



FreshLeaf
Analytics

Australian Medicinal Cannabis Market Patient, Product and Pricing Analysis

H2 2021

Real Data. Real Analysis. Real Results.



Summary

The H2 2021 report is FreshLeaf Analytics' seventh market report on patients, products and pricing in the Australian medicinal cannabis market.

Key highlights include:

- Market growth will exceed expectations in 2021 as active patient numbers surge towards 100,000
- Revenue from product sales forecast at \$230 million at year end
- Sharp uptick in SAS-B approvals coupled with ongoing growth in Authorised Prescribers suggests more mainstream acceptance by both patients and doctors
- Product count continues to climb although the growth rate of new products is slowing
- Oil remains the dominant product format but flower is gaining quickly in popularity, while growth in non-traditional formats is stagnant
- 40% of all SAS-B approvals are now for flower products
- The average price continues to drop although floor price lifts as new low-cost market entrants readjust pricing; wholesalers are given the squeeze
- Average monthly spend continues its slow downward trend while average daily dose increases
- 2022 will see continued transformation of the industry including improved patient access, the emergence of new markets, and an increase in R&D investment

2021 revenue forecast revised upwards to

\$230m

Active patients

70,000

forecast to grow to almost 90,00 by year end

Authorised Prescribers

430

up from 179 in December 2020

224

medicinal cannabis products now on the market

40%

of SAS-B approvals for flower products

Retail floor price rebounds

\$0.05/mg

cannabinoid

Avg. wholesale price drops

21%

compared with avg. RRP drop of 12%

Avg. patient spend

\$278

per month

Avg. daily dose

112 mg

cannabinoid

Methodology

The FreshLeaf H2 2021 product, pricing and patient analysis was based on data collected in the period July to September 2021. The team collected product and pricing data in September 2021 from 44 suppliers who have been granted authority from the Office of Drug Control to supply medicinal cannabis into the Australian market. Only suppliers who could demonstrate they had products available in the market on 15 September 2021 were included in the study. Some suppliers offer discounts for larger volume orders, but these discounts have not been reflected in the analysis.

Anonymised real world data covering patient, product and dosage was supplied through the CA Clinics network via the HREC approved CACOS study and is based on a random sample of 100 patients seen at the clinics June to August 2021.

Forecasts were generated from FreshLeaf Analytics' proprietary market models including our Australian Industry Model, Pricing and Patient Model, Dosing and Indication Model, and Value Chain Model. These models factor in variables including patient dosage, indication type, attrition rates, SAS-B approvals, Authorised Prescriber approvals, compounding scripts, wholesale pricing, retail pricing and pharmacy mark-ups.

Additional information was supplied from regulators based on Freedom of Information requests.

All currency figures are expressed in Australian dollars unless stated otherwise.

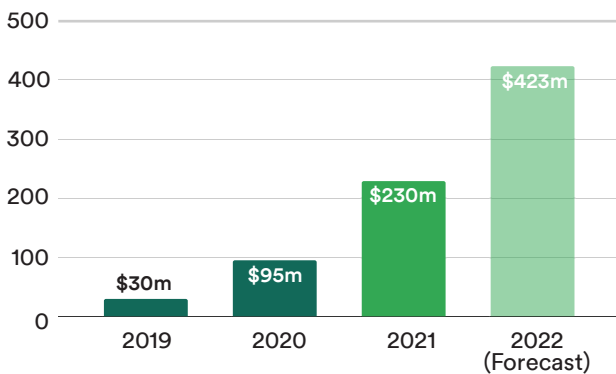
Market Growth

Market revenue exceeds expectations with a forecast of \$230M in 2021

The Australian medicinal cannabis market continues to grow, propelled by a surge in active patients over the past six months. Revenue from product sales in 2021 is forecast at \$230 million, up from an estimated \$200+ million in earlier projections, capping off another milestone year for the industry¹.

FreshLeaf expects this impressive growth trajectory to keep pace through 2022 with sales reaching over \$400M².

