FreshLeaf Analytics

Australian Medicinal Cannabis Market
Patient, Product and Pricing Analysis

H1 2021

Real Data. Real Analysis. Real Results.

- **2021 revenue forecast to double** from ~$100M in 2020
- 45,000 **active patients forecast to grow to 75,000** by year end
- **179 Authorised Prescribers** up from 29 in December 2019
- **190 medicinal cannabis products** now on the market
- Retail **floor price now $0.03/mg** cannabinoid
- **Average patient spend $359 per month**
- **Average daily dose 87mg** cannabinoid

Methodology

The FreshLeaf H1 2021 product, pricing and patient analysis was based on data collected in the period January and February 2021. The team collected product and pricing data in January and February 2021 from 45 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 28th February 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 were supplied through the CA Clinics network via the HREC approved CACOS study and were based on a random sample of 1,000 patients seen at the clinics during January and February 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 approaches 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.

Summary

The H1 2021 report is FreshLeaf Analytics' sixth market report on patients, products and pricing in the Australian market.

Key highlights include:

- Medicinal cannabis revenue expected to exceed expectations in 2021, hitting the $200m mark.
- Patient numbers have grown by a factor of 15x over the past two years.
- Significant increase in Authorised Prescribers after a long period of stagnation is a key driver of market growth.
- Intense product competition continues as new products flood the market keeping downward pressure on price.
- Average daily dose and average monthly spend stabilise.
- Slow-down in delivery format innovation with only one new format introduced in the last six months.
- Sizable patient cohort expected to migrate to the pharmacy channel once low-dose CBD products become available over the counter in pharmacies.
- 2021 will bring evolution in the regulatory landscape, a greater emphasis on product quality, growing investment in R&D, and further industry consolidation.

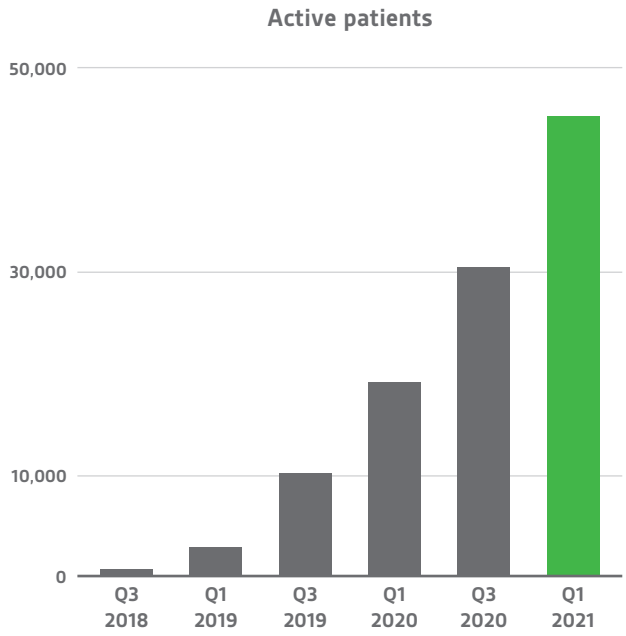
1.0 Market Growth

Market expected to exceed $200M in 2021

The Australian medicinal cannabis market continues its strong growth trajectory with revenue expected to more than double in 2021, hitting the $200m mark up from around $100m in 2020[1].

Growing patient numbers

Patient numbers have grown markedly having risen from ~30,000 active patients at the end of 2020 to ~45,000 at the close of Q1 2021. This is up from ~3,000 active patients just two years ago – a growth factor of 15x. FreshLeaf estimates that we will continue to see patient numbers climb with ~75,000 active patients forecast in December 2021[2].



Record SAS-B approvals

TGA reports that SAS-B approvals for 2020 were double those of 2019, with an estimated 100,000 SAS-B approvals granted to date[3]. February 2021 achieved a record-breaking 8,000 approvals for the month, a significant jump when you consider that the prior 12 month average is 5,000 per month. While some approvals can be attributed to doctors seeking reapproval for out-of-stock flower products, the question remains about whether we are seeing an increase in demand following the legalisation of pharmacist only low-dose CBD products.

