



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Another Year In The Grass

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Behold the Cannabis Conundrum whereby the international medicinal cannabis - or medical marijuana - industry is said to be booming; despite a lack of credible government-backed data being a major issue in most countries; despite strangling government regulations often designed by officials who may or may not have been using the product itself; despite the legit industry being subsumed by the black market in countries where medical marijuana is legal but recreational marijuana is not and despite being subsumed in recreational legal countries and states by recreational users themselves who in turn are subsumed by black market profiteers; and despite - and perhaps the most damning of all - increasing evidence that there isn't really all that much evidence to back most of the claims of conditions that can be cured by medical marijuana and that many conditions that were thought to be cured by marijuana medicine have now emerged as not being curable.

Indeed, anxiety may be setting in among companies producing medicines to treat anxiety - given that anxiety disorders were the second most common reason for the prescription of marijuana medicines last year, according to the Australian Journal of General Practice, and given that evidence is emerging that "there is little evidence to support this intervention" on top of other evidence that prescribing marijuana medicines for anxiety can be harmful and high doses of tetra-hydro-cannabinol (THC) may even cause anxiety.

In October, Cannabiz media reported that almost half of medical marijuana approvals in the first nine months of 2023 were for very high THC medicines, with anxiety prescriptions accounting for nearly a third of the 44,326 very-high-THC or category five medicines.

The Australian Journal of General Practice said in August 2022 that special access scheme-B (SAS-B) data showed that the Australian Therapeutic Goods Administration (TGA) provided 58,782 approvals for the prescription of medicinal marijuana for 'anxiety' from November 2016 until June 2022 and that "approvals for anxiety and [post-traumatic stress disorder] are now accumulating at more than 4,000 per month."

In fact, the journal added a cautious warning noting that “Clinical use of THC must proceed cautiously because of its tendency to induce anxiety in some patients at higher doses.”

This warning was also amplified in October this year by the New Scientist which reported evidence of potential harm in prescribing medical marijuana for anxiety. It also added depression, schizophrenia and attention deficit hyper-activity disorder (ADHD) to its potential-harm list.

The New Scientist, noting that support for medical marijuana sky-rocketed in recent years, gave detailed insight into its effectiveness, publishing evidence for 20 conditions. And while at one end of its spectrum it listed four conditions in its potential-harm-evidence category, at the opposite end of its spectrum, the ‘Strong Evidence of Benefit’ category, it only listed three conditions: epilepsy, multiple sclerosis symptoms and tuberous sclerosis complex.

Conversely, in late November, a 20-year-long study by the University of Sydney, published in the American Journal of Psychiatry, found that there was no evidence to suggest marijuana reduces illicit opioid use, but the New Scientist claimed: “One of the most promising effects of medical marijuana is preventing or treating opioid misuse.”

It added that a 2023 study of more than 8,000 people who were prescribed opioids for chronic pain showed that those using marijuana approximately halved their opioid use after 18 months, while those who only used opioids had a 15 percent reduction.

The publication also noted that cannabidiol (CBD) can reduce drug cravings in people addicted to heroin, and quoted New York psychiatrist Julie Hall saying, “Cannabis is sort of like the condom of drug policy. It’s a very clear harm reduction method that decreases the amount of people that die [from opioids].”

But in reality, the most provable property of medical marijuana is its ability to attract consumers. Business is booming. Or as the New Scientist succinctly puts it: “Medical marijuana use is sky-rocketing.”

The publication highlighted three hot spots: the UK, US and Australia - all three of which have bewilderingly divergent medical marijuana sectors.

Cannabis In The UK

Pot peculiarity prevails in the UK where medical cannabis was approved in 2018 but only for patients with rare illnesses.

GW Pharmaceuticals’ multiple sclerosis medicine nabiximols (brand name Sativex) was the first natural cannabis plant derivative to gain market approval in the world, but 100 percent of the marijuana medicine prescribed in the UK is imported. As of September 19, this year, the UK imported 23,890kg of cannabis (in base drug form) more than triple the 7,762kg of 2022.

Conversely, the UK is one of the world's biggest cultivators of medical marijuana and in 2019 the UK's marijuana exports accounted for 75 percent of the global market.

On December 3 this year, Britain's Sky News reported that five years after medical marijuana was legalized, the government still hasn't funded any clinical trials that could see it being used in the National Health Service.

And as of April 2023, no NHS prescriptions for medical marijuana had been written in the last two years, while 89,239 prescriptions for unlicensed marijuana medicines (the only type officially available) were issued between November 2018 and July 2022.

A survey of patients by the UK Centre for Medical Cannabis found that 1.4 million people were using illicit marijuana for medical problems in 2020.

In March 2023, it was estimated that there were about 20,000 people officially using medical marijuana with about 1.8 million people self-medicating on the black market.

Other figures suggested there may be 30,000 to 32,000 medical marijuana patients in the UK but there were no official figures on the exact number of patients prescribed marijuana. The only cannabis-based products for medicinal use (CBPMs) available in the UK are unlicensed medicines. According to the Cancard website, the Cancard is a medical identification card, recognized by the police, validating to any third-party that the bearer is consuming cannabis for medical reasons.

420 In The USA

In the US, marijuana medical use is legal in 38 states, four of five permanently inhabited US territories and the Federal District of Columbia, and the number of US citizens enrolling in medical marijuana programs more than quadrupled between 2016 and 2020, surpassing 2.97 million, according the Annals of Internal Medicine.