Australian medicinal cannabis market revenue

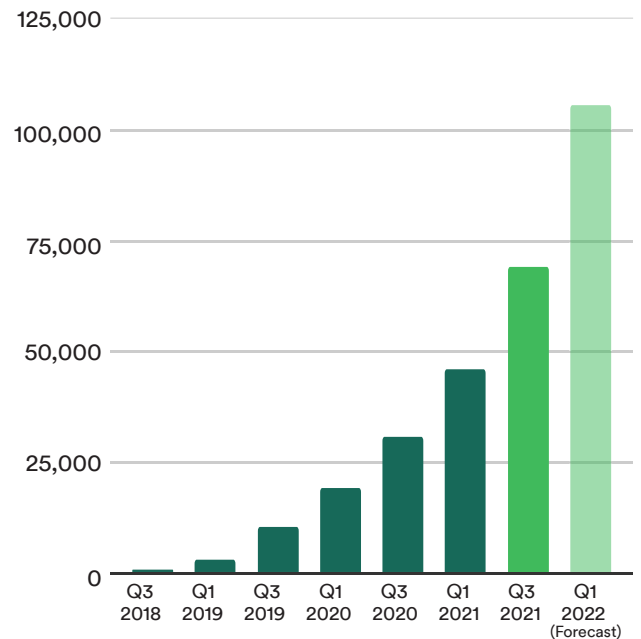


Active patient numbers surge towards 100,000

There were almost 70,000 active patients at the end of Q3 2021 - a marked increase of 50% from 45,000 patients at the end of Q1 2021. These are patients who have filled a prescription or consulted with a doctor about medicinal cannabis in the past six months. FreshLeaf estimates that by the end of 2021 there will be almost 90,000 active patients in Australia³.



Number of Active Patients



1 FreshLeaf Analytics Australian Industry Model

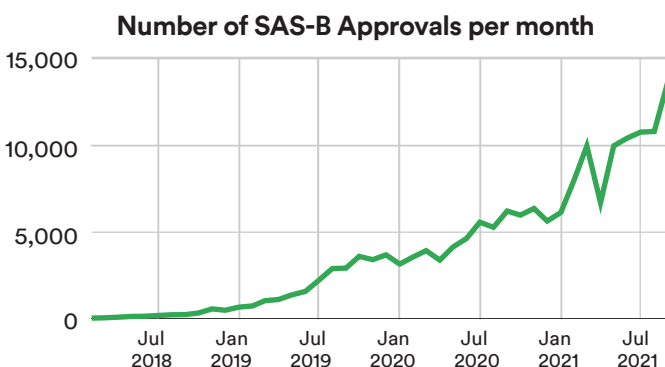
2 FreshLeaf Analytics Australian Industry Model

3 FreshLeaf Analytics Pricing & Patient Model



Sharp uptick in SAS-B approvals following a period of volatility in early in 2021

Special Access Scheme B (SAS-B) approvals experienced volatility earlier in the year as a result of Therapeutic Goods Administration (TGA) system upgrades as well as a shortage in flower products. Approvals subsequently stabilised with a sustained correction that delivered successive monthly all-time high approval numbers from May to September.



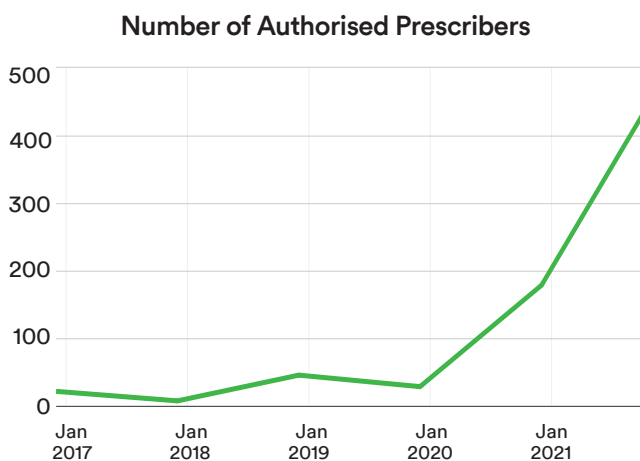
September SAS-B approvals dwarfed previous records with 13,666 approvals reported by the TGA, lifting average per month approvals in 2021 to 9,602. This is a significant leap up from average per month approvals in 2020 of 4,815, and bodes well for strong growth into 2022⁴.