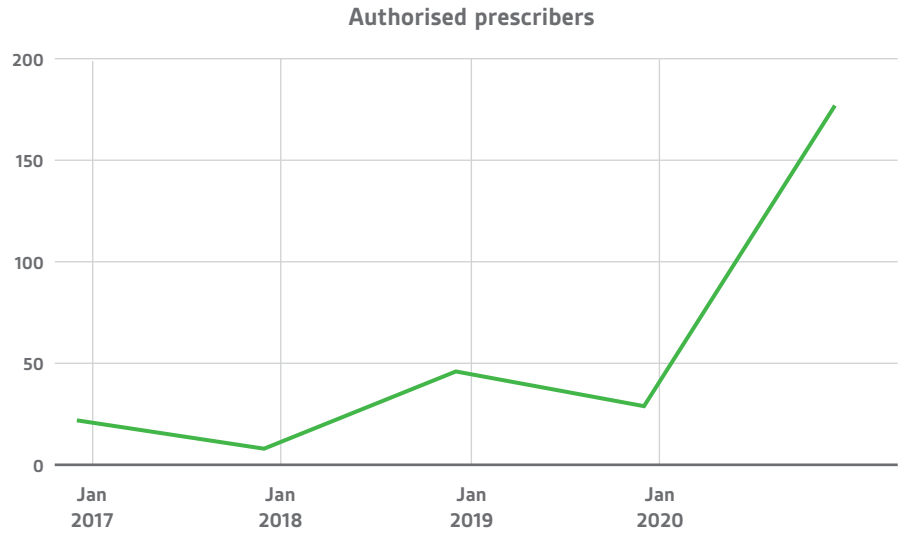
The down scheduling of low-dose CBD has gained attention not only from industry publications but also from mainstream media. Reports of patients arriving at pharmacies seeking to purchase low-dose CBD are abundant and FreshLeaf has heard anecdotally that demand for low-dose CBD products has gone up in both the legal and illegal markets.

Whether it's the impact of product supply issues, greater awareness of medicinal cannabis, reduced stigma, or a combination of the three, SAS-B numbers will be closely watched by many across the industry in the coming months.

[1] FreshLeaf Analytics Australian Industry Model
[2] FreshLeaf Analytics Pricing & Patient Model
[3] https://www.tga.gov.au/medicinal-cannabis-role-tga

Steep rise in Authorised Prescribers

While SAS-B remains the primary channel for patients accessing medicinal cannabis, there has been a significant increase in Authorised Prescribers after a long period of stagnation, with FreshLeaf estimating that almost 1 in 5 active patients are now prescribed medicinal cannabis by an Authorised Prescriber.



There are now 179 Authorised Prescribers with over 7,500 new patients notified to TGA for the period July 1 - Dec 31 2020[4]. Considering that Authorised Prescribers are positioned to support high volumes of medicinal cannabis patients, the substantial jump in Authorised Prescribers will be a significant driver of growth in patient numbers should this trend continue, especially if it is indicative of growing physician support for medicinal cannabis as a viable alternative to more traditional treatments.

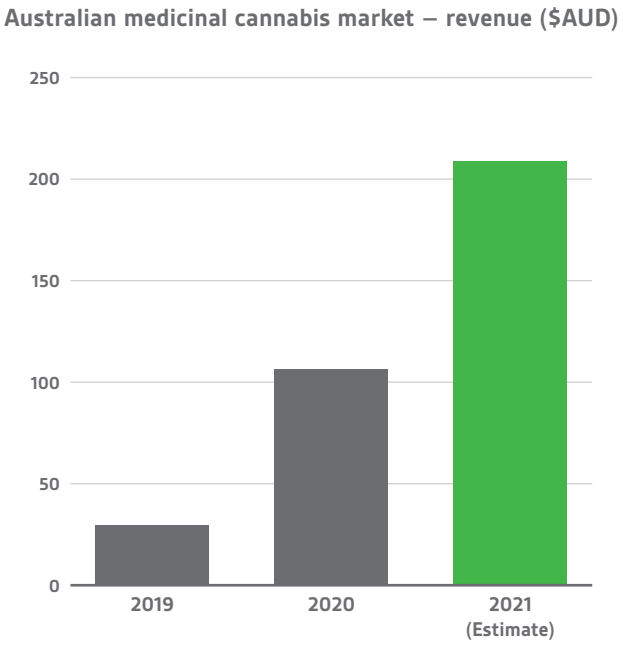
Compounding is also on the rise as a result of doctors being able to prescribe medicinal cannabis without using the SAS-B or Authorised Prescriber pathways. Given that the regulatory requirements of special access pathways don't apply to Compounding, it is not possible to accurately quantify the number of patients getting access to compounded products.

