



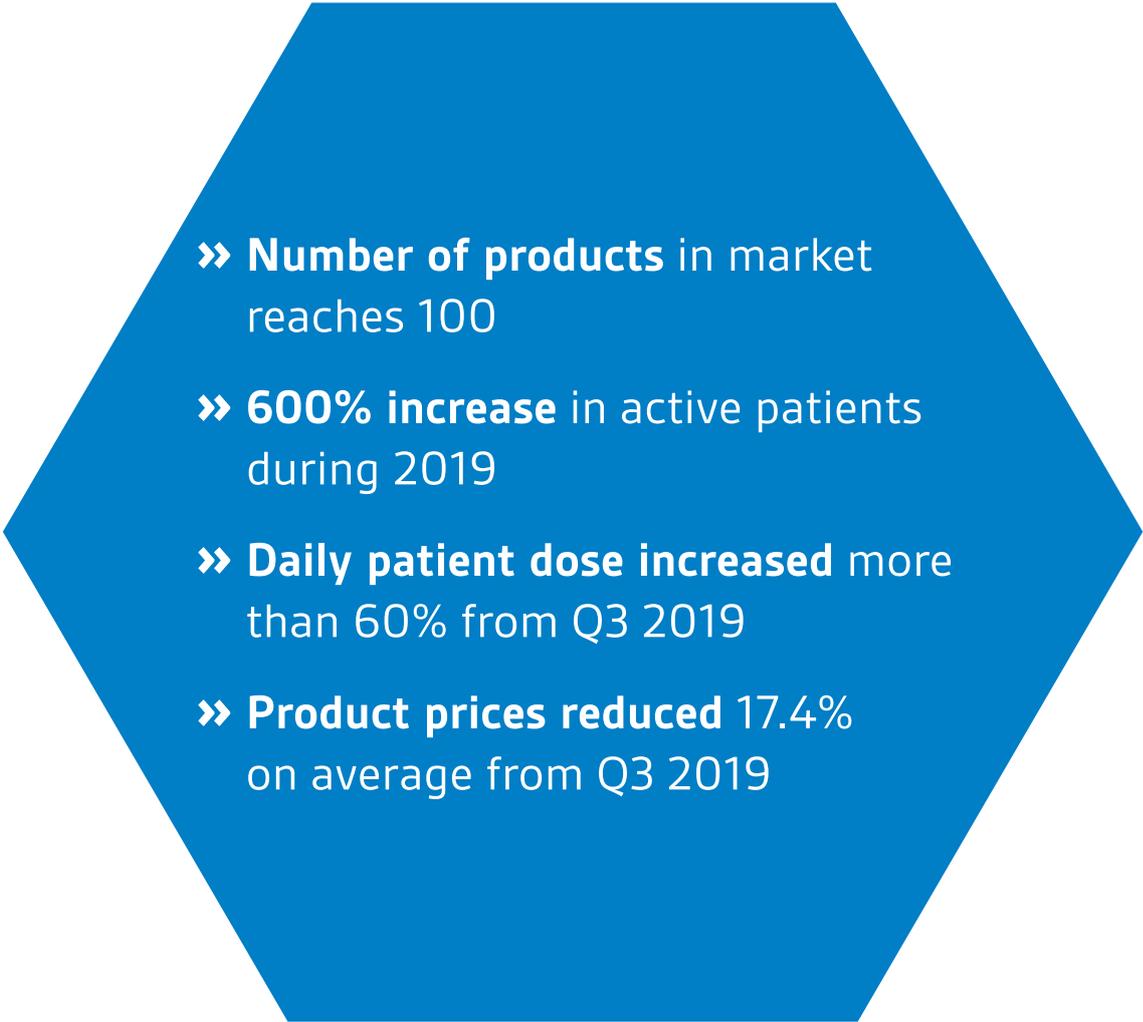
FreshLeaf
Analytics

Australian Medicinal Cannabis Market
Patient, Product and Pricing Analysis

Q1 2020



Real Data. Real Analysis. Real Results.

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- » **Number of products** in market reaches 100
 - » **600% increase** in active patients during 2019
 - » **Daily patient dose increased** more than 60% from Q3 2019
 - » **Product prices reduced** 17.4% on average from Q3 2019

Summary

This is FreshLeaf Analytic's fourth market report on patients, products and pricing in the Australian market.

Our Q1 2020 report includes our first ever historical price and patient dose analysis combining data from our previous publications to show long-term market trends.

We have found the number of products available for doctors to prescribe has now reached 100.

Product prices have continued their downward trend and are now 17.4% cheaper on average than reported in Q3 2019.