It's worth noting that SAS-B approvals gained increased momentum from February 2021, coinciding with the TGA's announcement about down-scheduling low-dose CBD products from S4 (prescription only) to S3 (over-the-counter), an announcement that was fuelled by an abundance of mainstream media exposure. This may have contributed to an uplift in awareness of medicinal cannabis as a viable treatment option for patients.

⁴ <https://www.tga.gov.au/medicinal-cannabis-role-tga>

Continued steep rise in Authorised Prescribers

The number of clinicians registering as Authorised Prescribers has continued to rise dramatically with 430 Authorised Prescribers registered as at 30 September 2021. This represents growth of approximately 40% from a mere three months ago⁵.



The increase in Authorised Prescribers is a promising sign for the industry with clinicians typically opting to become an Authorised Prescriber if they intend to prescribe relatively high volumes of medical cannabis but want to avoid the onerous paperwork required through the SAS-B pathway. There is clearly a growing subset of clinicians who are committed to utilising medical cannabis as a regular treatment option for their patients.

The rise in Authorised Prescribers has likely been aided by the TGA taking steps to simplify the application process for becoming an Authorised Prescriber. The evolved process enables Human Research Ethics Committees (HREC) to provide prescribers with endorsement for products at a category level (Schedule 4 or Schedule 8) although dosage form, route of administration, indication and class of patient must still be specified. HREC approvals can now also be issued for up to



five years. While this a positive step in improving patient access, the process hasn't yet been fully streamlined and prescribers are still required to gain approval from the TGA for the specific products they intend to prescribe.

With nearly 20,000 patients notified to the TGA as having been processed through this channel in the first half of this year, the Authorised Prescriber pathway continues to increase its relevance as an important metric for industry growth despite the majority of patients still accessing medical cannabis through the SAS-B pathway⁶.

⁵ <https://www.tga.gov.au/medicinal-cannabis-role-tga>

⁶ Therapeutic Goods Administration Freedom of Information Request



Compounding yet to be impacted by TGA review of the channel

Anecdotal reports suggest that there is also strong growth in the Compounding channel. Ease of access and lack of administrative burden are the likely drivers of growth given that doctors aren't required to seek approval from the TGA for writing a compounded medicinal cannabis prescription. Given the lack of regulation in this space it is not currently possible to quantify the number of patients accessing compounded products. Concerns have been raised about Compounding by the Department of Health and the channel is under review as part of a wider set of reforms to manufacturing, labelling and packaging. The results of this review are yet to be formally announced although it has been suggested that in the future compounding pharmacies may be required to submit an application or notification not unlike the SAS-B pathway.

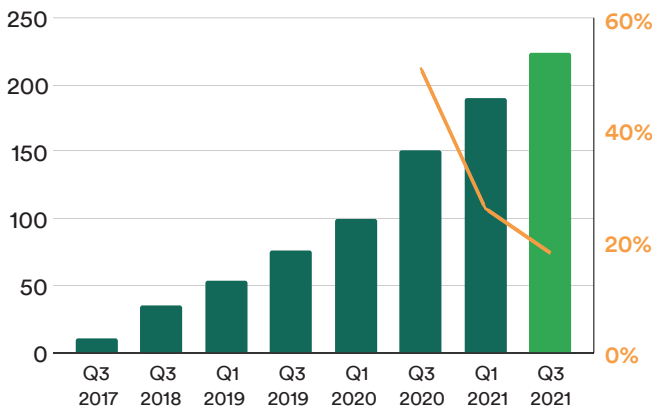
⁷ <https://consultations.health.gov.au/medical-devices-and-product-quality-division/medicinal-cannabis-reforms-2020/>

