MTPConnect
MedTech and Pharma Growth Centre

# AUSTRALIAN MEDICINAL CANNABIS INDUSTRY REPORT

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This report was commissioned by MTPConnect, a not-for-profit organisation that aims to foster growth across Australia's medical technology, biotechnology and pharmaceutical sector. It was developed in partnership with Deloitte Access Economics.

MTPConnect
MedTech and Pharma Growth Centre

Deloitte.

# EXECUTIVE SUMMARY

## In the five years since its inception, Australia's medicinal cannabis industry has established itself as a significant and growing player in the medical products sector.

The industry emerged in 2016 following an amendment to the Commonwealth's *Narcotic Drugs Act 1967* that legalised the cultivation and production of cannabis for medicinal and research purposes.

The demand and supply of medicinal cannabis has since grown quickly across Australia. Companies are expected to generate more than $31 million in revenues in 2020-21 and employ 1,300 workers. They also spent an estimated $62 million on research and development in 2019-20.

The opportunities for future growth, domestically and internationally, are significant with medicinal cannabis now legalised in over 30 countries and the global market estimated to be worth $80 billion (US$62.6 billion) by 2024.

At this inflexion point, there are many in the industry – pharmaceutical manufacturers, researchers, medical practitioners, patients and agricultural producers – seeking to understand how the industry might evolve sustainably to harness growth opportunities.

This report was commissioned by MTPConnect to provide an evidence base to articulate the current size of Australia's medicinal cannabis industry, as well as future estimates for the sector. It aims to serve as a valuable resource to inform policymakers, industry and consumers.

The report was developed in partnership with Deloitte Access Economics and involved consultation with several key stakeholders including the Medicinal Cannabis Industry Australia (MCIA), a variety of medicinal cannabis cultivators and manufacturers, research institutions, patient advocates, medical practitioners and pharmacists.

Key findings include:

- 39 organisations are licensed to extract and purify raw cannabis materials for medicinal purposes in Australia (as of May 2021)
- there have been approximately 126,500 approved applications for medicinal cannabis since 2016 (as of May 2021)
- by 2030, with new production capacity coming online gradually, approximately 188,000 kg of dried plant matter will be produced
- under a baseline scenario, by 2030 approximately 670,000 patients may be seeking access to medicinal cannabis in Australia, requiring approximately 79,000 kg of dried plant matter
- 'uplift' scenarios, where the industry evolves strongly over the short, medium and long term, suggest demand trajectories for as much as 147,000 kg of dried plant matter by 2030.

As with any rapidly growing industry, striking a balance between local supply and demand represents an ongoing challenge. This report expects that some consolidation and rationalisation in Australia's medicinal cannabis industry is likely, however, sustainable growth may be found through:

- provision of robust and appropriate clinical evidence of efficacy of medicinal cannabis products
- improving perceptions around medicinal cannabis use across both patients and prescribers
- learning from similar Australian industries, by establishing a domestic, end-to-end supply chain for medicinal cannabis production while the industry is still in its infancy
- capitalising on current and future regulatory changes, the potential for additional registered cannabis medicines and further products to be listed on the Pharmaceutical Benefits Scheme (PBS).

# 1 INTRODUCTION

The Australian medicinal cannabis industry was established in 2016 following changes to Commonwealth legislation and has since received great interest from agricultural producers, pharmaceutical manufacturers and patients. However, the industry is still developing and, as such, there are many agricultural producers, pharmaceutical manufacturers, medical practitioners, researchers, and industry representative bodies seeking to understand how the industry might – and should – evolve as it matures.

## 1.1 Purpose

MTPConnect is a not-for-profit organisation working to foster growth across Australia's medical technology, biotechnology and pharmaceuticals sector.[1] The organisation was established in December 2015 as part of the Australian Government's Industry Growth Centres Initiative.

This report was commissioned by MTPConnect to provide the broader medical products sector, consumers and policy makers with a resource to deepen understanding of a rapidly evolving new industry: medicinal cannabis.

Developed in partnership with Deloitte Access Economics, the report involved consultation with key stakeholders including the Medicinal Cannabis Industry Australia (MCIA), medicinal cannabis cultivators and manufacturers, research institutions, patient advocates, medical practitioners and pharmacists. It examines the current size of Australia's medicinal cannabis industry, explores supply, demand and access scenarios and discusses the challenges of future industry sustainability.

The scope of this report includes:

- an overview of the industry in a global context, as well as across the full value chain
- a summary of the current regulatory framework and the industry's operating environment
- estimates of the potential size of Australia's medicinal cannabis sector
- opportunities and threats to the sector
- insights into how the industry might position itself to realise sustained growth.

## 1.2 Structure of this report

The report is structured as follows:

**Section 2:** Industry context – provides an overview of the current legislative and regulatory framework in Australia, along with a summary of the global market.

**Section 3:** Domestic demand – profiles current demand for medicinal cannabis and provides an estimate of how this might change through to 2030.

**Section 4:** Domestic supply – details the current local suppliers of medicinal cannabis and provides an estimate of how supply might change in future given the planned capacity of these firms.

**Section 5:** Market potential – considers the challenges and opportunities facing the sector, and comments on steps the sector could take to help harness the opportunities while mitigating the threats.

1 MTPConnect, 'Overview' (2020) ‹https://www.mtpconnect.org.au/overview›.

# 2 INDUSTRY CONTEXT

## 2.1 Brief history

Australia's medicinal cannabis sector emerged in 2016 following an amendment to the Commonwealth's *Narcotic Drugs Act 1967* that legalised the cultivation and manufacture of cannabis for medicinal and research purposes.

The number of medicinal cannabis businesses operating in Australia grew rapidly following this legislative change, but patient demand was hampered by slow patient access pathways in some states and territories. With the approval of state health ministers in 2018, the (former) Council of Australian Governments (COAG) commenced a process to streamline patient access to medicinal cannabis at the national level. Federal and state approval processes were combined into a single online system, helping to spur demand for medicinal cannabis products.

Growth prospects for Australia's medicinal cannabis sector improved further in 2018 with the Australian Government legalising exports. This change does not encompass all international markets, only those nations that comply with the United Nations' *Single Convention on Narcotic Drugs 1961* (Narcotic Drugs Convention) and are willing to issue import permits to licensed Australian producers. However, it does provide Australian medicinal cannabis manufacturers access to high-value markets that demand high-quality Good Manufacturing Practice (GMP) standards, like those produced in Australian facilities.

With this change, Australia sought to establish itself as a global leader in medicinal cannabis markets worldwide, and in September 2019, the first Australian shipment of medicinal cannabis left for Germany.

More recently, in December 2020, Australia's Therapeutic Goods Administration (TGA) recommended that cannabidiol, an active ingredient in cannabis known as CBD, be down-scheduled to a Schedule 3 substance, meaning products registered on the Australian Register of Therapeutic Goods (ARTG), containing at least 98 per cent CBD and with a maximum recommended daily dose of 150 mg or less of CBD, could be made available over-the-counter (OTC) in pharmacies. This scheduling took effect on 1 February 2021.[2] At this stage, there is no timeline on availability, as listing on the ARTG requires submission of a dossier demonstrating safety and efficacy, among other things. An OTC product will be available when a company submits, and the TGA accepts, a registration dossier.

Since the first change to legislation in 2016, more than 50 medicinal cannabis businesses have set up operations in Australia, with over half of those estimated to hold a medicinal cannabis licence (for cultivation and/or commercial production),[3] a cannabis research licence (for cultivation and/or production for research purposes),[4] a narcotic manufacture licence (for extraction and purification of cannabis plant material) or a combination of these licences.[5]

In January 2020, the Australian Capital Territory (ACT) Government legalised the use of cannabis for recreational purposes. The decision indicates a continued evolution in societal preferences and the growth potential for cannabis-based products in medicine. This was followed by an Australian Government review of current barriers to patient access for medicinal cannabis in Australia, which was published in March 2020.

Today, Australia's medicinal cannabis manufacturing industry is set to realise revenues of approximately $31.2 million in 2020–21 and provide employment to nearly 1,300 workers.[6] By 2025–26, the number of Australians employed in the industry is expected to have risen to approximately 1,500 workers.[7]

The medicinal cannabis industry also indirectly contributes to the economy through its research and development expenditure. While there is no registry of all R&D expenditure across the sector, a survey found the 22 publicly listed Australian human-focused medicinal cannabis businesses spent $62 million on R&D in the 12 months to June 2020.[8]

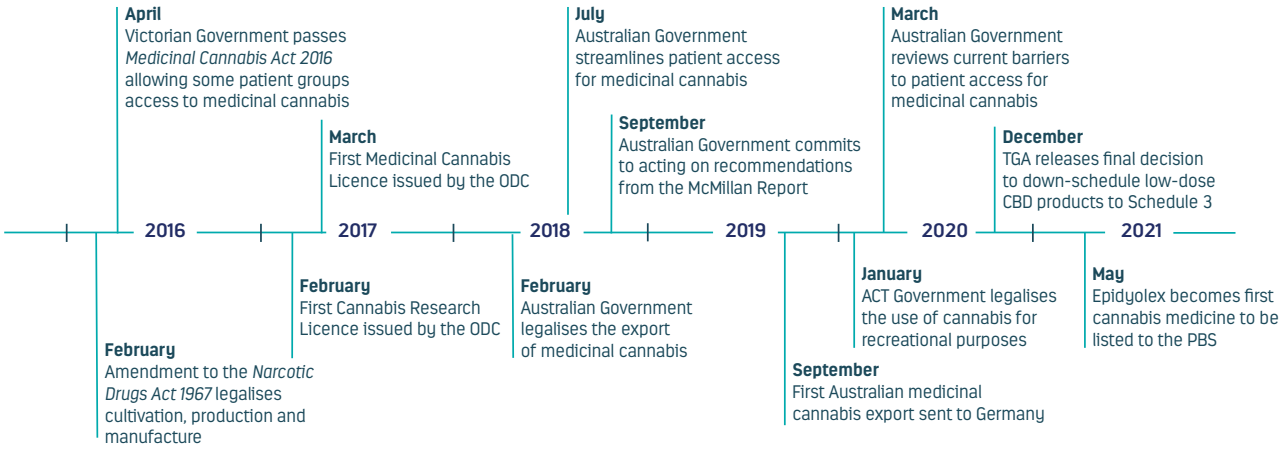
In general terms, successful R&D projects both improve industry outputs and drive higher economic growth across the economy more generally.[9]

2 Therapeutic Goods Administration, 'Notice of final decision to amend (or not amend) the current Poisons Standard' (15 December 2020) ‹https://www.tga.gov.au/scheduling-decision-final/notice-final-decision-amend-or-not-amend-current-poisons-standard-cannabidiol›.
3 An estimated 33 percent of firms.
4 An estimated five percent of firms.
5 An estimated 18 percent of firms.
6 IBISWorld, 'Growth op: 2021 spells green future for Australian cannabis' (8 Jan 2021) ‹https://www.ibisworld.com/blog/growth-op-2021-spells-green-future-for-australian-cannabis/61/1131/›.
7 IBISWorld, 'Growth op: 2021 spells green future for Australian cannabis' (8 Jan 2021) ‹https://www.ibisworld.com/blog/growth-op-2021-spells-green-future-for-australian-cannabis/61/1131/›.
8 Biotech Daily (2021) ‹www.biotechdaily.com.au›.
9 House of Representatives Standing Committee on Science and Innovation, Riding the Innovation Wave: The Case for Increasing Business Investment in R&D (June 2003), accessed online 23 Feb 2021.

The proportion of R&D expenditure by the industry directed to clinical trials is not publicly reported. However, given the immaturity of the industry in Australia, it is reasonable to expect that a substantial component of R&D expenditure is directed towards the support of clinical trials. Over and above the known economic benefits of private R&D expenditure, clinical trial operation generates further benefits. For example, they can provide early access to potentially improved treatment in Australia for trial participants, which in turn translates into flow-on benefits such as increased health and productivity.[10]

A timeline of key events leading to this point in the development of Australia's medicinal cannabis industry is provided below in Figure 2.1.

Figure 2.1: Timeline of key events in Australia's medicinal cannabis industry




Source: Deloitte Access Economics.

## 2.2 Australian medicinal cannabis legislation

Australia has a dual regulatory system for medicinal cannabis that jointly regulates the supply of medicinal cannabis as a narcotic substance and a medicine.

### 2.2.1 Existing legislation

Australia's medicinal cannabis industry is regulated by the Health Products Regulation Group,[11] which comprises the Office of Drug Control (ODC) and the TGA.

The ODC is responsible for ensuring all medicinal cannabis produced in Australia meets the requirements specified under the UN's Narcotic Drugs Convention. In doing so, the ODC controls the provision of licences and permits for the cultivation, extraction and purification of medicinal cannabis products in Australia.

The TGA regulates the manufacture of medicinal cannabis therapeutic goods and patient access to medicinal cannabis products. It establishes and audits the quality standards that apply to all medicinal cannabis products sold in Australia, which includes those detailed in the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017.*

Historically, cannabis and cannabis products had been listed as Schedule 9 prohibited substances under the Poisons Standard, which is given effect under state law.[12] However, this listing was reviewed by the TGA in 2016. Today, additional listings for cannabis are included under:

- Schedule 8 controlled substances – THC for human therapeutic use, and cannabis prepared for human therapeutic use, except where included in other schedules
- Schedule 4 – Essentially pure CBD for therapeutic use, analytical and scientific research
- and more recently Schedule 3 – Pure CBD, in oral, oromucosal and sublingual preparations, that are registered medicines, with a maximum daily dose of less than 150 mg/day.

10 MTPConnect (May 2021) 'Australia's Clinical Trials Sector: Advancing innovative healthcare and powering economic growth', accessed online. Last accessed 9 June 2021.
11 Office of Drug Control, 'Medicinal cannabis cultivation and production licences and permits' (2020) <https://www.odc.gov.au/medicinal-cannabis-cultivation-and-production-licences-and-permits>.
12 *Poisons Standard February 2021.*

Listing on the Poisons Standard at Schedule 8 (narcotic) and Schedule 4 enable patient access via doctor's prescription and pharmacy dispensing, while listing at Schedule 3 provides an over-the-counter pharmacy medicine where registered as such on the ARTG.

Most medicines available in Australia are registered on the ARTG. The registration process requires manufacturers to provide evidence demonstrating a pharmaceutical product's safety, its efficacy in treating a given indication(s) and its production quality, for approval by the TGA.[13] Once registered, a pharmaceutical product can be prescribed by medical practitioners without any further TGA approvals.

The first medicinal cannabis product to be registered to the ARTG was nabiximols, a standardised extract of THC, CBD and other cannabinoids (developed and marketed by UK company GW Pharmaceuticals under the brand name Sativex). Sativex is used for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis.

Another GW Pharmaceuticals product, Epidyolex, was registered to the ARTG in September 2020. More recently (1 May 2021) Epidyolex was also listed to the Pharmaceutical Benefits Scheme (PBS), making it the first medicinal cannabis product to be subsidised by the Australian Government under the scheme.[14] The product is used to treat seizures associated with two forms of epilepsy: Lennox-Gastaut syndrome and Dravet syndrome.[15] While the number of patients who will benefit from this is small, the decision will likely be pivotal in the industry's future development, serving as a precedent for other medicinal cannabis products to become listed to the PBS where the clinical evidence exists to support their efficacy.

All other medicinal cannabis products available in Australia are typically accessed using one of four pathways for unregistered products:

- Special Access Scheme (SAS)
- Authorised Prescriber Scheme
- Clinical trials
- Compound pharmacies.[16]

A further access pathway is set to be introduced, following the TGA's recent decision to down-schedule certain low-dose CBD preparations from Schedule 4 to Schedule 3.[17] The decision means that TGA-approved low-dose CBD preparations can now be supplied for over-the-counter purchase at Australian pharmacies.

However, no low-dose CBD medicine is currently registered on the ARTG for Schedule 3 supply. It is uncertain when the first CBD medicine that meets the Schedule 3 criteria will gain TGA approval and be made available for over-the-counter sale. Pharmaceutical companies seeking TGA approval for registration will need to demonstrate that they have control of the chemistry and manufacturing process for their product, demonstrate safety, and, within the dosing constraint of not more than 150 mg per day, meet the challenge of proving efficacy for their listed indication.

The remainder of this section summarises each of the access pathways for unregistered medicinal cannabis products in Australia. Due to significant limitations in the availability of information describing the compound pharmacy access pathway, no further discussion on this subject has been included.

### Special Access Scheme

Most prescriptions for medicinal cannabis are made under the Special Access Scheme, which is administered by the TGA, while a smaller number of prescriptions are made through Authorised Prescribers. Medicinal cannabis can also be accessed through clinical trials, or compound pharmacies, though these access routes are much less common.

The Special Access Scheme enables supply of an unapproved medicine (i.e. not listed on the ARTG) to a single patient on a case-by-case basis.

13 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 5.
14 Department of Health, 'Historic PBS listing for Australians with a rare epilepsy condition' (30 April 2021) ‹https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/historic-pbs-listing-for-australians-with-a-rare-epilepsy-condition›.
15 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 5.
16 Compounding pharmacies are a specific and constrained legislative provision that acts as a much less common access pathway relative to the other three access pathways mentioned.
17 Therapeutic Goods Administration, 'Over-the-counter access to low dose cannabidiol' (15 December 2020) ‹https://www.tga.gov.au/media-release/over-counter-access-low-dose-cannabidiol›.

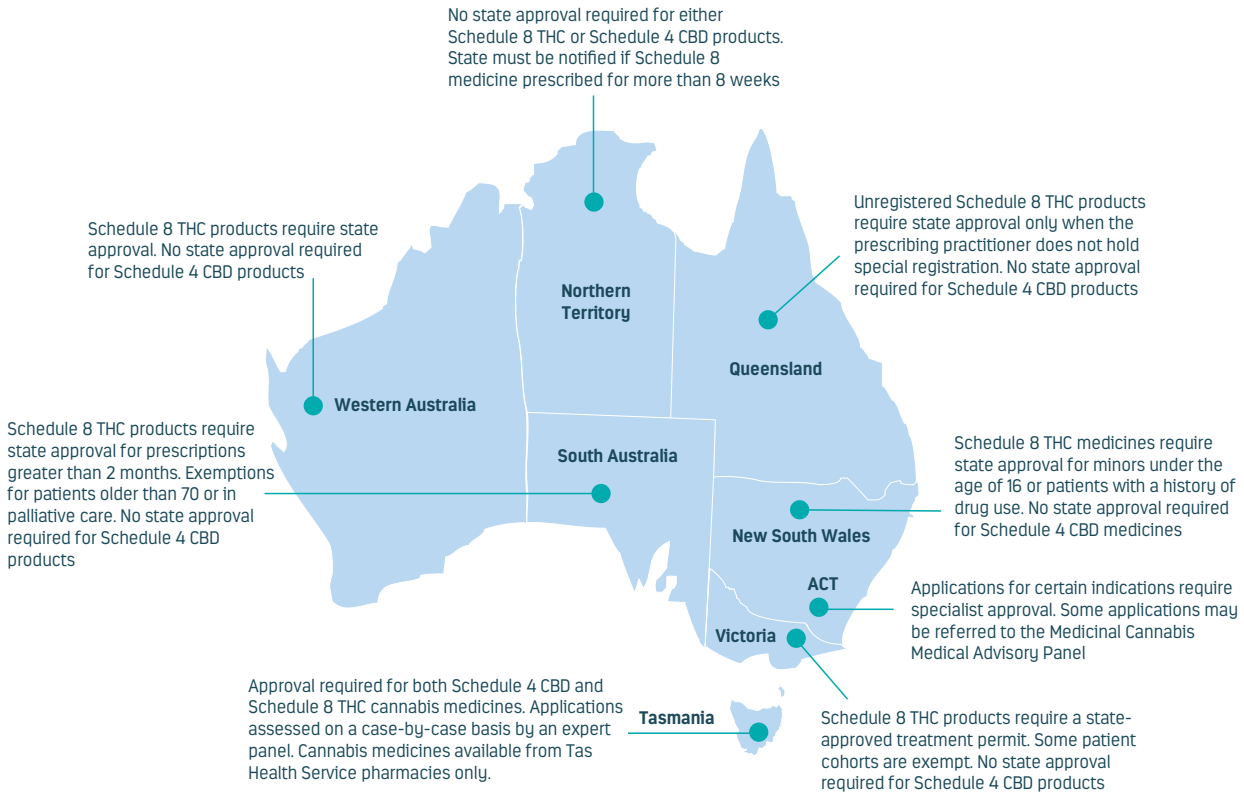
Following the legalisation of medicinal cannabis in 2016, the Special Access Scheme's application was extended to accommodate patient access to medicinal cannabis. While there are several categories under the Special Access Scheme, the key ones for medicinal cannabis are Special Access Scheme – Category A (SAS-A) and Special Access Scheme – Category B (SAS-B). The former is a notification pathway accessed by prescribers for patients who are seriously ill with a condition likely to result in death within a matter of months. TGA approval is not sought in advance, but the TGA must be notified. The SAS-B is an application pathway, where a prescriber must seek the approval of the TGA to supply an unapproved medicine to an individual patient. State-specific approvals and processes may also apply.

Not all jurisdictions require registered practitioners to receive state approval in prescribing medicinal cannabis products. In the Northern Territory (NT), for example, both Schedule 4 CBD and Schedule 8 THC products can be prescribed without state approval (Figure 2.2). By contrast, applications for Schedule 4 CBD and Schedule 8 THC products require specialist approval in the ACT and may be referred to the Medicinal Cannabis Medical Advisory Panel.

In general, however, registered practitioners can prescribe Schedule 4 CBD products without state approval in all Australian jurisdictions except the ACT. Schedule 8 THC products are more heavily regulated. They require some form of state approval in all jurisdictions (except the NT).

