



Australian Government

Department of Health

Submission to the
Senate Community Affairs References Committee

Senate inquiry into the current barriers to
patient access to medicinal cannabis in
Australia

January 2020

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Executive Summary

It is the policy of the Australian Government to treat medicinal cannabis products as medicines, subject to the same regulatory framework and strict standards of safety, quality and efficacy as all other medicines. In recent years, the Australian Government has taken a number of steps to improve patient access to medicinal cannabis products.

Australia's approach to the cultivation and manufacture of medicinal cannabis, is also consistent with our obligations as a signatory to the United Nations Single Convention on Narcotic Drugs.

As at 31 December 2019 the Department of Health, through the Office of Drug Control had granted 100 licences to cultivate, produce and/or manufacture medicinal cannabis, 92 of which are currently in effect. This includes 31 licences for cultivation of cannabis for medicinal use, 20 for cultivation for research, and 41 for manufacture of medicinal cannabis products. Further, licence holders with appropriate permits are, collectively, authorised to annually produce in excess of 35,000kg of medicinal cannabis (dry flower).

Approximately 30,000 approvals to access (which roughly equate to prescription numbers) for medicinal cannabis products have been written in Australia in the period to the end of 2019. Even if there were no increase to the current rates of prescribing, by the end of 2020, about 70,000 prescriptions are anticipated to have been written in Australia.

More than 18,000 patients have been approved to access medicinal cannabis products in Australia, with most access to medicinal cannabis products occurring since 2016. This follows the rescheduling of cannabis, tetrahydrocannabinol (THC) and cannabidiol (CBD) for human therapeutic use in the Poisons Standard. More than 1400 individual medical practitioners, in every state and territory have received approvals to prescribe medicinal cannabis for patients to treat more than 130 different medical conditions.

To date applications for 130-plus different medicinal cannabis products have been approved via existing unapproved access pathways, chiefly through the Therapeutic Goods Administration (TGA) Special Access Scheme Category B (SAS B). SAS B decisions for medicinal cannabis are, on average, made within 30 hours of submission. Only 5% of SAS B applications required further information to be provided from the prescriber in 2019.

In many instances additional state or territory authorisation has been required in order to access medicinal cannabis products (such as when they are Schedule 8 controlled drugs). The TGA (part of the Department of Health) has implemented a streamlined application portal, the SAS Online System, which enables simultaneous submission of applications to the Commonwealth and relevant state or territory health department. All states and territories except Tasmania are participating in this system and applications are processed within two working days. More than 90% of medicinal cannabis applications are now processed through the SAS Online System.

Domestic production of medicinal cannabis is also increasing. As at 11 December 2019, there are 87 licences to cultivate, produce and/or manufacture medicinal cannabis in effect in Australia. Those licence holders are collectively authorised to produce in excess of 35,000 kg of medicinal cannabis (dry flower) annually. This is estimated to be well in excess of current and anticipated future domestic demand.

While most prescriptions so far have been written for unapproved products, the Government's ultimate goal is to have a wider range of medicinal cannabis products included in the Australian Register of Therapeutic Goods (ARTG) as registered medicines. As for all registered medicines

this requires a submission for a particular product to be made to TGA and a review undertaken of its quality, safety and efficacy for a proposed indication/s (condition/s).

Currently, there is one medicinal cannabis product Sativex (nabiximols) included in the ARTG, while Epidyolex (cannabidiol) has recently received both Orphan designation and Priority review determination from the TGA. These designations allow the waiving of TGA application and evaluation fees and expedited assessment of the application for registration.

Although outside the normal role of a regulator, the Department through TGA has worked with universities, clinical and patient groups to develop clinical guidance documents that provide information about the current state of clinical evidence and raise awareness of how to prescribe medicinal cannabis under current access schemes. These documents were first published in December 2017 and are currently being updated, along with information on clinical trials of medicinal cannabis products. They are provided on the TGA website along with other educational and information resources for health professionals and consumers.

Although there are a number of clinical trials of medicinal cannabis products for different conditions underway in Australia and internationally, at present there are still only a limited number of well-designed published studies assessing the efficacy of medicinal cannabis products for different indications (conditions). Most clinical groups agree that medicinal cannabis requires more extensive research to inform safe therapeutic outcomes and routine use in clinical practice.

The Pharmaceutical Benefits Scheme (PBS) is the long-standing mechanism for government subsidy of prescription medicines. Medicines which have been approved by TGA and thus included in the ARTG may then apply for PBS listing, undergoing assessment of comparative cost-effectiveness with standard care. The Government is unable to compel sponsors to apply for either TGA approval or PBS listing.

Introduction

The Department of Health (the Department) welcomes the opportunity to provide a submission to the Senate Community Affairs References Committee *Inquiry into the current barriers to patient access to medicinal cannabis in Australia*.

The Department's submission outlines:

- The regulatory roles of the Department relevant to medicinal cannabis, including the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC)
- The scheduling of medicinal cannabis products in Australia
- Information on cultivation licences and permits and manufacture under the *Narcotic Drugs Act 1967*
- Details and data on the access pathways for medicinal cannabis in Australia
- An overview of state and territory legislation relating to medicinal cannabis
- An overview of international regulatory approaches to medicinal cannabis
- Information on education available to Australian prescribers of medicinal cannabis; and
- The current status of the domestic regulated medicinal cannabis industry.

The role of the Therapeutic Goods Administration (TGA)

The principal role of the TGA, as part of the Department, is to protect public health and safety by regulating therapeutic goods that are supplied in, or exported from Australia. The TGA administers the *Therapeutic Goods Act 1989* (TG Act), which establishes the Australian regulatory framework for all therapeutic goods, including medicines.

Under the TG Act, the TGA employs a risk management approach designed to ensure that therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy. This requires the application of scientific and clinical expertise to decision making, to ensure that the benefits to consumers outweigh any risks associated with the use of therapeutic goods.

It is the policy of the Government to treat medicinal cannabis products as medicines, subject to the same regulatory framework and strict standards of safety, quality and efficacy as all other medicines. TGA's remit relevant to medicinal cannabis includes scheduling, product registration, unapproved product access pathways and quality (including manufacturing) standards.

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into 'schedules' in the Poisons Standard according to the risk of harm and the level of access control required to protect public health and safety. The scheduling history of medicinal cannabis is outlined in *History of cannabis scheduling for therapeutic use in Australia*, below.

Generally, medicines used in Australia must be entered in the Australian Register of Therapeutic Goods (ARTG). For a prescription medicine to be registered in the ARTG, a sponsor of the product (usually a pharmaceutical company) is required to submit a dossier of evidence on the clinical efficacy, safety and manufacturing quality for evaluation by the TGA. However, the Government has no power to compel a sponsor to make a submission to the TGA for registration in the ARTG.

Under the provisions of the TG Act, the TGA administers a number of mechanisms to enable access to therapeutic goods which are not registered on the ARTG, which are otherwise termed as 'unapproved' therapeutic goods. These mechanisms, described below in *Access Pathways for Medicinal Cannabis*, include the Special Access Scheme (SAS), the Authorised Prescriber (AP) pathway and access through clinical trials. Importantly, unapproved therapeutic goods accessed through these pathways are considered to be experimental as they have not been evaluated by the TGA for safety, quality and efficacy. This is why for the main SAS Category B (SAS B) and AP there is additional oversight of the prescribing and the product being prescribed. A further difference is that almost all other products obtained through the Special Access Scheme have successfully been through the evaluation and approval process by a comparable overseas regulator. In contrast, very few of the medicinal cannabis products provided through the SAS and AP schemes have been assessed for quality, safety or efficacy by any medicines regulator internationally.

In considering requests to supply unapproved therapeutic goods, the TGA has a responsibility to ensure individuals can gain timely access to important new therapeutic goods. However, where it is anticipated that particular products will be used to a significant extent in the future, sponsors are encouraged to develop the data required for a product submission for TGA registration. Potential advantages of registration may include wider prescriber confidence in the quality, safety and efficacy of the product; availability at community pharmacies on a standard prescription; and the ability of the sponsor to apply for PBS subsidy for the product.

The TGA also provides quality standards for therapeutic goods that are imported, exported or supplied in Australia.¹ In recognition that medicinal cannabis products differ from the vast majority of medicines accessed via unapproved product access pathways in that they are not registered in comparable overseas jurisdictions, the TGA established the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*². The TGO 93 specifies the minimum quality requirements for all medicinal cannabis products available in Australia.

There are two licences that may be required for manufacturing medicinal cannabis in Australia. These are a licence to manufacture therapeutic goods (GMP), issued by the TGA, which focuses on quality and a narcotic manufacture licence, issued by the ODC, which specifies what drug may be produced and in what quantities. Australian manufacturing sites require a licence to manufacture therapeutic goods for both medicinal cannabis products included in the ARTG and for unapproved medicinal cannabis products provided through SAS, AP or for clinical trials (other than first in man trials).³

For medicinal cannabis products intended to be supplied through the available unapproved medicine access pathways that involve an overseas manufacturer, the medicinal cannabis product must be manufactured in accordance with an acceptable manufacturing standard. In general, this means that the country in which manufacture of the product occurs has active oversight of medicinal cannabis products and holds them to its own manufacturing standards, and the product is supplied to patients in the country of its manufacture; and is not manufactured solely for export to other markets. The countries that demonstrate compliance the above principles currently include Canada, Germany, the Netherlands, Switzerland and Israel.

¹ TG Act, s 14.

² Determined under TG Act, s 10(1).

³ In December 2019 updated regulatory guidance was published on manufacturing requirements www.tga.gov.au/book-page/manufacture-medicinal-cannabis

Cannabis scheduling for therapeutic use in Australia

Cannabis (the plant) and tetrahydrocannabinol (THC, a psychoactive component of cannabis) were historically included in Schedule 9 (Prohibited substance)⁴ of the Poisons Standard in Australia which severely restricted patient access to medicinal cannabis for many years. Figure 1 below outlines the evolution of scheduling decisions which led to access to medicinal cannabis in Australia.

Any individual or organisation can apply to reschedule a particular substance; the Department can also submit an application. Scheduling decisions are made by a senior departmental medical officer who is advised by the Advisory Committee on Medicines Scheduling which comprises medical, pharmaceutical and scientific experts as well as state and territory representatives⁵ and informed by extensive public consultation. Each state and territory has its own laws that determine where consumers can access a particular drug or poison, and how it is to be packaged and labelled. It remains with the state and territory governments as to how they give effect to any decision to down-schedule a substance in their own jurisdiction.

Scheduling decisions take into account relevant matters of public health as set out under section 52E of the TG Act. These matters include the risks and benefits of the use of a substance, the purposes for which a substance is to be used, the substance's toxicity, dosage, formulation, labelling, packaging, presentation and any potential for abuse. The delegate must also comply with the Scheduling Policy Framework. Reasons for scheduling decisions are published on the TGA website.⁶

Reasons given for the Schedule 8 classification of cannabis and THC for therapeutic purposes include that the conditions for which they are prescribed require diagnosis, management and monitoring under an appropriate medical practitioner. In some individuals, high doses can cause psychoactive effects, and there is potential for misuse and/or abuse.

Reasons given for the Schedule 4 classification of CBD (in preparations for therapeutic use containing 2 percent or less of other cannabinoids found in cannabis) include that main condition that cannabidiol treats (refractory epilepsies) requires diagnosis, management and monitoring under an appropriate medical practitioner. However, it was felt that cannabidiol (at the doses used for refractory epilepsies) has a safety profile which is consistent with a Schedule 4 rather than Schedule 8 listing. It interacts with a number of prescription medicines and side effects at these doses include liver toxicity, sedation, diarrhoea and vomiting.

A recent (2018) application for downscheduling of nabiximols from S8 to S4 was not supported for the following reasons - *“while nabiximols has an established therapeutic value at therapeutic dosage levels, it is recognised to produce dependency and has a potential for misuse, abuse or illicit use..... therefore the loss of regulatory controls over prescribing for those with a drug dependency issue would seem premature”*. In addition, while the WHO Expert Committee on Drug Dependence has recently made a recommendation to ease the international restrictions on preparations containing delta-9-tetrahydrocannabinol by down scheduling it to Schedule III in the United Nations Single Convention on Narcotic Drugs of 1961, a decision by the United Nations Commission on Narcotic Drugs (CND) on the WHO recommendations has been postponed. This maintains one of the scheduling factors under the Scheduling Policy Framework for Schedule 8 for THC-containing medicines.

⁴ Substances in Schedule 9 are described as Prohibited Substances – Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory health authorities.

