Access to Medicinal Cannabis in Australia: 03 November 2017

This paper provides information on access to medicinal cannabis in Australia.

The Current Situation in Australia

Patients can access medicinal cannabis in Australia with a doctor's prescription under two schemes: the Authorised Prescriber Scheme (APS) and the Special Access Scheme (SAS). Medicinal cannabis can also be accessed through clinical trials. The doctor must apply to the Federal regulator, the Therapeutic Goods Administration (TGA), for permission to prescribe cannabis under these schemes. In addition to the Federal requirements, some states also require the doctor to have a State-level approval. For example, New South Wales (NSW) requires doctors to have approval from the TGA and from NSW Health before they can prescribe medicinal cannabis. Further information is provided below.

Background on Australia's medicines framework

Australia requires most therapeutic goods to be evaluated for quality, safety, and efficacy, and be included on the Australian Register of Therapeutic Goods (ARTG), before they can be prescribed. The Therapeutic Goods Administration (TGA) administers the ARTG. Products that have not gone through this process, or were not approved, may be prescribed through the APS and SAS schemes.

How do the access schemes work?

Authorised Prescriber Scheme

The Authorised Prescriber Scheme (APS) allows a doctor to prescribe a therapeutic good that is not approved by the TGA to a class of patients with a particular medical condition (i.e. Multiple Sclerosis). A doctor can become an 'Authorised Prescriber' by applying to the human research ethics committee (HREC) or getting an endorsement from a specialist college. In their application, they must include their clinical justification for prescribing the product. This could include explaining why they are prescribing the product, addressing the potential harms and benefits, and providing supporting scientific evidence. The doctor also needs approval from the TGA to be an Authorised Prescriber.

The doctors must be knowledgeable about the use of medicinal cannabis products and follow an approved protocol, but once authorised, can operate with no further oversight. However, uptake is slow with 29 Authorised Prescribers to date, with four applications pending. Once the doctor becomes an Authorised Prescriber, they do not need to seek approval for an individual patient with that condition. They do not need to notify the TGA when they prescribe, but they must report to the TGA the number of patients they treated on a six monthly basis.

Special Access Scheme

The Special Access Scheme (SAS) allows the import or supply of an unapproved therapeutic good for a single patient on a case by case basis. There are three pathways available, which can be used by health practitioners.

The first pathway (Category A) allows medical practitioners to access and prescribe unapproved products to patients who are terminally ill. Medical practitioners must notify the TGA.

The second pathway (Category B) allows health practitioners (usually approvals are only issued to medical practitioners and dentists) to apply for approval to the TGA to use unapproved goods that do not have an established history of use. The TGA must provide an approval letter before the doctor issues the prescription.

The third pathway (Category C) allows a health practitioner to supply goods that have an established history of use without having prior approval and is not applicable to medicinal cannabis.

Cultivation

The Australians established a national regulatory framework for cultivation, under the Narcotic Drugs Act 1967. Some states also have legislation to regulate the cultivation of cannabis.
The Act was amended to do the following:

- Set up the Commonwealth Office of Drug Control (ODC) to oversee cultivation. This ensured that Australia complied with their obligations under the UN Drug Conventions. Australia is a signatory to the United Nations Single Convention on Narcotic Drugs 1961 (the Single Convention). This convention requires signatories to set up an agency to oversee the cultivation of cannabis for medicinal purposes.
- Establish a licensing and permit scheme for the cultivation and production of cannabis for medicinal and scientific purposes, and the manufacture of drugs covered by the Single Convention;
- Provide monitoring, inspection, and enforcement powers.

The Narcotic Drugs Amendment Act 2016 has been fully implemented, and 22 licenses have been granted to around 10 companies. 10 were granted for cultivation for medicinal purposes, 6 for research cultivation, and 6 for manufacture. **Australia does not expect local product to be available until next year.**

How does the cultivation legislation work in practice?
The ODC issues medicinal cannabis licenses under the Narcotic Drugs Act 1967:

- Cultivation (growing) of medicinal cannabis
- Harvest of cannabis resin
- Manufacture of medicinal cannabis.

