



1 April 2020

Special Report on ASX-listed Cannabis and Hemp stocks

An exciting new sector



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An exciting new sector

From humble beginnings in Canada around ten years ago the cannabis and hemp industries have blossomed into a major force to be reckoned with by investors the world over. Australia is no exception, with many cannabis and hemp companies having gone live on ASX over the last five years. However, many investors are unfamiliar with the dynamics of this exciting new sector. Pitt Street Research now seeks to close that information gap with our Special Report on Cannabis and Hemp, released 24 March 2020.

Welcome to the cannabis and hemp revolution

Cannabis and hemp have fuelled a major investment boom since 2014 largely because of the known therapeutic benefits of medicinal cannabis. Governments around the world have responded to the scientific evidence and made it easier for patients to access cannabis-based medicine. Concurrently, voters in many countries have become more favourably disposed towards the legalisation of recreational cannabis. These two trends have fuelled a boom in cannabis, while hemp, from a different plant, had also benefited as investors have moved to use this plant for a variety of purposes, most notably in food. It's fair to say that cannabis and hemp have quickly become respectable industries worthy of investor attention. Many have come to the view that cannabis and hemp are agents of serious economic change, with potential to seriously disrupt sectors as diverse as drinks, building materials and, of course, medicine.

Why should the Canadians have all the fun?

Canada was the origin of the current cannabis and hemp boom because the regulatory framework changed in that country around 2013 in a way that allowed entrepreneurs to flourish while the public equity markets allowed large amounts of capital to be raised. However, Australia is also now a contender because our capital markets have also been responsive to good stories in the cannabis and hemp space, and the local industry is now growing strongly.

Plenty of ASX-listed companies to look at

ASX is home to a lot of quality companies involved in the cannabis and hemp space. This report profiles many of them. Given the growth in the sector we expect there will be more.

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About Pitt Street Research

Pitt Street Research is Australia's leading provider of issuer-sponsored research on companies that are publicly traded on the Australian Securities Exchange (ASX). In our model, rather than waiting for conventional broker analysts to initiate coverage, listed companies commission and pay for research reports and video content showcasing their companies.

We believe in the power of issuer sponsorship to enlarge the quality pool and genuinely independent and widely accessible research on ASX-listed companies, and thereby contribute to the overall efficiency of the Australian equity market.

Pitt Street Research focuses on relatively new growth aspects of the capital market. One such area is the cannabis and hemp field. Ten years ago, cannabis was generally regarded by investors and the general public alike as an illegal drug with no prospect for near-term legitimacy. Today, cannabis (recreational and medicinal) and hemp are increasingly respectable commodities, and start-ups and established companies are rapidly developing a multi-billion dollar market globally that promises strong growth in shareholder value to the best-positioned companies.

In this Special Report we explore the background of this promising new field, considering issues surrounding cannabis and hemp in 2020 as well as focusing on the ASX-listed players in the field.

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Introduction – why ASX investors need to know about cannabis and hemp

That is not a drug, it's a leaf. - Arnold Schwarzenegger

Time was that in most civilised countries cannabis was an illegal drug and possession of it, or cultivation and trafficking of it, could get you a prison sentence. And the drug wasn't even all that well-regarded as an illicit, as evidenced in part by its nickname of 'weed', in honour of the weed-like appearance of the Cannabis indica plant.

However in little more than just the last half-decade cannabis and its botanical cousin hemp – from Cannabis sativa – have turned into respectable industries. Today around the world there are thousands of entrepreneurs labouring in start-up or established but fast-growing companies to create and market legal products based on cannabis and hemp. And those companies are focused not just on the medical applications, but on numerous other industrial applications, and, in the case of cannabis, products for legal 'recreational' use. No one seems to call cannabis 'marijuana' any more, and joke about the stocks of cannabis companies having the potential to 'get high' are becoming rarer.

The cannabis and hemp sector has now progressed to the point where many of the leading companies are publicly traded on established stock exchanges, allowing investors to easily get a piece of the action in what is still a relatively new sector. And in some cases the cannabis and hemp companies are getting multi-billion dollar valuations. One leading Canadian company, Canopy Growth, whose ticker on the TSX is 'WEED', was capitalised on that exchange on 10 March 2020 at a cool C\$6.8bn.

Not only is cannabis and hemp respectable today, it's also viewed by many as an agent of serious economic change, with potential to seriously disrupt sectors as diverse as drinks, building materials and, of course, medicine.

How did that happen?

As we note in this report, the scientific evidence on the therapeutic benefits of cannabis for conditions such as cancer pain and epilepsy had been building for decades, and in 1996 the US state of California, often a bellwether of social change in the world's largest economy, famously became the first state to legalise the drug for medical use. That was after voters passed Proposition 215 in November of that year by, interestingly a relatively slim 56/44 margin. That was over 20 years ago, however. We date the true transition of cannabis to commercial respectability to around 2014, largely because of developments well to the north of California.

Medicinal cannabis had been legalised nationwide in Canada in 2001 after court decisions had established the constitutional right of Canadians to access such products. In 2013 the Canadian government enacted new regulations for the production, distribution and use of medical cannabis which had the effect of creating legal certainty for would-be producers. This in turn allowed pioneering companies such as Aurora Cannabis and the aforementioned Canopy Growth to go public in Canada to fund the growth of their businesses. A lot of the capital for the cannabis boom that resulted came from the US, where by 2014 some 20 states had legalised medicinal cannabis and attitudes

Cannabis and hemp have potential to be highly disruptive industries

towards medicinal cannabis had changed to become broadly favourable. The combination of Canadian entrepreneurship and regulation and US and Canadian capital was a cannabis boom in Canada and later in America which went to the next level in late 2015 after the election of the current Liberal government of Prime Minister Justin Trudeau. That was because the Liberals favoured legalisation of recreational cannabis, which they legislated for in 2018. Recreational cannabis became legal at a Federal level in Canada from October of that year, which beat the US because that country has still not legalised recreational cannabis federally, eight years after the states of Colorado and Washington did so.

Australia was a natural beneficiary of the Canadian cannabis boom because the ASX, like the TSX and the TSX-V for the emerging companies, is a natural market for small-cap public venture capital. Australia's first medicinal cannabis company, Phytotech Medical Cannabis (now MMJ), went public on ASX in January 2015 and many others followed suit and enjoyed good investor reception in the light of the Canadian boom. By 2016 cannabis companies were presenting at Bioshares, the pre-eminent life sciences investment meeting for Australian and New Zealand investors. We profile the current crop of ASX-listed companies with a cannabis or hemp angle in the second and third sections of this report. It's instructive to us that cannabis-based companies have continued to list on ASX at a steady rate since 2015 rather than representing a 'one-off' boom in 2015. And no wonder. As we elaborate in this report, the regulatory environment for cannabis and hemp globally, while uneven in terms of the pace of change when viewed across jurisdictions, is generally becoming more liberal wherever you look. As a good example of this, consider the fact that while the US hasn't legalised recreational cannabis federally, it did legalise hemp in December 2018 when President Trump signed into law that year's Farm Bill.

Cannabis
and hemp
companies
are generally
very
innovative

A characteristic feature of the cannabis and hemp boom of the last five years has been the emergence of companies whose business plans involves new products and services differentiated from both what came before and what other companies are currently offering or working on. A good example is tools for administration.

Back in cannabis's 'Cheech and Chong era' the only way to administer black market 'medicinal' cannabis was to roll it into a joint and inhale. Now in the 'Justin Trudeau era' companies are working on rechargeable medical-grade vaporisers where the manufacturer is ISO 13485:2016 certified and where the device is connectable to the Internet of Medical Things. Another example of the innovation we're seeing in cannabis and hemp comes from new tools to grow products beyond the traditional greenhouse. And so on.

Another pleasing aspect of this boom is the ease with which products can make it to end-users. In the case of medicinal cannabis, Australia's Special Access Scheme, for example, allows patients to get GMP-manufactured product on the say-so of their treating physician and the Therapeutic Goods Administration without products having to go through long and expensive Phase 1 to 3 clinical studies.

A third attractive quality of this boom has been the high levels of motivation of the end-users. Patients and their caregivers in search of new treatments have given the medicinal arm of this sector an urgency to it often lacking in other aspects of the pharmaceutical and medical device space.

As for consumers seeking to experience the recreational aspect of cannabis in a way forbidden to previous generations, they have proved discerning and, dare we say it, sober while encouraging providers of recreational cannabis to be creative in their search for the best possible strains, and commercial in terms of making it available at reasonable price points.

A fourth quality of the sector we find admirable is the level of entrepreneurship and its diversity of experience. People like Dr Stewart Washer of Emerald Clinics (ASX: EMD) or Harry Karelis of Zelira Therapeutics (ASX: ZLD) already had a background in life sciences before they moved into the cannabis space and have brought the disciplines of that sector to foster the new sector down under. Others such as Jo Patterson at BOD Australia (ASX: BDA) and Layton Mills at CannPal (ASX: CP1) bring skills in marketing. Then there are people such as Alex Keach at ECS Botanics (ASX: ECS) who bring a background in agriculture and finance. The quality of the people attracted into this sector Down Under assure us that cannabis and hemp are not 'fly by night' industries.

The quality of many of the business plans, the rapid uptake from motivated end-users, the increasingly liberal regulatory environment, and the success of the Canadian pioneers are all good reasons why investors should consider ASX-listed companies involved in cannabis and hemp. Don't get us wrong – this is still a relatively new sector and therefore subject to the usual 'boom and bust' cycles ordinarily associated with new sectors. Investors need to consider the risks as well as the potential rewards when looking at this sector.

Pitt Street Research has yet to provide elaborate company-specific research on any of the companies in the second or third section of this report. However, as proponents of cannabis and hemp as potential creators of significant shareholder value, we commend this sector to investors as worthy of their attention.

This report comes in four parts. In Part 1 we provide a 'Cannabis and Hemp 101'. In Part 2 we briefly outline the main ASX-listed companies involved in cannabis and hemp. Then in Part 3 we look in detail at a few of those companies. Finally, in Part 4 we provide background on the cannabis and hemp industries globally with a specific focus on Australia. We commend Ksenija Cadajeva, who has done the bulk of the work that went into the report and in our opinion has done an outstanding job researching this exciting new investment opportunity. We learned something from Ksenija's work. We hope you do too.

Marc and Stuart, 1 April 2020

This sector, while promising, will still be 'boom and bust' for a while yet



Part 1 – Cannabis and hemp – the basics

I have always loved marijuana. It has been a source of joy and comfort to me for many years. And I still think of it as a basic staple of life, along with beer and ice and grapefruits.

- Hunter S. Thompson (1937-2005), American writer

What is cannabis? Cannabis is a genus of flowering plants in the family Cannabaceae. Cannabis indica is a source of the drug that was traditionally used illicitly by smoking. Cannabis sativa is the source of hemp.

Why has cannabis long been a dangerous plant to be associated with, from a legal standpoint? Cannabis indica contains two basic chemicals called cannabinoids – ‘cannabidiol’, (CBD) and delta-9 tetrahydrocannabinol (THC). It’s the THC that give Cannabis indica its psychoactive properties and that resulted in drugs from the plant being banned in most jurisdictions early in the 20th Century.

Why is cannabis so useful therapeutically? Cannabis indica is a complex plant with over 400 chemical entities, of which more than 60 are cannabinoids. Science is discovering that the cannabinoids are useful across a broad range of medical conditions including cancer, HIV/AIDS, multiple sclerosis, glaucoma, seizures/epilepsy, and pain. Cannabinoids bind to receptors in the body’s endocannabinoid system, specifically the CB1 and CB2 receptors. The endocannabinoid system regulates things like mood and immune function and so drugs that target it properly tend to have therapeutic effects.

Why is it called cannabis and not marijuana? Cannabis is obviously the plant’s scientific name and derives from the Persian name for the plant. Marijuana is a Spanish word originally used by Hispanic residents of the US who were in turn users of the drug. Over the years marijuana got a bad name so legitimate entrepreneurs today prefer the scientific name. **How is cannabis sourced?** Cannabis is generally grown in greenhouses and then processed using standard Good Manufacturing Practice from the pharmaceutical industry to extract the relevant medicines or recreational drug.

What form do cannabis medicines come in? Generally medicinal cannabis providers formulate their products as oil extracts, since oil from cannabis is rich in CBDs, which are non-psychoactive. That said, oil-based products with THCs are also supplied since THCs can be therapeutically useful. Oils are useful because they make doses easy to calculate in terms of the THC/CBD balance. Medicinal cannabis can also be supplied as resin or dried plant material. **Why is medicinal or recreational cannabis often supplied in vaporizers?** Vaporisers, also known as ‘vapes’, heat dried cannabis or concentrated cannabis extracts and/or resins to a temperature just below the combustion point of 200°C., creating an inhalable aerosol or vapor. Vaporisers are associated with less toxicant exposure relative to traditional smoking methods, increasing product appeal.

