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FreshLeaf  
Analytics

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

Q1 2019



*Real Data. Real Analysis. Real Results.*

- » **Products in market increase** substantially, up over 500% year on year
- » **Pricing continues to fall**, but CBD has hit a floor
- » **Patient monthly spend up 11.5%**, driven by increased dosages
- » **15,000-20,000 new patients** to enter the market in 2019

## Summary

It has been 18 months since the team at FreshLeaf Analytics started tracking products, patients and pricing in the Australian market.

Our Q1 2019 report is the most comprehensive review of the marketplace to date, giving insight for the first time into new metrics around product floor prices, revenue forecasts and market size.

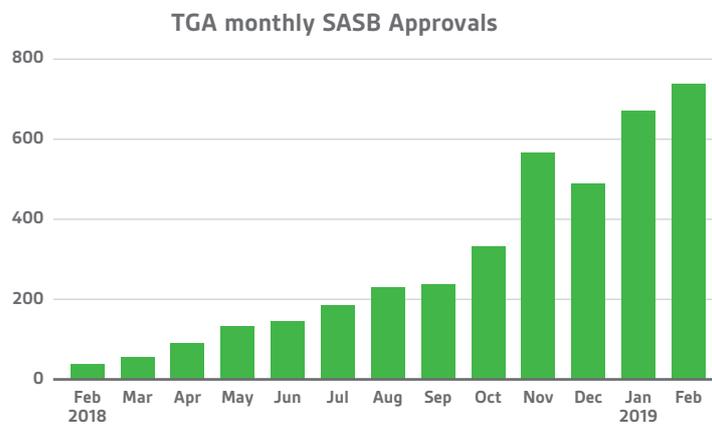
We have found that pricing competition continues to intensify as new products enter the market, with Australian doctors now having a choice of over 50 products to prescribe from.

Patient dosages have increased as the market matures and more patients find their 'optimal' dose requirements, and this has led to a slight increase in average monthly costs for patients.

We expect around 15,000 – 20,000 new patients to enter the market this year, with monthly product revenues to approach A\$3.6M by the end of 2019.

## Patient Growth – Australia hits a tipping point

Those watching the industry closely will have noted that towards the end of 2018, the Australian medicinal cannabis industry had its 'hockey-stick' moment where approvals started to trend upwards rapidly. November alone saw a 71% month on month jump, and despite an expected lull over the December holiday break, the upwards trend has continued at a breakneck pace in Q1 2019.



It is important to note that the TGA reports 'SAS-B approval numbers' which is not the same as the number of active patients in the market. SAS-B approvals are for a specific product, for a set period of time (usually 6 months, but sometimes 3 or 12) and so every month some of the approvals will be for patients who have previously been counted, and are being approved for an extension.

While SAS-B is still the predominant channel for patient access, patients can also access products through the Authorised Prescriber channel (51 prescriber's at end January 31 2019, adding an estimated additional 20-30% patients to monthly approvals) and through clinical trial programs.

FreshLeaf Analytics expects that between 15,000 – 20,000 new patients will enter the Australian market in 2019, creating for the first time a market that is substantial enough to generate meaningful cashflows for some of the leading businesses in each part of the value chain.

## Products flood the market

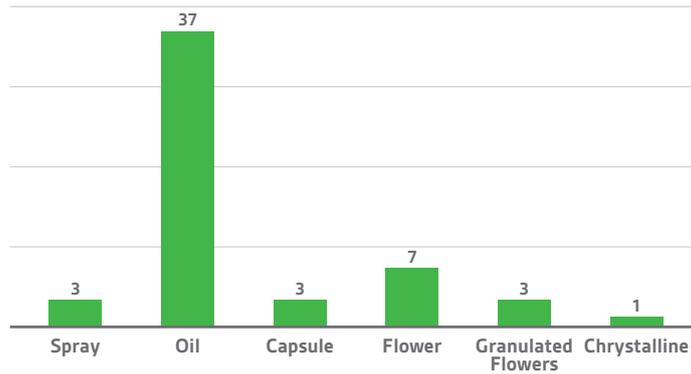
There are now a total of 31 players – up from 25 in Q3 2018 – licensed by the Office of Drug Control (Australia's regulatory authority for medicinal cannabis import and production) to supply foreign products into the market or cultivate and manufacture them here. With many more applications in the queue to be reviewed by the ODC, this number is expected to continue to trend up in 2019.

