



# FreshLeaf Analytics

## Australian Medicinal Cannabis Market **Patient, Product and Pricing Analysis**

Q3 2020



*Real Data. Real Analysis. Real Results.*

- » **Industry revenue** expected to grow 3x in 2020 to ~\$95M
- » **Number of available products** has doubled in the last year to 150
- » **Largest YOY drop in price** since inception of legal industry
- » **20% of products available are low-dose CBD**, a category that is likely to move to over-the-counter in 2021
- » **NZ going to the polls** to vote on legalisation for adult use
- » **2021 likely a turning point** in defining what a 'healthy' industry looks like

## Summary

Our Q3 2020 report is FreshLeaf Analytics' fifth market report on patients, products and pricing in the Australian market.

### Key highlights include:

- » The market has grown 3x year on year and will close 2020 with around 30,000 active patients, equating to almost \$95M in product sales.
- » The number of products available for doctors to prescribe has reached 150, up from 100 in our previous report.
- » Product prices have continued their downward trend, registering a new floor price that is only one-quarter of the level in 2017, our first year of analysis.
- » Recent price decline has brought the illegal and legal markets to parity and has put us in line, from a pricing perspective, with more mature markets such as Canada.
- » Patient doses have continued to rise as price has decreased, while average spend remains static.
- » It seems likely that CBD will be down scheduled to over-the-counter S3 although serious questions remain about product companies' ability to demonstrate efficacy at low doses.
- » FreshLeaf expects that in 2021 the prescription market for medicinal cannabis in Australia will generate in excess of \$150M in sales.
- » New Zealand goes to the polls on October 17th to vote on legalising medicinal cannabis for adult use, a watershed moment for the region.
- » COVID-19 has not significantly impacted sales, although FreshLeaf speculates it may drive a need for new taxable revenues, leading to discussion about legalisation in Australia for recreational use.

# 1.0

## Market Growth

### Industry grows by 3X in 2020

The Australian medicinal cannabis market has continued to show consistent, strong growth through 2020.

### Patient numbers

The most commonly cited metric of growth is SAS-B approval numbers. SAS-B approvals have overcome a somewhat stagnant period in late 2019 / early 2020 and are once again showing strong increases - apart from a short dip in April, an impact of COVID-19 containment measures. FreshLeaf expects that 2020 will close with around 60,000 SAS-B approvals (up from 25,000 in 2019).

SAS-B approval numbers, while cited regularly, have increasingly become an unreliable estimate of market activity. Patients have multiple SAS-B approvals - 2.3 on average - and alternative pathways such as Pharmacy Compounding and Authorised Prescribers (which allows a doctor to write a prescription for a product without patient-by-patient approval) are increasingly contributing to market numbers.

In the first half of 2020 there were a reported 2,343 new patients added by Authorised Prescribers, representing more than 10% of the net new patients added in this period. Pharmacy-compounded patient numbers are not routinely reported and growth via this channel is anecdotal.

The most meaningful metric of market size is active patients - those who have seen a doctor or taken a prescribed medicine in a given month. As of the end of Q3, FreshLeaf estimates the number of active patients in the market, reflecting all access pathways, to be at around 25,000. Based on the current growth rates, FreshLeaf anticipates there will be more than 30,000 active patients in the market by the end of 2020. This is a significant jump - 3X - up from just over 10,000 in December 2019.