What is hemp? Hemp is commonly used as a name for low THC strains of Cannabis sativa. In modern times, hemp has been used for industrial purposes including paper, construction, health food and fuel. A lot of hemp entrepreneurs are focused on the food aspect of hemp since hemp seeds contain only trace amounts of THC but are exceptionally rich in two essential fatty acids, linoleic acid (omega-6) and alpha-linolenic acid (omega-3). They are also a great protein source.

Part 2 – ASX-listed companies involved in cannabis and hemp

ASX-listed companies in cannabis and hemp

Please read this section in the light of the disclaimers at the back of this report.

Althea Group (Melbourne, ASX: AGH, althea.life). This company is a producer of pharmaceutical grade medicinal cannabis. Its products are manufactured by the Canadian cannabis company Aphria (TSX: APHA), which is also a part owner of Althea. Althea also provides cannabis education for medical professionals and patients. The company is currently expanding to Europe, introducing its products in Germany and the UK.

AusCann (Perth, ASX: AC8, auscann.com.au). This company is developing cannabis-based medicines for neuropathic and chronic pain. The company is currently completing development of a hard-shell capsule for delivery of its product, after which it will conduct clinical trials.

Australian Primary Hemp (Melbourne, ASX: APH, ausprimaryhemp.com.au). This company is an integrated producer of hemp food products sold under its own brands. It also wholesales to other companies.

BOD Australia (Sydney, ASX: BDA, bodaustralia.com). This company creates health and beauty products from plant-based extracts, with a specific focus on cannabis and hemp. In July 2019 the Hong Kong-based Health and Happiness Group took a major stake in BOD and the two companies are now working on cannabis and hemp products that H&H will market globally. BOD's Medicabilis Oil product is currently being sold in the Australian medicinal cannabis market.

Botanix Pharmaceuticals (King of Prussia, Pa, ASX: BOT, botanixpharma.com). This company develops therapies for serious skin diseases including acne, psoriasis and atopic dermatitis, where the active ingredient in the drug candidate is a synthetic cannabinoid. The company's lead product, BTX1503, is a gel for the treatment of moderate to severe acne which the company is preparing for Phase 3 studies.

Cann Global (Sydney, ASX: CGB, canngloballimited.com). This company develops hemp seed foods as well as medicinal cannabis products. The company has been working with scientists from the Technion in Israel on a cannabis-based treatment for Multiple Sclerosis. Cann Global intends to import an extended release cannabis pill manufactured by the Canadian company Canntab into Australia.

Cann Group (Melbourne, ASX: CAN, canngrouplimited.com). This company is seeking to become an integrated cannabis company with operations ranging from plant genetics through to the supply of approved medicinal cannabis products on global markets. The company is developing a cannabis production facility at Mildura in western Victoria. Cann Group has an offtake agreement with the Canadian company Aurora Cannabis which gives that company a first option to purchase product produced at the Mildura facility.

CannPal Animal Therapeutics (Sydney, ASX: CP1, cannpal.com). This company develops therapeutic products for pets that work through the endocannabinoid system. CannPal's lead product is CPAT-01, a product for the treatment of osteoarthritis that contains various THC and CBD extracts. This product is now in Phase 2b clinical studies.

Creso Pharma (Sydney, ASX: CPH, cresopharma.com). This company, which has cultivation facilities in Canada and Colombia, is a developer of a broad range of cannabis and hemp products. Its lead therapeutic products are cannQIX50,

a hemp extract, and Medicinal CBD Oil, both for the treatment of chronic pain.

Cronos Australia (Melbourne, ASX: CAU, cronosaustralia.com). This company is an Australian offshoot of Canada's Cronos Group (TSX:CRON), a major developer of medicinal cannabis. The company intends to import Cronos's 'Peace Naturals' products into Australia as well as develop its own products.

Ecofibre (Sydney, ASX: EOF, ecofibre.com). This company develops hemp products for use in food and medicine as well as other industrial applications. The company was built on a large database of cannabis genetics from various 'landraces'. Its main brand is 'Ananda Hemp'.

ECS Botanics (Sydney, ASX: ECS, ecsbotanics.com.au). This company is a supplier of hemp-based products sourcing its raw material from farms in Tasmania. The company has been granted cannabis production licenses and intends to cultivate and manufacture cannabis products in Tasmania.

Elixinol Global (Sydney, ASX: EXL, elixinolglobal.com). This company is a supplier of hemp-based CBD dietary supplements and skin care products that is currently working on entering the medicinal cannabis market.

Emerald Clinics (Perth, ASX: EMD). This company operates specialist clinics in Australia practising cannabis-based medicine. The model for Emerald is evidenced-based medicine where the company's data platform can capture the clinical evidence to justify a particular treatment approach.

eSense-Lab (Israel, ASX: ESE, esense-lab.com). This company is a creator of 'virtual' plants, where the company's scientists identify the terpene profile of those plants and then re-engineer the plant with similar terpenes of interest in order to capture different flavour and smell. eSense-Lab has used this know-how to create virtual cannabis plants that can be used to develop medicinal and other consumer products.

EVE Investments (Perth, ASX: EVE, eveinvestments.com.au). This company's main focus is tea tree and honey products sourced from various plantations in northern NSW. Under an July 2018 agreement with THC Global (ASX: THC) that company intends to grow cannabis on EVE's tea tree property and will work with EVE on creating a cannabis-based honey.

IDT Australia (Melbourne, ASX: IDT, idtaus.com.au). This company is a contract developer of pharmaceutical products encompassing API development as well as finished drug formulation. IDT has a Medicinal Cannabis Manufacturing Licence from the Office of Drug Control and has developed the capability to do GMP manufacturing of cannabis-based products.

Impression Healthcare (Melbourne, ASX: IHL, impression.healthcare). This company is a developer of medicinal cannabis products with a focus on newer indications than those to which cannabis has typically been applied to date. The company is currently trialling the use of CBD products in the treatment of gum disease and concussion, as well as a dronabinol variant (dronabinol is an oral synthetic version of THC) for severe Obstructive Sleep Apnea.

Jayex Healthcare (Melbourne, ASX: JHL, jayex.com). This company has been built around a cloud-based software platforms for managing patient engagement and workflow as well as prescription management. A particular focus of Jayex has been the medical cannabis market, working with companies such as Lyphe Group, a medical cannabis healthcare provider.

Lifespot Health (Melbourne, ASX: LSH, lifespot-health.com) This company that is primarily working on vaporizer devices for cannabis consumption. Lifespot originated in a health-monitoring system called BodyTel. In 2017 the company started

working on integrating BodyTel into vaporizer devices. The result is a device for medical use called MediHale which Lifespot believes can be world leading.

Little Green Pharma (Perth, ASX: LGP, littlegreenpharma.com). This producer of medicinal cannabis supplies a range of products where the mix between THC and CBD varies.

Medlab Clinical (Sydney, ASX: MDC, medlab.co). This company is a developer of both nutraceuticals and pharmaceuticals for early to moderate stage chronic diseases. A new product of Medlab's is NanaBis, a cannabis oil extract containing both THC and CBD which the company is developing for the treatment of cancer pain.

MGC Pharmaceuticals (Perth, ASX: MXC, mgcpharma.com.au). This company, founded in Israel, develops CBD-based products for the treatment of neurological disorders. The company is focused in epilepsy and dementia as early indications. It is initiating a Phase 2b study in Alzheimer's with a formulation that is 3:2 THD to CBD called CogniCann.

MMJ Group (Sydney, ASX: MMJ, mmjgh.com.au). This company makes investments in cannabis ventures such as Weed Me, a Canadian cannabis cultivator, and Fire & Flower, an adult-use cannabis retailer in Canada.

Rhinomed (Melbourne, ASX: RNO, rhinomed.com.au). This company has developed a nasal device to improve upper airway patency, which has benefits in terms of treating snoring and Obstructive Sleep Apnea. Since late 2018 Rhinomed has been working to adapt its device as a nasal delivery system for cannabis-based therapeutics.

Roots Sustainable Agriculture Technologies (Beit Halevy, Israel, ASX: ROO, rootssat.com). This company's technology allows better agricultural yields through root zone temperature optimisation. The company has shown that this technology can improve the yield of cannabis plants.

Roto-Gro International (Melbourne, ASX: RGI, rotogro.com). This company is commercialising a hydroponic plant-growing technology that stacks the plant beds in rotating cylinders for greater plant yield. The technology has been successfully adapted to cannabis as well as perishable fruits and vegetables.

Stem Cell United (Singapore, ASX: SCU, scu.com.sg). This company is commercialising technology for the isolation of plant stem cells. It uses this technology to produce various stem cells which have health and beauty applications. One plant on which Stem Cell United has focused its technology is Cannabis sativa.

THC Global (Sydney, ASX: THC, thc.global). This company cultivates cannabis on four sites in Australia and has a licensed facility for manufacturing medicinal cannabis at Southport on the Queensland Gold Coast. It produces a range of oils with varying mixes of THC and CBD.

Zelira Therapeutics (Perth, ASX: ZLD, zeliratx.com). This company is developing medicinal cannabis products for insomnia, autism, opioid reduction and cancer, with the insomnia product having moved to Phase 2. The company's 2019 acquisition of the US company Ilera Therapeutics brought a number of products already being marketed in America under the 'Hope' brand.

YPB Group (Sydney, ASX: YPB, ypbsystems.com). This company has smartphone-based technology allowing products to be authenticated and fakes identified. One of the markets being pursued is cannabis, with a number of cannabis producers having worked with YPB since 2018.

Part 3 – Focus on some key Australian companies in the cannabis

Emerald Clinics (ASX:EMD)

Emerald Clinics is building a network of medical cannabis clinics in Australia where the focus is evidenced-based medicine. The company's unique platform and digital health tools allows data relating to the effectiveness of cannabis-based therapies to be ethically sourced from patients and accessed by product developers and researchers on an anonymous and independent basis. The result is high-quality clinical evidence, often available in real-time.

Emerald Clinics basically represents the next step in cannabis medicine, where companies have moved from a focus on cultivation and commercial manufacturing of medicines towards providing more evidence into safety and effectiveness of the medicines. Emerald Clinic's team includes specialist physicians, experienced General Practitioners and clinical trials experts ready to deliver best-practice care through the clinics.

Currently there are four medical cannabis clinics, in Sydney, Melbourne, Perth and Tintenbar near Ballina in the Northern Rivers region in NSW. In the clinics, patients can be prescribed medical cannabis under the Federal Government's Special Access Scheme, with Emerald evaluating the safe and appropriate use of cannabinoid treatments and providing access to unregistered medicines, including medical cannabis for qualified patients in collaboration with referring health professionals. The clinical evidence that Emerald collects helps to create significant value to licensed producers, regulators, insurers and prescribers, as it accelerates the medicinal cannabis acceptance process, benefiting both producers and the patients that need treatments. Data that companies partnering with Emerald receive through their partnership include prescribed dosages, treatment responses and impact of opioid use on cannabis medicine. All this information will help to design future trials, reduce risks and make the path to market for new products smoother.

Since regulations in most countries requires high-quality clinical evidence for new drugs and medical devices, Emerald is well placed to grow its network of collaborators globally. The UK government for instance, has adopted an evidence-based approach to cannabis regulation and will require registration of all cannabinoid products by March 2021. Emerald is close to commence operations in the UK.

Emerald is one of a growing number of players globally in the field of Real World Evidence (RWE), which is the catch-all phrase for clinical evidence generated from patient and medical data collected during ongoing clinical care to determine the effectiveness of interventions as they applied to the patients. RWE is becoming more essential in all sorts of healthcare decisions, not just those related to cannabis. Indeed, regulators like the FDA and the EMA are currently developing guidance to use RWE pharmacovigilance for safety and adverse events. RWE is also required to support clinical trial design and observational studies, and major regulators in US, EU and Canada are also developing guidance on RWE to support faster drug approval.

Emerald Clinics is a very new company on ASX, having only started trading on 12 February 2020 after raising \$6m in the IPO. The funding will enable Emerald to advance its data platform and clinical trials, and establish new clinics, including, potentially, some in the UK.

Emerald is pioneering the market for cannabis clinics

Emerald's major goal currently is to grow its strategic and collaborative partnerships in the industry. It will also focus on research to increase the value of the Emerald's clinical evidence as collected from its network.