Patients have also reported significantly increasing their average daily dose, possibly due to price declines making higher doses more affordable.

It seems likely that CBD will become available for behind the counter pharmacy sales. But the path to market will be challenging for many cannabis companies.

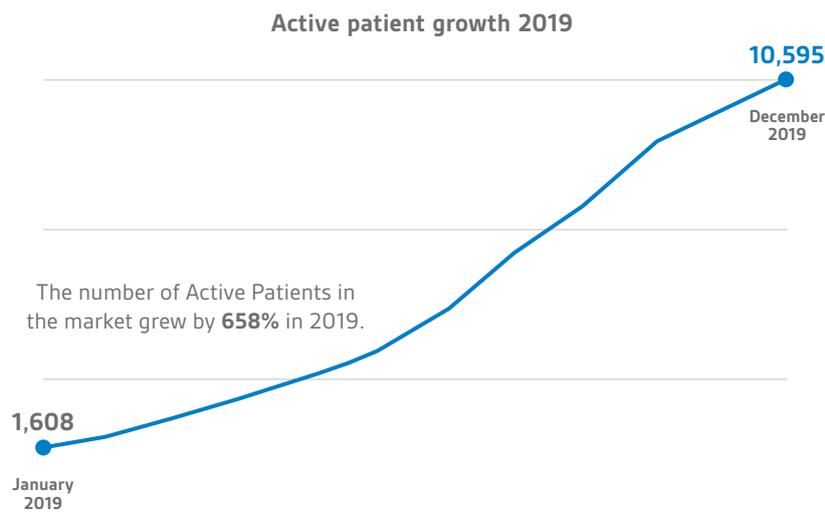
December 2019 saw an annualised product sales run rate of nearly \$50M. FreshLeaf expects that by December 2020 this will have nearly tripled to around \$150M.

1. Market Growth

2019 was a cracker year – what lies ahead for 2020?

2019 was the year where the Australian medicinal cannabis market became a commercial reality.

We saw strong and consistent growth in the number of active medical cannabis patients, from 1,600 in January to over 10,000 at the end of December, an average monthly growth rate of 19%. Over 10,000 patients in the marketplace meant that by year end, the leading players in the industry had real customers and real revenues - perhaps not enough of either to break even, but enough to validate their business models.



The period also saw a large increase in the number of unique prescribers using the SAS-B pathway, the main channel to market, with a rise of 227% over the year¹ to 1,465 in 2019. Not all of these doctors are regular prescribers, in fact many would have submitted only a few ad-hoc patient approvals, but the trend is clear - significantly more doctors are warming to the idea of medicinal cannabis as a therapy for their patients.

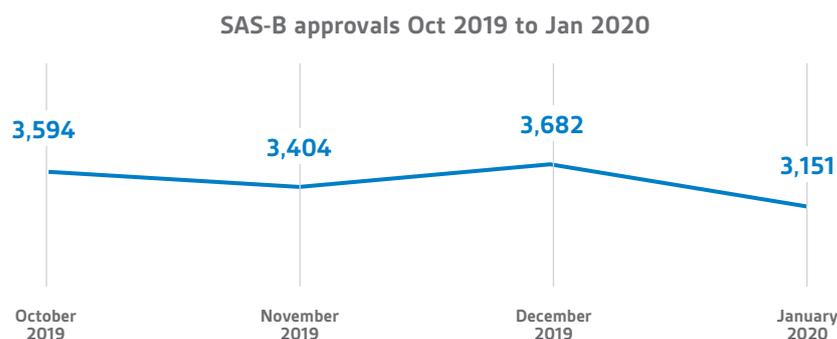
So what is in store for 2020 - will we see numbers continue to rocket upward?

If we look at recent SAS-B approvals we get a very different story.

In the period since November, new approvals appear to have flatlined, showing an average growth rate of -1.9% to end January 2020². So what is going on?

Is the long-promised patient market failing to materialize as predicted?

Has the market reached capacity?



