Response to Consultation: Reviewing the safety and regulatory oversight of unapproved medicinal cannabis products

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Dear Mr Wiseman

Montu Group Pty Ltd (Montu) welcomes the Therapeutic Goods Administration's (TGA) consultation on the regulation of medicinal cannabis in Australia (TGA, 2025). As one of Australia's leading medicinal cannabis providers, Montu is committed to advancing safe, evidence-informed clinical practice while ensuring patients can access appropriate treatments without undue barriers. Montu's submission reflects the findings and recommendations of the *Roundtable on Supporting High-Quality, Evidence-Based Medicinal Cannabis Care in Australia*, chaired by Professor Ian Freckelton AO KC. The Roundtable brought together leading experts in - but not limited to - law, medicine, pharmacology, patient advocacy, and regulatory policy to design a pragmatic, data-driven framework for reform.

The existing Special Access Scheme Category B (SAS-B) and Authorised Prescriber (AP) pathways, originally intended as temporary mechanisms for exceptional supply of unapproved medicines, have evolved into the predominant access channels for medicinal cannabis. This transformation has resulted in inefficiencies, inconsistent oversight, and a persistent gap in evidence on safety and efficacy (Senate Community Affairs References Committee, 2020).

Montu supports the establishment of a single, nationally consistent prescriber authorisation framework, enhanced oversight of product quality through a "Declared Medicinal Cannabis Products" category, and the systematic extraction and analysis of de-identified electronic medical record (EMR) data to strengthen evidence and pharmacovigilance. Montu recommends consideration of a standardised "THC–CBD dose equivalence" model to improve safe prescribing, and adoption of a proportionate, evidence-based approach to managing public health risks – including cannabis-induced psychosis – that is grounded in high-quality evidence. In line with the hierarchy of evidence, this requires more than isolated case reports and must include robust data capable of establishing causation before any regulatory action is contemplated.

These reforms will ensure a modern regulatory framework that aligns with current clinical practice, supports robust evidence generation, protects patients, and maintains public trust.

About Montu

Founded in 2019, Montu is the largest medicinal cannabis company in Australia. Montu's mission has always been to facilitate greater access to and affordability of medicinal cannabis for patients who can potentially benefit from its therapeutic properties, as determined in consultation with qualified health professionals. Montu's 850 Australian staff span patient care, clinical education, ordering and distribution and are underpinned by our four brands:

- Alternaleaf: A patient-centric telehealth clinic;

- UMeds: A platform for patients across Australia to order medication from a network of pharmacies, with delivery;

- Leafio: A distributor of Montu-owned brands and sponsored products, supplying pharmacies with medicinal cannabis and related products, much like a pharmaceutical wholesaler, and;

- SAGED: A clinical education platform equipping healthcare professionals, including doctors, nurses, and pharmacists, with evidence-based medical information on cannabis therapies.

Having seen over 200,000 patients since its inception, Montu is dedicated to improving quality of life for Australians, by addressing barriers to access, affordability, awareness, and stigma. Our submission focuses on actionable reforms to improve access for more Australians who may benefit from medicinal cannabis, ensuring a patient-first approach within a robust regulatory framework.

Background

In 2016, the Australian Government amended the *Therapeutic Goods Act 1989* and associated regulations to enable access to medicinal cannabis products through the TGA's SAS-B and AP pathways (TGA, 2016). These mechanisms were intended for exceptional circumstances where patients had exhausted conventional treatment options, and where sufficient clinical justification existed for the use of an unapproved medicine.

Between 2017 and 2020, the prescribing of medicinal cannabis increased markedly (Arnold et al, 2020). These pathways, originally conceived as temporary or exceptional measures, became the primary route for access (Senate Community Affairs References Committee, 2020). This shift was accelerated by several developments:

- Growth of the medicinal cannabis sector
- Increasing clinical familiarity with cannabinoid therapeutics;
- Patient demand for treatments, once recognised therapeutic options have been exhausted;

- Expansion of telehealth services, particularly during the COVID-19 pandemic(Hall Dykgraaf et al, 2021).

Despite the rapid expansion of prescribing, most medicinal cannabis products remain unapproved under the Australian Register of Therapeutic Goods (ARTG), limiting the TGA's capacity to apply the same quality, safety, and efficacy standards as for registered medicines. The Senate Community Affairs References Committee (2020) noted that the absence of systematic data collection has impeded the development of a robust evidence base for clinical use, and recommended reforms to strengthen pharmacovigilance, improve practitioner education, and streamline access pathways.