⁵ www.tga.gov.au/committee/advisory-committee-medicines-scheduling-acms

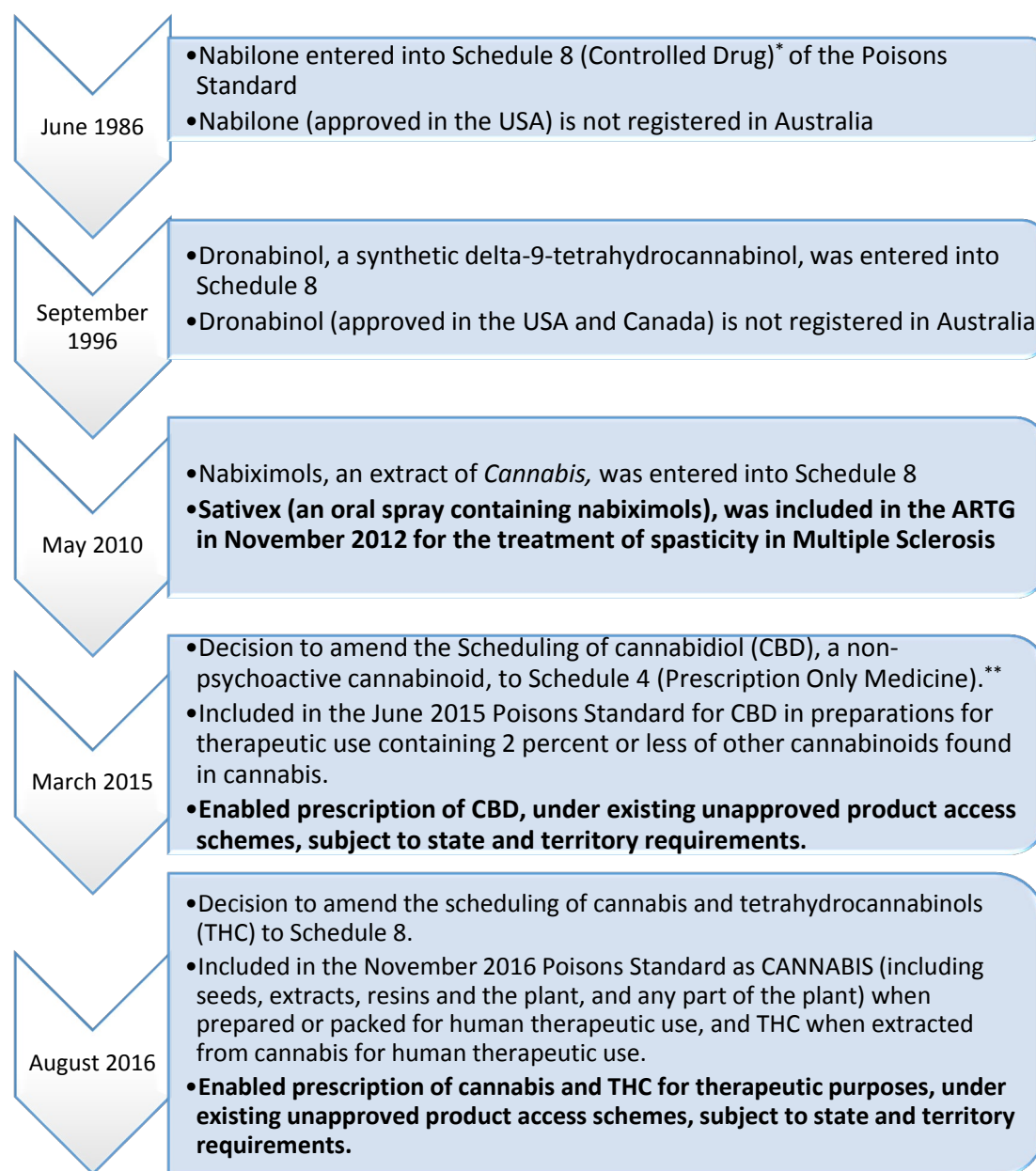
⁶ www.tga.gov.au/scheduling-decision-final/scheduling-delegates-final-decisions-cannabis-and-tetrahydrocannabinols-march-2016, www.tga.gov.au/book/part-final-decisions-matters-referred-expert-advisory-committee-2#canna

A range of products containing low doses of CBD products have been marketed in Europe and North America for some time. In the UK, CBD products that are made from hemp and do not contain detectable THC are legal. It is, however, illegal to advertise such products as medicine unless they are licensed by the Medicines and Healthcare Products Regulatory Agency. In the US, it is currently illegal to market low-dose CBD products under Federal Law although they are widely available on the internet and in physical markets.⁷

The doses of Cannabidiol in these products are far lower than the 10-20 mg/kg/day dose of CBD in products such as Epidyolex when indicated for use as adjunctive therapy of epileptic seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in children or adults. While there is little evidence of efficacy for low dose CBD documented in the medical literature, the oils and capsules are marketed wide range of recommended doses. However, these are much lower than for the epilepsies - usually in 15-100 mg per day range, which equates to 0.2-1.4 mg/kg/day. The TGA is currently undertaking a safety review of CBD at lower doses, although there are only limited published studies. Based on the outcome of these studies, it is possible that relaxation of the scheduling status of low dose CBD (e.g. to over the counter) could be considered during 2020.

⁷ www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#legaltosell

Figure 1: Overview of the scheduling decisions enabling access to cannabis for therapeutic purposes in Australia⁸



* Schedule 8 Controlled Drugs – “Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence”. ** Schedule 4 Prescription Only Medicines – “Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription”

⁸ www.tga.gov.au/scheduling-committees-meeting-dates-and-decisions-timeframes

Access pathways for medicinal cannabis

The Government decided to facilitate patient access to medicinal cannabis under the existing TGA regulatory framework rather than create a separate regulatory scheme for this group of medicines. Apart from considering that the current TGA patient access pathways were fit to enable prompt access, the Government is of the view that using the existing TGA pathways will facilitate clinical trials in Australia and provide easier transition of products to ARTG registration. Australian-manufactured unapproved medicinal cannabis products also already are required to meet TGO 93 Standards and medicines-level GMP (which would be required for a registered cannabis medicine).

Patient access occurs under four main pathways:

1. Registration in the ARTG:

Any medicinal cannabis product included in the ARTG can be lawfully supplied in Australia and prescribed by a registered medical practitioner, subject to state and territory law. Sativex (nabiximols), the only medicinal cannabis product included in the ARTG, was registered on 26 November 2012 as treatment for spasticity in certain patients with Multiple Sclerosis. Epidyolex (cannabidiol) for the treatment of seizures in intractable epilepsy, was granted orphan drug designation on 22 November 2019^{9,10} and priority review status on 18 December 2019 for use as adjunctive therapy for seizures associated with Dravet and Lennox-Gastaut syndromes in patients 2 years of age and over. Orphan designation and priority review determination precede the registration application. Orphan designation gives provision for application and evaluation fees to be waived for registration in the ARTG. Priority review determination provides for expedited assessment. Neither priority review determination nor orphan drug designation guarantee registration on the ARTG.

The majority of medicinal cannabis being currently supplied in Australia are unapproved products via the pathways described below.

2. Special Access Scheme (SAS) pathways:

SAS Category A (SAS A) is a notification pathway that allows a registered medical practitioner to access and prescribe an unapproved medicinal cannabis product for a patient who is seriously ill.¹¹ 'Seriously ill' is defined as having 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, and is determined by the patient's medical practitioner. Notifications are required to be provided to the TGA within 28 days of supply of the product, although it is very difficult to enforce this requirement. In addition, under SAS A, there is no checking of the quality of the product or the relevance of the indication and it is very difficult to monitor potential inappropriate use of SAS A by prescribers, for example, where that the patient may not really be suffering a terminal illness.

Special Access Scheme Category B (SAS B) is an application pathway through which a registered health practitioner may apply to the TGA for approval to prescribe an unapproved medicinal cannabis product for a patient under their care.¹² The applicant must provide a suitable clinical justification for the use of the therapeutic good, including reasons why products included in the ARTG are not suitable for treatment of the patient. The majority of medicinal cannabis being prescribed in Australia is under SAS B. There is no application fee.

⁹ TG regulation, reg 16

¹⁰ www.tga.gov.au/ws-designation-notice-index

¹¹ TG Act, s 18(1); TG Regulation reg 12A.

¹² TG Act, s 19(1)(a).

3. Authorised Prescriber (AP) pathway:

Under the AP pathway, the TGA is able to grant a medical practitioner authority to prescribe a specified unapproved medicinal cannabis product for particular indications to a class of patients in their immediate care.¹³ To become an AP, a medical practitioner must obtain approval from a Human Research Ethics Committee (HREC) or endorsement from an appropriate specialist college to prescribe the product. Once a medical practitioner becomes an AP they are not required to notify the TGA each time they prescribe the unapproved product, but they must report to the TGA the number of patients treated with the unapproved product twice yearly. There is no application fee.

4. Clinical Trials Notification (CTN) scheme:

The TGA regulates the use of medicinal cannabis supplied in clinical trials in Australia via the CTN scheme.¹⁴ The CTN pathway provides for the lawful importation into and/or supply in Australia of unapproved cannabis medicines, for use solely for this purpose. CTN involves a notification only to the TGA. This is because the overseeing Human Research Ethics Committee (HREC) reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.

There are additional provisions allowing for patient access to medicinal cannabis, such as the exemptions under the *Customs (Prohibited Import) regulations 1956* (traveller's exemption)¹⁵, or as an extemporaneously compounded product through a pharmacist.¹⁶

The role of the Office of Drug Control

Amendments to the *Narcotic Drugs Act 1967* allowing the legal cultivation, production and manufacture of cannabis for medicinal purposes in Australia commenced on 29 October 2016. These amendments, along with the *Narcotic Drugs Regulations 2016*, provide the framework for a licencing and permit scheme regulating the cultivation and production of medicinal cannabis for research purposes or for medicinal use, as well as for manufacturing medicinal cannabis products.

Australia is a signatory to the *Single Convention on Narcotic Drugs 1961*, which acknowledges the medicinal benefits of cannabis, among other narcotics, while recognising that cannabis should be subject to controls that prevent its misuse and abuse. The Convention requires that the cultivation and production of cannabis be regulated by a single government "agency". The Office of Drug Control (ODC) within the Department of Health is that regulator. ODC receives and assesses applications for licences and permits for cultivation, production and manufacturing of medicinal cannabis and medicinal cannabis products. A medicinal cannabis licence authorises either cultivation (the growing of cannabis plants) or production (the separation of cannabis and cannabis resin), or both.

ODC is not able to grant a medicinal cannabis licence unless it is satisfied that the cultivation and production of cannabis is for supply either to a person licensed to produce cannabis or a person licensed to manufacture medicinal cannabis products. In practice, this may mean the applicant demonstrating that they are known to the producer/manufacture and that the producer/manufacture is willing to enter into contracts for supply of cannabis raw material.

¹³ TG Act, 19(5),(6); TG Regulation reg 12B.

¹⁴ TG Act, s 18(1); TG Regulation reg 12(2)-12AD

¹⁵ TG Regulation, s 5

¹⁶ *Customs (Prohibited Import) Regulations 1956* subregulation 5(2)

A cannabis research licence authorises the cultivation and/or production of cannabis for research related to the medicinal use of cannabis. In order to obtain a cannabis research licence, an applicant will need to explain the purpose of the research and how it relates to medicinal cannabis and/or medicinal cannabis products.

In all cases, the licensee needs to hold a permit(s) issued under the ND Act before any cultivation or production commences. All persons interested in manufacturing narcotic drugs require a licence to manufacture from the Office of Drug Control. The licence is in addition to any licence issued by State or Territory Governments. Depending on the manufacturing activity, a manufacturing licence may also be required from the TGA.

The export of medicinal cannabis (extracts and preparations) is permitted if the product is listed as export-only or registered on the ARTG and the exporter holds a licence and permit to export drugs from the Office of Drug Control. As a condition of export, the exporter is required to demonstrate that there would still be adequate availability of the product(s) for Australian patients.

A person holding the appropriate ODC licence and permits may import cannabis products. They must also hold a state/territory licence allowing possession of cannabis material before import approval may be granted, and only import from countries where cannabis for medicinal use is approved at the national level.

Response to specific Terms of Reference

Submissions are made in response to terms of reference (a) to (i) inclusive only.

(a) The appropriateness of the current regulatory regime through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS), Authorised Prescriber (AP) Scheme and clinical trials

Medicinal cannabis products are considered to be therapeutic goods under the TG Act, as would any other product making therapeutic claims or being used to treat a medical condition. The regulatory framework applied to medicinal cannabis is appropriate and consistent with other medicines.

Currently there is only one approved cannabis product in the ARTG (Sativex); all other medicinal cannabis products are unapproved products and they are being accessed in exactly the same way as other unapproved medicines in Australia, chiefly through the SAS and AP.

The first TGA approval to access an unapproved medicinal cannabis product through the SAS occurred as early as 1992. However, since 2016 there has been a consistent and substantial increase in both SAS B approvals and AP authorisations that demonstrates expanding patient access under the existing regulatory framework.

Overall patient and prescriber numbers

Please note: Data provided in this submission has been retrieved from the Department's Customer Relationship Management (CRM) database and static databases. Figures are correct as at 31 December 2019, however are subject to change in order to reflect updates due to application cancellations, withdrawals and amendments. Approval under the SAS does not necessarily mean the patient has accessed or continues to access treatment. Following approval, the actual supply of medicinal cannabis is a matter for the medical practitioner and their patient.

NB: Use of the registered product Sativex (nabiximols), not included in these statistics.

As at 31 December 2019:

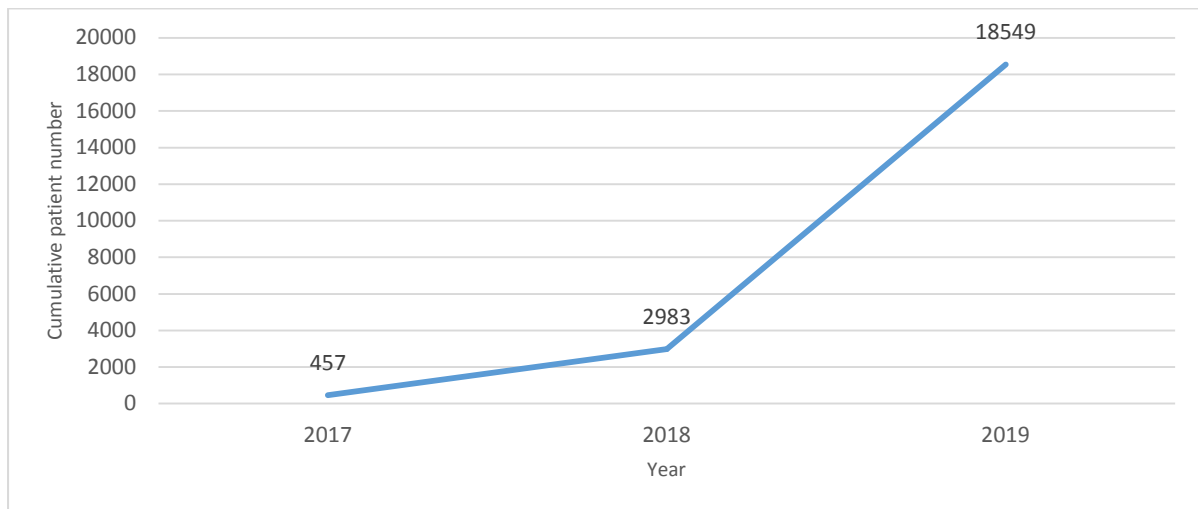
- **over 18, 000** patients in Australia have been granted access to unapproved medicinal cannabis products through both SAS and AP
- **28, 008** individual application approvals have been granted through the SAS B pathway
- **1465** individual registered medical practitioners have been granted approval or submitted notifications to supply unapproved medicinal cannabis products via the SAS and AP.

As depicted in Figure 2, the cumulative number of individual patients accessing medicinal cannabis via the SAS and AP pathway continues to rise, with a 600 percent increase from 2018 to 2019.