Emerald has already evaluated/treated over 1,000 patients since December 2018, when its first clinic opened. The majority of the patients were treated for chronic non-cancer pain and other conditions including cancer pain and Alzheimer's. In November 2019 Emerald signed a Letter of Intent to sell anonymised clinical data to Spectrum Therapeutics, which is a medical division of world's largest cannabis company, Canopy Growth. Emerald will collect real word data on the safety and effectiveness of Spectrum Therapeutics' products via clinical outcome data from 500 patients prescribed with medical cannabis in Australia.

Another company that has strategically collaborated with Emerald Clinics to support undergoing trials is Zelira Therapeutics. Through that collaboration, Zelira was able to access clinical findings from patients that were treated with medical cannabis for pain and insomnia. In February 2020, Zelira further expanded its partnership with Emerald through a Clinical Trial Research Agreement, with Emerald engaged as second trial site to accelerate recruitment for chronic non-cancer pain participants on long term opioid treatment.

Cannatrek (privately held)

Cannatrek Ltd is a Victorian based 'seed to patient' vertically integrated cannabis company that operates across the entire supply chain, with increasing sales and production activities. The company is positioning itself as lowest cost Australian operator. It already possesses required licenses, including research and growing, manufacturing and import and distribution.

Cannatrek's Shepparton facility is likely to be one of Australia's largest cannabis manufacturing facilities

For its cultivation process, Cannatrek sources the full-spectrum of medical cannabis seed from Australian, Dutch and Israeli research programs offering different botanic varieties. Currently, Cannatrek imports product from its' supply partner in Organigram out of Canada.

Cannatrek's greenhouses deploy innovative technologies that provide minimal environmental impact with fully automated propagation, which stabilises the mother plant genetics so that the product is uniform.

Cannatrek's 160,000 sq m facility, to be built over 5 phases, near the Victorian town of Shepparton is still to commence construction but scheduled for first production in 2021. The Shepparton facility received planning permission in August 2019. It is likely to be one of Australia's largest cannabis manufacturing facilities, being built at a cost of \$160m. It will have 400 workers when fully operational. After achieving full capacity, Shepparton will be able to produce 160 to 200 tonnes of medicinal cannabis per year. Due to such scale, Cannatrek will be able to pursue multiple exports markets as more countries legalise medicinal cannabis. In February 2020 Cannatrek announced that Shepparton was receiving Major Project Status from the Federal Government.

Last year, Cannatrek completed a 3,200 sq m facility in southern Queensland near Brisbane. In September that facility received approval to begin cannabis growing in climate-controlled greenhouses and after testing a variety of genetic strains. In February 2020 Cannatrek confirmed that the Queensland site is fully operational and initial plants were ready for a harvest that will ultimately yield 3 to 5 tonnes of medical cannabis annually, serving over 10,000 patients.

Cannatrek also operates an information portal – Cannahealth – to educate GPs and specialists on medical cannabis issues including Australian treatment guidelines. Cannatrek also has a number of clinical studies and trials in progress for academic research on cannabis.

Cannatrek's maiden products include THC and CBD dried herbal flower and oil extract cannabis products. It also has Medical Delivery Systems, including vaporisers, via its B2C platform and trademarked brand, UrbanLeaf.

Cannatrek is currently conducting a \$15m pre-IPO round (Tranche 1 \$5M and Tranche 2 \$10M) ahead of a potential \$30-\$50m IPO raising. The timing, however, is uncertain as company wants to get its sites fully operational and generate initial commercial revenues at scale prior to listing.

BOD Australia (ASX:BDA)

BOD Australia develops beauty and personal care products based on plants. BOD's product range includes nutraceuticals, skin care and other topical products, CBD tinctures, hemp seed oil and soft gel caps, and CBD soft gel caps. Previously, consumer plant-based herbals were its the major focus, including plant-based extracts products, however it has since pivoted into the cannabis space, with a medical cannabis division and a CBD and hemp consumer products division. BOD is planning to enter markets in the UK, the US, the Netherlands, Italy, France.

BOD's non-cannabis portfolio sells through pharmacy wholesalers as well as online and independent retailers. There are more than 1,000 pharmacy outlets in Australia, including Priceline Pharmacies and Chemist Warehouse. BOD continues to develop new products in this area. Recent examples include the Earth skincare range containing hemp seed oil and manuka honey, and a variety of capsules targeting memory, joint mobility, anti-inflammation, digestive system, hay fever and allergic rhinitis, stress relief, cardiovascular health and motion sickness.

However, these days most of the focus is on Medical Cannabis and CBD and Hemp Consumer Products licensed to H&H Global with BOD retaining all IP. Health & Happiness Group's NewH2 unit has made a ~\$7m strategic investment into BOD, acquiring around 17.6% of the company in July 2019. This investment allowed BOD to launch its first products in the UK market. H&H has a license from BOD to commercialise CBD and hemp products, including CBD soft gel caps, CBD tinctures, hemp seed oil soft gel caps, skin care and other topical products, nutraceuticals and lifestyle products. In December 2019 BOD's first CBD oil, derived from GMP hemp extract, launched in the UK under H&H Group brand 'CBII'. The product is currently available online but BOD and H&H are preparing for offline retail sales in the future. More products are expected to launch in H1 2020, and the company is also planning launches in Europe.

BOD Australia's flagship medicinal cannabis brand is Medicabilis, a range of oils and wafers which are THC-low and CBD-high, making them EU GMP compliant. The Medicabilis products are currently available through the SAS-B scheme in Australia, with further opportunities to grow in the UK via a distribution agreement with PCCA announced in July 2019. BOD has confirmed its participation in the TWENTY21 project headed by the UK cannabis company Drug Science, which is helping BOD to improve brand recognition in the medical community. The study will undergo for three years, covering 20,000 patients. BOD will be one of the five companies involved with a minimum of 1,000 new patients receiving prescriptions of MediCabilis.

BOD successfully completed a Phase 1 clinical trial of Medicabilis in March 2019. So far, the product has proved to be safe and tolerable and have low THC levels.

BOD's joint venture with H&H Global is significant

BOD entered into a research collaboration with UniSA in December 2019 to research the effects of MediCabilis on patients as well as to assist in ongoing product development initiatives. In February 2020 BOD received an import permit for two new MediCabilis products.

BOD registered 1,842 Medicabilis prescriptions domestically during 1H FY20. First overseas sales are planned for late in the current financial year, with the company set to earn royalties on net sales and costs plus margin on supply.

Impression Healthcare (ASX:IHL)

Impression Healthcare believes it has a potential cannabis-based therapy for gum disease

This company's original business was the supply of oral devices such as sports mouthguards for teeth protection and devices to assist with sleep apnoea, snoring and bruxism. More recently it has pivoted into medicinal cannabis with a focus on CBD oils. Under a March 2019 agreement with Cannvalate it is currently undertaking four medicinal cannabis clinical trials. After successful completion of these trials Impression will distribute its cannabis products through Cannvalate's network of 1,000+ prescribing doctors and 600 pharmacists.

One of the clinical trials is related to periodontitis, that is, gum disease, since CBD can act as a potent suppressor of inflammation and is able to reduce bone resorption and rate of bone loss coincident. IHL-668A, delivered either as a mouthwash or toothpaste, has been jointly developed with a US company called AXIM Biotechnologies.

Another clinical trial is related to sleep apnoea where Dronabinol will be compared to placebo. Impression, working with Swinburne University, will develop its own specialised formulation to enhance results. In January 2020 IHL received all relevant permits to import key cannabinoid constituents of IHL-42X. The medication will be delivered in the form of nocturnally administered pill. Impression is now working on formulation development and a Phase 1/2 study is intended to commence in Q2 CY20.

A third trial is focused on concussion, since CBD is believed to be able to act as a neuroprotective agent after concussion and traumatic brain injury due to anti-inflammatory mechanisms.

The fourth trial will be in traumatic brain injury, where, as with the concussion trial, the focus will be on the ability of CBD to shield the brain from secondary immune-mediated change. In January 2020 Impression announced that it had expanded its clinical protocol to use the drug, called IHL-216A, on sports people. By early March Impression had finalised the design of its clinical program.

Impression is also developing a CBD programme focused on Temporomandibular Joint (TMJ) Dysfunction. The thinking is that CBD, by acting as a potent suppressor of inflammatory activity, is able to lower muscular spasm, joint spasticity, TMJ joint pain and anxiety related symptoms.

Under its wholly-owned Incannex Pharmaceuticals brand, Impression last December launched an oil product called CBD-100 on the Australian market for conditions previously approved under SAS. This product is selling through the Cannvalate distribution network. In February 2020 Impression announced an expansion of the Incannex oil sales program, placing a purchase order for 3,000 bottles for sale through this network and introducing three new products to its mix.

Zelira Therapeutics (ASX:ZLD)

This company develops cannabinoid-based medicines indicated for pain, anxiety and sleep where the focus is on whole-plant extracts instead of single compounds, since whole plant extracts are believed to have improved drug activity and safety. In October 2019 Zelira merged with US-based company Ilera Therapeutics, whose HOPE brand of medicinal cannabis had launched the previous May.

Zelira has developed two HOPE formulations, targeting patient symptoms associated with Autism Spectrum Disorder, generating revenue in the state of Pennsylvania. Zelira has also established a HOPE franchise in the state of Louisiana, with a licensing agreement for immediate revenue generation. In addition, through its partnership with Ethicann, the company is developing a product called CAN-001 to treat chemotherapy-induced nausea and vomiting.

Zelira believes its product can cut provide a solution to opioid misuse

Zelira's Phase 1b/2a insomnia clinical trial was the first trial globally to evaluate the effect of full-spectrum cannabis extract on sleep. Specifically, it is evaluating the safety and efficacy of cannabis extract containing THC and CBD in patients diagnosed with chronic insomnia. In February 2020 the company was able to report that, in 23 chronic patients treated with Zelira's formulation, there was a statistically significant improvement in Insomnia Severity scores. Zelira is expecting to be able to launch this product commercially later in 2020.

Zelira's 150-patient Autism Observational Trial includes variety of measures to assess the impact of medical cannabis on pharmacological and behavioural data. The study, which will fully recruit this year, will identify differences in CBD and THC usage profiles between low, med and high severity groups.

Zelira's Opioid Reduction Study will examine the impact of medical cannabis for the reduction of opioid dependence in patients suffering chronic (non-cancer) pain. The objective is to identify whether medical cannabis can be used as a substitute for traditional medication. A Phase 1 trial to evaluate the safety and tolerability of whole plant extract was fully enrolled by late February 2020, with no serious adverse events reported and with dosing to be completed by end of April.



Part 4 – Background to the cannabis and hemp industries globally and in Australia

A growth industry in Australia and around the world

‘There are decades where nothing happens, and there are weeks where decades happen.’ - Quote attributed to Lenin, (1870-1924).

The medical community worldwide has been aware of the healing properties of cannabis for many years; however, due to the rising popularity of synthetic analgesics and a lack of research, the medical traits of cannabis were dismissed until 1996 when California first approved it for medical use. Medicinal cannabis only entered Australia in 2016, when health providers started to prescribe medical cannabis through the Special Access Scheme (SAS) of the Therapeutic Goods Administration (TGA). The cannabis market has continued to expand globally and, consequently, regulations have developed in many countries, however often this has been with the intent of slowing down the uptake of drugs. In Australia, only patients with serious illnesses are prescribed medical cannabis. Despite this, the number of patients requesting medical cannabis in Australia is rising – 3,682 (SAS category B only) applications gained approval in December 2019, which was six times higher than December 2018. The market potential in Australia is extremely high, with at least 200,000 patients eligible for medical cannabis, so the legal cannabis market is expected to increase from A\$52m in 2018 to A\$1.2bn in 2025.

The number of patients being prescribed medical cannabis in Australia is still low compared to other countries. However, there is high potential for demand from North America and Europe with producers of high quality, premium products benefitting the most. As the Asian market continues to expand, current partnerships with China, Japan, and Indonesia will strengthen opportunities to capitalise on Asia’s growing cannabis industry. Australia remains in the early phase of development due to the export of cannabis only being legalised in 2018. Several partnerships and collaborations exist between Australian and Canadian companies. Canada struggles to meet the demand in a rapidly expanding recreational cannabis market and is thus seeking new suppliers.

One of the major drivers of the industry is the rising number of medical cannabis applications. For example, the TGA has only approved applications for cancer pain, chemotherapy-induced nausea, refractory paediatric epilepsy, neuropathic pain, and certain other conditions. However, many companies are heavily investing in R&D to identify new uses of medical cannabis.