The Department of Health has raised concerns over the extent of compounding in medicinal cannabis, and compounding is under review as part of a wider set of reforms to manufacturing, labelling and packaging that are currently under consideration.

[4] Therapeutic Goods Administration Freedom of Information Request

Revenue milestone expected

Driven largely by rapid uptake of Authorised Prescribers, FreshLeaf expects medicinal cannabis revenue to exceed expectations in 2021, hitting the $200m mark – a two-fold increase from 2020. Year-to-date sales in 2021 have already surpassed full year revenues in 2019[5].



It should be noted that these forecasts exclude Schedule 3 low-dose CBD products given that it is unlikely products will be available in 2021.

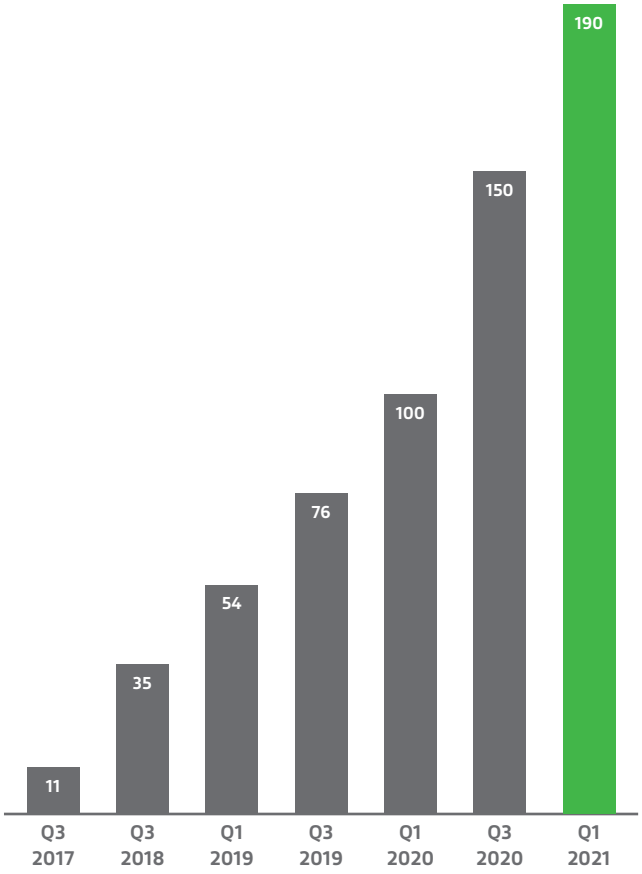
[5] FreshLeaf Analytics Australian Industry Model

2.0 Product analysis

Product numbers continue to climb

FreshLeaf observes that the number of products has more or less doubled each year since 2018. There are now 190 products available for physicians to prescribe to patients in Australia, bringing choice but also challenges. Medicinal cannabis products remain highly commoditised and there is little ability for physicians to differentiate between them beyond formulation and price.

Number of medical cannabis products available in the Australian market



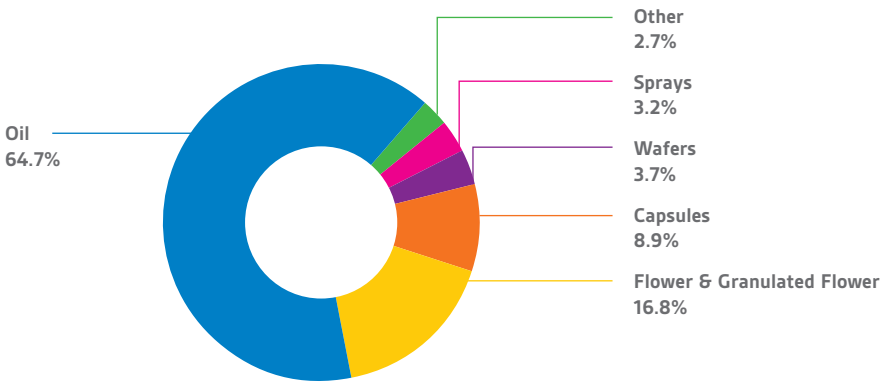
Product growth in the last six months has primarily come from oil with the number of oil products available shooting up to 123 from 89. There has been modest growth in flower products, while the number of wafer products tripled. Wafers, although still small in numbers, were the only delivery format outside of oil and flower to grow in product count and they are now the fourth biggest product type.

