THE GLOBAL CANNABIS REPORT

4TH EDITION





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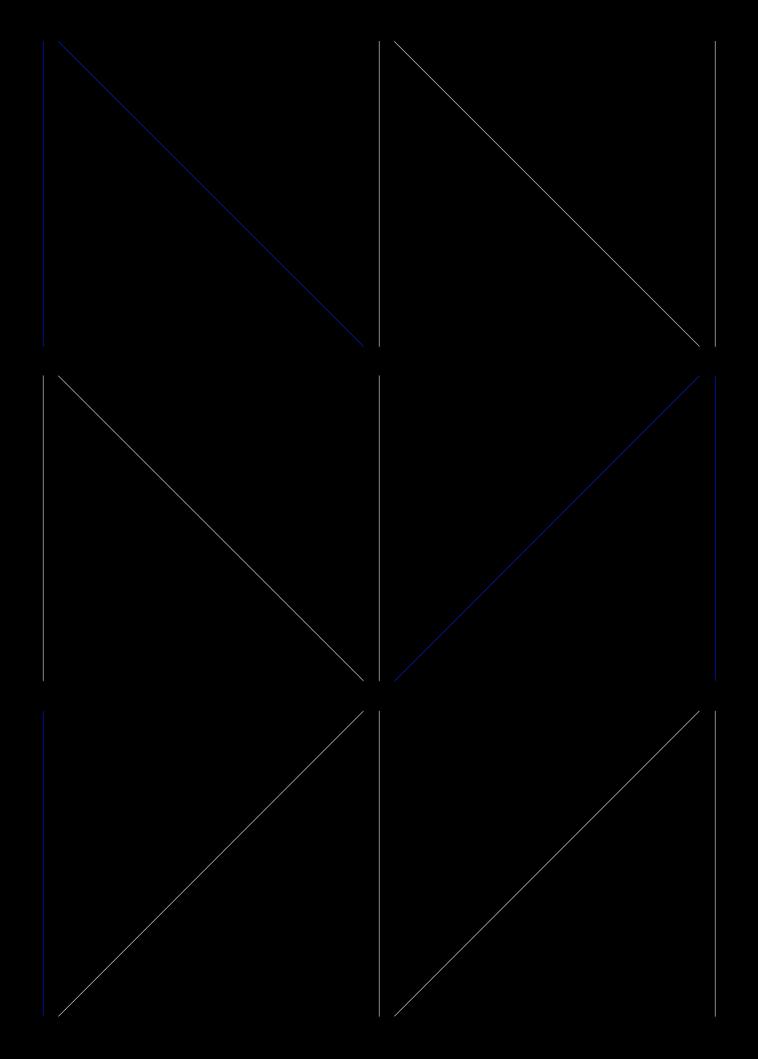
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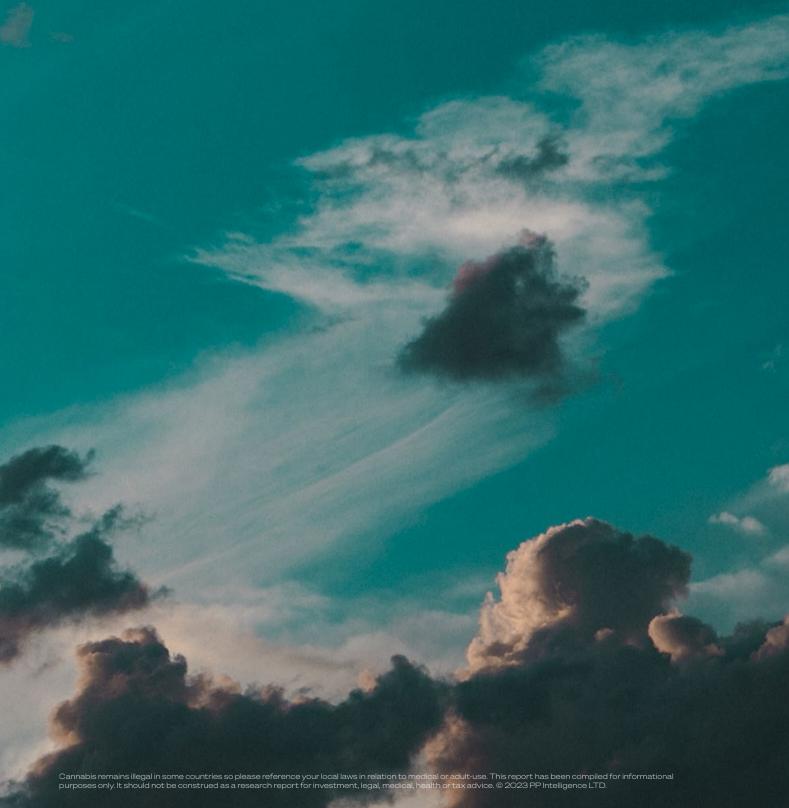
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Our reports are the leading source of data and insights for the global cannabis industry.