In 2019 the Australian cannabis industry received significant Federal government support, with the government announcing in August that it would prioritise cannabis projects that have been granted Major Project Status by the Department of Industry. Also in 2019, after the review of the Narcotics Drugs Act 1967, the government indicated that it would implement all 26 recommendations from that review, including initiatives for cannabis cultivation and manufacturing, for making the application for licences easier and for reducing the

The market potential in Australia is extremely high.

The legal cannabis market is expected to increase from \$52m in 2018 to \$1.2bn in the next five years.

process time. By September 2019 the ODC had issued 24 licenses for cultivation, 16 for research, and 23 for manufacturing. The government hopes its initiatives will substantially streamline the process of making medical cannabis available for Australian patients.

Since regulations in Australia only allow for medical cannabis use, it may be some time before Australia catches up to Canada in terms of having a liberal regulatory environment fostering strong growth in the sector. That said, right now Australia is well positioned to become one of the largest exporters of medical cannabis due to its strong reputation for agricultural best practices at a time when cannabis is becoming a major sector globally.

Access to medical cannabis in Australia

The main challenge facing the Australian cannabis industry is regulation. Since the first regulations were introduced the number of patients has increased significantly in what has become a patient-driven market. Long delays in receiving the medication due to the tedious process of registering for the SAS remains a challenge. An application to the TGA has to be made for each patient and a single product may only be used by a single patient, meaning that the same patient might need different applications for different medications.

More than 34,000 people had been granted access by March 2020. Since approvals in Australia are still in the early stages, the demand for medical cannabis is anticipated to increase when regulatory challenges ease up. Due to an increase in companies engaging in research, Australia has an opportunity to address 200,000 patients who would benefit from this medication.

Australia is currently the world's fourth largest market for medicinal cannabis. The amount of people turning to the 'black' market for medical purposes is estimated to be 100,000. Several other countries are rapidly shifting in favour of approval, especially in Europe and some US states. The global cannabis industry is expected to reach US \$153.7bn by 2027 due to more countries decriminalizing the use of cannabis, legalizing it for pharmaceutical use and rising awareness of benefits derived from cannabis.

At the moment, there are about 27 ASX-listed cannabis companies with license to grow and manufacture cannabis products who are in the process of creating what they hope can become approved, cannabis-based medicines.

History of medical cannabis

The earliest consumption of cannabis was documented in China 6,000 years ago when cannabis was used for rheumatic pain, gout, and malaria, and later identified as an analgesic that was used before surgery. From China cannabis use spread to India, where it was incorporated into religious practices. It was discovered that it could be used to treat a plethora of diseases and ailments, and it began to be used as an anticonvulsant, anaesthetic, antibiotic and anti-

The global cannabis industry is expected to reach US\$154bn by 2027

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inflammatory. Cannabis was also successfully used to treat epilepsy, rabies, anxiety, rheumatism, bronchitis, and asthma.

Historically, many cultures recognised the medical benefits of cannabis and it was introduced to Western medicine in 1839; however, the introduction of vaccines and the development of synthetic analgesics, such as aspirin, lowered the demand for medical cannabis. The most important factor that contributed to the decline of cannabis use was the development of hypodermic needles and opiates .

Following a significant increase in immigration from Mexico into the United States, criticism of the plant began as the new immigrants brought new customs, including the use of cannabis as a relaxant. Mexicans referred to the plant as 'marihuana' and the rest of the US were not aware it was the same substance already in their medicine. In 1930, after a significant rise in recreational use and claims that marijuana caused men to be violent, narcotics officers established a restrictive legislation on both recreational and medical use, and in 1941 its was completely removed from the US medicines list .

In 1970, medical interests in cannabis were revived as the prevalence of recreational cannabis use increased from 5% to 44% of the adult population between 1967 and 1971 . This resulted in the discovery of the active components within cannabis and further study of their effects. In 1988, cannabinoid receptors were found by organic chemists who concentrated on neural and immune cells and alluded to a possible mode of action that could be the source of the analgesic, sedative, and immunoregulatory properties of cannabis. This stimulated more research into the drug. In 1996, California became the first state to approve the use of cannabis for medical purposes; now, it has been legalised in 33 states. Currently, Uruguay and Canada are the only countries that have fully legalised the consumption and sale of cannabis. In the US, only 11 states have legalised it for recreational use. Other countries that have legalised medical use of cannabis include Argentina, Australia, Canada, Chile, Colombia, Croatia, Cyprus, Germany, Greece, Israel, Italy, Jamaica, Lithuania, Luxembourg, North Macedonia, Norway, Netherlands, New Zealand, Peru, Poland and Switzerland .

The upward trend of the medical cannabis market

Globally, the overall cannabis market, including the illegal market, is currently worth US\$150bn, and a Europe Consumer Staples report is projecting a potential rise to US\$272bn by 2028. Cannabis users are estimated to account for 3.9% of the global adult population, which would be roughly 200 million people, with the highest number of users in Europe, followed by the US and the Asia Pacific (APAC) region . The cannabis market is well positioned for further growth as more countries begin to legalise it and the availability of cannabis-based products increases .

The Australian market is still in the early phase of development as exports were only legalised in 2018. However, Australia has much experience in the agri-pharmaceutical business, as evidenced by the fact that 50% of the poppy seeds used legally by the

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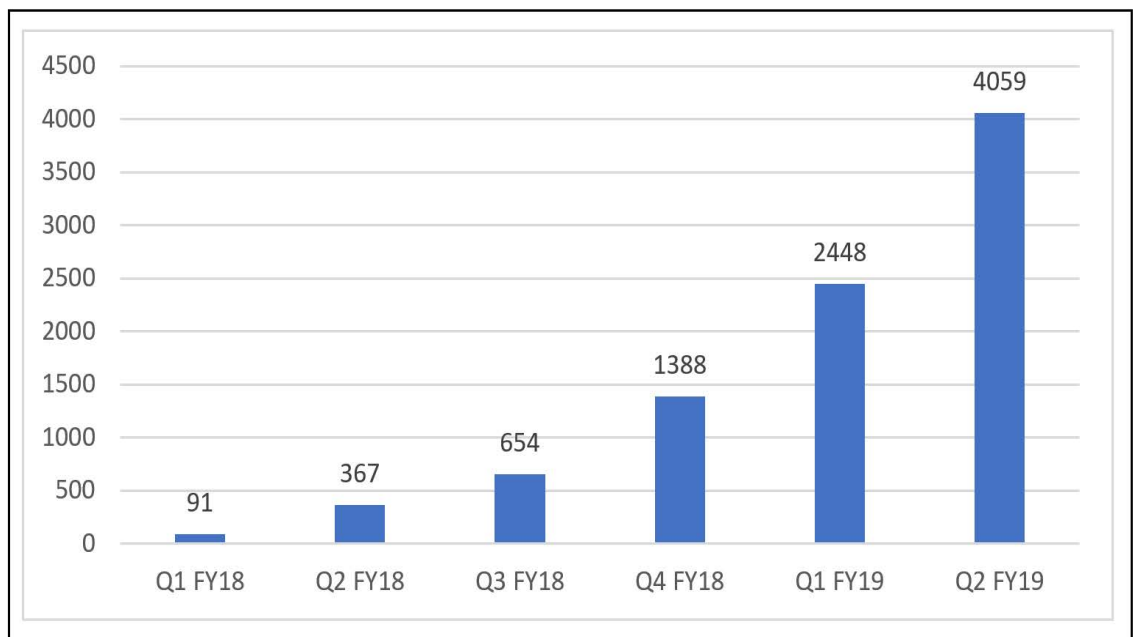
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world's pharmaceutical industry to make medical opiates come from Australia.

Most of the cannabis products in Australia are imported, therefore there is an opportunity for local cultivators to offer products to the market at a lower price. To diversify away from the local growth projections and strict regulations, companies can exploit large commercial opportunities by exporting their products overseas. The tough regulatory environment in Australia generates a big advantage for exporting companies, as the products of these companies have the highest global standards of quality control.

Nevertheless, the number of patients being prescribed cannabis is still low in comparison to other countries (Figure 1), and the greatest demand is still from North America and Europe, with producers of high quality, premium products benefitting the most. As the Asian market begins to expand, the current partnerships with China, Japan, and Indonesia will strengthen opportunities to capitalise on Asia's growing cannabis industry. In addition, there will be many opportunities going forward due to companies, such as AusCann, Althea, and Cann Group successfully building reputations abroad; similarly, the demand from Europe is growing. New Zealand is in the preparation for a non-binding referendum to decide whether to legalise recreational cannabis in 2020, which will improve Australian growers' positions.

Figure 1: Medical cannabis approved numbers (SAS-B)



Source: Fresh Leaf Analytics Q3 2019

The number of patient approvals continues to trend upwards as more people become aware of the medical properties of cannabis. Additionally, as medical practitioners search for the optimal dose for each patient it's reasonable to expect higher average doses per patient. In Australia, only patients with serious illnesses are prescribed medical cannabis. Last year, the Federal government relaxed the rules and made the system more user-friendly.

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Illegal use of cannabis in Australia

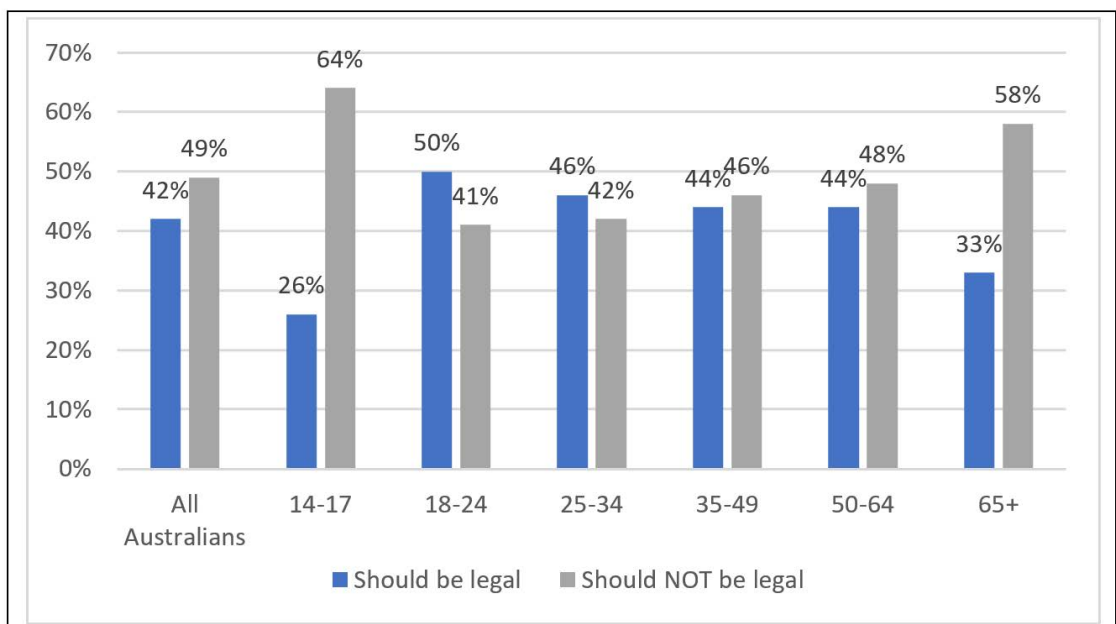
Cannabis is historically considered the most-used illegal drug in Australia and the second most frequently identified drug responsible for motor accident deaths, with 12.9% of the population aged over 14 using it in 2001, and 10.4% in 2016. In 2016, 36% of cannabis consumers were using it weekly. It was reported that 40% of prison entrants had consumed cannabis within the previous year.

Research indicates that 42% of Australians would favour the legislation of cannabis

Rising support for legalisation among Australians

Research in 2019 indicated that 42% of Australians would favour the legalisation of cannabis, which is 9% higher than four years previous, while the percentage of people suggesting cannabis should be illegal dropped by 7%. Research was done through face-to-face interviews with more than 50,000 people (Figure 2).

Figure 2: Attitude towards legalisation, by age, in 2019



Source: Roy Morgan 2019

Cannabis cultivation

Most commonly, cannabis is grown in greenhouses under artificial lights, although at certain latitudes it can be grown outdoors. Cannabis favours dry conditions with high temperatures but can adapt its genetics to new climates. High temperatures are less of a concern than colder temperatures, as plants rarely die from too much heat. Nevertheless, a dry environment will slow photosynthesis. The basic requirements needed for cannabis growth are heat, light, ventilation, nutrition, and water.

Outdoor cultivation

Cannabis can be grown outdoors in natural soil or in pots; however, to achieve good quantities of THC resin, the soil needs to be fertile and longer daylight hours are required. A favourable climate, a sufficient amount of water, and fertile soil will increase the quality of the crop. Ideal levels of THC are usually generated at around 35° north or south of the equator – the most common sites include Nepal, Mexico, northern India, Afghanistan, the United States, Australia, and most of Africa. Locations for outdoor cultivation are usually selected based on the amount of sunlight the area receives in a day, with at least 12 hours of daylight being the optimum amount .