Importantly, any medical practitioner seeking to prescribe medicinal cannabis through the SAS-B pathway must submit a clinical justification as to why they are seeking to supply an unregistered product.[18, 19]

Figure 2.2: Patient access requirements for medicinal cannabis across Australia's jurisdictions

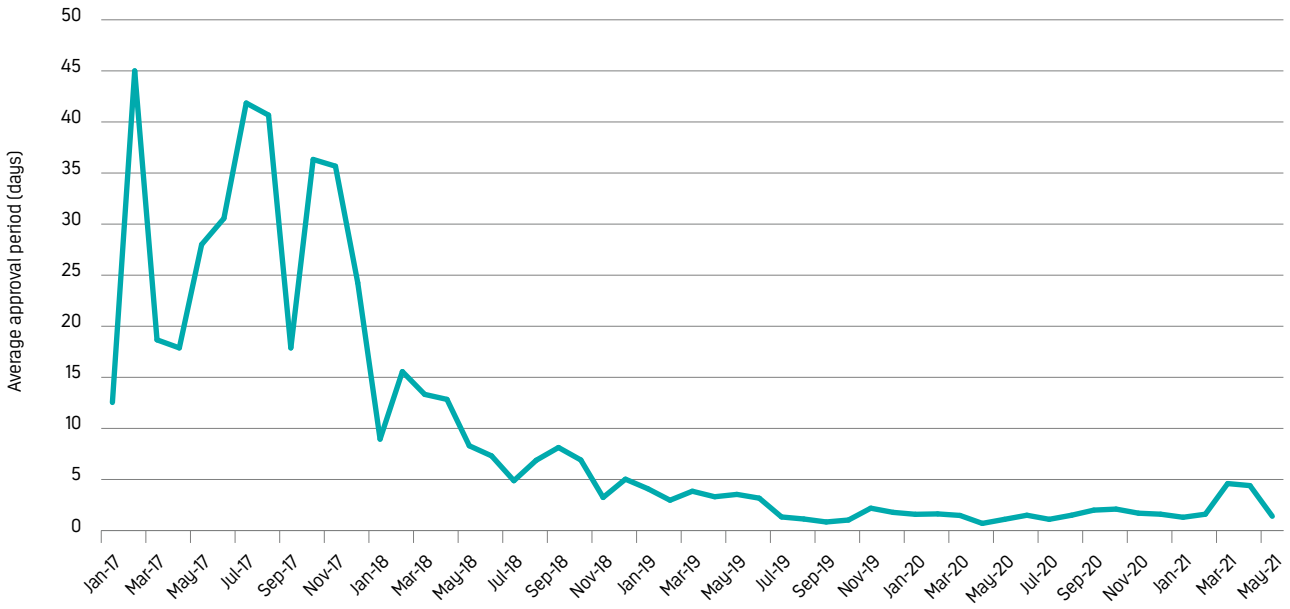



Source: Deloitte Access Economics, based on Senate Community Affairs References Committee[20] and Tetra Health.[21]

18 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
19 Special Access Scheme A (SAS-A) can also be used; however, this is for seriously ill patients who are likely to pass away within a matter of months, and the majority of medicinal cannabis is prescribed through SAS-B.
20 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) ‹https://parlinfo.aph.gov.au/parlInfo/download/committees/reportsen/024403/toc_pdf/CurrentbarrierstopatientaccesstomedicinalcannabisinAustralia.pdf;fileType=application%2Fpdf›.
21 Tetra Health, *Medicinal cannabis in Australia: A State-by-State guide for patients and prescribers* (accessed 10 September 2020) ‹https://www.tetrahealth.com.au/medical-cannabis-in-australia-a-state-by-state-guide-for-patients-and-prescribers/›.

The streamlining of patient access to medicinal cannabis by all Australian states and territories in July 2018 significantly reduced patient wait times. In 2017, the average approval period for SAS-B applications was about 30 days (Chart 2.1). By July 2018, when the online system was introduced, this figure had fallen to just under seven days. In December 2018, the online system was extended to accommodate the submission of Authorised Prescriber applications to the TGA, with approval periods today averaging just 1.5 days. The vast majority of applications are approved on the day of application or the next business day.

Chart 2.1: Average approval periods (in days) for SAS-B medicinal cannabis applications in Australia




Source: Deloitte Access Economics analysis, using TGA.[22]

### Authorised Prescriber Scheme

As an alternative to the SAS-B pathway, Australian medical practitioners can apply to become Authorised Prescribers. As an Authorised Prescriber, a medical practitioner can supply a specific medicinal cannabis product (brand and composition) directly to patients under their care. Unlike the SAS-B pathway, they are not required to notify the TGA each time they prescribe this specific medicinal cannabis product to a patient within their defined cohort. But they are required to report to the TGA every six months the number of patients for whom they have prescribed unapproved medicinal cannabis products.

While relatively few medicinal cannabis prescriptions are made under this scheme, the number of Authorised Prescribers is quickly growing. As of 30 April 2021, there were 279 Authorised Prescribers across Australia,[23] about three times the number there had been a year earlier.

Becoming an Authorised Prescriber is initially more onerous than the SAS-B pathway. Candidate practitioners must be able to demonstrate a history of prescribing medicinal cannabis for a specific indication or indications under the SAS-B pathway. They are also required to have their application approved by a Human Research Ethics Committee (HREC), or be endorsed by a specialist college.[24] Once authorised, Authorised Prescribers are able to supply the designated medicinal cannabis product to patients within the defined cohort who are in their care without having to seek further federal government approval.

Authorised Prescribers may concurrently seek approval to prescribe other medicinal cannabis products using the SAS-B scheme.

22 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020 and Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.*

23 Therapeutic Goods Administration, 'Accessing unapproved products – Medicinal cannabis' (2 October 2020) ‹https://www.tga.gov.au/access-medicinal-cannabis-products-1›.

24 Therapeutic Goods Administration, 'Authorised Prescribers' (2019) ‹https://www.tga.gov.au/form/authorised-prescribers›.

### Clinical trials

Medicinal cannabis products can also be accessed through participation in a clinical trial, with the TGA regulating the use of therapeutic goods in these trials (see Appendix C). Between January 2015 and November 2019, the Australian New Zealand Clinical Trials Registry (ANZCTR) was notified of 54 clinical trials related to the potential therapeutic uses of medicinal cannabis, using the search term 'cannabi' (i.e. the stem for cannabis, cannabinoid and cannabidiol).[25] This does not reflect Australian clinical trials that may have been registered with registries other than the ANZCTR (noting though that listing on ANZCTR is a requirement by most HRECs).

### Extemporaneously compounded

The final pathway to access an unregistered medicinal cannabis product in Australia is as an extemporaneously compounded product through a pharmacist.[26] Legislation related to this pathway has changed over time and differs between states. In practice, this pathway allows a medical practitioner to write a prescription for a compounded medicinal cannabis product for their patient (as per any other Schedule 4 or Schedule 8 medicine), which is compounded on demand by a compound pharmacy and individualised to that patient.

### Major Project Status

To help meet patient demand for medicinal cannabis and facilitate economic growth in the sector, the Australian Government made medicinal cannabis projects eligible for Major Project Status from August 2019, meaning eligible projects face a shorter approval process for licensing. Projects that are granted Major Project Status receive additional project support and coordination from the Major Projects Facilitation Agency, as well as coordinated approval processes (both at a state and federal level).[27]

To be granted Major Project Status, a project must be of strategic significance to Australia. It must also have Australian Government approval and investment greater than $50 million and possess financial resources to be commercially viable. As at June 2020, seven projects in the medicinal cannabis industry had been granted Major Project Status.[28]

## 2.2.2 Recent industry reviews

In September 2019, the Australian Government tabled a review of the Narcotic Drugs Act (the McMillan Review). All 26 recommendations were accepted by the government, with the recommendations aimed at reducing regulatory burden in the sector, as well as facilitating greater cultivation, extraction, purification and manufacture of medicinal cannabis in Australia.

A major reform recommendation from the McMillan Review was a single licensing structure for Australia's medicinal cannabis industry (Recommendation 7). Under the proposed structure, a single licence would authorise cultivation, extraction, purification, manufacture and research of medicinal cannabis products, eliminating some of the administrative burden associated with the existing dual licence system. The proposed reform continues to be reviewed by the ODC, with consultations conducted in early 2020.

In March 2020, the Community Affairs References Committee published a separate review of barriers restricting domestic access to medicinal cannabis. This review resulted in 20 recommendations, intended to improve education and raise awareness of medicinal cannabis in Australia, as well as streamline patient approval processes to access the medicine.

Australia's medicinal cannabis sector is expected to benefit from future legislative and other reforms, as government continues to act on the recommendations of these reviews.

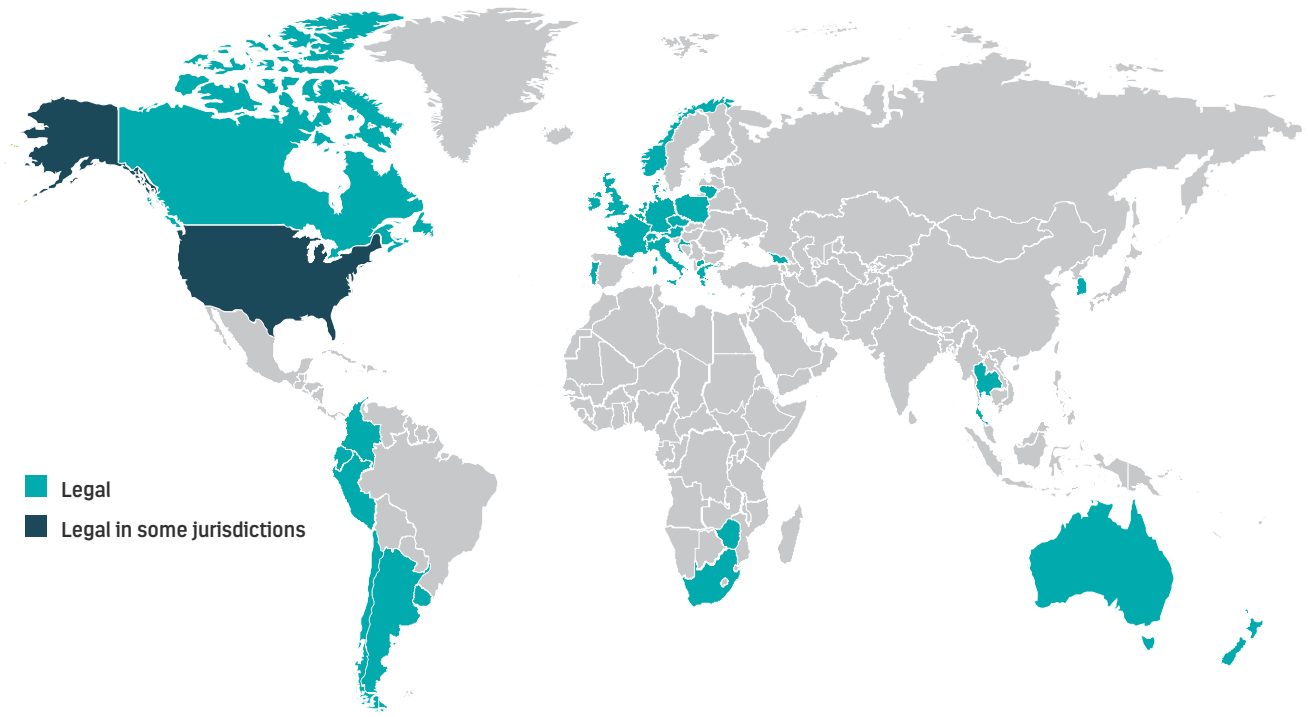
25 Therapeutic Goods Administration, 'Medicinal Cannabis: Information for Health Professionals' – Extracted trials ‹https://www.tga.gov.au/medicinal-cannabis-information-health-professionals›. Last accessed 21 April 2021.
26 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 11.
27 Australian Government, 'Recognition and support for major projects in Australia' (20 January 2021) ‹https://business.gov.au/grants-and-programs/major-project-status›.
28 Australian Government, 'Current Major Projects' (2020) ‹https://www.business.gov.au/Grants-and-Programs/Major-Project-Status/Current-Major-Projects›.

## 2.3 Global medicinal cannabis markets

The global medicinal cannabis market has rapidly expanded in recent years, with medicinal cannabis now legalised in over 30 countries (Figure 2.3). It is estimated that the global medicinal cannabis market will be worth $80 billion (US$62.6 billion) by 2024,[29] or about four per cent of the global pharmaceutical market at that time.[30]

The trend of countries loosening medicinal cannabis restrictions is expected to continue. While this has mostly occurred in nations across Europe, North and South America, and Oceania, parts of Asia are also beginning to relax restrictions. A recent example of this is Thailand, which became the first South-East Asian nation to do so, in February 2019.[31] In July 2020, Thailand's Ministry of Public Health approved 17 medicinal cannabis products for certain hospitals to prescribe to patients.[32] Several other countries in the region have also taken steps toward legalising medicinal cannabis, including Japan, Malaysia and the Philippines.

Figure 2.2: Global medicinal cannabis legality




Note: Medicinal cannabis remains illicit at a federal level in the United States.
Source: Deloitte Access Economics based on Prohibition Partners.[33]

29 Prohibition Partners, *The Global Cannabis Report* (2019).
30 IQVIA Institute for Human Data Science, *The Global Use of Medicine in 2019 and Outlook to 2023* (2019).
31 Prohibition Partners, *The Global Cannabis Report* (2019).
32 The Nation Thailand, *Use of medicines mixed with marijuana allowed in local health promotion hospitals* (accessed 11 June 2021) <https://www.nationthailand.com/in-focus/30391979>.
33 Prohibition Partners, *The Global Cannabis Report* (2019).

Currently, the North American and European markets are among the most established globally.

In 2001, Canada was one of the first nations to legalise medicinal cannabis. Since then, Canada has managed to capture a large share of the global medicinal cannabis export market. However, the country's medicinal cannabis manufacturers have faced several issues recently due to the way their GMP standards are recognised in Europe.[34, 35] Earlier in 2020, one Canadian manufacturer was alleged to have breached German permit requirements, causing some of its products to be barred from the market.[36] This manufacturer failed to obtain the necessary permit required to distribute medicines that have been treated with ionizing irradiation in Germany. Similar instances of non-compliance with European Union (EU) requirements have led other Canadian manufacturers to face similar bans in Malta, Italy and Denmark.[37, 38, 39]

In the United States (US), while it remains illicit at the federal level, the prescription and use of medicinal cannabis has been legalised in several states. The first state to make this step was California, which legalised medicinal cannabis in 1996. Today, 37 US states have legalised medicinal cannabis, with the most recent of these being South Dakota and Virginia in 2020 and Alabama earlier in 2021. The legalisation of medicinal cannabis also received popular vote in Mississippi in May 2021, however the result was struck down by the Mississippi Supreme Court due to a legal technicality.[40]

Recent employment estimates suggest that between 240,000 and 295,00 people are currently employed by the US cannabis industry (medicinal and recreational), slightly greater than the estimated number of US computer programmers.[41]

Similarly, there are inconsistencies in the legality of medicinal cannabis across Europe. However, after legalising the export of medicinal cannabis, the United Kingdom (UK) has emerged as a key market in the region. The largest exporter of medicinal cannabis globally is the UK-based pharmaceutical company, GW Pharmaceuticals.[42] Germany has also been a major regional market for medicinal cannabis. Up to July 2020, Germany had been the largest importer of medicinal cannabis globally, but has since been overtaken by Israel.[43]

While currently less prominent in the sector, medicinal cannabis industries in South America and Africa have also started to gain momentum as some large North American companies have recently directed substantial foreign investment to these regions.[44]

34 Under the Mutual Recognition Agreement between Canada and the European Union (EU), the GMP standards in Canada are considered equivalent. However, not all Canadian businesses have been certified to meet EU GMP standards when tested by EU GMP officials.
35 Government of Canada, 'Mutual Recognition Agreement between Canada and the European Union (EU)' (31 May 2021) ‹https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/international/mutual-recognition-agreements/updates/mutual-recognition-agreement-canada-european-community.html›.
36 MJBizDaily, 'Product supply interruptions hit German medical cannabis market, but government dismisses risk of shortages' (17 January 2020) ‹https://mjbizdaily.com/product-supply-interruptions-hit-german-medical-cannabis-market-but-government-dismisses-risk-of-shortages/›.
37 Lovin Malta, 'Canadian Medical Cannabis Company Fails Maltese Standards Inspection' (6 December 2019) ‹https://lovinmalta.com/news/canadian-medical-cannabis-company-fails-maltese-standards-inspection/›.
38 Reuters, 'Danish cannabis firm quarantines more products from CannTrust' (11 July 2019) ‹https://www.reuters.com/article/us-denmark-cannabis-stenocare/danish-cannabis-firm-quarantines-more-products-from-canntrust-idUSKCN1U61B5›.
39 MJBizDaily, 'Italy cancels one of Aurora's three cannabis supply lots' (1 November 2019) ‹https://mjbizdaily.com/italy-cancels-one-of-auroras-three-cannabis-supply-lots/›.
40 Britannica ProCon, 'Legal Medical Marijuana States and DC' (accessed 15 June 2021) ‹https://medicalmarijuana.procon.org/legal-medical-marijuana-states-and-dc/›.
41 MJBizDaily, 'US cannabis employment could climb nearly 50% in 2020, surpassing computer programmers' (28 July 2020) ‹https://mjbizdaily.com/chart-us-cannabis-employment-could-climb-nearly-50-in-2020-surpassing-computer-programmers/›.
42 Prohibition Partners, *The European Cannabis Report* (2019).
43 Prohibition Partners, 'Germany Imports 4,126kg of Medical Cannabis During the First Half of 2020' (2020) ‹https://prohibitionpartners.com/2020/07/29/german-medical-cannabis-imports-increase/›.
44 Prohibition Partners, *The Global Cannabis Report* (2019).

# 3 DOMESTIC DEMAND

## 3.1 Patient and clinician adoption

Currently available data on medicinal cannabis access mostly describes the SAS-B pathway. This is largely because SAS-B is the most common pathway to access medicinal cannabis in Australia, but also because its stringent approval processes require detailed information to be captured. As a result, and despite it being acknowledged that SAS-B is unlikely to remain the dominant access pathway over the long term, SAS-B approval data has informed the analysis of historical demand for medicinal cannabis presented in this section.

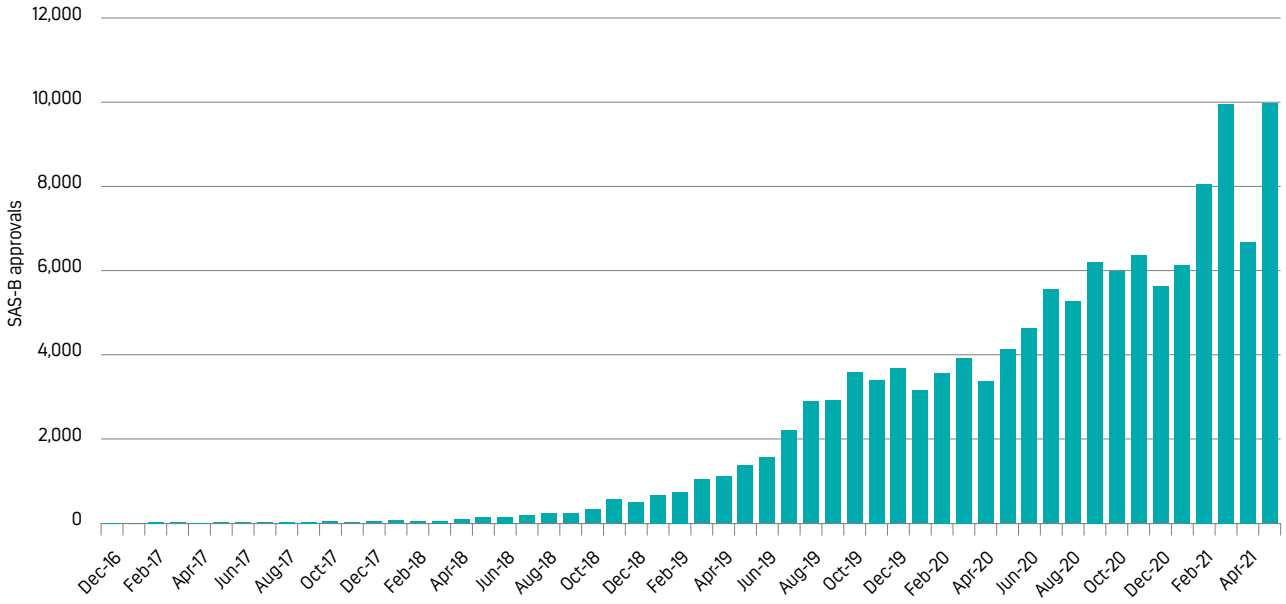
### 3.1.1 Applications over time

Several detailed datasets describing medicinal cannabis applications through SAS-B have been released by the TGA in recent months.[45] These data sources have been combined, where possible, to inform the analysis and description of the medicinal cannabis market in Australia.[46]

Deloitte Access Economics analysis of this TGA data finds that, as of May 2021, there have been approximately 126,500 approved applications for medicinal cannabis through SAS-B since 2016.[47, 48, 49, 50] There has been a strong increase in demand over time, albeit starting from a base of zero in 2016. This growth is demonstrated in Chart 3.1 below.

While growth was initially slow through 2017, from mid-2018 it started to accelerate, with 60 approved applications in January 2018, compared to 670 in January 2019. This acceleration continued through 2019, peaking in October that year with 3,587 approved applications. After remaining broadly flat from October 2019 to April 2020, SAS-B application approvals for medicinal cannabis continued to grow sharply through 2020 and 2021, reaching their highest level ever (almost 10,000) in May 2021.

Chart 3.1: SAS-B approvals for medicinal cannabis, December 2016 to May 2021




Source: Deloitte Access Economics analysis, using TGA.[51, 52]

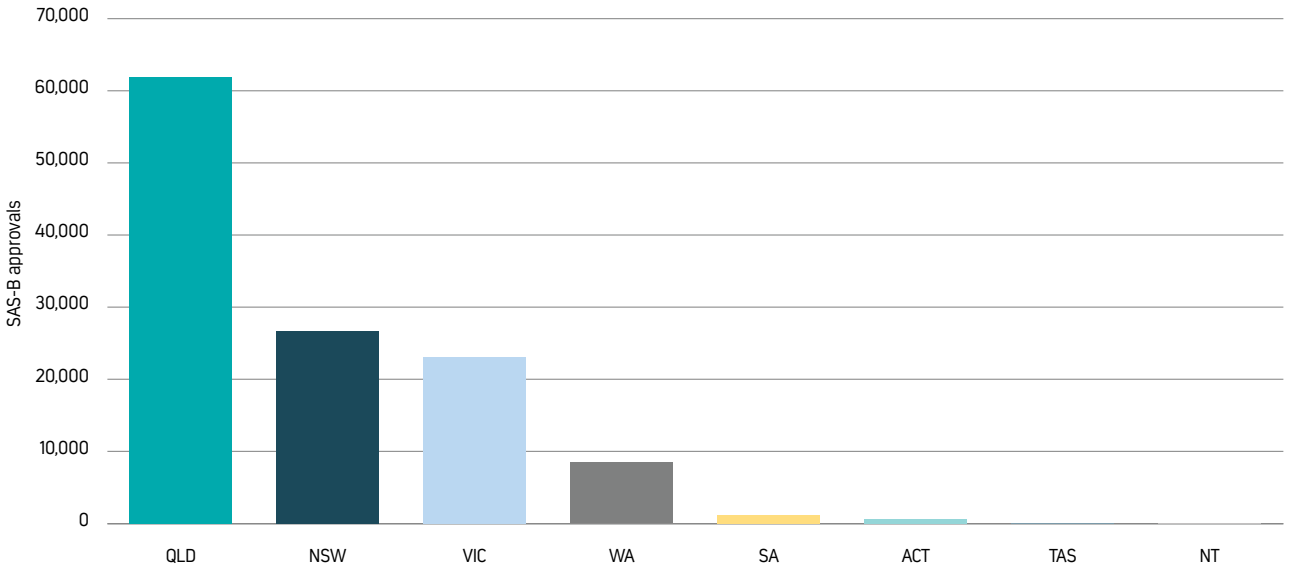
45 Therapeutic Goods Administration, 'FOI disclosure log' (3 May 2021) ‹https://www.tga.gov.au/foi-disclosure-log›.
46 Note that where data was incomplete or where duplications occurred, some assumptions were required prior to analysing this data. These assumptions are described in Appendix B.
47 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
48 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
49 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.
50 Deloitte Access Economics analysis, using Therapeutic Goods Administration, 'Accessing unapproved products – Medicinal cannabis' (3 September 2020) ‹https://www.tga.gov.au/access-medicinal-cannabis-products-1›.
51 Deloitte Access Economics analysis, using Therapeutic Goods Administration, (1) *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020, (2) Freedom of Information request 2250: Request for documents relating to SAS B approvals for medicinal cannabis product, (3) Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020 and (4) Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.*
52 Therapeutic Goods Administration, 'Accessing unapproved products – Medicinal cannabis' (2 October 2020) ‹https://www.tga.gov.au/access-medicinal-cannabis-products-1›.

