

Inquiry into Cannabis and Hemp

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Select Committee, which is inquiring and reporting on the potential to amend the current legislation and regulations which apply to cannabis and hemp in Western Australia, with particular reference to:

- a) the current barriers to pharmaceutical and nutraceutical use of cannabinoid products;
- b) medicinal cannabis, its prescription, availability and affordability; and
- c) the potential benefits and risks of permitting industrial hemp for human consumption.

About PSA

PSA is the only Australian Government-recognised peak national professional pharmacy organisation representing all of Australia's 35,000 pharmacists working in all sectors and across all locations. In Western Australia, there are approximately 3800 pharmacists registered with the Pharmacy Board of Australia.

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 healthcare 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.

Recommendation

Recommendation 1: Streamline the administrative requirements associated with medicinal cannabis products as a way to ease the burden on prescribers and pharmacists and improve access for patients.

Introduction

PSA notes reports that, in some medical conditions, cannabis has provided positive health outcomes to individuals who may not have experienced comparable benefits from other clinically proven medicines or conventional treatment protocols. Where under the treatment of a medical practitioner it is established that the potential therapeutic benefits outweigh the risks, PSA supports the use of medicinal cannabis with appropriate medical oversight.

Consistent with Australia's National Medicines Policy, the pharmacy profession supports timely access to medicines for all Australians, and pharmacists have a role in advocating for and supporting consumers and carers to access appropriate medicines. As such, PSA believes that access to medicinal cannabis should not cause unnecessary hardship or challenges for patients for whom this method of treatment is appropriate, safe and effective.

a) The current barriers to pharmaceutical and nutraceutical use of cannabinoid products

The TGA approved use and access to cannabinoids on the Pharmaceutical Benefits Scheme is limited to a single cannabidiol product for use in paediatric epilepsy. Patients who require alternative medicinal cannabinoids or need to use medicinal cannabinoids outside of this indication find access to be difficult to navigate. In addition, high fluctuating costs can prove cost prohibitive to the patient. Accessing proprietary medicinal cannabis products via the TGA Special Access Scheme (SAS) requires complex administration and labour intensive documentation for both the prescriber and pharmacist, impacting on patient care.

Nutraceutical cannabis products are not regulated by the TGA and do not require a prescription. This means some patients may opt for nutraceutical products rather than prescription cannabinoid products. This can result in sub-optimal management of medical conditions, potentially increasing the burden on the health system.

S3 Cannabidiol product availability

Despite the recent rescheduling of low dose cannabidiol to S3, there are currently no registered products available on the Australian market.

Prescription required from medical practitioner

Due to a lack of S3 cannabidiol products on the Australian market, all pharmaceutical cannabinoid products must be prescribed by a doctor. In Western Australia, prescribing usually falls to the general practitioner, placing additional strain on the primary healthcare system.

Paperwork is labour intensive and an administrative burden for health practitioners

When a medicine is not prescribed for a TGA approved use, in addition to completing TGA required documentation (SAS forms or authorised prescriber paperwork), an informed consent to use a medicine form needs to be completed by both the patient and prescriber. If the prescribed cannabinoid contains THC, then requirements outlined in the WA Health S8 prescribing code must also be followed. Longer appointments with prescribers are needed to complete all the paperwork resulting in fewer patients seen, which further increases the burden on the health system.

Pharmacies dispensing the prescription need to collate all relevant paperwork – including the SAS form (or authorised prescriber letter) and prescription. In line with regulations, only when all of the paperwork is collated can the medicine be ordered from the wholesaler. This means that patient treatment can be delayed for up to 2-10 days depending on the specific item prescribed and stock availability.

Cost and product availability

The cost of medicinal cannabis largely falls to the consumer. As all products are imported, availability, pricing and shipping can vary. This can also lead to instability in the range of standard products available to the prescriber, pharmacy and patient.

Delays in treatment

- Paperwork: Community pharmacies report delays in patient access to treatment if the paperwork supplied from the patient or prescriber is incomplete. From anecdotal discussions with prescribers, failure to submit all information to the TGA or TGA delays can also cause significant delays in treatment. Furthermore, in order to be prescribed S8 medicines, patients must also be reviewed by a second prescriber.
- For patients with paediatric epilepsy, where an alternative product is required outside of the PBS, treatment delays and access to a medicine may be impacted.
- Product ordering delays occur if the prescribed product is not available and new paperwork is required with the prescription for an alternative product. This also means time is wasted by the patient and non-billable time is required of the prescriber and pharmacist.