In 2025, Montu facilitated the establishment of the *Roundtable on Supporting High-Quality, Evidence-Based Medicinal Cannabis Care in Australia*, chaired by Professor Ian Freckelton AO KC. The roundtable is made up of individuals from both academia and clinical practice, and the breadth of their expertise encompasses a wide range of disciplines relevant to improving the quality of medicinal cannabis care in Australia. These include addiction medicine, adolescent health, clinical pharmacology, consumer welfare and advocacy, data governance and ethics, epidemiology, general practice, health practitioner regulation, health and medicines policy, law, medical education, mental health, pain medicine, pharmacoepidemiology, pharmacovigilance, pharmacy practice, pregnancy alcohol and drug care, public health, real world evidence and data science and therapeutics regulation. Over a six month period, the roundtable has developed a comprehensive and evidence-based policy proposal that includes a number of recommendations for government (cf. for specific regulators). It has submitted its proposal as part of the TGA's consultation process and Montu fully supports the recommendations therein.

The TGA's current consultation on reviewing medicinal cannabis regulation (TGA, 2025) represents an opportunity to implement the practical aspects of the reforms from the Senate Inquiry and the recommendations from the roundtable in a manner that aligns with contemporary clinical practice, reduces administrative burden, and ensures proportionate, risk-based oversight.

Montu's Position on Key Issues

A. Real-World Evidence (RWE) via De-identified Electronic Medical Record (EMR) Data

Problem

Australia's medicinal cannabis market has expanded rapidly, yet there remains a lack of systematic, scalable evidence on long-term safety, efficacy, and patterns of use. While clinical trials remain the gold standard, they are costly, time-consuming, and often unable to capture diverse patient populations or real-world usage scenarios (Tang et al., 2023). Traditional clinical registries, while

valuable, face limitations such as high setup costs, administrative burden on clinicians, and slow adaptability to emerging clinical questions.

Recommendation

The TGA should support the extraction and analysis of de-identified EMR data through secure, accredited repositories. This should be done in partnership with healthcare providers, data custodians, and academic institutions to ensure methodological rigour and patient privacy. The resulting evidence should inform regulatory decision-making, product labelling, clinical guidelines, and public health policy.

Rationale

Montu supports the routine extraction and use of de-identified patient data from electronic medical records (EMRs) to build a continuous real-world evidence (RWE) base. This approach is consistent with contemporary health data strategies and aligns with privacy and data governance frameworks.

Secure, privacy-preserving infrastructures - such as the University of Melbourne's PATRON platform - provide a proven model for large-scale, multi-site EMR data analysis (Manski-Nankervis et al., 2024; University of Melbourne, 2024). These systems can integrate with primary care software, aggregate de-identified data across sites, and allow linkage to other datasets (e.g., PBS, MBS, hospital admissions). Such linkage enables deeper insight into medication adherence, adverse drug reaction signals, cost-effectiveness, and public health impact.

When augmented by advanced algorithms, RWE repositories can serve dual purposes: retrospective analysis for safety and efficacy, and real-time clinical decision support for prescribers. This supports early detection of safety signals such as cannabis dependence, neurodevelopmental impacts, or pregnancy-related contraindications - without imposing excessive burden on clinicians.

B. Education and Accreditation of Prescribers

Problem

There is currently no nationally consistent, accredited education framework for health practitioners prescribing medicinal cannabis in Australia. While prescribers are required to comply with the TGA's SAS or AP processes, there is no mandatory minimum training requirement under any federal law. Education offerings are fragmented, vary in quality, and are often without independent accreditation, leading to variability in baseline knowledge and prescribing practices. Lack of easily accessible reliable clinical guidance poses a risk to patient safety, particularly when prescribing unapproved therapeutic goods (Dobson et al, 2024).

The Senate Community Affairs References Committee (2020) recommended standardised, high-quality prescriber education to address this gap, noting that knowledge of the endocannabinoid system, cannabinoid pharmacology, and evidence-based prescribing principles is essential for safe practice.

Recommendation

Montu recommends the development and implementation of a national curriculum for medicinal cannabis prescribing that:

1. Aligns with Ahpra's National Prescribing Competencies Framework (previously under the auspices of the National Prescribing Service), to ensure prescribing is within scope of practice and underpinned by sound clinical reasoning (NPS, 2021).