The number of approved applications is strongly correlated with the number of total applications, with Deloitte Access Economics analysis of TGA data up to June 2020 showing that approved applications represent over 98.8 per cent of total applications (with the remaining being withdrawn or yet to be assessed).[53, 54]

However, it is important to recognise that the number of approved applications does not necessarily equate to the number of prescriptions filled by patients. This is because there is likely a proportion of prescriptions that are written by a medical practitioner but not filled by the patient (as is the case with any prescription medication). Approvals are typically valid for a 12-month period, so beyond this it is possible that a patient may receive a repeat approval for the same product.

The majority of medicinal cannabis approvals were recorded to have a 'Consulting Location' in Queensland, accounting for about 51 per cent of approvals since April 2019. This figure is high given that only 20 per cent of Australia's population resides in Queensland.[55] The second largest proportion of medicinal cannabis approvals (about 22 per cent) are attributed to New South Wales, followed by Victoria (19 per cent) and Western Australia (seven per cent). Approvals across the remaining states and territories are relatively negligible, with each accounting for less than one per cent of the total.

Chart 3.2: SAS-B approvals for medicinal cannabis by state, April 2019 to May 2021



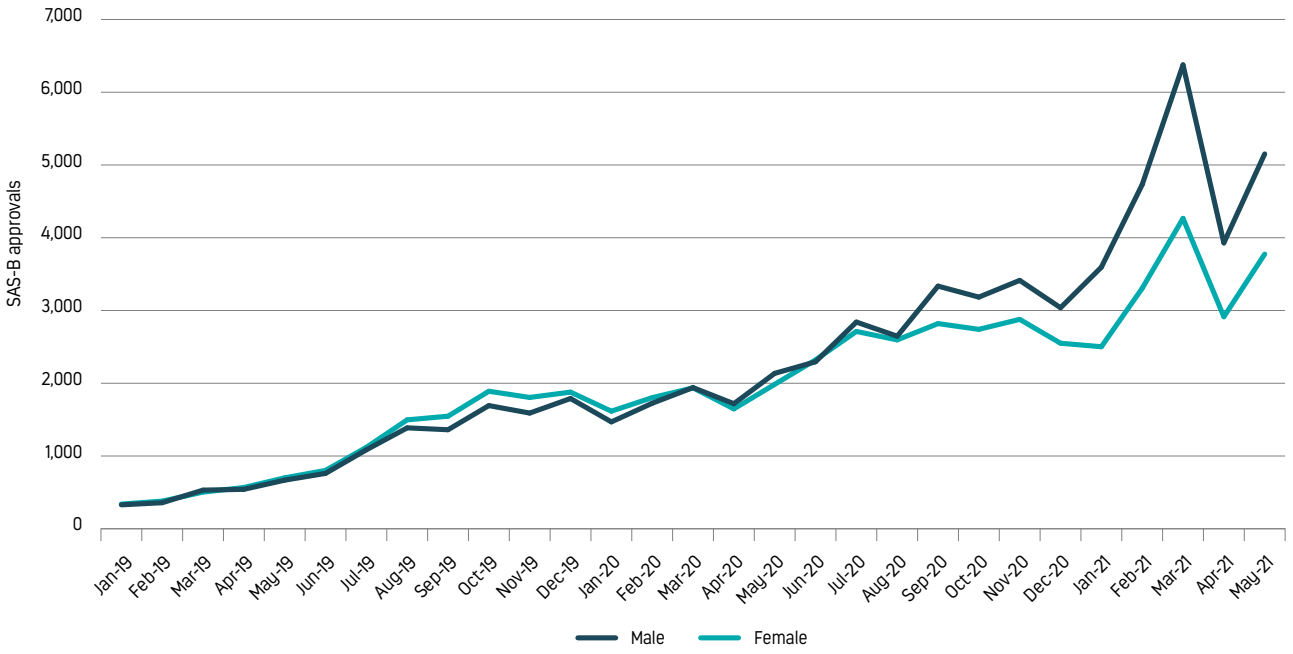

Source: Deloitte Access Economics analysis, using TGA.[56, 57, 58]

The number of approvals for most states and territories has increased since December 2019 (the earliest date for which this data was available), with the relative numbers between each state and territory remaining largely consistent (see Appendix A, Chart A.1 for a breakdown by state or territory over time).

For much of the time medicinal cannabis has been legal in Australia, there has been little difference in the use of the medicine between male and female cohorts. However, since March 2020, males have become increasingly prominent amongst those approved to access medicinal cannabis under the SAS-B access pathway. In the first five calendar months of 2021, males comprised nearly 59 per cent of medicinal cannabis approvals (see Chart 3.3).

53 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
54 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
55 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.
56 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2250: Request for documents relating to SAS-B approvals for medicinal cannabis product.*
57 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
58 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

Chart 3.3: SAS-B approvals for medicinal cannabis by gender, January 2019 to May 2021




Source: Deloitte Access Economics analysis, using TGA data.[59, 60]

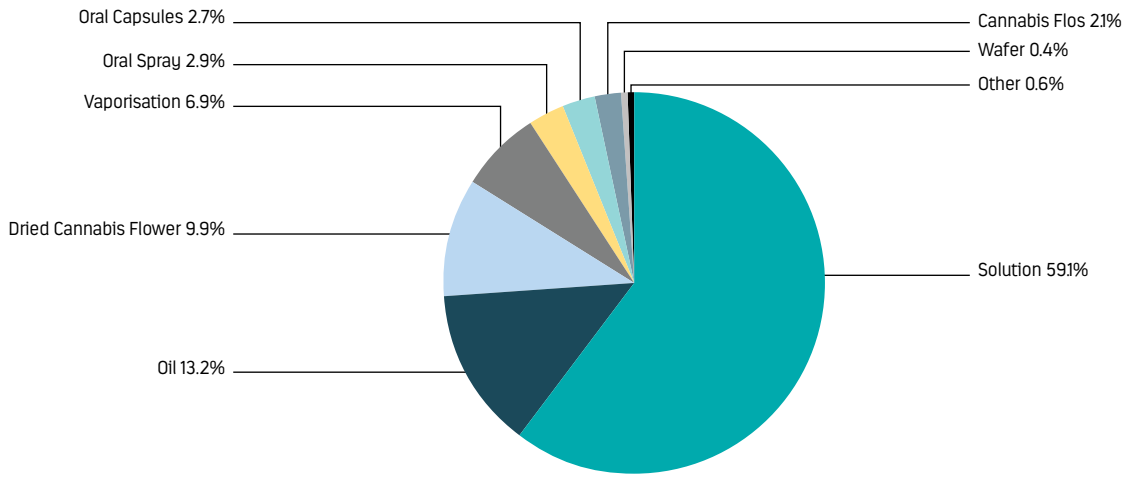
### 3.1.2 Medicinal cannabis products

Over 130 different medicinal cannabis products have been prescribed to Australian patients since 2016, according to the Department of Health.[61] This included a mix of medicines manufactured domestically and overseas. However, consultations suggest that very few TGA licensed manufacturers are currently able to supply finished medicinal cannabis products for domestic patient consumption. As such, a large proportion of domestic demand continues to be met by products imported from relatively mature overseas manufacturers.

These medicinal cannabis products can come in a variety of different forms. Most medicinal cannabis prescribed in Australia is purchased as an oil or a solution, to be consumed orally (Chart 3.4). Other products that are available include, but are not limited to, dried cannabis flowers, vaporisation products, capsules, sprays, cannabis flos and sublingual wafers.

59 Deloitte Access Economics analysis, using Therapeutic Goods Administration, Freedom of Information request 2275: Special Access Scheme Category B pathway specific to medicinal cannabis products during the period 1/11/2016 to 1/03/2020.
60 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.
61 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 3.

Chart 3.4: Most common product types through SAS-B, August 2020 to May 2021




Note: It is likely that 'solution' refers in part to oils that are consumed orally. Reporting by FreshLeaf Analytics suggests that this is likely the case for at least some of the solutions, with 57 percent of medicinal cannabis products reported as being delivered as oils.[62]
Source: Deloitte Access Economics analysis, using TGA.[63,64]

Consistent with variation in form, the concentration of active ingredients in medicinal cannabis can also vary significantly between products. While the cannabis plant contains over 500 cannabinoids (including 120 phytocannabinoids),[65] there are two that have been most studied. The first is CBD, which is understood to have anti-inflammatory and neuroprotective properties,[66] with little psychoactive effect.[67] The other is delta-9-tetrahydrocannabinol (THC), which is the primary psychoactive compound found in cannabis.

Medicinal cannabis products may include various combinations of these cannabinoids, including CBD only, THC only, or various blends of the two cannabinoids. As plant extracts, medicinal cannabis products typically contain other active ingredients (including terpenes and other cannabinoids); however, these are often made less clear in the product labelling.

When considering the different combinations of cannabinoids in medicinal cannabis products, it is also important to recognise the so-called 'entourage effect': a theory that the use of the whole plant may exert greater effects than the sum of its individual parts. This is yet to be proven clinically.[68]

Stakeholder consultations revealed mixed opinions on the cannabinoid combination most commonly prescribed in Australia. One stakeholder noted that a CBD-only product was the most common, while another suggested the same for a balanced product (where approximately equal concentrations of CBD and THC are used).

However trends in prescription may be slightly at odds with those observed in product manufacturing. According to a submission by the Department of Health, 70 per cent of medicinal cannabis products accessible in Australia contain a combination of both CBD and THC.[69]

62 FreshLeaf Analytics, *Australian Medicinal Cannabis Market: Patient, Product and Pricing Analysis* (Quarter 1, 2020) 7.
63 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2184: Request for spreadsheet of Special Access Scheme applications for medical cannabis for period 1 August 2020 to 16 January 2021.*
64 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.
65 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 2.
66 Poleg, S, Golubchik, P, Offen, D, Weizman, A. 'Cannabidiol as a suggested candidate for treatment of autism spectrum disorder', Prog Neuropsychopharmacol Biol Psychiatry. 2019;89:90–96.
67 Robson, P. 'Abuse potential and psychoactive effects of δ-9tetrahydrocannabinol and cannabidiol oromucosal spray (Sativex), a new cannabinoid medicine', Expert Opin. Drug Saf. 2011; 10: 675–85.
68 Santiago, M, Sachdev, S, Arnold, JC, McGregor, IS, Connor, M. 'Absence of entourage: Terpenoids commonly found in *Cannabis sativa* do not modulate the functional activity of Δ9-THC at human $CB_1$ and $CB_2$ receptors', Published in Cannabis and Cannabinoid Research (2019) ‹https://www.biorxiv.org/content/10.1101/569079v1›.
69 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 17.

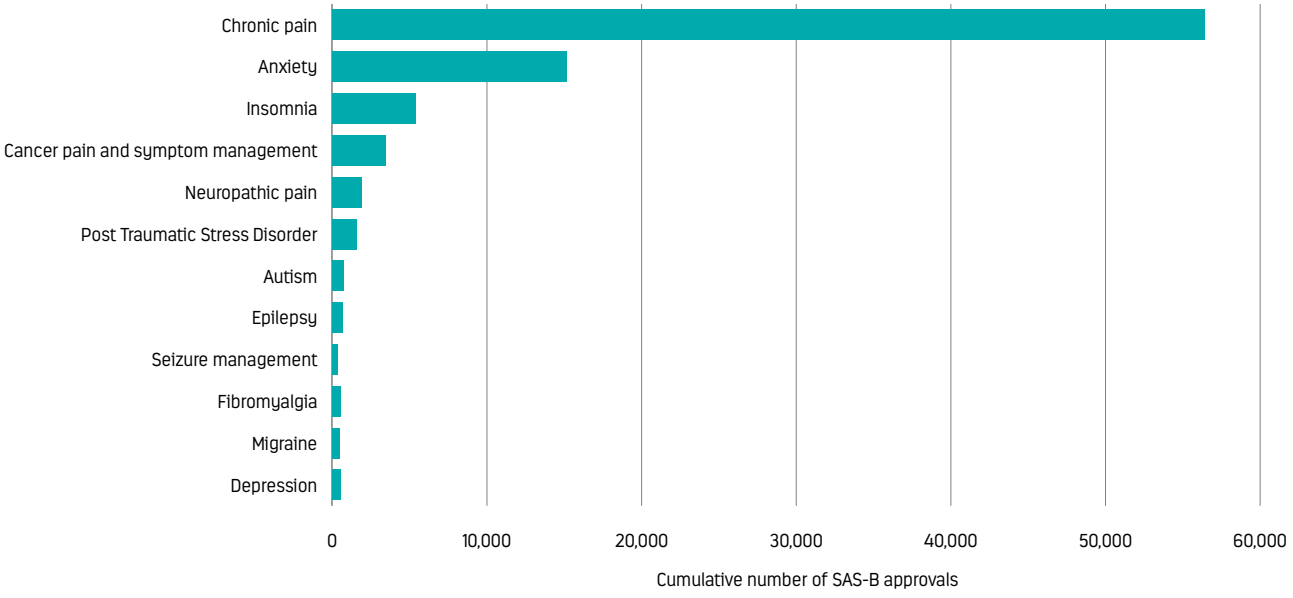
About one-third of all medicinal cannabis products currently available for patient access in Australia are CBD-only products.[70, 71] CBD-only products allow some patients to benefit from the drug without experiencing adverse psychological events commonly associated with cannabis use.[72] There is some evidence to suggest THC is effective in treating anorexia and behavioural symptoms in patients with dementia.[73] However, the drug is also known to have led some patients to experience adverse effects, including paranoia and hallucinations.[74] While no stakeholders consulted expressed concern about CBD being prescribed where it assists patients in treating their symptoms, concern were raised towards prescribing THC in isolation.

### 3.1.3 Indications that are treated using medicinal cannabis

There are no restrictions on the indications or symptoms for which an application can be made for medicinal cannabis to be prescribed. This has led to a long list of indications that have been approved by the TGA since 2016, with 140 indications identified as of March 2020.[75, 76] The top indications approved for medicinal cannabis under the SAS-B access pathway in the year to February 2021 are shown below in Chart 3.5. For a full list of indications that have been approved to date see Appendix B.

Chronic pain is overwhelmingly, and increasingly, the most common indication for which medicinal cannabis has been approved through SAS-B, accounting for 65 per cent of all approvals between March 2020 and May 2021.

Chart 3.5: Top 10 indications approved for medicinal cannabis under the SAS-B access pathway, March 2020 to May 2021



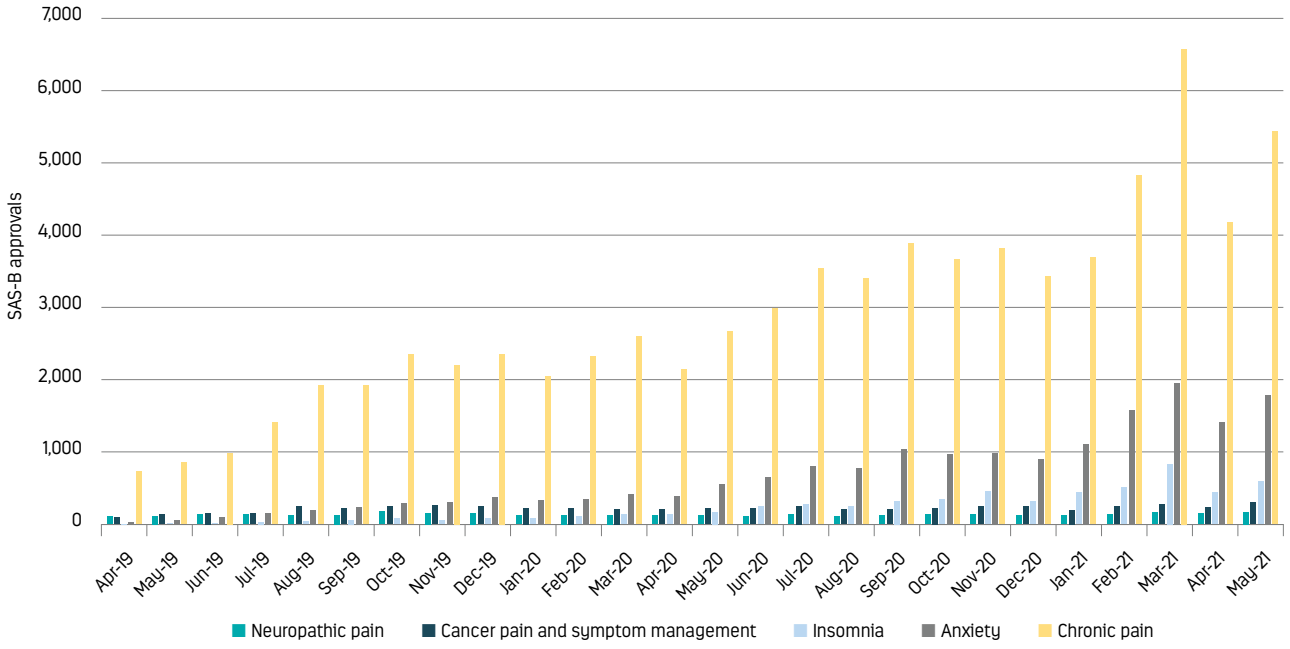

Source: Deloitte Access Economics analysis, using TGA.[77, 78]

70 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 17.
71 Lambert Initiative, Submission No 36 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 10.
72 Efron, D, Freeman, J, et al. 'A pilot randomised placebo-controlled trial of cannabidiol to reduce severe behavioural problems in children and adolescents with intellectual disability', *British Journal of Clinical Pharmacology* (2020).
73 Bridgeman, M and Abazia, D. 'Medicinal Cannabis: History, Pharmacology, And Implications for the Acute Care Setting', *Pharmacy and Therapeutics* (2017) 42(3), 180–188.
74 Efron, D, Freeman, J, et al. 'A pilot randomised placebo-controlled trial of cannabidiol to reduce severe behavioural problems in children and adolescents with intellectual disability', *British Journal of Clinical Pharmacology* (2020).
75 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
76 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
77 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2250: Request for documents relating to SAS-B approvals for medicinal cannabis product.*
78 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

Chronic pain has been the leading indication for medicinal cannabis approvals since 2018, taking over from epilepsy, which had been the leading indication since 2017. A review of the clinical evidence for pain reduction with cannabis administration in adults published in 2020 by researchers from the Nordic Cannabis Research Institute found varying levels of effectiveness across different indications.[79] More promising effects were identified in the non-randomised controlled clinical trials examined than those that were randomised.

Approvals for anxiety, as well as cancer pain and symptom management, started to become more common in 2019, eventually surpassing approvals for neuropathic pain. Other notable indications that are now seeing relatively high numbers of medicinal cannabis approvals through the SAS-B access pathway include insomnia, seizure management and post-traumatic stress disorder (PTSD). For each of these indications, at least 1,400 patients were approved for access to medicinal cannabis under the SAS-B pathway in 2020. It is unclear whether the increase in approvals for these indications is caused by new clinical evidence or not.

Chart 3.6: SAS-B approvals for medicinal cannabis by top five indications, April 2019 to May 2021




Source: Deloitte Access Economics analysis, using TGA.[80, 81]

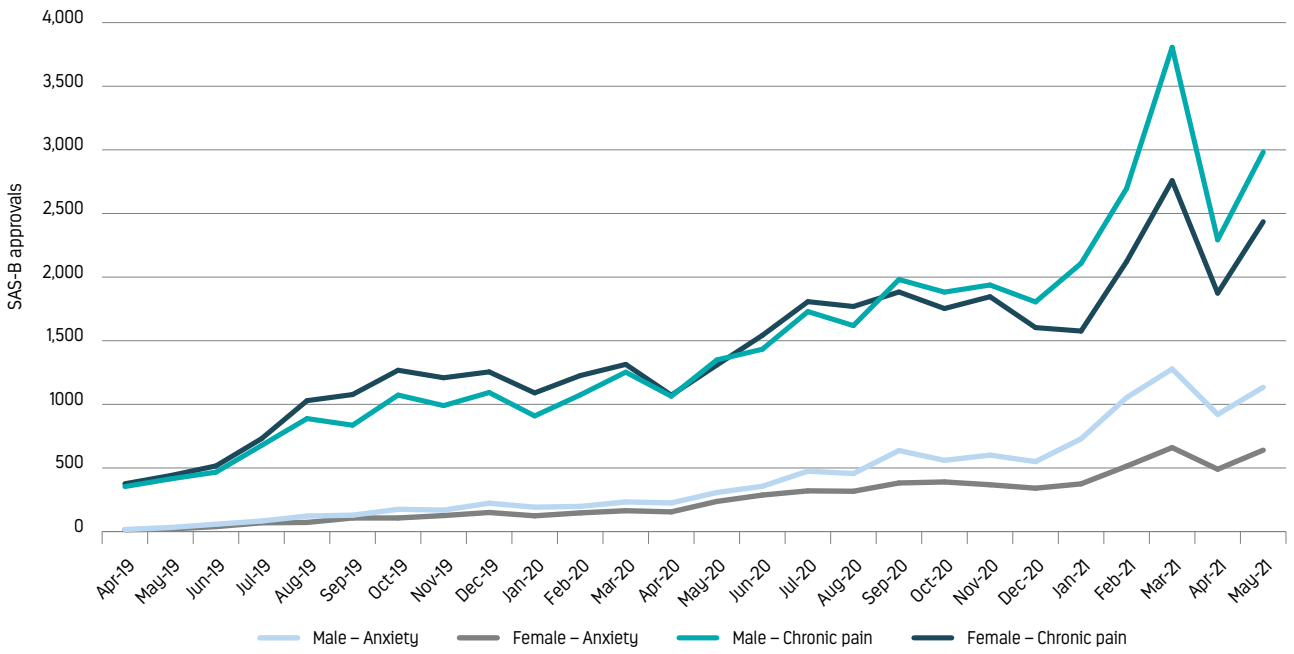
Approval numbers for these indications fluctuate on a monthly basis. Specific figures underpinning Chart 3.6 are provided in Appendix A, Table A.3.

