

## Senate Community Affairs References Committee

### *Inquiry into the current barriers to patient access to medicinal cannabis in Australia*

JAN  
2020

#### **Purpose of this submission**

The Pharmaceutical Society of Australia (PSA) makes this submission to the Senate Community Affairs References Committee (the 'Committee') on the [Inquiry into the current barriers to patient access to medicinal cannabis in Australia](#).

PSA's submission has been informed largely by its member pharmacists who have current or past experience in coordinating and supplying medicinal cannabis products to patients, and supporting patients and carers in navigating through the processes and arrangements.

#### **About PSA**

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 31,000 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.

## Terms of reference

According to the published terms of reference, the Committee will inquire into matters including:

- (a) the appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber Scheme and clinical trials;
- (b) the suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products;
- (c) the interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes;
- (d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access;
- (e) the availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients;
- (f) the education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications;
- (g) sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened;
- (h) delays in access, and the practice of product substitution, due to importation of medicinal cannabis and the shortage of Australian manufactured medicinal cannabis products;
- (i) the current status of the domestic regulated medicinal cannabis industry;
- (j) the impacts on the mental and physical wellbeing of those patients struggling to access medicinal cannabis through Australia's regulatory regime;
- (k) the particular barriers for those in rural and remote areas in accessing medicinal cannabis legally;
- (l) the significant financial barriers to accessing medicinal cannabis treatment;
- (m) the number of Australian patients continuing to rely on unregulated supply of medicinal cannabis due to access barriers and the impacts associated with that; and
- (n) any related matters.

## The professional practice of pharmacists

Pharmacists use their expertise in medicines to optimise health outcomes and minimise medication misadventure. Consistent with the [National Medicines Policy](#), pharmacists have a primary responsibility to contribute to the [quality use of medicines](#), to support the safe, appropriate, judicious and effective use of medicines.

Pharmacists provide health care, education and advice across all settings to promote good health and to reduce the incidence of illness. Pharmacists provide direct care to patients and also have a broader role in improving public health and optimal use of medicines in the community.

Medicines are the most common intervention in health care. Safe and appropriate use of medicines can help transform people's health, whether through, for example, curing infectious and other diseases, reducing likelihood of heart attacks or strokes, providing temporary relief from debilitating pain or numerous other positive impacts.

Pharmacists practise under a rigorous and robust professional and ethical framework which includes:

- Commonwealth, state and territory legislation
- [Pharmacy Board of Australia's](#) Registration Standards, codes and guidelines
- codes of ethics and codes of conduct (e.g. PSA's [Code of ethics for pharmacists](#))
- [National competency standards framework for pharmacists in Australia](#)
- professional practice / quality standards (e.g. PSA's [Professional practice standards](#))
- professional / practice guidelines.

A fundamental principle of professional ethics for pharmacists is that the health and wellbeing of the patient is their first priority and, using their medicines expertise, care is provided in a professional and compassionate manner.

## Current regulatory arrangements

PSA supports a rigorous but flexible national regulatory framework for the medicinal use of cannabis which can accommodate changes or enhancements in a timely manner as more information on the evidence of efficacy of cannabis and cannabinoids becomes available.

## Timeliness and clarity of processes

PSA supports uniformity in relation to access to cannabis products for medicinal use. Whilst acknowledging the sovereignties of the states and territories, PSA believes there should be, as far as practicable, national consistency in patient access to such products. National uniformity in access arrangements will minimise confusion (for patients, carers, prescribers, pharmacists and other health professionals), promote efficient processes to help deliver care in a timely manner and ensure equity of access by all patients.

PSA aims to support pharmacists by providing information on state or territory specific arrangements. However this is generally limited to providing links to medicinal cannabis sites for each jurisdiction or referring pharmacists to contact points within their state or territory. Maintaining currency of external hyperlinks on PSA's web site is an inefficient and onerous task and could be circumvented if there is national uniformity in regulatory arrangements and processes.

Given the unique or non-standard supply arrangements, it is vitally important that there is clarity of information for patients and carers on how to access medicinal cannabis products and to be engaged in shared decision making in an informed manner. This also means health professionals, specifically medical practitioners and pharmacists, need to be armed with the same information so that consistent and timely responses can be provided to support patients and carers.

