Government of **Western Australia**
Department of **Health**

Department of Health submission to:

Select Committee Inquiry into Cannabis and Hemp

January 2022

health.wa.gov.au

Contents

1. Overview of current regulatory frameworks for medicines, including cannabis

1.1. Regulation of medicines

The regulation of medicines occurs at both Commonwealth and state/territory level. The Commonwealth Government is responsible for regulation of commercial products that are supplied for therapeutic use and operates a product registration and listing scheme aimed at ensuring therapeutic products available to Australian consumers are efficacious and safe and meet manufacturing quality standards. State and territory legislation determines the level of health professional oversight required for a consumer to access a particular medicinal substance. State and territory legislation refers to the active ingredient rather than branded products.

Individual medicinal substances and other chemicals are included in the national Poisons Schedules[1]. The chosen schedule (or schedules) for the substance is based on the substance's risk to human health. A set of regulatory controls is then applied to all substances within a 'schedule'.

For example, medicines in Schedule 3 (S3) can only be supplied to a consumer from a pharmacy and only after a pharmacist has assessed that the particular medicine is suitable for that individual. S3 medicines have the words "Pharmacist Only Medicine" on their labels. Medicines in Schedule 4 (S4) are 'prescription only' medicines and must be prescribed for patients by certain health professionals, such as medical practitioners, nurse practitioners and dentists. Schedule 8 (S8) medicines also require a prescription but are included in this schedule because of the risk of dependency associated with their use and the risk of diversion into the illicit drug supply market.

In Western Australia (WA), in common with other states and territories, manufacturers and wholesale suppliers of medicines in S2, S3, S4 and S8, including cannabis-based medicines, must be licensed. In towns where there is no community pharmacy, a retail licence can be issued for S2 medicines. Otherwise, only a pharmacy can supply scheduled medicines to consumers, either over the counter (S2 and S3) or on prescription (S4 and S8).

Some medicines are considered safe enough to be available to consumers in supermarkets and other general sales outlets. Sometimes all forms of the medicine will be 'unscheduled': such as many vitamin and herbal preparations. Sometimes small packs of a medicine that is otherwise scheduled will be exempted from scheduling. Small packs of paracetamol and ibuprofen available in supermarkets are examples of products that are 'exempted'.

Regardless of whether a medicinal substance is scheduled or not, the requirement for products containing the substance to be included on the Australian Register of Therapeutic Goods (ARTG) will apply. Medicines cannot be generally marketed and supplied across Australia unless they are included on the ARTG. However, the

[1] A link to the national Poisons Standard is available at: https://www.tga.gov.au/publication/poisons-standard-susmp

Commonwealth's Therapeutic Goods Administration (TGA) administers a number of schemes which allow certain health practitioners to access therapeutic goods that are not on the ARTG, for individual patients.

There are two levels for inclusion on the ARTG: AUST R (registered) products and AUST L (listed) products. The approval of AUST R products is based on satisfactory assessments of their quality, efficacy and safety by the TGA and prescription medicines will be approved via this pathway. The AUST L pathway is reserved for intermediate and lower risk products and includes medicines referred to as 'complementary' medicines including many herbal medicines, vitamin and mineral supplements, aromatherapy products and some traditional medicines, such as traditional Chinese medicines and Ayurvedic medicines. The general rule is that if a substance is included in Schedule 2, 3, 4 or 8, therapeutic goods containing this substance as an active ingredient will need to be approved via the AUST R pathway.

The AUST L pathway has two tiers: AUST L(A) where the 'A' stands for 'assessed' (intermediate risk products) and AUST L (low risk products) where there is no 'up front' assessment by the TGA. The TGA makes a pre-market assessment of efficacy for AUST L(A) products. For AUST L medicines, the sponsor must have information to support the claims they make about their medicine and evidence that their product is manufactured in accordance with the principles of Good Manufacturing Practice (GMP) but they do not have to provide this information to the TGA unless requested.

In circumstances where a substance is used as both a scheduled medicine and as a food, there is an exemption from the Poisons Schedules provided the food meets the requirements of the national Food Standards Code. In WA, the *Food Act 2008* requires products intended for sale, or sold as food, to meet the Food Standards Code.

1.2. Regulation of medicinal cannabis

Cannabis is classified as a drug under international control, through the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (the Single Convention). As a signatory, Australia has obligations under the Single Convention, including to have a system of controls over the cultivation of cannabis plants and production of cannabis and cannabis resin. The Commonwealth Government's cultivation and licensing scheme, through the *Narcotic Drugs Act 1967 (Cth)*, has been developed to comply with the requirements of the Single Convention.

Cannabis preparations for therapeutic use are included in S3, S4 and S8 of the *Medicines and Poisons Act 2014*. Cannabis that is not for therapeutic use is classified as a Schedule 9 (S9) 'prohibited substance'. The term cannabis is defined in the national Poisons Standard as including seeds, extracts, resins and the plant, and any part of the plant.

Cannabis based medicines that contain tetrahydrocannabinol (THC) were first included in S8 at the end of 2016. Cannabis in S8 can only used for human therapeutic use. The schedule entry does not allow use of cannabis as a veterinary medicine. Dronabinol and nabixamols were listed prior as individual chemical substances but their listing did not allow other cannabis derivatives to be present.