Indications for which medicinal cannabis is used are beginning to differ slightly between males and females, as illustrated by Chart 3.7. Chronic pain is the leading indication for both genders. The number of females with chronic fatigue being treated with medicinal cannabis exceeded that of males by an average of nearly 20 per cent between August 2019 and February 2020. However, since then, the number of males with chronic pain approved for medicinal cannabis treatment has grown to exceed that of females. In May 2021, approvals for males were approximately 25 per cent higher than for females.

The number of males with anxiety approved for treatment with medicinal cannabis has typically exceeded female approvals since the beginning of 2019. However, the gap between the two has been growing in recent months.

79 Reham Haleem and Robert Wright, 'A Scoping Review on Clinical Trials of Pain Reduction With Cannabis Administration in Adults' (2020) 12 (6) *Journal of clinical medicine research* 344.
80 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2250: Request for documents relating to SAS-B approvals for medicinal cannabis product.*
81 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

Chart 3.7: SAS-B approvals for chronic pain and anxiety by gender, April 2019 to May 2021




Source: Deloitte Access Economics analysis, using TGA.[82, 83, 84]

### 3.1.4 Price of medicinal cannabis

High costs are broadly accepted as the primary barrier to accessing medicinal cannabis in Australia. The prohibitive nature of medicinal cannabis prices has been described by stakeholders consulted as part of this report and is supported by the findings of the recent Senate inquiry.[85] These costs can be incurred both through the price of the medicinal cannabis product, but also in costs to visit cannabis clinics to obtain a prescription (which may be the only option for a patient if they cannot find a GP who is adequately educated and/or willing to subscribe medicinal cannabis).[86] The cost of visiting a medicinal cannabis clinic could range from $300 to $500 for an initial appointment[87] and further costs could be incurred for subsequent prescriptions, follow-up appointments and other incidental activities that may be required.[88]

Price analysis conducted by FreshLeaf Analytics has found that the average cost per day for Australian patients for medicinal cannabis is between $5 and $15, but can be greater than $50 per day for paediatric epilepsy patients.[89] The high costs for epilepsy patients has been mentioned by multiple stakeholders during consultations and through numerous submissions to the Senate inquiry.[90]

82 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
83 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
84 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.
85 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 75.
86 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 76.
87 Australian Pain Management Association, Submission No 32 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 8.
88 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 76.
89 FreshLeaf Analytics, Submission No 14 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 6.
90 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 78.

It is possible that the high price of visiting a cannabis clinic (if a GP visit is not feasible) could discourage potential medicinal cannabis patients from submitting an application to access medicinal cannabis. By contrast, it is unclear whether price acts as a deterrent to the use of medicinal cannabis prior to a medical practitioner making an application to the TGA, or whether this revelation occurs after a prescription is received, resulting in unfilled prescriptions. In reality, both of these scenarios are likely to have occurred for different patients. When a patient is informed of potential costs during the initial consultation, they may opt out of treatment before an application is made; however, in the absence of this an application may be made, approved, but a prescription subsequently not filled.

It should be noted that the price of medicinal cannabis in Australia has fallen sharply over the past six months, with some product prices sitting at just 25 per cent of what was observed three years ago.[91] FreshLeaf Analytics reports that medicinal cannabis prices in Australia are now roughly on par with those in Canada.

### 3.1.5 Illicit markets

A recent survey conducted by the Lambert Initiative for Cannabinoid Therapeutics at The University of Sydney suggests that 97 per cent of Australians currently using cannabis for medicinal purposes access the drug via illegal pathways.[92] Published in the *Harm Reduction Journal*, the survey found that only 2.4 per cent of respondents reported having accessed medicinal cannabis via prescription from a registered doctor.[93] Key factors identified as disincentivising patients from accessing medicinal cannabis through legal pathways include limited access to medical practitioners who were willing to prescribe, a lack of awareness that medicinal cannabis could be obtained legally, and the high price of purchasing licit medicinal cannabis.

However, it is difficult to estimate how many of those accessing illicit cannabis would be eligible for prescriptions under legal pathways. It is also unclear the extent to which the sample of survey respondents was representative of the broader population in Australia, particularly those accessing medicinal cannabis through legal pathways.

Future demand growth for legally manufactured medicinal cannabis therapeutics is expected to be driven by a mixture of first-time and repeat users of the drug. Some repeat users will have previously accessed licit medicinal cannabis, while others will be new to the licit market, substituting away from the illicit market for the first time.

As the licit market for medicinal cannabis matures and product prices continue to fall, it is likely that patients substituting away from the illicit market will comprise an increasingly large share of total demand. However, the rate of substitution from the illicit to licit market and the relationship to price is not known. There is currently insufficient data available to estimate the rate at which medicinal cannabis users might transition between the two markets (illicit and licit).

Acknowledging this uncertainty, demand for medicinal cannabis modelled in this report only considers official government data describing patient access to licit medicinal cannabis. As a result, estimates may underestimate the full extent of demand for medicinal cannabis in Australia. However, it is likely that projected growth in sector-level demand captures some of those patients that might transition from illicit to licit cannabis in the future, as well as new patients using medicinal cannabis for the first time.

#### 3.1.5.1 Pricing in the illicit market

While there is not a large body of work considering the cross-price elasticity between the licit and illicit markets, existing work suggests that cannabis users treat licit cannabis as a superior commodity compared with illicit cannabis and therefore favour the licit product.[94]

For Q3 2020, FreshLeaf Analytics reported that a pricing analysis of 30 illicit products found that the average price to market was seven cents per milligram of extract.[95] This sat slightly higher than the six cents per milligram of pure cannabinoids minimum for licit products.

91 FreshLeaf Analytics, *Australian Medicinal Cannabis Market: Patient, Product and Pricing Analysis Q3 2020 (2020)* ‹https://freshleafanalytics.com.au/wp-content/uploads/2020/09/FreshLeaf-Analytics-Q3-2020.pdf›.
92 Nicholas Lintzeris, Llewellyn Mills, Anastasia Suraev, et al. 'Medical cannabis use in the Australian community following introduction of legal access: the 2018–2019 Online Cross-Sectional Cannabis as Medicine Survey (CAMS-18)' (2020) 17 (37) *Harm Reduction Journal*.
93 Nicholas Lintzeris, Llewellyn Mills, Anastasia Suraev, et al. 'Medical cannabis use in the Australian community following introduction of legal access: the 2018–2019 Online Cross-Sectional Cannabis as Medicine Survey (CAMS-18)' (2020) 17 (37) *Harm Reduction Journal*.
94 Amlung, M, et al. 'Price elasticity of illegal versus legal cannabis: a behavioural economic substitutability analysis', *Addiction* (2019) Jan(1): 112–118 accessed online: here, last accessed 23 February 2021 https://pubmed.ncbi.nlm.nih.gov/30194789/.
95 FreshLeaf Analytics, *Australian Medicinal Cannabis Market: Patient, Product and Pricing Analysis Q3 2020* (2020) ‹https://freshleafanalytics.com.au/wp-content/uploads/2020/09/FreshLeaf-Analytics-Q3-2020.pdf›.

Such research is hampered by the ability to conduct research in the illicit market and to find 'like' products. However, the implication of this is that the equilibration point of the licit and illicit market is close – if not already passed. This means it is reasonable to assume that substitution between the markets is already well in train. This substitution could be expedited with decreased regulation/improved access to products, increased knowledge, prescribing behaviours of GPs and the potential subsidisation of licit products.

## 3.2 Estimating future domestic demand

The size of the domestic medicinal cannabis market depends on:

- the number of patients using medicinal cannabis across different indications
- the rate at which medicinal cannabis is used to treat these indications (adoption rate)
- the dosage of medicinal cannabis that these patients require.

The price of approved medicinal cannabis products is also an important factor, as it impacts the uptake of medicinal cannabis as a treatment.[96, 97] However, there is currently a lack of data on price for these therapeutics – and the response of domestic demand to changes in price – for this to be built into the model.

Unlike in Section 3.1 (which considered historical SAS-B data only), the following analysis extrapolates SAS-B data from the TGA,[98, 99] to account for demand across other access pathways. These additional pathways include the Authorised Prescriber scheme and clinical trials, but not compound pharmacies due to the uncertainty surrounding volumes distributed through this avenue.[100] The modelling also does not consider medicinal cannabis accessed via the SAS-A pathway or demand for registered medicinal cannabis products (i.e. Sativex and Epidiolex).

In this report it is assumed that medicinal cannabis is consumed in the form of oil; however, it is likely that over the next 10 years new forms will be demanded in the Australian market.

### 3.2.1 Indications using medicinal cannabis as treatment

As discussed in Section 3.1.3, over the last few years there has been a long list of indications that have been treated using medicinal cannabis in Australia. This model assumes that the number of indications, the types of indications, and the proportion of approvals for each indication remains constant between 2020 and 2030. While there will likely be some (perhaps significant) movement in these factors over time (likely driven by increases in clinical evidence provided by industry), there is insufficient evidence to suggest where and when these changes may occur. For this reason, a business-as-usual approach to the proportion of approvals for each indication is adopted in this model.

Accordingly, it is assumed that chronic pain continues to account for about 63 per cent of all medicinal cannabis approvals over the next 10 years, anxiety for about 14 per cent of approvals, insomnia and sleep management for about five per cent, cancer pain and symptom management for nearly five per cent and chronic neuropathic pain for nearly three per cent.

96 Deloitte Access Economics consultation with stakeholders.
97 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
98 Deloitte Access Economics analysis, using *Therapeutic Goods Administration, Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
99 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
100 Current patient numbers could be up to 17 percent higher based on one estimate of compound pharmacy patient numbers provided confidentially during consultations. However, due to the uncertainty and lack of other confirming data, compound pharmacies have been excluded from the current demand estimates.

Table 3.1: Proportion of medicinal cannabis SAS-B approvals attributed to each indication group

| Indication group | % of total indications |
|---|---|
| ADHD and ADD | 0.23% |
| Alzheimer's disease and dementia | 0.20% |
| Anorexia | 0.21% |
| Anxiety | 14.03% |
| Autism spectrum disorder | 0.90% |
| Cancer pain and symptom management | 4.84% |
| Chronic neuropathic pain | 2.53% |
| Chronic pain | 63.23% |
| Epilepsy and seizure management | 1.42% |
| IBS and IBD | 0.20% |
| Insomnia and sleep management | 5.11% |
| Migraine and headache | 0.70% |
| Mood disorders | 0.49% |
| Movement disorders | 1.07% |
| Multiple sclerosis | 0.45% |
| Nausea and vomiting | 0.26% |
| Palliative care | 0.33% |
| Parkinson's disease | 0.60% |
| Post-traumatic stress disorder | 1.81% |
| Other indications | 1.30% |
| *Other neurological disorders* | *0.11%* |

Source: Deloitte Access Economics analysis, using TGA.[101]

These proportions have been estimated based on data from the TGA detailing medicinal cannabis approvals through SAS-B, and have then been scaled according to the estimated proportion of other access pathways (Authorised Prescriber pathway and clinical trials). The relative proportion of each pathway has been estimated using TGA data and stakeholder consultations.[102]

This modelling assumes that the same proportions across indications apply to all access avenues. This is likely to be a reasonable approach for those accessing medicinal cannabis via clinical trials, as data from the ANZCTR and International Clinical Trials Registry Platform (ICTRP) indicates that there is a range of indications that are being considered in clinical trials, including but not limited to epilepsy, cancer pain and symptom management, Parkinson's disease, and other more specific indications such as Fragile X syndrome.[103, 104] Conversely, due to a lack of publicly available data on the indications that are accessing medicinal cannabis through the Authorised Prescriber pathway, this assumption cannot be tested for this avenue.

101 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2250: Request for documents relating to SAS-B approvals for medicinal cannabis product.*
102 Deloitte Access Economics analysis, using Therapeutic Goods Administration, *Freedom of Information request 2250: Request for documents relating to SAS-B approvals for medicinal cannabis product.*
103 Deloitte Access Economics analysis, using Australian New Zealand Clinical Trials Registry data accessed via Therapeutics Goods Administration website, 'Clinical trials on medicinal cannabis substances, extracts and products' (1 January 2015 to 30 November 2019) ‹https://www.tga.gov.au/medicinal-cannabis-information-health-professionals›.
104 Deloitte Access Economics analysis, using World Health Organization, *International Clinical Trials Registry Platform* (Accessed 31 August 2020) ‹https://apps.who.int/trialsearch/›.

### 3.2.2 Adoption rate

The uptake of medicinal cannabis over time is estimated in this report using the Bass adoption model. The Bass adoption model is a common mathematical representation of diffusive adoption. It describes the number of new adopters per unit of time, driven by the additive effects of external and internal forces. The model has been demonstrated as a reliable model for hundreds of new innovations, often repeated in multiple marketplaces and is commonly used to consider the uptake of a pharmaceutical treatment or product. The uptake of a treatment or product is estimated through using the following two parameters:

- Coefficient of innovation: Measures the rate at which people independently adopt a new product as a result of external factors.
- Coefficient of imitation: Measures the influence of the previous adoption level upon the new level of adoption. This reflects the effect of word-of-mouth upon drug adoption.

The adoption rate reflects a number of factors that could influence the length of time for full adoption of medicinal cannabis by applicable patients. These factors include a patient's willingness to adopt medicinal cannabis, prescriber willingness to prescribe medicinal cannabis and an evolving understanding of the effectiveness of medicinal cannabis as a treatment for each indication.

The estimated adoption of medicinal cannabis is informed by a 2012 Australian study of 103 commonly prescribed drugs.[105] The modelled adoption rate is based on the drug Topiramate, selected for its similarity in clinical characteristics and target patients to medicinal cannabis (of the 103 drugs in the study). The adoption rate of Topiramate estimates a 16-year path to saturation (95 per cent of full adoption).

While Topiramate has been chosen as the reference drug, it is worth noting that it does not reflect treatment for all indications for which medicinal cannabis is considered. Further, it is a PBS-listed drug that is also registered on the ARTG. While medicinal cannabis products may ultimately follow a similar path, this is currently unknown, so the path to saturation may well differ.

Indeed, there is also potential to influence the levers inherent within the Bass adoption model, which has the effect of changing the rate of adoption. For example, changing willingness to prescribe directly drives an increase in the coefficient of innovation and, indirectly, an increase in the coefficient of imitation.

As discussed in Section 3.1.1, the number of approved applications is likely not equal to the number of prescriptions that are filled, as there is likely a proportion of prescriptions that are written by a medical practitioner but not filled by the patient (as is the case with any prescription medication). This proportion is assumed to be 20 per cent for the purposes of this modelling.[106]

The rate of adoption described in this section does not account for a potential future uplift in demand for medicinal cannabis as a result of the recent decision to down-schedule low-dose CBD products (up to a maximum of 150 mg/day) to Schedule 3 in Australia. Further adoption of medicinal cannabis via this pathway is considered below in Section 3.2.4.

### 3.2.3 Dosage

The most suitable dosage of medicinal cannabis is highly individualised, dependant on not only the indication that is being treated, but also the individual patient. This variation means that each patient may require different volumes of CBD and THC, with the relative volumes of each of these cannabinoids also being an important consideration.

Some international medicinal cannabis products can be used to provide guidance on the dosage for some indications. Epidyolex, manufactured by GW Pharmaceuticals, contains 100 mg/ml of CBD per 50 ml bottle of medicinal cannabis oil, and is used to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex.[107] The recommended dosage is typically 10 mg/kg/day after a few weeks, but could be increased up to 20 mg/kg/day. Sativex (nabiximols), also manufactured by GW Pharmaceuticals, contains 25 mg/ml of CBD and 27 mg/ml of THC per 50 ml bottle of oil, which is administered as a spray, with a median of eight sprays per day used in clinical trials.[108] Sativex is a '… treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication …'.[109]

105 Dunn, A, Braithwaite, J, Gallego, B, Day, R, Runciman, W, Coiera, E. 'Nation-scale adoption of new medicines by doctors: an application of the Bass diffusion model', BMC Health Services Research. 2012;12:248 ‹https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3441328/›.
106 Deloitte Access Economics consultation with stakeholders.
107 Epidiolex, 'What is Epidiolex (cannabidiol)?' (Accessed 1 September 2020) ‹https://www.epidiolex.com/›.
108 Therapeutic Goods Administration, *Product information for AusPAR Nabiximols Sativex Novartis* (27 September 2013) ‹https://www.tga.gov.au/sites/default/files/auspar-nabiximols-130927-pi.pdf›.
109 Department of Health, 'The Pharmaceutical Benefits Scheme: Nabiximols, oral spray, 10 ml (90 actuations of 100 microlitres), Sativex – July 2013' (Accessed 8 June 2021) ‹ https://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/psd/2013-07/nabiximols›.

Stakeholder views on the most common combinations of CBD and THC in medicinal cannabis products in Australia varied, with some observing that 100 per cent CBD products are the most common, while others view more balanced CBD:THC products as more common.[110]

Table 3.3 below summarises the dosage assumptions used in this modelling exercise for the 21 indication groups. Sativex was used as a guideline for multiple sclerosis and other movement disorders, as well as chronic pain and chronic neuropathic pain due to nabiximols being used in numerous clinical trials related to this indication.[111] Epidyolex was used as a guideline for epilepsy and seizure management. Finally, a balanced product with less CBD and THC per ml of oil was used for all other indications. The use of CBD:THC mix was informed by stakeholder consultations, and applied to the majority of indications due to a lack of evidence to differentiate the most common products for these indications. As such, the estimates presented here are more likely a conservative estimate of the volumes of CBD and THC consumed for these indications, rather than an overestimate.

Table 3.2: Dosage assumptions for medicinal cannabis indication groups

| Indication group | CBD:THC mg/ml, for 50 ml bottle of oil |
|---|---|
| ADHD and ADD | 10:10 |
| Alzheimer's disease and dementia | 10:10 |
| Anorexia | 10:10 |
| Anxiety | 10:10 |
| Autism spectrum disorder | 10:10 |
| Cancer pain and symptom management | 25:27 |
| Chronic neuropathic pain | 25:27 |
| Chronic pain | 10:10 |
| Epilepsy and seizure management | 100:0 |
| IBS and IBD | 10:10 |
| Insomnia and sleep management | 10:10 |
| Migraine and headache | 10:10 |
| Mood disorders | 10:10 |
| Movement disorders | 25:27 |
| Multiple sclerosis | 25:27 |
| Nausea and vomiting | 10:10 |
| Palliative care | 10:10 |
| Parkinson's disease | 10:10 |
| Post-traumatic stress disorder | 10:10 |
| *Other indications* | *10:10* |
| Other neurological disorders | 10:10 |

Source: Deloitte Access Economics modelling, informed by stakeholder consultations.

110 Deloitte Access Economics consultation with stakeholders.
111 Therapeutic Goods Administration, *Guidance for the use of medicinal cannabis in the treatment of chronic non-cancer pain in Australia* (21 December 2017) ‹https://www.tga.gov.au/publication/guidance-use-medicinal-cannabis-treatment-chronic-non-cancer-pain-australia›.

Dosage rates for each of these indications is estimated to be between 0.8 ml and 1 ml of oil per day for the majority of indications.[112, 113] The exception to this is epilepsy and seizure management, where Epidyolex generally aims for 10 mg/kg/day,[114] which would mean a 40 kg child would be taking approximately 4 ml per day (four times greater than the average estimates for other indications).

Note that the dosage of medicinal cannabis is likely to increase for each patient within the first few weeks or months of treatment, until they reach the optimal dosage. This change in dosage per patient over time has not been accounted for in this modelling exercise due to the difficulty of applying this assumption with limited data.

### 3.2.4 Accounting for down-scheduling

A further uplift in demand has been modelled to account for the potential impact of the recent decision to down-schedule low-dose CBD products (up to a maximum of 150 mg/day) to Schedule 3 in Australia. As this is a very recent decision there is no Australian data on which to forecast likely demand, and as a result Deloitte has looked internationally to estimate demand.

A 2019 survey conducted in the UK (where low-dose CBD products are available for over-the-counter sale in pharmacies) suggests approximately nine per cent of respondents[115] have used CBD products in their lifetime.[116] A slightly more recent (2020) survey conducted by the same organisation found that 11.36 per cent of UK respondents have purchased a CBD product in their lifetime.[117]

Noting that these results capture a mixture of repeat and one-off users, modelling assumes that 5.09 per cent (i.e. the mid-point of the two survey results noted above) of Australia's population will be regular users of medicinal cannabis products (both THC/CBD blends and low-dose CBD products) annually by 2030.

Population projections for Australia are taken from the Australian Bureau of Statistics (ABS) to 2030.[118] The ABS presents three population projections: Low, Medium and High. Given the recent constraints on immigration resulting from the coronavirus pandemic, the Low population projection is used. The Low projection also broadly aligns with actual population growth since 2017.

From the level already projected using the methodology described above, the proportion of Australian adults consuming medicinal cannabis products is assumed to grow exponentially from 2022, reaching 5.09 per cent in 2030. The difference between the number of Australians forecast to use medicinal cannabis using the methodology described above, and 5.09 per cent of Australia's forecast adult population to 2030, is assumed to comprise those individuals consuming low-dose Schedule 3 CBD products.

Average consumption levels for Schedule 3 CBD products are assumed to be as follows:

| Assumption | Figure |
|---|---|
| Assumed daily dose of CBD resin | 150 mg |
| Assumed average number of days consuming CBD resin per year | 14 days |
| Conversion, kg dried plant matter to produce 1 kg CBD resin | 7.27 |

It should be noted that our modelling assumes some medicinal cannabis manufacturers will be able to demonstrate the efficacy of their products to allow for their sale over-the-counter. This may not be the case.

112 Deloitte Access Economics consultation with stakeholders.
113 According to an Australian Public Assessment Report for prescription medicines (AusPAR) published by the TGA on Sativex (nabiximols), the median dose for patients with multiple sclerosis in clinical trials was eight sprays of Sativex per day, where each spray contains 0.1 ml of oil, equal to 0.8 ml of oil per day. Therapeutic Goods Administration, *Product information for AusPAR Nabiximols Sativex Novartis* (27 September 2013) ‹https://www.tga.gov.au/sites/default/files/auspar-nabiximols-130927-pi.pdf›.
114 EpidiolexHCP, 'Epidiolex (cannabidiol) offers flexible dosing for tolerability and response optimization' (Accessed 1 September 2020) ‹https://www.epidiolexhcp.com/dosing-and-calculator›.
115 Respondents to the survey were adults aged 18 years and older.
116 YouGov, *YouGov Survey Results* (29–30 August 2019), (2019). ‹https://d25d2506sfb94s.cloudfront.net/cumulus_uploads/document/l9y6o9trts/YouGov%20-%20CBD%20Results.pdf›.
117 Association for the Cannabinoid Industry, 'CBD Poll Data' (11 March 2020). ‹https://www.theaci.co.uk/cbd-poll-data-march-2020/›.
118 Australian Bureau of Statistics, *Population Projections, Australia* (Catalogue No 3222.0, 22 November 2018).