It is noteworthy that the rate of growth in patient and prescription numbers has actually been much faster (from the commencement of the regulatory scheme) in Australia than in Canada. For example, by mid-2014, 13 years after implementation of the first medicinal cannabis regulatory framework in Canada there were only 7900 registered patient users and by mid-2015, 23930 registered patients. During 2019, registrations plateaued at about 370,000, coinciding with the legalisation for recreational cannabis.¹⁷

¹⁷ www.statista.com/statistics/603356/canadian-medical-marijuana-clients-registered-by-quarter/

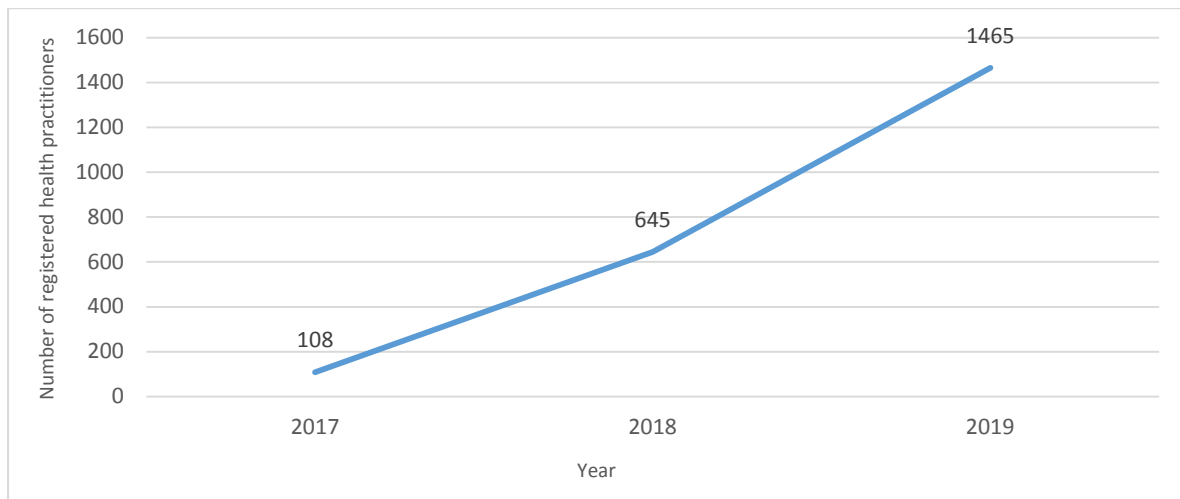
Figure 2: Cumulative number of patients estimated to have accessed medicinal cannabis as at 31 December 2019 (not including Sativex patients)



Note: Patient numbers are estimates only. Applications are de-identified and it is not always possible to identify unique patients. AP patient numbers are reported retrospectively and therefore the cumulative total is an underestimate.

The significant growth in estimated patient numbers correlates with an increase in the number of individual prescribers granted approval to supply medicinal cannabis through the SAS B and AP which more than doubled in 2018-2019. This trend demonstrates improved confidence among prescribers and increased uptake in medicinal cannabis prescribing.

Figure 3: Number of registered health practitioners granted approval or submitted notifications to supply medicinal cannabis under the SAS and AP pathways

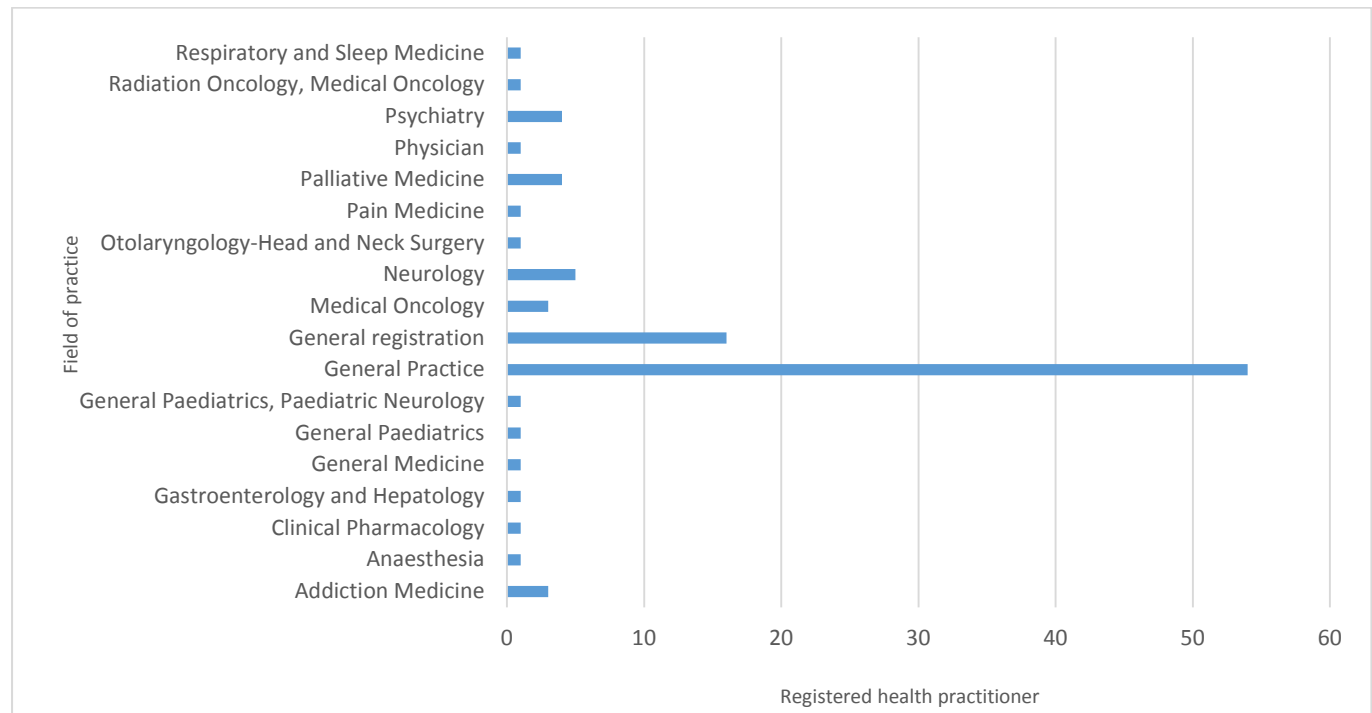


Note that specific approval from the TGA is not required to prescribe Sativex as it is in the ARTG.

Prescriber types

Prescribers from a broad range of specialities, as well as general practitioners are accessing medicinal cannabis through SAS and AP. Random sampling data in figure 4 demonstrates that prescribers in general practice account for the majority of SAS B approvals followed by neurology, psychiatry, oncology and palliative medicine.

Figure 4: Random sample data of 100 prescribers indicating the common specialties of prescribers granted SAS B approval for unapproved medicinal cannabis products



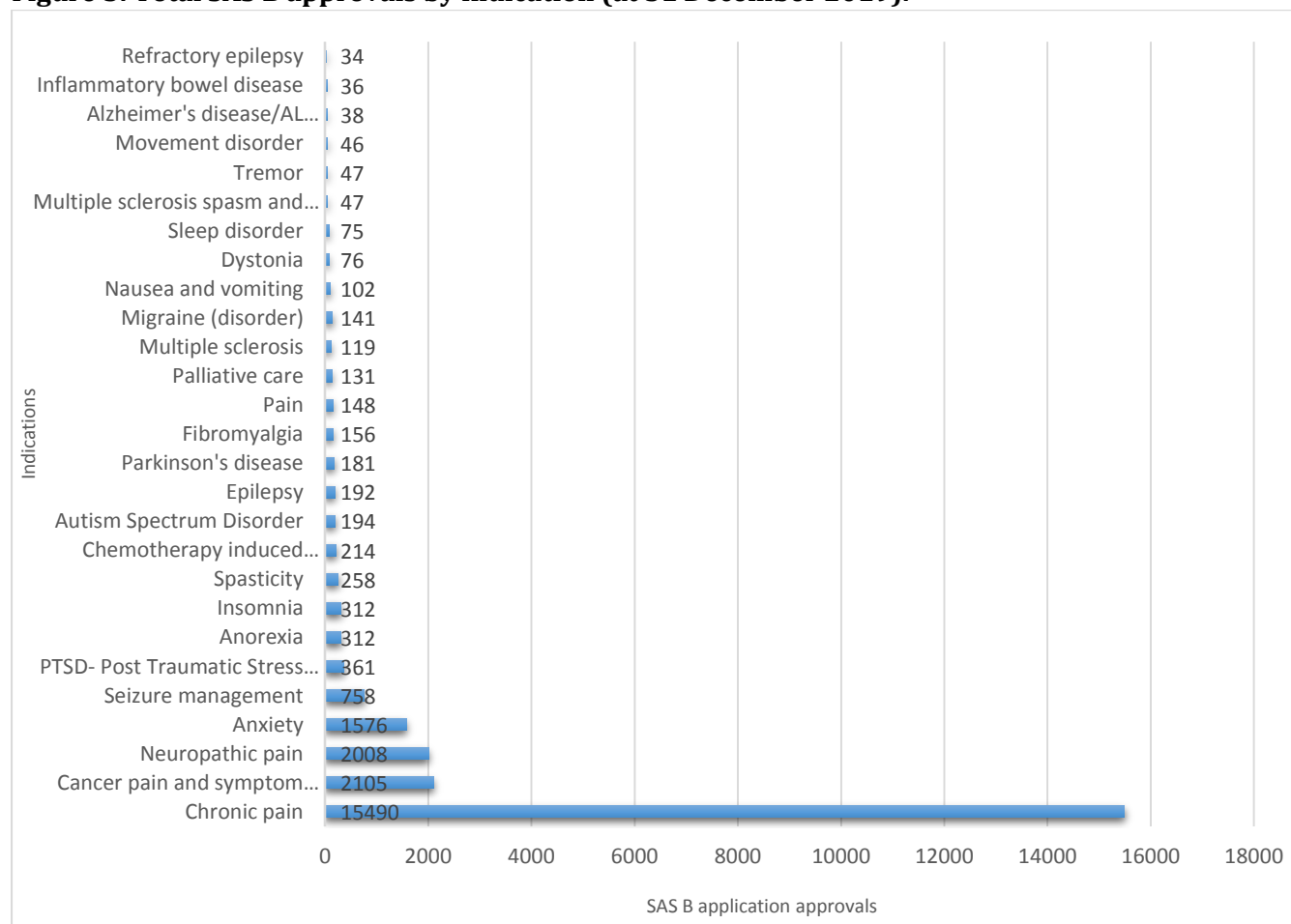
Note: This data was obtained by manually checking AHPRA registration speciality status of 100 SAS B prescribers for medicinal cannabis products. All SAS B Prescribers in the database are listed alphabetically by surname and were selected to ensure even alphabetic coverage of surnames.

Indications (uses) for medicinal cannabis

There are no restrictions imposed by the TGA on the conditions or symptoms for which a medical practitioner may apply to access an unapproved medicinal cannabis product for their patient. However, in making the application the prescriber needs to supply sufficient clinical justification that supports the use of medicinal cannabis for the particular symptom or condition. The prescriber is also required to have considered available treatments on the ARTG. These considerations apply to accessing any unapproved product, not just medicinal cannabis.

The number of indications continues to expand and as at 31 December 2019, over 130 conditions (as described by the applicant) have been accepted for medicinal cannabis use. Over 60% of SAS B approvals have been granted for the treatment of chronic pain of unspecified origin. As shown in Figure 5, other common indications include other pain conditions (cancer pain and symptom management and neuropathic pain and fibromyalgia), seizure management/epilepsy and psychological conditions (anxiety, anorexia, insomnia, post-traumatic stress disorder) and multiple sclerosis and movement disorders.

Figure 5: Total SAS B approvals by indication (at 31 December 2019).

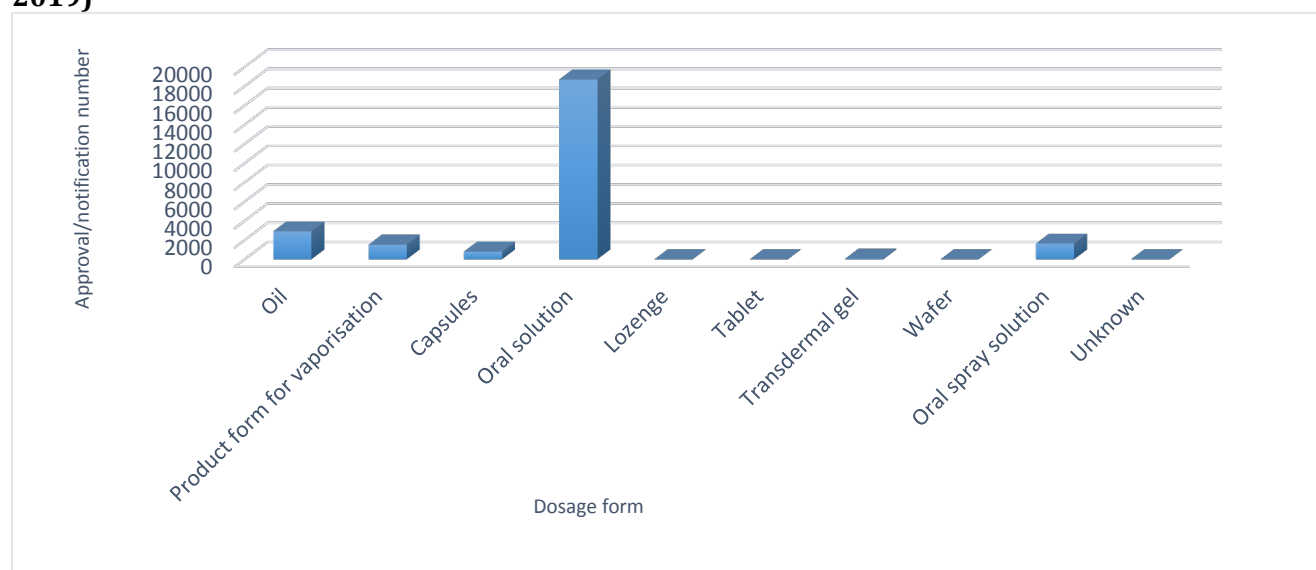


Note: Data is representative of the most common indications authorised and does not distinguish between conditions with similar clinical features that may be captured in a broader term.

Product types

The number of medicinal cannabis products available through the SAS and AP also continues to increase. To date, in addition to nabiximols (an oro-mucosal spray) over **130** different unapproved medicinal cannabis products have been accessed via the patient access pathways. These constitute a range of contents and ratios of CBD and THC, and also a wide variety of dosage forms. As shown in Figure 6, oral solution and oil formulations are the main dosage forms accessed in Australia.

