Briefing Paper
Medicinal cannabis patient access reforms

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Medicinal cannabis patient access reforms

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Purpose: Investigate the potential for reform of the medicinal cannabis patient access regulatory framework in Australia. This paper presents three options which can be implemented separately or through a staged implementation approach.

Overall Strategy:

- Implement a new patient access framework to help ensure supply of acceptable quality products, ideally through an application pathway for approval as a prescription medicine on the Australian Register of Therapeutic Goods (ARTG) allowing products to progress to consideration for PBS listing.
- Shift the regulatory risk from 'prescriber' to the product 'sponsor'.

To achieve these objectives the proposal requires:

- Government support for changes to be made.
- A full open consultation process with all interested parties – patients, HCPs, peak bodies, industry, S&T governments.

Background and identified risks

- The legislative environment for cannabis in Australia is complex and largely focused on preventing illicit use and involves Commonwealth, State and Territory law, including the *Crimes Act 1914*, the *Criminal Code Act 1995*, the *Customs Act 1901* and the *Narcotic Drugs Act 1967*.

- In 2016, the medicinal cannabis patient access scheme was established with the aim to provide easy patient access with the responsibility for risk-management and product safety placed on the prescribing medicinal practitioner.

- At the time, the well-established Special Access Scheme (SAS) and Authorised Prescriber (AP) scheme provided provisions to meet consumer expectations for fast patient access aligned with the scheduling decisions of cannabidiol and tetrahydrocannabinol (THC).

- It was the expectation that the SAS and AP pathways would allow sponsors to collate the required quality, efficacy and safety data to support future ARTG registration.

- Since 2016, over 300,000 patients, including over 3,000 paediatric patients, have reported to have accessed an 'unapproved' medicinal cannabis product via the SAS and AP schemes. Access of medicinal cannabis products is pushing the boundaries of the intention of these schemes, which is primarily to provide access to goods for use in rare and extenuating circumstances where the patient has exhausted approved and available treatments in Australia, typically approved in overseas jurisdictions.

- SAS Category B approvals continue to rise at an increasing rate, with a 53% increase in approvals from 86,105 approvals in the 2020-21 financial year to 131,618 approvals in the 2021-22 financial year. More than 88% of all SAS Category B medicine applications in 2021 were for medicinal cannabis products. AP applications for medicinal cannabis applications also continue to soar with a 200% increase in approvals in 2021-22 financial year compared with 2020-21.

- The prolonged therapeutic use of 'unapproved' medicinal cannabis products, especially in the vulnerable paediatric population calls into question the appropriateness of the TGA to continue to place the risk of prescribing of these products with the medical profession whilst an unregulated industry continues to grow.

- Furthermore, the current framework does not support the pharmacovigilance system afforded to ARTG medicines. There is little scrutiny on whether the risk-benefit ratio remains favourable over time for patients who use them. This concern is especially relevant when it comes to long term use of THC containing products, especially in children, who are more vulnerable to the deleterious effects of this cannabinoid.

- Over the past 5 years, the TGA has made it clear that the primary goal for the medicinal cannabis industry should be to include their medicinal cannabis product/s in the ARTG. However, to date there are only two medicinal cannabis products included in the ARTG: Sativex (nabiximols) is approved for spasticity associated with multiple sclerosis; and Epidyolex (cannabidiol) has recently been approved for the treatment of seizures associated with Dravet's and Lennox-Gastaut syndromes. There are no further applications for ARTG registration in the pipeline.

- Further, despite the decision to down-schedule low dose cannabidiol to Schedule 3 when included in the ARTG in December 2020, no applications have been submitted to the TGA to include a low dose cannabidiol product in the ARTG.

- Use of the SAS and AP access schemes is well established in the medicinal cannabis industry and appetite to apply for ARTG registration appears low.

Potential options

1. Maintain status quo, but look to restructure team to manage increasing workload

Growth in SAS B and AP application rates is anticipated to continue at a high trajectory due to a thriving medicinal cannabis industry accustomed to utilising the unapproved access pathways, increasing confidence and familiarity of prescribers, increasing numbers of medicinal cannabis clinics, and growing patient awareness.