The industry has recently experienced significant supply issues with flower, driven by an anecdotally reported increase in demand, supply chain disruptions caused by COVID19, and regulatory delays in major exports to the local market from Canada. There are currently 32 flower products on the market (including granulated flower) supplied by 9 manufacturers, but only 4 of these products are cultivated locally. Australia is still heavily dependent on Canada and Europe for both cultivation and manufacture of flower products. Local cultivators and manufacturers have responded quickly to shortages, with some releasing home-grown flower products for the first time while others have altered production plans to meet demand.

A quiet period for innovation in delivery formats

While 2019/2020 brought a range of different delivery formats from sprays to patches, wafers and capsules, only one new format has been introduced since FreshLeaf's last report: chews.

Delivery formats by count of product type



With a proliferation of products, differentiation remains a challenge. Innovative product formats and formulations are key to standing out from the competition and previous FreshLeaf analysis has revealed that innovative delivery formats typically attract a higher asking price than more commoditised formats such as oil and flower. This gap, however, has begun to close as evidenced most recently with wafers. Expanded manufacturing capacity has enabled a significant reduction in the manufacturing cost of wafers and this saving has been passed on to patients. The cheapest wafer product is now available for a retail price of $0.09/mg – a reduction of 40% over the past six months. Capsules and lozenges are similarly closing the gap, the cheapest of which are $0.10 and $0.07 respectively.

Shuffling of low-dose CBD products

While the last six months saw total product numbers rise by 40, there were products that left the market. Almost three quarters of products that exited were low-dose CBD products containing either 10 or 25 mg/mL of CBD. These departures, however, were counterbalanced by the introduction of new low-dose CBD products (almost a quarter of new products entering the market were in this category). It appears there has been a shuffling of seats.

FreshLeaf can only speculate as to the reason low-dose CBD comprises the majority of products withdrawn, however it would be reasonable to conclude that companies who manufacture low-dose CBD products that may not be suitable for Schedule 3 (over-the-counter) are shifting their focus elsewhere, whether that means introducing suitable Schedule 3 formulations or moving away from the low-dose CBD category entirely.

There are a number of reasons that products may not be suitable for Schedule 3:

- they may not meet the manufacturing requirements for registering a product on the Australian Register of Therapeutic Goods (ARTG)
- companies may choose not to invest in the clinical research that would be required to demonstrate efficacy and safety of the product (particularly as concerns remain about the ability to demonstrate efficacy at >150mg/day); or
- the product concentration is so low that it would require unfeasible amounts of medicine to meet the maximum daily-dose of 150mg/day (for example, one would need to ingest 15mL of a 10mg/mL CBD formulation to reach 150mg)

Increase in products containing THC

Almost 70% of products that entered the market over the past six months were Schedule 8 products (containing >2% THC). Analysis of SAS-B data reveals that this mirrors demand, with 71% of all SAS-B approvals for the period November 1st 2016 to September 20th 2020[6] being for Schedule 8 products (the remaining 29% of SAS-B approvals were for Schedule 4 products).

[6] Therapeutic Goods Administration Freedom of Information Request

3.0 Price

Substantial drop in retail floor price

Retail pricing

The price war we've observed over the past three years is heating up. Continued downward pressure as a result of intense competition and record numbers of products has brought an astonishing drop in the retail floor price to around $0.03/mg with an average price of $0.16/mg.