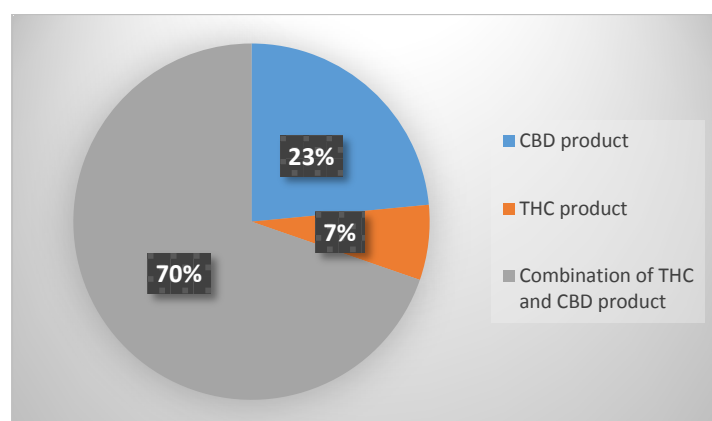
Figure 6: Analysis of dosage forms accessed through the SAS pathway (at 31 December 2019)



Note: 'Unknown' dosage form category is due to a small number of SAS A notifications which do not state dosage form

Most of the products available for access in Australia are combination THC/CBD products as depicted in Figure 7.

Figure 7: Cannabinoid profile (THC, CBD, THC+CBD) of products available for patient access.



SAS approvals/notifications by month

The majority of medicinal cannabis use in Australia has been through the SAS B pathway. As at 31 December 2019:

- **28,008** application approvals have been granted through the SAS B pathway
- **363** notifications have been submitted under the SAS A pathway
- **1298** registered health practitioners have been granted approval through the SAS B pathway.

Figure 8 depicts the monthly breakdown of the number of notifications received through the SAS A pathway and approvals granted through the SAS B since 2017.

Figure 8: SAS A notifications and SAS B application approvals by month 2017-19.



Note: Approval/notification numbers do not equate to unique patients. There is a possibility of repeat applications/notifications for the same patient. It is also possible for individual patients to be associated with separate approvals/notifications for multiple products. Approval or notification does not necessarily mean that supply occurred.

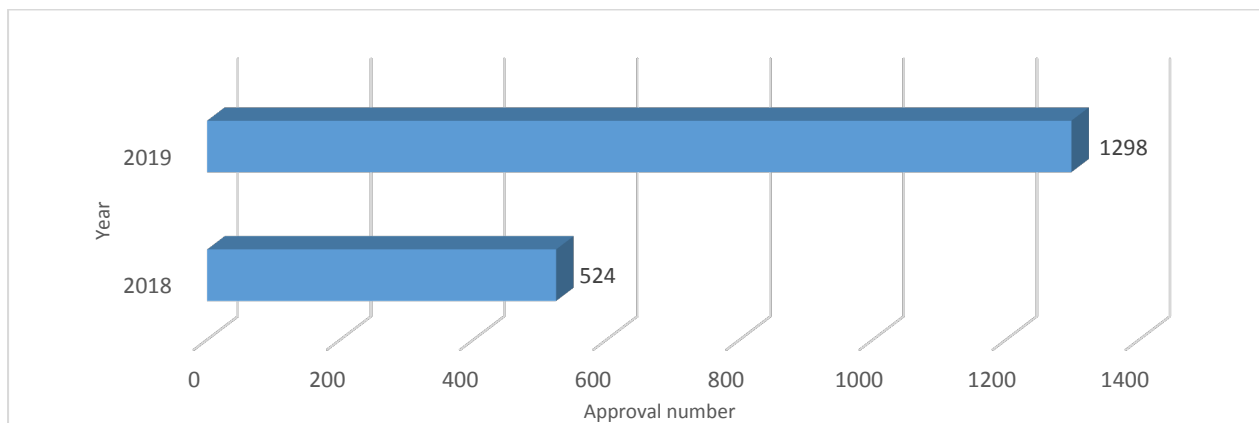
Patients receiving a medicine under SAS A are required to have “a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment”. For these patients, the choice of whether to use SAS A or B is at the discretion of the prescriber. Products that are supplied under SAS A are imported ones under the provisions of the *Narcotic Drugs Act 1967*.¹⁸

SAS prescriber figures

Figure 9 illustrates the growth in the number of registered health practitioners approved to supply unapproved medicinal cannabis through the SAS B pathway in 2019 compared with 2018.

¹⁸ ND Act, s 11K

Figure 9: Number of registered health practitioners granted approval to supply under SAS B 2018 – 2019

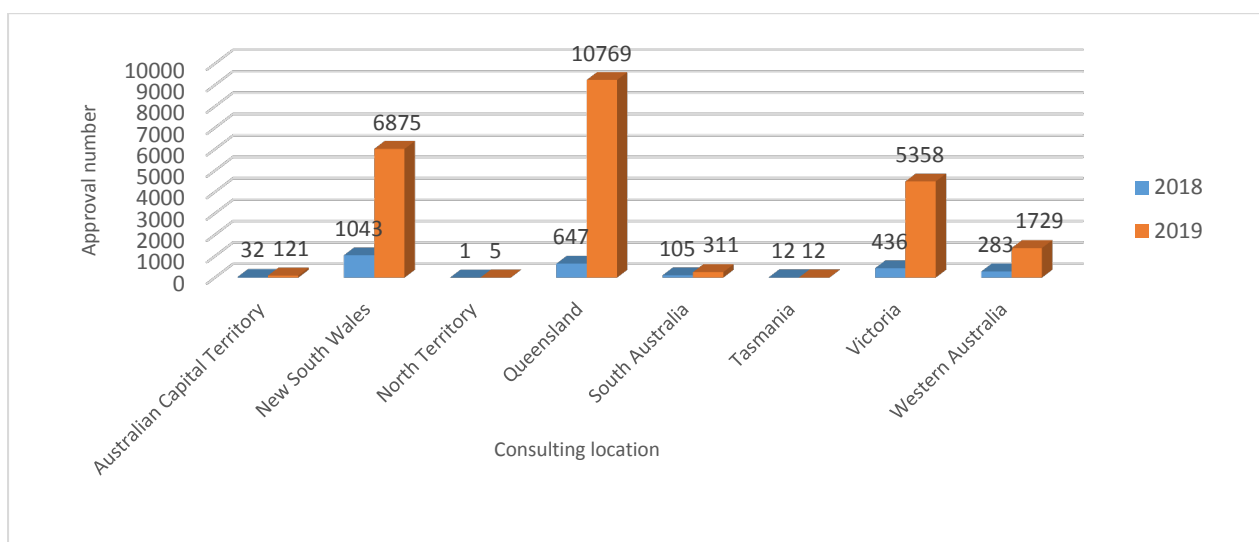


SAS approvals state/territory distribution

As shown in Figure 10 there has been a significant increase in approvals granted to prescribers in New South Wales, Queensland, Victoria and Western Australia in 2019. This increase may be partially explained by the relaxation in jurisdictional controls for prescribing medicinal cannabis in New South Wales and Queensland, and a policy change in Western Australia (see response to Term of Reference C below).

Importantly, the location of prescribers does not reflect the number of prescriptions dispensed in each jurisdiction, nor the patient's place of residence. It is also recognised that a number of prescribers engage in telehealth services, delivering clinical prescribing services outside their state or territory of practice.

Figure 10: SAS B application approvals by prescriber consulting location (2018-31 December 2019)



SAS B timeframes

On 30 July 2018, an online system was introduced to enable the electronic submission of SAS applications and notifications to the TGA. On 1 December 2018, this system was updated to allow the submission of AP applications to the TGA. Use of this online system reduces administrative burden on health practitioners and provide users with additional ability to manage their SAS applications and notifications. While lodgement of SAS application and notifications and AP applications to the TGA via the online system is not mandatory, it is the preferred method of submission.

The portal provides a single application process through which medical practitioners could notify or apply to both the Commonwealth and the relevant State or Territory Health Department (where applicable) to prescribe and supply medicinal cannabis products. Prior to the introduction of the SAS online system, prescribers of unapproved medicinal cannabis products were required to separately apply to the TGA and relevant state or territory health department for authorisation.

The service standard, announced by the Government was for SAS B applications to be reviewed by both the TGA and the state and territory (if required) within a 48 hour period. This service standard has been met in virtually all cases by the TGA, with a median approval period of just over one day. When state or territory approval is required, both approvals are sent to the applicant together in a single email. In a small number of cases, despite TGA approval occurring within the timeframe, there can be a delay to approvals being sent due to mismatched public holidays between the ACT and particular states and territories, system errors, or unforeseen processing delays by the state/territory health department.

The Therapeutic Goods regulatory framework requires each SAS B application to be reviewed by either a medical doctor, pharmacist or dentist, principally to determine whether the information in the application is complete, and whether the product choice, dosage and indications are relevant. This is the process for all products applied for under SAS B.

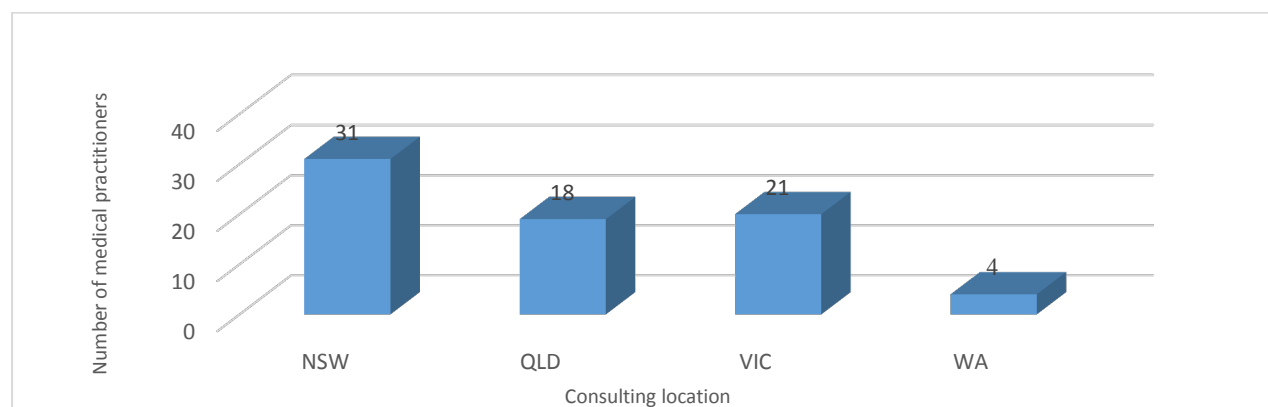
Authorised Prescriber (AP) scheme data

Use of the AP scheme also continues to increase. As at 31 December 2019:

- **74** medical practitioners have been granted authorisation under the AP pathway
- **279** individual product authorisations have been granted
- at least **655** patients have accessed medicinal cannabis through the AP pathway.

Figure 11 represents the number medical practitioners granted authorisation and their respective consulting location since 2017- 31 December 2019.

Figure 11: Medical practitioners granted authorisation under the AP pathway by consulting location as at 31 December 2019



The majority of authorisations under the AP pathway have been granted for management of cancer-related pain or for cancer-related symptom management. Other conditions that are authorised include chronic pain, management of palliative related symptoms and epilepsy. Table 1 provides a comparative summary highlighting the total product authorisations and approved indications relative to the authorised medical practitioner's consulting location.

Originally it had been anticipated that individual practitioners who prescribed medicinal cannabis on a regular basis would seek to become authorised prescribers, so as to remove the necessity to apply for SAS B access for each prescription. However, in discussions by Departmental staff with a number of regular prescribers during 2019, the prescribers indicated that the online SAS application portal was simple to use and approval fast, so they did not see a significant benefit from applying to become an Authorised Prescriber.

Table 1: Overview of number of product authorisations and indication relative to AP consulting location (at 31 December 2019)

Consulting location of medical practitioner	Indication category	Total product authorisation
New South Wales	Cancer pain and symptom management	81
	Chronic non-cancer pain	
	Intractable epilepsy	
	Refractory epilepsy/paediatric refractory epilepsy	
Queensland	Refractory paediatric epilepsy	87
	Cancer pain and symptom management	
	Chronic non-cancer pain	
	Palliative care management	
Victoria	Cancer pain and symptom management	58
	Chronic non-cancer pain	
	Compassionate access to medicinal cannabis products, a small group of children with very severe intractable epilepsy.	
	Continuation of Compassionate Access Paediatric Scheme Pilot trial for young people with Refractory Anxiety disorders	
	Severe refractory epilepsy	
	Patient meets the inclusion criteria and are approved by an independent panel of the Office of Medicinal Cannabis, Department of Health and Human Services Victoria	
Western Australia	Cancer pain and symptom management	53
		279

Clinical Trial Notification (CTN) data

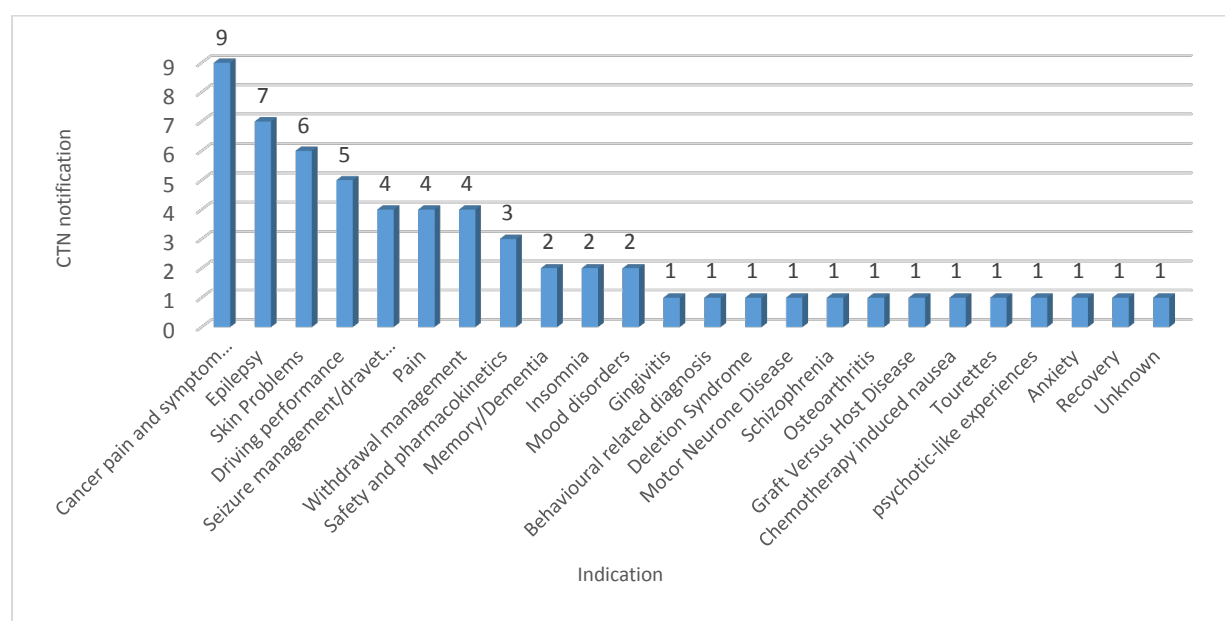
Australian patients are also accessing medicinal cannabis as part of clinical trials. Although the TGA does not hold data on the number of patients in medicinal cannabis trials, sponsors are required to notify the TGA before conducting a clinical trial with an unapproved product. As of 31 December 2019, 61 notifications have been received which indicates a growing number of clinical trials for medicinal cannabis in Australia.

