




FreshLeaf
Analytics

Australian Medicinal Cannabis Market
Patient, Product and Pricing Analysis

Q3 2019



Real Data. Real Analysis. Real Results.

- 
- » **Number of products** in market jumps 40% in 6 months
 - » **Patient growth continues** at break-neck speed, up 1000% year on year
 - » **Overall spend declines** as doctors go for cheaper products
 - » **Issues around vehicle driving** and government subsidies remain

Summary

This is Southern Cannabis Holdings company FreshLeaf Analytics' third report on patients, products and pricing in the Australian market.

Our Q3 2019 report is the most comprehensive review of the marketplace to date, the product of two-and-a-half years constantly and cumulatively tracking data.

We have found that the number of new products available has jumped by 40% in just 6 months, with Australian doctors now having a choice of 76 products to prescribe from.

The good news for patients is that while the product prices have stabilised, the greater availability of cheaper products has resulted in overall lower monthly costs for the patient.

One obstacle to costs coming down even further remains – the lack of federal government subsidy, via the Pharmaceutical Benefit Scheme.

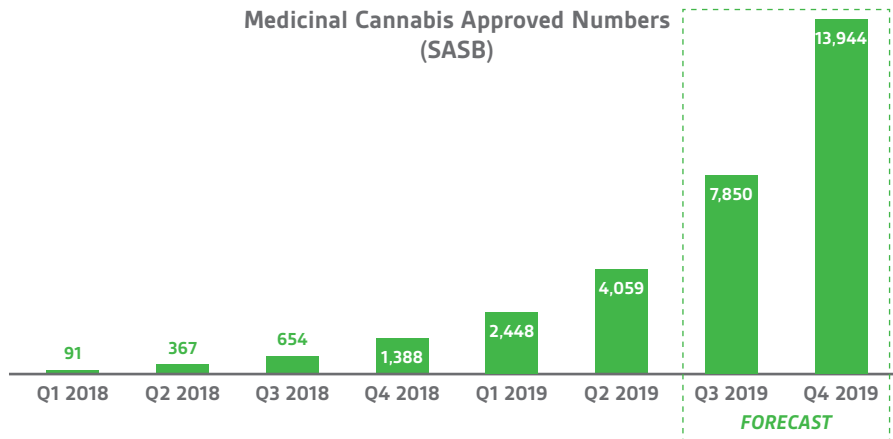
Driving regulations also remain a factor for both doctors and patients due to Australia's no-tolerance stance towards being tested for THC.

Patient growth continues at break-neck speed, but is still far from reaching its full potential, leaving a huge opportunity for product innovation, diversification and addressable patient outreach.

With the current trend in patient approvals, FreshLeaf expects the Australian medicinal cannabis industry to grow to around \$50 million of annualized revenue (products and services) by the end of the year.

Patient Approval Rate Up Over 1000% In 2019

In Australia, patient approval numbers for medical cannabis continue to explode. Towards the end of 2018, the Australian medicinal cannabis industry had its 'hockey stick' moment where approvals started to trend upwards rapidly. This trend has continued unabated through Q3 2019, with July alone seeing 40% growth month on month. FreshLeaf is now forecasting a total of 28,301 new patient approvals in 2019 – growth of 1023% on the 2500 approvals in 2018.



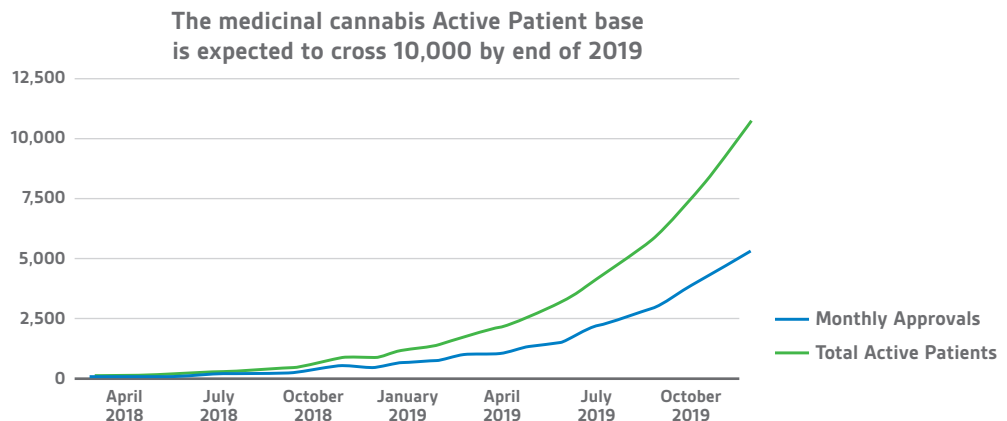
It is critical to note that these numbers reflect the TGA's reported 'SAS-B approval numbers', which is not the same as the number of **Active Patients** in the market.

