

Medicinal cannabis

June 2023

Summary

1. PSA supports investment into research to investigate the potential therapeutic benefits of cannabis in the Australian population to help inform any future policy on their use for medicinal purposes.
2. PSA does not support the recreational use of cannabis due to potential and known adverse effects. PSA supports pharmacists to deliver services to reduce harms from substance use and substance use disorders.
3. PSA supports the use of cannabis for medicinal purposes with appropriate medical oversight and informed patient consent. PSA advocates for policy-makers and regulators to work with the pharmacy profession to ensure rules that apply to patients using legally prescribed medicinal cannabis align with rules applicable to other legally prescribed medicines with similar therapeutic effect.
4. PSA advocates for national consistency in arrangements to access cannabis products for medicinal use by patients and to minimise administrative burden for prescribers and pharmacists.
5. PSA must be provided with opportunity and resources to partner with regulators in order to develop guidelines and practice support tools for pharmacists to assist in the provision of over-the-counter cannabidiol products.

1. Research investment needed

PSA supports investment into continuing research and research grants to investigate the potential therapeutic benefits and appropriate clinical use of cannabis in the Australian population. Research outcomes should be captured through an appropriate national evidence database or framework and inform any future policy on the use of cannabis for medicinal purposes. PSA believes particular focus on Schedule 3 cannabidiol products is important due to the change in access.

Australian production of cannabis products for medicinal use is evolving. Commonwealth legislation was amended in 2016 to permit cultivation, production and manufacture of cannabis products for medicinal use and research purposes.

PSA is aware that, as of June 2020, there were over 4,500 approvals granted for medicinal cannabis per month in Australia.¹ With the significant amount of medicinal cannabis use in this country, it is important to ensure there is evidence of health benefits related to these products.

Medicinal cannabis is not listed as first-line treatment for any health condition² although there is some evidence to support its efficacy in treating childhood epilepsy, muscle spasticity in multiple sclerosis and chemotherapy-induced nausea and vomiting.² This evidence is relatively limited³ and, by all accounts, there is still much to learn about medicinal cannabis products and their role in treating different ailments.

PSA believes that due to the limited evidence available, it is of utmost importance that research, and research grants are considered a priority to ensure the benefits of using medicinal cannabis clearly outweigh the risks. PSA also believes it is important to ensure immediate dissemination of evidence as it becomes available.

2. Pharmacist services to reduce harm from substance use

PSA does not support the recreational use of cannabis due to the potential for short-term and long-term adverse effects. Pharmacists are committed to delivering services and care to reduce harms from substance use and substance use disorders.

PSA is aware that use of non-prescribed cannabis, while being decriminalised in some jurisdictions, is not legal in Australia. There are reportedly around 600,000 people who use cannabis to self-medicate for conditions such as anxiety and chronic pain, with only about 3.9% of this population obtaining cannabis legally.⁴ The limited amount of legal cannabis use has largely been attributed to issues related to a lack of clarity surrounding access to these products, and that they are not listed on the Pharmaceutical Benefits Scheme, thereby rendering them cost prohibitive for many.⁵

PSA does not support the use of cannabis recreationally, or in a medicinal capacity without supervision of a health professional. The lack of oversight from a medical professional while using cannabis recreationally or medicinally may lead to poor health outcomes, and the non-pharmaceutical cannabis product being used may contain dangerous adulterants. Further, there may be issues related to interactions with other medications, and the possibility of a patient ceasing a medication with the belief they are successfully medicating themselves.

PSA remains committed to delivering education and services to patients and prescribers as a way of reducing harms related to substance use and substance use disorders.

3. Cannabis use for medicinal purposes

PSA supports the use of cannabis for medicinal purposes where a medical practitioner has established that the potential therapeutic benefits outweigh the risks. The patient and/or carer must provide informed consent, and there must be appropriate medical oversight and ongoing monitoring of outcomes. PSA advocates for policy-makers and regulators to work with the pharmacy profession to ensure rules that apply to patients using legally prescribed medicinal cannabis align with rules applicable to other legally prescribed medicines with similar therapeutic effect.

As mentioned previously, PSA notes that medicinal cannabis is not considered first-line therapy for any indication.² This is reflected in a recent statement made by the Australian and New Zealand Faculty of Pain Medicine, which submits there is a distinct lack of evidence supporting the benefits offered by cannabinoids in treating any kind of non-cancer pain.⁶ Despite this, there are reports that pain is the most commonly given reason for using cannabinoid products.⁴

However, PSA also notes that there is a significant and growing level of public interest surrounding medicinal cannabis, and this, along with the registration of cannabinoid products by the Therapeutic Goods Administration (TGA), means that prescribers may commonly receive requests to prescribe these products.