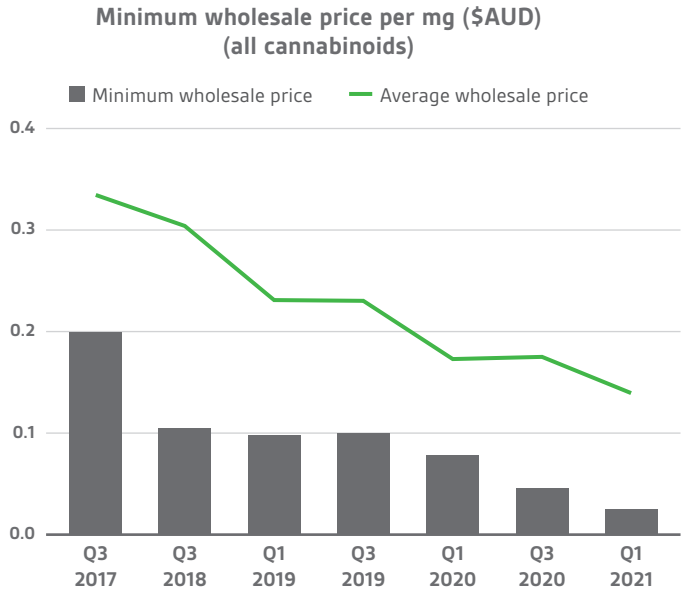
	Minimum retail price per mg by product formulation $AUD				
	Balanced	CBD Isolate S4	High CBD	High THC	THC Isolate
H2 2020	**0.11**	**0.06**	**0.06**	**0.16**	**0.09**
H1 2021	**0.11**	**0.03**	**0.05**	**0.11**	**0.08**

Price drops can be observed across almost all product formulations, with a notable drop for High THC products and CBD Isolate S4 products. Balanced products are the only group which has not experienced a drop in floor price, holding steady at $0.11/mg.

It should be noted that of the 190 products on the market, 35 (or 18%) have a retail floor price below $0.10/mg[7].

Wholesale pricing

The minimum wholesale price – the price that a pharmacy pays to the manufacturer – has also decreased over the past six months and now sits at $0.025/mg, with an average price of $0.14/mg[8]. This follows steep declines over the past three years.



Low prices, however, do not necessarily translate into sales. FreshLeaf understands that a number of low priced products are failing to gain traction in the market. This could be for a variety of reasons: doctors could be concerned about the quality or efficacy of these products or are sticking with the tried and tested, or companies supplying these medicines have limited budgets which restrict doctor education and engagement activities.

[7] FreshLeaf Analytics Pricing & Patient Model
[8] FreshLeaf Analytics Pricing & Patient Model

FreshLeaf's qualitative research with prescribing physicians reveals that after doctors have completed their clinical assessment, a patient's need to drive (affecting the suitability of products containing THC) as well as price are the key decision making factors in determining which product to prescribe. With a growing number of products available for patients, physicians are likely engaging in satisficing behaviour: prescribing the cheapest and most suitable product they are aware of, not the cheapest product on the market.

Physicians are time poor and may not have the time or inclination to learn about every new product that enters the market. It is also worth noting that during our research doctors have commented that trying new delivery formats can feel risky. The challenge therefore for product companies lies in thinking creatively about strategies for raising awareness of new products (particularly within strict regulatory guidelines) and helping physicians understand why their product is better than other product on the market.

Regardless of which factors are at play, it presents an interesting dilemma for the industry - introducing low priced products does not guarantee success.

Subsidy landscape remains unchanged

The Pharmaceutical Benefits Advisory Committee (PBAC), the body that decides whether Australians can have certain medicines subsidised by the taxpayer, have not yet handed down their final decision on subsidising Epidyolex (a medicinal cannabis product used to treat children suffering from rare forms of epilepsy) after deferring the decision in August 2020. The committee concluded that further clarity on the clinical place of CBD in therapy was required and that consultation with stakeholders regarding the role of CBD in treatment was required to inform the appropriate initial and continuing restriction criteria, cost-effectiveness and financial implications of listing cannabidiol. The PBAC also noted that while there is a clinical need for additional effective and safe treatment options the magnitude of the benefit of CBD was uncertain[9].