### 3.2.5 Limitations

There are five main assumptions underpinning this modelling exercise:

1. Indications have been derived using SAS-B data, which may not be representative of all avenues to access medicinal cannabis. That is, clinical trials may see a greater proportion of access related to epilepsy, and Authorised Prescribers may see other indications.
2. Compound pharmacies have not been included as an access avenue.
3. Medicinal cannabis products registered to the ARTG (e.g. Sativex, Epidyolex) are not included in the modelling exercise.
4. It is assumed that medicinal cannabis is only used to treat the same indications as currently reflected in SAS-B applications. Modelling does not consider potential changes to use cases for medicinal cannabis that might impact future demand.
5. The illicit market is not explicitly modelled. Instead, interactions between the licit and illicit market are assumed to be captured in the Bass adoption rate. This modelling exercise assumes that the number of indications, the types of indications, and the proportion of approvals for each indication remains constant between 2020 and 2030.

## 3.3 Future domestic demand projections

Deloitte Access Economics estimates that by 2030, approximately 670,000 patients will be seeking to access medicinal cannabis in Australia.

Table 3.3 below provides estimates for the number of Australian patients using medicinal cannabis in 2030, by indication. Estimates assume the distribution of patients using medicinal cannabis across different indications remains constant into the future, relative to that observed over the two years to March 2021.

Table 3.3: Estimated number of Australian patients seeking to use medicinal cannabis in 2030, by indication

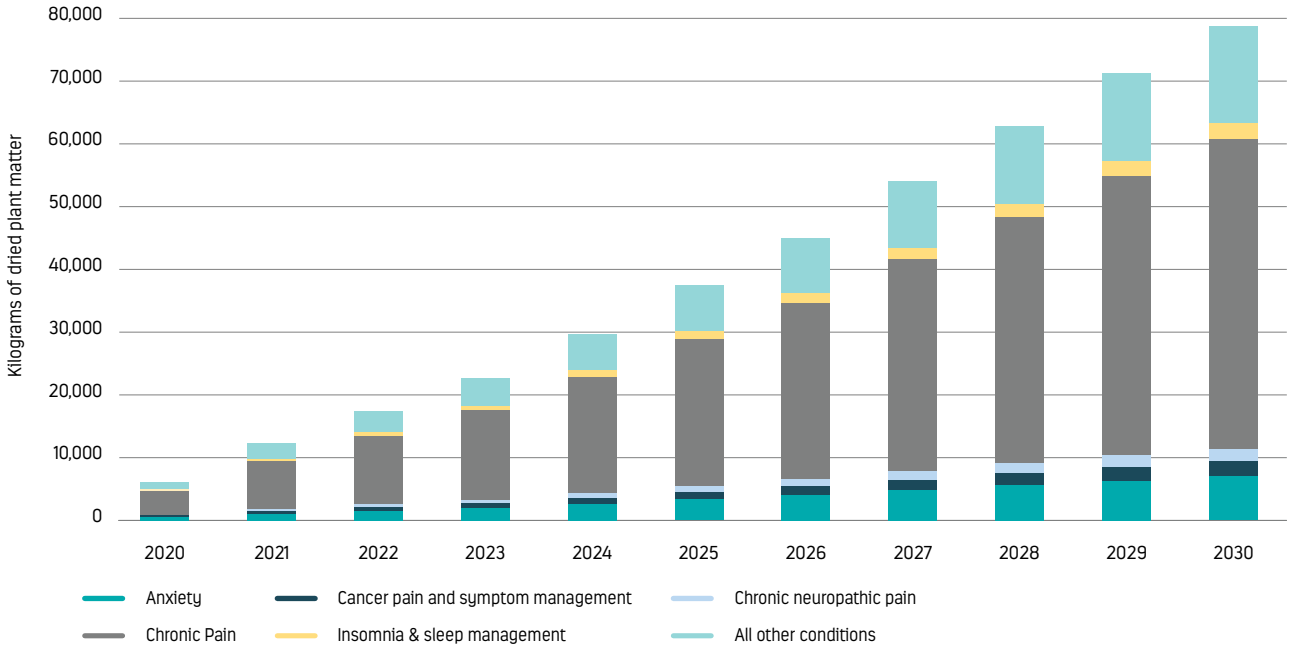
| Indication | Estimated number of patients in 2030 |
|---|---|
| ADHD and ADD | 1,510 |
| Alzheimer's disease and dementia | 1,359 |
| Anorexia | 1,382 |
| Anxiety | 94,056 |
| Autism spectrum disorder | 6,063 |
| Cancer pain and symptom management | 32,440 |
| Chronic neuropathic pain | 16,992 |
| Chronic pain | 423,915 |
| Epilepsy and seizure management | 9,547 |
| IBS and IBD | 1,324 |
| Insomnia and sleep management | 34,264 |
| Migraine and headache | 4,681 |
| Mood disorders | 3,264 |
| Movement disorders | 7,155 |
| Multiple sclerosis | 2,985 |
| Nausea and vomiting | 1,765 |
| Palliative care | 2,207 |
| Parkinson's disease | 4,042 |
| Post-traumatic stress disorder | 12,137 |
| *Other indications* | 8,688 |
| Other neurological disorders | 708 |

Source: Deloitte Access Economics.

This level of demand would translate to nearly 79,000 kg of dried plant matter by 2030.[119]

119 Results are reported using kilograms of dried plant matter as a common metric. However, in reality, they reflect a broad range of medicinal cannabis products, including dried flowers, oils and resins based on their required inputs.

Chart 3.8: Estimated baseline demand for medicinal cannabis by indication, 2020 to 2030




Source: Deloitte Access Economics.

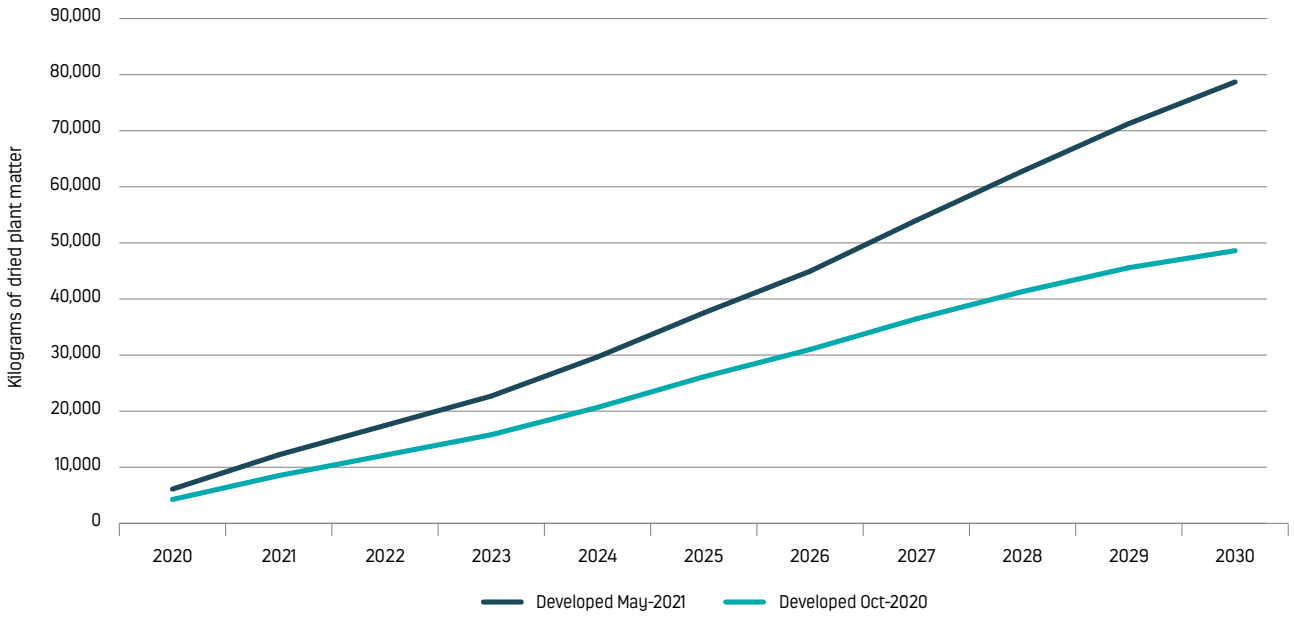
Most of this demand is expected to be driven by chronic pain, as it is today. The other indications expected to be driving demand are anxiety, cancer pain and symptom management, and insomnia and sleep management.

A table of key modelling outputs is provided in Appendix D.

### 3.3.1 Rapid change in demand for medicinal cannabis in Australia

A series of medicinal cannabis demand forecasts were first developed for this report in October 2020. Since this time several announcements have caused the modelling to be updated. In particular, the TGA recently released more up-to-date data describing SAS-B approvals for medicinal cannabis across Australia to early March 2021. In December 2020, the TGA also announced its final decision to down-schedule low-dose CBD medicines to Schedule 3 substances (noted above). Chart 3.9 below compares the medicinal cannabis demand forecasts first developed in October 2020 against those developed more recently in May 2021. Incorporating the latest SAS-B approvals data, as well as accounting for the likely impact of down-scheduling low-dose CBD medicines, has seen the level demand forecast for medicinal cannabis in 2030 rise approximately 60 per cent above that estimated approximately eight months ago (see Chart 3.9 below).

Chart 3.9: Comparison of medicinal cannabis demand forecasts, October 2020 vs May 2021




Source: Deloitte Access Economics.

## 3.4 Demand uplift scenarios

The above baseline projections have been developed based on historical data and industry trends to date. They represent a continuation of current trajectories and do not seek to speculate on the occurrence of future events that are inherently uncertain. It should be noted, however, that several events may occur in the future that drive significant demand growth for Australia's medicinal cannabis sector.

Three hypothetical scenarios are considered to illustrate alternative demand trajectories that might occur if 'things go right' for the industry over the short, medium and long term.

### 3.4.1 Demand drivers

#### Efficacy research and relevant indications

Evidence describing the efficacy and safety of medicinal cannabis in treating many indications remains in its infancy. The evidence base comprises patient advocate stories outlining the benefits of the drug, as well as results from more robust sources, such as clinical trials.

To the extent that the body of research articulating the medicinal benefits of certain cannabinoids (both in isolation and combination) continues to grow, it is likely that demand for medicinal cannabis will respond in turn. Demand growth may occur from both an increase in the number of indications medicinal cannabis can be used to treat, as well as improved perceptions of the drug and wider acceptance of its use in medicine.

The recent listing of Epidyolex to the PBS (from 1 May 2021) is a key government decision that will likely serve as a precedent for other medicinal cannabis products seeking government subsidisation, where the clinical evidence exists to demonstrate their efficacy. Further PBS listings for medicinal cannabis products are expected to see industry demand grow sharply.

### Subsidisation

There are early indications that public sector funding may become available for medicinal cannabis in treating some indications – pending the further progression of clinical evidence.

Some public funding is already made available through the Department of Veterans' Affairs[120] and many private insurers have extras options that provide some subsidisation per prescription (albeit with annual maximum claim limits).[121]

The trend of note here is increasing tendencies to provide consumer subsidisation – both from the private but also public sector. An increase in awareness and demand may highlight equity issues in accessing these private subsidies which could give rise to some level of 'special fund' style public subsidisation on the grounds of equitable access in the short term.

If prices faced by consumers reduce then this will drive (all else held constant) a rise in demand.

Price elasticity for licit medicinal cannabis is not widely studied. However, pharmaceutical products tend to be relatively price inelastic – varying on the basis of condition, severity and intractability to other treatments. The relatively new nature of cannabis in medical treatment landscapes, however, suggests that adoption is still in a process of exponential growth, suggesting that in the short to medium term, prices may reasonably be expected to influence rates of adoption for the medication.

### Willingness to prescribe

Consultations conducted in developing this report indicate that many practitioners remain sceptical of medicinal cannabis and often hesitate to prescribe it to their patients. Concerns typically stem from uncertainty regarding the efficacy and safety margins of cannabis medicine, as well as historical stigma and cost burdens incurred to prescribe the drug.

As the breadth of medicinal cannabis research continues to grow, it is likely that perceptions of the drug will improve and medical practitioners will become increasingly willing to prescribe it. This effect may be compounded by further improvements and revisions to existing medicinal cannabis access pathways (or the development of alternative pathways).

### Cost of production

The cost of production may decline through the application of more efficient processes and economies of scale.

Noting the significant differences in regulatory environment, it is instructive to consider trends in the cost of production in the US and Canada. Setting aside regulatory and scale constraints to implementation of similar cost-saving innovations in Australia, production in these larger markets still point to potential trends that may impact the costs of Australian production in years to come.

Reports indicate that in the US and Canada, cultivators are running increasingly efficient operations. The median cost of production per pound has fallen by 10 per cent between 2018 and 2020. Cost efficiencies have been realised largely through automation – including in light/supplemental lighting control, environmental control for temperature and irrigation.[122]

Economies of scale – either through growth of individual players (including through industry consolidation) or external economies of scale through the growth of the industry as a whole – can also impact on the overarching cost of production. The ratio of current players to prescriptions in the cannabis market (37 to 100,000, compared with 23 to 15 million in the opioid market) is high and suggests the market is headed for consolidation. Consolidation has the potential to increase internal economies of scale for producers where there are diminishing marginal costs or fixed costs of production that can be spread over a larger scale of output (e.g. capital equipment not yet at capacity). Equally, the growth and organisation of the industry as a whole has increased its capacity to inform and influence regulatory processes that may constrain its growth (both on the demand and supply side) with shared effort – reducing the burden to advocate for any one player, an example of external economies of scale.[123]

Similar savings can reasonably be expected to occur in Australia as the industry faces similar competitive pressures (and with a highly saturated market).

A reduction in cost of production can reasonably be expected to flow through to lower prices, which in turn could drive adoption above the baseline level.

120 Department of Veterans' Affairs, 'Medicinal Cannabis' (24 July 2020) ‹https://www.dva.gov.au/health-and-treatment/help-cover-healthcare-costs/manage-medicine-and-keep-costs-down/medicinal›.
121 honahlee, 'PBS & Private Health Cover For Legal Medical Cannabis' (15 February 2021) ‹https://honahlee.com.au/articles/health-insurance-cover-cbd-cannabis/›.
122 Cannabis Business Times and NEXUS Greenhouse Systems, *2020 State of the Industry Report: Five years of data reveals key trends in the cannabis cultivation market*, accessed online: here, last accessed 23 February 2021 http://giecdn.blob.core.windows.net/fileuploads/document/2020/05/29/soi%20book%20-%20high%20res.pdf.
123 Hawken, Angela, *Economies of Scale in the Production of Cannabis*, BOTEC, I-502 Project 430-5c, October 22 2013.

### 3.4.2 Scenarios considered

Acknowledging the possibility that these demand drivers could lead to significant future demand uplifts for Australia's medicinal cannabis industry, three hypothetical growth scenarios have been considered.

These three scenarios provide alternative hypothetical demand growth trajectories, intended as stylised representations of what might occur under specific positive outcomes for the industry. A summary of the demand drivers and assumptions underpinning trajectories reported for each scenario is provided below in Table 3.4.

Table 3.4: Summary of demand uplift scenarios

| Demand drivers | Scenarios | | |
|---|---|---|---|
| | **Scenario A – incremental increase in demand above baseline** | **Scenario B – strong increase in demand** | **Scenario C – rapid increase in demand** |
| **Efficacy research and relevant indications** | • Positive research outcomes for medicinal cannabis advance at a slightly greater rate than forecast in the base case. | • Positive research outcomes for medicinal cannabis gain further momentum, demonstrating medicinal cannabis' efficacy in treating a small number of additional indications. | • Positive research outcomes for existing medicinal cannabis products continue to gain momentum. Medicinal cannabis used to treat a large number of additional indications not currently considered. |
| **Subsidisation** | • Government introduces specialised funding grants/ pools outside of the PBS for a small number of cannabis medicines or vulnerable cohorts to improve/equalise access, to sit alongside growing private health funding. | • A single additional cannabis medicine registered to the ARTG gains PBS listing. | • Further cannabis medicines are registered to the ARTG and are listed to the PBS. |
| **Willingness to prescribe** | • Growth in the body of efficacy research leads to slight improvements in practitioner perceptions of medicinal cannabis.<br>• Improvements to existing access pathways slightly reduce administrative burden incurred by practitioners in prescribing restricted cannabis medicines. | • Practitioner perceptions of medicinal cannabis continue to improve, responding to further growth in the body of evidence describing its efficacy.<br>• Practitioners are able to prescribe a greater number of cannabis medicines through the standard prescription process due to additional ARTG registrations. | • Rapid developments in efficacy research leads to significant improvements in practitioner perceptions of medicinal cannabis.<br>• Replacement of existing access pathways significantly reduces administrative burden incurred by practitioners in prescribing restricted cannabis medicines. |
| **Cost of production** | • Industry consolidates at a slightly greater rate than expected, driving slightly greater efficiency benefits from economies of scale. | • New production technologies are developed, leading to further production efficiencies. | • 'Game-changing' production innovations lead to significant production efficiencies from 2027. |
| **Demand uplift assumption** | • Total potential demand pool assumed to increase by 10 per cent relative to baseline.<br>• Adoption rate assumed to accelerates by a single year from 2022, relative to baseline adoption. | • Total potential demand pool assumed to increase by 50 per cent relative to baseline.<br>• Adoption rate assumed to accelerates by a single year from 2025, relative to Scenario A adoption. | • Total potential demand pool assumed to increase by 100 per cent relative to baseline.<br>• Adoption rate assumed to accelerate by a single year from 2027, relative to Scenario B adoption. |

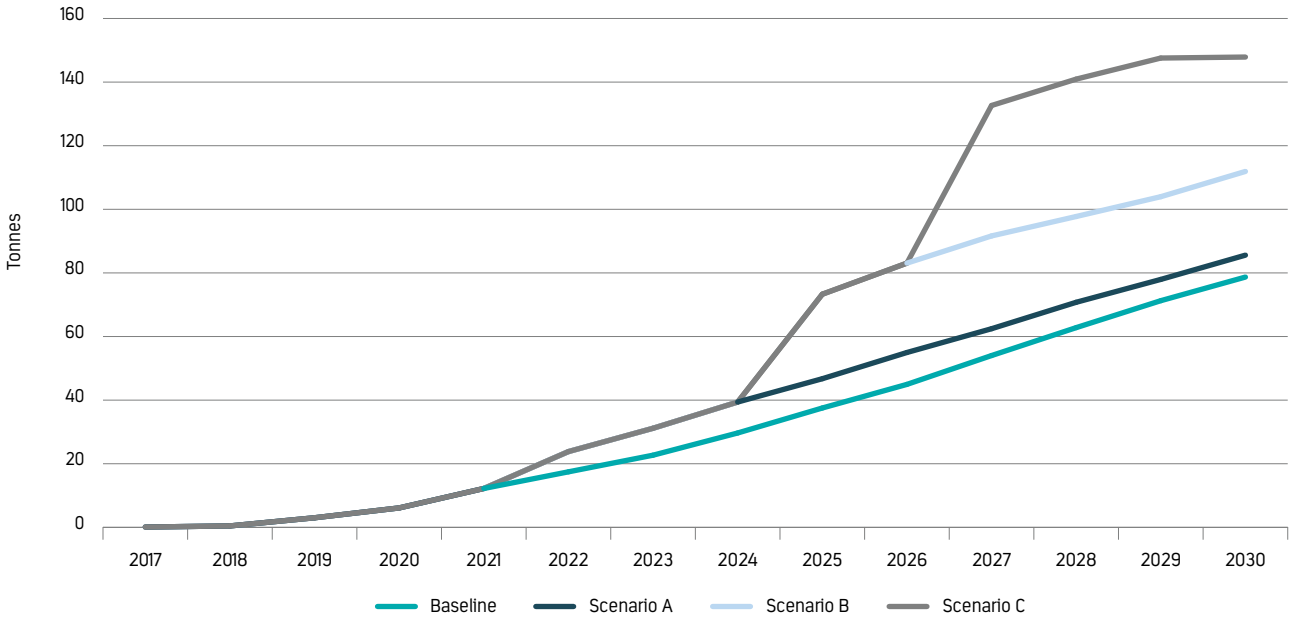
### 3.4.3 Results

Chart 3.10 compares the baseline demand forecasts against scenario demand trajectories. Under Scenario A, annual demand for medicinal cannabis (measured in kilograms of dried plant matter) is projected to reach over 85,000 kg in 2030, up nearly nine per cent on baseline forecasts. Under Scenario B, demand is projected to reach just over 110,000 kg in 2030 (up 42 per cent on baseline forecasts).

The most significant demand growth is projected under the 'High' scenario. Nearly doubling the potential demand pool for medicinal cannabis, alongside a further increase in the rate of adoption, sees demand jump from approximately 83,000 kg in 2026 to about 132,000 the following year. By 2030, demand for medicinal cannabis is projected to rise close to 148,000 kg in Scenario C (up almost 90 per cent on baseline forecasts).

While increases in the rate of adoption lead to some growth in projected demand for medicinal cannabis in Australia, the most substantial demand uplifts are driven by growth in the pool of potential demand for the medicine.

Chart 3.10: Comparison of baseline demand forecast and scenario projections




Source: Deloitte Access Economics.
Note: Demand volumes based on historical data to end of calendar year 2020.

### 3.4.4 Limitations

There are two main assumptions to the above modelling exercise:

- It is assumed that Australian medicinal cannabis manufacturers do not reach their planned production capacity by 2030. Instead sector-wide supply is estimated with reference to demand and the implied export level.
- It is assumed that all manufacturers operating in the sector have identical production input to output ratios.

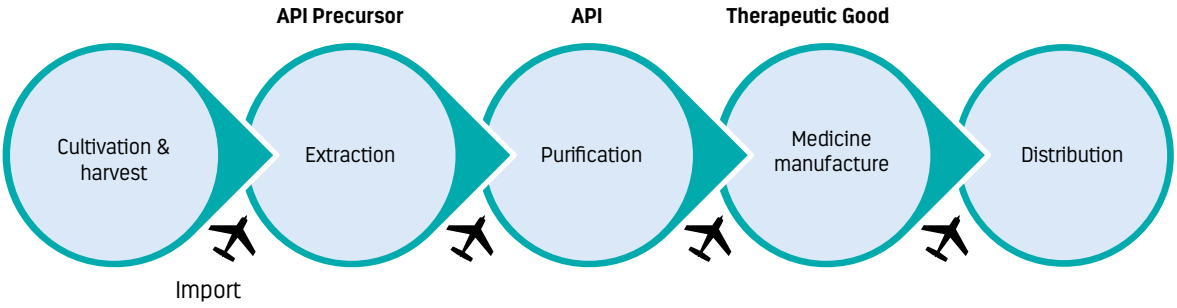
# 4 DOMESTIC SUPPLY

Australian organisations aim to add value at all stages of the medicinal cannabis manufacturing pathway, from research, through to cultivation and manufacture, and finally distribution. Much of the value is captured at either end of the manufacturing supply chain, leading the distribution of value capture in the sector to be commonly described as following a 'smile curve'.

