrome[22] and Lennox-Gastaut syndrome[23]. These findings have led to international regulatory approvals (e.g., Epidiolex by the FDA, EMA, and TGA). However, such benefits apply primarily to purified CBD, not THC or THC-dominant formulations.

Therefore, while cannabinoids may play a role in selected paediatric indications, these cases must remain under specialist care with stringent oversight. THC products in particular

[22] New England Journal of Medicine 2017 - https://www.nejm.org/doi/full/10.1056/NEJMoa1611618
[23] New England Journal of Medicine 2018 - https://www.nejm.org/doi/full/10.1056/NEJMoa1714631

carry significant risks for neurodevelopment, cognition, and psychiatric health, and should not be used outside very limited, justified contexts.

Q13 - Are there any additional risk mitigation elements you consider should be applied to paediatric patients?

Response: Yes. THC should be capped at 5 mg per unit dose in paediatric formulations. This will limit the potential for THC toxicity (See AAP Study[24]). Non-metered inhalation forms should be prohibited for minors, except in rare cases, approved by the TGA under a specific application to use the medication. Microdose metered inhalers such as SyqeAir may be considered appropriate.

Q14 - Do you have concerns with specific types of products being prescribed to paediatric patients?

Response: Yes. Flavoured gummies, pastilles, and oils should be prohibited, with only neutral or mint-based adjuvants considered acceptable. In addition, any non-metered inhalation product (herbal vaporisers, vape pens) should be prohibited for paediatric use due to dose variability and excipient risks. High-potency concentrates (distillates, waxes, shatter, resins) should likewise be excluded from paediatric prescribing. Only metered-dose inhalation systems (e.g. SyqeAir) may be considered in rare cases where inhalation is clinically required, and all compounded oils must comply fully with GMP quality standards.

Q15 - Should restrictions be applied for pregnant or breastfeeding women?

Response: Yes. Novachem strongly supports applying restrictions for pregnant and breastfeeding women, consistent with the precautionary principle and aligned with recommendations against alcohol use during pregnancy. Current evidence demonstrates significant risks associated with cannabis exposure during pregnancy and lactation[25], and these must be highlighted with mandatory labelling warnings.

Cannabinoids cross the placenta and are detectable in breast milk, exposing infants during critical developmental windows. Studies have shown associations with reduced birthweight, smaller head circumference, shorter gestation, and long-term neurodevelopmental concerns, including attention and behavioural issues. Evidence from Australian cohorts, such as the Raine Study[26], supports these findings.

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[24] American Academy of Paediatrics 2023 - https://publications.aap.org/pediatrics/article/152/3/e2023061374/193757/Toxic-Tetrahydrocannabinol-THC-Dose-in-Pediatric

[25] MJA 2020 - *The deleterious effects of cannabis during pregnancy on neonatal outcomes* – https://www.mja.com.au/journal/2020/212/11/deleterious-effects-cannabis-during-pregnancy-neonatal-outcomes

[26] Raine Study: Maternal use of marijuana during pregnancy and developmental outcomes – https://rainestudy.org.au/research-paper/maternal-use-of-marijuana-during-pregnancy-and-developmental-outcomes-in-their-children/

While some studies acknowledge gaps and uncertainties in quantifying risk levels, the prevailing international consensus — including guidance from ACOG[27] and the American Academy of Pediatrics — is that no use of cannabis during pregnancy or breastfeeding can be considered safe.

Therefore, Novachem recommends:

- Mandatory pregnancy warning labels on all medicinal cannabis products, modelled on alcohol warning labels.
- Explicit contraindication in pregnancy and lactation included in product information.
- Ongoing pharmacovigilance and research to refine risk assessment and provide clearer advice to prescribers and patients.

Q16 - Should restrictions be applied to other vulnerable groups?