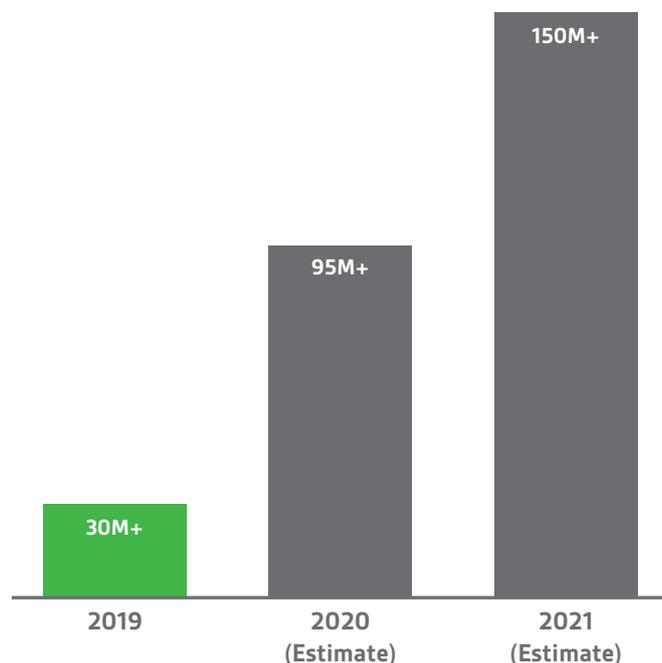
## Market volumes and sales

At the most fundamental level, the cannabis value chain starts with cultivation of raw material, and many companies in Australia and overseas have staked their future on the ability to produce this material for manufacture into products. In this context, insights about raw material values, land under cultivation and, obviously, product revenues become important.

Based on typical dosage and product profiles (discussed later), the active patients in 2020 will consume approximately 1.5 tonnes of cannabinoid API (Active Pharmaceutical Ingredient - pure CBD or THC molecules used to make a finished product). Growing the plants to generate this amount of cannabinoid API unsurprisingly, does not require a lot of space. Assuming standard plant potencies and extraction efficiency less than 1 hectare of indoor greenhouse space would be needed to supply all the cannabinoids used in the legal Australian market in 2020<sup>1</sup>.

Despite the small sounding volume numbers, the dollars are rising. Active patients will spend around \$95M on products this year, up from just \$30M in 2019.

**Australian medicinal cannabis market – revenue (AUD)**



<sup>1</sup> Assumptions 0.3 kg dried flower yield per per sqm, 4 growing cycles pa, 14% API extraction yield

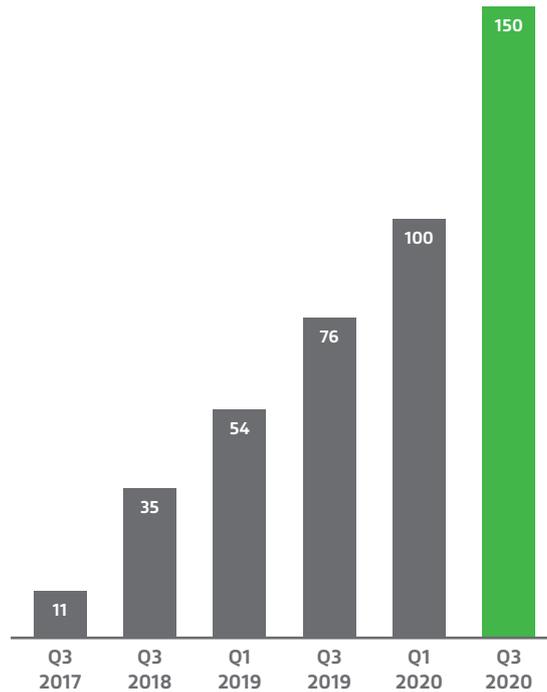
# 2.0

## Product analysis

### Number of products double in last 12 months

The number of available products continues to jump, and in the last six months alone we've seen a 50% increase with 150 products now on the market. Should this growth trajectory continue, we could expect to see over 300 products available to doctors at the end of 2021.