The players today have delivered a large range of products to the market – in Q1 2019, 54 products<sup>1</sup> were confirmed by the FreshLeaf Analytics team as being available for doctor prescription – up almost 500% from just 11, eighteen months ago. Canada still leads the market in terms of country of origin, but European suppliers are catching up with a range of offerings sourced from pharmaceutical grade facilities in several countries including Switzerland, Netherlands, Slovenia and Germany.

Australia now has its first locally grown product available - from the Western Australian producer Little Green Pharma, who launched their first product in Q3 2018 and followed up swiftly with a second in Q1 2019. With a large number of well funded local competitors we expect continued growth of domestic product through 2019.

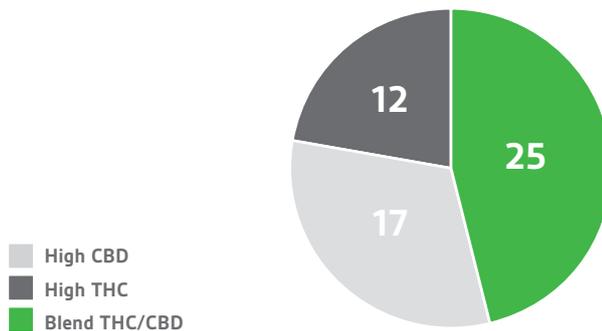
Oils were still the primary delivery mechanism for product in the market, comprising 43 of the 54 available. Other delivery mechanisms available include sprays, capsules, flower – raw dried and granulated – and a new option for doctors, crystalline form.

Product Types Available in the Australian Market Q1 2019



Review of formulations available suggests there is still a greater need for innovation and diversification – with most products simply falling into various ratios of THC and CBD – the two most common active ingredients. At the time of publication there were 25 'blend' products which were typically a 1:1 ratio (or thereabouts), 17 high CBD products which were typically pure CBD (a schedule 4 medicine) or mostly CBD with a small amount (typically a 1:50 or a 1:20 ratio with THC) and 12 high THC products (including some pure THC products).

Product Count by Cannabinoid Ratios, Q1 2019



Interestingly, a small number of products have come onto the market since our last report with specifically stated amounts of other cannabinoid products including one from Switzerland stating the inclusion of CBDA (cannabidiolic acid – the 'raw' form of CBD, as it exists in the live plants) – hopefully a sign of things to come as more products with rare cannabinoid profiles become available.

## The Israelis enter the market

A key development for Australia, and for the world, in terms of product supply was the passing of laws in Israel, December 2018, to allow export of medicinal cannabis. This development, while perhaps long overdue for a country that has been pioneering research and development of cannabinoid medicines for over 30 years, is welcome from a consumer standpoint. Currently 2 suppliers from Israel have started to make oil products available in Australia.

<sup>1</sup> Only companies that could demonstrate they have products available for prescription by our doctors were included in our analysis. FreshLeaf Analytics does not publish brand names on the basis that medicinal cannabis products available for prescription in Australia are not registered medicines and cannot be promoted

## List prices continue to plummet, but CBD hits a floor price

The larger number of players in the market has led to a reduction in list prices, particularly in cannabis oil products.

The average list price<sup>2</sup> per milligram for oil-based cannabinoids<sup>3</sup> fell a further 26% in the past 6 months to 0.23 cents per milligram.

While this may sound like welcome news from a consumer perspective, a more meaningful measure is the price of the cheapest product(s) in the market. This is because many doctors, in the absence of any clinical data to suggest otherwise, will consider products of similar formulation 'clinically equivalent' and prescribe the lowest priced product in the market.

This dynamic has led to many high priced product companies reducing their list prices in search of doctor prescriptions, but this 'price-revision' activity is not likely to result in lower costs to most patients who may be already receiving cheapest available products.

Compared to the period 6 months earlier, the cheapest CBD products in the market remain unchanged at \$0.10 per mg. Cheapest high THC products however have dropped substantially from \$0.30 to \$0.16 per mg and blend products similarly have seen a substantial price drop falling from \$0.23 to \$0.17.