Indoor cultivation

To grow cannabis indoors, artificial light, water, fertilisers, and nutrients are required. Generally, cultivating indoors is more expensive and complex; however, it has the advantage of allowing full control over the environment. Plants grow faster indoors due to 24-hour access to light, atmospheric CO₂, and managed humidity. Indoors cannabis can be grown either in soil or soilless, that is, via hydroponics. In hydroponic cultivation plants are fed a liquid solution containing nutrients and minerals. This method is preferred over soil-based methods as plants grow faster, which results in higher yield .

On average, the whole process, from a seedling to a plant, takes three to six months and requires the following:

- Warmth - The most suitable temperature is a daytime temperature ranging from 24°C to 30°C. Temperatures below or above that range will reduce the potency of the THC and result in slower growth. At very low temperatures, the plant goes into shock; however, some strains are able to resist freezing temperatures for some time .
- Light - There are a variety of options for light since cannabis plants can be grown in both natural and artificial light. When a plant is grown indoors under artificial light it will be exposed to 16 to 24 hours of light and up to eight hours of darkness. On average, cannabis requires 13 hours of persistent light to stay in a vegetative stage. Overall, cannabis grows well in places with a higher-than-average percentage of sunlight .

Overall, Australia is well positioned to meet global demand and become a global supplier

Potential for market growth

It is expected that the Asia-Pacific region will become the largest supplier of medical cannabis globally due to the high demand for cannabis-based treatments. Australia has a strong reputation for agricultural practices, high standards, and good crop safety management systems, which all contribute towards patients' confidence in the product. Researchers predict that the Asian market will be worth as much as US\$5.8bn by 2024 .

The Cann Group is typical of Australian cultivators who understand local sentiment and see the likelihood of legalisation of cannabis down the track but are currently working mainly in export markets as the local market is still restricted and in the development stage. The market value for medical cannabis in Australia is predicted to reach A\$1.2bn by 2024 and over A\$3bn by 2028.

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However, it has the potential to increase three times more if cannabis becomes fully legalised.

Due to high integration with Asia, Australian suppliers have potential to capitalise on the rising demand for medical cannabis in China, Japan, and other Asian countries. Demand for medical cannabis in China is estimated at US\$178bn while in Japan it is US\$16bn; consequently, the market position, economic growth, and stability of the country will attract foreign customers. Australia could also benefit from Canadian interest considering that cannabis is fully legalised in Canada and suppliers struggle to meet demand. Exporting to the US is also an option as more states move towards legalising cannabis for recreational use. Overall, Australia is well positioned to meet global demand and become a global supplier and, as a result, production will continue to grow .

What is medical cannabis prescribed for?

It is estimated that in the US, nearly 10% of cannabis users use it for medical purposes. Currently, there are 33 states that allow the use of cannabis for management of specific conditions; however, the Federal government still classifies cannabis as illegal, limiting its medical use and research into its effectiveness. As a result, the evidence of the efficacy of cannabis in managing various diseases is often lacking due to the restrictions on research .

Research done on cannabinoid (CBD found in the cannabis plant) has shown its potential to treat epilepsy, schizophrenia, and other psychological disorders, as well as Type 2 diabetes, inflammatory bowel disease, various cancers, and drug dependency. Another cannabinoid, THC, was identified as an analgesic with anti-inflammatory and antioxidant properties that is also able to prevent and reduce vomiting. The endocannabinoid system, which is comprised of natural molecules known as cannabinoids, is in charge of communications in the brain and body and can affect many significant functions. This system work is to regulate a number of activities, such as memory, mood, sleep, and appetite and it's believed that medical cannabis can treat several of these activities by modulating the endocannabinoid system .

A common medical use of cannabis is in CNS disorders such as the epilepsy syndromes Dravet and Lennox-Gastaut. Epilepsy is a common disorder - there are approximately 50 million people with epilepsy according to a 2017 World Health Organisation (WHO). A rise in road accidents has contributed to an increase in brain injuries, which in turn causes epilepsy, as well as an increase in neurological disorders and Parkinson's Disease. The valuation of the epilepsy market is estimated to reach US\$9.5bn by 2023 and a projected Compound Annual Growth Rate (CAGR) of 8.2% until 2023 . Some studies have identified that the combination of cannabis with Parkinson's Disease (PD) and Multiple Sclerosis (MS) therapies is a better option to improve motor and non-motor systems in PD patients and relieve symptoms like nausea, insomnia, somnolence, and dizziness in MS patients . Moreover, it was found that medical cannabis can cause muscle relaxation and patients with PD

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observed less tremors when using it. Cannabis is perceived to be effective in conditions with chronic pain.

Additional findings have supported the potential use of cannabis for treatment of localised and advanced pancreatic cancer after a demonstrated increase in survival of animals with pancreatic cancer, driving more studies towards clinical translation.

A US study of cancer patients' attitudes towards legalised versus non-legalised states regarding medical and recreational legalisation found that cancer patients from both types of states support legalisation of cannabis for medical purposes. Furthermore, support for medical use was higher than for recreational use, and cancer patients strongly believe in its medical benefits.

In terms of application, smoking cannabis is a harmful way to ingest it due to carcinogenic substances being inhaled directly into the lungs; therefore, it is not recommended by health authorities. Health experts are only able to prescribe medicines if they know exactly what the product consists of so they are able to prescribe the correct dose and monitor the effects of the drug, as well as adjust it according to a patient's needs. The challenge associated with using cannabis as a medicine is determining the correct dosage; vaporisers with integrated monitoring systems could solve this issue.

Medical cannabis as a substitute for opioids

The drugs most commonly used for pain relief are the opioids, however they have addiction potential and their misuse has resulted in a major crisis all over the world. Moreover there is a high risks when using them alongside with other drugs or alcohol, causing problems of dependence and death due to overdose. For instance, in 2018, over 1,100 Australians lost their live due to misuse of opioids prescription. Due to rising worries on the addictive nature of codeine, Australia in early 2018 rescheduled all codeine-containing OTC medicines, so that they are only prescription based.

In one study, participants noticed statistically significant effects from using medical cannabis to manage non-migraine headaches, neuropathy, spasticity, and joint pain. In 2016, research determined that using cannabis for cancer pain led to a 64% decrease in opioid use, better quality of life, and less side effects from medication; it also encouraged participants to use fewer medications. In a study of 17,000 cancer sufferers, 70% felt improvement in pain and general wellbeing and people suffering chronic migraines noticed less migraine episodes after using the drug. A 2018 study in Australia concluded that cannabis did not reduce pain symptoms or opioid use; however, the research was primarily based on recreational as opposed to medical cannabis use.

Medical cannabis is clearly safer and less addictive than opiates. When comparing medical cannabis to opioids, to date, it has been concluded that medical cannabis can be an effective alternative. In a sample of 900 medical cannabis users who previously consumed opioids, 81% concluded that cannabis was more effective without opioids, and 97% agreed that they could downgrade their opioid usage when taking cannabis.

Medical cannabis is most commonly used for pain management, especially chronic pain, and it is clearly safer and less addictive than opiates

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Medical cannabis can potentially treat insomnia

Research shows that between 13% to 33% of Australians are diagnosed with insomnia as a primary disorder. The typical pharmacological treatment includes antihistamines, benzodiazepine-receptor agonists, antidepressants, antipsychotics, and melatonin. However, all benzodiazepines are identified as potentially addictive, can cause memory and attention problems, and are not recommended for long-term use. Barbiturates can depress the central nervous system and cause sedation; they are usually used for anaesthesia and can cause death in overdose . In September 2018 the Australian Parliament initiated an investigation to examine the causes, economic costs, and treatment options for inadequate sleep and disorders. It is expected that by raising the issue, demand will increase for over-the-counter (OTC) sleep aids by encouraging consumers to take medication for insomnia, etc.

A major driving factor behind sleep disorders is the rise in digital device usage exposing users to blue light emitted by LCD screens, which disrupts sleep patterns. Another significant factor is the ageing population as sleeping issues increase with age. Overall, the sleeping aids market is anticipated to increase by a CAGR of 2% until 2023, to reach A\$21m .

Due to relaxing and sedative effects, cannabis has ability to reduce the time it takes to fall asleep. It was found that medicinal cannabis lead in average of 30 minutes less in falling asleep for people with sleeping issues, while it also took 15 minutes less to fall asleep for strong sleepers. Moreover, due to THC active ingredient, cannabis seemed to shorten the time spent in rapid eye movement (REM) sleep . Medical cannabis offers less severe side effects comparing to sleeping pills, but requires low THC dosage. Larger THC dosage may cause opposite effects, resulting in anxiety and other psychological effects.

Medical cannabis as a treatment for autism

The prevalence rate of autism has increased from 1 in 100 to 1 in 70, which is an approximately 40% increase and translates to around 350,000 Australians with autism . To date, the scientific evidence that medical cannabis is a potential solution for autism has yet to be fully built out; however, several studies in Israel have identified that cannabis oil can be effective for the treatment of Autism Spectrum Disorder (ASD) symptoms – 30% of patients noticed significant improvement and 50% noticed moderate improvement –but placebo-controlled trials are still lacking . In the current market, there is no cure for autism, but several medications can treat specific symptoms, such as insomnia, depression, and seizures.

Medical cannabis products

Initially, medical cannabis products were available in two forms – in an oral spray and in oil-based products. Currently, oil-based products have become the most popular way to take medical cannabis; however, there are several forms available today, such as

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G. Mammoser, "Here's What Experts Say About Medical Marijuana as Treatment for Autism", Healthline (Feb 2019)

- capsules;
- dried-leaf cannabis, which can be inhaled or vaporised; and
- topical creams that are all available in other markets, but not in Australia yet.

Recreational and medical vapour market

Vaporisers have become increasingly popular in the legal cannabis market, and medical acceptance of cannabis use will drive more first-time users to this market. Vaporisers are a healthier alternative to traditional methods and vaping has high support from physicians. The use of inhalers provides easier, safer and more self-controlled methods to deliver medicine, which is especially beneficial for patients who have difficulty swallowing a tablet or when medications are highly metabolised prior to entry into the bloodstream.

The global market for recreational and medical vapour was valued at US\$11bn in 2016 and is anticipated to reach US\$86bn by 2025, rising by a 23.25% CAGR for the next five years due to the rising demand for recreational and medical cannabis .

Hundreds of companies compete in the vaporiser industry as cheap vape pens can be easily purchased from China on the wholesale market and rebranded for resale. However, there are very few good quality products available, especially those suitable for medical purposes and recommended by medical professionals.

Regulation varies widely

Canada at the forefront

The legalisation of recreational cannabis represents a significant transition for Canadian society, opening doors of opportunity. The total cannabis market in Canada is forecast to generate up to C\$3.2bn in revenue in 2020 rising from 2019 forecast of C\$1.5bn , with legal sales contributing to more than half of the total because consumers are willing to pay more for legal products. With the recent legalisation, spending is expected to increase by as much as 68% .

Cannabis is not advertised in Canada because the government is cautious about excessive use of recreational cannabis. Almost a year after full legalisation, licensed manufacturers are struggling to meet the demand levels and ensure the quality of neighbourhood dealers. Many people are finding cannabis from stores to be too expensive and prefer to buy from neighbourhood dealers – a gram of illegal cannabis is approximately 36% cheaper. Moreover, there are a rising number of complaints that legal cannabis doesn't have the same quality as the cannabis on the black market. As long as the price differential exists, the black market will be in demand.

On 17 October 2019, Canada legalised the sale of edibles and beverages containing cannabis - this move will contribute to a rise in an additional stream of demand . Products will include candy, baked goods, and cannabis extracts, as well as topicals like oils, make-up products, and ointments.

United States

Cannabis can be used for medical purposes in 33 states, while recreational cannabis is allowed in 11 states for adults over the age of 21, namely:

1. Alaska
2. California
3. Colorado
4. Illinois
5. Maine
6. Massachusetts
7. Michigan
8. Nevada
9. Oregon
10. Vermont
11. Washington

Medical cannabis in some states is limited to CBD and cannabis with a low THC content, while others allow full recreational usage. The main reason the remaining states are not legalising it is due to concerns it raises regarding cannabis abuse, issues it poses to society in general, and safety uncertainties. It is still highly likely that more states will legalise cannabis or at least amend certain laws to promote broader access. In addition, one of the biggest drivers for the states to legalise cannabis is the resultant revenue. In general, the public is highly supportive of more liberal cannabis laws; however, the older population tends to be against such moves.