Cannabidiol, as a chemical substance, is classified as a S4 'prescription only' medicine. The schedule entries for cannabidiol includes an allowance for low level residual concentrations of other naturally occurring cannabinoids, which recognises that cannabidiol in medicines will often be extracted from cannabis plants rather than being produced via chemical synthesis. Cannabidiol has been classified as a prescription medicine since June 2016. The S4 cannabidiol entry allows therapeutic use for both humans and animals.[2]

There is also an entry for cannabidiol in S3. This entry followed a review of the safety of low dose cannabidiol by the TGA and flowed from recommendations made in the March 2020 Report of the Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia.[3] The S3 entry only applies to cannabidiol products included on the ARTG. This ensures such products have an approved indication suitable for supply by a pharmacist. Despite the S3 entry commencing on 1 February 2021, there are currently no S3 cannabidiol products available in Australia.

Before a S3 cannabidiol product can be marketed, the manufacturer will need to apply to the TGA for product registration and will need to be able to provide clinical trial evidence of efficacy and safety for the indications for which they are requesting approval.

Because the majority of cannabis-based medicines are unapproved therapeutic goods, these medicines can only be prescribed in accordance with the TGA's access schemes for this category of therapeutic goods, such as the Special Access Scheme, the Authorised Prescriber Scheme or a Human Research Ethics Committee (HREC) endorsed clinical trial.

Within WA, cannabis-based medicines are regulated in the same manner as other S4 and S8 medicines. All cannabis-based medicines can be prescribed by any registered medical practitioner for their patients and prescriptions for cannabis-based medicines can be dispensed at any community pharmacy. Similar to other S8 medicines, there are authorisation and/or notification requirements when prescribing cannabis in S8.

[2] The Australian Veterinary Medicines and Pesticides Authority (APVMA) operates a product registration scheme for all veterinary medicines. There are currently no cannabidiol products approved for marketing and supply as veterinary medicines in Australia. Through AgVet legislation, there are provisions allowing veterinary surgeons to prescribe unregistered products and prescribe 'off-label'.

[3] Available at: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Medicinalcannabis/Report

1.3. Summary of the regulation of prescription medicines, including medicinal cannabis

Regulatory area	Responsible jurisdiction	Applicable legislation	Comments
Designation of chemical substances as pharmacy only (Schedule 2), pharmacist only (Schedule 3), prescription only (Schedule 4, S4), controlled drug (Schedule 8, S8) or prohibited substance (Schedule 9, S9).	Commonwealth	Therapeutic Goods Act 1989 (Cth)	The *Medicines and Poisons Act 2014* (the Act) provides for 'WA only' scheduling of individual substances if required. However, as with all states and territories, WA has agreed to adopt the national schedules by reference.
Authorisation of who can prescribe S4 and S8 medicines and who can dispense prescriptions for same (Authorisation linked to health profession).	State	Medicines and Poisons Act 2014	The nationally agreed Poisons Schedules are adopted into the Act by reference.
Authorisation to prescribe S8 medicines to individual patients.	State	Schedule 8 Medicines Prescribing Code, made under the Medicines and Poisons Act 2014.	See also approval requirements exercised by the Commonwealth Government to prescribe unapproved therapeutic goods.

Regulatory area	**Responsible jurisdiction**	**Applicable legislation**	**Comments**
Determination of which commercially manufactured therapeutic products can be supplied across Australia (approved therapeutic goods).	Commonwealth	Therapeutic Goods Act 1989 (Cth)	Regulatory scheme intended to ensure only products meeting manufacturing quality standards and with documented safety and effectiveness for the approved indications are marketed across Australia.
Schemes to allow prescribing and use of unapproved therapeutic goods (Special Access Scheme, Authorised Prescriber Scheme)	Commonwealth	Therapeutic Goods Act 1989 (Cth)	These schemes recognise that not all products marketed as medicines in comparable overseas countries are marketed in Australia. The schemes provide Australians with a 'right of access' to medicines that are not approved for marketing in Australia.
Allowance for pharmacists to manufacture an unapproved therapeutic good for an individual patient.	Commonwealth	Therapeutic Goods Act 1989 (Cth)	Usually referred to as 'pharmacy compounding'.
Scheme to allow cultivation and production of medicinal cannabis and manufacture of a drug or product.	Commonwealth	Narcotic Drugs Act 1967 (Cth)	Regulatory scheme required for Australia to comply with obligations as a signatory to the international drug conventions.
Importation of medicinal cannabis and other medicines that are subject to international border control (includes all S8 medicines)	Commonwealth	Customs (Prohibited Imports) Regulations 1956 (Cth)	For seeds and plants, biosecurity import conditions may also apply (Commonwealth and State).

