Pharmaceutical Society of Australia

Senate Community Affairs Legislation Committee

Improving Access to Medicinal Cannabis Bill 2023

MAY 2023

Purpose of this submission

The Pharmaceutical Society of Australia (PSA) makes this submission to the Community Affairs Legislation Committee on the *Improving Access to Medicinal Cannabis Bill 2023* (the 'Bill'). PSA's submission and comments are based on the perspective and experience of pharmacists.

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 36,000 pharmacists working in all sectors and across all locations.

PSA is committed to supporting pharmacists in helping Australians to access quality, safe, equitable, efficient and effective health care. PSA believes the expertise of pharmacists can be better utilised to address the health care needs of all Australians.

PSA works to identify, unlock and advance opportunities for pharmacists to realise their full potential, to be appropriately recognised and fairly remunerated.

PSA has a strong and engaged membership base that provides high-quality health care and are the custodians for safe and effective medicine use for the Australian community.

PSA leads and supports innovative and evidence-based healthcare service delivery by pharmacists. PSA provides high-quality practitioner development and practice support to pharmacists and is the custodian of the professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy.

Comments on the Bill

PSA supports the use of cannabis for medicinal purposes with appropriate medical oversight and informed patient consent.

Since November 2016, unapproved medicinal cannabis products have been able to be legally accessed when prescribed by a prescriber with appropriate approvals via the Special Access Scheme and the Authorised Prescriber scheme.

PSA appreciates the efforts of governments and regulators to improve patient access to legally prescribed medicinal cannabis. It is important that patient access arrangements are clear and equitable, and also pose minimal administrative burden for prescribers and pharmacists.

Given the evolving nature of the evidence base for the use of cannabis for medicinal purposes, PSA supports investment into research to investigate the potential therapeutic benefits of cannabis in the Australian population to help inform any future policy.

PSA provides comments relating to the following aspects of the Bill:

- pathways to access unapproved medicinal cannabis
- cannabis-related entries in Schedule 3 and Schedule 4 of the Poisons Standard
- compliance with the Therapeutic Goods Order (TGO) 93.

Access to prescribed medicinal cannabis

- Cannabis, by its nature, possesses diverse chemical compositions. Medicinal cannabis is generally categorised by the proportion of active ingredients, primarily of two cannabinoid substances, cannabidiol (CBD) and tetrahydrocannabinol (THC). The two substances possess different pharmacological profiles which also influence the medical conditions they are most likely to benefit, albeit while evidence on their therapeutic effects continue to build.

- PSA understands that sponsors must provide to the Therapeutic Goods Administration (TGA) six-monthly reports of unapproved medicinal cannabis products supplied in Australia. Information on volumes, dose forms and quantities of products supplied by active ingredient category is collated, and also made available to support prescribers and pharmacists.

- The reported number of supplies by active ingredient category for the six-month period **1 July – 31 December 2022** was as follows:

Category	**Active ingredient** CBD = cannabidiol THC = tetrahydrocannabinol	**Number of supply entries**
1	CBD ≥ 98%	80
2	CBD dominant, ≥ 60% and < 98%	58
3	Balanced, CBD < 60% and ≥ 40%	54
4	THC dominant, THC 60–98%	23
5	THC > 98%	156

  This summary information suggests to PSA that Australian patients are being assessed, prescribed and able to access a range of medicinal cannabis products spanning the full spectrum of active ingredients, for different medical conditions.

- PSA understands the volume of medicinal cannabis prescriptions continues to increase. However, PSA has not received any information from pharmacists to indicate that patients are experiencing barriers to accessing prescribed medicinal cannabis, noting that procurement of unapproved medicines may take longer due to additional logistical steps.

- Given medicinal cannabis products are currently predominantly unapproved therapeutic goods, PSA continues to support the available patient access pathways — the Special Access Scheme (SAS) and the Authorised Prescriber (AP) scheme — which provide for a range of patient conditions and clinical circumstances. PSA also believes the operation of the schemes embed appropriate patient safety considerations and help to capture necessary information and data to improve knowledge of medicinal cannabis as a therapeutic option based on patient needs and preferences.

Cannabis entry in Schedule 4 of the Poisons Standard

- PSA understands the Bill proposes amendments to cannabis-related entries in the Poisons Standard which would allow the prescribing of medicinal cannabis by any medical practitioner or veterinarian.

- Current provisions allow for unapproved medicinal cannabis products to be prescribed by a healthcare practitioner who has been authorised under the SAS or the AP scheme, and for human use.

- As information about the evidence base of the use of medicinal cannabis (and most effective dosage forms and dosages) for different indications grows, PSA believes it may be appropriate that consideration is given to any amendments to scheduling and/or authorised prescriber types in the future. The therapeutic goods landscape may also change if more medicinal cannabis products meet the requirements for inclusion in the Australian Register of Therapeutic Goods (ARTG). However, at present, PSA believes it is premature to consider amending these factors given the relatively limited experience of prescribed medicinal cannabis use in Australia as well as the general reliance on unapproved products.

- In addition to informing future scheduling policy decisions, PSA would also highlight the importance of health professional access to new data or evolving evidence on medicinal cannabis use by Australian patients. Prescribers and pharmacists, in particular, must be kept informed to support contemporary clinical decision-making around therapeutic medicinal cannabis products to improve and refine health outcomes for patients. PSA would welcome the opportunity to work with regulators and government agencies to facilitate dissemination of information to pharmacists and provide up-to-date clinical articles.

Cannabis entry in Schedule 3 of the Poisons Standard

- PSA understands the Bill proposes to amend the Schedule 3 entry of cannabis in the Poisons Standard to provide for low-strength preparations to be made available over the counter at a pharmacy or veterinary practice for purchase by adults.

- The current Schedule 3 entry is specifically for cannabidiol, and also stipulates that the relevant preparation must be included in the ARTG. In practical terms, and irrespective of the strength of any product, PSA is unaware of any registered cannabidiol product for supply in Australia as a Schedule 3 (Pharmacist Only) medicine.

- Further, the current limits under Schedule 3 allow 2% or less of total cannabinoid content to be any cannabinoid (other than cannabidiol) of which tetrahydrocannabinol cannot exceed 1% of total cannabinoid content.

- The decision to create the Schedule 3 entry to allow access through a pharmacist (without a prescription) of low dose cannabidiol came into effect in 2021 following a comprehensive TGA safety review. PSA does not believe there is adequate new evidence or justification to amend this scheduling at this time.

Quality of medicinal cannabis products

- PSA is aware that any medicinal cannabis product imported into or supplied in Australia (or any plant or ingredient used in their manufacture) must comply with the ***Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017***. PSA believes TGO 93 has been appropriate in ensuring unapproved medicinal cannabis products procured and supplied to Australian patients are meeting agreed standards of quality, and therefore must be retained. In addition, PSA strongly supports a commitment to ongoing TGO 93 compliance monitoring and

recommends evaluation outcomes be used to review and refine TGO 93, if needed, as relevant data and information are acquired over time.

Summary

Recent regulatory reforms have helped to improve patient access to prescribed medicinal cannabis in Australia. While the reliance on unapproved medicinal cannabis products may not be ideal, the access pathways implemented benefit many patients. PSA supports the current arrangements but strongly suggests parameters such as scheduling, access pathways, authorised prescriber categories and quality product standards must continue to be monitored and evaluated. Support for health professionals, especially prescribers and pharmacists, must also be a priority to ensure best practice patient care based on available evidence can be implemented in a timely manner.

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