Product Analysis

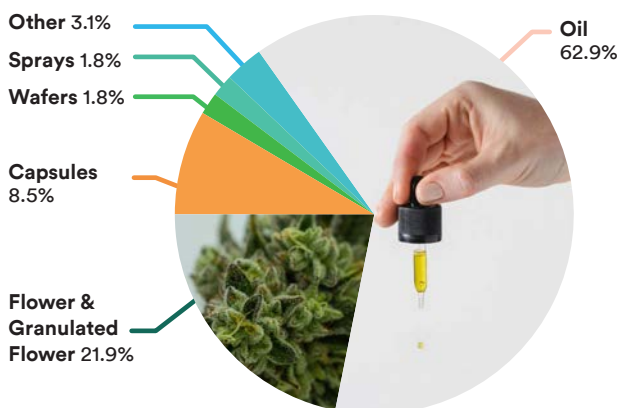
Product counts continue their steady march although the growth rate is slowing

The number of products available in the market has also grown in the last six months, with 224 products now available⁸. This represents an 18% increase since April 2021 when there were 190 products for doctors to choose from. While this is a significant increase in a short period of time, period-on-period growth has been slowing over the last three reporting periods.

Product count vs. growth rate
 ■ Product count — Growth rate



Oil and flower remain by far the most dominant product formats within the Australian medicinal cannabis market, together accounting for more than 80% of the number of available products.

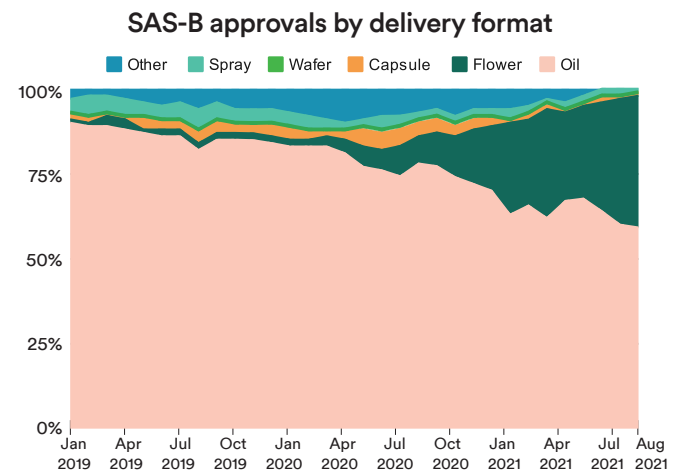


Flower gains popularity in the market

While oil represents 63% of the products available, flower (including granulated flower) has outpaced growth in numbers of all competing product formats. With an increase of 17 products (a growth factor of 1.5 in just six months), this segment has expanded from 15% of products available to 22% of products available.

Growth in flower products is translating into prescriptions, with growth in the number of products available accompanied by continued growth in the number of SAS-B approvals for flower. These shifts are likely a case of supply meeting demand as falling prices attract green market patients, supercharging popularity of the product format and likely contributing to the flower shortage experienced in early 2021.

It is to be noted that growth in the flower segment is at the expense of all other segments in the market and now sits at just under 40% of all SAS-B approvals, as can be seen in the new data dashboard on the TGA website⁹.



⁸ FreshLeaf Analytics Australian Industry Model

⁹ <https://www.tga.gov.au/medicinal-cannabis-special-access-scheme-category-b-data>

The nature of this trend remains unclear. While it is possible that some of these patients are new to using flower, it's also possible that this represents a migration of patients from the green market to the prescription market. There is also the possibility that some of these new patients are seeking cannabis for non-medical reasons, or that their medical use of cannabis closely resembles the patterns and preferences of non-medical users.

It is interesting to observe that currently the majority of SAS-B approvals for flower are for males in the 18-44 age group, accounting for 60% of all flower approvals¹⁰. Regardless, we may be seeing the start of blurred lines between the adult-use and medical markets with some product companies testing the waters by bringing new product formats to market that are traditionally considered more recreational formats such as bubble hash.

Growth in non-traditional delivery formats is stagnant

Product growth in non-oil / non-flower delivery formats remains stagnant. With the overall market increasing its product count, representation of these formats continues to decline.