The Australian Government's Modern Manufacturing Strategy provides a framework to strengthen the competitiveness and resilience of medical products manufacturers operating at all points along the manufacturing 'smile curve', including those in the medicinal cannabis industry.[124] The strategy's road map clearly identifies a series of goals it seeks to achieve for medical product manufacturing in Australia over the next decade:[125]

- Two years: Unlock commercialisation opportunities through co-investment in translation, integration and collaboration
- Five years: Strengthen local manufacturing capability and increased international demand for Australian-made critical and sophisticated medical products
- Ten years: Develop Australia's international reputation as a world-class medical product manufacturer, with significant end-to-end collaboration.

Some Australian organisations specialise in growing and processing cannabis plants for supply to patients, while others focus on meeting patient needs by distributing imported therapeutic goods. Medicinal cannabis therapeutics produced in Australia are subject to higher quality standard of good manufacturing practice (GMP), relative to those produced overseas. However, all medicinal cannabis products distributed in Australia must meet the quality standards imposed by TGO 93.




At the end of 2019, the ODC had 92 licences in effect – consisting of 31 licences to cultivate cannabis for medical use (Medicinal Cannabis Licence), 20 licences for cultivation for research (Cannabis Research Licence) and 41 for the manufacture of medicinal cannabis (Narcotic Manufacturing Licence).[126] Domestic manufacture of a therapeutic good requires a further licence from the TGA. Several companies holding one or more ODC licences also hold applicable TGA licences, as do companies focused solely on contract manufacture for other parties (such as IDT Australia and Pharmaceutical Packaging Professionals). A company holding an applicable TGA licence need not be licensed under the ODC if cannabis material is supplied to them by an appropriately licensed entity – domestically or internationally.

There are currently 29 Australian entities listed as licensees under Regulation 5 of the Customs (Prohibited Imports) Regulations 1956 for the import of cannabis material.[127] Imported material may be for research purposes or entry into the domestic supply pipeline at any of the points indicated above.

Over 900 permissions have been granted for sponsored imports of medicinal cannabis products since 2017 for a wide range of individual products.[128]

124 Department of Industry, Science, Energy and Resources, *Our Modern Manufacturing Strategy* (accessed 11 June 2021) ‹https://www.industry.gov.au/data-and-publications/make-it-happen-the-australian-governments-modern-manufacturing-strategy/our-modern-manufacturing-strategy›.
125 Department of Industry, Science, Energy and Resources, *Road map at a glance* (accessed 11 June 2021) ‹https://www.industry.gov.au/data-and-publications/medical-products-national-manufacturing-priority-road-map/road-map-at-a-glance›.
126 Department of Health, Submission No 10 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
127 Office of Drug Control, 'Manufacturers and suppliers of medicinal cannabis products' (20 May 2021) ‹https://www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products›.
128 Office of Drug Control, 'Manufacturers and suppliers of medicinal cannabis products' (20 May 2021) ‹https://www.odc.gov.au/manufacturers-and-suppliers-medicinal-cannabis-products›.

## 4.1 Australian cultivation and manufacture, and future supply projections

The estimate of future supply to the domestic market from Australian manufacturers is assumed to be a function of current planned production capacity and expectations around export opportunities – described below.

In reality, it is likely that some domestic manufacturers also source production inputs from overseas producers, particularly during periods where certain inputs are in short supply domestically. For example, earlier in 2020, a shortage of cannabis flower products (as opposed to oils, solutions, sprays, etc.) was reported in Australia.[129] However, while it is acknowledged that this business model is currently being pursued by some manufacturers operating in the Australian market, the extent to which this occurs is unclear.

As a result, analysis presented in this report does not seek to capture future production supported by this business model.

### 4.1.1 Planned production capacity

Data describing the planned future production capacity of medicinal cannabis producers currently operating in Australia is a key input to the supply side modelling. This information has been sourced from stakeholder consultations, as well as publicly available information.

Analysis of this data reveals planned production capacity for the Australian sector to be extremely high. The sum of individual expansion plans totals well over one million kg of dried plant matter, annually. This would imply the sector's future production capacity could service current Australian demand for medicinal cannabis (see Section 3) more than 150 times over, or demand in 2030 more than 10 times over. As such, were this capacity to be reached (alongside regulations to support this), local manufacturers would be exporting an estimated 95 per cent of their production.

As a point of comparison, the pharmaceutical product manufacturing industry currently exports approximately 54 per cent of products.[130] This is still significantly below the proportion that would be exported if planned production capacity was met for Australian medicinal cannabis. Further, in order to obtain a licence from the ODC, licence holders are required to demonstrate the purpose of their manufacture and the market it will likely service, prior to being granted a permit.[131] As such, the above figure has been used to sense check a more realistic estimate of exports for the medicinal cannabis industry as it develops in Australia, with just under 60 per cent of cannabis medicine manufactured in Australia assumed in our modelling to be exported by 2030.

Table 4.1: Proportion of product exported across industries

| Industry | Proportion of product exported |
|---|---|
| Medicinal cannabis (at planned production capacity) | 95% |
| Pharmaceutical product manufacturing | 54% |

Source: Deloitte Access Economics, using IBISWorld.[132, 133]

However, it is unclear if or when manufacturers in the sector expect to reach their current planned production capacity, with consolidation among firms in the sector highly likely given the estimated imbalance between local supply and demand.

It is likely that some medicinal cannabis manufacturers operating in Australia are currently sourcing raw materials from overseas suppliers for use as inputs to their manufacturing process. However, this analysis does not seek to consider the extent of this practice in Australia, due to limitations in the available data.

129 Cannabiz, 'Flower shortage hits Australian patients' (4 March 2021) ‹https://www.cannabiz.com.au/flower-shortage-hits-australian-patients/›.
130 Richardson, A, *IBISWorld Industry Report C1841 Pharmaceutical Product Manufacturing in Australia* (September 2020) ‹https://my.ibisworld.com/au/en/industry/c1841/key-statistics›.
131 Office of Drug Control, 'Medicinal cannabis cultivation and production licences and permits' (2 January 2020) ‹https://www.odc.gov.au/medicinal-cannabis-cultivation-and-production-licences-and-permits›.
132 Richardson, A, *IBISWorld Industry Report C1841 Pharmaceutical Product Manufacturing in Australia* (September 2020) ‹https://my.ibisworld.com/au/en/industry/c1841/key-statistics›.
133 Chapman, W, *IBISWorld Industry Report A0149 Grain Growing in Australia* (March 2020) ‹https://my.ibisworld.com/au/en/industry/a0149/key-statistics›.

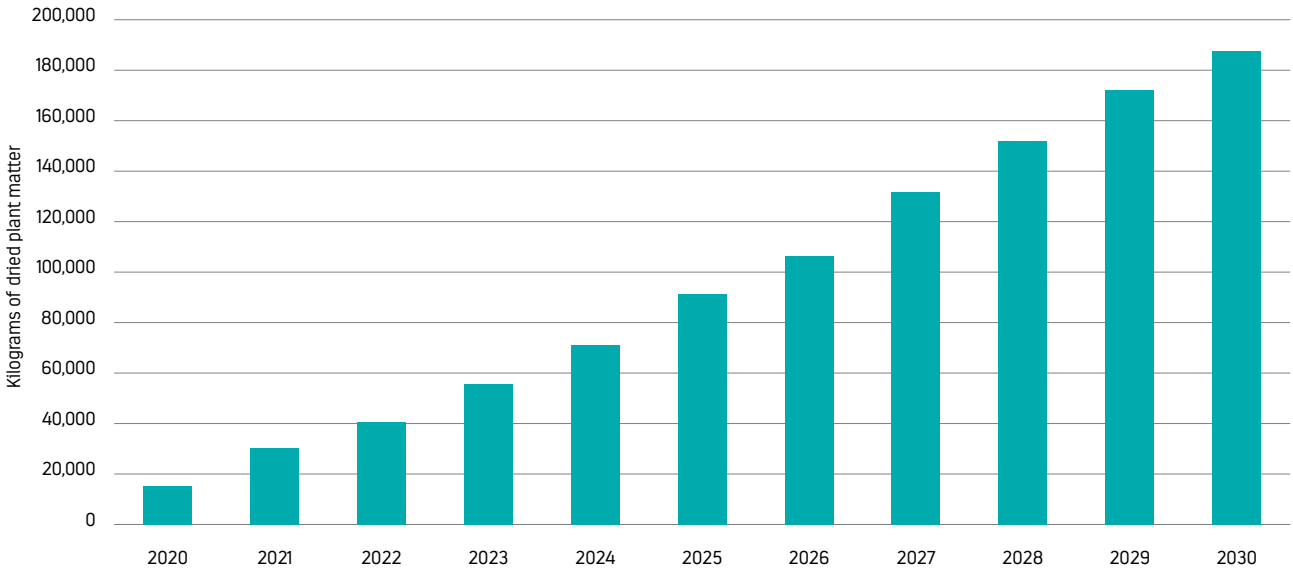
### 4.1.2 Estimated future supply from Australian cultivators and manufacturers

Production capacity is therefore assumed to come online gradually in response to demand. Total estimated production in 2030 reflects planned production capacity, local demand and reasonable exports compared to benchmark industries in Australia. It is likely that not all currently planned capacity will eventuate. As with any rapidly growing industry, it is likely there will be consolidation and rationalisation, particularly in a global economy.

Model results are presented in terms of kilograms of dried plant matter. Where information from stakeholders is not available in kilograms it has been converted based on ratios of square metres of floor space to dried kilograms of plant matter to resin to oil. These ratios were provided in stakeholder consultations.


This level of supply would translate to nearly 188,000 kg of dried plant matter by 2030.[134]

Chart 4.1: Projected supply of medicinal cannabis, 2020 to 2030




Source: Deloitte Access Economics.

Industry stakeholders estimate their production facilities will be able to support upwards of 2,200 jobs on an ongoing basis.[135] However, given the large production capacity planned by the industry may not eventuate, the total job numbers could also be significantly fewer.

134 Results are reported using kilograms of dried plant matter as a common metric. However, in reality, they reflect a broad range of medicinal cannabis products, including dried flowers, oils and resins based on their required inputs.
135 Australian Government, 'Current Major Projects' (30 September 2020) <https://www.business.gov.au/Grants-and-Programs/Major-Project-Status/Current-Major-Projects>.

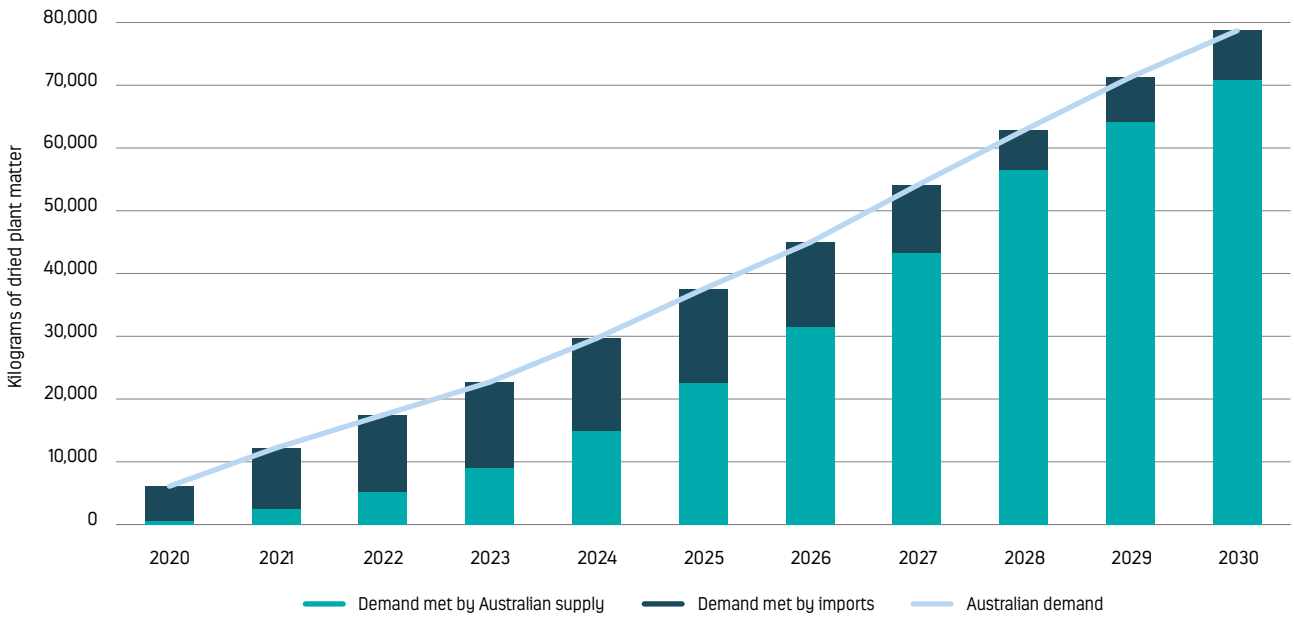
## 4.2 Import projections

Medicinal cannabis therapeutic goods imported into Australia are required to comply with the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017.* However, several industry stakeholders have voiced concerns around Australian cannabis imports failing to meet the required standard.[136, 137, 138] Concerns have also been raised regarding imported products not being required to comply with the TGA's GMP standards, which domestic manufacturers must meet.

Deloitte Access Economics estimates that approximately 90 per cent of medicinal cannabis consumed in Australia in 2020 has been imported from overseas. In terms of dried plant matter, this is equivalent to approximately 5,500 kg (Chart 4.2).

The proportion of total domestic demand serviced by import of medicinal cannabis therapeutic goods is expected to fall over the next decade to approximately 10 per cent in 2030 (noting that the import of precursor material may rise with further commoditisation). However, in terms of dried plant matter, this would translate to a greater volume of medicinal cannabis being imported to Australia (nearly 7,900 kg in 2030). See Appendix D for table of key outputs.

Chart 4.2: Projected Australian supply and imports, 2020 to 2030




Source: Deloitte Access Economics.

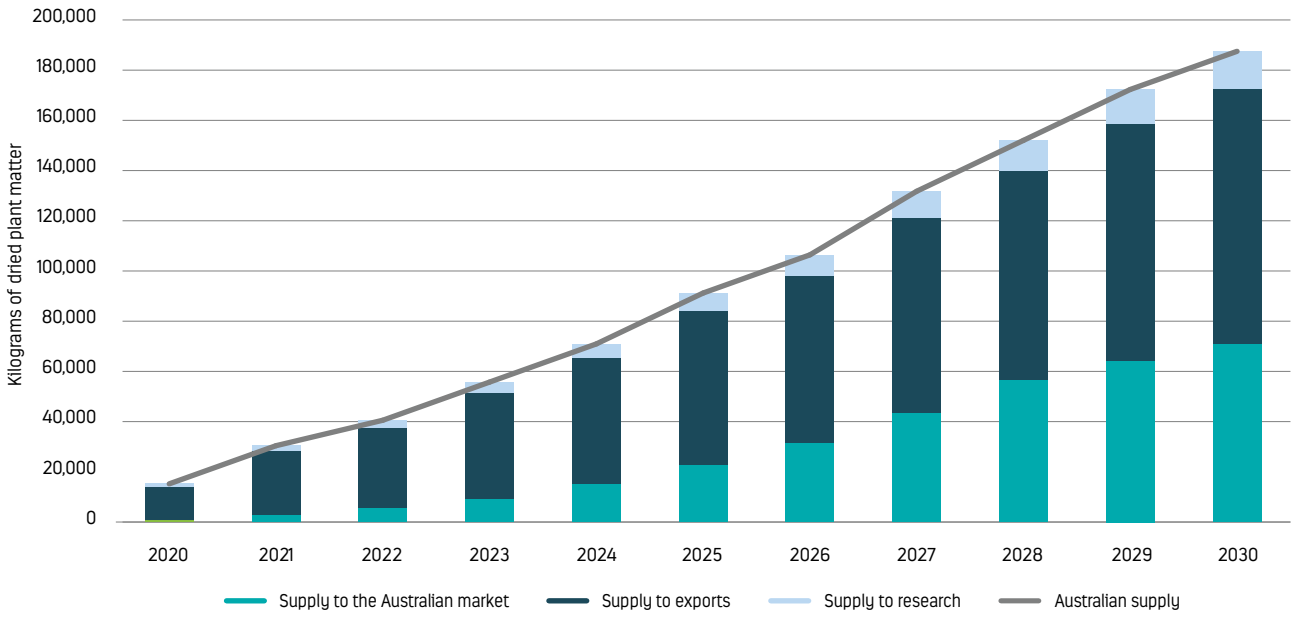
## 4.3 Future international export opportunities

Deloitte Access Economics estimates that approximately 88 per cent of medicinal cannabis manufactured in Australia in 2020 has been exported to overseas markets. In terms of dried plant matter, this is equivalent to approximately 13,400 kg (Chart 4.3).

The proportion of total domestic supply exported to overseas markets is modelled to fall over the next decade to just under 59 per cent in 2030. However, in terms of dried plant matter, this would still translate to a significant increase in the volume of medicinal cannabis being exported from Australia (about 109,000 kg in 2030). See Appendix D for table of key outputs.

136 Entoura, Submission No 25 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 4.
137 CANNATREK, Submission No 33 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 4.
138 ACNEM, Submission No 29 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 7.

Chart 4.3: Projected Australian supply and exports, 2020 to 2030




Source: Deloitte Access Economics.

### 4.3.1 Markets

Germany was the first nation to import Australian manufactured medicinal cannabis and German demand for medicinal cannabis remains strong, with reports that local supply has been struggling to meet demand in early 2020.[139] Local distributors continue to rely heavily on imported products.[140] Future growth in German demand for medicinal cannabis is supported by government legislation, with Statutory Health Insurance companies covering expenses for medicinal cannabis prescriptions since March 2017.[141]

The UK is the global leader in medicinal cannabis exports, with registered products such as Sativex and Epidyolex currently exported globally. However, patients using medicinal cannabis in the UK continue to rely heavily on imports. This could see the UK become a future export destination for Australian manufacturers.

Demand for medicinal cannabis in the UK is currently relatively low.[142] This may be, in part, due to current regulations making imports difficult and time consuming. This will likely be made easier with changes to import restrictions announced by the Department of Health and Social Care in early March 2020.[143] The introduction of a private patient registry – Project Twenty21 – may also assist in promoting demand into the future.

Relative to European nations, medicinal cannabis legislation is developing at a slower pace throughout Asia. Policies and attitudes towards medicinal cannabis are relatively conservative in the region. While this may change in the future, it is likely that Asia will not be a viable export market for some time. However, when demand for medicinal cannabis does begin to ramp up in Asia, Australia's geographic proximity to the region, as well as its 'clean, green image', make it well placed to service demand in these markets.[144]

Regardless of the country-level regulations, Australian products are likely to be the most competitive in markets that value Australia's GMP standards. Otherwise, patients may preference potentially inferior quality imports from other producing nations that do not adhere to these strict standards and so can be produced at a cheaper price point.

139 MJBizDaily, 'Product supply interruptions hit German medical cannabis market, but government dismisses risk of shortages' (17 January 2020) ‹https://mjbizdaily.com/product-supply-interruptions-hit-german-medical-cannabis-market-but-government-dismisses-risk-of-shortages/›.
140 MJBizDaily, 'Medical cannabis flower imported into Germany doubles again in 2019, confirming strong growth' (30 January 2020) ‹https://mjbizdaily.com/medical-cannabis-flower-imported-into-germany-doubles-again-in-2019-confirming-strong-growth/›.
141 Library of Congress, 'Germany: Medical Marijuana Act Enters into Force' (13 March 2017) ‹https://www.loc.gov/law/foreign-news/article/germany-medical-marijuana-act-enters-into-force/›.
142 Prohibition Partners, *The European Cannabis Report: Edition 5* (February 2020) 20.
143 Forbes, 'Cannabis patients in the United Kingdom are granted faster access to their medicine' (3 March 2020) ‹https://www.forbes.com/sites/sarabrittanysomerset/2020/03/03/cannabis-patients-in-the-united-kingdom-are-granted-faster-access-to-their-medicine/#122481617823›.
144 Complementary Medicines Australia, *Exporting to Asia: Australian Complementary Medicines* (May 2016) 2.

# 5 MARKET POTENTIAL

The Australian medicinal cannabis market is still in its infancy and is likely to face challenges as it matures. There are also opportunities that the market can harness to ensure Australia positions itself for success in a global market, as discussed below.

## 5.1 Challenges

Australia's medicinal cannabis sector has experienced strong growth in the number of businesses and patient demand since its inception in 2016. However, the sector remains in its infancy and the future trajectory is uncertain. Several challenges are expected to impact the sector as the operating environment continues to develop. These challenges include the current lack of clinical efficacy and safety of medicinal cannabis products, product affordability, and regulatory restrictions.

### 5.1.1 Efficacy

Efficacy research for medicinal cannabis is currently mixed, both in its quality and its conclusions. Overwhelmingly, the evidence base comprises patient advocate stories outlining the benefits of medicinal cannabis. While many of these stories allude to the products being efficacious, they do not provide robust assessments of their efficacy and safety – a prerequisite for any medical product to be listed on the ARTG.

A growing number of clinical trials have sought to verify anecdotal efficacy claims in robust and transparent research settings. These trials have focused on cannabis treatments across a wide range of indications, including chronic non-cancer pain,[145] epilepsy,[146] and multiple sclerosis.[147]

However, for many indications, it remains unclear how efficacious medicinal cannabis might be as a treatment option. Further research will likely be required for the drug to become more common in global medicine. A summary of key factors currently limiting further research in this space is provided below.

#### Stringent regulations

Despite many countries moving to legalise medicinal cannabis, the drug remains illegal across several jurisdictions. Even where it has been legalised, regulations describing how it must be stored, handled and disposed of are often stringent.

Australia's medicinal cannabis industry is highly regulated. Stakeholders consulted generally agreed that strict regulations have contributed to the high production quality observed in the sector. However, many also viewed the regulatory environment as being too restrictive, limiting the industry's future growth potential.

For example, Australian research institutions seeking to extract and purify active ingredients from the cannabis plant must first obtain a manufacture licence from the ODC. Licence holders must have 'physical security systems and documented procedures in place to detect and respond to intrusion or unauthorised access, theft, or loss of cannabis'.[148] They are also required to take several other precautionary measures to ensure medicinal cannabis is stored safely and securely onsite.

Strict requirements like these can cause researchers to incur significant costs and can act as a barrier to conducting further research to support future industry growth. One stakeholder suggested the ODC introduce a new licence that enabled organisations with a sole research purpose to access the necessary cannabis materials without the same level of scrutiny.

#### Investment incentives

Stakeholders noted in consultations that specific incentives for medicinal cannabis cultivators and manufacturers to invest in research programs are currently weak (although the general R&D Tax Incentive scheme is applicable). Naturally occurring substances cannot be patented under many countries' laws. Commercial entities are therefore unable to patent active cannabis ingredients across many jurisdictions. This has led some operators in the sector to hesitate in pursuing a planned program of efficacy research. Several stakeholders noted concerns that their competitors might leverage their findings to support their own products.