¹ Source: Department of Health

² TGA reported SAS-B numbers

FreshLeaf believes that three key factors are influencing the TGA's reported SAS-B numbers:

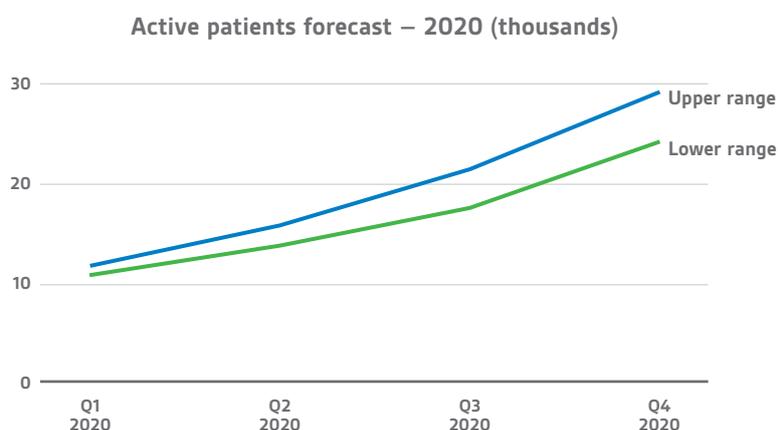
- 1. Seasonality:** The December / January period is typically a low period for many industries and healthcare is no exception, with business activity in the sector typically down by 20-30% in these months.
- 2. Increase in Authorised Prescriber activity:** In the early days of the industry, doctors attempted the Authorised Prescriber (AP) route on the promise that it would provide an easier pathway than the SAS-B process. But the maintenance of parallel State-level approval processes actually meant it was quicker and easier to use the SAS-B portal. The 2019 removal of State-level approval requirements in NSW, combined with the growth in the number of specialty cannabis clinics, has recently encouraged more APs to register. The barriers to AP registration are significant in terms of time and cost requirements, so this pathway is most attractive to high-volume prescribers. FreshLeaf expects that the vast majority of cannabis prescribing doctors will continue to use the SAS-B pathway while heavy prescribers will transition into the AP system. As of 31 January 2020, there were 63 APs with current registration.
- 3. Rise of compounding:** Compounding pharmacies are exempt from many provisions in the Therapeutic Goods Act. This means that doctors can write prescriptions for compounded products without requiring a SAS-B approval or AP registration. Patients can have their compounded product manufactured on demand by an appropriate pharmacy without that product being manufactured to PIC/S GMP quality standards. This product can be dispensed without requiring any TGA approval, and compounded products are often affordably priced. Due to lower regulatory overheads and often lower costs to patients, this channel to market has risen in popularity in the past 6 months and is not reflected in any publicly reported figures.

While the seasonal decrease in sector activity has now passed, the expansion of access options means that SAS-B approvals will increasingly become a less useful metric for assessing market growth.

FreshLeaf analytics views active patients (patients who have seen a doctor or taken a prescribed medicine in a given month) as a more useful metric for market assessment and, using this measure, sees continued strong growth in the sector over 2020.

Active patients shows strong growth

Even after adjusting for lower monthly SAS-B growth rates, the FreshLeaf patient model, which factors in Authorised Prescriber and compounding rates, forecasts that by December 2020, the market will triple year-on-year to 25,000 - 30,000 active patients in the Australia market.



FreshLeaf expects this growth will be driven by a range of factors including:

- ongoing price declines across the market as competition and product availability continues to increase
- increasing doctor familiarity and uptake as more doctors become aware of cannabis-based therapeutic options for their patients
- continuing expansion of specialist clinic chains which have driven substantial growth across 2019
- wider access options including via Authorised Prescribers and compounding prescriptions

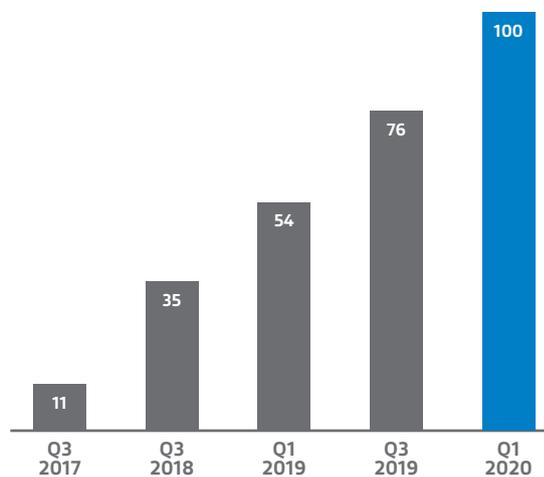
As the market grows towards 30,000 active patients this year, revenues and volumes of products sold will, naturally, grow substantially. Based on our forecasts FreshLeaf expects the Australian market for medicinal cannabis to close the year at a run rate (annualised) approaching \$150m in product sales and a product consumption rate (annualised) approaching 1,000kg of cannabinoids.

2. Product Growth

Number of products available hits triple digits

The last 6 months has seen the number of available products in the Australian market jump again, continuing a trend of rapid product growth that has remained consistent since our first report in 2017. Doctors in Australia now have exactly 100 products to choose from, a jump of around one-third since we last reviewed the market in September 2019.