The Strategy & Data team provides cutting-edge intelligence to help business leaders, investors and policymakers understand and engage with the nascent cannabis markets across the world.



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Prohibition Partners is the number one source for data and information on established and burgeoning cannabis and psychedelics markets. Read by over 150,000 global cannabis investors and entrepreneurs, and creating more than six million social impressions annually, Prohibition Partners produces thought-leading industry reports. If you would like to partner with us and support independent data and research please contact our Events & Media Director

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Sponsorship with Prohibition Partners is a unique opportunity to promote your business and brand to the most influential figures in the international cannabis market. Our research, data and content reaches key stakeholders in the industry: from politics to pharma and cannabis to consumer-packaged goods. As companies and investors scramble to get a foothold in the market, sponsorship is an invaluable opportunity to put your brand front and centre in many of the industry's most influential reports.









FOREWORD

Rokshaw Laboratories

As the European market continues to grow at an increasing rate year by year, Rokshaw is proud to present Prohibition Partners' 4th annual Global Report as Headline Sponsor. As the UK leading manufacturer and distributor of medical cannabis, we can attest to the fantastic work that Prohibition Partners provide, to deliver cutting edge analysis for the global market and discover the key trends that are driving growth.

Market growth, particularly in Europe is driven by various companies in the Curaleaf International group, primarily in the UK and Germany. As we look to North America to understand the potential of the European opportunity, individual markets have taken great strides in improving access to patients and prescribers.

In the UK, awareness is at an all-time high despite key regulatory barriers still in place. The majority of prescriptions can still only be written by doctors listed on the specialist register and can only be provided on private prescription. The UK population is still largely unaware of the legalities surrounding medical cannabis. Not only this, but the population who are aware may not understand its benefits in a medical sense which require a big educational push from the entire industry to increase overall access.

Despite this, 2023 has been a watershed year with a record number of private clinics now providing medical cannabis treatment for lower appointment costs than ever before. As a traditional oil and flower market, more formulations and dosage forms have entered the market, broadening the treatment options available for patients. As the UK market has matured, patients and clinicians alike are starting to look at products with detailed terpene profiles, which has seen exciting new brands and producers entering the UK medical cannabis market to fill this need.

Further work is needed in the UK's industry to increase access further, which is why data provided by Prohibition Partners is vital in coming together to grow access.

Further afield, key markets in Europe such as Germany are on the cusp of substantial growth with the impending legislation on adult-use on the horizon. The Global report will show how these key markets are growing and showcase the size of the opportunity that other countries can learn from.

As an industry, we all ultimately want to unlock the potential of medical cannabis to patients who will truly benefit from treatment. The free flowing movement of data, research, education and investment will go a long way in establishing cannabis as a generational medical breakthrough. Every and any effort to push this forward from an industry perspective is pivotal in improving general patient welfare across the globe.



Your UK-Leading Medical Cannabis Partner



- Rokshaw are the UK-leading experts in the manufacture and distribution of medical cannabis as part of Curaleaf International, the biggest cannabis company in the world.
- The first manufacturer of full spectrum EU-GMP medical cannabis in the UK, producing a full range of oils, dried flowers and other novel product formats containing varying levels of THC & CBD.
- Supplying the widest range of medical cannabis in the UK, providing a market entry point to high quality producers and brands through our best-in-class manufacturing and distribution service.
- Working with clinics and prescribers across the UK, providing end-to-end support and CPD-accredited training, to help with prescribing, dispensing and identifying medical cannabis as a treatment option for their patients.