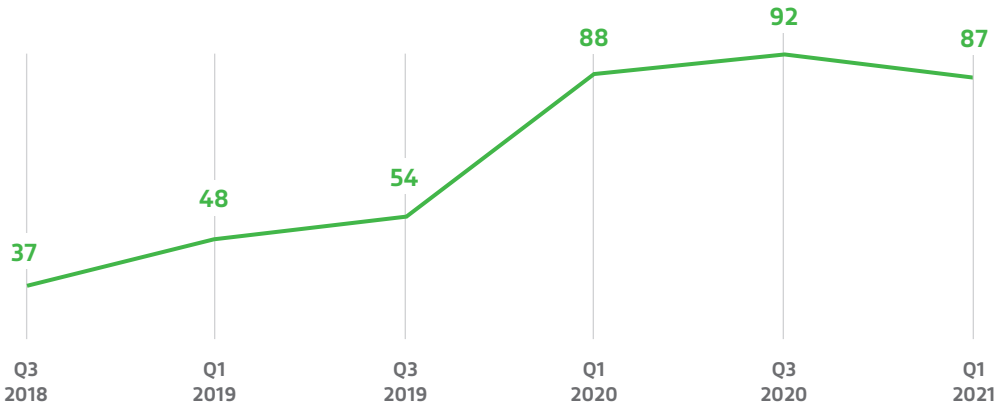
If approved, it would be a significant milestone for patients and industry alike. Sufferers of Lennox Gastaut or Dravet Syndrome would pay a maximum of $41 per month for the medicine, a saving FreshLeaf calculates at well over $1,000 per month based on the large amounts of cannabinoids needed to treat these conditions.

[9] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2020-07/deferrals-07-2020.pdf

4.0 Patient spend and dose

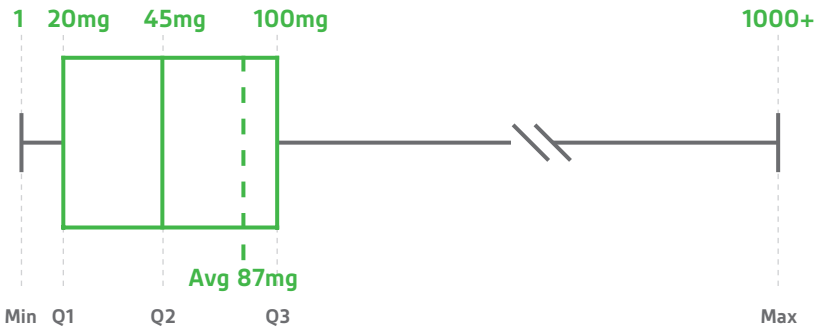
While previous FreshLeaf reports have shown that average dose increases over time, this trend appears to be stabilising as the market matures. The average daily dose is now 87mg[10].

Patient average daily cannabinoid dose (mg)



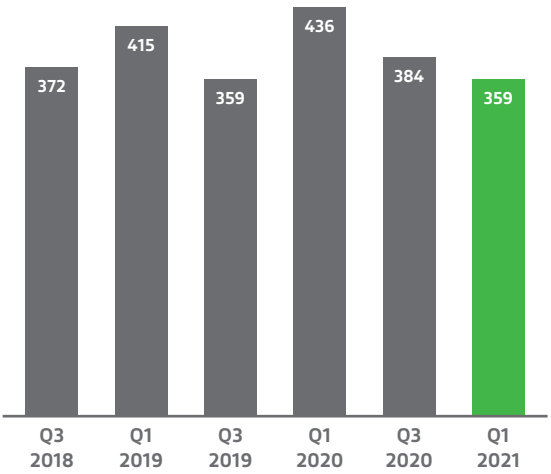
Also unchanged since our last report is the fact that the dose curve is positively skewed, meaning that the majority of patients have much lower doses than the average. FreshLeaf analysis of patient reported dose data suggests that three quarters of patients' daily dose remains at less than 100 milligrams per day.

Daily dose box plot mg/ day (patient reported)



Patient spend over the past three years is flat with patients now spending, on average, $359 per month or $0.14/mg cannabinoid[11].

Average monthly spend ($AUD)



[10] FreshLeaf Analytics Dosing & Indication Model
[11] FreshLeaf Analytics Dosing & Indication Model

5.0 Low-dose CBD

The Therapeutic Goods Administration (TGA) reached a final decision in December 2020 to down schedule low-dose CBD (with a maximum dose of 150 mg/day). These medicines are now Schedule 3 (S3) and are legal to purchase over-the-counter in a pharmacy without a prescription subject to certain conditions (for example, products must be oral, oral mucosal or sublingual and with no more than 30 day supply in a pack).