Regulatory area	**Responsible jurisdiction**	**Applicable legislation**	**Comments**
Quality standard for medicinal cannabis products (both S4 and S8)	Commonwealth	Therapeutic Goods Act 1989 (Cth)	Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017
Penalties for illegal possession and supply of S8 and S9 substances, including cannabis.	State	Misuse of Drugs Act 1981	Administered by WA Police.
Licensing to allow supply of S4 and S8 medicines to pharmacies, medical practices and hospitals.	State	Medicines and Poisons Act 2014	
Funding of medicines in the community, with reimbursement of community pharmacies for dispensing Pharmaceutical Benefits Scheme (PBS) prescriptions.	Commonwealth	National Health Act 1953 (Cth)	Only approved therapeutic goods are eligible to be approved as PBS medicines. With the exception of Sativex® and Epidyolex®, medicinal cannabis products are unapproved therapeutic goods.
Funding of PBS medicines for patients discharged from public hospitals and PBS medicines prescribed for public hospital outpatients.	Commonwealth	Formal agreement between Commonwealth and State under the National Health Act 1953 (Cth)	All WA public hospitals participate in Pharmaceutical Reform Agreements, which means PBS medicines for outpatients and on discharge are funded via the PBS scheme.

Regulatory area	**Responsible jurisdiction**	**Applicable legislation**	**Comments**
Funding of medicines used for admitted patients in public hospitals and non-PBS medicines supplied to patients at discharge or as outpatients.	State	Patient contribution fees set under the Health Services Act 2016.	There is also a WA Government Pharmaceutical Products common use arrangement.
Availability of particular medicines to be prescribed for WA public patients.	State	Statewide Medicines Formulary (SMF), via mandatory policy made under the Health Services Act 2016	Medicines not included in the SMF require approval to prescribe on an individual patient basis by the health service's Drug and Therapeutics Committee, when therapeutic need is justified.

2. Availability of medicinal cannabis

There are only two cannabis-based medicines on the ARTG[4]: Sativex® and Epidyolex®. The majority of cannabis-based medicines prescribed in Australia are unapproved therapeutic goods.

Data from 2019 indicate that, at that time, Little Green Pharma (LGP) products were the most commonly dispensed brand of medicinal cannabis in WA. Other brands being used were produced by Cannimed and Tilray. Since 2019, a number of other manufacturers have entered the market. However, LGP products remain popular in WA.

Sativex® contains nabiximols, a botanical extract from the cannabis plant which contains equal portions of cannabidiol and tetrahydrocannabinol (THC), where these cannabinoids comprise at least 90 percent of the total cannabinoid content. Sativex® is a S8 medicine and is approved for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis. Sativex® is not currently a Pharmaceutical Benefits Scheme (PBS) medicine.

Epidyolex® contains cannabidiol and is indicated as an adjunctive therapy for seizures associated with two severe forms of epilepsy that develop in infancy and early childhood, Lennox-Gastaut syndrome and Dravet syndrome. Both Lennox-Gastaut syndrome and Dravet syndrome fall into the category of ‘rare diseases’ and account for only a few percent of all children with epilepsy. Epidyolex® is subsidised under the Commonwealth’s PBS for Dravet syndrome, in children aged 2 years and older.

There are no S3 medicines that contain cannabidiol currently available. Although Epidyolex® is a cannabidiol product, the medical conditions Epidyolex® is used to treat are not suitable for management by a pharmacist and Epidyolex® will remain a ‘prescription only’ medicine. Treatment with Epidyolex® will be initiated and monitored by a specialist neurologist.

Epidyolex® is included on the WA Statewide Medicines Formulary for outpatient treatment of public patients for the PBS indications and criteria, under the direction of a neurologist. Inpatient initiation of Epidyolex® requires the clinician to obtain Individual Patient Approval from their relevant hospital drug and therapeutics committee.

Prior to the availability of Epidyolex®, a number of Individual Patient Approvals had been issued to allow treatment of patients of Perth Childrens’ Hospital (PCH) with unapproved therapeutic goods containing cannabidiol. All these patients were under the care of a paediatric neurologist and had complex, intractable epilepsy. As of December 2021, 22 of these patients continue to have their cannabidiol products dispensed at PCH.

The extensive utilisation of the TGA’s alternative access pathways for medicinal cannabis products means manufacturers and importers of these products are making increasing sales of their products. The TGA’s dashboards of SAS Category A notifications and Category B applications shows 112,022 applications/notifications

[4] As at 13 December 2021.

were submitted across Australia during 2021. These applications/notifications relate to both S4 and S8 products. This compares to only around 25,450 SAS applications/notifications across Australia in 2019, meaning there has been more than a four-fold increase in SAS applications/notifications over the last two years. In addition, there will be prescriptions written by TGA Authorised Prescribers of whom there are 440 around Australia (as at 31 October 2021).[5]

These increases in the prescribing of medicinal cannabis mean there is little incentive for manufacturers and importers to apply to the TGA for product registration, which will require clinical trial data to support both their proposed therapeutic indications and the safety of their product. The TGA charges around $250,000 for an application and evaluation of a new prescription medicine product.

Once a product can be fully marketed in Australia, the sponsor may also choose to apply for PBS listing. The information requirements for PBS submissions not only require evidence of efficacy and safety but must also provide an economic evaluation of substituting the proposed medicine for its main comparator products for the proposed use and information about the use of the medicine in practice, such as the likely extent of use and financial estimates.