This decline was consistent when looking at prescription rates across the different formats. Looking at SAS-B data from January to August 2021, non-oil / non-flower products saw a decline from approximately 10% of prescriptions in January to approximately 2% by August, a steep decline and a testament to the popularity of the dominant two formats.

One of the challenges facing these products is price. Given the high price of medicinal cannabis and the lack of subsidies, patients are highly price sensitive and price remains one of the key factors in prescribing decisions. If product companies are unable to establish and effectively communicate a meaningful value proposition for these more innovative delivery formats, the added manufacturing costs will be a prohibitive factor in their growth.

An increase in locally cultivated and manufactured products

FreshLeaf has observed a year-on-year increase of products available in Australia that sourced raw material locally or that were manufactured locally, with the number of Australian-grown and Australian-made products doubling over the past 12 months. Australia is largely stealing product share from Canada, while the USA is the only other country to register an increase in product share during this time. This is good news for patients who have been negatively impacted by supply chain disruption due to COVID-19 causing some imported products to go out-of-stock.

Regulation on imports is a hot topic in the industry with a change in the quality standards imposed on imports likely to be introduced. A review of manufacturing standards on imported products has been conducted by the Department of Health (DOH) with reforms seeking to address inequality in the GMP requirements for products manufactured in Australia versus products imported from overseas¹¹. The public consultation period for reforms has concluded and it has been reported that the TGA is likely to require imported medicinal cannabis products to be manufactured in a TGA-recognised GMP facility. While new regulation is yet to be publicly announced, it is expected that imposing GMP standards on imported products will affect the number of products we see in the market and the pricing of products. There are concerns that when new quality requirements are announced some companies will race to import cheap, low quality products subsequently stockpiled in high volumes, while others race towards compliance.

¹⁰ <https://www.tga.gov.au/medicinal-cannabis-special-access-scheme-category-b-data>

¹¹ <https://consultations.health.gov.au/medical-devices-and-product-quality-division/medicinal-cannabis-reforms-2020/>

Price

Average price continues to drop with wholesalers feeling the squeeze



Retail pricing

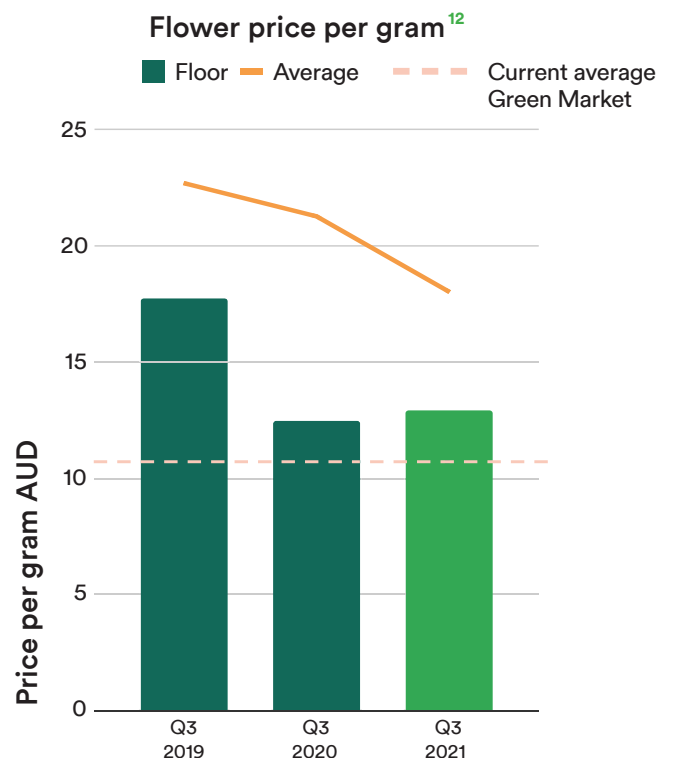
The downward pressure on price has continued over the past six months, with the average price per mg of cannabinoid now sitting at \$0.14/mg, down 12% from \$0.16/mg in March earlier this year.