Number of medical cannabis products available in the Australian market

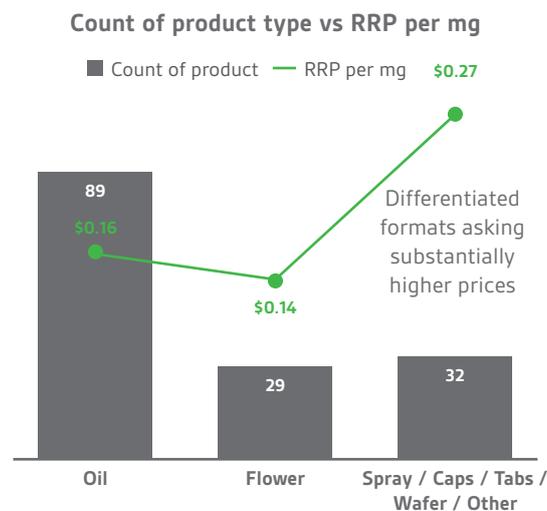


It's difficult to identify other prescription categories with such a wide range of choice and with such a large number of companies fighting for a piece of the pie. FreshLeaf analysis identifies 37 companies vying for a share of less than 100,000 prescriptions this year. Compare this to the opioid market where 23 companies compete for 15 million scripts per year <sup>2</sup>. These data points certainly suggest the Australian cannabis market is saturated and that the current product growth trajectory is unsustainable. It would be reasonable to conclude that in the next 12-18 months we will begin to see a reversal in growth of prescription product numbers and consolidation in the number of players.

<sup>2</sup> <https://www.safetyandquality.gov.au/sites/default/files/migrated/5.7-Text-Opioid-medicines-dispensing-all-ages.pdf>

## Differentiated products formats continue to emerge asking higher prices

Oil and Flower product formats are still the most common, together representing around 80% of the products in the market. These products are also the most commoditised with average recommended retail prices substantially lower than other delivery formats. Since our last report, we have seen the entry of some new formats, namely Wafers and Patches, and together these newer delivery formats (along with Capsules and Sprays) are as a group asking, on average, double the price per mg. We do note that higher asking prices do not necessarily translate into higher sales or net margins - the performance of these products from a sales and profit perspective still remains to be seen.



## The rise of isolates, lower pack prices

While innovative delivery mechanisms emerge and ask higher retail prices, 2020 has seen a proliferation of CBD isolate oils which are classified as Schedule 4 because of their low presence of other cannabinoids. There are now an overwhelming 36 products to choose from in this category, the largest category on offer.

CBD isolates are cheap because they are usually extracted from hemp grown on an industrial scale and that low price, along with less risk of failing roadside drug tests, makes them popular among doctors and patients.

Interestingly of these S4 CBD products, 17 (almost half) already meet the proposed dose requirements for over-the-counter CBD which are capped at 60 milligrams per day and 1800 milligrams per pack / unit. These products would be well positioned to take advantage of new proposed regulations down-scheduling CBD to an over-the-counter medicine (see section later in the report on this subject).

# 3.0 Price

## A race to the bottom on price

The price war is escalating and the last year has brought the largest drop in price since the inception of the legal industry in Australia with the minimum recommended retail price sitting at around 6 cents per milligram. This is only 25% of where market pricing sat 3 years ago at the dawn of the industry - a huge benefit to consumers and a clear example of market forces, not regulation, being successful in driving prices down.

There are now sub-10 cents per milligram products in all product formulation categories except balanced and high THC products, where the minimum price sits at 11 and 16 cents per milligram respectively.

Minimum retail price per mg by product formulation AUD				
Balanced	CBD Isolate S4	High CBD	High THC	THC Isolate
0.11	0.06	0.06	0.16	0.09

Examining wholesale price - the price that a pharmacy pays to the manufacturer - we see prices falling aggressively across the past 6 months with cheapest products coming in under 5 cents per milligram - less than half of where the market sat 12 months ago and one quarter of where the market started in our first year of analysis.



No segment of the market has been untouched by intense pricing competition and we have seen almost one third of all products in the market hit by price cuts in the past 6 months.

## Australia on par with Canada

In previous reports we have compared the Australian market to the Canadian market to get a sense of where we sit relative to international pricing.

Our research team did a random sample of 30 Canadian products and found the minimum retail price to be 6 cents Canadian per milligram - on par with the Australian minimum. The Canadian market is well known to be suffering from massive oversupply at the moment, resulting in dumping of soon-to-expire products at steep discounts.

Australian pricing dropping to similar levels is great for patients but the 'race to the bottom' raises questions about industry sustainability. It is highly likely that some players will not have forecast such rapid and aggressive falls in market price, and will not have structured their businesses to operate profitably at these levels. FreshLeaf expects to see the effects of these declines filter through the market in the coming 6 months.

## The illegal market and legal market equalise

Pricing comparisons between illegal products, particularly Oils or Capsules, and the legal market are challenging because of the difficulty of knowing what an illegal product contains.