Overall, the cannabis market in the US is large (Figure 3). The total market, including illegal cannabis, reached US\$52bn in sales in 2019 and has the potential to reach US\$77bn by 2022, with a 76% increase in cannabis-related jobs in 2019, significantly contributing to the US economy.

The major challenge facing US distributors where recreation cannabis is legal is fear of the Federal government. Cannabis shops operate as cash-based businesses since major banks avoid the cannabis industry due to a fear of federal drug charges. Consequently, businesses have difficulties paying taxes and obtaining loans; therefore, dispensary owners are required to carry large sums of cash.

States that are close to legalise recreational use of cannabis in 2020 include New Jersey, Arizona, Nebraska, New York, Florida, Kentucky, and Ohio.

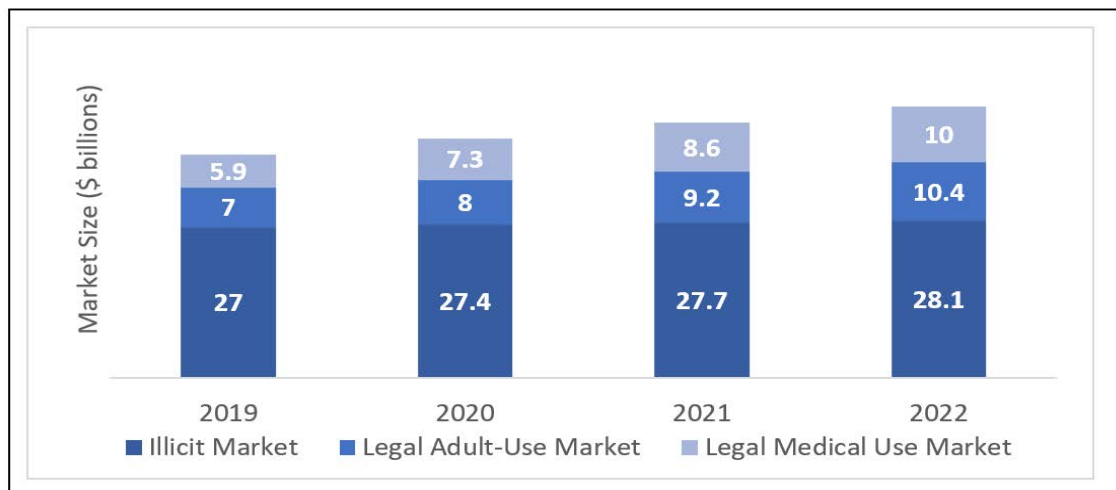
The total market, including illegal cannabis, has the potential to reach US\$77bn by 2022

P. Evans, "8 incredible facts about the booming US marijuana industry", Business Insider Australia (May 2019)

A. Graf, "Marijuana Legalization in US: Is End of Cannabis Prohibition in Sight?", The Globe Post (Sep 2019)

S. Williams, "These 3 States Are Likely to Legalize Marijuana in 2020", The Motley Fool (Jan 2020)

Figure 3: US Cannabis market forecast



Source: New Frontier Data, 2019

Europe

It's been three years since Germany's parliament voted to legalise medical cannabis, which supported interest from other European countries and involved the European commission. Poland has considered a domestic cannabis law to import medical cannabis products, allowing licensed producers from North America to enter a new market. Malta now allows licensed growing and exporting of cannabis to other EU states. In late 2018, the EU Parliament encouraged the European Commission to begin a harmonisation process for a legal structure for medical cannabis products in all states, which might take longer. Cannabis grown in EU markets is most likely to have a lower cost of production and rising price competition and will be based on the German market. The medical cannabis market in Germany is projected to grow from US\$73m in 2018 to US\$2.7bn in 2023, while the total EU cannabis market is projected to grow from US\$316m in 2018 to US\$8bn in 2023.

The use of recreational cannabis is still illegal in most European countries; however, several countries are moving towards decriminalising regulations. Medical forms of cannabis are legal in 22 countries, and 12 more countries are in the process of decriminalising the personal use of cannabis for recreational purposes.

The market leader in Europe is likely to be Germany, which is in the process of distributing cultivation licences. In terms of sales, €50m was achieved in three quarters in 2018 and around 40,000 patients received prescriptions. It is anticipated that the number of patients will reach one million in Germany and around five million in Europe. The second biggest market in Europe is expected to be Italy, where medical cannabis was accepted in 2013. It is projected that Italy could reach sales of US\$1.2bn by 2027.

A number of EU countries have developed exceptional use programmes to permit access to medical cannabis to treat a limited range of conditions. Countries that have established these programmes include Croatia, Denmark, Finland, Norway, Poland, and Sweden.

P. Homberg, "Medical Cannabis in Europe: Recent Developments, New EU Policies, and Brexit – What's Next?", Labiotech UG (Apr 2019)

Brightfield Group, "Europe's CBD Market is Estimate to Grow Over 400% Through 2023", Brightfield Group Report (Mar 2019)

Cannabis Business Plan, "Europe could be the largest cannabis market in the world", Cannabis Business Plan (2018)

European Monitoring Centre for Drugs and Drug Addiction, "Medical use of cannabis and cannabinoids", EMCDDA (Dec 2018)

Recreational cannabis legalisation is not currently a priority; however, the first country decided to legalise recreational cannabis is Luxembourg, where the government has confirmed that it will need at least two years to legalise the drug.

In Europe, medical cannabis is illegal in:

1. Iceland
2. Latvia
3. Lithuania
4. Slovakia
5. Hungary
6. Bulgaria
7. Serbia
8. Kosovo
9. Albania
10. Sweden

Latin America

After Canada, Uruguay was the second country to fully legalise cannabis. Other Latin American countries allow medical use only, excluding:

1. Bolivia
2. Guyana
3. Suriname
4. Venezuela

Sales of cannabis products were projected at US\$125m in 2018 with potential to reach US\$12.7bn by 2028. Mexico is also trying to legalise cannabis and is planning to allow consumers to grow up to 20 plants at a time for personal consumption. Another significant contender is Chile, which has the highest consumption rates per capita . Legalising medical cannabis is profitable for these countries - for example, there are already three international firms in Chile that have invested around US\$14m, which has benefitted the local economy .

Asia

Due to several restrictions in Asia, the medical cannabis market will experience slower growth; the market is projected to reach US\$5.8bn by 2024 .

Countries in Asia where medical use of cannabis is legal are:

1. Turkey
2. Sri Lanka
3. Thailand
4. South Korea

C. Schnuer, "Recreational cannabis law at least two years away", Luxembourg Times (Dec 2019)

C. Dempsey, "Medical Cannabis: Latin America Market Overview", Medium (Dec 2018)

J. D. Bogota, "Medical marijuana: which countries lead in Latin America", LatinAmerican Post (Jun 2019)

Prohibition Partners, "Three things we learned from the Asian Cannabis Report", Prohibition Partners (May 2019)

5. Israel
6. Georgia
7. Cyprus

South Korea was the first Asian country to legalise medical cannabis in 2018.

The Thai government has considered decriminalising the use of cannabis. Thailand legalised medical cannabis in 2019, giving it a first-mover advantage in the Southeast Asian region and creating opportunities for farmers and the agrarian industry. Recently, Thailand began producing pharmaceutical-grade THC and CBD oils, chocolate wafers, tablets, and oral sprays.

One potentially significant market for medical cannabis in Southeast Asia is Malaysia. Under the Malaysian Dangerous Drugs Act of 1952, offenders faced receiving the death penalty; however Malaysia has decided to end criminal prosecution of drug users. Singapore has no tolerance for drugs, however it has started looking into the medical uses of cannabis.

In recent years there have been efforts to legalise medical cannabis in the Philippines.

China has recently granted permission to extract CBD and allows hemp seeds and oils on the market, but has only approved use of CBD for cosmetics.

Current legislation in Australia

In February 2016, medical cannabis was legalised in Australia at a Federal level and thousands of patients are currently taking medical cannabis for around 30 medical conditions approved by the Therapeutics Goods Administration (TGA). If cannabis were to be completely legalised for recreational as well as medical use, it is envisaged that an 'Australian Cannabis Agency' (ACA) would act as a primary regulator and intermediary, buying from farmers and selling to licensed retailers.

In a recent review of the Narcotics Drugs Act, several changes in the licensing process were recommended. Out of 246 cannabis research or cultivation licences, 63 have been granted since June 2019. The review has inspired the Office of Drug Control (ODS), which is currently in charge of cannabis regulation and advises on imports, exports and manufacturing in Australia, to take more initiative. One of the recommendations of the review was a single licence scheme for cannabis production, instead of granting separate licences for cultivation, production, research, and manufacture. A single licence scheme would enforce the adoption of an easier and more streamlined process for application and approval.

Australia's medical cannabis industry is growing rapidly due to Research and Development (R&D) incentives, favourable rules, and experienced scientists. As soon as regulation relaxes, more industry participants will be able to enter the market.

For example, there were 2,500 patient approvals in 2018 and in 2019, the number reached approximately 28,000, including existing users who renewed approvals or had multiple approvals due to expiry. The whole market in Australia is ultimately expected to reach 500,000 active users.

R. S. Ehrlich, "Thailand rolling out its legal weed wares", Asia Times (Apr 2019)

R. Lee Katz, "Legalization and Acceptance of Cannabis on the Rise in Asian Countries", JD Supra (Sep 2019)

No more need for medical marijuana bill? by Atty. Lorna Patajo-Kapunan, Business Mirror, 24 February 2020

S. Williams, "Why the popularity of these Australian cannabis clinics is soaring", Commercial Real Estate (Sep 2019)

Cannabis Sector Experts, "Australia's cannabis legalization a potential multi-billion-dollar industry", Biz Latin Hub (Jun 2019)

Baker McKenzie, "Reforms underway for Medicinal Cannabis in Australia", Baker McKenzie (Oct 2019)

S. Jacobs, "Weed Week: Australia's medicinal cannabis sector had its 'hockey stick' moment in 2019", Stockhead (Sep 2019)

The biggest shift within the Australian market will happen when cannabis products become legal to sell via retail outlets or OTC

The biggest shift within the Australian market will happen when cannabis products become legal to sell via retail outlets or OTC; at present they are only sold via medical professionals.

Currently in Australia, the following conditions are considered treatable with medical cannabis:

- AIDS/HIV
- Alzheimer's Disease
- Arthritis
- Nausea and vomiting
- Cancer
- Diabetic peripheral neuropathy
- Multiple Sclerosis
- Anxiety and depression

Major results include pain reduction, appetite stimulation, improvement in mood scale, improvement in spasticity, assistance with joint suppression, and inhibition of neurodegeneration.

In October 2019, the Australian Government decided to contribute A\$3m towards research on medical cannabis for cancer-related diseases. The grants will be used to discover ways to treat cancer pain and the related side effects. The aim is to do further clinical studies and to increase evidential results to assist medical professionals .

While the process may seem difficult, current regulation strategy makes it simple to observe patient data, giving the opportunity for medical researchers and regulators to better understand the needs of patients. Recently, the TGA has initiated an online access system, allowing patients in some states to submit an application to the state government and the TGA at the same time.

Differentiation in legislation and processing

ACT

The Australian Capital Territory (ACT) government was the first in Australia to legally allow the growth and possession of cannabis for personal use from January 2020. The territory allows users to grow up to four plants of naturally cultivated cannabis or consume 50g for personal use . However, since the drug still remains illegal on a Federal level, consumption and growth of the plant can still result in criminal prosecution. The Federal Government has stated that it will review the final version of the bill and might override the ACT .

NSW

New South Wales (NSW) is the state with the most patient access as well as the most prescriptions issued. The processing times have been reduced and the requirement is now a single clinical assessment from the TGA, instead of the previous assessment requirements of both Commonwealth and NSW regulators.

NSW has also established an advisory service that enables medical practitioners to make a phone call to find out how medical cannabis is able to assist a patient. Additionally, cannabis pharmaceutical prescriptions are not limited to specific symptoms for which they can be prescribed. The NSW Greens have promised to introduce a bill to legalise, license, and regulate recreational cannabis, which would allow NSW residents to grow up to six cannabis plants for personal use.

Northern Territory

The Northern Territory (NT) is still struggling to decide whether it should focus on the industrial hemp industry or cultivation of medical cannabis. The decision to legalise the growth of industrial hemp was passed by the Northern Territory's Legislative Assembly on August 2019 and new act will commence for 2020 growing season. It is believed that the NT could have a strong competitive advantage due to its favourable climate. Medical cannabis can be accessed through Special Access or Authorised Prescriber Schemes administered by the TGA.