The current landscape, where most medicinal cannabis products are unapproved therapeutic goods, means that health practitioners do not have access to standardised product information (with indications, doses and potential adverse effects) via published resources, as they would for other medicines. This may explain the reluctance of some medical practitioners to prescribe medicinal cannabis products and may have fuelled the development of stand-alone cannabis clinics, some of which are known to have links to particular manufacturers and importers.

The fact that, although any medical practitioner could choose to prescribe medicinal cannabis, many do not has resulted in consumers frequently contacting the Department of Health for contact details of practitioners approved or willing to prescribe a cannabis–based product. The Department does not maintain a register for consumer use of medical practitioner preferences in relation to the prescribing of these products.

3. Prescribing of medicinal cannabis

At the time the Medicines and Poisons Regulations 2016 were being developed, there was limited information about the type of medicinal cannabis products that may become available and the projected uptake by prescribers. It was anticipated that, because medicinal cannabis is not considered a first-line treatment for any indication, specialist medical practitioners would be involved in the care of patients commencing treatment with this therapeutic option.

These factors resulted in the development of a regulatory scheme similar to that used for stimulant medicines, where suitable specialists could be designated as a ‘cannabis-based product prescriber’ and they could appoint a general practitioner or other medical practitioner as a co-prescriber for their patient. Similar to the stimulants regulatory scheme, the patient’s situation must meet specific criteria and

[5] See https://www.tga.gov.au/medicinal-cannabis-role-tga

the specialist prescriber must notify the Department of their prescribing for each patient.

Through the Schedule 8 Medicines Prescribing Code (the Prescribing Code), the 'cannabis-based product prescriber' notification scheme is applicable to TGA registered products and limited other circumstances, including treatment within a clinical trial and prescribing by a TGA Authorised Prescriber (TGA AP).

Unless prescribing of medicinal cannabis products that are unapproved therapeutic goods is within a clinical trial or by a TGA AP, prior authorisation by the Department is currently required to prescribe each product for each patient.

This is consistent with the Prescribing Code rules for other S8 medicines that are unapproved therapeutic goods. This requirement recognises that the risks associated with unapproved therapeutic goods, including preparations compounded by pharmacists, may be higher as there is:

- Less Australian regulatory control over product quality
- Limited documentation of the appropriate dose, indications and side-effects
- A professional responsibility for prescribers to advise patients that they are being treated with a product that has not been assessed by the national medicines regulator as being suitable for supply in the Australian market.

The situation for cannabis-based products is slightly different to other unapproved therapeutic goods in S8 in that products must comply with a quality standard issued by the TGA, *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017*.

It has been argued that as the TGA is already approving prescribing of unapproved therapeutic goods, authorisation at a state level is redundant. However, these two approvals are for separate purposes.

The TGA is focussed on the risk of patients being exposed to an unapproved product rather than an approved product whilst the focus of the states and territories is on managing public health risks associated with use of drugs that can cause dependency and addiction.

Although it was envisaged that specialist medical practitioners would be involved in recommending treatment with medicinal cannabis, this has not turned out to be the case. Most prescribing appears to be either by the patient's usual general practitioner (GP) or by a different GP with a particular interest in cannabis as a medicine. Around half the prescribing of medicinal cannabis in S8 is by prescribers associated with dedicated cannabis clinics.

The Department of Health has frequent telephone, email and written interactions with individual medical practitioners regarding medicinal cannabis, as part of regulatory activities providing authorisations for S8 medicines and, as part of general advice and information offered in relation to the prescribing and dispensing of cannabis-based products.

The most common issues raised by these medical practitioners relate to the lack of readily accessible, evidence-based, reliable and validated sources of product information to:

- readily assess likely efficacy in an individual patient and inform prescribing decisions;
- guide treatment and dosing (including starting doses, dose response and safe maximum doses);
- compare relative properties of brands, formulations and strengths (including absorption, comparative efficacy and pharmacokinetic behaviour) so as to select a therapy best tailored to the patient;
- assess drug interactions;
- counsel patients on adverse drug effects;
- compare costs; and
- counsel patients in relation to the legality and safety of driving while taking a cannabis-based medicine.

Many of these information deficits are an inherent issue with these products being unapproved therapeutic goods. Part of the registration of a prescription medicine by the TGA is the issuing of both an approved product information document and a consumer medicines information document.

Since November 2019, the Department of Health has only required GP prescribers to seek specialist support where particular high-risk criteria are met, such as where the patient is recorded as a drug dependent person or where the patient is under 18 years of age.

Because most medicinal cannabis products are unapproved therapeutic goods, there are regulatory requirements for prescribers via both the TGA and the WA Department of Health. Since October 2018, WA has participated in a streamlined application process where the application to satisfy both Commonwealth and state requirements has been via a TGA administered electronic portal. Provided the prescriber includes all the required information on the application form, the Department has committed to a two business day turnaround for decisions on these applications.