However, the floor price has lifted from \$0.03/mg to \$0.05/mg. CBD Isolate which previously had a floor price of \$0.03/mg lifted to \$0.05/mg as a result of products entering the market at exceptionally low prices to capture the attention of prescribers and patients alike, only to return to somewhat more sustainable levels after their initial launch period. \$0.05/mg is now the floor price for three cannabinoid profiles - CBD Isolates, THC Isolates and High CBD products.

The average price of flower is \$17.64 per gram, with a minimum of \$12.90 per gram. The most expensive product available is a bubble hash product with a per gram price of \$50. FreshLeaf has observed pricing of legal flower products moving closer toward green market pricing over the past three years.

Minimum retail price per mg by product formulation

	H1 2021	H2 2021
Balanced	0.11	0.08
CBD Isolate S4	0.03	0.05
High CBD	0.05	0.05
High THC	0.11	0.12
THC Isolate	0.08	0.05

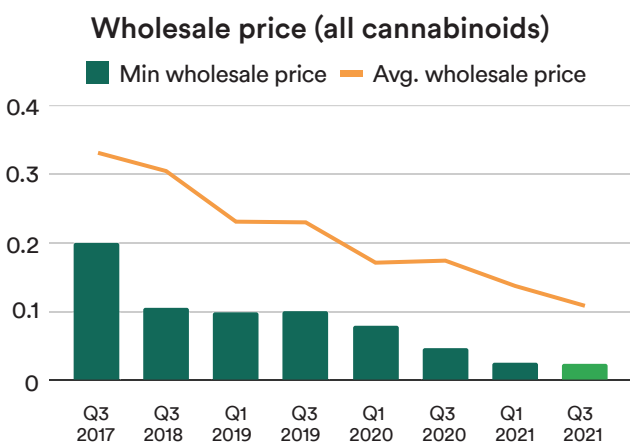


¹² <https://www.cannabisplace.com.au/learn/australia-price-weed/#how-much-does-weed-cost-in-australia>



Wholesale pricing

The average price to pharmacies has also experienced downward pressure in the previous six months, in line with long term trends. It should be noted, however, that average wholesale prices dropped significantly further than that of retail suggesting that product company margins are being squeezed.



Wholesale prices on average dropped 21% during the reporting period compared with retail's drop of 12%

There could be a number of dynamics putting pressure on wholesale pricing. With pharmacies typically operating with fixed labour costs for dispensing, this relative decline of wholesale price to RRP may mean that we are experiencing the start of a stable market floor

price as pharmacies maintain their margin, at least until over-the-counter low-dose CBD products enter the market in 2022/2023. It may also be the result of bulk purchasing in response to increased market demand or simply more competition forcing wholesalers to trim profit margins.

Price relief for Epidyolex patients

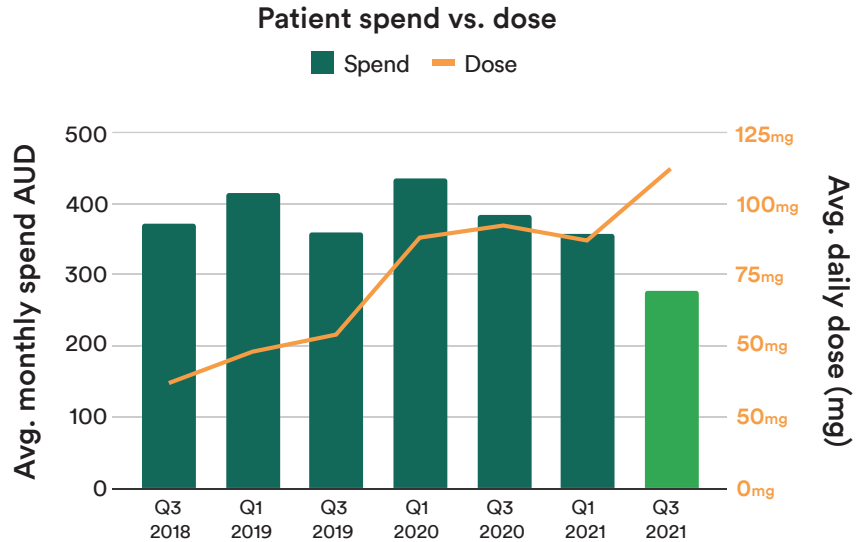
On 1 May 2021, Epidyolex became the first medicinal cannabis product to be listed on the PBS to assist in the treatment of patients with Dravet syndrome (a rare form of childhood epilepsy) in a key milestone for both patients and industry alike. Just over 100 patients a year are expected to benefit from this listing, paying only \$41.30 per script (\$6.60 for concession card holders) who would have otherwise paid more than \$24,000 per year for the treatment¹³. Epidyolex under the PBS must be prescribed by a neurologist and as an adjunctive therapy (as a third-line treatment with at least two other antiepileptic medicines).