## Pharmacy markups are stabilising

In Australia, medicinal cannabis products are dispensed at a pharmacy<sup>4</sup> and are generally marked-up for sale to the patient. In most cases the amount of the markup is decided by the pharmacy. As with many early stage markets, the amount of markup varies widely, but our current review has found that more extreme markups are disappearing.

In Q1 2019, based on the pharmacies sampled, the average markup on medicinal cannabis was 22%, which would be expected for a product of this nature. The highest markups observed were 52%, considerably less than the more extreme cases seen in 2018 where product price more than doubled between manufacturer and pharmacy.

Some of the pharmacies interviewed have moved to a 'fixed dispense fee' model of around \$25 - \$30 per patient, which reduces their margin as volume of product purchased increases. This dispensing model is particularly favorable to patients suffering from conditions that require a large volume of product to be consumed each month - for example \$30 as a dispense fee on a prescription value of \$600 becomes marginal.

As an interesting anecdote in the unfolding Australian medicinal cannabis market, some pharmacies interviewed, particularly those in NSW, had reported that dispensing medicinal cannabis products had resulted in them coming under additional scrutiny from their state Department of Health, resulting in them making the decision to stop dispensing medicinal cannabis due to business disruptions and regulatory costs.

<sup>2</sup> Price analyzed is sale price to pharmacy

<sup>3</sup> Average of all oil based products (CBD only, THC only and Blend)

<sup>4</sup> Cannabis Access Clinics does not dispense products

## Patient monthly costs higher, driven by increased dosages

Understanding the patient costs of medicinal cannabis in Australia is important because it is currently not covered by the Pharmaceutical Benefits Scheme (PBS), so costs are paid by patients out of pocket.

Monthly price paid by patients is a function of a number of variables including:

- product prescribed
- the manufacturer price to pharmacy
- the pharmacy markup
- any shipping costs
- monthly dosage required

Of the above list, the variable that most significantly impacts individual cost is the required dosage.

Most patient prescriptions in Australia follow a 'titrate up' dosage model that requires the patient to start at a low dose and increase the amount of product consumed until maximum benefit is achieved.

The required dose can be impacted by a range of factors including the indication the patient suffers from, delivery mechanism of the product (an oil vs dried plant), the size and age of the patient and the patient-specific response to therapy.

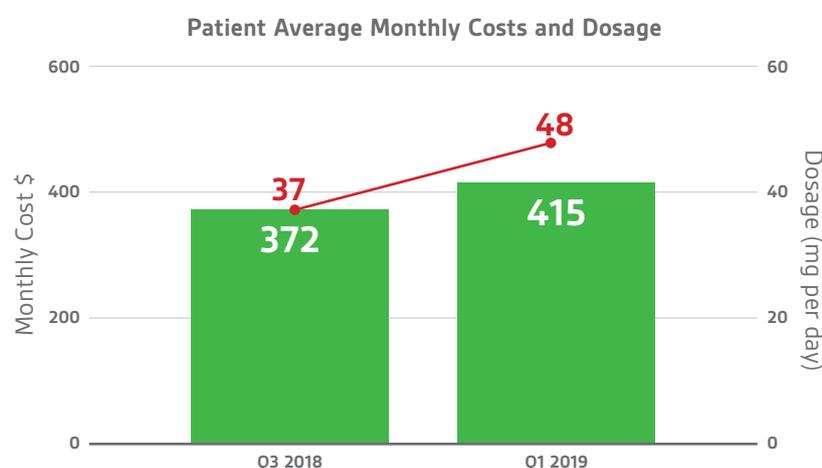
Reported dosages fall in the range of 1mg - 90mg per day for THC and 2.5mg - 1000mg per day for CBD. Extreme cases would include indications that require a large volume of cannabinoids to have an effect, such as epilepsy.

Given the up to 1000x variability in cannabinoid dose requirement, it can be difficult for patients to get a sense of what their monthly costs will be before they are on treatment for long enough to determine their optimal dosage.

FreshLeaf Analytics has analyzed monthly patient costs for the period based and found that average price to patient in Q1 2019 was \$415, a 11.5% increase over the period 6 months earlier.

The key factor in driving monthly costs up, in a market where unit costs are trending down, was increasing dosage.