FreshLeaf's analysis reveals that most patients will receive more than one approval due to a range of reasons, including:

- Doctor has changed medicine due to it not working, having side effects or patients being unable to afford the cost
- Product company had stock-out and doctor has had to re-apply for another approval (when popular products stock-out, we typically see a larger-than-expected jump in approval numbers)
- Patient's previous approval has expired (most approvals are for 6 months, with others given for 3 or 12 months). Interestingly, the majority of patients do not use their approval for its full duration, with most ceasing treatment or switching to another product before their approval ends.

FreshLeaf defines Active Patients as patients who have shown some measure of active treatment in the current month, including seeing a doctor, receiving a script or receiving a new or replacement approval.

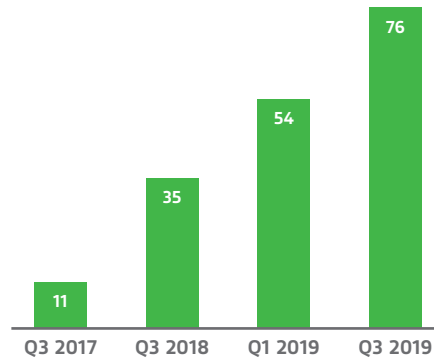
Based on this view of patient numbers we see the market as being less than 5000 Active Patients in July 2019, although growth rates are strong and we expect this number to double by the end of 2019.



Product Competition Intensifies. Again.

There are now 76 products available for doctor prescription in the Australian market – a jump of more than 40% from 54 confirmed by the FreshLeaf Analytics team in Q1 2019.

Number of medicinal cannabis products in the Australian Market

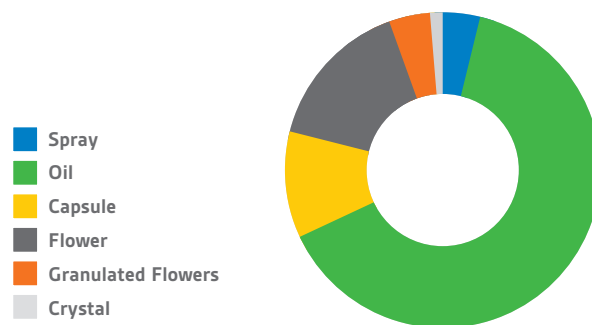


Oil still dominates the market as the primary delivery mechanism, comprising around two thirds of all product types in the market.

Product categories that have shown the most diversification are:

- Dried flower, which now offer 12 different product types, for the first time giving doctors a wide range of options for this delivery mechanism
- Capsules, with 8 product options, an increase from just 3 products at the start of the year.

Product types in the Australian market (Q3 2019)



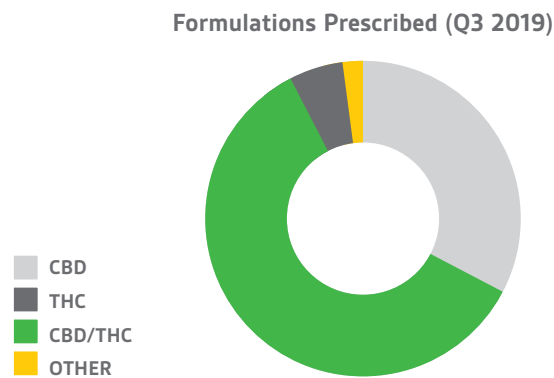
It is interesting to note that no new delivery formats have entered the market in the past 6 months, creating an opportunity for product innovation in areas such as sublingual strips, topicals, nasal sprays, patches or suppositories.

There are now 21 discrete brands available in Australia licensed by the Office of Drug Control (Australia's regulatory authority for medicinal cannabis import and production). Only one of these is cultivated locally while a few others are manufactured here using raw ingredients imported from overseas. We expect more Australian-made products to enter the market this year, although serious doubts remain about the ability of local cultivators / manufacturers to compete against low-cost imports of finished goods from large global suppliers.