Number of medical cannabis products available to Australian doctors

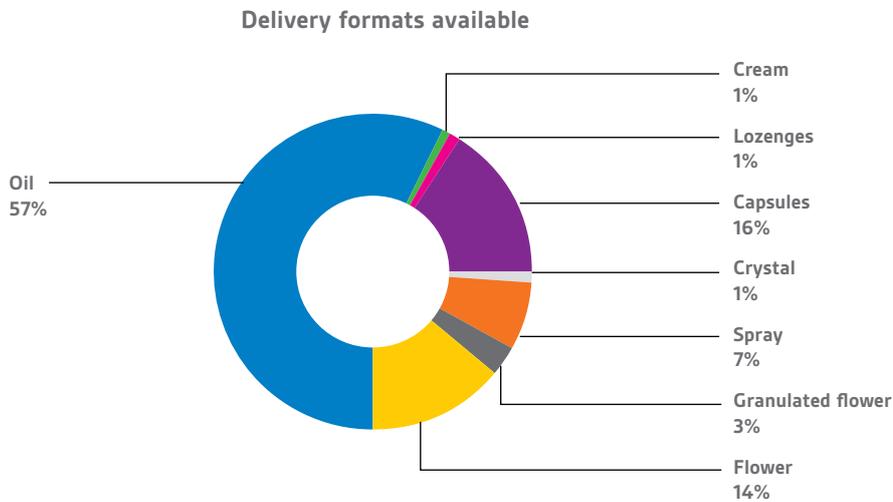


The past 6 months has also been a period of product rationalisation for many companies. FreshLeaf has identified that at least 13 products which were available during the FreshLeaf Q3 2019 report have now been pulled from the market.

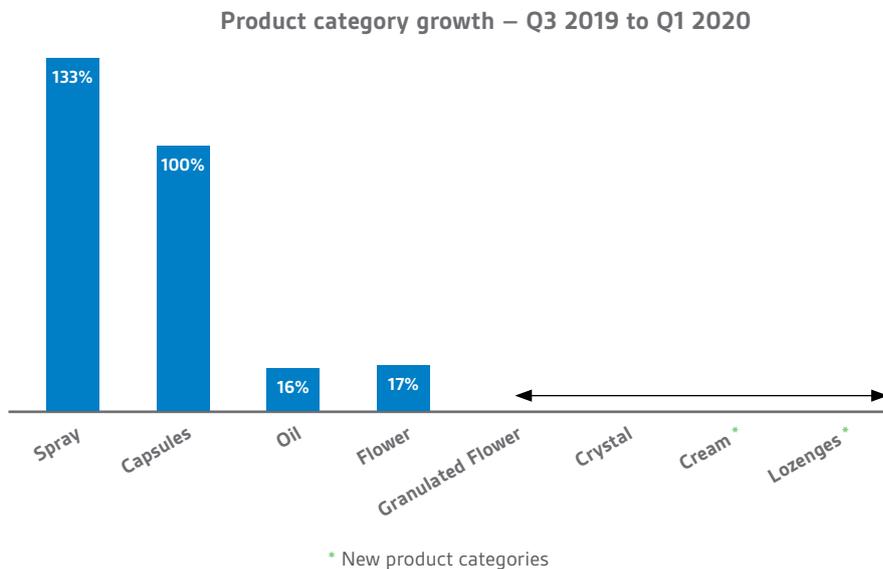
The reasons for these product exits are varied and include regulatory breaches, changes of strategy and de-duplication of product offerings.

Product variety continues to expand

Types of delivery mechanism available to doctors also continued to expand, with a total of 8 different options available for doctors to choose from, including 2 new entrants: “creams” and “lozenges”.



Oil products remain the single largest product category, with 57 entrants, and oils are the most prescribed product type. But the fastest growing product categories are sprays and capsules, both more than doubling in the number of different brands available over the past 6 months.



The rise of capsule and spray products is encouraging, but we have yet to see significant doctor and patient uptake of these products. This is probably due to their relatively recent presence in the market and the time it will take doctors and patients to become educated about new product ranges. It may also reflect the competitive pricing market, with oils still out-competing most other oral products in terms of price per mg of cannabinoid.