To tap into our expertise, contact us now

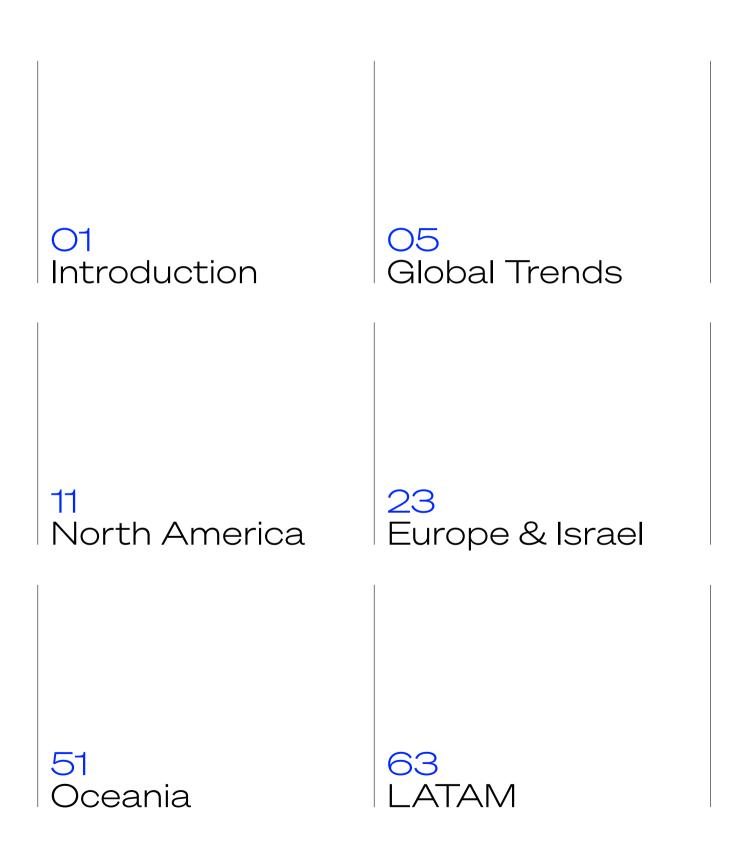
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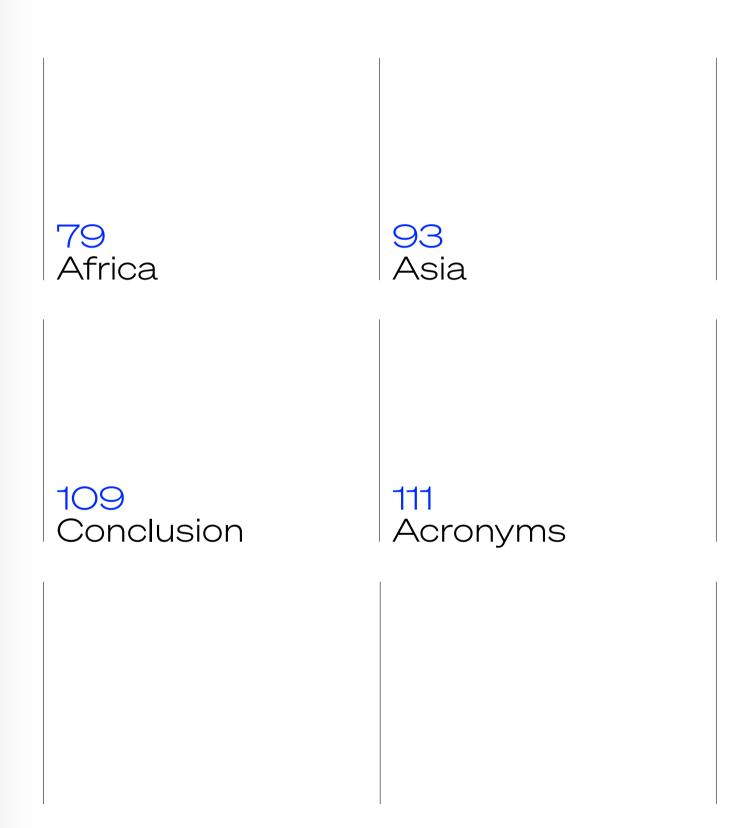
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Introduction