2. Covers core curriculum areas:
    - Endocannabinoid system and cannabinoid pharmacology.
    - Evidence-based clinical indications, including levels of evidence for each condition.
    - Risk-benefit assessment, contraindications, drug interactions, and potential adverse effects.
    - Informed consent and shared decision-making with patients.
    - Regulatory requirements under the TGA and state/ territory legislation.
    - Safe prescribing, monitoring, and deprescribing principles.

3. Is modular, with clinical modules in areas such as pain management and mental health, allowing tailoring for general practitioners, specialists, nurse practitioners, and pharmacists.

4. Integrates into both undergraduate and postgraduate programs, with endorsement by relevant professional bodies such as the Royal Australian College of General Practitioners (RACGP) and the Pharmaceutical Society of Australia (PSA).

5. Is supported by ongoing CPD modules, ensuring practitioners remain updated with emerging evidence, new product categories, and evolving regulatory requirements.

Rationale

Standardising education will ensure that all prescribers operate with a minimum evidence-based competency, reducing unwarranted variation in practice. Embedding medicinal cannabis education in undergraduate programs will normalise its consideration as part of a broader therapeutic toolkit, while postgraduate and CPD offerings will ensure ongoing professional competence as evidence and regulations evolve.

C. Regulatory Status of Medicinal Cannabis Products and Reform of Prescriber Authorisation

Problem

As stated, the majority of medicinal cannabis products in Australia are accessed via the TGA's SAS-B and AP pathways and, over time, these mechanisms have become the primary access routes for medicinal cannabis, diverging from their intended temporary role. This has led to:

- Quality assurance gaps – most products are unapproved and have not undergone the full safety, efficacy, and quality evaluation required for ARTG registration.
- Pharmacovigilance challenges – limited post-market safety monitoring for unapproved products.
- Administrative inefficiencies – duplication of processes between the TGA and some state/territory health departments.
- Regulatory inconsistency – variation in prescriber authorisation requirements across jurisdictions.

Recommendation

Montu proposes two complementary reforms:

1. **Creation of a Declared Medicinal Cannabis Products category on the ARTG**

A new regulatory category specifically for medicinal cannabis products, loosely similar to the declared therapeutic vapes framework (TGA, 2024), would facilitate TGA having powers to:

- Require Good Manufacturing Practice (GMP) compliance.
- Mandate independent laboratory verification of cannabinoid content, contaminant absence, and batch consistency.
- Introduce standardised labelling, clearly stating cannabinoid content per unit dose in milligrams (mg), total package content, and dosage form.
- Require adverse event reporting and periodic safety updates.
- Be maintained on a publicly accessible national list administered by the TGA.

2. **Reform of Prescriber Authorisation**

Replace the current SAS-B and AP processes with a unified, nationally consistent single-step authorisation system for medicinal cannabis prescribers, which:

- Integrates prescriber registration, training completion, and jurisdictional approvals into one streamlined process.
- Operates similarly to annual medical registration endorsements.
- Links prescriber status to demonstrated completion of an accredited medicinal cannabis education program aligned with the National Prescribing Competencies Framework (NPS, 2021).
- Allows for proportional oversight - higher-risk products, such as those with higher amounts of THC per dose, could require additional safeguards.
- Eliminates duplication between federal and state/territory authorisation requirements.

Rationale

The proposed reforms would address both product quality and prescriber oversight. A Declared Products pathway ensures that products meet minimum quality, safety, and labelling standards without imposing the data requirements of full registration. A single national prescriber authorisation system would eliminate

inefficiencies, create a clear professional accountability framework, and support consistent, evidence-based prescribing.

These measures directly align with the TGA's current consultation on improving access pathways for medicinal cannabis (TGA, 2025) and the recommendations of the Senate Community Affairs References Committee (2020). Together, they provide a proportionate regulatory response that safeguards patient safety while ensuring continued access.

D. Dosing and Product Strength: THC Dose Equivalence

Problem

The way medicinal cannabis strength is currently described in Australia lacks standardisation and can cause confusion for prescribers, pharmacists, and patients. Presently, product descriptions may use cannabinoid ratios (e.g., THC:CBD), potency as a percentage of total cannabinoids, or the total milligram content of active constituents. These differences in labelling are compounded by inconsistent reporting between product formats (e.g., oils versus dried flower) and variations in jurisdictional conventions, both domestically and internationally (TGA, 2025a; Health Canada, 2023).