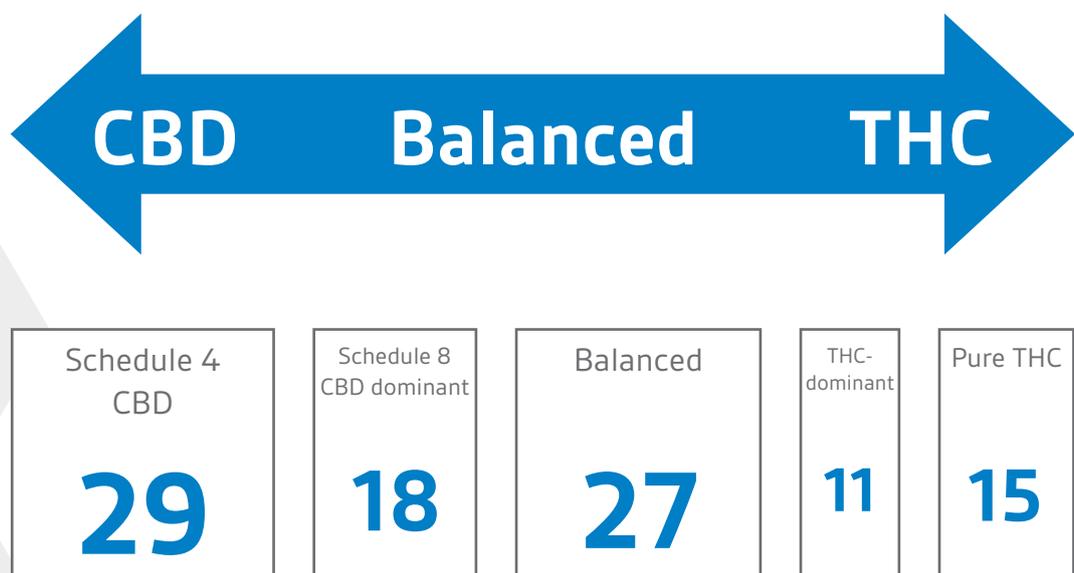
Formulation types continue to expand

New products and formulations are contributing to a dizzying range of possible therapeutic options. But this doesn't necessarily make prescribing (or market analysis for that matter!) any easier.

To simplify things, in the Q3 2019 report we provided information on the product formulations available across three categories: CBD; CBD/THC; and THC. In this report, we have expanded those categories to group products into 5 formulation types:

- 1. Schedule 4 CBD products.** These are products where more than 98% of the cannabinoids in the product are cannabidiol (CBD). They are often made from cannabinoids isolated from outdoor hemp plantations and have little to no detectable levels of THC. These products are typically prescribed when there is a concern that any THC may have a negative outcome for the patient.
- 2. Schedule 8 CBD-dominant products.** We have classified these products as ones with 66 - 98% CBD. These products are often 'whole plant' extracts and have cannabinoid ratios that are determined by the strain of the plant that has been used.
- 3. Balanced products** (with a CBD/THC ratio of between 1:2 and 2:1 inclusive). Products in this category have 33% to 66% CBD (and inversely, a similar range of THC) and are prescribed when doctors want the patient to have a balanced dosage of the two main active ingredients.
- 4. THC-dominant products.** These products have THC levels where this cannabinoid is 66 - 98% of the total cannabinoids.
- 5. Pure THC.** These products are more than 98% THC and will often be called "pure" THC. They are typically made by isolating THC from plant matter.

Available products by formulation



It is interesting to note that 85% of all products contain some amount of CBD, and nearly half of all products contain more CBD than THC.

Schedule 4 CBD products, those with >98% CBD, now represent the single largest category for product availability as well as being the most frequently prescribed product type. There are two main reasons for this:

- a)** Drivers with any detectable level of THC in their system are at risk of failing a roadside drug test and being charged with a driving offence. Using a Schedule 4 CBD product with no detectable level of THC is a good way of managing this risk.
- b)** Some patients or their doctors may want to avoid the side effects of THC which can include drowsiness, dry eyes or mouth, paranoia and other effects.

CBD down-scheduling is on the horizon

In January 2020 the Department of Health announced that it was reviewing the safety literature on low-dose CBD to inform a potential recommendation to make these products available behind the counter (Schedule 3) or even possibly off the shelf (Schedule 2) at pharmacies. The Department of Health considers 15-100mg of CBD per day to be low-dose. Currently, CBD (in any amount) with less than 2% other cannabinoids for human therapeutic use is Schedule 4, requiring a doctor's prescription. Should this change come to pass, companies would still need to register their low-dose Schedule 3 CBD products on the Australian Register of Therapeutic Goods (ARTG).

The main effect of this down-scheduling would be that companies could expect to easily sell many more units from behind the counter than via doctors' prescription. It is also possible to advertise registered Schedule 3 medicines to the general public. So the commercial incentives for companies to pursue S3 ARTG registration would be greatly increased.