PSA acknowledges the work that has been progressed through the TGA and the Office of Drug Control (ODC) to improve mechanisms and processes to enable access to unapproved therapeutic goods, including medicinal cannabis products. PSA is aware that approvals for applications to access unapproved medicinal cannabis products have been increasing through the Special Access Scheme pathway. Figures for Category B approvals only **reported** by the TGA were 331 in October 2018 and 3,404 in November 2019.

However, pharmacists feel that the available information is still onerous and not streamlined as well as it could be (see also **Box 1**). Just by way of example, a pharmacist (or other health professional) looking for information on accessing medicinal cannabis products may go to the TGA page, **Access to medicinal cannabis products**, then the **Special Access Scheme** page, including the **online system** which is intended to “reduce administrative burden on health practitioners” through a single application process for medical practitioners to apply to both the Commonwealth and relevant State or Territory Health Department (where applicable) – except this is not currently possible for Tasmanian prescribers.

It is also inefficient and complicated to have additional information on a **separate site**, through the ODC. Some information is duplicated with the TGA’s web site. Having to navigate between two parent sites and their respective web site pages is confusing, onerous and not user friendly.

**Box 2** is an example of the frustrations voiced recently by a pharmacist on the ground.

**Box 1: Feedback from a pharmacist regarding access arrangements**

*...Confusion still exists amongst prescribers and patients, for example, about how to access medicinal cannabis, the approval process (e.g. preparing the application and responding to requests for additional information), prescribing (particularly dose titration), monitoring and the need to re-apply for another product if the current prescribed product is out of stock.*

*...the process is not streamlined... ..it is very lengthy and time consuming for patients – waiting for the approval application, waiting for the product while it is being ordered [by] the pharmacy and then waiting again if a new approval needs to be applied for if the current medication they are using is out of stock...*

**Box 2: Feedback from a pharmacist regarding access arrangements for unapproved medicinal cannabis products**

*...the current pathway [to access an unapproved medicinal cannabis product] is complex and time consuming, often leaving patients waiting in stress due to the uncertainty of whether their application will be approved or not.*

*The current... ..pathway is very specialised, with limited numbers of prescribers choosing this treatment option, making patients feel like they are being judged upon previous medication usage (including illicit drug use) and treatment pathways as they must supply additional information to access the [medicinal cannabis] medication, whereas approved medicines that have a high potential of abuse do not have this requirement...*

Despite the efforts to broaden access to medicinal cannabis, some pharmacists were aware that, in some situations, the burdensome processes were so significant that they impacted negatively on patients who, with high acuity needs, end up accessing cannabis from 'illicit' pathways or the black market.

Pharmacists have observed that patients can become trapped in a cycle of illicit use. Some people have reportedly commenced illicit use of cannabis, often as a last resort, and found that it helped to manage their condition better and improved their overall quality of life. As they would prefer to access cannabis legally for medicinal use, the patients try to locate doctors who will consider prescribing medicinal cannabis. However, patients feel frustrated when they cannot find a medical practitioner who is either willing to prescribe or write a referral to another doctor who will consider medicinal cannabis for their therapy.

Pharmacists who have spoken to patients and medical practitioners also discovered that many doctors voiced concerns including, "I don't believe medicinal cannabis works" and "I don't want anything to do with unregistered medications", or that their clinic or practice preferred to not be associated with patients who could be regarded as exhibiting drug-seeking behaviour. When patients encounter barriers and misunderstandings such as these and are turned away multiple times, they then seek the illicit market despite their knowledge of the risks of their unlawful actions as they are desperate for therapeutic relief.

### **Appropriateness of current scheduling**

Evidence on the safety and efficacy of cannabis and cannabinoids for medicinal use is still limited and therefore the risk profile of individual substances is yet to be comprehensively established. PSA acknowledges the work of the Australian Government together with states and territories to coordinate trials and review of clinical evidence for the medicinal use of cannabis in various conditions. As the evidence base for cannabis and cannabinoids expands, this will help inform the complete risk profile of each substance and thereby consideration can be given to the most appropriate schedule for the substance.