Illegal products (also known as "green-market" products) may not have a label, may not have any quantities in their description, or may have vaguely defined ingredients (1 gram of "cannabis extract"). Even the most robustly described illegal products that claim "100 milligrams of THC" are unlikely to have been assayed with a valid method to determine whether the label claim is correct.

Noting the above challenges the FreshLeaf team attempted to analyse pricing of 30 illegal products that contained written descriptions of contents and that were being promoted to Australian patients in Q2 2020. We interpreted descriptions of quantities (such as "extract", "essence", "oil") as measures of pure cannabinoids, so if an illegal product claimed to contain 1 gram of "extract" we compared it to the cost of 1 gram of pure cannabinoids in a legal product.

Using this approach, we assessed the cheapest illegal products on the market to be 7 cents per milligram (of "extract"), slightly higher than the 6 cents per milligram (of pure cannabinoids) minimum for legal products.

The conclusion of this observation is startling - patients in Australia now have access to similarly priced Oil and Capsule products through both illegal and legal channels even when we optimistically assume for comparison purposes that the illegal product has a label claim and that label claim is valid and accurate.

## Could we be on the precipice of a change in the subsidy landscape?

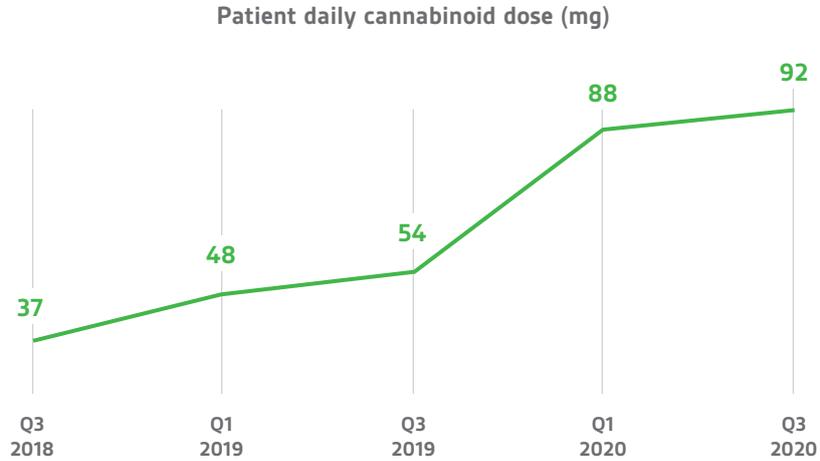
Despite legal medicinal cannabis prices tumbling to an all time low and moving to parity with the illegal market, patients often perceive prices to be high because they are not subsidised. This may be about to change.

The Pharmaceutical Benefits Advisory Committee (PBAC), the body that decides whether Australians can have certain medicines subsidised by the taxpayer, deferred a decision in August to subsidise Epidyolex, a medicinal cannabis product used to treat children suffering from rare forms of epilepsy. If approved, sufferers of Lennox Gastaut or Dravets Syndrome would pay a maximum of \$41 per month for the medicine, a saving FreshLeaf calculates at over \$1,000 per month based on the large amounts of cannabinoids needed to treat these conditions.

Regardless of the PBAC decision, FreshLeaf expects Epidyolex to be included on the ARTG as a registered medicine soon, meaning that doctors will be able to freely prescribe it without further authorisations. This listing along with any decision to subsidise the medicine would be a significant milestone for the industry.

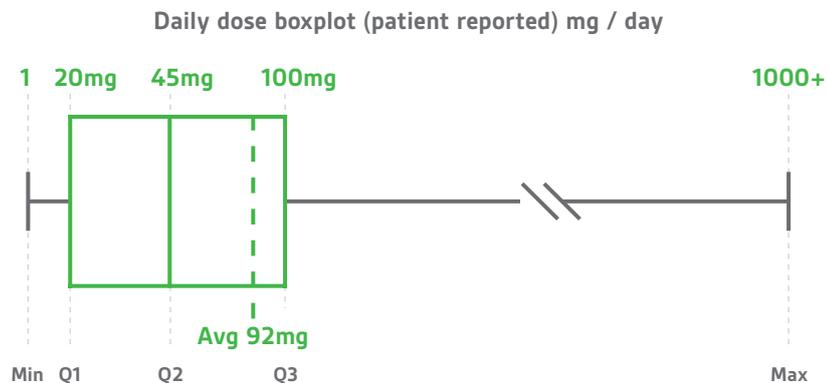
## Patient spend and dose

Previous FreshLeaf reports have shown that average dose increases over time, and this trend has continued in Q3 2020, with average dose increasing to 92 milligrams per day.