As shown in Figure 12, clinical trials are being conducted to investigate the use of medicinal cannabis for a number of conditions and clinical scenarios including (but much wider than) cancer symptom management, seizure management and pain management. More detail on most of the trials is provided in the Australian and NZ Clinical Trials Registry (www.anzctr.org.au).

A database with information on clinical trials of THC, CBD and cannabinoids for therapeutic purposes is also provided on the TGA website.¹⁹

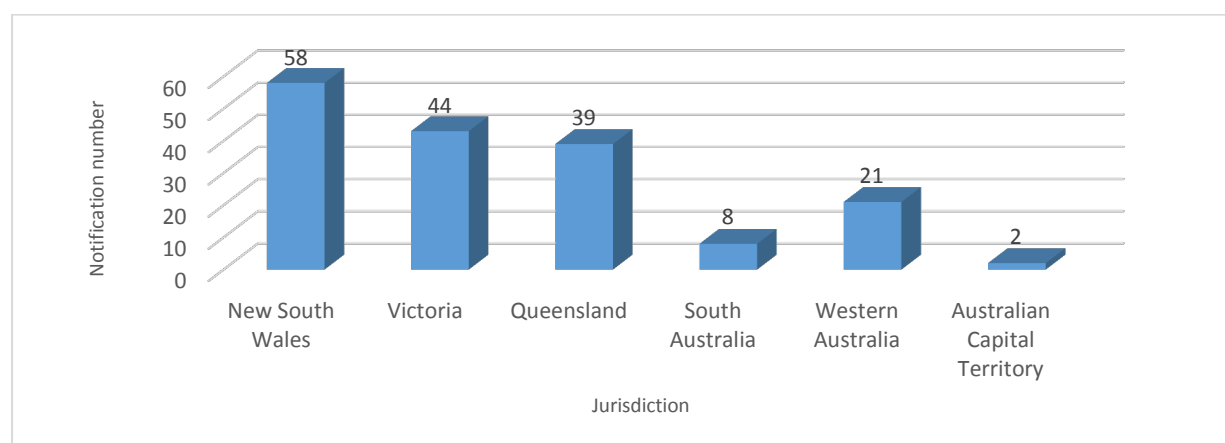
¹⁹ <https://www.tga.gov.au/access-medicinal-cannabis-products-1>

Figure 12: Number of Clinical Trial Notifications (CTNs) and corresponding indication



As illustrated in Figure 13, the majority of CTNs have been received for trial sites in New South Wales, Victoria and Queensland.

Figure 13: Clinical Trial Notifications (CTNs) by trial site location



Note: A large number of CTNs are submitted for multiple trial sites (jurisdictions).

(b) The suitability of the Pharmaceutical Benefits Scheme for subsidising patient access to medicinal cannabis products

The regulation and funding of therapeutic goods are two separate processes in Australia.

The Pharmaceutical Benefits Scheme (PBS) is the main mechanism through which the Government can subsidise the cost of medicines for the treatment of Australian patients. A comprehensive range of medicines are subsidised through the PBS, including over 5200 branded products to treat a wide range of medical conditions.

Under the *National Health Act 1953*, a new medicine cannot be listed by the Government on the PBS unless the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, makes a recommendation in favour of listing. When considering a medicine proposed for PBS listing, the PBAC is required by that legislation to give consideration to the

effectiveness and cost of the medicine, including by comparing the effectiveness and cost with that of alternative treatments.

The PBAC's consideration against its statutory obligations needs to be informed by evidence about the clinical effectiveness and safety of the medicine when compared with alternative treatments. The PBAC's consideration is therefore generally initiated by the pharmaceutical company responsible for a medicine making an application to it for the medicine to be considered for PBS listing. It is usually the pharmaceutical company that holds the scientific data and other information necessary to inform the PBAC's consideration.

Medicines are not generally made available on the PBS to treat conditions for which they have not been approved by the TGA. TGA approval is important because the PBS listing process relies in part on the scientific assessment of evidence regarding safety and clinical effectiveness that serves as the basis for TGA approval.

PBAC considered Sativex for listing on the PBS in 2013. However, the PBAC was not able to recommend Sativex for PBS listing at that time due to insufficient evidence to establish comparative efficacy and safety compared with alternative treatments.²⁰ The PBAC's decision in 2013 in relation to Sativex does not represent a final PBAC view. The PBAC meets regularly and would accept a further application for Sativex that addresses the PBAC's concerns at any time. However, pharmaceutical companies cannot be compelled to make an application to PBAC.

(c) The interaction between state and territory authorities and the Commonwealth, including overlap and variation between state and territory schemes

The interaction between the Commonwealth and states and territories is crucial to facilitating access to medicinal cannabis. To promote a uniform national approach to the regulation of medicines, the TGA administers the Poisons Standard. The Poisons Standard is a Commonwealth legislative instrument classifying different medicines and poisons into 'Schedules' and operates as a recommendation for adoption by states and territories.²¹ As previously described, medicinal cannabis products are currently listed as either Schedule 4 or Schedule 8 substances in the Poisons Standard, depending on cannabinoid content.

In most cases the current state and territory requirements principally derive from the fact that medicinal cannabis products containing THC are Schedule 8 drugs, and all jurisdictions have legal requirements relating to the prescription, storage, documentation and destruction of medicines in S8. The checks that relate to initial prescription of medicinal cannabis are of patient suitability (in regard to whether the patient has a history of drug dependence) and whether there are concerns relating to the nominated prescriber. States and Territory regulations may also impose maximum duration for prescription of an S8 substance, and this can affect medicinal cannabis prescriptions. While there are common principles, there are differences in regulatory requirements between each state and territory requirements. These can complicate intrastate travel with medicinal cannabis products and the filling of prescriptions interstate.²²

However, states and territories, as regulators of the prescribing and pharmacy supply of prescription medicines, are responsible for controlling medicines within their jurisdiction in accordance with their own drugs and poisons regulations. Therefore, each state and territory

²⁰ Further information about the PBAC's assessment of Sativex is available on the PBS website: www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/nabiximols.

²¹ Poisons Standard December 2019 (No. 26)

²² Hua, A.C., Shen, F., and Ge, X. (2015) 'State-based legal requirements for Schedule 8 prescriptions: why so complicated?', *Med J Aust* 203 (2): p 64-66

has the power to implement its own regulatory requirements for supply of medicinal cannabis products which can result in different prescribing and authorisation requirements as described in Table 2, below. Until recently, a number of states enforced specific and additional requirements for the prescription of medicinal cannabis products such as controls on the prescribing of S4 cannabidiol products, restriction of prescribing to specialists, and referral of requests for prescribing to medical review committees. In many cases, over the last 12-18 months these additional requirements have been removed.

On 1 July 2019 the Qld Government introduced changes to legislation which allow all medical prescribers to prescribe Schedule 4 medicinal cannabis products without prior approval from Queensland Health. Changes to the NSW *Poisons and Therapeutic Goods Regulation 2008*, effective 30 September 2019, mean that NSW authority is now only required where the Schedule 8 cannabis medicine is for prescribing or supplying to a drug dependent person, prescribing or supplying for a clinical trial (if it is an unregistered cannabis medicine); or prescribing or supplying to treat a child aged under 16 years.

On 11 November 2019, the WA Government announced that effective immediately, general practitioners would be able to prescribe medicinal cannabis for the vast majority of patients, without reference to a specialist or a Health Department Board. Children under 16 and those who are drug dependent or have a history of drug use will still need to see a specialist.

The number of prescriptions is low in Tasmania and may relate to the additional requirements of that state's Controlled Access Scheme, wherein patients need a referral to a specialist who is in turn required to apply to the Tasmanian Department of Health and Human Services for an authorisation. Products can also only be dispensed through a hospital. Because of these requirements Tasmania is also not a participant in the online SAS application scheme. The reason for the low numbers of prescriptions in the Northern Territory is unclear.

Table 2: Overview of the jurisdictional requirements for prescribing medicinal cannabis

Jurisdiction	Prescriber eligibility	Authorisation requirements	Jurisdiction specific information	Relevant legislation
Australian Capital Territory (ACT)	Any registered medical practitioner can apply – general practitioners may require specialist support	Applications submitted by specialists for the following indications may be approved: <ul style="list-style-type: none"> - spasticity in multiple sclerosis - nausea and vomiting from cancer chemotherapy - pain and/or anxiety related to active malignancy from a life limiting disease with a prognosis of 12 months or less - refractory paediatric epilepsy. Applications for other conditions may also be approved where there is sufficient clinical justification and may be referred to the Medicinal Cannabis Medical Advisory Panel for advice.	ACT Authorisation requirements must be met if dispensing or supply occurs in ACT.	<i>Medicines, Poisons and Therapeutic Goods Regulation 2008.</i> <i>ACT Controlled Medicines Prescribing Standards</i>
New South Wales (NSW)	Any registered medical practitioner can apply.	Authorisation is required to prescribe or supply Schedule 8 medicines if the patient is a drug dependent person, including a person treated under the Opioid Treatment Program. Exemption is required for Schedule 8 medicines if the patient is aged under 16 years.	Authorisation requirements to be met if prescribing or supply occurs in NSW.	<i>Poisons and Therapeutic Goods Act 1966</i> <i>Children and Young Persons (Care and Protection) Act 1998</i>

Jurisdiction	Prescriber eligibility	Authorisation requirements	Jurisdiction specific information	Relevant legislation
Northern Territory (NT)	Any registered medical practitioner can apply.	No requirements for prescriber authorisation. Schedule 8 requirements apply. Notification required if prescribing for more than 8 weeks	Schedule 8 prescription must be written in the NT to be dispensed.	<i>Medicines Poisons and Therapeutic Goods Act 2012</i>
Queensland (QLD)	Any registered medical practitioner can apply.	Queensland instrument of approval is required for Schedule 8 medicine if; - medical practitioner does not hold a specialist registration - prescribing for a drug dependant person.	Only lawful to possess where medical practitioner holds approval in QLD.	<i>Health (Drugs and Poisons) Regulation 1996.</i> Instruments of approval issued under Sections 18(1) and 78A.
South Australia (SA)	Any registered medical practitioner can apply.	Authority required to prescribe any Schedule 8 medicine for longer than 2 months. However, exemptions for authority include: - patients aged 70 years or older - notified palliative care patients (notification must be made to SA Drugs of Dependence unit).	Authority required if prescriber practice location is in SA.	<i>Controlled Substances Act 1984 (SA).</i> <i>Controlled Substances (Poisons) Regulations 2011.</i>
Tasmania (TAS)	Specialist only.	Authorisation required for Schedule 4 and Schedule 8 cannabis medicines. All applications assessed on a case by case basis by a multidisciplinary expert panel of clinicians and dispensed from TAS Health Service pharmacies only.	Where an authorisation has been issued, a prescription is to be written and dispensed in Tasmania according to the requirements of the Tasmanian Medical Cannabis Controlled Access Scheme.	<i>Poisons Regulations 2018.</i>
Victoria (VIC)	Any registered medical practitioner can apply.	Authorisation permit required for Schedule 8 medicines. However, exemptions from the requirements for authorisation include: - prisoners - patients receiving inpatient treatment in a hospital - patients receiving treatment in a hospital emergency department or a day procedure centre - residents being treated in a residential aged care service - patients receiving palliative care.	Authorisation requirements to be met if prescriber practice location is in VIC.	<i>Drugs, Poisons and Controlled Substances Act 1981.</i> <i>Drugs, Poisons and Controlled Substances Regulations 2017.</i>
Western Australia (WA)	Any registered medical practitioner can apply.	Authorisation permit required for cannabis based medicines in Schedule 8.	Authorisation required if dispensing or supply occurs in WA.	<i>Medicines and Poisons Act 2014.</i>

Adopted from information supplied by individual state and territory departments of health.

A number of approaches foster coordination between the Commonwealth and jurisdictions:

The SAS Online System was implemented by the TGA in July 2018. The system provides medicinal cannabis prescribers with an interactive mechanism to seek Commonwealth approval and fulfil their jurisdictional requirements in a single application process. Currently all states and territories except Tasmania are participating in the system and approvals are issued within two working days. The TGA sends a single email containing both the TGA and relevant state or territory decision letter once the assessment processes have been completed. There has been excellent uptake with 91% of medicinal cannabis applications/notifications being submitted through the online system during 2019.

In addition, the Department coordinates and contributes to a number of intergovernmental working groups to share information and provide advice on administration, regulation, policy and legislation of the Medicinal cannabis scheme:

- The Australian Advisory Council on the Medicinal Use of Cannabis, appointed by the Minister for Health, provides advice to the Minister and the Department on the implementation of the medicinal cannabis scheme. The 16 members of the council are drawn from government, the medical profession and the community, and have expertise in the fields of cancer, epilepsy, palliative care, toxicology, law, pharmacology, law enforcement and botany. Several members are senior jurisdictional officials or clinicians with joint appointments in state health systems. The Committee's current term is until 2021.
- The Medicinal Cannabis Access Working Group consists of representatives from each of the state and territory health departments to promote collaboration across jurisdictions on issues relating to patient access to medicinal cannabis. The meetings are held once to twice annually, and have provided a platform for a number of policy alignments and regulatory improvements. There is a similar medicinal cannabis working group involving law enforcement officials.