Response: Prescribing psychoactive cannabinoids should remain at the discretion of the treating practitioner, with responsibility for patient management retained by prescribers. However, Novachem notes that certain groups are at higher risk of harm and therefore warrant additional caution, clinical justification, and monitoring:

- Adolescents (<18 years): Already identified as a vulnerable group due to neurodevelopmental risks and higher susceptibility to cannabis use disorder (CUD).
- Pregnant and breastfeeding women: Contraindicated due to risks of impaired fetal and neonatal development (see Q15).
- Patients with current or prior psychiatric disorders (e.g. schizophrenia, psychosis, severe anxiety, depression, bipolar disorder): High-THC products in particular are associated with worsening psychiatric outcomes and elevated risk of psychosis.
- Patients with a personal or family history of substance use disorder: These patients have elevated risk of dependence and misuse if exposed to high-THC products.
- Patients with cardiovascular disease: Inhaled or high-THC products can increase heart rate, blood pressure, and myocardial oxygen demand, raising the risk of cardiac events.
- Elderly or cognitively impaired patients: Increased risk of falls, sedation, confusion, and drug–drug interactions.

[27] American College of Obstetricians and Gynaecologists (2025) - https://www.acog.org/clinical/clinical-guidance/clinical-consensus/articles/2025/10/cannabis-use-during-pregnancy-and-lactation

- Patients likely to self-medicate or transition into recreational use: Those with prior cannabis use, particularly heavy recreational use, may attempt to exploit the medicinal access system, blurring the line between therapeutic use and misuse.

In each case, restrictions should not be absolute bans, but prescribing must be justified, closely monitored, and documented within the patient's clinical record.

Section 5: Addressing Current Issues and Future Reform

Q17 - Do you have specific feedback on elements or principles that could be considered when developing regulatory options?

Response: Novachem strongly supports the establishment of a clear, enforceable regulatory framework to ensure patient safety, product quality, and accountability across the medicinal cannabis sector. Current arrangements are fragmented and insufficient, with products entering the market under variable quality and evidence thresholds. To address these issues, the following principles are recommended:

1. Creation of a Dedicated Cannabis Product Register (ARCTG/ARAT)

    - Establish a new register — the Australian Register of Cannabinoid Therapeutic Goods (ARCTG) or Australian Register of Alternative Therapeutics (ARAT).
    - All products must be listed with a unique identifier, e.g. AUST C, similar to AUST L or AUST R numbers for complementary medicines and registered medicines.
    - Register coverage should include:
        - Finished imported goods
        - Locally cultivated and manufactured products
        - APIs finished locally
        - Associated medical devices (e.g. vaporisers, metered inhalers).

International precedent: New Zealand already requires medicinal cannabis products to comply with minimum quality standards and be published on a centralised register before prescription[28].

2. Mandatory Transition and Timeframes

[28] New Zealand minimum quality standards (Medicinal Cannabis Scheme): https://www.health.govt.nz/regulation-legislation/medicinal-cannabis/information-for-health-professionals/minimum-quality-standard-medicinal-cannabis-products

- From 1 January 2026, all products entering the market must commence transition to ARCTG/ARAT registration.
- By 1 January 2027, supply of unregistered products should be prohibited.
- Structured pathways should assist sponsors to submit dossiers and meet compliance requirements.

International precedent: Canada implemented a clear transitional timeline under the *Cannabis Act* (2018)[29] to phase out unregulated products and bring all supply under Health Canada oversight.

3. Registration Dossier Requirements

- Evidence of compliance with GACP and PIC/S GMP (including supplier validation).
- Batch-to-batch stability and validated shelf-life.
- Independent batch testing at registration (three batches upfront), followed by surveillance testing (1st, 3rd, 6th, 10th, then every 10th batch).
- Regular randomised testing in Australia under TGA oversight.
- Certificates of Analysis lodged in a standardised format with TGA, accessible via a centralised online database.

4. Cost Recovery and Sustainability

- Registration fees should reflect administrative assessment burdens.
- An ongoing per-milligram levy on active cannabinoids could fund post-market surveillance, testing, and pharmacovigilance.
- Suggestion of a fee of 0.5¢ per mg THC may be appropriate.
  e.g. 15g 22% THC Flower = $16.50 levy
  30 mL 10:10 THC:CBD oil = $1.50 levy
  1 g 88 THC% Vape Cart = $4.40 levy
  SyqeAir Cartridge (max 60 x 1mg) = $0.30 levy

International precedent: Canada and Germany have used cost-recovery levies to fund regulatory oversight and quality testing of cannabis products.