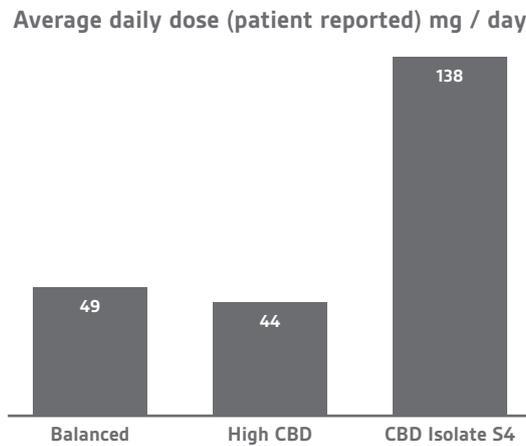
It is likely that this increase in dose is driven by a combination of lower prices which have previously been shown to drive patient dose intake <sup>3</sup>, as well as patients increasing titration levels over time.

A point of interest is 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 more than three quarters of patients daily dose at less than 100 milligrams per day. Perhaps more topically, almost 20% of patients take an S4 CBD product at less than 60 milligrams per day. This group would represent the number of patients who would no longer require a doctor prescription under potential CBD S3 down-scheduling regulations. This clearly has implications for product companies who will need an S3 CBD product to retain revenue from this segment of the market.



<sup>3</sup> FreshLeaf Analytics Q1 2020

Another aspect of dose which often becomes relevant in a clinical setting is whether different product types require different dosages. Specifically the question of whether an isolated CBD (S4) product that contains almost no other cannabinoids requires a higher dose than a high CBD product which contains other cannabinoids including THC. Interestingly when we look at dosage by product category, patients who are consuming CBD are taking doses at 2-3 times non-CBD isolate products.



It is critical to point out that clinical conclusions should not be drawn from these observations. Higher dose could be driven by lower price for CBD isolates, lower levels of side effects or other factors. Further research and analysis would be needed.

Dose taken by a patient, along with the product they purchase, determines how much they spend per month. When we cross reference dose with product price (retail price paid by patient to pharmacy), we see that, although dose has risen slightly, monthly spend has dropped to \$384 per month.



Similar to the analysis of **product price**, when we compare **patient spend** in the legal market with the illegal market we find that a tipping point has now been reached where patients purchasing legal medicinal cannabis are now spending about the same as a patient in the illegal space.

The CAMS18 survey<sup>4</sup> reported that illegal spend for patients who buy products is a weekly median of \$50 (Interquartile range: \$20, \$100) and the “willing to pay” amount for the illegal market is also a median of \$50 (Interquartile range: \$25, \$100). Comparing this to the legal market, the median for actual weekly spend is \$51 (Interquartile range: \$14, \$91). For the non-mathematically inclined, what all this means is that not only do legal patients spend about the same as illegal market patients, they also spend about what they say they would be willing to spend.

<sup>4</sup> CAMS18 Study

# 5.0

## What's next?

The next 12 months will be a pivotal time for the legal cannabis industry in Australia. There will undoubtedly be headwinds, particularly for loss-making product suppliers, yet FreshLeaf remains optimistic about the year ahead. While we expect the landscape could look substantially different to today we believe that changes will be for the better - improving patient access to high quality medicinal cannabis and aiding the long-term viability of the industry.

### What impact will CBD down-scheduling have?

The recent interim-decision from the TGA on Sept 9th reaffirmed the intention to make CBD a Schedule 3 medicine. Subject to final decision on November 25th, from June 2021 companies will be able to apply to register products in doses up to 60 milligrams per day (1800 milligrams per pack) for sale over the counter in pharmacies. This will be the most significant thing to happen in the industry since the legalisation of medicinal cannabis.

