RE: Patient access to Medicinal Cannabis in South Australia

The Society of Hospital Pharmacists of Australia’s (SHPA) SA & NT Branch would like to express our appreciation to South Australian Department of Health and Ageing for their invitation to provide a submission to their consultation on patient access to medicinal cannabis.

SHPA is the national professional organisation with more than 4,000 pharmacists, pharmacist interns, students, technicians and associates working across Australia’s health system and are supported by Branches around the country.

SHPA members lead the Pharmacy Departments at all 29 of the principal referral hospitals in Australia, as well as the vast majority of both Public Acute A and Public Acute B hospitals, including the Royal Adelaide Hospital, Women’s and Children Hospital and Flinders Medical Centre. SHPA members are also employed in a range of innovative outreach and liaison services in community healthcare settings.

Hospital pharmacists provide care to the most unwell and complex patients who require specialist, innovative and new medicines that are often exclusively available in hospitals due to their specialised nature. SHPA anticipates that hospital pharmacists will oversee the clinical review and supply of medicinal cannabis to patients prescribed by specialists, in both the inpatient and outpatient setting, due to the limited literature and evidence base at present.

Indicate preferred option or describe alternative

Of the options that are presented in the discussion paper, SHPA broadly supports Option 3. This option recognises that medicinal cannabis is a new and emerging treatment in Australia, warranting appropriate monitoring by authorities in public interest, and also can help to abate diversion in the community.

Option 3 also aligns with intentions to have national consistency with respect to scheduling of medicinal cannabis which can improve understanding amongst clinicians and not cause confusion which can often be a barrier to treatment.

1. Should a medical practitioner be required to hold a section 18A authority before prescribing an unregistered schedule 8 medicinal cannabis product?

Yes. In recognition of the specialised and unique nature of medicinal cannabis in the setting of limited literature, it is appropriate for a medical practitioner be required to hold a
section 18A authority before prescribing and supplying an unregistered Schedule 8 medicinal cannabis product, such that the South Australian government is able to oversee and keep track of all prescribing and supply of medicinal cannabis.

This will also help the South Australian government to systematically collect clinical and population data to enable different health and hospital networks to compare data, and empowering the South Australian government to evaluate medicinal cannabis use across the state to inform future policy.

Unlike other Schedule 8 medicines which have established clinical efficacy profiles for similar indications, medicinal cannabis is unique in several ways. The evidence base for medicinal cannabis is still evolving and it is expected that the literature and evidence pertaining to use of medicinal cannabis will increase greatly in the short to medium term future. Clinically, medicinal cannabis will be used to treat a variety of serious health conditions that span disciplines such as oncology, neurology, auto-immune disorders and chronic pain. The medicine forms and routes of administration for medicinal cannabis will also be different to most Schedule 8 medicines which are injected medicines or oral tablets and capsules.

These differences create more incentive to ensure that the prescribing and supply arrangements for medicinal cannabis are appropriately gathered for analysis and review to inform future policy.

2. Should a medical practitioner be required to hold a section 18A authority before prescribing an unregistered schedule 8 medicinal cannabis product for patients over 70 years of age and Notified Palliative Care Patients?

Yes. SHPA supports the desire for consistency to the national scheduling to medicinal cannabis and believe the exemptions with respect to the medical practitioner holding a section 18A authority for patients over 70 years of age and Notified Palliative Care Patients should not apply for medicinal cannabis.

The role of the expert advisory panel in assessing individual patient applications for use of medicinal cannabis will be crucial to the success of its implementation. The discussion paper does not specifically mention what type of clinical information, or the extent of evidence (subjective and objective) that conventional treatment was unsuccessful, that is required by the expert advisory panel for clinical assessment. It is also silent on the timeframes for assessment by the expert advisory panel, and whether the applications will be done electronically (preferred) or be paper-based. It is important that this process does not impede timely access to medicinal cannabis, which currently is a last line treatment for some serious conditions where time is of the essence.

3. Should there be consideration of a provision for a general practitioner to be able to hold a section 18A authority to continue treatment initiated and overseen by a specialist medical practitioner?

SHPA believes that at this point in time, it is not appropriate for medicinal cannabis to be accessed in the community through general practitioners at any stage of treatment. As noted above, medicinal cannabis is an emerging treatment that is at its infancy in the medical sector. However it also has the risk of diversion due to its use recreationally, which could
cause issues and attract unwanted attention to general practices that prescribe and/or supply medicinal cannabis.

Furthermore, for a treatment where the literature and evidence base is only starting to build, it is imperative for the South Australian government to regulate and be custodians of medicinal cannabis in its state. As mentioned above, this will enable the South Australian government to systematically gather clinical and population data with a decent population size for evaluation and contribute to the literature. Allowing general practitioners to prescribe medicinal cannabis, even for maintenance therapy, at this premature stage of medicinal cannabis treatments, would not allow for such data to be collected in a systematic and timely manner that is also consistent in its reporting.

Hospital pharmacists operate at the highest levels of clinical pharmacy and are a critical part of the multidisciplinary healthcare team. SHPA believes that the prescribing, supply of medicinal cannabis and the care provided to patients using medicinal cannabis, should be limited to hospital outpatient clinics where hospital medical officers are able to prescribe medicinal cannabis under the guidance of specialists. In this approach high pharmacy standards of dispensing and patient counselling can also be maintained.