What might a Schedule 3 entry mean in terms of product specifications? One plausible scenario is that low-dose CBD might be initially treated with similar caution to pseudoephedrine. The Schedule 3 entry for pseudoephedrine specifies that packs must contain no more than 720mg of pseudoephedrine and the recommended maximum daily dose is 240mg, meaning each pack contains three days worth of medication.

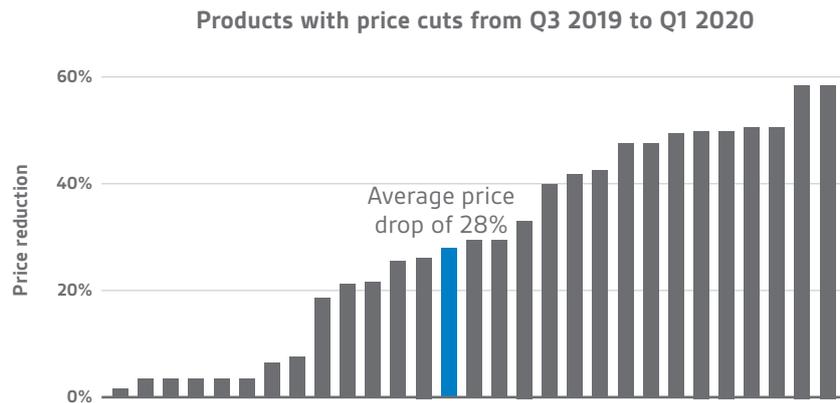
If low-dose CBD were to be scheduled in a similar way, that would mean each unit could contain up to 300mg of 98% pure CBD.

Of course, low-dose CBD has zero abuse potential and a lower harm profile to pseudoephedrine, so it could be that low-dose CBD has fewer restrictions placed on its packaging. The comparison with pseudoephedrine is a deliberately conservative one.

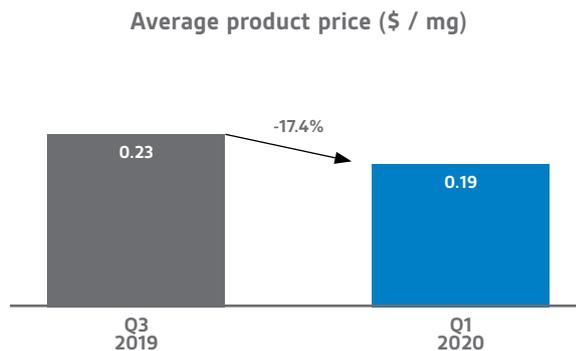
3. Price

The price war ramps up

A total of 63 products were available in Q3 2019 and remained available in Q1 2020. Of those 63 products, 30 have seen price reductions. This is encouraging news for patients. Across these 30 products, the average percentage price decrease was 28.3% (price to pharmacy). The biggest decrease observed for a single product was just over 58%.



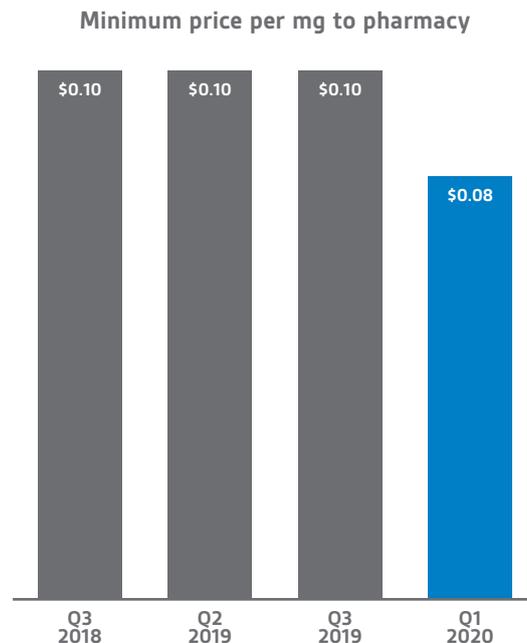
Across all products, including newly added products and continuing products which have not had price reductions, the average percentage decrease in price to pharmacies over the last 6 months was 17.4%.



Competition at the low end

In our previous report from Q3 2019 we identified that the floor price of cannabis products had remained stable for at least six months. This stable price floor has now been broken. The previous floor price of \$0.10 per mg has now moved to \$0.08: a 20% reduction.

In Q3 2019 there were only two products at \$0.10 per mg (price to pharmacy). In Q1 2020 there are now 19 products at \$0.10 per mg or cheaper, representing a huge range of low cost options.



This represents an intensifying price war at the affordable end of the market, with existing products being heavily discounted to remain competitive against new, cheap market entrants.