Cannabis can only be cultivated to supply a person or organization that is licensed to produce or manufacture medicinal cannabis. The ODC has set out minimum quality requirements in a Therapeutic Goods Order that all producers must comply with. For instance, contaminant levels must be under the limit set in the Order.

How will Australian patients access cannabis cultivated in Australia?
When a domestic supply is available, Australian patients will be able to access cannabis with a doctor's prescription. Applications to prescribe these products will continue to go through the Special Access Scheme B or the Authorised Prescriber pathway.

Description	Discussion Points	Questions for the Minister
1. Cultivation and Manufacture		
Implementing the Narcotic Drugs Amendment Act 2016, which allowed domestic cultivation, took approximately 18 months. Key dates included: • drafting commenced in September 2015 • legislation received Royal Assent on 29 February 2017 • local product is expected to be available in 2018. Both licenses (allowing cultivation and manufacture) and permits (providing specific details) are required for cannabis cultivation. Although Australia has issued 22 licenses, they have only issued 5 permits to date.	Despite the high priority placed on developing a domestic supply, the Australian example illustrates that it takes time to develop, implement, and produce product under a new scheme. New Zealand would need to set up an agency to oversee cultivation in order to be compliant with United Nations conventions.	*Allowing cultivation of cannabis, and producing a supply to an approved manufacturing standard will take time. Is there an expectation to have a supply available sooner?*

None of the permits are for manufacturing. Currently Australia has a ban on exporting products. They expect to be able to export early next year, but currently it is not known whether they will have domestic production ready for export at that time.		
2. Clinical trials		
New South Wales are undergoing clinical trials in three areas (epilepsy, palliative care, and chemotherapy induced nausea) to explore the use of cannabis products. The adult clinical trials are underway in the pilot phase, with the aim to include more patients in the definitive stage in 2018, depending on results. No published data has been released to date. 1) *Children with severe, drug-resistant epilepsy* This trial is through a partnership with the Sydney's Children's Hospitals Network. This uses a novel cannabinoid, cannabidivarin. This is expected to begin in early 2018. 2) *Adult palliative care patients* This focuses on quality of life, particularly appetite and the appetite-related symptoms. Stage one is underway, which involves around 30 patients. This looks at whether the product can be used through a vaporiser, if the product is well tolerated by patients, or causes side effects, and what the ideal dose is. The second part may enrol up to 250 patients, and will explore the effect on appetite, quality of life, and the impact on other cancer-related symptoms. 3) *Adults with chemotherapy-induced nausea and vomiting*, where standard treatment is ineffective. This trial has been underway since December/January. This is in stage one, which involves around 80 patients. The larger trial	Clinical trials provide a pathway to increase access for patients, outside the usual pathway. There is one clinical trial underway in New Zealand a cannabis gel for adult epilepsy.	*How would introduction of further clinical trials be funded?*

involving around 250 patients will start next year. Clinical trials in other states are also planned or underway.		
3. Compassionate access		
New South Wales has a Medicinal Cannabis Compassionate Use Scheme for terminally ill patients that allows possession of specified amounts of cannabis. The Scheme provides guidance for NSW police officers when using their discretion to charge (or not) adults with a terminal illness who use cannabis to alleviate their symptoms. It is not a legislated scheme. The Scheme was designed as an interim measure introduced when there was no legal pathway to access medicinal cannabis via a doctor. The Scheme was intended to be used while more robust efficacy data for cannabis use by terminally ill patients was sought via clinical trials.	The main criticism of the Scheme is that there is no legitimate supply route for patients who register. Patients must source their own product. The Scheme has also been criticised as being too narrow in terms of eligible patient groups. A review was undertaken in the second half of 2016 looking at the value of the Scheme, whether eligibility should be extended to other patient groups (including children) and whether the maximum amounts should be increased.	*What is your view on the idea that patients who are terminally ill could be treated differently to other patient groups?*