The down scheduling of low-dose CBD has been a frustrating milestone for the medicinal cannabis industry and patients alike. While the ability to legally buy a medicinal cannabis product without prescription is undoubtedly the most significant thing to happen in the Australian market since the legalisation of medicinal cannabis, the onerous path to market has resulted in frustration for patients who are unable to access products over-the-counter in pharmacies, and for medicinal cannabis companies who are navigating an expensive and time consuming process to get products on shelves.

S3 products are not available through Special Access or Authorised Prescriber pathways and must be approved by TGA and included on the ARTG before they can be supplied. This has created a sizable challenge for organisations pursuing S3 registration as applications must be supported by data demonstrating the quality, safety and efficacy of the medicine.

S3 should ultimately improve patient access to low-dose CBD products and attract new patients, for example, those who have been curious about CBD but reluctant to try it, or those who have been accessing low-dose CBD products through black market channels. Its presence in pharmacies is also expected to help legitimise medicinal cannabis more broadly.

Impact on the market

FreshLeaf estimates that the pharmacist only CBD market in Australia will grow to $250m in product sales at market maturity, capturing around 2 million consumers[12].

Today, almost 1 in 4 medicinal cannabis patients take a CBD product at a daily dose below 150mg, spending an average of $8.02 per day[13].

FreshLeaf expects that this patient cohort will migrate to the pharmacy channel once low-dose CBD products become available over the counter meaning that the first product/s to hit the S3 market will take the lion's share of this group – around 10,000 patients spending almost ~$29M a year.

Around 1 in 5 products currently available fit the product profile for Schedule 3 low-dose CBD (dose up to 150mg/day, oral/ oral mucosal/ sublingual, no more than 4,500mg cannabinoids per pack). The average unit price of these products is $193 – a price point that is unlikely to be attractive for an over-the-counter product. It is likely that we will see smaller, more accessibly priced units as a key feature of this category.

As outlined earlier in the report, we have begun to see evidence of low-dose CBD products leaving the market and it is conceivable that the S4 product category could rapidly shrink to a dozen or so products. FreshLeaf expects that once Schedule 3 products become available, more manufacturers will exit this category as not all companies will be able to register their product, or they may be too late to market with few patients left accessing low-dose CBD through the unapproved pathway. Speed to market will be a critical competitive advantage for those looking to tap into this new and lucrative market.

[12] FreshLeaf Model assessing CBD penetration of US and UK populations applied to Australian context
[13] FreshLeaf Analytics Dosing & Indication Model

Impact on the green market

While the size of the illegal low-dose CBD market is difficult to analyse, it is anticipated that most of those who have been accessing low-dose CBD through these channels will transition to pharmacies. This shines a light on impending challenges for green market operators as patient access to medicinal cannabis becomes easier and more convenient, and there is a sizable market at stake.

The National Drug Strategy Household Survey 2019[14] revealed that only 3.9% of those who used cannabis for medical purposes obtained it by prescription. They further reported that 600,000 Australians are believed to be using cannabis for medicinal purposes. When you consider there are currently 45,000 patients actively accessing medicinal cannabis through legal channels, that leaves a substantial 555,000 who are obtaining medicine illegally.

The CAMS18 survey[15] reported median spend on illicit cannabis was $50 per week. Applying this spend to both the legal and illegal patients groups across a year would indicate total market revenue today could be as high as $1.5B per year.

The test for the legal industry is transitioning as many of these 555,000 patients who are still accessing medicinal cannabis illegally to legal channels. The challenges are many: regulatory hurdles, stigma, doctor education and willingness to prescribe, patient awareness and experience, and of course price.

[14] https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey-2019-in-brief/contents/summary
[15] https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-020-00377-0

6.0 What's next?

In our last report, FreshLeaf remarked that 2021 would be a pivotal time for the legal cannabis industry in Australia, bringing industry consolidation and changes in the regulatory, product and pricing landscape. These shifts are beginning to take shape: multiple regulatory changes are underway impacting patient access and product quality, there has been a flurry of M&A activity, and some industry players have altered their focus in the value chain as the market begins to move away from vertical integration.