The Special Access Section has approximately 16 staff (and growing) dedicated full-time to managing medicinal cannabis applications, highlighting the large resourcing requirements for processing the high volume of SAS and AP approvals, sponsor and prescriber reporting reports and managing the high volume of correspondence related to medicinal cannabis access.

To manage the increase in SAS B and AP approvals, applications deemed 'low risk' (i.e. adult patients and for indications that have been previously approved) are 'bulk' approved.

Furthermore, recent IT enhancements to the online system to include a tick box functionality for prescribers to declare prior consideration of an ARTG therapy, calls into question the value of imposing the additional administrative burden on already overextended medical professionals.

Currently, there are no application fees or costs to applicants when accessing the SAS and AP schemes.

To manage the workload, two distinct workstreams, with nominated staff assigned to each, have been created within the Special Access Section: Workstream 1 - SAS and AP approvals for medicinal cannabis; and Workstream 2 - SAS and AP approvals for all other medicines and medical devices.

Consideration could be given to splitting the team, creating a Medicinal Cannabis team to manage SAS and AP approvals, but to also work with the Chief Medical Adviser on potential reforms for Government consideration.

2. Allow specified medicinal cannabis products for specified indications to be accessed via the SAS Category C notification pathway

Currently health practitioners seeking access to unapproved goods for patients who are not seriously ill (which would be supplied under SAS Category A) or for therapeutic goods without an established history of use (which would be supplied under SAS Category C) must apply to the TGA for approval under section 19(1)(a) of the *Therapeutic Goods Act 1989*. The current approval process requires the prescriber to provide patient and product details as well as a clinical justification for the use of the product. Each application is assessed by a TGA delegate and approved if it meets regulatory requirements.

There is precedent in New Zealand for the provision of unapproved goods through a notification only scheme. This option removes administrative barriers placed on prescribers in accessing medicines deemed appropriate for their patients and reduces TGA administrative burden in processing of SAS Category B applications. This would allow the TGA to focus on a compliance approach to the use of unapproved good, to identify deviations from safe prescribing practices and regulatory requirements.

Sensitivities

Regulation 12B(5) of the *Therapeutic Goods Regulations 1990* (the Regulations) stipulates that medicines included in Schedule 8, 9 or 10 are unable to be included in the Category C instrument. An alternative course may be to amend the Regulations to create a new notification pathway specific to medicinal cannabis products.

Patients may mistakenly be led to believe that unapproved medicinal cannabis products that they are accessing have been subjected to the same regulatory scrutiny by the TGA as other prescription medicines. State and territory requirements would still apply so doctors may still need to apply to state/territory health departments in many instances to prescribe medicinal cannabis products. However, this misunderstanding is likely a current issue as, anecdotally, we understand patients are reassured by the prescriber that the products are via the legal pathway but unaware that the products are 'unapproved'.

3. Creation of a new application pathway for inclusion in the ARTG

This option is for creation of a new pathway for ARTG registration specific to medicinal cannabis products and would place responsibility for the product with product sponsors rather than individual healthcare practitioners. It could also provide for fees and charges to be imposed on product applicants.

This pathway would impose requirements currently not mandatory for unapproved medicinal cannabis products. For example, requirements for GMP certification or equivalence to ensure standards of quality, labelling requirements for improved patient safety, and obligations for safety monitoring and reporting.

When designing a new pathway, there are a range of options as to the level and type of information and data applicants could be required to submit. For example, this could range from a 'Listed medicines' type of situation where a product is automatically 'Listed' provided the application passes the electronic validation rules in the on-line application system and the sponsor makes a number of electronic 'certifications'; a monograph type of application as seen with certain OTC medicines; through to full data packages requiring evaluation for product quality, safety and effectiveness, as is the case of prescription medicine applications.

Such an option would provide an opportunity for sponsors to apply for subsidisation through the PBAC/PBS, addressing another barrier to patient access.

This option represents a significant departure from the current Government policy for medicinal cannabis, however, has many advantages from a public health perspective including greater assurance of the quality, safety and efficacy of medicines supplied in Australia, provides for potential cost-recovery of TGA's work, and places the risk management for the products with sponsors rather than individual prescribers.