A Comment On CBD

There has been much interest in the CBD market globally as sales of these products sky-rocket around the world in jurisdictions where CBD can easily be bought by consumers in pharmacies, retailers or online.

In Australia, CBD is still available only via doctor prescription and makes up around one-third of all prescriptions for cannabis-based medicine.



Doctors interviewed by FreshLeaf Analytics commented that they were more likely to prescribe CBD to patients as an “initial trial of cannabis medicine” before proceeding in some cases to products with higher levels of THC if desired results were not seen with CBD alone.

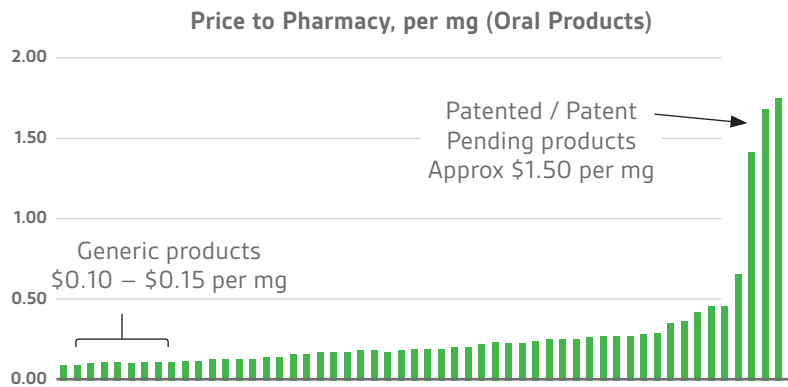
Driving regulations are also a factor in CBD prescriptions. Australian law takes a no-tolerance stance in terms of being tested for THC of any level, meaning it is an offence to drive with any amount of THC in the body, regardless of whether it has been prescribed or not. This can result in a disincentive for patients to take medicinal cannabis containing THC and lead to doctors prescribing CBD-only products even in situations where the patient may benefit more from products containing some THC.

A key question remains about where CBD will sit in the regulatory framework in coming years in Australia. In most markets around the world where CBD is legal, the regulatory framework regarding this cannabinoid allows broad access, either as a consumer product through retail channels, or as a nutraceutical product via pharmacy. This is true even in laggard, conservative markets such as the UK where regulations allowing access to THC were passed only last year, but CBD is widely available online and through retail channels. Given, however, that CBD does have a material physiological effect on the human body, unrestricted access may not be an acceptable scenario here in Australia, and a hybrid model where low-dose products are more freely available alongside high-dose products that require additional approvals or prescriptions may be worth considering.

Product Prices Have Stabilized

A point of note since FreshLeaf Analytics' last report in Q1 2019 is that patient monthly costs of medicinal cannabis appear to have stabilized. Minimum (\$0.10 per mg) and average prices¹ (\$0.23 per mg) for oral products have remained unchanged in the past 6 months.

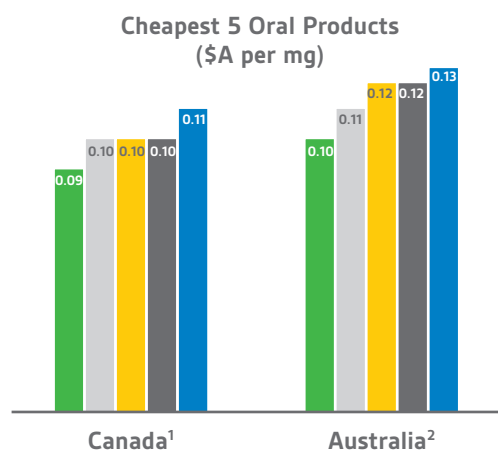
While prices vary significantly in the market (the highest cost products are 17X the price of the lowest), Australian doctors now have more products to select from in the low end of the pricing continuum.



The major reason behind this price differential results from companies that have adopted a purely pharmaceutical approach to the marketplace and invested in patents and clinical trials, vs those which manufacture high volume generic products with limited research backing and no defensible or substantial intellectual property. The 'generics' category represents the majority of players in the sector today although there are suppliers who are investing in research with a view to registering medicines with regulatory authorities, and others who have already done so. The most obvious example of an R&D-backed registered medicine is Sativex, a product supplied by UK company GW Pharmaceuticals. This is one of the few plant-based cannabis medicines on the Australian Register of Therapeutic Goods (ARTG), meaning it can be prescribed without special approval, although its high cost and lack of government subsidy means that it faces significant obstacles in the market.