In late 2020, the Marijuana Policy Project reported that 246 million people lived in medical-marijuana-legal states and that medical marijuana patients in those states numbered 3,866,746, although it was noted that this was an undercount because some states do not have mandatory registries.

To enrol in a US medical marijuana program, people must obtain a doctor's referral and sign up on their state's registry. Then, for a fee, they are given a card that allows them to buy medical marijuana from an approved dispensary.

The number of medical marijuana dispensaries open in each state varies as does the number of patients, and pertinent laws also vary from state to state as do prices which can vary dramatically even in cities within the same state.

The US was a world leader in reintroducing legal medical marijuana when California passed a proposition doing that in 1996, after the 1970 Controlled Substances Act officially banned marijuana for any use throughout the US.

But medical marijuana research in the US lags significantly because, as the Washington Post reported in June 2020, US law makes scientific research on marijuana too expensive and complicated. There are now movements to counter this and in late November, the National Institutes of Health announced funding of a 'Resource Centre for Cannabis and Cannabinoid Research' to "address challenges and barriers to conducting research on cannabis and its constituents".

And on December 2 US President Joe Biden signed a new law that will, according to Science.org, make it "easier for US scientists to get their hands on some pot - for research, that is".

US scientists struggle to get pot to study even if they are living in one of 24 states, three territories and DC where recreational marijuana use has been legalized.

The new law will improve access to marijuana for medical research by speeding up government permit issuance to the scientists who want to study marijuana.

Marijuana In Australia

In Australia, a common complaint is that government red tape hinders the market and in turn the Therapeutic Goods Administration claimed in September that the rapid growth in prescriptions was hindering its ability to hinder - or at least intervene - to limit some possible patient harm.

In May this year, the Nine Entertainment newspapers also said medical marijuana use was booming with more than 1.17 million prescriptions issued since medical pot legalization in 2016.

In 2019, there were 144 doctors authorized to issue medical marijuana prescriptions and in January 2023 that figure had risen to 1,701. In 2022, doctors prescribed it to 316,879 patients, compared to 150,117 in 2021 and just 292 in 2018. Between January and June this year, 291,469 patients began medical marijuana treatment through authorized prescribers - only three years ago that figure was 3,086.

Analytics and technology firm Nostra Data compiled figures from 5,100 of Australia's 5,800 pharmacies showing that more than 350,000 marijuana medicines worth \$41.6 million were dispensed in the three months to June 30, 2023, almost triple that of two years ago.

Late last year, the TGA warned Federal Health Minister Mark Butler about such growth and suggested more regulatory overhaul. But it had already increased controls and by July 2023 all imported marijuana medicines released in Australia had to prove they were produced under good manufacturing practice (GMP) except for starting material.

The TGA warned that boundaries were being pushed and that "there are very few approved cannabis medicines". It had tracked 521 adverse reactions to medical marijuana to February this year, with 77 requiring hospitalization and 16 being life-threatening. It was also notified of four deaths in children using medical cannabis, although "the deaths appear related to underlying health conditions".

The TGA's document said: "There is little scrutiny on whether the risk-benefit ratio remains favorable over time for patients who use [marijuana medicines]. This concern is especially relevant when it comes to long-term use of THC-containing products, especially in children, who are more vulnerable to the deleterious effects of this cannabinoid."

It added: "The prolonged therapeutic use of 'unapproved' medicinal cannabis products, especially in the vulnerable paediatric population calls into question the appropriateness of the TGA to continue to place the risk of prescribing of these products with the medical profession whilst an unregulated industry continues to grow."

And grow it has. The medical marijuana industry grossed about \$244 million in revenue in 2022, with revenue increasing at 41 percent from the first half of the year to the second.

On December 8, the Office of Drug Control released figures showing that Australian medical marijuana companies produced 24,900kg of marijuana in 2022, up from 16,700kg in 2021.

In January 2018, approval was granted to begin exporting medical marijuana and the-then Federal Health Minister Greg Hunt said he hoped Australia would become the world's top supplier of medicinal cannabis.

Subsequently, marijuana exports increased by almost six percent from 1,426kg in 2021 to 1,510kg in 2022 and imports were up dramatically, from 7,173kg in 2021 to 24,887kg in 2022.

Australia's marijuana inventory in 2022 was 15,400kg, down from 17,700kg in 2021.

Figures aren't compiled for the dollar amount of medical marijuana research being undertaken in Australia but the boom's largesse doesn't extend to the "purists" in the sector: companies intent on research to develop medicines rather than profit growth through cultivation and preparing for recreational legislation.

Biotech Daily has 11 such ASX companies in its new Cannabis Corner suite and Biotech Daily's founder David Langsam says: "Biotech Daily looks for companies that give benefit to human health, and are likely to produce a profit in the longer term."

The current Cannabis Corner's collective market capitalization was up 1.0 percent to \$588 million for the month but down 29.9 percent for the year to November 30, 2023 – and nowhere near the all-time high, so to speak, of \$1,973 million at April 30, 2021 when there were 22 companies or even the \$1,405 million at the end of 2021 after the reduction to 11 companies.

The writer was the co-founder of the Australian Marijuana Party and stood as Senate candidate JJ McRoach in the 1977 Australian Federal Election. Biotech Daily editor David Langsam was his campaign director.

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