PSA believes that a cannabinoid with low or no amounts of delta-9-tetrahydrocannabinol (THC) and therefore minimal or no psychoactive properties should be considered proactively for inclusion in Schedule 4 (Prescription Only Medicine) of the Poisons Standard.

Appropriate and timely scheduling decisions are important as they can impact on patient access, prescribing by medical practitioners, as well as arrangements for dispensing, handling, storage and disposal by pharmacists.

PSA also suggests that ongoing government investment in scientific research and conduct of trials in Australia will be critical in expanding our knowledge and evidence base for the medicinal use of cannabis for different clinical conditions or symptoms and patient groups.

### **Barriers to access**

PSA has received feedback from members that difficulties in accessing medicinal cannabis products have been experienced by patients and carers as well as pharmacists. Some of these issues are expanded on below. These factors impact on the ease and timeliness of access to therapy for patients and the ability for pharmacists to provide a healthcare service in a legal, timely and viable manner.

### **Procurement of products by pharmacists**

Pharmacists who have been involved in arranging for the procurement of cannabis products for medicinal use by patients have reported of a limited supply channel, cumbersome paperwork, delays in the arrival of orders, and substantial costs to patients and the pharmacy business (see also **Box 3**).

One pharmacist commented that the procurement of medicinal cannabis products is lengthy and delayed due to the extra time required to set up new accounts with wholesalers, ordering requirements (the need to have approval information prior to placing an order) and dispensing products in the pharmacy (additional time and resources required with regards to handling and correct storage).

Pharmacists have noted that resources about currently available medicinal cannabis products are limited particularly with unapproved therapeutic goods. This impacts on pharmacists who have reported of the need for numerous phone calls and emails (e.g. to wholesalers, pharmaceutical company representatives, online access and training portals) to facilitate procurement and access for patients. The 'unconventional' route of supply also adds to additional processes and resourcing.

Procurement of products through approved SAS applications must be handled individually i.e. details of each patient's approval must be supplied when placing the order – and this can be a time-consuming and cumbersome task and process for pharmacists.

Pharmacists have highlighted that delivery costs associated with the procurement of medicinal cannabis products can be significant, and there is variability in arrangements amongst wholesalers. At the higher end, the delivery fee may represent over 30% of the total cost of the order while some wholesalers may not charge a delivery fee if a large quantity of products is requested through a single order. Other wholesalers charge a Dangerous Drug (DD) handling fee to offset some of the costs associated with the special storage, delivery and inventory recording requirements of these products.

These fees, which cannot realistically be absorbed by the pharmacy business, are ultimately passed on to the patient. This creates negative perceptions or suspicion by patients and carers that the pharmacist is overcharging or exploiting their circumstances of ill health.

## Financial factors

The cost to pharmacists and pharmacy businesses was mentioned above.

PSA understands it is possible for a sponsor to implement a compassionate supply arrangement (i.e. the product is provided to the patient at reduced or no cost). However, PSA is not aware of how often or to what level this may occur.

Regarding costs to patients and carers, pharmacists highlighted that medicinal cannabis products are currently not recognised by private health insurers and therefore rebates are not available to patients. This often means the patient needs to consider and arrange a significant financial investment before proceeding with and commencing treatment and needs to also consider how their treatment can be funded on an ongoing, long-term basis.

### **Box 3: Feedback from a pharmacist regarding their experience with the procurement of a particular medicinal cannabis product**

*The supply of product 'X' is burdensome to pharmacists and intrusive to patients.*

*Patients are required to supply personal details to a commercial third-party prior to supply from the distributor to the pharmacy. This process... ..increases the risk of breaching patient privacy.*

*The paperwork burden [for the pharmacist] is high... ..and the price [is] fixed by the manufacturer/wholesale distributor. The product is purchased by the pharmacy at the same price as what the patient pays for it with a stipend fee being paid to the pharmacy about three months later. Commercially, this is not a viable way of [conducting] business for [the] supply of any medicinal product.*



The financial impact on the patient is also often compounded by the fact that they are only able to work part-time or are unable to work due to their state of health and requirement for treatment.

Clearly, pharmacists are aware that listing on the Pharmaceutical Benefits Scheme will improve affordability and allow more equitable access to medicinal cannabis products when clinically warranted by the patient.