The legal cannabis industry in each global region has recognisable patterns of development that characterise industry, regulatory and market activity. Over the past year, each region has generally followed a familiar path of development, without diverging significantly from patterns seen in previous years. North America remains the global powerhouse of legal cannabis, with strong state-by-state growth, promising regulatory reform and international isolationism in the US, while Canada's strong international presence but challenging domestic environment persists. Europe continues to be a somewhat fragmented and heavily regulated business environment, seeing steady growth concentrated in key countries, incremental but important progress on adult-use legalisation, and ongoing legal confusion over CBD. Latin America and Africa are moving slowly along the path of becoming sources of supply for the global industry, while keeping patient access limited. Oceania continues to be a hotspot for both imports and exports. Asia's potential remains mostly untapped, apart from a handful of pioneering countries such as Thailand and Japan. Despite the slow pace of change, the direction of progress is constant - facilitation of product access, integration of markets, growth of sales, standardisation of regulations, rising product quality, widening public support, etc.. This progress is present to greater or lesser degrees in each region, but the forward momentum in positive cannabis reform is consistent amongst them all.

EXPERT INTERVIEW



Sasho Stefanoski CEO, PHCANNINT

Recently you've been appointed as the new CEO of PHCANN International Group, tell us about yourself?

My beliefs are strongly connected to the benefits of cannabis for medical use for patients, those who most need cannabis to improve their health, alleviate the symptoms of their illness, restore their will to live and fight for recovery. I consider myself as one of the pioneers of medical cannabis in Europe, as I have been actively involved in this industry since its beginnings in Europe in 2017, and consider myself a connoisseur of the industry. Prior to my recent appointment, I held the position of General Executive Director of Nysk Holdings, a daughter company of PHCANN International. It is an honour for me to lead such a promising company - the PHCANN International group has subsidiary companies in Germany, Poland, Macedonia and Croatia. Together with my team, we will open new horizons for the cannabis industry in the coming period.

My portfolio is quite extensive and related to the management of health systems and their financing, while my formal and informal education relating to medicine and pharmacy gives me a strong platform for positioning medical cannabis within the pharmaceutical industry.

PHCANN International is one of the biggest European indoor producers; you are already established as a premium producer worldwide, what are your goals and your strategy moving forward?

Yes, PHCANN International is a multinational pharmaceutical company, operating in accordance with EU-GMP standards. It is known for its state-of-the-art facility, the biggest in Europe with a production capacity of approximately 15 tonnes of premium flower per annum. We have established our own worldwide infrastructure and our own independent distribution channels across three continents, with the ability for constant and stable supply in a timely manner, which is one of our main advantages. Our strategy is based on long-term analysis of the European market but also the development course of the medical cannabis market worldwide.

Our corporate social responsibility is to provide patients in need of products containing high-quality cannabinoids of natural origin and to disseminate knowledge about the therapeutic use of cannabinoids. We work closely with partners, doctors, and patients to fully understand patient needs. Our mission is to make a wide range of medical cannabis preparations available to patients who can benefit clinically - at the right time, and at an affordable cost. Moving forward our strategy is clear: to build strategic alliances for growth and future expansion into new markets.

What are your key markets and how do you see the development of the cannabis industry by the end of this decade?

PHCANN International is focused on delivering premium medical cannabis products to patients around the globe where medical cannabis is available. We deliver products to the UK, Germany, Poland, the Czech Republic, Australia and Brazil. The cannabis industry is evolving, and more and more countries and their governments are considering medical cannabis as a therapy for people in need. The next phase of the development of the industry should be strong interaction between medical doctors, medical doctors' societies, patients, and medical cannabis producers, building trust and understanding. Investments in education, understanding cannabis as a herbal product, but also as a pharmaceutical product, is a prerequisite for breaking stereotypes and gaining trust from broader populations across countries. We try to operate at the highest levels, working with government officials in various countries, by making sure that all pharmaceutical compliance standards and reguirements are followed in delivering products to patients.