For example, a dried flower labelled "THC 20%" represents 200 mg of THC per gram of flower, whereas an oil with "100 mg/mL THC" represents a liquid formulation in which each millilitre contains 100 mg of THC. Without a common reference framework, clinicians face difficulty comparing potencies, determining dose equivalences across product types, and ensuring safe titration - particularly when switching patients between formulations (Freeman & Lorenzetti, 2020).

Montu has developed an explainer document which outlines the most common methods of describing medicinal cannabis strength, examines their clinical and regulatory implications, and explores options for standardisation. It is attached as Appendix 1 to this submission (Montu, 2025).

Recommendation

Montu recommends that the TGA investigates the viability of a THC/ CBD dose equivalence model, modelled on the opioid oral morphine equivalent (OME) system. This would require standardising the expression of THC and CBD content in milligrams of THC and CBD per standardised unit (e.g., per gram for flower, per mL for oil, per capsule for oral forms) and evidence-based dose-conversion guidance across product types.

Rationale

Such a model would:

- Improve safety by enabling prescribers to identify and avoid unintended high-dose exposures.
- Facilitate consistent patient counselling and informed consent.
- Support pharmacovigilance and post-market surveillance by enabling clearer signal detection for dose-related adverse events.

Standardised labelling should include both THC and CBD content in mg/unit, as well as percentage concentration, to enable use by both clinical and consumer audiences. This approach would align with international best practice and respond directly to safety concerns raised in the current TGA consultation (TGA, 2025).

E. Clarifying the Evidence Around Risk: Psychosis and THC

Problem

Public discourse and some regulatory commentary continue to emphasise a potential link between cannabis use and psychosis. While there is epidemiological evidence supporting an association between high-frequency, high-potency *recreational* cannabis use and increased psychosis risk, particularly with synthetic cannabinoids (Di Forti et al., 2019; Murray et al., 2017), there is insufficient data publicly available which specifically addresses the risk profile of medicinal cannabis prescribed within a regulated, clinical framework. The TGA's consultation paper notes concerns about high-THC products and mental health outcomes, but does not reference any data source for this.

Some stakeholders have called for a ban on all medicinal cannabis products with a high ratio (cf. potency) of THC, due to limited anecdotal case reports on ED presentations of drug-induced psychosis for patients who were concomitantly prescribed medicinal cannabis. The management of public health risks, including cannabis-induced psychosis, should be informed by a proportionate, evidence-based methodology. In accordance with established hierarchies of evidence, regulatory action should not be predicated on isolated case reports or anecdotal observations, but rather on high-quality, systematically collected data capable of demonstrating both association and causation specific to *medicinal* cannabis use (see Appendix 2 - Montu, 2025).

Recommendation

Montu recommends that the TGA:

- Require prescribers to follow risk mitigation protocols for patients with pre-existing psychiatric conditions, incorporating informed consent and documented clinical reasoning.
- Support longitudinal studies utilising real-world evidence (RWE) from de-identified electronic medical records to assess psychiatric adverse event incidence in patients using medicinal cannabis.
- Consider mechanisms for increased monitoring of adverse events in young adults (18-25 y.o.), such as a black box warning for medicinal cannabis in these patients to provide early warnings of psychotic disorders, which may be underdiagnosed in this group and thus fall outside of 'pre-existing psychosis'.

Rationale

Certain conditions - such as chemotherapy-induced nausea, multiple sclerosis spasticity, and refractory cancer pain - require THC-containing products for optimal therapeutic effect (Whiting et al., 2015; National Academies of Sciences, Engineering, and Medicine, 2017). An indiscriminate prohibition or severe

restriction of THC could harm patients whose symptoms cannot be adequately managed with CBD-only formulations. Furthermore, the existing psychosis literature often fails to control for critical confounding factors, such as concurrent substance use, underlying mental illness, and product type. By leveraging structured RWE systems, including linkages to PBS/MBS data, the TGA can consider a more accurate, indication-specific risk profile, thereby informing proportionate regulatory measures.