In particular, Schedule 4 CBD products have experienced steep price declines alongside a surge in new products. In Q3 2019 there were only eight S4 products and this number has increased to 29 in Q1 2020.

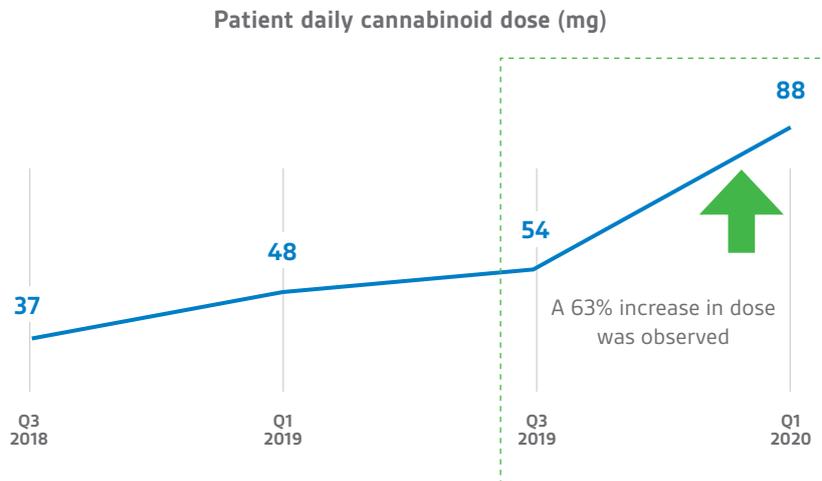
4. Patient spend and dose

Wide ranging price cuts by product companies is great news, but how does this trend translate to the most important metric, the amount patients spend on their medicine each month? The two key factors that determine the price a patient pays is the **dose** they consume, and the **unit price** of the product they are prescribed.

Looking at the numbers, we see two insights emerging in Q1 2020: significantly increased dosages and slightly increased spend.

Patient dose increased significantly from Q3 2019 to Q1 2020

In a continuation of a trend that has been consistent since FreshLeaf started reporting on dose figures, we saw a strong upwards trend in patient reported dose. In Q3 2019, the average mg of cannabinoids consumed by patients on a daily basis was 54mg. In Q1 2020 that has jumped to 88mg per day: a 63% increase.



The implications of higher dose are varied, not least to product companies who can expect to move more product, but also to patients, who will spend more if price remains unchanged.

Why are patients taking much more medication than they used to? This could be due to a combination of factors. One explanation is that patients were previously under-dosing due to cost, and as prices drop, they are increasing their doses to get better therapeutic effects.

Another possibility is that doctors are becoming more familiar and comfortable with prescribing cannabis medicines, and are recommending higher doses to patients.

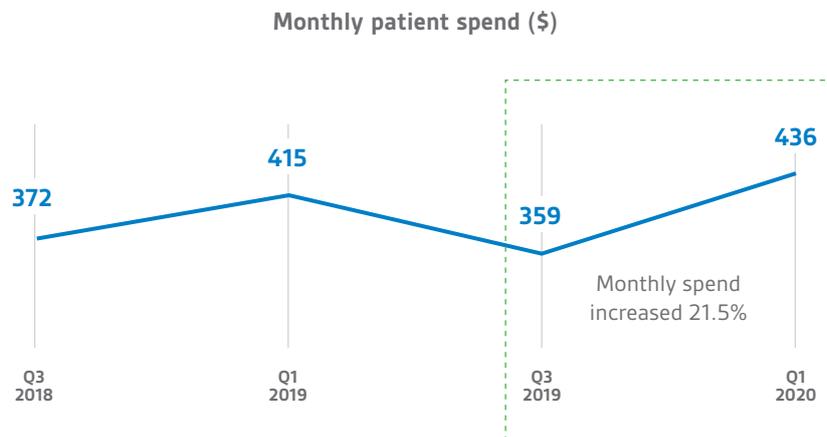
It is also possible that continuing patients are developing tolerance to the medication and require higher doses to maintain the same therapeutic outcomes.

It is also important to note that the clinic chain that provided dosing analysis, CA Clinics, is the longest operating clinic in the country and may therefore have a disproportionately large number of patients who have been on treatment long-term and have self-titrated to higher doses.