Recommendation 1: PSA recognises that many of the aforementioned barriers are unavoidable due to the relatively recent introduction of the therapeutic use of medicinal cannabinoid products. However, due to the extensive amount of paperwork required by WA Health and TGA, PSA suggests access to these products may be improved by streamlining certain processes. For example, if the patient informed consent form was merged with the S8 patient treatment contract, this would reduce the administrative burden, which may lead to improved access for patients.

b) Medicinal cannabis, its prescription, availability and affordability

There is significant community interest towards the use of medicinal cannabis products. The flow-on effect has been a steady increase in the number of prescriptions presented to community pharmacies for dispensing. The prescribing and supply of medicinal cannabis must meet both the Commonwealth and WA State government regulations.

Prescription

While any doctor in Western Australia is able to prescribe medicinal cannabis (subject to TGA and WA Health approval), the process can be confusing, labour intensive and time-consuming resulting in fewer doctors prescribing these products. Due to this lengthy and time-consuming process it can be difficult finding prescribers who are willing to prescribe medicinal cannabis. Anecdotally, some patients have needed to travel a significant distance to access a medicinal cannabis prescriber depending on their location.

Prescribers need to meet the Commonwealth guidelines for prescribing an 'unapproved' medicine which includes the TGA SAS form (unless an authorised prescriber) and informed consent form. For products that contain THC, WA Health requirements also include completing an S8 authority to prescribe form and patient treatment contract. This is all in addition to writing a prescription.

Recent TGA changes have streamlined the process for medicinal cannabis access by allowing prescriptions to be written for the active ingredient under a category based on cannabinoid content, as opposed to written by trade name. These changes mean new prescriptions may not be required if a product is unavailable, with pharmacists now able to substitute brands if required as long as the CBD/THC concentrations match those prescribed. It is yet to be known how these changes will affect access in any real sense with the changes only recently being initiated.

Availability

There may be difficulty gaining access to medicinal cannabinoid products in Western Australia with the cannabinoid industry in this state still in its infancy. There can be significant delays in accessing products from other states, particularly in light of the current situation with COVID-19 affecting many facets of the transport industry.

Accessing cannabinoid products from international suppliers can be more difficult still with wholesalers reporting a significant increase in the cost associated with global shipping, limited shipping avenues from some countries (such as USA and Japan) meaning these products are sometimes unable to be delivered or significantly delayed. Further, the cost associated with international products can vary significantly due to the exchange rate, causing frustration for both patients and suppliers. When considering the difficulty accessing international products, it is to be expected that more pressure is placed on Australian suppliers. However, due to limited Australian suppliers, product availability within Australia is uncertain and patients may need to change products or brands which can affect patient treatment.

Affordability

Not all medicinal cannabis prescribed in Australia is subsidised by the Pharmaceutical Benefits Scheme and as a result, there can be a significant cost imposed to the patient with this method of treatment. Further, there may be additional costs related to consultations with the prescriber which are not covered by Medicare. The cost of using medicinal cannabis varies widely and can range from around \$90 to \$400 per month dependent on the product prescribed and ingredients,

meaning the cost of this method of treatment can be prohibitive for many people. As noted previously, due to many products being imported from international suppliers, costs can vary significantly dependent on the current exchange rate. For the many people on fixed incomes, fluctuation in prices is unsustainable and can lead people to abandon medicinal cannabinoids as a treatment method, even if they are obtaining health benefits.

c) The potential benefits and risks of permitting industrial hemp for human consumption

Benefits

There are reportedly various benefits associated with human consumption of hemp, which may provide additional dietary nutrients.

Risks

Strict regulatory requirements related to monitoring and testing of hemp products is necessary to ensure there are no significant levels of CBD or THC in these products. If this testing is not done accurately, it is possible there may be health implications for people on medication due to the way CBD and THC act on enzymes which can then affect other medication.

It is important there are strict regulations surrounding any hemp products so as to separate these for food use as opposed to medicinal use. Anecdotal reports from pharmacists are that some patients are choosing to source hemp oil for therapeutic benefits such as pain relief. This leads to delays in these patients seeking medical attention for their condition resulting in poorer patient outcomes and management of chronic conditions. Further, it is necessary that the public is informed of the differences between hemp products (being those with negligible THC and CBD levels) and medicinal cannabinoid products so there is no confusion in this regard.

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23 December 2021