What is on your roadmap for 2024-2025? Do you plan to expand further?

Our strategy is based on our values and goals. We try to build synergies with all of our partners worldwide to bring medical cannabis closer to patients and make it more easily available. Our growth strategy is connected to opening new markets and investing in better understanding of medical cannabis benefits.



Global Trends



European Adult-Use Legalisation Bypassing International Law

As adult-use legalisation continues to develop throughout the globe, governments have implemented specific frameworks in regard to harm reduction and scientific research to bypass international laws. The regulatory hurdles associated with adult-use legalisation in a given country are associated not only with national regulatory frameworks but also with international treaties and laws, such as the 1961 Single Convention on Narcotic Drugs, also implemented in EU law, which can make it difficult for countries and policymakers to create a legal adult-use market. For countries looking to legalise adult-use cannabis, incorrect implementation could mean a violation of international laws and treaties they abide to, which could possibly cause an international backlash.

To bypass international regulatory barriers, countries in Europe have framed adult-use cannabis legalisation for scientific research, as seen in Switzerland, the Netherlands, and Germany (Pillar 2), which aim to use pilot projects to examine the social, health and youth protection effects of legal commercial supply chains of adult-use cannabis. Additionally, countries frame adult-use cannabis legalisation for harm reduction purposes, as under international law a country may seek to end prohibition and allow private consumption if it is conducive to the prevention and treatment of addiction to narcotic drugs and psychotropic substances. With these structures in place and with countries being able to interpret international laws to a certain extent, it will be exciting to see how other countries in Europe, as well as globally, will justify and frame adult-use legalisation in the future.

Big Tobacco Doubles Down on Cannabis

It was only going to be a matter of time before big tobacco companies entered the cannabis landscape, as there have always been synergies between the two, not only in the classic mixing of the two products for consumption purposes but also in the similarities of the two industries in terms of supply chains, regulatory oversight, production processes and product variety. As the tobacco industry continues to receive a negative reception due to the dangers and health risks of tobacco, the shift towards cannabis is a viable option for larger tobacco players in the industry, especially as the use of vape products continues to rise, adult-use legalisation continues, and the medical and wellness aspects of CBD and cannabis become normalised. Although tobacco companies entered the cannabis market as early as 2018, with Altria investing US\$1.8 billion into Cronos, the cannabis industry is currently seeing a significant rise in cannabis investments by larger tobacco companies that are eager to enter the growing space.

British American Tobacco (BAT), together with its venture capital arm Btomorrow Ventures, is one of the few who have made significant strides in the space, acquiring stakes and investing in funding rounds throughout the global cannabis industry. In Canada, the company invested US\$221 million for a 19.9% stake in the cannabis producer Organigram Holdings in 2021. In the same year, BAT closed a C\$31 million Series A funding round for the water-soluble cannabinoid company Trait Biosciences, with another round closed in October 2023. In the US, BAT closed a US\$20 million to US\$25 million Series C funding round for the cannabinoid ingredient and finished product producer Open Book Extracts, in 2022. Additionally in 2022, BAT acquired a 20% stake for US\$57 million in the leading CBD company Charlotte's Web, contributing another US\$10 million for a 20% stake in a joint venture to acquire FDA approval for a hemp-based botanical drug for neurological disorders. In Europe, BAT acquired a minority stake in a German cannabis company focusing on CBD and medical cannabis, Sanity Group, for an undisclosed amount in 2022.