Queensland

The government approval in this state requires up to four weeks before the drug is available to a patient; however, the Queensland Government is set to improve patient access by revoking the laws that limit the speed of prescriptions. Changes in regulations will make the prescription process more efficient due to the removal of state-level approval, and visitors to Queensland with valid prescriptions will no longer need specific Queensland approval. Prescriptions in this state are limited only to patients who suffer conditions which can't be treated with the conventional treatments or where those treatments have caused intolerable side effects.

South Australia

South Australia is strongly against recreational use. However it continues to support medical cannabis and wants to lead the production and development of the drug, focusing on education, research, and industry innovation for the international cannabis market. This state is moving towards hemp cultivation and further distribution of cultivated products in Asia.

Victoria

Victoria was the first state to legalise medicinal cannabis in 2016 and has competitive advantage in the research. Through the Victorian Access to Medicinal Cannabis Scheme and the Access to Medicinal Cannabis Act 2016, it is also possible to access cannabis for children with intractable epilepsy where the child is under the care of a specialist pediatric neurologist.

Western Australia

From November 2019, health professionals in Western Australia have had approval to prescribe medicinal cannabis without applying for Special Approval. However, if a prescription is needed for a patient under the age of 16, Special Approval will still be required. Western Australia doesn't require

any state-based approval for Schedule 4 CBD products, but it does require an approval for THC Schedule 8 drugs.

In most of the states, only patients with certain conditions, mainly chronic, and terminally ill patients, have been able to get access to cannabis. As we noted above, the Federal government is set to further support medical cannabis projects through the Major Project Status system as well as the recent review of the Narcotics Drugs Act 1967.

How do you get approval to use medical cannabis?

The Special Access Scheme

This scheme is used to gain access to unapproved therapeutic products that are not in the Australian Register of Therapeutic Goods (ARTG). Medications that have entered the ARTG are assessed for quality, safety, and performance. There are three pathways in the SAS:

SAS Category A – notification pathway for seriously ill patients - This notification pathway may be identified by the prescribing medical or health practitioner. Patients are defined as seriously ill when a person's death is likely in the absence of early treatment.

SAS Category B – application pathway for patients not fitting into Category A or who can't be prescribed under Category C- This application pathway may be identified by a health practitioner. Applicants from this category are required to be approved by the TGA in order for the medication to be available to them; the TGA wants to know the full diagnosis, clinical justification, and reasons why current medication within the ARTG list can't be used for treatment.

SAS Category C – notification pathway - This application gives the opportunity to certain types of health practitioners to supply medication with a sufficient history of use. Therapeutics must specify indications and the type of health practitioners allowed to supply this product.

In terms of application methods, products used by inhalation through a vaporising device are excluded from the ARTG to be used for medical cannabis. Therefore, a vapourising device can only be accessed through unapproved medical device access pathways.

To import products containing cannabis, cannabis resin, extracts, oils, or cannabidnoids, a licence and permission is required.

Authorised prescribers

In situations where patients need access to medicines that haven't been approved by the TGA, medical practitioners may have to become 'Authorised Prescribers' of a particular drug for a specific patient. In order to become an Authorised Prescriber, a medical specialist is required to have expertise on the conditions being treated, identify the patient's needs, and have the ability to monitor the outcome of the therapy. They also need to be able to supply the medication directly to patients under their control and will need to report to the TGA every six months on the number of patients being treated.

Clinical trials

Another way of accessing medicinal cannabis in Australia is through clinical trial. The TGA regulates the use of therapeutic goods supplied in clinical trials and clinical trial sponsor must notify TGA of its intent to sponsor a trial involving an unapproved drug before starting to use the medicine.

What are the costs and benefits for the Australian economy?

Pricing

Due to the rise in the number of pharmaceutical-grade cannabis products available to Australians, prices have decreased. Nevertheless, costs remain highly volatile as they are affected by a variable pharmacy margin and dosage adjustments. Overall, prices are anticipated to fall as more participants enter the market.

Costs remain highly volatile as they are affected by a variable pharmacy margin and dosage adjustments.

One of the challenges within the medicinal cannabis market is that spending on illegal cannabis still prevails, as it is much cheaper. It's estimated that the average spend, per person, on illegal cannabis is A\$297 per month and for legal cannabis it is A\$372 per month, which is 25% higher.

Demand in Australia is mostly supported by imported products. Currently, imported medical cannabis products cost between A\$300 and \$350 per bottle. Conversely, Australian products could be priced around A\$200 per bottle. For example, the average price for oil-based cannabinoids dropped by 11% in 2018 to A\$0.30 per mg. The price changes based on the type of cannabinoid. THC is significantly more expensive; on average, it's A\$0.50 per mg, while CBD is, on average, A\$0.21 per mg, which is mainly due to higher production costs and less restrictions on CBD .

In terms of pharmacy mark-ups, on average, the products are marked up by 26%, but it can reach 140% due to additional handling costs, tracking, paperwork, and prescriptions for unregistered medicines.

In addition, medicinal cannabis is not covered by the Pharmaceutical Benefits Scheme (PBS); consequently, all the costs are covered by patients and will always be higher than pharmaceuticals subsidised by the government. The cost to patients is affected by the condition that requires treatment, the required dosage, and the amount of THC and CBD required. Research by Cannabis Access Clinics has estimated that the most common condition for patients receiving prescriptions in Australia is chronic pain, with an estimated spending, per patient, of A\$353 per month, on average, in Q3 18. The second most common condition is epilepsy, where patients require much higher dosages to see an effect and spending is, on average, A\$992 per month. Other conditions that are treated with pharmaceutical-grade cannabis in Australia include insomnia, fibromyalgia, anxiety, and multiple sclerosis with an average spending of A\$212 per month .

Competition with regards to pricing continues due to new offerings on the market. In Australia, in total, there are around 76 products that doctors can prescribe and 21 brands available that are licensed by the ODC. It is expected that more Australian-

made products will enter the market this year; however, they will face competition from low-cost importers of finished goods from large global suppliers.

The average price to pharmacy throughout FY19 ranges from A\$0.10 per mg to A\$0.23 per mg, which is mostly for generic products, while much higher pricing is applicable to companies that have heavily invested in research, patents, and clinical trials. Here products can be priced as high as A\$1.50 per mg.

A comparison made by Fresh Leaf Analytics has found that oil-based products in Australia are priced at 16% more than in Canada. The price differential is mainly due to shipping overheads, local supply chains, and sales maintenance. The products can't be sold directly to patients, as they are in Canada, and only pharmacies can distribute medications, which adds significant overheads to consumer costs.

Pricing for the pharmacy for dried cannabis flowers, which is the second most popular delivery option, ranges between A\$18 to A\$28 per kg, which is around two to three times higher than prices in Canada and is expected to decrease in the near future .

Production cost and cost to patient

The current cost of production in Australia is 10% to 15% higher than overseas, which challenges competition in the export markets. Those who adopt efficient manufacturing techniques have higher potential to take a bigger market share. Some producers have started to adopt new growth methods and are switching from growing cannabis indoors in warehouses to glasshouses, where it is possible to capture sunlight and save on electricity. The price stabilised by year-end due to the availability of cheaper medications.

It is common practice in Australia to prescribe a gradual dosage because optimal dosage is dependent on a specific patient's needs or disease conditions; therefore, the amount paid for the treatment is highly variable. Recently one market observer noted that the average dosage prescribed to patients had risen by 15% over a six month period, from 47mg to 54mg per day. It's reasonable to expect further increases as more long-term patients continue to use the drug.

A recent study has estimated that, on average, A\$5 to A\$10 per day is spent by one third of all patients. This figure has since declined by 13%, possibly due to more doctors switching from higher- to lower-cost products.

CBD has received more attention than THC in the Australian market and makes up around 33% of all prescriptions, mainly because it can easily be obtained with a doctor's prescription via a pharmacy, via retailers, or online.

Additionally, CBD is better as an initial trial prior to prescribing THC to determine a patient's response to medical cannabis as a treatment. Since THC is the psychoactive ingredient associated with the euphoric effects of cannabis, governments and prescribers are treading carefully in terms of considering any product with a noticeable THC content.

Medical cannabis and job creation

Canadian companies continue to invest in the Australian market due to challenges they face in meeting local demand after recreational use was made legal. As a result, there are many job opportunities that international producers operating in Australia can

The government appreciates the economic power of the medical cannabis market and offers subsidies to overseas firms

offer. Over the next five years medical cannabis production expects to create around 10,000 new jobs across the horticulture, science, pharmaceuticals and medical industries .

The government appreciates the economic power of the medical cannabis market and offers subsidies to overseas firms to set up their facilities in Australia, create new jobs and support the local economy, as well as reduce major barriers to entry.

The recreational cannabis market

The use of cannabis for recreational purposes is not legal in Australia. The Australian Government, however, is considering making changes to the Narcotic Drugs Act of 1967 which would authorise cannabis growing for medicinal and research purposes and might consider recreational use in the future .

The Australian Greens political party is proposing for full legalisation of cannabis on the basis that the legal cannabis market would change the business model and contribute significantly to the economy. It is anticipated that the recreational cannabis in Oceania could reach A\$5bn yearly .

The Greens want to allow Australians to grow up to six plants for their own use. This would allow the government to take full control over the market to reduce crime, remove 'black' market revenue streams, and lower the amount of people contacting illegal drug distributors.

Other arguments for full legalisation include the missed opportunities from licensing fees, the extra Goods and Services Tax (GST) that could be gained, and the unnecessary spending on criminal justice that would be reduced. As we noted above, the ACT Legislative Assembly has cancelled the definition of an offence in the 'Drugs of Dependence Act 1989', which has removed the drug from the list of prohibited substances and decriminalised 50g consumption or the ownership of four plants at home .

High demand for hemp-based products

Hemp is a strain of the cannabis plant – Cannabis Sativa – used historically as a fibre and oil source. Hemp is protein-rich, has essential vitamins and minerals, and polyunsaturated fatty acids in the form of omega-3 and 6. In short, hemp can be considered a 'superfood'. The combination of beneficial ingredients in hemp tend to improve the cardiac system, stabilise mood swings, and improve skin and joints. Hemp generally doesn't have any medicinal effects due to its low cannabidiol level, which is the main substance used for medical treatment, but it also has very low levels of THC (tetrahydrocannabinol), which is linked to the psychoactive features of marijuana.

Edible hemp became legal in Australia in 2017 and comes in products such as hemp seeds, oil, protein powder, and flour. Hemp oil products currently hold the highest market share. Initially, hemp products were used for industrial, clothing, and pet food purposes but they went on to be approved for human consumption in the UK, the US, Canada, and several European countries. The demand for plant-based protein and a supply shortage of hemp are major contributors to the higher demand within the industry. The

PharmOut, "Medicinal Cannabis Academy – Responding to the 10,000 new Australian jobs expected in Medicinal Cannabis Cultivation and Exportation", PharmOut (May 2019)

R. Laycock, "Medicinal cannabis in Australia", Finder (2018)

B. Song, "Examining the Oceania Cannabis Market", New Frontier Data (Oct 2018)

M. Evans, "Personal cannabis use in Australia: is legalisation close?", Finfeed (Apr 2019)

Food Standards Australia & New Zealand, "Hemp seeds as food", Food Standards Australia & New Zealand (Jun 2017)

ingredients in hemp are associated with many dietary and health benefits that are highly desirable. Consequently more and more food and beverage manufacturers have been willing to include hemp-based products in their offerings. Hemp also contains gamma-linolenic acid (GLA) and is the only edible seed that contain this acid . GLA is used to treat arthritis, nerve damage, eczema, and high blood pressure, among other things. Moreover, the presence of CBD in hemp products is a powerful antioxidant, with natural anti-ageing and immunity enhancing properties.

Hemp is used in many supplements, food, and drinks. When companies manufacturing nutraceuticals start buying hemp in their home countries, they will have better control over the supply chain and finding better qualified suppliers will be easier. CBD is not considered valid for food and dietary supplements and the Food and Drug Administration (FDA) has ruled that it can only be used as a drug product .

Hemp seeds also contain a variety of essential amino acids and as a result have the ability to improve the digestive tract and increase energy levels. After the rapid growth of the health foods market in the US, whole seeds, hulled seeds, and hemp seeds are being used to make protein and energy bars, granola, and other supplements and dietary products; their low glycemic index is beneficial for diabetics, and hemp protein is beneficial for muscle growth as it's an efficient vegetable source of protein.

Another product with rising popularity is hemp oil, which is rich in minerals, vitamins, and essential fatty acids and is used as a light body oil. Other products containing hemp oil include soap, hair care products, and lip balms .