145 Therapeutic Goods Administration, 'Pain – randomised controlled trials and other studies' (2020).
146 Therapeutic Goods Administration, 'Epilepsy – randomised controlled trials and other studies' (2020).
147 Therapeutic Goods Administration, 'Multiple sclerosis – randomised controlled trials and other studies' (2020).
148 Office of Drug Control, *Guideline: Security of Medicinal Cannabis* (2020).

### 5.1.2 Affordability

While the affordability of medicinal cannabis is directly driven by product prices, costs associated with obtaining approvals and filling prescriptions also contribute to the total cost incurred by consumers.

#### Product prices

The price of medicinal cannabis is currently very high in Australia. Depending on the format, concentration and quantity of medicinal cannabis prescribed, prices can range from about $89 to $491 for a single product (Table 5.1).

Annual treatment costs can be particularly substantial for indications where large doses of medicinal cannabis are necessary for the drug to be efficacious. One stakeholder suggested certain forms of epilepsy might require up to $30,000 of medicinal cannabis treatments in a single year (at current prices). However, on average, it was suggested that annual medicinal cannabis treatment costs typically range between $1,800 and $3,000.

Table 5.1: Snapshot of medicinal cannabis products currently available in Australia

| Attributes/Product | Oil | Capsule | Oral spray | Lozenge |
|---|---|---|---|---|
| Concentrations (CBD/THC) | [25–100]/0 mg/ml<br>0/25 mg/ml<br>25/25 mg/ml<br>15/10 mg/ml | 15 mg/capsule (CBD only) | 5 mg/ml (CBD only) | 50 mg/lozenge (CBD only) |
| Quantities | 30–50 ml | 60 capsules | 10–20 ml | 30 lozenges |
| Price range | $135–$491 | $89.10 | $116–$449.50 | $169 |

Source: Biotech Daily Medical Marijuana Survey.

The high price of medicinal cannabis is particularly apparent when compared to more traditional pharmaceuticals. Assessing value for money across drug classes is an inherently difficult exercise. Different drugs function via different pathways and can lead to different outcomes in the patients who use them. However, the following example is intended to illustrate the stark difference in the retail price of medicinal cannabis relative to other pharmaceuticals used to treat similar indications.

As discussed earlier (Section 3.1), medicinal cannabis is most commonly prescribed for the treatment of chronic pain. Analgesics, such as opioids, are also commonly prescribed for this indication. Many analgesics are widely available to Australian patients at low prices under the PBS. For example, a 20 pack of 5 mg oxycodone tablets is registered under the PBS with a general patient charge as low as $24.75.[149]

In part, high product prices for medicinal cannabis are driven by the relatively small-scale operations of businesses manufacturing cannabis therapeutics in Australia. Low production volumes often translate to high product prices for final consumers, as manufacturers seek to recover fixed costs across a limited number of sales.

Stringent regulations governing production in the sector have compounded this issue. Medicinal cannabis cultivators and manufacturers often incur significant compliance costs in meeting government requirements, which impact throughout the supply chain. One stakeholder noted that this has led some domestically manufactured cannabis resins to be more expensive than those imported from overseas suppliers.

As the industry develops, it is likely that medicinal cannabis prices will continue to fall as production volumes increase, leading to lower unit production costs.

A recent parliamentary inquiry also noted that registering medicinal cannabis products for subsidy under the PBS scheme would greatly benefit the Australian public through cheaper access to the medicine.[150] This was evidenced by the recent listing of Epidyolex to the PBS, which saw prices for the medicine fall dramatically. The Department of Health notes a general patient charge for Epidyolex of just $41.30 in May 2021.[151]

149 Department of Health, 'The Pharmaceutical Benefits Scheme: Oxycodone' (2021) ‹https://www.pbs.gov.au/medicine/item/12023t-12025x-12031f-12044x-12048d-12074l-2481n-2622b-5190e-5191f-5194j-5195k-5197m-8385h-8386j-8387k-8388l-8464l-8501k-8502l-8644y-9399q-9400r›.
150 Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (2020).
151 Department of Health, 'The Pharmaceutical Benefits Scheme: Cannabidiol' (2021) ‹https://www.pbs.gov.au/medicine/item/12467E›.

#### Medical practitioner prices

In some instances, patients seeking access to medicinal cannabis also face additional charges from their medical practitioners. As mentioned earlier (Section 2.2), existing legislation requires practitioners to invest significant amounts of time and effort to prescribe medicinal cannabis. Under the SAS-B scheme, for example, practitioners must complete and lodge an application with the relevant state and/or federal government authorities. Practitioners often pass on the time taken to lodge this application as an additional cost to the patient seeking the prescription.

Even where clinics have been specifically set up to prescribe medicinal cannabis, consultation costs can still be high compared to a bulk billing clinic. The cost of visiting a medicinal cannabis clinic typically ranges between $300 and $500 for an initial consultation.[152]

It was also noted that some pharmacists apply their own mark-up to medicinal cannabis products, further increasing retail prices faced by final consumers. Pharmacists spend relatively large amounts of time and effort in processing medicinal cannabis prescriptions, particularly where they are not familiar with the process. They sometimes look to recoup this additional time and effort through elevated product prices.

#### Implications for patients

Stakeholders consulted generally viewed the high cost of medicinal cannabis as a deterrent to patients seeking to access medicinal cannabis. It was also suggested that patients requiring repeat prescriptions were more likely to discontinue treatment once they become aware of the cost after filling their first prescription.

It is likely that some patients unable to afford medicinal cannabis have accessed treatments through the black market. Stakeholders consulted viewed this as particularly concerning. The chemical composition of cannabis products sold on the black market is unlikely to conform with quality standards (such as TGO 93) that apply to licit medicinal cannabis products and has the potential to represent risk to patients (e.g. due to pesticide contamination or drug-drug interactions).

High medicinal cannabis prices are a problem experienced in many countries across the globe. However, some governments have introduced measures to reduce the costs imposed on patients. In Germany, for example, health insurers are allowed to cover some of the costs associated with medicinal cannabis treatments.[153]

However, price has not deterred all patients from seeking medicinal cannabis in Australia. Some can afford the cost, while others have sought financial support to pay for the medication. Anecdotal evidence suggests some patients and their families have taken on mortgages, additional employment and made other significant savings as a way to pay for expensive medication.

Further to patient access, high medicinal cannabis prices have restricted the ability of some researchers to conduct investigator-initiated efficacy research – increasing reliance on sponsored trials/research. Clinical trials typically require large quantities of medicine to be readily available for patient use. In a sector where research funding is relatively limited, expensive product costs prevent some researchers from purchasing the quantity of medicinal cannabis required to conduct a study.

Going forward, recent economic fallout from the COVID-19 pandemic may see the high price of medicinal cannabis act as a greater deterrent to patient access, as well as further efficacy research for medicinal cannabis.

### 5.1.3 Regulatory environment

State and federal government regulations have presented several challenges to Australia's medicinal cannabis sector, some of which are summarised below.

#### Inconsistency across jurisdictions

Several stakeholders interviewed noted inconsistencies in regulations governing medicinal cannabis across Australia's jurisdictions. For example, distinctions drawn between hemp and cannabis can vary by state. In Victoria, licensed hemp cultivators must only grow low-THC cannabis with less than 0.35 per cent THC content.[154] In Queensland this threshold is 0.5 per cent.[155] Stakeholders consulted also indicated that there are differences in requirements for how medicinal cannabis is handled, stored and destroyed across Australian jurisdictions.

Regulatory inconsistencies like this create uncertainty for organisations operating in the sector, particularly where they operate across jurisdictions, or are seeking to expand from one jurisdiction to another.

152 Australian Pain Management Association, Submission No 32 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020) 8.
153 Health Europa, 'Medical cannabis policy and practice in Germany' (2020).
154 Agriculture Victoria, 'Industrial hemp' (2020).
155 Business Queensland, 'Industrial cannabis production' (2020).

### Prescriptions

Not all of the regulatory mechanisms governing Australia's medicinal cannabis industry have been tailored to meet the unique requirements of the industry. As noted earlier (Section 2.1), the SAS-B scheme was originally devised to provide Australian patients access to experimental cancer treatments. The scheme has since been extended to provide patient access to other unregistered treatments, including medicinal cannabis.

Some stakeholders who were consulted expressed a perception that the SAS-B scheme imposes a level of administrative burden that does not exist with other products. They felt that the time and effort required to prescribe medicinal cannabis makes the process commercially unviable (noting that commercial viability is not the concern of a GP). The typical GP consultation in Australia is 15 minutes; however, some medicinal cannabis clinics allocate up to an hour for consults where a patient is seeking to access medicinal cannabis.

Not only do the time and effort required to prescribe medicinal cannabis in Australia impact costs, but it might also mean GP clinics are hesitant to consult patients seeking medicinal cannabis, as tight scheduling constraints might make it impractical to do so. This, in part, has contributed to the emergence of medicinal cannabis clinics operating across Australia.

As described earlier (Section 2.1), the current regulatory environment only allows medical practitioners to become Authorised Prescribers of specific branded products. Prescribers may hold multiple authorisations concurrently for different products.

### Road safety regulations

State road safety (driving) regulations disincentivise patient access to medicinal cannabis in Australia. In all states and territories, it is an offence for licence holders to operate vehicles with detectable concentrations of THC in their system.[156] Because THC has a high degree of fat solubility,[157] it can remain present in bodily tissues for relatively long periods of time. This can mean patients are unable to legally drive without ceasing treatment for several days.

Even where patients can provide evidence that they have been legally prescribed medicinal cannabis, they may still be subject to legal penalties including loss of licence, fines, and in some instances, jail time.

One stakeholder suggested driving regulations have impacted clinical trials where medicinal cannabis products contain THC. It was noted that some patients might choose not to be involved in these trials because doing so would limit their ability to drive over the period.

Concerns were consistently voiced throughout stakeholder consultations that roadside drug testing assesses the presence of THC, rather than driver impairment. In the case of alcohol, an acceptable legal threshold is used to assess whether or not a driver is impaired by the substance (0.05 per cent blood alcohol concentration).[158] Stakeholders generally believed that a similar principle should be used to ensure patients being treated with medicinal cannabis can drive both safely and legally.

### Recreational cannabis

Currently, recreational cannabis has only been legalised by the ACT Government for personal growing and consumption only. While it is yet to be seen in this market what the effect is on medicinal cannabis users, there is a risk in the ACT (and other jurisdictions, if they legalise recreational use) that medicinal cannabis patients could seek treatment using a recreational product instead. This risk is more likely if the recreational product is cheaper and more readily accessible.

One stakeholder observed that when Canada legalised recreational cannabis there was a general feeling in the industry that the medicinal cannabis market suffered. This could disincentivise medicinal cannabis cultivators and manufacturers from investing in research and technologies suited to cannabis for medicinal use.

However, the risk to patients is that recreational products may not be subject to the same stringent GMP standards that Australian-manufactured medicinal cannabis products must meet, meaning the consistency of product is not guaranteed across prescriptions. Patients would also lose the oversight of medical practitioners accessing cannabis through this pathway.

156 MCUA Submission No 9, FreshLeaf Analytics Submission No 14 and ACNEM Submission No 29 to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
157 Sharma, P, Murthy, P, Bharath, M, 'Chemistry, metabolism, and toxicology of cannabis: clinical implications', *Iranian Journal of Psychiatry* (2012) 7(4), 149–156.
158 Alcohol and Drug Foundation, 'Blood alcohol levels' (2017).

## 5.2 Opportunities

While there are several challenges facing Australia's medicinal cannabis sector, there are also many opportunities for growth. A summary of key opportunities for Australia's medicinal cannabis sector is provided below.

### 5.2.1 Perceptions of medicinal cannabis

Cannabis use continues to carry some stigma in Australia; however, interest in medicinal cannabis is growing from both patients and healthcare workers.

Stakeholder consultations indicated patient perceptions of medicinal cannabis are typically positive in Australia, particularly where cannabis products take conventional pharmaceutical forms, such as capsules or orally administered oils.

Even where patients are children, positive sentiments towards the drug are often voiced by parents. One paediatrician consulted noted recent growth in the number of parents expressing interest in medicinal cannabis for their child's treatment.

Patients seeking access to medicinal cannabis have often tried more traditional medicines, but to limited benefit. One stakeholder interviewed suggested that by the time some patients are prescribed medicinal cannabis they are willing to accept any treatment that could plausibly alleviate their symptoms, having found nothing else that works.

Several stakeholders suggested positive patient perceptions of medicinal cannabis have likely softened views across some segments of Australia's medical community.

While healthcare professionals consulted generally viewed medicinal cannabis as having relatively benign characteristics, including low toxicity levels and high safety margins, it was noted that many Australian practitioners remain cautious in prescribing medicinal cannabis. For example, while the Royal Australian College of General Practitioners acknowledges a possible role for medicinal cannabis in some areas of medicine, it also highlights a need for further research into the safety and efficacy of the drug, given the limited and inconclusive nature of the existing evidence base.[159]

Consistent with this, the number of medical practitioners currently prescribing medicinal cannabis in Australia remains low. The Senate inquiry noted that 'the first hurdle in a patient's journey to access medicinal cannabis is to find a medical practitioner who is knowledgeable about medicinal cannabis, understands how to prescribe it, and who has an understanding of the range of products available'. There are still practitioners that refuse to prescribe medicinal cannabis to patients under their care.[160]

Stakeholder consultations, as well as the recent Senate inquiry, identified several factors driving ongoing negative perceptions of medicinal cannabis in Australia's medical community, including:

- **Longstanding negative perceptions of cannabis:** Cannabis continues to carry some stigma in Australia across both healthcare professionals and the general community. There remains a lack of evidence of the efficacy of medicinal cannabis for many indications, which is driving this perception, along with personal views around the use of cannabis.
- **Limited understanding of medicinal cannabis and its uses:** As noted in Section 5.1.1, medicinal cannabis is in its infancy as a treatment for many medical indications. Given the current lack of evidence around its efficacy, few doctors are confident in prescribing it, having been trained to deliver medicines that have been properly researched and demonstrated to be efficacious. Stakeholder consultations suggested that medical practitioners across other jurisdictions, such as the US, are more receptive to a trial and error approach when prescribing medicinal cannabis to their patients.
- **View that medicinal cannabis is a last resort treatment:** Evidence provided to the recent Senate inquiry suggests many practitioners continue to view medicinal cannabis as a treatment of last resort.[161] This was thought to stem from guidance notes issued under the Special Access Scheme, which state that practitioners 'will have considered all appropriate treatment options before considering accessing an unapproved medicine under the SAS for their patients'.[162]
- **Onerous and confusing regulations:** Several stakeholders consulted suggested regulations governing medicinal cannabis across Australia are confusing and require significant effort from practitioners to meet compliance requirements.

159 Royal Australian College of General Practitioners, 'Use of medicinal cannabis products: Position statement – 2019 update' (accessed 11 June 2021) <https://www.racgp.org.au/FSDEDEV/media/documents/RACGP/Position%20statements/Medicinal-use-of-cannabis-products.pdf>.
160 APMA Submission No 32 (9), Submission 60 (2), MCUAA Submission 9 (20), Submission 42 (1), MSRA and MSA Submission 3 (6) to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
161 MCIA Submission No 5 (3), United in Compassion Submission No 6 (Attachment 2, 38) and Australasian College of Nutritional and Environmental Medicine Submission No 29 (5) to the Senate Community Affairs References Committee, *Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia* (January 2020).
162 Therapeutic Goods Administration, *Special Access Scheme: Guidance for health practitioners and sponsors* (2017).

There is an opportunity for industry and government to improve perceptions of medicinal cannabis, particularly in Australia's healthcare community, through greater provision of training and education materials. Several submissions to the recent Senate inquiry viewed education and public awareness campaigns as central to reducing stigma around the drug. The Senate inquiry also revealed a critical need for greater access to training materials for Australian healthcare practitioners.

Consistent with this view, one stakeholder interviewed suggested a central educational body should be formed to ensure Australian healthcare practitioners receive the information necessary to safely and appropriately prescribe medicinal cannabis to patients in their care. This body would serve to both educate, as well as assess the knowledge of practitioners already prescribing medicinal cannabis, to ensure a consistent experience for patients seeking medicinal cannabis products.

There also remains an opportunity to educate patients about the benefits of being treated with licit, rather than illicit, cannabis products. It is likely that some patients do not fully understand the risks associated with using illicit cannabis products for medical purposes, nor the benefits of using pharmaceutical grade cannabis therapeutics which are developed based on clinical research. Educating patients in this way may further improve perceptions of licit cannabis medicines and assist in transitioning some patients away from the illicit market.

### 5.2.2 Future regulatory changes

It is likely that future regulatory changes will support those operating in Australia's medicinal cannabis sector to expand their operations, produce greater product volumes and meet the needs of increasingly large patient numbers (both domestically and abroad).

The recent TGA decision to down-schedule low-dose CBD preparations may see CBD becoming more accessible to Australian patients over the coming years.

The recent listing of Epidyolex to the PBS is also a key government decision that will likely serve as a precedent for other medicinal cannabis products seeking government subsidisation, where the clinical evidence exists to demonstrate their efficacy.

As the base of medicinal cannabis efficacy research continues to grow, more cannabis medicines may be approved for registration. However, as noted throughout stakeholder consultations, the process of registration comes at a significant expense to pharmaceutical companies and can take several years to reach a positive outcome. Also, following ARTG registration, a further period of time and expense usually follows for pharmaceutical companies, as they often seek to secure subsidised supply via the PBS.

## 5.3 Next steps for the industry to realise sustained growth

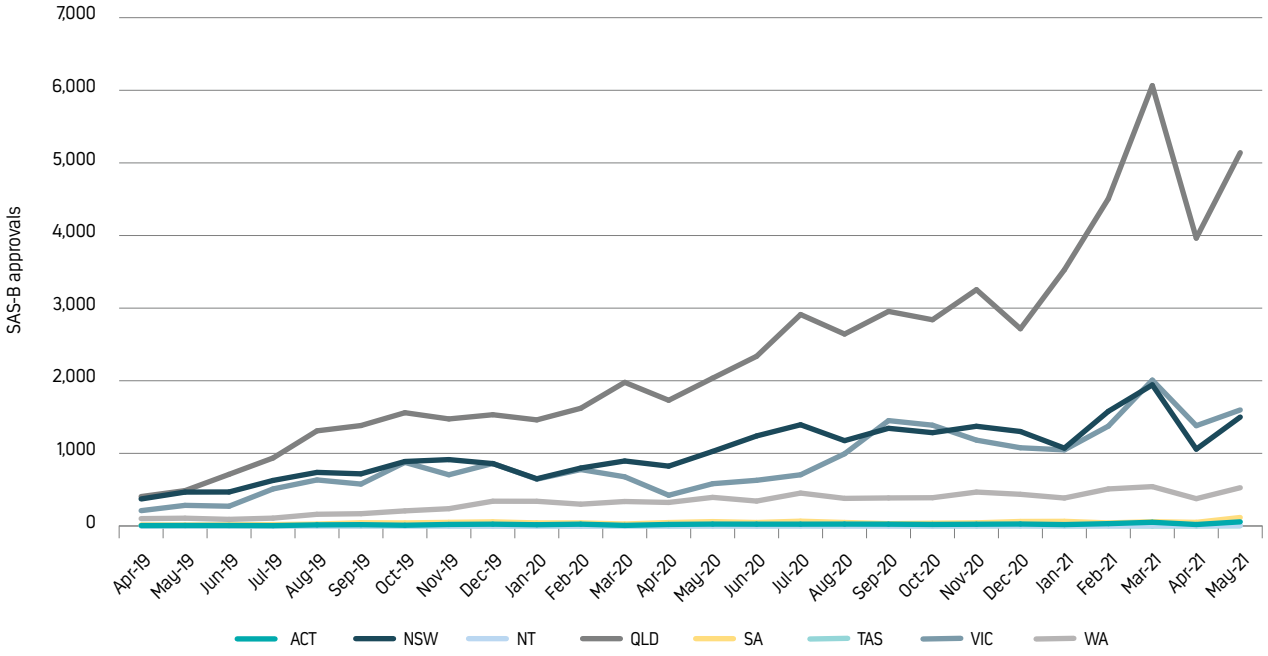
Given Australian and international medicinal cannabis markets remain in their infancy, the Australian sector still has an opportunity to define its positioning in the global market.

Below is a list of steps that the industry could consider as it seeks sustained growth. Each of these should be considered in further detail before being implemented, including a detailed assessment of the costs, benefits and risks associated with each.

- Undertake greater research into the efficacy of medicinal cannabis products. This would have a double benefit of (1) providing medical practitioners an evidence base, helping to implicitly encourage them to feel confident prescribing medicinal cannabis products, and (2) providing the evidence base that is required for listing on the ARTG, and the ultimate goal of industry, listing on the PBS.
- Establish a pathway for practitioners to easily access relevant and current data on medicinal cannabis products and evidence of efficacy for given indications.
- Consider streamlining and consolidating replicated parts of the industry so that Australian producers can reach economies of scale within their niche market segment.