F. Conclusion

Montu strongly supports the TGA's initiative to review and reform Australia's regulatory framework for medicinal cannabis. The current reliance on the SAS-B and AP pathways - originally intended for exceptional access to unapproved medicines - has become unsustainable as these mechanisms have evolved into primary routes of supply. This shift has introduced inefficiencies, hindered evidence generation, and created inconsistencies in prescriber authorisation and product oversight.

Drawing upon the expert consensus of the Roundtable chaired by Professor Ian Freckelton AO KC, Montu proposes a coherent, evidence-informed regulatory model that aligns with contemporary clinical practice while maintaining high standards of safety and patient care. The core elements of this proposed reform include:

1. **Use of Real-World Evidence (RWE)** – Leveraging secure extraction of de-identified electronic medical record data, linked where appropriate to PBS/MBS datasets, to inform ongoing safety and effectiveness monitoring without imposing excessive administrative burden on clinicians.

2. **Unified Prescriber Authorisation Framework** – Replacing SAS-B and AP with a single, nationally consistent process integrating training, registration, and jurisdictional requirements.

3. **Appropriate Regulatory Oversight of Products** – Creating a "Declared Medicinal Cannabis Products" category on the ARTG to ensure GMP compliance, clear labelling, and pharmacovigilance without requiring full registration dossiers for every product.

4. **Nationally Consistent Education Standards** – Developing a comprehensive medicinal cannabis curriculum embedded into undergraduate, postgraduate, and continuing professional development (CPD) frameworks, aligned with the National Prescribing Competencies Framework.

5. **Standardised THC-CBD Dose Equivalence Model** – Exploring the viability of a labelling and dosing framework analogous to oral morphine equivalents in opioid prescribing, enabling safer and more consistent clinical practice.

6. **Evidence-Proportional Approach to Psychosis Risk** – Ensuring that policy decisions distinguish between recreational cannabis use and clinically

supervised medicinal use, with targeted safeguards rather than blanket restrictions on THC.

These reforms will better align regulatory oversight with the realities of clinical practice, address public health concerns proportionately, and maintain patient access to clinically indicated therapies. By integrating robust data collection, targeted education, and product oversight, the TGA can create a regulatory environment that is safe, sustainable, and supportive of high-quality patient care.

Montu looks forward to working closely with the TGA and other stakeholders to ensure that the next iteration of Australia's medicinal cannabis framework reflects the best available evidence, delivers genuine patient benefit, and supports the responsible growth of this important sector.

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Appendix 1

Explainer: Describing Medicinal Cannabis Strength

- Medicinal cannabis strength is described in multiple ways - ratios (e.g. THC:CBD), potency percentages, and total milligrams. This can lead to confusion, due to a lack of standardisation across product types and jurisdictions.
- The inconsistency in terminology can sometimes hinder safe prescribing, complicate patient education, and pose risks when switching products or interpreting prescriptions.
- This document outlines the most common methods of describing medicinal cannabis strength, as well as the category system the TGA uses for medicinal cannabis products, and how this categorisation can be misinterpreted as indicating total milligram content.

Describing the strength of medicinal cannabis is essential to ensuring both clinical appropriateness and patient safety. However, unlike standardised pharmaceutical products, medicinal cannabis formulations vary significantly in their cannabinoid profiles, leading to multiple ways of expressing "strength." These include cannabinoid ratios (e.g. THC:CBD), potency percentages, and total milligram content. Further complicating this are differing international and jurisdictional labelling practices, as well as the evolving nature of cannabis regulation and education globally.

This multiplicity of descriptors can lead to confusion among prescribers, pharmacists, patients, and the wider health sector. For instance, a product described as "THC 10%" could also be labelled as "100 mg/mL THC," depending on whether the formulation is an oil or a flower, or whether strength is reported by concentration or by dose unit. These inconsistencies may create barriers to safe prescribing and informed patient decision-making.

The need for clarity is further underscored by the complexity of the Australian medicinal cannabis market, where products are accessed through the TGA's Special Access Scheme (SAS) and Authorised Prescriber (AP) pathways. A lack of products approved by TGA may be a further barrier to access (Senate Community Affairs References Committee, 2020, p. 57). Some quarters are calling for a standardised vocabulary and method for describing strength to facilitate pharmacovigilance, dosing equivalence, and education, similar to how opioid dosages are standardised using oral morphine equivalent (OME) measures (ANZCA FPM, 2021).