There is an exemption from adherence to the SAS or TGA AP scheme, when prescribing a medicinal cannabis preparation that must be compounded by a pharmacist for an individual patient. A limited number of pharmacies in WA are compounding these type of preparations but the majority of cannabis-based medicines supplied in the state are commercially manufactured. It is only over the last two years that applications for compounded cannabis-based preparations have been seen in WA.

During 2022, real-time prescription monitoring (RTPM) will become available to clinicians in WA, which will mean prescribers and dispensers will be able to see all S8 medicines currently being prescribed and dispensed for their patient. They will also be able to see whether their patient has high-risk factors, such as experiencing drug dependence or active ‘doctor shopping’. Although this information is already available via the Department of Health’s Prescriber Information Service, this telephone service does not operate 24/7.

Roll-out of RTPM presents an opportunity to reconsider regulatory controls over the prescribing of medicinal cannabis and creates potential to reduce regulatory burden for both prescribers and the regulator. A similar regulatory scheme to that used for

S8 opioids could be considered for medicinal cannabis in S8, where criteria associated with the medicine and the patient allow prescribing to be divided into lower risk and higher risk, with only higher risk prescribing requiring prior authorisation. This will require public consultation and the usual checks and balances associated with amendment of regulations.

The Department of Health does not currently actively monitor prescribing of any medicines in S4, including cannabidiol.

The Department conducted an internal review of applications to prescribe cannabis in S8 during 2019 prior to the implementation of the streamline TGA application process.

It was found that 83 per cent of applications were for indications included in the guidance documents produced by the Commonwealth Department of Health.[6]

Table 2: Indications specified in applications received in WA during 2019 (S8 products only)

Indication	**Authorisations (%)**
Anorexia (cancer)	1
Cancer pain	10
Chronic pain	44
Clinical trial	7
Dementia	< 1
Epilepsy	1
Fibromyalgia	1
Headache	1
Insomnia	4
Multiple sclerosis	2
Neuropathic pain	27
Palliative care	1
Parkinson's	1
PTSD	< 1

Around 8 per cent of applications involved patients stated as suffering from a terminal illness or receiving palliative care. Patients in this cohort were generally older with an average age of 55 years (range 18 to 97 years).

Thirty-two per cent of patients were already receiving therapy with S8 opioid medicines. Around 10 per cent were considered to be receiving therapy classified as high-risk, predominantly through use of doses greater that 90 mg of morphine dose-equivalents per day.

[6] Available at: https://www.tga.gov.au/medicinal-cannabis-guidance-documents

The TGA has a dashboard showing the number of SAS Category A and SAS Category B applications received from across Australia.[7] These data are about approval numbers, not patient numbers.

TGA data for 2021 indicate that for SAS Category B applications, which cover both S4 and S8 cannabis products, the most common indications included on applications were chronic pain and anxiety, accounting for 58.1 per cent and 17.6 per cent of applications from WA based prescribers respectively.

As at the beginning of December 2021, 5837 SAS applications/notifications had been received from prescribers located in WA since cannabis first became available for therapeutic use. These applications/notifications relate to both S4 and S8 products. There will also be prescriptions written by TGA Authorised Prescribers which are not included in these data.

During 2021 (until 13 December), the TGA received SAS Category B applications from 320 different prescribers in WA, representing 12 per cent of all prescribers in Australia who submitted such applications.

Interestingly, the proportion of SAS applications/notifications from each jurisdiction does not correspond to the proportion of the Australian population resident in each jurisdiction, as shown in the table below. A possible explanation for this skewed distribution of prescribers is that prescribers located in one jurisdiction are prescribing cannabis-based products via telehealth for a patient in another state or territory. This appears to commonly occur from dedicated cannabis clinics.

There are anecdotal reports of patients obtaining multiple supplies of medicinal cannabis via telehealth consultations with prescribers at cannabis clinics located in multiple states and territories. It appears each prescriber is unaware that the patient has been prescribed medicinal cannabis by another medical practitioner.

Table 3: Special Access Scheme notifications and applications received by prescriber location[8] compared to proportion of the population, 1 January to 13 December 2021

State or territory	**Percentage of all SAS notifications and applications received**	**Percentage of Australian population[9]**
New South Wales	17.7	31.8
Victoria	20.2	25.9
Queensland	55.5	20.3
South Australia	0.6	6.9
Western Australia	5.2	10.4

[7] Available at: https://www.tga.gov.au/medicinal-cannabis-access-data-dashboard
[8] Prescriber may be located in a different state or territory to their patient.
[9] From https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2021/31010do001_202103.xls

State or territory	Percentage of all SAS notifications and applications received	Percentage of Australian population[9]
Tasmania	0.2	2.1
Northern Territory	No data available	1.0
Australian Capital Territory	0.4	1.7

In WA, as at 14 December 2021, there were 2824 current authorisations to prescribe medicinal cannabis products in S8 and 2726 currently active notifications (total 5550). Notifications are applicable to prescribing by TGA Authorised Prescribers, prescribing within a clinical trial and prescribing of a TGA approved product by specialist medical practitioners.

4. Cost of medicinal cannabis

For patients prescribed medicinal cannabis, the most common concern raised with the Department of Health is the cost of purchasing the medicine.