Spend increased slightly over the period analyzed

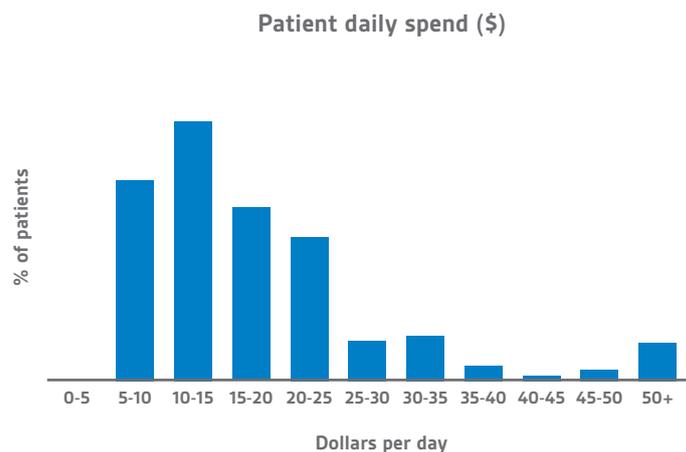
An increase in average dose means more product is being consumed, and is also likely to mean patients spend more.

Fortunately for patients, although there was an increase in monthly spend of 21.5% from Q3 2019 to Q1 2020, the spend increase was significantly less than the dosage increase observed over the same time period.



As with all medicines, some patients on very high doses will skew the average spend levels. A more meaningful analysis is to look at the spend level on a patient by patient basis.

When we cut the data this way, we see that approximately half of all patients spend less than \$10 per day on medicinal cannabis treatments, with around two thirds spending less than \$15 a day. This is roughly consistent with patient spend patterns analysed in our Q3 2019 report.



As we have noted in previous reports, while this daily spend level is not wildly misaligned with costs in other markets globally, it can appear high when contrasted with medicines in Australia that are taxpayer subsidized through the Pharmaceutical Benefits Scheme (PBS), which caps medicine costs at \$41.00 per script for general patients and \$6.60 for concessions.³

³ http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_4_Explanatory_Notes

5. What lies ahead for 2020?

Since 2016, Australia's medical cannabis industry has faced the usual cost and efficiency challenges of a new industry. But over the last few years, we have seen many State/Territory level barriers to patient access be streamlined; the creation of the online SAS-B portal; significant price declines in products; dozens of new products enter the market; and hundreds of doctors start prescribing.

We closed 2019 with meaningful patient numbers and revenues. December 2019 product sales run rate (annualized) was just under \$50M. FreshLeaf expects to close out 2020 with a run rate (annualized) approaching \$150M in product sales across ~30,000 active patients. We also expect annualized demand for medicinal cannabis to approach 1,000kg of cannabinoids.

These forecast volumes and revenues are exciting for companies operating in the sector but they will be split across a highly competitive landscape of local and international companies all vying for a bigger slice of this growing pie. With 100 products currently in the market, and more on their way, product competition will be fierce. At the low end, generic products will continue to compete on price per mg. But this presents opportunities for technologically innovative producers to bring differentiated products to market.

And by that we don't mean just another oil with a slightly different CBD:THC ratio, or a special plant 'strain' with an organic certification. Truly differentiated products require innovative and useful improvements to bioavailability and therapeutic outcomes, backed by published peer-reviewed studies and actual data. We are also excited about the possibilities for new cannabinoids not previously commercially available to enter the market, and the potential for combination therapies with both drug and non-drug interventions.

Medical scientific research will increasingly take the front seat in the Australian industry. Even bringing an over-the-counter low-dose CBD product to market will require substantial research activity to demonstrate dosage and safety. For producers trying to differentiate themselves, FreshLeaf expects to see many more dose-finding studies; PK studies; open label trials; case series reports; and RCTs launched in 2020.

These commercial trends will play out against the backdrop of a rapidly evolving regulatory landscape. The move towards over-the-counter low-dose CBD; ongoing reforms to harmonise patient access pathways; lobbying efforts to update driving laws; and the possibility of the TGA imposing GMP quality standards on imports to match those placed on local producers.

FreshLeaf is optimistic for the year ahead. There are major changes on the horizon with wide-ranging implications for both patients and industry. We will endeavour, as always, to provide up-to-date analysis and commentary as events unfold, underpinned with detailed, rigorous and unbiased insights for our clients and collaborators.

Methodology

The FreshLeaf Q1 2020 product, pricing and patient analysis was based on data collected in the period January and February 2020.

The team collected pricing data in January and February from 25 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 on February 15 2020 were included in the study. 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 200 patients seen at the clinics during December 2019 and January 2020

About FreshLeaf Analytics

FreshLeaf Analytics is the leading supplier of data about the medicinal cannabis industry in Australia. We have 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 a division of Southern Cannabis Holdings, Australia's leading vertically integrated pharmaceutical cannabis business with interests in market intelligence, clinical research, medical services and product services.





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