The expected gross value of Australian hemp production in 2012 was approximately A\$300,000 but is forecast to reach A\$3m by 2023

Australia has a perfect climate for hemp grain crops and expansion of its production will provide economic and social benefits and great potential for increasing its export value . The expected gross value of Australian hemp production in 2012 was approximately A\$300,000 but is forecast to reach A\$3m by 2023; however, the current US hemp industry is worth US\$150m . Zion Market Research suggests that the hemp food market was around US\$3.9bn in 2018 and is predicted to generate US\$4.89bn by 2026 and grow 6.2%, on average, annually. Since cultivation of industrial hemp is illegal in many countries, these countries will be dependent on imports of raw fibres, seeds, and finished goods.

Due to the steep increase in hemp seeds on the market, the market for hemp food products has developed and countries have begun to invest a significant amount in R&D, especially China and the UK. Moreover, hemp has been integrated into the superfoods segment and has opportunities in many distribution channels, such as supermarkets, convenience stores, hypermarket stores, and specialty superfood shops.

Another demand driver could come from an increase in products such as corn chips and snack bars, which has the potential to strengthen hemp-based food products. A consumer shift has occurred towards healthier products with less fat, as well as a demand for an increase in specific dietary requirements due to lifestyle and food preferences. Customers continue to demand allergen- and gluten-free products.

Zion Market Research, "Global Hemp-Based Market Will Reach USD 4.89 Billion By 2026: Zion Market Research", GlobeNewswire (May 2019)

S. Beale, "Top 5 Nutraceutical Trends in 2019 – Cannabis Is In", Master Control (Apr 2019)

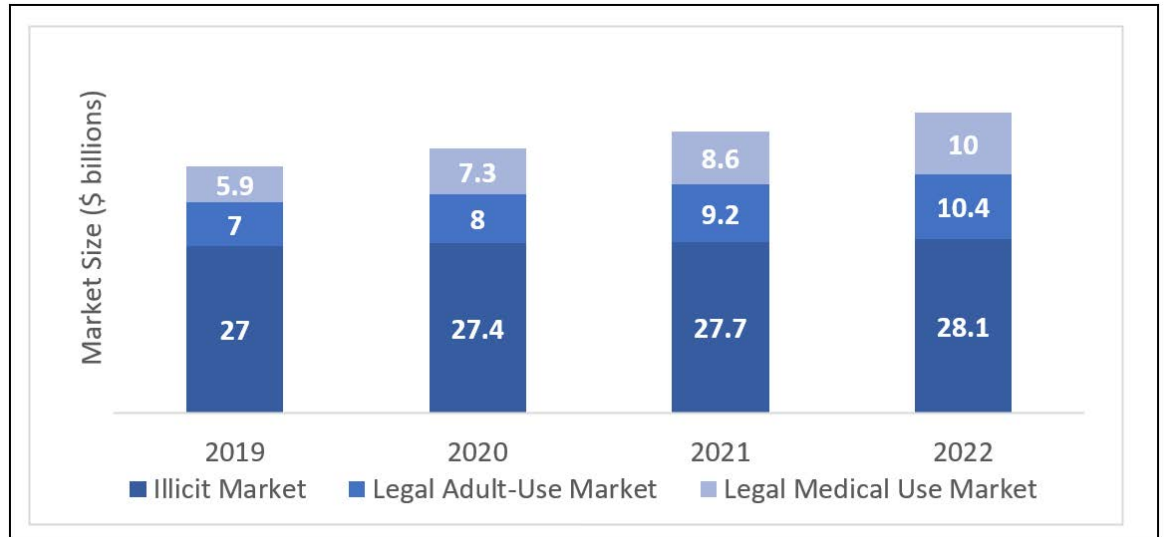
T. A. McKeon, "Emerging Industrial Oil Crops", ScienceDirect (2016)

Australian Industrial Hemp Alliance, "Growing Australia's Industrial Hemp Industry", AIHA (2017)

A. Martinello, "5 questions you may have about the hemp industry", Australian Farmers (Nov 2018)

In terms of region, the APAC region has the highest potential for growth due to large investments into R&D and an increase in production capacity due to efficient collaboration with innovation centres. Additional demand into the APAC region will be fuelled by emerging markets like China and India. The APAC region has produced a very low number of hemp products; however, this region has the biggest sales for health and wellness products. The market for health and wellness products was US\$236bn in 2017, accounting for 33% of global retail sales in this segment and is projected to grow at 6.4%, reaching US\$321bn by 2022.

Figure 4: Projected retail sales of health and wellness products by type in Asia Pacific from 2018 to 2019 (% growth)



Source: Mintel & Euromonitor, 2017

The main reason that the APAC region experiences fewer releases of hemp-based products (Figure 4) is a lack of public awareness and confusion regarding the product, which remains the biggest challenge within the industry. The policy related to hemp is still evolving and some major pharmaceutical companies have anti-hemp practices; subsequently, it will take some time to adjust to hemp-based food products as a normal food source.

Recent M&A activity within the industry

Rising Merger and Acquisition (M&A) activity will benefit small cannabis and hemp ventures and contribute to their survival. The most recent M&As occurred between different state operators and firms who've aggregated their licences. It is expected that the majority of future consolidations will focus on companies operating abroad or holding a licence, medical cannabis companies, CBD and hemp products, and food and beverages containing cannabis. The actual number of applications compared to the expected number of licences awarded suggests there is low probability of getting approval. Therefore, larger companies will aim to acquire companies that have licences, providing further growth within the cannabis marketplace.

CBD-infused products will be the main driver with a high chance of non-cannabis companies (including tobacco and alcohol companies) with a global

presence entering the market and partnering with cannabis companies to develop new products, such as CBD-infused drinks for existing brands.

Zelda Therapeutics merger with US-based Ilera Therapeutics, October 2019

In this merger Zelda provided access to international markets, including Australia, Germany, and the United Kingdom. Ilera, based in the US, is focussed on the treatment of anxiety and pain, and it also develops technologies to treat specific conditions. This merger will assist both companies to operate in a heavily regulated global market. Ilera Therapeutics will provide the main revenue stream from its cannabis formulations under the HOPE brand in the US and continue clinical developments; it will enter the market in 2020. In addition, the companies will also focus on dermatology products within the cannabis and retail markets through its subsidiary. The merged entity was renamed Zelira Therapeutics (ASX:ZLD) and development will continue in the pain, sleep, and anxiety markets. The entity will apply its experience in clinical trials, research and development, product commercialisation, and marketing .

Greenfield MC & Emerald Plants Health Source

The Australia medical cannabis distributor, Greenfield MC, is becoming a cannabis cultivator with the help of a US-Canadian company, Emerald Plants Health Source. Under an August 2019 agreement the companies will create a Joint Venture (JV) to cultivate cannabis in Australia and export in the APAC region . The JV will allow companies to achieve affordable access to cannabis, participate in education programmes, R&D and help Australian patients to access the medication.

Cronos Australia has completed its IPO

Cronos Australia (ASX:CAU) plans increase its presence in the APAC region through its partnership with one of the largest cannabinoid companies – the Cronos Group. Its main focus will be on supplying established branded products, rather than growing and cultivating cannabis itself, as well as product development, sales, and advertising. Cronos Australia will import dry flower cannabis and oils produced by the Cronos Group in Canada. It will be able to generate early revenue before its own branded products from Pace Naturals are released, which include dry cannabis and CBD oils with different THC and CBD concentrations that can be used to treat conditions including muscle pain, mental illness, and depression. Sigma Healthcare (ASX: SIG), will assist Cronos Australia with distribution .

Challenges in the Australian market

It is anticipated that the overall industry generated \$50m in revenue in 2019; however, the currently small addressable market remains a significant obstacle. It is estimated that the market size consists of around 500,000 patients in Australia, while currently only 5,000 patients actively use the

treatment and receive new or replacement approval, leaving a huge gap in the possible potential.

The major challenges that Australia faces are:

- 1) Progress within the regulatory landscape not being fast enough to offer adequate demand for rising supply capacity.
- 2) Uncertainty in the regulations with regards to driving and when it is legal to drive after consuming the drug. This issue is causing medical practitioners to prescribe CBD-only products.
- 3) Adoption of CBD products, which needs to be better organised in order to attract a larger patient base and support local companies. In comparison to the UK, the US and Canada, Australian regulation doesn't allow the distribution of CBD products over-the-counter.
- 4) Costs to patients remaining high, resulting in a loss of potential patients who find the products too expensive. If the major suppliers in the market are mostly generic-product companies that do not hold exclusive patents or do not actively participate in clinical trials, it is unlikely that in the short term costs will decrease.
- 5) The Australian Medical Association (AMA) being reluctant to support the Greens efforts on behalf of cannabis legalisation due to the possible physical and mental health problems of cannabis use.

Risks within the industry

Regulatory/Legal risk

Variable legislation around the globe causes higher costs of operation. It mainly arises due to the risk associated with obtaining a licence to operate. There are many rules guiding companies on how to operate and changing laws will force companies to adjust their operations to comply with new regulations. For example, in some US states the sale and use of cannabis is authorised; however, it is still illegal under federal law.

Financing risk

Cannabis companies face challenges due to the limited options available for financing. US federally regulated banks avoid accepting proceeds from licensed cannabis businesses because they risk losing federal statute. Due to the unavailability of bank financing, cannabis companies are forced to pay taxes and other expenses in cash.

Black market risk

Cannabis deals will still occur illegally on the black market, and it will continue to remain the main competitor to the legal market. A reduction of demand in this market will only occur when there is an improvement in legislation and administration. Legal cannabis products should be consequently priced below the black market in order to attract customers. The black market is able to randomly reduce prices, putting legal companies at risk.

A reduction of demand on the 'black market' will only occur when there is an improvement in legislature and administration

Valuation risk

Cannabis company stock valuations may not reflect growth prospects and profitability. Most companies within the sector are growth-stage companies and stock prices over-reflect growth prospects. Valuations should only take the legal market into account.

Dilution risk

The dilution effect is relevant to cannabis stocks due to the legal challenges that prevent companies from bank borrowing to fund their growth and operations. Issuing additional shares to raise money will be undertaken at a cost to existing shareholders because their ownership percentage will decline and dilute, reducing the value of their investment.

Commoditisation risk

Since cannabis is an agricultural crop, it can be commoditised. Commoditisation can lower the pricing power for products when they become over-supplied.

Operating costs

Development and operating costs in the cannabis industry are high due to its being in the early stages of its growth.

Taxation risk

Since operating a cannabis business is highly reliant on state and federal taxation laws, cannabis companies might be required to pay more tax due to being illegal under US federal law.



Appendix I - Glossary

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

ARTG – Australian Register for Therapeutic Goods.

Barbiturates – Central nervous system depressants, used as sedatives, hypnotics, anaesthetics and anticonvulsants

Cannabidiol (CBD) – A chemical found in the cannabis plant, commonly used for seizure disorders, Parkinson's, Crohn's, and other diseases.

Cannabinoids – A chemical compound that acts on cannabinoid receptors within the endocannabinoid system and affects the release of neurotransmitter into the brain.

C. indica – A cannabis strain that is characterised by physically sedating effects and is used for relaxing, with higher CBD and lower THC.

C. sativa – A cannabis strain that provides invigorating and uplifting cerebral effects, and is lower in CBD and higher in THC.

Endocannabinoid system – A biological system regulating feeding behaviour and energy balance through peripheral mechanisms that is made up of cannabinoids and the routes they connect. By working together these parts of the system regulate mood, memory, sleep, and appetite.

Endocannabinoids – Lipid-based molecules similar to cannabinoids, that act as neurotransmitters.

GLA – Short for Gamma-Linolenic acid, a fatty acid found in vegetable oils. Used as medication for disorders such as breast pain, eczema, scleroderma, nerve pain or damage due to diabetes.

GMP – Good Manufacturing Practice.

Hemp – A strain of the C. sativa species that has 0.3% or less of THC concentration.

Hydroponics – A method of growing plants without soil in a water and nutrient-based solution.

Marijuana - The common name used for the Cannabis sativa plant.

ODC – Office of Drug Control.

Opioids – A wide range of pain-relieving drugs that act interconnect with opioid receptors in human cells. Usually made from the poppy plant (e.g. morphine)

SAS – Short for Special Access Scheme, an arrangement that allows the import/supply of unapproved therapeutic goods for a particular patient.

Tetrahydrocannabinol (THC) – The chemical responsible for the psychological effects of marijuana that stimulates brain cells to release dopamine, creating euphoria.

TGA – The Therapeutic Goods Administration, which regulates medical devices and drugs that are required to meet Australian quality standards, safety, and quality.

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