It is frequently suggested by patients that the monthly retail cost is beyond the reach of most individuals, and specifically so for persons with chronic illness who may have limited financial means. In particular, the Department of Health is commonly asked why these products are not subsidised on the PBS and when these medicines will be included in this Commonwealth program which funds medicines used in the community.

The difficulty is that registration of the product by the TGA is a precursor to consideration for PBS listing. This means the majority of cannabis-based products are not eligible for consideration as PBS medicines and means patients must continue to pay market price for these medicines.

Patients with private health insurance may be able to seek some reimbursement from their provider. However, this will usually be subject to both annual and per prescription limits. Some health funds only provide reimbursement for TGA approved medicinal cannabis products.

There is also some funding for medicinal cannabis available on a ‘case by case’ basis for veterans through the Commonwealth Department of Veterans’ Affairs (DVA).[10] For funding for medicinal cannabis to be considered, the DVA requires written support for the treatment from an appropriate specialist. To be eligible, veterans must have had other treatment for a medical condition accepted and funded by the DVA.

Of those products that are eligible for PBS listing, Sativex® was not recommended for listing by the Pharmaceutical Benefits Advisory Committee (PBAC) in March 2020. This decision followed a re-submission by Emerge Health Pty Ltd, the Australian sponsor for this product. A positive recommendation by the PBAC is

[10] See https://www.dva.gov.au/health-and-treatment/help-cover-healthcare-costs/manage-medicine-and-keep-costs-down/medicinal

required before the Commonwealth Minister for Health can consider inclusion of a product on the PBS.

In November 2020, the PBAC gave a positive recommendation for Epidyolex®, but only for Dravet syndrome. Epidyolex® was PBS listed from 1 May 2021.

The Commonwealth Government has a robust process for the listing of medicines on the PBS, which includes review by the PBAC, an independent expert body comprising medical practitioners, other health professionals, health economists and consumer representatives. The PBAC considers the medical condition(s) for which the medicine is registered for use in Australia and the clinical effectiveness, safety and cost effectiveness ('value for money') compared with other treatments, including non-medical treatments. During the PBS listing process there are formal opportunities for public comment and agreement between the Commonwealth Government and the pharmaceutical company with respect to the PBS listing arrangement, including the subsidised rate. The Commonwealth Minister for Health (or an approved delegate) must agree to the listing. The WA Government does not have a role in this process.

The PBS funds medicines supplied for use in the community, including for patients being discharged from, or being treated as outpatients at, public hospitals across WA. The WA Government is responsible for funding the acquisition and supply of medicines within public hospitals, such as to treat inpatients.

5. Cannabis as a 'nutraceutical'

Neither Commonwealth nor state and territory regulators of medicines or foods use the term 'nutraceutical'.

Invention of the term 'nutraceutical' is attributed to Dr Stephen DeFelice, an American physician with an interest in encouraging clinical research, particularly in relation to natural substances. Dr DeFelice defined 'nutraceuticals' as meaning "food or part of a food that provides medical or health benefits, including the prevention and/or treatment of a disease".[11]

The Macquarie Dictionary defines 'nutraceutical' as being the same as a 'functional food', the definition of which is "a food containing a component which offers some specific health benefit beyond the provision of simple nutrients; nutraceutical."

Within the Australian regulatory context, Standard 1.2.7 of the Australian New Zealand Food Standards Code defines what health claims a food can make and this Standard includes a prohibition of claims being 'therapeutic in nature'. Claims about the health effects of food cannot refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition or compare a food with a good that is represented in any way to be for therapeutic use or likely to be taken for therapeutic use.[12] In Australia, products that make therapeutic claims are regulated as 'therapeutic goods' through the TGA. Based on Dr DeFelice's original definition of a 'nutraceutical', from

[11] An interview with Dr Stephen DeFelice by Sheldon Baker. Available at: https://www.nutraceuticalsworld.com/contents/view_health-e-insights/2011-10-28/an-interview-with-dr-stephen-defelice (accessed 13 December 2021).
[12] See https://www.legislation.gov.au/Details/F2018C00942

an Australian regulatory perspective, 'nutraceutical' products would appear to meet the requirements of being a 'therapeutic good' rather than a 'food'.

The regulation of 'complementary medicine' products in Australia would most likely be applicable many products considered to be 'nutraceutical' in nature. The TGA regulates 'complementary medicines' through their lower risk pathway, with a list of designated allowable active ingredients, limits on the nature of the therapeutic claims that can be made for these type of products, manufacturing in accordance with the principles of GMP and requirements for the Australian sponsor of the product to hold suitable evidence to support the indications and claims made about their medicine. A complementary medicine will be listed on the ARTG (labelled AUST L or AUST L(A)) rather than registered (labelled AUST R).

However, the low-risk listing pathway cannot be used for products that contain ingredients that are scheduled medicinal substances. Products that contain scheduled medicines must undergo pre-market assessment by the TGA and be registered on the ARTG. As cannabidiol is currently included in S3 and S4 and other therapeutic cannabis-based preparations are included in S8, no medicinal cannabis products are eligible for the low-risk listing pathway.