# APPENDIX A – AUSTRALIAN DEMAND

Chart A.1: SAS-B approvals for medicinal cannabis by state/territory, April 2019 to May 2021




Source: Deloitte Access Economics analysis using TGA.[163, 164, 165]

163 Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
164 Therapeutic Goods Administration, 'Accessing unapproved products – Medicinal cannabis' (2 October 2020) <https://www.tga.gov.au/access-medicinal-cannabis-products-1>.
165 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

Table A.2: SAS-B approvals for medicinal cannabis by month, December 2016 to May 2021

| Month-Year | SAS-B approvals | Month-Year | SAS-B approvals |
|---|---|---|---|
| Dec-16 | 1 | Mar-19 | 1,038 |
| Jan-17 | 0 | Apr-19 | 1,109 |
| Feb-17 | 26 | May-19 | 1,368 |
| Mar-17 | 13 | Jun-19 | 1,566 |
| Apr-17 | 6 | Jul-19 | 2,206 |
| May-17 | 10 | Aug-19 | 2,887 |
| Jun-17 | 15 | Sep-19 | 2,913 |
| Jul-17 | 14 | Oct-19 | 3,587 |
| Aug-17 | 28 | Nov-19 | 3,404 |
| Sep-17 | 30 | Dec-19 | 3,676 |
| Oct-17 | 32 | Jan-20 | 3,155 |
| Nov-17 | 22 | Feb-20 | 3,565 |
| Dec-17 | 35 | Mar-20 | 3,924 |
| Jan-18 | 60 | Apr-20 | 3,372 |
| Feb-18 | 37 | May-20 | 4,129 |
| Mar-18 | 54 | Jun-20 | 4,624 |
| Apr-18 | 89 | Jul-20 | 5,559 |
| May-18 | 132 | Aug-20 | 5,269 |
| Jun-18 | 146 | Sep-20 | 6,198 |
| Jul-18 | 188 | Oct-20 | 5,963 |
| Aug-18 | 229 | Nov-20 | 6,348 |
| Sep-18 | 236 | Dec-20 | 5,625 |
| Oct-18 | 331 | Jan-21 | 6,119 |
| Nov-18 | 567 | Feb-21 | 8,052 |
| Dec-18 | 490 | Mar-21 | 9,959 |
| Jan-19 | 670 | Apr-21 | 6,682 |
| Feb-19 | 738 | May-21 | 9,965 |

Source: Deloitte Access Economics analysis, using TGA.[166, 167, 168]

166 Therapeutic Goods Administration, *Freedom of Information request 1799: Request for details about medicinal cannabis applications through SAS from 1 December 2019 – 24 June 2020.*
167 Therapeutic Goods Administration, *Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.*
168 Therapeutic Goods Administration Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

# APPENDIX A – AUSTRALIAN DEMAND

Table A.3: SAS-B approvals for medicinal cannabis by indication, July 2019 to May 2021

| | Jul 19 | Aug 19 | Sep 19 | Oct 19 | Nov 19 | Dec 19 | Jan 20 | Feb 20 | Mar 20 | Apr 20 | May 20 | Jun 20 | Jul 20 | Aug 20 | Sep 20 | Oct 20 | Nov 20 | Dec 20 | Jan 21 | Feb 21 | Mar 21 | Apr 21 | May 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Chronic pain | 1,409 | 1,918 | 1,917 | 2,344 | 2,203 | 2,354 | 2,041 | 2,324 | 2,596 | 2,141 | 2,664 | 2,981 | 3,537 | 3,404 | 3,883 | 3,658 | 3,814 | 3,430 | 3,694 | 4,827 | 6,576 | 4,177 | 5,431 |
| Anxiety | 153 | 195 | 238 | 283 | 298 | 375 | 330 | 348 | 407 | 381 | 545 | 644 | 798 | 778 | 1,029 | 959 | 982 | 897 | 1,111 | 1,573 | 1,947 | 1,414 | 1,778 |
| Insomnia | 31 | 38 | 57 | 75 | 52 | 83 | 74 | 102 | 130 | 131 | 167 | 248 | 273 | 248 | 321 | 342 | 449 | 311 | 436 | 511 | 832 | 437 | 586 |
| Cancer pain and symptom management | 147 | 240 | 218 | 247 | 258 | 242 | 223 | 224 | 211 | 203 | 213 | 218 | 252 | 205 | 207 | 223 | 247 | 247 | 196 | 249 | 276 | 232 | 301 |
| Neuropathic pain | 131 | 118 | 128 | 175 | 153 | 155 | 119 | 128 | 126 | 116 | 116 | 103 | 138 | 110 | 118 | 129 | 138 | 122 | 123 | 138 | 165 | 148 | 167 |
| Post-traumatic stress disorder | 41 | 43 | 51 | 40 | 47 | 44 | 57 | 59 | 70 | 61 | 68 | 86 | 83 | 87 | 119 | 103 | 135 | 117 | 104 | 164 | 187 | 88 | 115 |
| Migraine | 11 | 11 | 16 | 27 | 29 | 34 | 20 | 24 | 30 | 22 | 21 | 29 | 34 | 29 | 51 | 42 | 32 | 37 | 36 | 44 | 51 | 20 | 33 |
| Autism | 18 | 29 | 23 | 39 | 39 | 49 | 25 | 42 | 40 | 27 | 35 | 42 | 57 | 61 | 55 | 43 | 46 | 43 | 52 | 58 | 49 | 43 | 76 |
| Seizure management | 65 | 64 | 45 | 54 | 60 | 53 | 27 | 30 | 31 | 20 | 18 | 21 | 26 | 12 | 31 | 29 | 61 | 12 | 16 | 26 | 27 | 13 | 17 |
| Epilepsy | 2 | 18 | 19 | 32 | 31 | 45 | 30 | 36 | 36 | 48 | 34 | 37 | 39 | 48 | 45 | 49 | 51 | 50 | 40 | 47 | 77 | 45 | 60 |
| Fibromyalgia | 21 | 18 | 26 | 36 | 36 | 28 | 19 | 26 | 31 | 19 | 29 | 26 | 42 | 42 | 41 | 56 | 50 | 62 | 27 | 43 | 51 | 31 | 13 |
| Depression | 2 | 3 | 0 | 6 | 5 | 2 | 3 | 7 | 10 | 8 | 12 | 19 | 29 | 30 | 29 | 27 | 22 | 39 | 55 | 84 | 93 | 34 | 49 |

Source: Deloitte Access Economics analysis, using TGA.[169, 170]

169 Freedom of Information request 1588: SAS Category B for medicinal cannabis products during the period 1/11/2016 to 12/03/2020.
170 Freedom of Information number 2419, https://www.tga.gov.au/foi-disclosure-log, accessed 24 August 2021.

# APPENDIX B – CATEGORISATION OF INDICATIONS

In July 2020 the TGA released detailed data on medicinal cannabis applications through SAS-B from 1 December 2019 to 24 June 2020, in response to Freedom of Information (FOI) request 1799. Another FOI request (1588) released less detailed data, dating back to 1 November 2016 (when the scheduling of some medicinal cannabis products was amended from Schedule 9 to Schedule 8), through to 12 March 2020. Further information was released in FOI 2419 of 5 July 2021.

Deloitte Access Economics has analysed this data to inform modelling on demand for medicinal cannabis. FOI 1799 and FOI 1588 have been combined, where possible, (using data from FOI 1588 through to 30 November 2019, and data from FOI 1799 from 1 December 2019).

Some data cleaning was also required to analyse these sources. These processes, and any required assumptions, are described in this section.

Where the duration of the prescription appeared incorrect:

- 122 years was changed to 12 months
- 365 years was changed to 12 months
- 365 months was changed to 12 months

If a previous SAS number was recorded, this was assumed to be a repeat prescription. Where the SAS number began with MB19, these original prescriptions were assumed to occur in 2019, whereas MB20 was assumed to refer to an original prescription in 2020.

Some variability in how indications were listed was addressed by combining the same indications with different spelling. For example, some indications were listed as 'Autism', 'Autism spectrum disorder', and 'Autism disorder'. These were combined to represent the one indication. This resulted in a total list of 143 indications. To make any analysis by indication more meaningful, these indications were then further combined into 'indication groups'. The categorisation of each indication to an indication group is detailed in Table B.1. The 22 most commonly occurring indications, which were treated with medicinal cannabis during this period 50 times or more, were assigned indication groups, such as 'Chronic pain', 'Cancer pain and symptom management', and 'Mood disorders'. Relatively less common indications, which were treated using medicinal cannabis fewer than 50 times, were grouped into 'Other indications'.

Table B.1: Indications approved for treatment with medicinal cannabis through SAS-B, mapped to indication group

| Indication | Indication group |
|---|---|
| Achalasia | Other indications |
| Aggressive behaviour | Other indications |
| Agitation | Other indications |
| Alzheimer's disease | Alzheimer's disease and dementia |
| Amyotrophic lateral sclerosis | Other indications |
| Anorexia | Anorexia |
| Anxiety | Anxiety |
| Arthritis | Other indications |
| Asperger syndrome | Autism spectrum disorder |
| Asthma | Other indications |
| Ataxia | Other indications |

## APPENDIX B – CATEGORISATION OF INDICATIONS

| Indication | Indication group |
|---|---|
| Ataxia telangiectasia | Other indications |
| Atopic dermatitis | Other indications |
| Atrophy | Other indications |
| Attention deficit disorder | ADHD and ADD |
| Attention deficit hyperactivity disorder | ADHD and ADD |
| Autism | Autism spectrum disorder |
| Barrett's oesophagus | Other indications |
| Behaviour management | Other indications |
| Bell's palsy | Other indications |
| Bipolar disorder | Mood disorders |
| Brainstem infarction | Other indications |
| Brainstem glioblastoma multiforme | Other indications |
| Bronchiectasis | Other indications |
| Cachexia | Other indications |
| Cancer pain and symptom management | Cancer pain and symptom management |
| Cannabis use disorder | Other indications |
| Cerebral palsy | Other indications |
| Cervical spondylosis | Other indications |
| Chemotherapy induced nausea and vomiting (CINV) | Cancer pain and symptom management |
| Chronic fatigue syndrome | Other indications |
| Chronic headache disorder | Migraine and headache |
| Chronic inflammatory demyelinating polyneuropathy | Other indications |
| Chronic nausea | Other indications |
| Chronic pain | Chronic pain |
| Cluster headache | Migraine and headache |
| Complex regional pain syndrome (CRPS) | Chronic pain |
| COPD | Other indications |
| Crohn's disease | IBS and IBD |
| Dementia | Alzheimer's disease and dementia |
| Depression | Mood disorders |
| Dermatitis | Other indications |
| Dysequilibrium | Other indications |
| Dyskinesia | Movement disorders |

| Indication | Indication group |
|---|---|
| Dysplasia | Other indications |
| Dystonia | Movement disorders |
| Eczema | Other indications |
| Ehlers-Danlos syndrome | Other indications |
| Endometriosis | Other indications |
| Epilepsy | Epilepsy and seizure management |
| Essential tremor | Movement disorders |
| Extrapyramidal syndrome | Movement disorders |
| Fatigue | Other indications |
| Fibromyalgia | Other indications |
| Gastroparesis | Other indications |
| Genetic disease | Other indications |
| Glioblastoma | Cancer pain and symptom management |
| Graves' disease | Other indications |
| Grover's disease | Other indications |
| Hashimoto's disease | Other indications |
| Headache | Migraine and headache |
| Huntington's disease | Other indications |
| Hyperhidrosis | Other indications |
| IBD – Inflammatory bowel disease | IBS and IBD |
| IBS – Irritable bowel syndrome | IBS and IBD |
| Impaired gastric emptying | Other indications |
| Inflammation | Other indications |
| Insomnia | Insomnia and sleep management |
| Insulin dependent diabetes mellitus | Other indications |
| Intellectual impairment | Other indications |
| Intention tremor | Movement disorders |
| Involuntary movement disorder | Movement disorders |
| Lennox-Gastaut syndrome | Epilepsy and seizure management |
| Macular degeneration | Other indications |
| Mal de debarquement syndrome | Other indications |
| Mast cell activation syndrome | Other indications |

## APPENDIX B – CATEGORISATION OF INDICATIONS

| Indication | Indication group |
|---|---|
| Mastocytosis | Other indications |
| Meniere's disease | Other indications |
| Migraine | Migraine and headache |
| Mood disorder | Mood disorders |
| Motor neuron disease | Other indications |
| Movement disorder | Movement disorders |
| Multiple myeloma | Cancer pain and symptom management |
| Multiple sclerosis | Multiple sclerosis |
| Multiple system atrophy | Other indications |
| Muscle rigidity | Movement disorders |
| Muscle spasm | Movement disorders |
| Muscle spasticity | Movement disorders |
| Myasthenia gravis | Movement disorders |
| Myoclonic disorder | Movement disorders |
| Myoclonus | Movement disorders |
| Nausea and vomiting | Nausea and vomiting |
| Neoplasia | Cancer pain and symptom management |
| Neuralgia | Other neurological disorders |
| Neuropathic pain | Chronic neuropathic pain |
| Neuropathy | Other neurological disorders |
| Obsessive compulsive disorder | Mood disorders |
| Occipital neuralgia | Migraine and headache |
| Oesophagitis | Other indications |
| Osteoarthritis | Other indications |
| Palliative care | Palliative care |
| PANDAS – Paediatric autoimmune neuropsychiatric disorder associated with streptococcal infection | Other neurological disorders |
| Panic disorder | Mood disorders |
| Parkinson's disease | Parkinson's disease |
| Penile irritation | Other indications |
| Peripheral neuropathy | Other neurological disorders |
| Pityriasis rubra pilaris | Other indications |
| Polyposis coli | Other indications |

| Indication | Indication group |
|---|---|
| Post-traumatic stress disorder | Post-traumatic stress disorder |
| Primary orthostatic tremor | Movement disorders |
| Progressive supranuclear palsy | Other indications |
| Pruritis | Other indications |
| Psoriasis | Other indications |
| Psoriatic arthritis | Other indications |
| PSP – Progressive supranuclear palsy | Other indications |
| Refractory nausea and vomiting | Nausea and vomiting |
| Restless leg syndrome | Other neurological disorders |
| Rheumatoid arthritis | Other indications |
| Rosacea | Other indications |
| Schizophrenia | Mood disorders |
| Scleroderma | Other indications |
| Seizure management | Epilepsy and seizure management |
| Sepsis | Other indications |
| Silicosis | Other indications |
| SIRS – Systemic inflammatory response syndrome | Other indications |
| Sleep disorder | Insomnia and sleep management |
| Smoking cessation assistance | Other indications |
| Spasticity | Movement disorders |
| Supranuclear palsy | Other indications |
| Tardive dyskinesia | Other indications |
| Tinnitus | Other neurological disorders |
| Tourette's syndrome | Other neurological disorders |
| Tremor | Movement disorders |
| Trigeminal neuralgia | Chronic pain |
| Trismus | Other indications |
| Ulcer | Other indications |
| Ulcerative colitis | Other indications |
| Vasculitis | Other indications |
| Vertigo | Other indications |
| Vestibular neuronitis | Other indications |

Note: Indications have been combined to remove duplicates and were then assigned to a broader indication group.
Source: Deloitte Access Economics.

# APPENDIX C – CLINICAL TRIALS

Table C.1: Clinical trials recorded by the ANZCTR, between January 2015 and November 2019

| Trial ID | Start date | End date | Sample size |
|---|---|---|---|
| 369132 | 13/07/2016 | 5/12/2016 | 42 |
| 369197 | 22/02/2016 | 15/06/2017 | 139 |
| 369767 | 6/02/2017 | | 10 |
| 369831 | 23/12/2015 | 6/05/2016 | 36 |
| 370006 | 2/10/2017 | 2/04/2018 | 14 |
| 370241 | 21/03/2016 | 15/12/2016 | 8 |
| 370473 | 16/12/2016 | | 80 |
| 370735 | 31/05/2016 | 27/06/2016 | 42 |
| 371042 | 1/08/2016 | 15/12/2016 | 15 |
| 371985 | 6/06/2018 | | 27 |
| 372687 | 8/11/2018 | | 1 |
| 372824 | 8/05/2017 | 1/06/2017 | 20 |
| 372924 | 25/05/2018 | 28/06/2019 | 31 |
| 372955 | 12/07/2017 | 4/10/2017 | 7 |
| 373094 | 23/06/2017 | 20/04/2018 | 60 |
| 373369 | 24/10/2017 | 8/12/2017 | 21 |
| 373486 | 2/05/2018 | | 20 |
| 373556 | 20/11/2018 | 21/08/2019 | 82 |
| 373670 | 17/11/2017 | 10/04/2018 | 37 |
| 374727 | 28/06/2018 | | 0 |
| 374807 | 10/04/2018 | | 0 |
| 375050 | 29/06/2018 | | 2 |
| 375242 | 6/09/2018 | 12/10/2018 | 24 |
| 375496 | 15/10/2018 | 2/01/2019 | 21 |
| 375628 | 13/06/2018 | | 15 |
| 376288 | 31/10/2018 | 6/02/2019 | 15 |
| 376331 | 8/01/2019 | | 5 |
| 376599 | 12/03/2019 | | 10 |
| 377330 | 19/08/2019 | | 3 |
| 377873 | 17/10/2019 | | 2 |

Source: Deloitte Access Economics, using ANZCTR.[171]

171 Deloitte Access Economics analysis, using Australian New Zealand Clinical Trials Registry data accessed via Therapeutics Goods Administration website, 'Clinical trials on medicinal cannabis substances, extracts and products' (1 January 2015 to 30 November 2019) ‹https://www.tga.gov.au/medicinal-cannabis-information-health-professionals›.

Table C.2: Clinical trials recorded by the ICTRP, enrolled between January 2015 and November 2019

| Trial ID | Date enrolled | Target size |
|---|---|---|
| ACTRN12615000414516 | 29/02/2016 | 224 |
| ACTRN12616000103460 | 22/02/2016 | 142 |
| ACTRN12616000267459 | 13/07/2016 | 40 |
| ACTRN12616000414415 | 2/10/2017 | 21 |
| ACTRN12616000516482 | 6/02/2017 | 30 |
| ACTRN12616001036404 | 16/12/2016 | 250 |
| ACTRN12616001104448 | 30/08/2016 | 320 |
| ACTRN12617000012370 | 4/08/2016 | 600 |
| ACTRN12617000825358 | 25/05/2018 | 30 |
| ACTRN12617001028392 | 23/06/2017 | 20 |
| ACTRN12617001287325 | 20/11/2018 | 82 |
| ACTRN12617001480370 | 6/06/2018 | 30 |
| ACTRN12617001491358 | 21/03/2019 | 16 |
| ACTRN12618000078257 | 6/06/2019 | 30 |
| ACTRN12618000183280 | 5/02/2018 | 40 |
| ACTRN12618000391279 | 24/07/2018 | 24 |
| ACTRN12618000487213 | 1/05/2018 | 100 |
| ACTRN12618000545268 | 1/03/2019 | 24 |
| ACTRN12618000612213 | 29/04/2019 | 18 |
| ACTRN12618001063202 | 28/06/2018 | 204 |
| ACTRN12618001205224 | 15/10/2018 | 15 |
| ACTRN12618001220257 | 13/02/2019 | 144 |
| ACTRN12618001424291 | 6/09/2018 | 24 |
| ACTRN12618001802291 | 31/10/2018 | 15 |
| ACTRN12618001852246 | 8/01/2019 | 10 |
| ACTRN12618001894280 | 3/01/2019 | 150 |
| ACTRN12618002032235 | 31/08/2019 | 400 |
| ACTRN12619000037101 | 9/09/2019 | 144 |
| ACTRN12619000216112 | 27/05/2019 | 36 |
| ACTRN12619000443190 | 12/03/2019 | 32 |
| ACTRN12619000491167 | 1/05/2019 | 250 |

# APPENDIX C – CLINICAL TRIALS

| Trial ID | Date enrolled | Target size |
|---|---|---|
| ACTRN12619000623190 | 13/06/2018 | 36 |
| ACTRN12619000673145 | 3/06/2019 | 20 |
| ACTRN12619000714189 | 19/08/2019 | 20 |
| ACTRN12619000882123 | 1/08/2019 | 40 |
| ACTRN12619000932167 | 1/08/2019 | 40 |
| ACTRN12619001013156 | 17/10/2019 | 9 |
| ACTRN12619001120167 | 2/09/2019 | 40 |
| ACTRN12619001552178 | 18/11/2019 | 30 |
| ISRCTN89498802 | 8/07/2015 | 22 |

Source: Deloitte Access Economics, using ICTRP.[172]

172 Deloitte Access Economics analysis, using World Health Organization, 'International Clinical Trials Registry Platform' (Accessed 31 August 2020) ‹https://www.who.int/clinical-trials-registry-platform›.

# APPENDIX D – DEMAND AND SUPPLY OUTPUTS

Table D.1: Demand and supply outputs

| | 2020 | 2021 | 2022 | 2023 | 2024 | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Australian supply** | 15,203 | 30,407 | 40,542 | 55,746 | 70,949 | 91,220 | 106,423 | 131,762 | 152,034 | 172,305 | 187,508 |
| Supply to the Australian market (dried kg) | 611 | 2,443 | 5,236 | 9,075 | 14,835 | 22,514 | 31,153 | 41,887 | 53,406 | 58,903 | 62,830 |
| % | 4% | 8% | 13% | 16% | 21% | 25% | 29% | 32% | 35% | 34% | 34% |
| Supply to exports (dried kg) | 13,376 | 25,531 | 32,063 | 42,210 | 50,438 | 61,408 | 66,756 | 79,334 | 86,465 | 99,617 | 109,677 |
| % | 88% | 84% | 79% | 76% | 71% | 67% | 63% | 60% | 57% | 58% | 58% |
| Supply to research (dried kg) | 1,216 | 2,433 | 3,243 | 4,460 | 5,676 | 7,298 | 8,514 | 10,541 | 12,163 | 13,784 | 15,001 |
| % | 8% | 8% | 8% | 8% | 8% | 8% | 8% | 8% | 8% | 8% | 8% |
| | | | | | | | | | | | |
| **Australian demand** | 6,109 | 12,217 | 17,453 | 22,689 | 29,670 | 37,524 | 44,948 | 54,016 | 62,792 | 71,269 | 78,696 |
| Demand met by imports (dried kg) | 5,498 | 9,774 | 12,217 | 13,613 | 14,835 | 15,009 | 13,484 | 10,803 | 6,279 | 7,127 | 7,870 |
| % | 90% | 80% | 70% | 60% | 50% | 40% | 30% | 20% | 10% | 10% | 10% |
| Demand met by Australian supply (dried kg) | 611 | 2,443 | 5,236 | 9,075 | 14,835 | 22,514 | 31,464 | 43,213 | 56,513 | 64,142 | 70,827 |
| % | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 90% | 90% |

Source: Deloitte Access Economics.
Note: Totals may not sum due to rounding

# LIMITATION OF OUR WORK

### General use restriction

This report is prepared solely for the use of MTPConnect. This report is not intended to and should not be used or relied upon by anyone else and Deloitte accepts no duty of care to any other person or entity.

# GLOSSARY

| Acronym | Full name |
|---|---|
| ABS | Australian Bureau of Statistics |
| ACT | Australian Capital Territory |
| ADD | Attention Deficit Disorder |
| ADHD | Attention Deficit Hyperactivity Disorder |
| ANZCTR | Australian New Zealand Clinical Trials Registry |
| ANZSIC | Australian and New Zealand Standard Industrial Classification |
| ARTG | Australian Register of Therapeutic Goods |
| CBD | Cannabidiol |
| CGE | Computable General Equilibrium |
| CINV | Chemotherapy Induced Nausea and Vomiting |
| COPD | Chronic Obstructive Pulmonary Disease |
| CRPS | Complex Regional Pain Syndrome |
| DPMQ | Dispensed Price for Maximum Quantity |
| EBITDA | Earnings Before Interest, Taxes, Depreciation and Amortisation |
| EU | European Union |
| FTE | Full-Time Equivalent |
| GDP | Gross Domestic Product |
| GMP | Good Manufacturing Practice |
| GOS | Gross Operating Surplus |
| GP | General Practitioner |
| GSP | Gross State Product |
| GVP | Gross Value Product |
| HREC | Human Research Ethics Committee |
| IBD | Inflammatory Bowel Disease |
| IBS | Irritable Bowel Syndrome |
| ICTRP | International Clinical Trials Registry Platform |

| Acronym | Full name |
|---|---|
| IO | Input-Output |
| MCIA | Medicinal Cannabis Industry Australia |
| NT | Northern Territory |
| ODC | Office of Drug Control |
| OTC | Over The Counter |
| PANDAS | Paediatric Autoimmune Neuropsychiatric Disorders Associated With Streptococcal Infections |
| PBS | Pharmaceutical Benefits Scheme |
| PSP | Progressive Supranuclear Palsy |
| PTSD | Post-Traumatic Stress Disorder |
| SAS-B | Special Access Scheme – Category B |
| TGA | Therapeutic Goods Administration |
| THC | Delta-9-Tetrahydrocannabinol |
| UK | United Kingdom |
| US | United States |

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# INFORMATION

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