Evolution of the regulatory landscape

In March 2021, the Australian Government published its response to a Senate enquiry into barriers to patient access to medicinal cannabis in Australia[16]. A total of 20 recommendations were made including education and resources for medical practitioners, amendments to patient approval pathways, and activities aimed to reduce the administrative burden associated with medicinal cannabis.

Half of the recommendations were accepted or accepted in part and we can expect that in 2021 we will see changes to the SAS-B authorisation pathway, potential reforms to the Authorised Prescriber Scheme, additional ongoing funding of $1.7m for the ODC, changes to the medicinal cannabis license and permit system, and possible changes to the Medicare Benefits Scheme for primary care.

While the regulatory environment continues to evolve, questions have been raised about the pace at which the industry is moving forward, with concerns that if regulatory frameworks continue to change slowly Australia may miss its opportunity to become the gateway to the medicinal cannabis industry in Asia. Australia has much to gain from taking a pharmaceutical approach to medicinal cannabis although it brings with it the challenge of balancing pharmaceutical rigour with speed so that the industry matures in strides.

Greater emphasis on product quality

Manufacturing standards will be a key focus for the medicinal cannabis industry in 2021. A review of manufacturing standards on imported products is underway with the Department of Health (DOH) as part of a wider set of potential reforms to medicinal cannabis manufacturing, labelling and packaging requirements[17]. The proposed reforms seek to address inequality in the GMP requirements for products manufactured in Australia versus products imported from overseas as well as address quality concerns in compounded medicinal cannabis products. While the public consultation period for reforms has concluded, the outcome of the review has not yet been announced. A number of options for imported products are under consideration. Whatever the outcome of this review, imposing GMP standards on imported products will likely affect the number of products we see in the market and potentially also the pricing of products.

Outside of the review by the Department of Health, medicinal cannabis companies are coming to grips with the manufacturing data requirements for registering a Schedule 3 medicine. This includes a requirement for GMP manufacturing in a facility that is certified by the Therapeutic Goods Administration.

[16] https://www.odc.gov.au/sites/default/files/australian-government-response-senate-community-affairs-references-committee-report.pdf
[17] https://consultations.health.gov.au/medical-devices-and-product-quality-division/medicinal-cannabis-reforms-2020/

Growing investment in research and development

The recent acquisition of GW Pharmaceuticals by Jazz Pharmaceuticals for an eye watering US$7.2B[18] and recent increases in the valuation of ASX listed medicinal cannabis companies who are pursuing a registered pharmaceutical product pathway has drawn attention to the market value of owning products that are protected by IP and are registered or on the path to being registered.

With growing interest in cannabinoid therapies, 2020 appeared to be a record year for research into medicinal cannabis across a range of indications covering most aspects of the research pipeline – from preclinical research and veterinary medicine, to systematic reviews and analyses[19]. FreshLeaf anticipates that growing investment in research & development will continue throughout 2021, driven by substantiation of the commercial advantages of pursuing a product registration strategy, as well as clinical research requirements for registering a Schedule 3 product.

A flurry of market activity

2020 saw mixed results for medicinal cannabis companies and is best described as turbulent for the industry's largest players with a shuffling of the top 20 listed firms by market cap in comparison to 2019.

Developments have also been seen at the business and operational level including refined business models, improved manufacturing capacity, new production facilities, introduction of new technologies and the arrival of new players, which bodes well for 2021.

FreshLeaf's prediction that 2021 will bring industry consolidation is also coming to life with recent M&A activity including acquisitions by Auscann (acquired CannPal Animal Therapeutics), ECS Botanics (acquired Murray Meds and Flowerday Farms), Releaf (acquired Cannoz) and Cann Group (acquiring Satipharm). We expect these trends to continue throughout 2022 as the market further matures and consolidates around the major players.

[18] https://www.odc.gov.au/sites/default/files/australian-government-response-senate-community-affairs-references-committee-report.pdf
[19] https://consultations.health.gov.au/medical-devices-and-product-quality-division/medicinal-cannabis-reforms-2020/

About FreshLeaf Analytics

FreshLeaf Analytics is the leading supplier of data about 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.

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Real Data. Real Analysis. Real Results.

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