So how does Australian pricing for medicinal cannabis compare with global markets?

A useful benchmark market for comparison is Canada, which has similar demographics and economic profile, albeit with a much larger and more mature medicinal cannabis market.



¹ <https://hmed.ca/cbd-oil-apr-25-2019/>

² Price to pharmacy. Pharmacy markup varies

¹ Price to pharmacy

When we compare the 5 lowest priced oils in both markets we see that Canadian suppliers sell products at around 16% cheaper in Australian dollar terms. This pricing differential would seem small given the additional overhead of shipping products to Australia and maintaining local supply chain, sales and support functions. One key difference that does emerge is the impact of pharmacy dispensing costs. While Canadian suppliers are permitted to sell directly to patients, Australia requires a pharmacy to dispense product. The additional overhead of this function adds on average 22%² to patient costs.

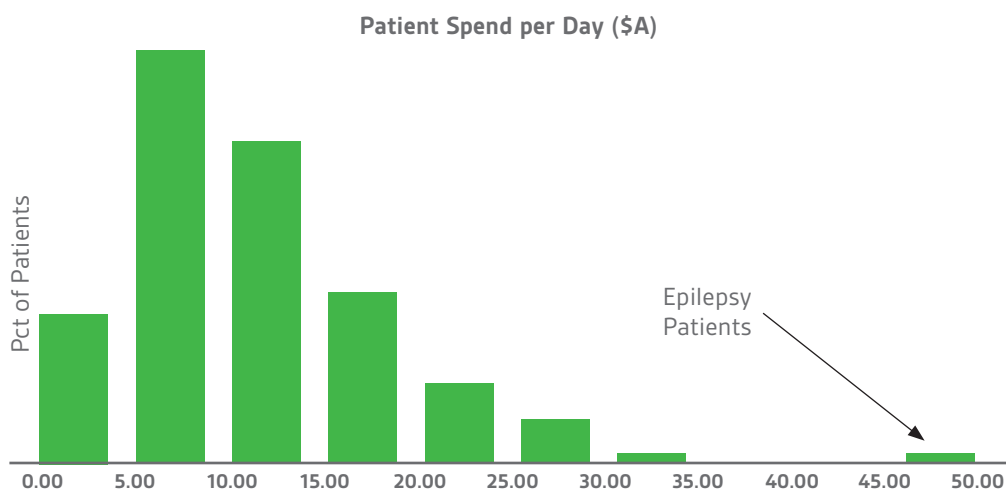
While oil-based products would seem quite well priced in Australia, the same does not apply to flower products. The increased number of flower products on the market have for the first time allowed us to do a meaningful analysis of pricing in this category. Prices for dried cannabis flower products in Australia range between A\$18 and A\$28 dollars per gram (price to pharmacy) – 2 to 3 times higher than Canadian prices for dried flower products, which are typically between \$A8–\$9 per gram. This substantial price differential would suggest this product category has potential for substantial downward pricing movement as our market matures.

The Cost To Patients

While price per milligram (for oils or sprays) or gram (flower) is a useful metric for comparing pricing of different products, it falls short in helping us consider the most important aspect of cost – the amount a patient has to pay to treat their condition.

In Australia, doctors typically prescribe using a 'titrate-up' model, meaning patients will start on a small amount of product and increase the dose gradually, monitoring for side-effects, until an optimal outcome is achieved. Since the optimal dosage varies substantially from patient to patient and from condition to condition, the amount a patient pays for treatment is also highly variable.

By analyzing dose and cost for a random sample of 100 patients, we have been able to determine typical costs for patients in Australia.



The most common spend range was \$5–10 per day accounting for around one-third of all patients. Based on the \$11 per day that the CAMS study³ determined as 'affordable', we find that around 55% of patients spend \$11 or less – suggesting most patients would find treatment costs acceptable.

As usual, we note that in Australia, medicines that are subsidized by the federal government (via the Pharmaceutical Benefit Scheme) are cost-capped in 2019 at approximately \$40.10 per prescription (\$6.50 per month for concession card holders). By comparison, any price points above these amounts will likely make unsubsidized medicine such as cannabis seem 'expensive' to patients.