It appears to be products that contain cannabidiol alone that are most commonly seen as being at the edge of the food:medicine interface. It seems more generally accepted that cannabis-derived products that contain psychoactive cannabinoids, such as THC, are medicines.

The different regulatory regimes for food and medicines in other countries may also lead consumers to believe that cannabidiol products are suitable for regulation as foods.

In mid-2020, the United States Food and Drug Administration (FDA) stated that "It is currently illegal to market CBD [cannabidiol] by adding it to a food or labelling it as a dietary supplement".[13] However, the FDA acknowledges that there is substantial public interest in marketing and accessing cannabidiol in food, including dietary supplements and is exploring various pathways to regulating cannabidiol products, with a focus on science-based decision making.

From a regulatory perspective, the US situation is somewhat complex and some states do allow the use of CBD in food and dietary supplements, although this appears to only be applicable where the CBD is derived from industrial hemp. This situation may create risk to the public because the pharmacological effects of CBD are unlikely to be affected by the source of the CBD. In other words, whether CBD is extracted from cannabis plants with low THC (industrial hemp) or higher THC content or synthetically prepared will not affect the molecular targets of this substance within the human body and will not affect the potential for adverse effects or the risk of interactions with other medicines the person may be taking.

In 2016, the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) stated that they consider products containing cannabidiol used for medical purposes to be medicines and therefore products that require a product

[13] See https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

licence (marketing authorisation) before they can be legal sold, supplied or advertised in the United Kingdom (UK).[14] Cannabidiol only products are included in the UK regulatory scheme for cannabis-based products for medicinal use in humans.[15]

However, in both the EU and the UK, cannabidiol could be used as part of a food provided the particular food product is approved as a 'novel' food. In these jurisdictions, novel foods must go through a pre-market authorisation process.

There is currently an inconsistency in the *Medicines and Poisons Act 2014*, which could potentially allow the supply of a product intended for therapeutic use, derived from industrial hemp without medical practitioner or pharmacist oversight, even where this product contained significant amounts of CBD. However, the requirements of the Commonwealth's *Therapeutic Goods Act 1989* and *Narcotic Drugs Act 1967* mean this loophole would only be applicable to a sole trader who was cultivating, processing, manufacturing and supplying their product entirely within WA. In addition, the Department of Primary Industries and Regional Development advises on their website that the *Industrial Hemp Act 2004*:

"does not allow for the production of low THC industrial hemp for the purposes of medicinal cannabis or cannabinoid extracts from the leaves and flowers of the hemp plant.

A hemp licence issued by the Department of Primary Industries and Regional Development cannot authorise the processing of leaves and flowering heads, which is where the cannabinoids are found.

Only the Australian Government, through the Office of Drug Control, can authorise the production and supply of cannabis related products for human medicinal or therapeutic purposes."[16]

Despite controls through other legislation, it would be preferable for this regulatory gap to be closed, to provide certainty for industrial hemp growers. The exclusion of a preparation for therapeutic use that contains CBD, merely because it is derived from industrial hemp, is inconsistent with the scheduling of CBD as a Schedule 4 and Schedule 3 substance, when used therapeutically for both humans and animals. The exclusion does not recognise the significant pharmacological effects of this particular non-psychoactive cannabinoid. The source of the CBD is unlikely to affect its ability to have both beneficial and adverse effects when taken by a human or administered to an animal.

It continues to be appropriate for industrial hemp plants as well as fibre and seeds from these plants to be exempted from the Medicines and Poisons Act, as these products contain only trace amounts of cannabinoids. However, the risks associated with consumption of cannabinoids extracted from the leaves and flowers of industrial hemp plants are very different to the risks associated with hemp products prepared

[14] See https://www.gov.uk/government/news/mhra-statement-on-products-containing-cannabidiol-cbd
[15] See https://www.gov.uk/government/news/government-announces-definition-for-cannabis-based-products-for-medicinal-use
[16] See https://www.agric.wa.gov.au/plant-biosecurity/licensing-industrial-hemp-activities-western-australia (last accessed 15 December 2021).

from fibre and seeds. The exemption of industrial hemp from the Medicines and Poisons Act was agreed well before the legalisation of medicinal cannabis in Australia and is appropriate to ensure industrial hemp plants as well as fibre and seed products are not captured as a prohibited substances (Schedule 9).

6. Industrial hemp as a source of food products

The *Food Act 2008* WA (Food Act) is the legislation that adopts the *Australia New Zealand Food Standards Code* (the Code). Food Standards Australia New Zealand (FSANZ) develops standards that regulate the use of food ingredients, processing aids, food additives, vitamins and minerals. The Code covers the composition of some foods, such as dairy, meat and beverages as well as foods developed by new technologies such as genetically modified foods. The Code also restricts and prohibits certain botanicals (plants and fungi) from being sold as food, such as *Cannabis* species; and provides some qualification, exemptions to these restrictions and prohibitions. FSANZ is also responsible for labelling requirements for packaged and unpackaged food.