We are aware that not authorising general practitioners may limit initial access to medicinal cannabis, especially for patients in rural and regional areas. We believe at this early stage, this is justified due to public health and safety, and data collection requirements. It is anticipated that broader prescribing rights may be extended as the literature and evidence base grows. In the short to medium term, we support the extension of patient access transport schemes for patients in rural and regional areas to attend hospitals and outpatient clinics.

4. Should there be different requirements (compared with the usual requirements that apply to sale or supply of drugs of dependence) for pharmacists in relation to dispensing medicinal cannabis on prescription or supplying medicinal cannabis on order and recording such supply? If so, please detail what requirements should apply.

No. SHPA believes that the current requirements pertaining to dispensing, supply and recording of drugs of dependence are appropriate to mitigate the risks of diversion for medicinal cannabis. Hospital pharmacies have the appropriate infrastructure to store, manufacture and reconstitute medicinal cannabis products in a regulated and controlled environment.

Hospitals generally carry, supply and administer much higher amounts of drugs of dependence compared to community-based health service facilities. Hospitals and hospital pharmacies also must seek accreditation from the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme and are assessed against the National Standards for Quality Health Service (NSQHS) Standards.

Hospital pharmacies already have rigorous policies in place to appropriately manage drugs of dependence to ensure continuing accreditation. Hospital pharmacies also invest in new technologies and electronic medication storage solutions such as Pyxis MedStation™ to manage their inventories. Thus, any further or different requirements for pharmacists in relation to medicinal cannabis would only create variation and potential confusion. This adds
to the administrative burden and red tape for hospital pharmacists and detract them from
providing clinical care to patients at the coalface.

5. Should there be different requirements (compared with the usual requirements that apply to administration and supply of drugs of dependence) for recording administration or supply of medicinal cannabis by a registered health practitioner, including when the drug is administered in a health service facility? If so, please detail what requirements should apply.

As stated earlier, SHPA believes that health service facilities that undergo accreditation through the AHSSQA Scheme are able to appropriately manage and monitor the use of drugs of dependence without introducing extra requirements for medicinal cannabis. However, SHPA is cognisant that the NSQHS Standards only apply to hospitals, day service facilities and public dental services.

It is anticipated that there will be patients being treated with medicinal cannabis in other setting such as aged care facilities, rehabilitation facilities, and transition care facilities. These facilities are subject to different standards depending on the jurisdiction, and whether they are funded by the Commonwealth or jurisdictional government. For example, nurses in hospitals are all Registered Nurses (RN), whereas in aged care facilities, there is often only one RN who is the Director of Nursing, and the rest of the nursing team is comprised of Enrolled Nurses and nursing aides. As such, the South Australian government should be aware of the type of facilities and the healthcare workers and instil appropriate safeguards for them to handle medicinal cannabis and minimise risk of diversion.

6. Should there be different requirements for the destruction of medicinal cannabis products? If so, what requirements should apply?

No. The current administrative requirements pertaining to destruction of drugs of dependence are appropriate for medicinal cannabis.

However, as noted earlier, SHPA anticipates that dosage forms of medicinal cannabis will be different to other drugs of dependence, and it is expected that pharmacists will query how to adequately destroy certain dosage forms, such as inhaled medicinal cannabis. SHPA is able to provide advice to the South Australian government on this matter if required.

7. Are there any factors unique to medicinal cannabis products that need to be taken into account in relation to the storage and transport requirements for these products? If so, please provide details of any relevant factors.

A unique factor about medicinal cannabis is that it is already a widely used drug amongst recreational drug users, and hence the risks of diversion are greater than other drugs of dependence. However, hospital pharmacies have the appropriate infrastructure, technology and policies to mitigate the risks of diversion appropriately, and should be used as a benchmark for any other healthcare settings in future that may procure and store medicinal cannabis.
8. Are there any other matters that need to be considered in developing the access pathway? If so, please provide details.

SHPA notes that the South Australian government has observer status for the medicinal cannabis trials being conducted in New South Wales. The discussion paper is silent on whether the regulatory controls and requirements for treatment with medicinal cannabis will differ if it is prescribed to clinical trials patients. SHPA would appreciate advice on this matter.

As noted in the proposed approval process for medicinal cannabis, a specialist medical practitioner that decides to prescribe an unregistered medicinal cannabis product for a patient will have to concurrently apply to the South Australian government for a section 18A authority, as well as to the Commonwealth Therapeutic Good Administration (TGA) to import and prescribe an unregistered medical product via the Special Access Scheme (SAS).

However, the SAS has two categories:

- Category A patients are defined as ‘persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment’
- Category B patients are all other patients that do not fit the Category A definition.

Category A patients only require retrospective notification by the prescriber to the TGA after it’s been supplied to the patient, whereas Category B patients require prospective approval by the TGA before the unregistered medical product can be supplied to the patient. Depending on the patient, the indication and the progression and severity of their condition, applications under the SAS for unregistered medicinal cannabis products can be either Category A or B.

SHPA believes it would be judicious for the South Australian government to deliberate on whether the access pathways will differ for South Australian patients depending on what SAS category they are under. Hospital pharmacies handle the majority of procurement of SAS products in Australia with supply and care being provided by hospital pharmacists, SHPA is willing to work with the South Australian government to provide practical advice on this matter.

If you would like to discuss the matters raised in our submission, please contact Johanna de Wever, General Manager, Advocacy & Leadership on 03 9486 0177 or jdewever@shpa.org.au.

Yours sincerely

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