Philip Morris International is another player aiming to hold a significant share of the cannabis market, as in July 2023 the tobacco monolith announced its plan to acquire the Israeli medical cannabis inhaler company Syqe Medical for up to US\$650 million. In its first stage, Philip Morris plans to invest an initial US\$120 million to aid Syqe Medical's metered dose inhaler in receiving approval status from the FDA. Once approval is granted, the company aims to acquire all of Syqe Medical's shares for US\$650 million. As the tobacco industry continues to face public scrutiny, with falling cigarette sales and governments seeking to implement further restrictions on the use and sale of tobacco products, for

example the New Zealand government implementing laws to make the country 'smoke-free' by 2025, it can be expected that the cannabis industry will see more investment from traditional tobacco players in the near future, as cannabis provides them with an exciting opportunity to capture growth and transition their businesses to ones that are more socially acceptable.

US Cannabis Consumption Rates Normalised Post-COVID-19

During the coronavirus pandemic, there was a surge in the growth of legal US cannabis sales, which reached all-time highs in 2020, leading many in the industry to believe that sales figures would remain consistent throughout the following years. However, as vaccines rolled out and restrictions began to drop, US cannabis sales started to fall and normalise – the general public minimised their usage as they were able to leave their homes, return to work, and socialise again.

The COVID-19 virus massively affected the world's public health infrastructure, education systems and economy, as businesses and schools were forced to shut down and people were mandated to stay at home. Although it was disastrous for many, it proved to be beneficial for some US cannabis companies as they and cannabis dispensaries were considered 'essential' businesses, similar to pharmacies and groceries, by 28 US state health departments. Alongside certain states legalising delivery and kerb-side pick-up options, adult-use cannabis consumption and sales witnessed monumental highs in 2020, with legal adult-use cannabis sales in Colorado reaching over US\$180 million in July 2020 alone, as adults consumed legal cannabis to treat their COVID-19-related anxiety, boredom, stress and depression. However, as the COVID-19 vaccinations began to roll out and certain restrictions were dropped, throughout 2021 and 2022, many people were able to go back to work and socialise in public spaces. This led to a continual decrease, followed by a steady, slow growth curve, in adult-use cannabis sales as they began to normalise just above pre-pandemic levels



Celadon Pharmaceuticals PLC (AIM: CEL) is a leader in the medical cannabis industry and has successfully paved the way with regulators to achieve EU-GMP approval for the production and supply of High-THC medical cannabis.

Celadon's research has led to the first MHRA-approved clinical trial for chronic non-cancer pain in the UK using medicinal cannabis flowers and is dedicated to addressing unmet patient needs, pioneering new paths in healthcare innovation.

Having successfully negotiated a number of commercial contracts, the most recent contract being valued up to £26 million over the next 3 years, Celadon is laying the foundation for continued growth, research and development and further commercial partnerships.

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- +44 (0)203 150 0252

Celadon is seeking partnerships to use our expertise in cultivating high-quality medical cannabis at our UK nextgeneration indoor growing facility.

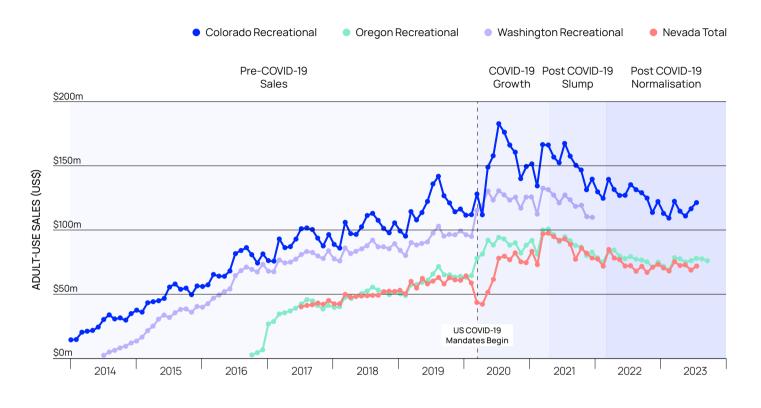
Benefits of working with us include:

- EU-GMP Manufacturer Supplier of API for clinical trials
- Advanced level infrastructure
- Bespoke environmental control systems
- Closed loop, fully automated operations Groundbreaking track and trace system to
- follow the journey of each and every plant Access to exclusive pharmaceutical-grade
- genetics Turn-key business solutions available to enter UK market