The TGA website includes a website link and contact details to each state and territory health department to assist prescribers in accessing different jurisdictional regulations regarding prescribing and dispensing medicinal cannabis.²³

(d) Australia's regulatory regime in comparison to international best practice models for medicinal cannabis regulation and patient access

Cultivation regime

Australia is a signatory to the *United Nations Single Convention on Narcotic Drugs of 1961*, as amended, which requires all signatories to implement controls on the cultivation of the cannabis plant. Commentary to the *Single Convention* provides an overview of the standard regime that signatories have committed to:

*The principal features of that regime are: limitation to medical and scientific purposes of all phases of narcotics trade (manufacture, domestic trade, both wholesale and retail, and international trade) in, and of the possession and use of, drugs; and requirement of governmental authorization (licensing or state ownership) of participation in any phase of the narcotics trade and of a specific authorization (import and export authorisation) of each individual international transaction...*²⁴

The Commentary to the Single Convention makes it clear that possession, use, manufacture and cultivation of any drug in Schedule I of the Convention (including cannabis, cannabis resin and extracts and tinctures of cannabis) is limited exclusively to medical and scientific purposes.

On 17 October 2015, the Australian Government announced its intention to sponsor amendments to the *Narcotics Drugs Act 1967* to enable the cultivation of cannabis in Australia for medicinal and scientific purposes. The changes commenced operation on 29 October 2016. The scheme was designed to meet Australia's obligations under the convention, protect Australia's international reputation and support the development of the medicinal cannabis industry. Departing from obligations under the Convention would pose significant reputational and economic risk to Australia. As one of the world's major legal producer of opiate raw

²³ www.tga.gov.au/access-medicinal-cannabis-products-using-access-schemes

²⁴ Commentary on the *Single Convention*, Article 2 paragraph 1, [1], pages 51 - 52.

material and the developing medicinal cannabis industry, Australia has a strong interest in maintaining the integrity of the existing international drug control regime.

The medicinal cannabis scheme and the role of the Office of Drug Control is described on pages 11 and 12 of this submission. Since the commencement of the Scheme in October 2016 there has been a significantly higher volume of licence applications than was forecast when the scheme was developed. This has created resourcing and processing challenges for ODC in administering the scheme.

A range of reforms are currently progressing to address these challenges. An independent review of the Act was conducted earlier in 2019, focussing on the operation of the medicinal cannabis scheme, with the final report tabled in Parliament in September 2019. The Minister for Health has committed to implementing the 26 recommendations arising from the Review. Initial amendments to the *Narcotic Drugs Regulation 2016* commenced on 1 January 2020 and will simplify some aspects of the licence application process relating to the provision of information and better align terminology with the Act. In the second stage amendments to the Act will be introduced into Parliament in 2020 to implement most of the recommendations including a single licence model for regulating medicinal cannabis. A consultation paper relating to this model is available at: www.odc.gov.au/consultation-single-licence-model.

In addition to these reforms, the ODC is implementing a number of administrative changes to enable it to more efficiently assess licence and permit applications and to focus on compliance and enforcement matters. As part of this process, applications for permits are now assessed separately within the office, increasing the ODC's capacity to focus in a more-timely way on the operations of existing licence holders.

In summary, the cultivation and manufacture scheme for medicinal cannabis in Australia aims to address Australia's commitments under the Single Convention, minimise the risk of diversion of cannabis to illegal uses and provide a product of high and consistent composition and quality suitable for use as a prescription medicine. For these reasons the Australian Government did not consider that personal cultivation of cannabis was appropriate for medicinal purposes. For example, a survey of illicit cannabis obtained for treatment of childhood epilepsies in Australia demonstrated "profound variation" in CBD and THC content, with some samples lacking any detectable CBD.²⁵

In addition, surveys of medicinal and recreational cannabis supplied in other countries in have found a range of contaminants²⁶ with media reports of a fungally-contaminated medicinal cannabis causing the death of a patient in the USA²⁷ and adverse events from pesticide-contaminated medicinal cannabis in Canada²⁸.

Apart from enabling a supply of medicinal quality product for Australia patients, the high production and quality standards of the Australian product should enable Australian medicinal cannabis to be in demand in export markets.

²⁵ Suraev, A., Lintzeris, N., Stuart, J. *et al.* Composition and Use of Cannabis Extracts for Childhood Epilepsy in the Australian Community. *Sci Rep* 8, 10154 (2018) doi:10.1038/s41598-018-28127-0

²⁶ Dryburgh LM, Bolan NS, Grof CPL, Galettis P, Schneider J, Lucas CJ, Martin JH. Cannabis contaminants: sources, distribution, human toxicity and pharmacologic effects. *Br J Clin Pharmacol*. 2018;84(11):2468-2476. doi: 10.1111/bcp.13695.
Seldenrich, N Cannabis Contaminants: Regulating Solvents, Microbes, and Metals in Legal Weed, *Environmental Health Perspectives* 127 (8) August 2019 pp 1-6 doi:10.1289/EHP5785

²⁷ www.cbsnews.com/news/contaminated-medical-marijuana-pot-believed-to-have-killed-cancer-patient/

²⁸ www.cbc.ca/news/canada/nova-scotia/medical-marijuana-cannabis-health-canada-random-testing-1.3971601

Patient access schemes

There are 53 countries which enable access to medicinal cannabis in some capacity as of October 2019²⁹:

- Europe - Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Slovenia, Spain, Sweden, Switzerland, and the UK.
- Asia – South Korea, Sri Lanka and Thailand
- Middle East – Israel and Turkey
- Americas – Argentina, Brazil, Bermuda, Canada, Chile, Colombia, Costa Rica, Jamaica, Mexico, Peru and Uruguay (see note on US below)
- Africa – Lesotho, South Africa and Zimbabwe
- Oceania – Australia, New Zealand and Vanuatu.

The nature of access schemes in different countries vary greatly – for example in several countries listed above access to “medicinal cannabis” extends only to the ability of doctors to prescribe pharmaceutical Sativex where it has been approved by the regulator. In simple terms the schemes can be classified by three parameters - the types of products able to be provided; the conditions for which cannabis is permitted and by the permissions required for access (some form of medical authorisation versus a requirement for a prescription).

Product types available under medicinal cannabis schemes in different countries can be summarised as follows:

- Access to “pharmaceutical” medicinal cannabis products only (e.g. Austria, Belgium, South Korea, Sweden, Turkey). Globally, products containing dronabinol, nabiolone, nabiximols and CBD are registered and regulated as medicines in overseas jurisdictions. Over 25 countries³⁰ have given marketing authorisation to the cannabis derived nabiximols oral-mucosal spray.
- Access to pharmaceutical medicinal cannabis products, cannabis extracts and botanical cannabis (e.g. Australia, Canada, Germany)
- Access only to CBD and/or to low-THC products (e.g. Argentina, Mexico, some US states)
- Potential access to commercial medicinal cannabis products but also enabling cultivation at home or by clubs of cannabis for medical (and in some jurisdictions, recreational) purposes (e.g. Canada, Netherlands, Uruguay)

Only a limited number of countries allow the medicinal use of whole-plant cannabis. These include Australia as well as Canada, Chile, Colombia, Germany, Greece, Israel, Italy, the Netherlands, Peru, Poland, Portugal, and Uruguay. Some countries also only permit cannabis to be prescribed for a very limited number of “severe” conditions such as cancer, HIV-AIDS (Croatia, Czech Republic, Denmark), while a number of other jurisdictions (such as most US states) have (longer) lists of conditions for which medicinal cannabis may be prescribed. In contrast, Australia does not have a list of conditions for which cannabis may (or may not) be prescribed and in this sense is more flexible than many other countries.

²⁹ <https://cannigma.com/regulation/cannabis-regulation-around-the-world/>

³⁰ Further information available at www.emergehealth.com.au/news/media-release-sativex-nabiximols-now-available-in-australia-for-ms-spasticity

In most countries (e.g. Denmark, Germany, Netherlands UK, Israel) a doctor's prescription is required for provision of medicinal cannabis, recognising that the products are treated as medicines. Australia's position aligns with these.

Medicinal cannabis can be obtained without the need for a prescription in Canada, Uruguay and in some US states, although a formal authorisation from a doctors is required – for example in Canada the authorisation is called a “Medical document supporting the use of cannabis for medical purposes under the Cannabis Regulations”. Canadians with such documents also need to register as a patient with a licensed producer to acquire medical cannabis legally.

In the USA as of late 2019, 33 states and the District of Colombia have medicinal (and 11 have recreational) cannabis schemes. However, at the federal level, cannabis remains a prohibited substance by way of the *US Controlled Substances Act 1970*. Under this Act, cannabis is classified by the Drug Enforcement Agency as a Schedule I drug prohibiting its use for any purpose. In December 2014, the Rohrabacher-Farr amendment was signed into law, prohibiting the Justice Department from spending funds to interfere with the implementation of state medical cannabis laws. In effect this means that there is no action taken by US Federal justice agencies.

The US medicines regulator, the Food and Drug Administration (FDA) has published detailed information explaining the US regulatory stance.³¹ The FDA does undertake compliance activities against companies marketing cannabinoid-containing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to foods across state borders.³²

Notwithstanding the large numbers of countries which have legalised various forms of medicinal cannabis only four countries (Canada, USA, Germany, Israel) are known to have provided a larger number of medicinal cannabis authorisations or prescriptions to patients than Australia over the last 12 months (with there being a roughly similar number in the Netherlands). With the exception of Germany, each of these countries has medicinal cannabis schemes dating back 10-20 years. Medicinal cannabis has only been available in Germany since early 2017, but the higher prescription numbers in that country (from media reports, about 240,000 prescriptions for 60,000 patients) are attributed to reimbursement of medicinal cannabis through various health insurance schemes.

Figure 14 provides a visual representation of the various international models of medicinal cannabis supply in 2018. Table 3 provides a comparison of the medicinal cannabis regulatory framework in different international jurisdictions.

Figure 14: International models of medicinal cannabis supply³³

³¹ www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

³² www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details

³³ Sofia Aguilar et al. Medicinal Cannabis Policies and Practices Around the World. International Drug Policy Consortium. 2018 Available at http://fileserv.idpc.net/library/Medicinal%20cannabis%20briefing_ENG_FINAL.PDF

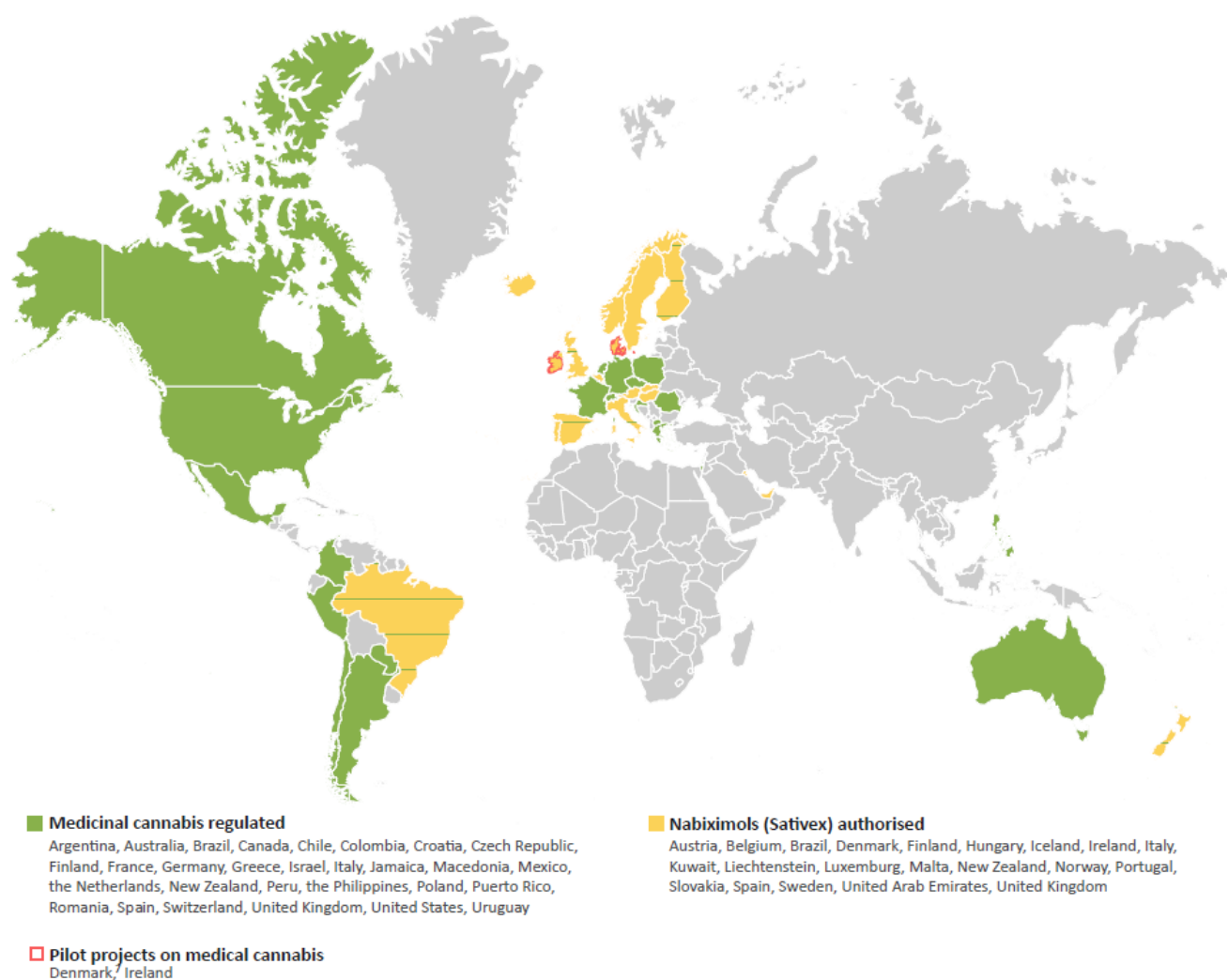


Table 3: Comparison of medicinal cannabis regulatory framework for patient access in international jurisdictions

Caveat: the following information is not exhaustive and is subject to change. The information is adapted from S. Halliday, A Churchill Fellowship to investigate variances of international approaches to the regulation of medicinal cannabis- USA, Canada, Germany, Netherlands, Austria and Israel, 2018. Available at www.churchilltrust.com.au/media/fellows/Halliday_S_2018_International_approaches_to_the_regulation_of_medical_cannabis.pdf

Location	Patient access scheme	Prescriber eligibility	Products available	Clinical guidance documents	Recreational access	Cultivation/ manufacture and personal cultivation allowance
Australia ³⁴	Commenced 2016. <ul style="list-style-type: none"> All cannabis products require a prescription from a prescriber. Access then requires an exemption, unless included in the ARTG and state/territory health approval. Only funded in TAS, and for 90 children with epilepsy in Victoria. 	Governed by individual state/territory legislation. See Table 2.	Sativex (nabiximols) is currently the only approved cannabis-derived medicine. All others are unapproved medicines.	TGA evidence-based Guidance Documents.	No.	Domestic supply and export. cannabis or cannabis resin cannot be exported unless export-only listed on ARTG. In 2018 the ACT territory government passed laws permitting limited personal cultivation.
New Zealand ³⁵	Commenced 2017 <ul style="list-style-type: none"> Ministerial approval required for THC-containing medicinal cannabis products (except Sativex), while CBD products can be prescribed under a normal prescription. Prescribing requirements will change on 1 April 2020. Individuals requiring medically-diagnosed palliative care have a statutory defence to possession of illicit cannabis Scheme to enable domestic commercial cultivation and manufacture to commence 1 April 2020. 	Cannabis-based products usually to be prescribed by a specialist doctor, and patients required to meet strict criteria.	Imported unregistered products, domestic supply chain still developing.	No – but has a specialist advisory group	No.	Domestic supply and export (with licence required to export controlled drugs including cannabis). Personal cultivation not allowed.