² FreshLeaf Analytics Q1 2019 Pricing Report

³ <https://www.mja.com.au/journal/2018/209/5/medicinal-cannabis-australia-2016-cannabis-medicine-survey-cams-16>

Patients Spending Less

Average dosage rose slightly to 54mg per day (up from 47mg per day in the period 6 months earlier) – a modest rise of 15%. This is consistent with the titrate-up prescription model used by most doctors which will see higher average doses as the proportion of more long-term patients increases.

An interesting observation is that while dosages have risen slightly, average spend has actually declined in the past 6 months by an average of 13%.

Given that the price profile of products sold to pharmacy has remained fairly stable over the period, the FreshLeaf team believes that this patient price drop has been caused by doctors switching patients from higher-cost products to lower-cost products.



Market Forecasts: Enormous Runway for Growth

The Australian market has clearly overcome early obstacles to patient access and is now in a rapid growth phase. Over 2000 new approvals were issued in July, a jump over over 40% compared to the month before. We expect this trend to continue, and for the industry to grow to around \$50mil of annualized revenue (products and services) by the end of the year.

The proportion of the market being addressed, however, is still miniscule. With an estimated addressable market of up to 500,000 in Australia and a current market of only 5,000 Active Patients, only around 1% of the potential has been unlocked. This leaves an enormous runway for future growth as this multi-billion dollar industry unfolds.

However, FreshLeaf Analytics concludes that to move forward and realize the market's full potential, a few key issues need to be addressed:

Firstly, regulations pertaining to driving, and accurately assessing when a patient is fit to drive after dosing, need to move out of the grey and into the black and white. The current driving framework influences doctors' prescribing decisions and leads to many patients not receiving treatment or receiving CBD-only cannabis products that are clinically sub-optimal for their condition. Efforts and government engagement by industry stakeholders to address this issue are ongoing.

Secondly, for wide-spread adoption of CBD products, the pathway for accessing this category of product needs to become more streamlined. While we note that the impact of sustained high dosages of CBD over a long period needs to be studied more closely (and Australia with a pharmaceutical framework for cannabis, rapidly growing patient base, established clinical trials infrastructure, and strong R&D incentives would be a favourable location to do this work), there are far more dangerous medicines that are more easily available to Australians so the case for easing the pathway for CBD, at least, would seem to exist.

And finally, cost. Although patients are spending less on average, and many are spending an amount that could be seen to be 'affordable', for most patients, any amount above PBS thresholds will be seen as too 'expensive'. The Victorian Government, which currently supplies Canadian-made CBD product⁴ to a small number of children with epilepsy, has been vocal in urging the Federal Government to list medicinal cannabis products on the PBS⁵. However, as long as the major medicinal cannabis suppliers remain generics-product companies without exclusive patents or budgets for pharma-style clinical trials, this looks unlikely in the short term.

While patience will be required for these issues to resolve, companies operating in the right parts of the value chain stand to win big in coming years. With patient numbers now growing rapidly, and 99% of the addressable market still waiting to be accessed, the future looks exciting.

⁴ <https://www.premier.vic.gov.au/fast-tracked-medicinal-cannabis-for-kids-with-severe-epilepsy/>

⁵ <https://ajp.com.au/news/govt-urged-pbs-list-cannabis/>



Methodology

The FreshLeaf Q3 2019 product, pricing and patient analysis was based on data collected in the period June and July 2019.

The team collected pricing data in June and July 2019 from 30 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 product available in the market at the time of the analysis were included in the study. One supplier declined to provide data – this supplier is not known to be a major player in the market at the time of data collection. Product information and price were based on the suppliers reported list price to pharmacy, including shipping, for one unit (vial, packet etc) of product. Some suppliers offer discounts for larger volume orders, but these discounts have not been reflected in the analysis.

Anonymized patient product and dosage data were supplied through the Cannabis Access Clinics network and were based on a random sample of 100 patients seen at the clinics during July 2019.

About FreshLeaf Analytics

FreshLeaf Analytics is the leading supplier of data about the medicinal cannabis industry in Australia. We have access to medicinal cannabis product and clinical data sets from some of Australia's leading healthcare companies and organizations including healthcare clinics, pharmacies, product companies and the TGA. The FreshLeaf team provides custom research, analysis and consulting services in the Medicinal Cannabis market in Australia.

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FreshLeaf Analytics is a division of Southern Cannabis Holdings, Australia's leading vertically integrated pharmaceutical cannabis business with interests in market intelligence, clinical research, medical services and supply chain operations.



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Real Data. Real Analysis. Real Results.

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