The subsidy landscape remains otherwise unchanged, however, FreshLeaf expects that with this new precedent medical cannabis companies will seek PBS listing for future products registered on the ARTG.

¹³ <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/historic-pbs-listing-for-australians-with-a-rare-epilepsy-condition>

Patient spend & dose

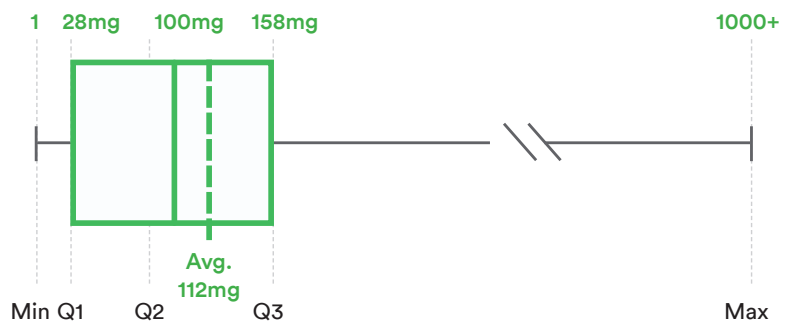
Patient average monthly spend has continued its slow downward trend, reaching its lowest level since FreshLeaf reporting began, and is now \$278 per month¹⁴.



Patient average daily cannabinoid dose has seen a sizable increase to 112mg/day after a period of stabilisation throughout 2020 at the ~90mg/day mark. This follows the overall trend towards increased average daily dose¹⁵. As mentioned in previous reports, it is likely that a combination of decreasing cost of medication and increasing levels of titration over time are key drivers of this trend.

The dose curve remains positively skewed, with the majority of patients taking doses lower than the average. However, it is interesting to note that only 50% of patients have a daily dose of less than 100mg compared to 75% in the previous two six-month periods.

Daily dose box plot (patient reported) mg/day



¹⁴ FreshLeaf Analytics Pricing & Patient Model

¹⁵ FreshLeaf Analytics Pricing & Patient Model

What's next?



2022 will see continued transformation of the industry characterised by wider acceptance of medicinal cannabis, improved access for patients, an increase in R&D investment, and industry players looking to new markets in which to expand.

Greater mainstream acceptance of cannabis as a medicine

2021 has brought signs that the stigma surrounding cannabis is beginning to dissipate. The down-scheduling of low dose CBD and the promise of access through pharmacies has given some legitimacy to cannabis as a 'medicine for the masses'. The subsequent jump in SAS-B approvals is no coincidence and the significant jump in Authorised Prescribers (despite their overall numbers still being relatively small) signals that a growing number of doctors are embracing cannabis prescribing. Notably, global businesses such as Amazon and Apple are taking a stewardship role on cannabis reform internationally with Amazon, for example, publicly calling for reform of the USA's cannabis laws¹⁶.

¹⁶ <https://assets.aboutamazon.com/3e/53/014acc0843c3b6d5c12b06d8603a/amazon-response-cannabis-administration-and-opportunity-act.pdf>

Continued improvements in patient access although driving laws remain a hurdle

It is anticipated that patient access will continue to improve as the government implements the accepted recommendations made as a result of the Senate inquiry into barriers to patient access to medicinal cannabis¹⁷. This includes possible changes to the SAS-B authorisation pathway, further reforms to the Authorised Prescriber scheme, and possible changes to the Medicare Benefits Scheme for primary care.