There may, however, be a catch. The traditional registration pathway for Schedule 3 requires efficacy data that will be challenging to produce for CBD at a 60 milligram dose. This raises substantial questions around the ability of any company to successfully register its products, even if the regulatory pathway exists. FreshLeaf is working with our clients and the TGA to better understand the type and quality of efficacy data that the TGA will require for low-dose CBD registration applications.

Assuming products can be successfully registered and made available to patients, FreshLeaf estimates the addressable market for low dose CBD to be substantial. Based on the trajectory of the UK CBD market where products are available in pharmacies (albeit front-of-shop and with marketing authorisations) Australian patient numbers could quickly exceed 2M people and generate \$200M in revenue<sup>5</sup>.

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<sup>5</sup> Market research shows that **9% of people** (YouGov, Aug'19) in the UK have used a CBD product  
Market size is estimated over £300 million meaning average annual expenditure per person is AUD ~\$96 (CMCUK, Jun'19)  
For Australia, that would equate to **2.25 million consumers** spending more than AUD **\$200 million per year**

## What about New Zealand?

FreshLeaf estimates that the New Zealand market is expanding at a compound monthly growth rate of 6.3% and will generate close to NZ\$10M of revenue in 2020.

New Zealand has followed a regulatory approach that is slightly different to Australia but maintains a focus on existing pharmaceutical and healthcare regulations. New Zealand's Medicinal Cannabis Scheme came into effect 1 April 2020 with the aim of improving access to quality products for patients. Under this scheme medicinal cannabis products are available following prescription by a doctor of a product that has been verified to meet minimum quality standards. Products broadly fall into three categories: CBD products, other medicinal cannabis products that are approved (of which there is only one - Sativex®), and unapproved medicinal cannabis products for which Ministerial approval must be granted for a named patient.

The next milestone for the industry in New Zealand is the Cannabis Referendum scheduled to take place alongside the general election on October 17, 2020<sup>6</sup>. People in the cannabis industry around the world are waiting with great anticipation to learn whether New Zealanders will vote in support of the Cannabis Legalisation and Control Bill. The Bill is a regulatory model that covers how people can produce, supply or consume cannabis. It would allow a person aged 20 or over to enter a licensed premises where cannabis is sold or consumed, buy up to 14g of dried cannabis (or equivalent) per day from a licensed premises, consume on private property or at a licensed premise, and grow up to 2 plants (with a maximum of 4 plants per household). Limits will be placed on potency and there will be licensing and production caps, for example no license holder will be able to hold more than 20% of the cap on the amount of cannabis available for sale in the licensed market. In deciding how to allocate portions of the cap, the degree to which businesses meet social principles such as building community partnerships, promoting employment opportunities and career pathways will be considered.

Interestingly, New Zealanders will also be given the opportunity to vote at this time on an End of Life Choice referendum which is an Act that would give people with a terminal illness the option of requesting assisted dying. It is unclear whether the coupling of this referendum with the Cannabis Referendum will have a negative impact due to greater mobilisation of conservative groups.

At the time of writing, polls suggest the outcome of the Cannabis Referendum could go either way with the 'Yes' vote leading by a very narrow margin<sup>7</sup>. The economic argument is a compelling one with The New Zealand Institute of Economic Research calculating that legalisation in New Zealand could result in NZ\$490M in tax revenue per year<sup>8</sup>. It should be noted that the economic benefits will take time to realise. Should 'Yes' achieve more than 50% of votes, recreational cannabis wouldn't become immediately legal although the incoming Government would be in a position to introduce a Bill to Parliament that would legalise and control cannabis. This is a process that takes time. If it comes to pass, FreshLeaf expects licenses to be hotly contested and the first products to be available no earlier than 2022.