Compared to the period 6 months earlier, patients reported taking on average 28.9% more product. This is likely due to the standard 'titrate-up' prescribing regime, which results in patient doses increasing over time, such that in a more mature market, with more long-term patients on higher dosages, the overall prescribed average will increase.



Perhaps the most important aspect of price is the question of affordability. The method FreshLeaf Analytics uses for affordability is to benchmark against the CAMS16 study. CAMS16 reported that patients considered a medicinal cannabis price of \$11 per day (\$334 per month) as affordable – defined as “amount willing to pay”. Based on the patients sampled, only 41% of patients spent less than this amount suggesting that much needs to be done to bring costs down, or to offer subsidized pricing through PBS or other mechanisms.

Regardless of average affordability, many medicinal cannabis patients, who are often suffering from complex conditions which limit their ability to generate an income, will not be able to afford any amount of cost above PBS limits. The authors of this study believe that more work needs to be done by government and private insurers to quantify the benefits of medicinal cannabis treatments in terms of patient outcomes, and assess whether cost offsets through insurance, PBS or other mechanisms can be justified.

## Market forecasts for 2019

Many players, particularly those in the cultivation and manufacturing segments of the value chain, have invested substantial amounts in the medicinal cannabis market in Australia. Many of these have raised substantial amounts of capital and in some cases have listed on public markets with valuations suggesting high expectations of revenue and profit growth. So, in the 3rd year after legalization, how does the market look from a size perspective?

FreshLeaf Analytics is expecting the patient market in Australia to grow at around 9% per month over the coming year, resulting in around 15,000 – 20,000 new patients entering the market in 2019.

Converting patient volumes to a market revenue estimate requires consideration of a number of factors including expectations of attrition, product pricing changes, streamlining of pharmacy operations and margins and of course major regulatory changes.

Based on our current market forecast models, the team at FreshLeaf Analytics expects that the Australian legal medicinal cannabis market in 2019 will be turning over product revenue of around \$3.6M per month by December of 2019, resulting in an annualized run rate of around \$43M as we move into 2020.

Our current models assume no major regulatory change in 2019, although we recognize that a reduction in the scheduling of CBD to allow more streamlined distribution is something that is a possibility this year and would result in substantial market growth.

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<sup>5</sup> Medicinal-cannabis-australia-2016-cannabis-medicine-survey-cams reported average weekly usage. Nicholas Lintzeris, Jessica Driels, Natalie Elias, Jonathon C Arnold, Iain S McGregor and David J Allsope.

## The Future

The Australian medicinal cannabis market continues to evolve at an exciting pace. As we move into the 3rd year since the rescheduling of medicinal cannabis the market is finally growing to a meaningful size.

Significant obstacles still face patients, doctors and industry players. Some of these include intense competition in the market, ongoing resistance in some parts of the medical fraternity and lack of government subsidies / private insurance coverage resulting in high out-of-pockets costs.

Progress however, continues to be made. The first Australian products have entered the market and a plethora of foreign-made medicines are available for doctors to prescribe. Patients are being approved in ever-increasing numbers each month and we expect the Australian market to hit a patient population similar to levels Canada saw in circa 2014 when it started to emerge as a significant market.

2019 is expected to be a year of great change, where the industry leaders of tomorrow consolidate their positions in the value chain, costs continue to come down and most importantly more patients get access to medicine that will benefit them.





## Methodology

The FreshLeaf Analytics Q1 2019 product, pricing and patient analysis was based on data collected in the period January to March 2019.

The team collected pricing data in January and February 2019 from 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. Two suppliers declined to provide data, although neither is known to be a major supplier in the market at time of data collection. Product information and price was based on the suppliers reported list price to pharmacy, including shipping, for 1 unit (vial, packet etc) of product. Some suppliers offer discounts for larger volume orders, but these discounts has not been reflected in the analysis.

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

Pharmacy pricing data was based on pharmacy interviews performed in February 2019 with 30 pharmacies who had a history of dispensing medicinal cannabis.





## FreshLeaf Analytics

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

The FreshLeaf Analytics team can be contacted on **+61 2 8203 8741** or **info@freshleafanalytics.com.au**

FreshLeaf Analytics is a division of the Biologics Research Institute of Australia Pty Ltd.



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