In 2017, the Code was amended to permit low tetrahydrocannabinol (THC) hemp seeds as food. In Standard 1.4.4 – Prohibited and restricted plants and fungi, of the Code, an exemption is provided for *Cannabis sativa* seeds and seed products to be sold as food or used as an ingredient in food, by meeting certain conditions set out in this standard. The following is applicable, as extracted from the Code:

1.4.4 – 6 Exception relating to *Cannabis sativa* seeds and seed products

(1) *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale if:

(a) the seeds:

(i) are seeds of low THC *Cannabis sativa*; and

(ii) contain not more than 5 mg/kg of total THC; and

(iii) if the food is for retail sale – are non-viable and hulled; and

(b) the only cannabinoids in or on the seeds are naturally present.

(2) Subject to subsection (3), all or any of the following seed products may be a food for sale or used as an ingredient in a food for sale:

(a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg of total THC;

(b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg of total THC;

(c) any other product that is extracted or derived from seeds of low THC *Cannabis sativ*a and contains not more than 5 mg/kg of total THC.

(3) The only cannabinoids in the product must be those that were naturally present in or on the seeds from which the product was extracted or derived.

(4) In subsection (2):

***seeds of low THC* Cannabis sativa** includes viable and unhulled seeds.

(5) In this section:

hulled seeds means seeds from which the outer coat or hull of seeds has been removed.

***low THC* Cannabis sativa** has the meaning given by subsection (6).

non-viable seeds means seeds that are not able to germinate.

seeds includes a part of a seed.

total THC means the total amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid.

(6) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 1% delta 9-tetrahydrocannabinol *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale if:

(a) the seeds:

(i) are seeds of low THC *Cannabis sativa*; and

(ii) contain not more than 5 mg/kg of total THC; and

(iii) if the food is for retail sale – are non-viable and hulled; and

(b) the only cannabinoids in or on the seeds are naturally present.

(2) Subject to subsection (3), all or any of the following seed products may be a food for sale or used as an ingredient in a food for sale:

(a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg of total THC;

(b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg of total THC;

(c) any other product that is extracted or derived from seeds of low THC *Cannabis sativ*a and contains not more than 5 mg/kg of total THC.

The only cannabinoids in the product must be those that were naturally present in or on the seeds from which the product was extracted or derived. Standard 1.4.4-8 sets a limit for cannabidiol (a type of cannabinoid), such that it must not be present in any food for sale at a level greater than 75 mg/kg. FSANZ and food regulators considered there to be a need to set a cannabidiol limit in the Code, for the purposes of distinguishing food from therapeutic goods. Therapeutic goods within the meaning of the *Therapeutic Goods Act 1989*, do not meet the definition of food, and are outside the remit of the Food Act.

There are also restrictions on claims and representations about hemp food products, in Standard 1.4.4-7. There is a prohibition on nutrient content claims and health claims about cannabidiol in low THC hemp seed foods. Images and representations of any part of the *Cannabis sativa* plant, including the leaf; statements referencing ‘cannabis’ or ‘marijuana’, are all prohibited by the Code. The relevant extract from Standard 1.4.4 of the Code is as follows:

1.4.4—7 Restriction on claims and representations about foods that are or which contain hemp food products

(1) This section applies to a food for sale that consists of, or has as an ingredient, a hemp food product.

(2) The food for sale must not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect.

(3) The label for the food for sale must not include:

(a) a nutrition content claim about cannabidiol; or

(b) a *health claim about cannabidiol; or

(c) an image or representation of any part of the *Cannabis sativa* plant (including the leaf of that plant) other than the seed; or

(d) the words 'cannabis', 'marijuana' or words of similar meaning.

(4) The label for the food for sale may include the word 'hemp'.

(5) In this section:

Hemp food product means *Cannabis sativa* seeds and/or a seed product that are permitted by section 1.4.4—6 to be a food for sale or used as an ingredient in a food for sale.

Psychoactive effect means:

(a) stimulation or depression of a person's central nervous system, resulting in hallucinations or in a significant disturbance in, or significant change to, motor function, thinking, behaviour, perception, awareness or mood; or

(b) causing a state of dependence, including physical or psychological addiction.

FSANZ undertook a hazard assessment of industrial hemp as a food which included both, a safety assessment and a nutritional assessment in Application A1039. This was used to underpin FSANZ's final approval report for Proposal P1042 – Low THC Hemp Seeds as Food, which led to the permission for the sale of food derived from the seeds of low THC varieties of *Cannabis sativa* in 2017. Further information on FSANZ risk and nutritional assessment assessments are available at the following links:
https://www.foodstandards.gov.au/code/proposals/Pages/P1042LowTHChemp.aspx; and
https://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx.

Internationally, there are differences in the regulation of hemp seed foods. Some jurisdictions, including Canada, Germany, United Kingdom, The Netherlands, Belgium, Switzerland and Austria permit the sale of low THC hemp seed foods. According to FSANZ, in 2017, no international organisations or other countries have set limits on the cannabidiol content of low THC hemp seed foods. In the UK you can sell hemp food and oil with CBD as a food supplement. However, whilst FSANZ must have regard to the objective of achieving consistency between domestic and international food standards when it is considering the development of the standards, the FSANZ Act does not permit the direct adoption of international standards.

This document can be made available in alternative formats on request for a person with disability.