5. Labelling and Risk Communication

[29] *Cannabis Act (S.C. 2018, c.16)* and regulatory framework: https://www.canada.ca/en/health-canada/services/cannabis-regulations.html

- All products must comply with TGO 91, TGO 93, and SUSMP requirements.
- Labelling must be generic (restricted colours, no overt branding).
- Mandatory warnings to include:
    - Pregnancy and breastfeeding pictogram and statement.
    - Black Triangle (▼) symbol for enhanced pharmacovigilance.
    - AUST C identifier for verification.
- Labels should direct patients and prescribers to the centralised registry for product and batch-specific data.

International precedent: Canada mandates standardised cannabis warning labels with pregnancy warnings and rotation of health messages[30].

6. Prescriber Accreditation

- Establish a Cannabinoid Approved Prescriber (CAP) framework.
- Accredited training modules (RACGP, ANZCCP, NIIM, or other clinical colleges) to ensure prescribers understand cannabinoid pharmacology, risks, and therapeutic scope.
- Nurse practitioners may qualify for CAP accreditation.
- CAP prescribers can prescribe any registered ARCTG/ARAT product.
- Non-CAP prescribers may only access products via a restricted SAS-B pathway.

International precedent: Germany requires cannabis prescriptions under medical supervision with specialist training for prescribers; NZ also mandates clinical oversight frameworks for prescribers.

7. Device Regulation

- All vaporisers and inhalers intended for medicinal cannabis use must be registered medical devices.
- Consumer-grade vape pens or non-metered devices should be prohibited.

[30] Health Canada – Packaging and Labelling Guide for Cannabis Products: https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/regulations-support-cannabis-act/packaging-labelling-guide.html

- Only validated metered-dose inhalers (e.g. SyqeAir) that deliver microdoses consistently should be permitted.

International precedent: The FDA and EMA regulate inhalation devices under medical device frameworks, requiring safety and performance data before approval.

8. Clinical Governance

- AHPRA should oversee prescriber conduct, including prescribing volumes and identifying outliers.
- Consider caps on prescribing to align with good clinical practice.
- Sponsors are accountable for product quality and safety; prescribers remain responsible for patient management and efficacy.

Summary:

This framework aligns Australia with global best practice while ensuring stricter quality, oversight, and accountability mechanisms than currently exist. The goal is to protect patients, ensure public confidence, and create a sustainable, transparent pathway for medicinal cannabis regulation.

Q18 - Would you support restricting or preventing access to most or all unapproved medicinal cannabis products via SAS/AP?

Response: Yes. Novachem strongly supports restricting access to unapproved medicinal cannabis products via SAS/AP pathways to exceptional cases only.

At present, SAS/AP has become the default mechanism for patient access, allowing products of variable quality and unverified consistency into the market without sufficient oversight. This undermines both public confidence and the development of a robust regulatory framework.

As outlined above, the establishment of a dedicated ARCTG/ARAT register with mandatory product registration (AUST C identifiers, batch validation, GACP/GMP compliance, and centralised product dossiers) would provide a clear and sustainable pathway for access to safe, quality-assured products. Once this framework is in place:

- CAP prescribers (Cannabinoid Approved Prescribers) would be able to prescribe any registered product directly.
- SAS/AP should be reserved for exceptional circumstances only, such as:
    - Access to investigational products undergoing clinical trials.

- Compassionate use where a product is not yet registered but may provide unique benefit.
- Transitional situations prior to the 1 January 2027 deadline for all products to be registered.

Restricting SAS/AP in this way would ensure that it remains a safety valve rather than the main channel of access. Patients and prescribers would be guided toward the regulated ARCTG/ARAT system, where quality, safety, and accountability are guaranteed.

This transition also aligns with international best practice. For example:

- New Zealand requires products to meet *minimum quality standards* before being available, with no broad SAS-style mechanism.
- Canada and Germany similarly restrict cannabis supply to products authorised under national regulatory frameworks, with compassionate access pathways available only in exceptional cases.

Q19 - Would you support a time-limited mechanism to allow sponsors to gather evidence?

Response: Novachem strongly supports restricting SAS/AP access to exceptional cases only. Currently SAS/AP has become the default, allowing products of variable quality and undermining public confidence. Establishing an ARCTG/ARAT register with mandatory product registration (AUST C IDs, batch validation, GACP/GMP compliance, central dossiers) would ensure safe, quality-assured access. CAP prescribers could prescribe any registered product directly; SAS/AP should apply only for investigational products, compassionate use, or transitional access before 1 Jan 2027. This keeps SAS/AP as a safety valve, not the main pathway, aligning with international best practice where NZ, Canada, and Germany restrict cannabis supply to registered products, with exceptions only in rare cases.