Despite this, patient access remains hampered by driving laws with medicinal cannabis yet to gain equal footing with the legal defence offered by other prescription medicines including opioids. Legally prescribed medicinal cannabis containing even small amounts of THC risks detection in road-side tests and drivers are at risk of losing their license even if they are not impaired. Proposed drug-driving laws in South Australia, for example, would see drivers immediately lose their license if they return a positive roadside drug test. As a result, many doctors avoid prescribing THC-containing medicine even in situations where it would be beneficial to the patient. The 'Drive Change' advocacy group are working tirelessly to challenge these laws but it's been somewhat of an uphill battle. There are, however, some green shoots with a precedent set in Tasmania. Under Tasmanian law, an unimpaired person is not considered to have committed an offence if the product was obtained and administered in accordance with the Poisons Act 1971¹⁸.



Companies look to new pathways for expansion

Despite record growth, the hyper-competitive environment and continued downward pressure on price has resulted in ongoing consolidation of the market in the form of mergers and acquisitions, downgrades in revenue forecasts (and in some cases reports of sizable losses), and companies looking to the export market for growth. M&A highlights in 2021 include Cann Group's acquisition of Satipharm, the merger of Cronos Australia and CDA Health, as well as AusCann's acquisition of CannPal Animal Therapeutics. Meanwhile Little Green Pharma, Cannim and MediPharm Labs are among the companies capitalising on the export market.

¹⁷ <https://www.odc.gov.au/sites/default/files/australian-government-response-senate-community-affairs-references-committee-report.pdf>

¹⁸ http://www.dhhs.tas.gov.au/psbtas/medicinal_cannabis/information_for_patients_carers

Companies look to psychedelics for a new future-growth narrative

Cannabis companies around the world have staged moves into the psychedelic industry as a way of adding a new and exciting narrative around future revenue opportunities. The addition of initiatives in the psychedelics space follows the playbook of North American cannabis companies who have been entering this emerging sector for a number of years, and the psychedelics industry in Australia is following suit after announcements from a number of cannabis companies. This includes Little Green Pharma, who were recently granted a Schedule 9 licence by the WA Department of Health to supply psilocybin to eligible license holders, and Creso Pharma who have completed their acquisition of Canadian Halucenex Life Sciences. A \$40M psychedelic medicine institute has also launched in Melbourne with a world first research collaboration between researchers from leading world universities¹⁹.

The regulatory framework for psychedelics in Australia is also approaching a turning point, with the TGA currently finalising its review process to down-schedule MDMA and psilocybin from Schedule 9 (prohibited drug) to Schedule 8 (controlled drug), potentially opening up the door for therapeutic use of these products. An independent expert panel commissioned by the TGA has recently concluded its review of these substances for the treatment of mental health conditions, with the verdict that they may show promise in highly selected populations when administered with close clinical supervision and support. The final decision will be published in the first week of December 2021.



Down-scheduling of CBD helps drive R&D investment

The race to Schedule 3 (S3) low-dose CBD product registration is heating up with a number of companies announcing plans for clinical research that will support an S3 registration. Availability of cannabis products as an over-the-counter medicine is a critical milestone for greater mainstream acceptance of medicinal cannabis and will vastly improve patient accessibility from a financial, physical and administrative perspective.

¹⁹ <https://www.smh.com.au/national/40m-psychedelic-medicine-institute-launches-in-melbourne-20210728-p58d1o.html>

About FreshLeaf Analytics

FreshLeaf Analytics is the leading supplier of data for the medicinal cannabis industry in Australia. FreshLeaf has access to medicinal cannabis products and clinical data sets from some of Australia's leading healthcare companies and organisations including healthcare clinics, pharmacies, product companies and the TGA. The FreshLeaf team provides custom research, analysis and consulting services to medicinal cannabis companies, pharma companies, government clients and others.

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FreshLeaf Analytics is part of the Southern Cannabis Holdings group, Australia's leading vertically integrated pharmaceutical cannabis business with interests in market intelligence, clinical research, medical services, and product services.



FreshLeaf
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**Real Data.
Real Analysis.
Real Results.**

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