This document outlines the most common methods of describing medicinal cannabis strength, examines their clinical and regulatory implications, and explores options for standardisation. The aim is to equip professionals with a consistent framework for interpreting product information, reducing the potential for medication errors and promoting best practice across prescribing, dispensing, and patient communication.

How Medicinal Cannabis Strength is Described

- **Ratios (e.g. THC:CBD)** express the balance between cannabinoids but do not indicate actual dose; clinical decisions require reference to specific THC and CBD quantities or percentages.
- **Potency (%)** describes the concentration of cannabinoids as a percentage of product weight (e.g. 15% THC = 150 mg THC per gram of dried flower); it's especially useful for comparing inhaled or topical products.
- **Total cannabinoid content (mg)** specifies the absolute amount of THC and/or CBD per unit (e.g. capsule, gummy, spray), and is the most clinically relevant measure for accurate dosing—similar to conventional medicines.
- **Patient tolerance** significantly influences safe dosing; cannabis-naïve patients require much lower doses than experienced users, making it essential to "start low and go slow" and consider individual use history when interpreting strength (TGA, 2025a).

1. **Cannabinoid ratios (e.g. THC:CBD):** Many cannabis products list a THC:CBD ratio to indicate the balance of the two main active cannabinoids. For example, a "20:1 CBD:THC" oil contains roughly 20 parts CBD for every 1 part THC. A 1:1 ratio means equal amounts of THC and CBD. High-THC products (e.g. 20:1 THC:CBD) are generally more psychoactive, while high-CBD products (e.g. 20:1 CBD:THC) may have milder effects. In practice, THC is considered the primary psychoactive component (Petrilli et al., 2023), and CBD is thought to modulate THC's effects (Hudson et al., 2019). Ratio labels are useful for quickly comparing formulations, but they do not convey the actual dose. (For example, a 1:1 product could be 2.5 mg + 2.5 mg or 25 mg + 25 mg.) Thus, clinical use requires looking at the actual cannabinoid quantities or percentages, not just the ratio.
2. **Potency (% of THC or CBD):** Potency is commonly reported as the percentage of product weight that is THC or CBD. For dried cannabis flower (herb), labels often state "THC 15%" (meaning 150 mg THC per gram). In many jurisdictions (e.g. Canada) product labels specify cannabinoid content per weight. For instance, "THC 180 mg/g" means the product is 18% THC, so 1 g contains 180 mg THC (Health Canada, 2023). Oils and tinctures usually list potency in mg/mL (which can be converted to % by weight, since 10 mg/mL ≈1% w/v). For example, an oil labelled 5 mg/mL THC is equivalent to 0.5% THC by weight. Potency percentages help

compare the strength of plant material or extracts, especially for inhaled or topical forms. Higher-percentage products are more potent and may require smaller doses (Leung et al., 2021).

3. **Total cannabinoid content (mg):** Besides percentages, cannabis medicines specify the total dose of THC and/or CBD in each unit or package. This is crucial for dosing. For example, an oral capsule might contain "THC 5 mg, CBD 5 mg" per tablet. Edible products list mg per piece and per package. If a package of 4 gummies says "THC per unit 2.5 mg, Total THC 10 mg," it means each piece has 2.5 mg THC and the whole package has 10 mg (Health Canada, 2023). Sublingual sprays or inhalers often specify "THC 2 mg per spray," etc. In general, labels will state the exact milligrams of each cannabinoid per dose or per container (*Sativex*, 2022). This mg-based approach is analogous to how other medicines are dosed (e.g. 5 mg morphine). Healthcare guidelines emphasise looking at mg content for accurate dosing (ACSQHC, 2016).

Other Relevant Factors

Patient tolerance and cannabis-naïve status: Individual response to a given strength varies widely. Cannabis-naïve patients (first-time or very infrequent users) are much more sensitive than tolerant patients. Australian guidance notes that a cannabis-naïve person often needs only 10–50% of the dose that an experienced user would take (TGA, 2025a). In other words, a long term treated patient's dose may overwhelm a new patient, so one must "start low and go slow" (TGA, 2025a). Patients who have regularly used cannabis can develop tolerance (and THC accumulates in fat) (Chayasirisobhon, S 2021), meaning they may require higher doses for effect. This is analogous to opioid tolerance: a long-term user of cannabis usually needs a larger strength or higher mg dose. Thus, when considering strength, clinicians always consider patient history. Tolerant patients might safely use products labelled with higher THC percentages or mg amounts, whereas naive patients should begin with very low doses (often a fraction of the labeled amount) and titrate up carefully (TGA, 2025a).