A time-limited mechanism may be appropriate during the transition period (2026–2027) to allow currently supplied products to remain available while sponsors gather the required data for ARCTG/ARAT registration. This should:

- Be strictly limited to products already in the market prior to 1 January 2026.
- Require evidence of progress toward ARCTG/ARAT registration within a defined timeframe.
- Expire fully once the 1 January 2027 deadline passes, at which point only registered products should remain accessible outside exceptional SAS/AP use (see Q18).

This approach ensures that patients retain access during the transition, while also driving sponsors toward full compliance with the new regulatory framework. It also encourages

investment in ARTG-level clinical trials, by making it clear that long-term efficacy claims require full therapeutic registration.

Once the framework is established, ARCTG registered products should be listed on ARCTG immediately they are reviewed. Successful registration of products prior to the 1 January 2027 deadline should allow practitioners access to the data and the ability to choose to engage with the products which are fully registered. This will encourage the early registration of products on the database and get sponsors, practitioners and distributors aligned on quality and safety.

Q20 - What do you consider to be an appropriate length of time to allow sponsors to gather sufficient clinical evidence?

Response: No fixed time limits should apply. The ARCTG/ARAT framework should provide a permanent pathway for registration based on quality and safety, ensuring patients and prescribers have confidence in product integrity even where efficacy data is not yet available.

Sponsors who wish to make efficacy claims for specific indications should do so via the ARTG process, which can apply its established clinical evidence standards and timelines.

This two-track approach avoids creating unnecessary barriers for products that are safe, consistent, and compliant, while still encouraging and rewarding sponsors who invest in clinical research.

Q21 - What potential scheduling amendments could address safety concerns?

Response: Under the current SUSMP (June 2025), cannabis is restricted under S9 and S8, while THC is classified as S8 for therapeutic use and CBD is primarily S4, with limited down-scheduling to S3 for ARTG registered low-dose products. Novachem proposes:

- THC: Maintain Schedule 8 status but introduce a formal daily maximum intake cap of 50 mg/day, adjusted for bioavailability and route of administration, to guide prescribers and mitigate misuse.
- CBD: Expand Schedule 3 to include ARCTG registered products up to 200 mg/day, while retaining Schedule 4 for higher-dose formulations and unregistered products.
- Other cannabinoids: Retain current cross-referencing to S8/S9 cannabis scheduling but introduce Appendix D or F warnings for compounds with psychoactivity (e.g., CBN), ensuring emerging cannabinoids are not exempted by omission.
- Vulnerable groups: Explicit protections should be embedded into scheduling entries and Appendix K (such as contraindications for children, pregnant/breastfeeding women, and psychiatric patients).

This approach balances alignment with the SUSMP framework while tightening quality and safety controls, consistent with the broader ARCTG regulatory pathway.

Q22 - Please provide your feedback on certain labelling requirements that could be implemented?

Response: Labelling for medicinal cannabis must be clear, standardised, and safety-focused, aligned with both TGO 91 and the SUSMP framework.

Building on our comments in Q3, Novachem proposes that labels should:

- Display ARCTG registration (AUST C number) prominently, providing patients and practitioners with assurance of regulatory oversight.
- Require batch Certificates of Analysis (CoAs) to be lodged with the TGA in a centralised system, with batch-specific compliance accessible via QR code or web link.
- Include mandatory dosage information, including maximum recommended daily dose and route of administration, aligned with the scheduling framework (see Q21).
- Carry contraindication statements for vulnerable groups, particularly children, pregnant and breastfeeding women, and patients with psychiatric illness (see Q15–Q16).
- Incorporate a Black Triangle Scheme information requirement for all cannabinoid medicines, indicating additional monitoring is required.
- Use generic packaging, restricted to a maximum of three colours, with only limited use of company logos, to avoid promotional branding.
- Conform fully to TGO 91 and SUSMP Appendix K warning statements, ensuring consistent national alignment.

This approach ensures labels communicate regulatory assurance, safe use instructions, and key risk warnings, while preventing promotional branding inconsistent with the therapeutic use of cannabis products.