As with any health service provision and use of a medicinal substance, the patient has the right to consider available options and participate in shared decision-making. The patient must be fully informed about the limits of clinical use, evidence of effectiveness and safety, and therefore the possibility that the treatment may not provide the anticipated therapeutic benefits. This information is particularly relevant when they are accessing an unapproved product^{7,8} or an approved product for off-label use. Ensuring the patient is aware of these factors is of particular importance when considering the limited evidence in support of medicinal cannabis. While knowledge about the evidence base of medicinal cannabis therapy continues to grow, it is important that prescribers and pharmacists work closely with the patient and contribute to robust documentation when trialing dosages and refining treatments to build on available scientific information.

Medicinal cannabis products, by their nature, possess diverse chemical compositions and formulations. Despite the establishment of an appropriate regulatory framework to support legitimate medicinal access and use, PSA is aware there are some apparent policy anomalies which negatively impact on medicinal cannabis patients. Examples include the use of prescribed medicinal cannabis in the workplace or within educational institutions, and 'drug driving' rules. The latter issue has reportedly⁹ been particularly challenging for some current and prospective medicinal cannabis patients due to criminal penalties associated with the presence of tetrahydrocannabinol (THC) in the body, even if the person is not impaired while driving. This regulatory approach is not consistent with road safety rules that currently apply to other prescribed medicines that may cause impairment.

As with all medicines, prescribed cannabis is subject to patient safety and risk mitigation considerations, and any necessary controls or restrictions must be commensurate with risk posed by the substance in

the context of the broader range and classes of substances and their spectrum of risk. As a legitimate and growing therapeutic option, due consideration must be given, and necessary action taken, to ensure patients are not subject to unintended or inequitable consequences. It is paramount that patients who have been legally prescribed medicinal cannabis are supported accordingly, consistent with the prescriber's intentions, and to help achieve the patient's health goals.

4. National uniformity in access arrangements

Whilst acknowledging the sovereignties of states and territories, PSA advocates for national consistency in approval processes and patient access to cannabis products as well as administrative arrangements for prescribers and pharmacists. Where there are differences in arrangements between jurisdictions, clear guidance must be provided to prescribers and pharmacists on the legal mechanisms for accessing cannabis products and preparations for medicinal use.

The Australian Government through the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC) as well as the health departments of states and territories play a role in the regulation of cannabis. Ease of access to medicinal cannabis varies depending on the state or territory in which the patient resides. There are differences in requirements for different jurisdictions, including variations on who can prescribe medicinal cannabis products, documentation requirements, and patient populations who can obtain prescriptions.¹

Nationally uniform arrangements in medicines access will not only contribute to better patient care and understanding, there will also be benefits for health practitioners such as enabling more efficient and consistent service delivery and continuity of care through less burdensome administrative requirements.

5. Co-development of guidelines and practice support tools for pharmacists

PSA must be provided with opportunity and resources to partner with regulators in order to develop guidelines and practice support tools for pharmacists to assist in the provision of over-the-counter cannabidiol products. Given the novelty of Schedule 3 cannabidiol products, clear guidelines and training for pharmacists is of utmost importance.

TGA recently made the decision to classify some cannabinoid products as Schedule 3.¹⁰ As the peak body for pharmacists in Australia, PSA is an integral partner in the implementation of processes for access to over-the-counter products and preparations containing cannabis for medicinal purposes. PSA can assist at national and state/territory levels to provide advice on the impact regulatory arrangements may have on the practice of pharmacists as well as patient access to Schedule 3 cannabis and cannabinoid products and preparations.

PSA also has experience and expertise in developing practice standards and professional guidelines for pharmacists as well as education resources and practice support tools. PSA supports a collaborative approach in developing resources¹¹ and education programs for pharmacists in the dispensing of Schedule 3 cannabis-based therapies and disseminating information appropriate for patients, carers and prescribers. PSA is aware there are not yet any over-the-counter products available in Australia.

PSA believes funding must be provided in order to create resources to assist pharmacists in the safe and legal provision of over-the-counter cannabis products, particularly considering the novelty of over-the-counter cannabis products.

Supporting evidence/reference

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Updated statement approved by PSA National Executive June 2023