TGA categories by CBD percentage:

Category	Description (CBD percentage of total cannabinoids)	Schedule
1 – CBD medicinal	CBD ≥ 98% (essentially pure CBD; ≤2% other cannabinoids).	S4
2 – CBD dominant	CBD ≥ 60% and < 98% of total cannabinoids.	S8
3 – Balanced	CBD ≥ 40% and < 60% of total cannabinoids.	S8

4 – THC dominant	CBD 2%–<40%.	S8
5 – THC medicinal	CBD < 2%.	S8

Table 1. TGA medicinal cannabis product categories (by CBD proportion) (adapted from Therapeutic Goods Administration, 2025b). (Category 1 products are Schedule 4; Categories 2–5 are Schedule 8.) Each category is used for prescribing via the Special Access or Authorised Prescriber schemes, aligning with the product's dominant cannabinoid.

The TGA classifies unapproved medicinal cannabis into five categories based **only on the percentage of CBD in the product** (TGA, 2025b). Table 1 (above) summarises these categories.

It should be noted that while Category 5 is described by the TGA as 'THC medicinal', products are designated as Category 5 only on account of the percentage of total cannabinoids which is CBD content (<2%), rather than any consideration of THC content (TGA, 2025b). Both in theory and in practice, there are products which contain little THC in terms of total milligrams, but are designated Category 5 simply because they have only trace amounts of CBD or instead contain other cannabinoids such as cannabigerol (CBG) or cannabinol (CBN). Put another way, it is not a given that a Category 5 product has a high concentration of THC.

- **TGA categorisation is based solely on the proportion of CBD**, not the total strength or amount of THC in the product, which can lead to misunderstandings in clinical use (TGA, 2025b).
- **Five categories exist**, ranging from Category 1 (≥98% CBD, Schedule 4) to Category 5 (<2% CBD, Schedule 8), reflecting the CBD % relative to total cannabinoids - not potency.
- **All categories except Category 1 are Schedule 8**, meaning they contain psychoactive components, even if labelled as "CBD dominant" or "balanced."
- **Clinicians must review actual cannabinoid content (mg or %)**, as a product in a "CBD dominant" or "balanced" category may still contain significant THC levels, with associated psychoactive effects.

Towards a standardised dose ("morphine-equivalent") model: Unlike opioids (where morphine equivalents allow dose conversion between drugs), cannabis has no universally accepted standard dose. However, researchers have proposed using THC content as a common measure. For example, Freeman and Lorenzetti suggest a "standard THC unit" of

5 mg THC for any cannabis product (Freeman & Lorenzetti, 2020), analogous to a standard drink in alcohol. The idea is that one unit represents a typical psychoactive dose, helping clinicians and researchers compare doses across forms. This 5 mg figure is based on experimental and epidemiological data and the view that THC drives most effects (Freeman & Lorenzetti, 2020).

However, consensus on a cannabis equivalency model is far from settled. Critics note multiple challenges: cannabis contains many active compounds (CBD, THCV, etc.) not captured by a THC-only unit; products range from flowers to edibles to vapes; and individual patient factors (tolerance, genetics, concomitant meds) greatly affect response (Lorenzetti et al., 2023). In practice, current medical use relies on stating the actual THC and CBD doses. Ongoing efforts - such as the Index of Cannabis Equivalence - are exploring dose equivalencies across different administration routes and potencies (St. Pierre et al., 2025) . For now, healthcare professionals must interpret product strength by considering both THC and CBD mg amounts and patient factors, rather than relying on a single conversion factor.

Key takeaways: Medicinal cannabis strength is communicated via different metrics. Ratios (THC:CBD) describe composition, potency (%) gives concentration by weight, and mg content gives the absolute dose per unit. Patient tolerance (cannabis-naïve vs experienced) heavily influences effective dosing (TGA, 2025a). TGA classifies products into five CBD-based categories (TGA, 2025b). While a standardised dosing metric (like morphine equivalents) is attractive, complexities in cannabis chemistry and use mean that clear labeling of THC/CBD amounts per dose is currently the best practice (Health Canada, 2023).

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Appendix 2