<sup>6</sup> <https://www.referendums.govt.nz>

<sup>7</sup> <https://www.drugfoundation.org.nz/news-media-and-events/poll-shows-support-more-information/>

<sup>8</sup> [https://nzier.org.nz/static/media/filer\\_public/68/bc/68bc4d23-bf82-4c9e-b3ef-09d540ff1442/nzier\\_wp\\_2020-01\\_cannabis\\_referendum\\_paper.pdf](https://nzier.org.nz/static/media/filer_public/68/bc/68bc4d23-bf82-4c9e-b3ef-09d540ff1442/nzier_wp_2020-01_cannabis_referendum_paper.pdf)

## Could COVID-19 cause Australia to reconsider its position on legalisation of cannabis for recreational use?

Australia is watching the New Zealand referendum closely as many in the industry believe a positive outcome in New Zealand will encourage Australia to look more deeply at legalising recreational use of cannabis. While going back a few years this was a hot topic for debate, conversations seem to have dampened and there has been firm protest from government agencies such as DHHS as well as the Minister for Health. The cannabis conversation in Australia has instead centred around improved access through healthcare channels and the pharmaceutical framework designed to improve product quality and safety for those who wish to use cannabis for medical purposes.

FreshLeaf speculates that with the social and economic challenges brought on by COVID-19 this may change.

No industry has been left untouched by COVID-19 and the impact on the cannabis industry has been fascinating to watch. Players in the Australian market were impacted, but the effects were minimal and short term for most. Product companies and clinics FreshLeaf spoke to reported monthly declines of 10-30% in Q2 mostly due to patients being unable or unwilling to visit doctors during lockdown or product supply chain disruptions impacting ability to fill scripts. Most market players have recovered to pre-COVID levels by the time of this report.

In an environment where countries around the world are grappling with how to stimulate economic recovery from COVID-19, the social and economic argument for the legalisation of recreational use of cannabis is compelling. Australia is in recession for the first time in 30 years and it has been reported that the number of unemployed people across the nation will soon exceed 1.3M. Furthermore the government budget deficit is heading to a new record peacetime high with an underlying budget deficit of \$85.8B in 2019/20 and \$184.5B in 2020/21<sup>9</sup>.

The government will need to focus on job creation and find new sources of revenue and, as evidenced in the USA, the cannabis industry has the ability to make a significant contribution. The state of Colorado, for example, has recorded US\$1.4B in tax revenue<sup>10</sup> from medical and retail cannabis since 2014. Additionally, it has been reported that the cannabis industry employs over 240,000 people in the US with a 15% year-on-year increase<sup>11</sup> making it one of the fastest growing industries in America.

Looking at tax revenue generated by the cannabis industry around the world, it wouldn't be unreasonable to conclude that legalisation of cannabis for recreational use in Australia would produce tax revenue in the billions. It would be intriguing to see the results of an economic model assessing these benefits.

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<sup>9</sup> <https://www.lowyinstitute.org/publications/costs-covid-australia-economic-prospects-wounded-world>

<sup>10</sup> <https://www.colorado.gov/pacific/revenue/colorado-marijuana-tax-data>

<sup>11</sup> <https://www.leafly.com/news/industry/243700-marijuana-jobs-how-many-in-america>

## 2021: Redefining what a healthy medicinal cannabis industry looks like in Australia

FreshLeaf anticipates that 2021 will be the year for re-evaluating what a healthy medicinal cannabis industry looks like in Australia.

So, what comprises a healthy industry? Our view is that it's an industry that enables informed patients to easily access high quality medicinal cannabis products that meet mild to severe medical needs at the best possible price. It's an industry that isn't weighed down by innumerable commoditised products but instead makes it easy for healthcare professionals to understand the safety and efficacy evidence supporting available products so they can differentiate between them and feel equipped to have informed and informative conversations about treatment options with patients.

Yet this alone isn't enough.

In order to make this happen, industry players across the value chain need business models that generate healthy profits that can be reinvested in research & development, clinical data, new innovative formats, job creation, technology, and patient and HCP experience that's centred around meaningful education.

It's FreshLeaf's view that the above will not only help drive the industry forward for the benefit of patients but will result in an industry that can sustain itself over the long-term. We believe that 2021 will bring industry consolidation and changes in the regulatory, product and pricing landscape that will help make this happen.



## Methodology

The FreshLeaf Q3 2020 product, pricing and patient analysis was based on data collected in the period July and August 2020.

The team collected product and pricing data in July and August from 37 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 15th August 2020 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 1000 patients seen at the clinics during June and July 2020.

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

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



## 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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