Partnership Enquiries

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Effect of COVID-19 on Legal Adult-Use Cannabis Sales



Source: Colorado Department of Revenue, Oregon Liquor and Cannabis Commission, Washington State Liquor and Cannabis Board, State of Nevada Department of Taxation, Prohibition Partners, 2023

The Incremental Evolution of Global Cannabis

Across regions, 2023 has seen incremental, rather than abrupt, changes in cannabis-related regulations and activity. Global market growth has continued in a linear fashion, as operators and consumers have more successfully navigated existing structures of regulation, and as authorities have slowly developed new systems for cannabis-related activity. Few reforms that have taken place can be said to have been economically significant in a global context or to have led to strong growth of the industry currently. Reform has instead been slow and steady. In Oceania, import/ export regulations are being modified, and Australia is slowly moving towards adult-use legalisation. In Europe, existing medical cannabis programmes persist, while the slow rollout of adult-use cannabis across the region is important from a symbolic and long-term perspective, it is not expected to see rapid growth. CBD markets globally are gradually growing and developing, but the industry still awaits normalisation and mainstream adoption due to a lack of clear regulation. The US still sees strong growth but from

the steady state-by-state implementation of cannabis frameworks rather than from action at the federal level. The opening or widening of large potential cannabis markets such as Mexico, Japan, India, Brazil, Spain or France is on the horizon but remains there for the time being.

There are apparent macro-scale reasons why the pace of development in global cannabis is slow. There is a clear capital crunch in cannabis, with funding hard to come by for companies involved in the industry. This is not unique to cannabis – rising interest rates, which have tightened money supplies, as well as a shaky economic outlook in the face of rising inflation, cost-of-living crises and post-pandemic recovery, have created a difficult economic environment for companies operating in many industries. However, in the face of such pressing issues, cannabis reform is often low on the agenda for governments and voters. These factors contribute to the slow pace of progress on the regulatory side, which in turn exacerbates the funding problems for cannabis companies as opportunities for expansion and growth are restricted.

This does not mean that significant change is not forthcoming. On the contrary, there are multiple significant milestones on the horizon. The descheduling of cannabis in Germany and the rescheduling of cannabis in the US are both highly promising developments for the respective cannabis industries of each country. Multiple European countries are discussing or implementing adultuse systems, and depending on the shape that Ukraine's emerging medical cannabis system takes, the region could soon see a new large market come on line. Mexico is also committed to opening a cannabis market at some stage in the future. European regulators are working on common medical cannabis product quality regulations that could streamline the regional industry by establishing further standardisation. The place of CBD will become recognised and adopted in mainstream consumer channels eventually. It is certain that reform and growth will continue across regions; it is just the pace at which they will occur that is unknown.

Cannabis Access Expanded in Countries Seeing Conflict

In the last two years [2022 and 2023], the world has witnessed significant international conflicts, the most prominent of which are Russia's invasion of Ukraine and Israel's war against Hamas, which has brought forth immediate medical responses by governments and healthcare authorities to treat soldiers and civilians affected by the ongoing hostilities. In the case of Ukraine and Israel, these responses have included measures to facilitate medical cannabis treatment. In Ukraine, this has taken the form of legislative action to allow medical cannabis treatment in the country for the first time. In Israel, medical cannabis licences, which generally expire every three months, have been extended to allow patients to access cannabis under the same licence for longer periods of time. These developments reflect the growing recognition from health authorities of the effectiveness and versatility of cannabis in treating a broad range of conditions associated with conflict, such as pain, anxiety, post-traumatic stress disorder (PTSD) and insomnia. These are the types of conditions for which cannabis treatment is currently being tested through clinical trials, and for which there is significant and growing evidence of the effectiveness of medical cannabis.