³⁴ www.tga.gov.au/access-medicinal-cannabis-products-1

³⁵ www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis/prescribing-medicinal-cannabis-products

Location	Patient access scheme	Prescriber eligibility	Products available	Clinical guidance documents	Recreational access	Cultivation/ manufacture and personal cultivation allowance
United Kingdom ³⁶	Commenced 2018. <ul style="list-style-type: none"> Licence required from the home office to import prescribed medicinal cannabis.³⁷ No other approval required, but only on prescription from specialist prescriber. Access is very limited despite law changes. 	Only specialists can prescribe THC containing products. CBD oil is legal for use and sale in the UK without a doctor's prescription.	Sativex (nabiximols) and Epidyolex (CBD) are the only approved cannabis-derived medicines. All others are unapproved medicines.	Yes – Guidance available from the National Health Service, Home Office, Royal College of Physicians and Medicines and Healthcare Products Regulatory Agency.	No.	Domestic supply and international export. Personal cultivation not allowed.
Israel ³⁸	Commenced 2001. <ul style="list-style-type: none"> All cannabis products require a prescription from a prescriber and a cannabis permit³⁹ with a specialist recommendation and evidence to be approved by the Ministry of Health if the doctor is not on the Ministry's authorised list. Topical CBD products available over the counter. 	Cannabinoid course administered by the Ministry of Health must be completed by pharmacists and prescribers, Certain pharmacies can fill prescriptions. ⁴⁰	Cannabis, THC and CBD products can be bought from pharmacies with a prescription from an authorised prescriber. Ministry holds a list of physicians authorised to prescribe cannabis. Non-authorised can still apply to the Ministry for individual patients.	<i>The Green Book</i> non-referenced book providing advice on the use of cannabis for many medical conditions.	No.	Domestic supply (international export to commence soon). Personal cultivation not allowed.
Brazil ⁴¹	Commenced 2019. <ul style="list-style-type: none"> Domestic cultivation not permitted – all products imported. Prescriptions dispensed by pharmacies and goods imported with limits and licences required. New regulatory 	Prescribing rules vary according to THC concentration. Products with concentrations of THC > 0.2% only prescribed to terminally ill or those who	All goods are unapproved.	No.	No.	No – Import only. Personal cultivation not allowed.

³⁶ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753366/Medicinal_Cannabis_-_Home_Office_Circular_2018_FINAL.pdf

³⁷ www.gov.uk/government/collections/drugs-licensing

³⁸ www.health.gov.il/English/Topics/cannabis/Pages/default.aspx

³⁹ www.health.gov.il/English/Services/Citizen_Services/Pages/kanabis.aspx

⁴⁰ www.haaretz.com/israel-news/.premium-israeli-health-ministry-allows-pharmacies-doctors-to-access-cannabis-market-1.6651450

⁴¹ http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/content/produto-de-cannabis-aprovado-regulamento-para-uso-medicina/219201?p_auth=iOKRM5M

Location	Patient access scheme	Prescriber eligibility	Products available	Clinical guidance documents	Recreational access	Cultivation/ manufacture and personal cultivation allowance
	framework effective early 2020. Also covers quality and manufacturing.	have exhausted options.				
Germany ⁴²	Commenced 2017. <ul style="list-style-type: none"> All cannabis products require a prescription. Products funded under national insurance scheme Domestic supply legal but not yet available - first harvests expected by 2021, controlled by the Cannabis Agency.⁴³ 	No, however mandatory data submission requirements exist to inform epidemiology of prescribing.	No domestic product yet available	No.	No.	Domestic and export – Government-owned process tendered to multiple commercial entities (includes growing, packaging and distribution). Personal cultivation not allowed.
Netherlands ⁴⁴	Commenced 2003. <ul style="list-style-type: none"> Products require a prescription and are dispensed from community pharmacies.⁴⁵ 	No specific requirements	Five products produced on behalf of Government.	'Summary of Product Characteristics' provides unreference d details on the five products available on prescription in the Netherlands.	Coffee Shops can sell cannabis for recreational use within the premises.	Domestic and export -- tendered to a contracted commercial entity Personal cultivation not allowed.
Canada ⁴⁶	Commenced 2001. <ul style="list-style-type: none"> Patients who have an authorisation from a prescriber can purchase from a licensed seller, produce their own supply or designate a producer. Individuals must register with the Regulator to produce or possess medicinal cannabis. Patients are permitted to also possess and use cannabis for recreational purposes. 	Prescribers must be registered but no specific training is mandated.	Not product specific.	Health Canada have produced an <i>Information for Health Care Professionals – Cannabis (marihuana, marijuana) and the cannabinoids</i> document which provides an evidence brief, but is not clinical guidance.	Yes – Commenced 2018.	Domestic supply and export of proprietary products (export excludes plant leaves, flower or resin). Personal cultivation allowed.
Massachusetts (USA) ⁴⁷	Commenced 2013. <ul style="list-style-type: none"> Written 	Yes – Prescribers must have	A patient can grow their own supply or	No – However a CPD course	Yes – 2018.	State only (federally prohibited).

⁴² www.bfarm.de/DE/Bundesopiumstelle/Cannabis/_node.html

⁴³ <https://mjbizdaily.com/germany-confirms-cannabis-licenses-domestic-cultivation/>

⁴⁴ <https://english.cannabisbureau.nl/>

⁴⁵ <https://english.cannabisbureau.nl/exemptions-from-the-opium-act>

⁴⁶ www.canada.ca/en/health-canada/services/registering-produce-cannabis-own-medical-purposes.html

Location	Patient access scheme	Prescriber eligibility	Products available	Clinical guidance documents	Recreational access	Cultivation/ manufacture and personal cultivation allowance
	certification by prescriber for a <i>'debilitating medical condition'</i> which dispensed from cannabis dispensaries or grown at home. Patients must have a state issued registration card which allows 60 day supply. <ul style="list-style-type: none"> CBD sold in many food products (as it is throughout the USA), although not legal under Federal Law. 	completed the Massachusetts Controlled Substances Registration and have completed an approved continuing professional development course on cannabis.	obtain the particular product certified from a cannabis dispensary.	is available.		Personal cultivation allowed (enough to allow a 60-day supply as certified by prescriber).
New York (USA) ⁴⁸	Commenced 2014. <ul style="list-style-type: none"> Certification required from practitioner, then a Medical Marijuana Registration Card is issued. Patient must be suffering from one or more eligible conditions. 	Mandatory education required and practitioner must be registered with the Medical Marijuana Program .	Any form of cannabis can be approved. Patients purchase from a registered organisation's dispensary. Must be registered with Department of Health.	No, but the Department approves the training packages. The Program also mandates the qualifying medical conditions for which medical cannabis may be used	No. Recreational use laws failed to win approval in 2019.	State only (federally prohibited). Personal cultivation not allowed.
Colorado (USA) ⁴⁹	Commenced 2000 . <ul style="list-style-type: none"> Patients are included on a Registry and receive a Registration Card. Written certification by prescriber for a <i>'debilitating medical condition'</i> dispensed from cannabis dispensaries or grown at home. 	No.	FDA approved products (prescription) from a pharmacist and cultivated cannabis products as per the registry.	The Colorado Department of Public Health and Environment has published brief a information for physicians.	Yes – 2014.	State only (federally prohibited). Personal cultivation allowed

⁴⁷ <https://mass-cannabis-control.com/>

⁴⁸ www.safeaccessnow.org/becoming_a_patient_in_new_york

⁴⁹ www.colorado.gov/pacific/marijuana/medical-marijuana-0

Location	Patient access scheme	Prescriber eligibility	Products available	Clinical guidance documents	Recreational access	Cultivation/ manufacture and personal cultivation allowance
California (USA) ⁵⁰	Commenced 1996 <ul style="list-style-type: none">Cannabis dispensaries. Program is voluntary for registration by patients through city Departments of Public Health.	No.	FDA approved products (prescription) from a pharmacist and cultivated cannabis plants.	Qualifying conditions are published and include 'Any debilitating illness where the medical use of marijuana has been deemed appropriate and has been recommended by a physician'.	Yes – 2016.	State only (federally prohibited). Personal cultivation allowed- no limits.

(e) The availability of training for doctors in the current TGA regulatory regime for prescribing medicinal cannabis to their patients.

The TGA has developed educational material for health practitioners to improve understanding of regulatory processes, provide transparency of regulatory decision-making and to reduce the number of SAS applications that are returned because they have been submitted incomplete. Apart from specific guidance on the regulatory system (see below) on the TGA website, a 1-800 telephone line and email contact is available for prescribers who have specific queries.

Guidance on use of SAS was published in September 2017⁵¹ The guidance is for health practitioners and sponsors involved in supplying unapproved therapeutic goods through the SAS, including medicinal cannabis. It outlines the various access pathways, health professional responsibilities and the regulatory obligations when accessing and supplying unapproved therapeutic goods in Australia. In addition, the TGA has published specific information about accessing unapproved medicinal cannabis products including the role of the TGA, the various access schemes, approval statistics and other pertinent information⁵².

The SAS online application system employs an interactive workflow to assist prescribers in complying with both Commonwealth and jurisdictional requirements when making an application for medicinal cannabis. Use of the online system is also supported by specific guidance material.⁵³ Authorised Prescriber guidance is also provided on the TGA website, with information on the scheme and how to make an application using either the online system or a manual application process⁵⁴.

The TGA has worked with the Australian Medical Association⁵⁵ and the Pharmaceutical Society of Australia⁵⁶ to publish online Continuing Professional Development modules outlining the SAS and AP pathways for healthcare professionals. These modules include information on how to

⁵⁰ www.sfdph.org/dph/comupg/oservices/medSvs/MCID/default.asp

⁵¹ www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf

⁵² www.tga.gov.au/access-medicinal-cannabis-products-1

⁵³ www.tga.gov.au/sites/default/files/special-access-scheme-sas-online-system-guidance.pdf

⁵⁴ www.tga.gov.au/form/authorised-prescribers

⁵⁵ www.dplearning.com.au/

⁵⁶ www.psa.org.au/resource/medicinal-cannabis-resources/

access medicinal cannabis. Over the last three years, a number of educational institutions and clinical colleges have also provided training courses and workshop sessions for prescribers on medicinal cannabis and the Department has provided lecture materials and lecturers for several of these courses. In addition, in the first full year of the medicinal cannabis scheme (2017), the TGA organised information session for clinicians and patient groups in most capital cities. The Department is also aware of a number of other training sessions and workshops on medicinal cannabis organised by other groups.

Advertising of prescription medicines directly to the public is prohibited in all OECD countries (except for the United States and New Zealand). Therefore, because individual medicinal cannabis products are S4 or S8 prescription medicines, their advertising to the public is not permitted, although they can be promoted to healthcare professionals. However, it is permissible to direct health practitioners to information about specific unapproved medicinal cannabis products. Therefore the TGA website hosts a link to the ODC website, which has a list of sponsors who have been authorised to import and hold medicinal cannabis stock in Australia.⁵⁷

The Department has also provided advice on request to medicinal cannabis clinics about what types of promotion of their services and products are permissible. Advertising Guidance for businesses involved with medicinal cannabis products was published in October 2019 by the TGA.⁵⁸ The guidance aims to assist providers of medicinal cannabis products and therapies (including health professionals) to comply with the therapeutic goods advertising restrictions.

The TGA will continue to use its webpage to educate health professionals, consumers and industry and provide updates with new information as it becomes available. Senior departmental staff also continue to participate in educational events on medicinal cannabis and information on prescribing and the Special Access Scheme are provided at the TGA booths at a number of healthcare professional conferences annually.

(f) The education of doctors in the Endogenous Cannabinoid System (ECS), and the appropriateness of medicinal cannabis treatments for various indications
and

(g) Sources of information for doctors about uses of medicinal cannabis and how these might be improved and widened

As the national medicines regulator, provision of clinical practice education around the use of a particular group of medicines is outside the normal role and resourcing of the TGA. However, in recognition of the lack of medicinal cannabis clinical guidance material available at the time, the TGA, in conjunction with state and territory governments and with the involvement of relevant clinical and patient groups, developed clinical guidance documents during 2017. The guidance documents, along with annotated bibliographies summarising individual clinical studies on medicinal cannabis were published in December 2017.

The guidance is based on reviews of the clinical literature performed by the Universities of New South Wales, Sydney and Queensland, under the co-ordination of the National Drug and Alcohol Research Centre, and their drafting which was coordinated by senior Departmental staff involved a series of face to face workshops with clinician and patient groups. The documents review and summarise the available clinical evidence for the use of medicinal cannabis published in refereed medical journals since 1980 and include an overview as well as specific

⁵⁷ www.tga.gov.au/access-medicinal-cannabis-products-1

⁵⁸ www.tga.gov.au/sites/default/files/advertising-guidance-businesses-involved-medicinal-cannabis-products.pdf

guidance for chemotherapy-induced nausea and vomiting, epilepsy, multiple sclerosis, chronic non cancer pain and palliative care. These conditions were chosen on the advice of clinician and patient groups because they were the ones that had been most studied in relation to the therapeutic effects of medicinal cannabis products. The guidance documents focus on summarising what has been published on evidence for efficacy of medicinal cannabis and its major constituents in these conditions rather than intending to provide an educational resource on endocannabinoids.