## Geographical considerations

As with any healthcare service delivery in Australia, geographical considerations are important in the context of ensuring reasonable access to care for patients in rural and remote locations. Currently, it is likely that medical practitioners approved to prescribe medicinal cannabis are not as readily located in more rural locations with patients having to travel long distances. This may also apply to the collection of the dispensed medicinal cannabis product from the pharmacy.

PSA is aware that, in some cases, the pharmacist has been involved in teleconferences with the prescribing medical practitioner to facilitate interprofessional communication and improve the provision of care to the patient who has been prescribed medicinal cannabis.

The broader provision and funding of telehealth services have been suggested through the Medical Benefits Schedule Review Taskforce process. It is important to consider improved linkages to all members of the healthcare team through virtual environments. PSA has previously identified the need to embrace digital transformation to improve the quality use of medicines, to support the delivery of safe, effective and efficient health care, and to facilitate collaborative models of care.

## Supporting pharmacists

As medicines and medication management experts, pharmacists have a core role in assisting patients and carers in the supply of medicinal cannabis products, supporting them in the use of those products and monitoring therapeutic outcomes. It is important that pharmacists are appropriately supported and resourced with clinical information and practice support resources, and updated with any new information on access arrangements or the evidence base of therapies.

As the Australian Government-appointed peak health and advisory body for pharmacists, PSA has a core role in developing and delivering high quality professional education and training for the pharmacy profession. PSA is the largest provider in Australia of continuing professional development activities and implementation tools and resources to support the professional practice of pharmacists.

PSA has created an online medicinal cannabis resource hub for pharmacists (some content restricted to member pharmacists) which currently includes regulatory, education and practice support information. This was deemed necessary to support pharmacists in the absence of external coordination of consolidated resources.

The resources currently include those developed by PSA (solely or collaboratively with other partners) or refer pharmacists to relevant external content (see **Box 4**):

Broadly speaking, pharmacists have reflected that there is limited availability to easily accessible, concise information about access to medicinal cannabis products, and the role pharmacists can play in the supply and education of currently available products.

Pharmacists reported that sometimes available clinical information about a certain medicinal cannabis product is limited to what is developed by the grower, manufacturer or supplier of that product. Further it has been observed that such information is not necessarily tailored in the most useful or appropriate way for pharmacists.

PSA would welcome the opportunity to work with governments and other stakeholders to increase the scope and coordination of resources and reach of information to health professionals as well as patients and carers.

## Australian Advisory Council on the Medicinal Use of Cannabis

The pharmacy profession is represented on the Australian Advisory Council on the Medicinal Use of Cannabis (the 'Council') which has a role in providing advice to the Minister for Health on issues relating to the medicinal use of cannabis and the implementation of the regulatory scheme under the *Narcotic Drugs Act 1967*.

PSA is aware that the appointment of Council members for a second tenure was **announced** in June 2019. However, it is unclear what discussions or activities have been progressed as meeting communiques have not been available since March 2019.

## Summary

As with all therapeutic products, pharmacists have an important and integral role in supporting patients and carers in the supply, use and management of cannabis products for medicinal purposes. From the perspective of pharmacists, challenges have been experienced by patients, carers and health professionals in accessing medicinal cannabis products.

While acknowledging the current limited experience in therapeutic use and evidence base of medicinal cannabis products, PSA believes it is in the long term interests of Australian patients that governments continue to invest in research and trials and work with health professionals and patients to improve access arrangements.

PSA would welcome the opportunity to discuss or clarify details in this submission.

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### **Box 4: Examples of resources in PSA's medicinal cannabis resource hub for pharmacists**

- Online modules: [Cannabis and cannabinoids for medicinal use](#), [Current evidence for medicinal cannabis](#)
- TGA information: [Guidance for the use of medicinal cannabis in Australia](#), [Access to medicinal cannabis products in Australia](#), [Guidance documents for the use of medicinal cannabis](#), [Patient information sheet](#)
- [The Office of Drug Control](#)
- [Medicinal Cannabis Medicines Portal](#)
- [Cannabis Access Clinics](#)
- Medicinal cannabis product specific information: [Sativex](#) (including [Product Information](#) and [Consumer Medicine Information](#)), [NanaBis](#) (including [Consumer Medicine Information](#))