The TGA has also published a consumer resource on medicinal cannabis with the aim to support the discussion between health practitioners and patients about medicinal cannabis as a treatment option. The guidance documents and consumer resource are available on the TGA website.⁵⁹

Since that time, some other groups have published resources, although published evidence based information on the appropriate dosage of various cannabis products is scant. While a number of clinical trials are underway in Australia and internationally, only a few of these (most notably for CBD therapy of paediatric genetic epilepsies) have published results. On the advice of the Australian Advisory Council for the Medicinal Use of Cannabis, it was agreed that there was insufficient new information to warrant updating of the bibliographies or guidances in 2018 or early-mid 2019. However, given the passage of time the clinical guidance documents and bibliographies are currently undergoing review to include new clinical studies, and will be updated as necessary with a view to publication by June 2020.

TGA's guidelines closely align to the National Institute for Health and Care Excellence (NICE) guidelines recently published in November 2019. The NICE guidelines were developed for clinicians in the United Kingdom and provide evidence summaries to improve clinical knowledge. They also provide evidence based information on prescribing medicinal cannabis for intractable nausea and vomiting, chronic pain, spasticity, severe treatment resistant epilepsy and general prescribing guidelines.⁶⁰ A link to these guidelines is provided on TGA's website.

In addition, some states (Queensland⁶¹ and New South Wales⁶²) have funded the publication of clinical guidance documents for health professionals, and are likely to update these as new evidence becomes available. A link to the NSW guidelines, published by the Australian Centre for Cannabinoid Clinical and Research Excellence, which are publicly available, is provided on TGA's website.

Further, the Royal Australian College of General Practitioners (RACGP) have developed webinars with the aim to provide further education and training on prescribing medicinal cannabis.⁶³ A link to these webinars is also provided on TGA's website.

As for all prescription medicines, the final decision whether or not to prescribe medicinal cannabis for a particular patient and particular indications is a matter for individual doctors. The evidence reviews and bibliographies mentioned above summarised the available published evidence over the last four decades for medicinal cannabis for a number of conditions, but as these reviews show in several cases the quality of the studies is variable and only a limited number of published studies show significant, and clear cut effects in particular indications. There is variation among prescribers in their beliefs on the quality of evidence around medicinal cannabis and if they appreciate that evidence remains comparatively limited and variable whether it is appropriate to prescribe cannabis medicine. We believe that some recent

⁵⁹ www.tga.gov.au/medicinal-cannabis-guidance-documents

⁶⁰ www.nice.org.uk/guidance/ng144

⁶¹ www.health.qld.gov.au/_data/assets/pdf_file/0023/634163/med-cannabis-clinical-guide.pdf

⁶² www.australiancannabinoidresearch.com.au/resources

⁶³ www.racgp.org.au/education/professional-development/online-learning/webinars/medicinal-cannabis

media reports of patients complaining of ‘barriers to access’ are in fact due to their doctor not wishing to prescribe because they are unconvinced about the efficacy of cannabis.

The Australian Government has progressed several initiatives to promote further scientific research to inform safe, quality and effective use of medicinal cannabis. This complements the clinical trials being undertaken by individual jurisdictions and the private sector. The goal is to make better use of existing cannabinoid clinical and research data. In 2017, the National Health and Medical Research Council (NHMRC) through the Centre for Research Excellence scheme funded the Australia Centre for Cannabinoid Clinical and Research Excellence (ACRE), Australia's first federally-funded research centre in medicinal cannabinoids. ACRE will enable the Government to build capacity in medicinal cannabis research and provide a national response to current challenges.

In the period from 2009-2018, NHMRC provided \$3,367,657 million for research related to medicinal cannabis (Table 4)

Table 4: NHMRC expenditure on medicinal cannabis research (2009-18)

2009	2011	2012	2013	2014	2015	2016	2017	2018
\$170,367	\$441,460	\$443,788	\$345,154	\$188,599	\$14,293	\$256,015	\$364,121	\$1,143,860

On 6 October 2019, the Government announced \$3 million from the Medical Research Future Fund to examine the benefits of medicinal cannabis for pain, symptom and side effect management for cancer patients. The Department of Health is currently designing the grant opportunity, including consulting with relevant stakeholders to support the development of priorities for funding.

(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

The regulatory scheme for licensing and permits for domestic medicinal cannabis cultivation and manufacture commenced in late October 2016. To manage commercial risk, most licence applicants waited until they were well into the licensing process before completing capital raising and undertaking construction of cultivation facilities. The first licences were granted in 2017 and the first Australian-grown medicinal cannabis provided on prescription on a commercial basis in August 2018. Licensing, construction of facilities, production, manufacture and sale of a prescription medicine product within a 22 month period is remarkable.

Further local cultivation and manufacture came on line in 2019, and it was estimated that in 2019 about 10% of SAS B prescriptions were for locally cultivated and manufactured product. A number of Australian cultivators have announced that very significant production and manufacturing capacity will come on line in 2020 (see section (i) below). Depiction of the situation as a “shortage” is not accurate.

Sponsored imports

In early 2017, the government recognised that importation of medicinal cannabis to address individual shipments was administratively cumbersome for the prescriber, patient and department, expensive and delayed patient access. In February 2017, the Government announced that it would be possible for companies to sponsor “bulk” imports of medicinal cannabis products, so that these products would be available to dispatch (often on an overnight

basis) from Australian capital cities through the local pharmaceutical supply chain for dispensing to patients.

The sponsored importation scheme works as follows. Under Regulation 5 of the Customs (Prohibited Imports) Regulations 1956 all forms of cannabis, resins and extracts and cannabinoids require a licence and permit to import. Supply routes, are strictly controlled, as required under the international drug conventions. Importers may apply for a licence and permit to import, in accordance with Regulations 5 of the PI Regulations, for an importer to supply medicinal cannabis products, for patient supply through the Special Access Scheme, Authorised Prescriber or Clinical Trials. The importer must establish that they are permitted to supply medicinal cannabis products within their state/territory.

Imported medicinal cannabis products are subject to Therapeutic Goods Order 93 which describes required quality standards; they may also be required to be manufactured overseas in accordance with appropriate manufacturing standards. Over 900 permissions have been granted for sponsored imports since early 2017, and a very wide range (over 130) of different products has been imported. In this sense it is not accurate to describe sponsored imports as a “practice of product substitution”.

Timeliness of SAS approvals

The Department through the TGA facilitates access to unapproved medicinal cannabis via the patient access schemes outlined above, however the Department does not play a role in the actual supply of the products. It is the responsibility of the prescriber, in conjunction with the dispensing pharmacy, to source the product from the relevant sponsor. This is the case for all unapproved therapeutic goods supplied under access schemes, not just medicinal cannabis. However, to assist health professionals, the Office of Drug Control has published information about manufacturers and suppliers of medicinal cannabis in Australia.⁶⁴

Although the Department is not directly involved in supply, as described above in response to Term of Reference (c) the TGA has partnered with state and territories to consolidate regulatory decision making and reduce regulatory burden on applicants. Since the introduction of the SAS Online System in July 2018, approval letters for medicinal cannabis are sent electronically to health practitioners within an average of 30 hours from receipt of the required information, Furthermore, prescribers are generally granted 12-month approval for SAS B applications from both the TGA and the relevant state or territory health department in order to reduce the need to re-apply regularly.

Upon review of an application a TGA delegate may seek further information from the prescriber to assist in decision making. Further information is typically requested for the following reasons:

- Inadequate information supplied in relation to therapeutic goods on the ARTG that have been considered prior to the clinical decision to trial an unapproved medicine.
- Clarification of discrepancies in patient details, product details or diagnosis to ensure completion of SAS B application requirements.

However, this does not unnecessarily delay applications. TGA sought further information from prescribers in only 5% of the 22,389 SAS B applications for unapproved medicinal cannabis products submitted between 1 January and 30 November 2019. Once the requested information is provided, the application usually proceeds to the approval stage. In a small number of cases (<1%) the prescriber does not respond to the request for information.

⁶⁴ www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products

Most medicinal cannabis products being supplied in Australia are unapproved products. Should a product be included in the ARTG it would be subject to the requirement to mandatorily report a product shortage to the TGA, so that any shortage can be managed in a timely fashion.

(i) The current status of the domestic regulated medicinal cannabis industry

Although the first licences were only granted in 2017, the medicinal cannabis industry in Australia is quite significant with 18-20 Australian Stock Exchange (ASX) listed companies with a major focus on medicinal cannabis cultivation and/or manufacture and a similar number of other listed companies with indirect involvement in the industry. As of mid-2019, the top 20 ASX listed companies had a market capitalisation of \$1.8 billion.⁶⁵

In addition, there are a number of private companies developing significant medicinal cannabis operations. The companies have different areas of business focus – some emphasising cannabis genetics and cultivation, others working closely to supply prescriptions for oils and tinctures from Australian medicinal cannabis clinics while a final group of companies have a focus on clinical trials and development of drug delivery systems for potential TGA registration.

As of December 2019, three medicinal cannabis projects have also been awarded “Major Project Status”. Major Project Status is the Commonwealth Government’s recognition of the strategic significance of a project to Australia. It provides companies with extra support from the Major Projects Facilitation Agency, including a single entry point for Commonwealth Government approvals, project support and coordination, and help with state and territory approvals. The decision to grant Major Project Status is made by Minister Andrews, Minister for Industry, Innovation and Science.

Companies with major project status include Asterion for the development of new medicinal cannabis facilities in South East Queensland and regional Victoria, Hydrogenics for a multi-stage medicinal cannabis facility in Queensland and Canopy Growth for a facility in Victoria. The ODC prioritises review of applications submitted by companies that have been awarded Major Project Status, although the overall approval timeframes may be out of ODC’s control as in some cases completion of an application requires the provision of critical information from law enforcement agencies.

As at 31 December 2019 the ODC has granted 100 licences to cultivate, produce and/or manufacture medicinal cannabis, 92 of which are currently in effect. This includes 31 licences for cultivation of cannabis for medicinal use, 20 for cultivation for research, and 41 for manufacture of medicinal cannabis products. Further, licence holders with appropriate permits are, collectively, authorised to annually produce in excess of 35,000kg of medicinal cannabis (dry flower). Under the ND Act, licence holders must demonstrate that Australian demand is being met prior to any export being approved.

The 2016 amendments to the ND Act which implemented the medicinal cannabis framework required the Minister to commission a review of the operation of the ND Act to be carried out during the third year of operation of the scheme. This Review commenced in January 2019 and was tabled in Parliament on 5 September 2019.

The review found that the ODC had received a far higher number of medicinal cannabis licence applications than expected, and a far higher number than the ODC was resources to review. This has led to slower review times than anticipated and during the Review strong interest was expressed for legislative and administrative reforms to improve the operation of the medicinal

⁶⁵ www.businessnewsaus.com.au/articles/australia-s-top-20-cannabis-companies.html

cannabis scheme. Licence applications can be lengthy and intricate and require time-consuming consultation with applicants. This contributed to processing delays in the ODC and to frustration and criticism on the part of licence applicants and holders. In addition, some of the legislative standards in the ND Act and ND Regulation were found to be ambiguous, inexact or inordinately demanding while others went further than the Single Convention requires. These add to the ODC's administrative burden and to the obligations imposed on licence applicants and holders.

The Report made recommendations to amend the ND Act and the ND Regulation to delete or rephrase some legislative standards and to introduce simpler administrative processes (for example, to allow notification rather than formal approval of minor permit variations).

The Government has accepted all recommendations of the Review. Amendments to the *Narcotic Drugs Regulation 2016* commenced January 1 2020 as part of Stage 1 of the implementation of recommendations in the Report on the Review and these will streamline some aspects of the licence application process. The ODC is also improving internal processes to enact other recommendations from the review. Other simplifications to the regulatory scheme in a second stage of implementation of the recommendations of the Review, such as establishment of a single licence to authorise all or some of cultivation, production, manufacture and research, would require amendment to the ND Act. A public consultation on the proposed single licence model is currently underway.⁶⁶

⁶⁶ www.odc.gov.au/consultation-single-licence-model

Glossary

Australian Register of Therapeutic Goods (ARTG)	The register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia.
Cannabidiol (CBD)	A cannabinoid compound which occurs naturally in <i>Cannabis</i> plants.
Cannabinoid	A drug that acts on the endocannabinoid system. The cannabis plant synthesises many cannabinoids such as tetrahydrocannabinol (THC) and cannabidiol (CBD).
Cannabinoid profile	The amount of all cannabinoids in the plant.
Cannabis	Cannabis is a genus of flowering plant in the family <i>cannabaceae</i> . Cannabis contains a variety of compounds (cannabinoids) which are ligands (binding agents) for cannabinoid receptors in the body. A variety of plant-derived and synthetic cannabinoids have been developed for medical use.
Dossier	A collection of files and documents that contains data (administrative, quality, nonclinical and clinical) relating to a therapeutic good.
Endocannabinoid system	A group of neurons, substances and receptors that make up a complex regulatory system throughout the brain, body, and central and peripheral nervous systems. The endocannabinoid system is believed to contribute to maintaining internal stability (homeostasis) by adjusting release of neurotransmitters and regulating bodily functions, including appetite, sleep, emotion, and movement.
Orphan drug	A medicine, vaccine or in vivo diagnostic agent that meets the requirements of regulation 16J of the <i>Therapeutic Goods Regulations 1990</i> .
Prescription medicine	<p>A registered therapeutic good included in the ARTG that:</p> <ul style="list-style-type: none"> • is a medicine within the meaning of the Therapeutic Goods Act; • contains a substance mentioned in Schedule 4 or 8 to the Poisons Standard; and • is normally available for supply in Australia. <p>Prescription medicines require an authorised health professional's written instruction (prescription) before they can be obtained from a registered pharmacist. The types of therapeutic goods that are regulated as prescription medicines are listed in Part 1 of Schedule 10 of the <i>Therapeutic Goods Regulations 1990</i>.</p>
Poison Standard	The legal title of the Standard for the Uniform Scheduling of Medicines and Poisons. It is a Legislative Instrument consisting of decisions regarding the classification of medicines and poisons into Schedules. Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety
Sponsor	Described in Section 3(1) of the <i>Therapeutic Goods Act 1989</i> . A person who exports, or arranges the exportation of, the goods from Australia; or a person who imports, or arranges the importation of, the goods into Australia; or a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply.
Tetrahydrocannabinol (THC)	Chemical name - <i>trans</i> -delta ⁹ -tetrahydrocannabinol. A cannabinoid compound which occurs naturally in <i>Cannabis</i> plants. THC is the principal psychoactive constituent in cannabis.