North America



States are driving the legalisation process in the US. Cannabis remains federally illegal in the US, whether for medical or adult-use, but 24 states have already legalised adult-use, while 38 have legalised medical cannabis. Legal sales in these states reached almost US\$26 billion in 2022 (US\$17 billion adult-use and almost US\$9 billion medical), and we estimate total sales should reach over US\$33 billion in 2023 with medical-to-adult-use conversion driving growth. The growth potential is significant, considering six (seven if we include NY, which is on the cusp) of the ten most populous states have not legalised adult sales yet. Typically, when a state goes from medical to adult, total sales double and even triple in some cases. We estimate total legal and illicit sales in the US to amount to more than US\$100 billion. Over time, the eventual shift from illicit to legal products, breakthroughs in product innovation, wider distribution, and greater social acceptance (less stigma) should all drive further growth, both of the medical and adult markets.

For cannabis stocks, besides industry growth and potential consolidation (at present, the largest US multi-state operator (MSO) has only 5% national share), several regulatory tailwinds are lining up:

- Rescheduling. The Biden White House is seeking to reschedule cannabis out of Schedule I to Schedule III. Such a move could have state and/or federal-level implications, lower the effective income tax rate on operators, bolster research, and legalise its medical use. A move to Schedule III could result in tax savings of over US\$100 million per annum for the largest operators.
- Banking reform. The Secure and Fair Enforcement Regulation
 Banking Act (SAFER) was recently voted 14-9 by the Senate
 Banking Committee. A Senate floor vote should follow in 2023,
 and House passage could take place next year. The bill would allow
 banks with a federal charter to service the cannabis industry (cash
 management, debit card, lending and potentially credit cards), and
 brokers to provide custody services to investors. All this would lead
 to a marked increase in involvement from institutional investors.

• DOJ Safe Harbor Memo. A separate dictum from the Department of Justice (DOJ) may open the door for US exchanges to uplist US cannabis stocks, while protecting states' adultuse and medical programmes from federal interference (i.e. no interstate trade; no changes to the retail model of sales done only via dispensaries).

In Canada, sales are now close to C\$6 billion (93% adult-use and 7% medical). Canada began adult-use sales on 20 October 2018 and the market continues to grow (low teens Y-o-Y), but unrestricted licensing (of stores and producers) has impacted economics. Close to 3,600 stores are now open (implying only C\$1.5 million sales per store in 2023), with over 900 licensed cultivators and processors. Retail prices are now in line with some of the lowest prices seen in the US (Colorado/Washington/Oregon). All this is exacerbated by a three-tier system (producers, wholesalers, retailers) that does not allow for vertical integration in most of the provinces. Moreover, the government in most provinces owns the wholesalers ('boards' act as the only wholesalers), and in the case of Quebec province, the government also controls all retail stores. Restrictions on advertising, packaging, and omnichannel services (in some provinces), plus a minimum tax of C\$1/ gram (excise taxes account for more than 30% of gross revenues for most licensed producers), make it difficult for operators to be cash-flow positive. There is no clear line of sight on regulatory relief for now, despite intense lobbying by industry operators. All this said, nimble, efficient producers are showing they can still operate profitably and grow in this tough market.

US Adult-Use Market

As of 30 September 2023, 23 states had legalised adult-use cannabis and 21 had begun sales. The first state to legalise adult-use was Colorado, commencing sales on 1 January 2014, and the latest is Maryland, which began selling on 1 July 2023. The legalisation process has been state-driven, with cannabis remaining federally illegal in the US. None of the states that have legalised adult-use cannabis allow interstate commerce, but that is about all they have in common. Tax structure varies by state, as does the restrictiveness of the licensing process; states with more limited licences tend to have superior economics, for growers, manufacturers, and retailers. Access, affordability, and assortment (all key drivers of consumption) vary by state, and, as a result, these markets have developed quite differently, in terms of size, per capita spend, and growth rates.

Billion \$ markets with further growth potential

Based on official state data, as well as scanner data suppliers, we calculate that adult-use sales accounted for **65%** of total legal cannabis sales in 2022. Six states posted more than US\$1 billion in adult-use sales in 2022: California led with **US\$5.4** billion followed by Michigan **US\$2** billion, Illinois **US\$1.6** billion, Massachusetts **US\$1.5** billion, Colorado **US\$1.5** billion and Washington state **US\$1.3** billion (Oregon was just a shade below **US\$31** million).

Several states have only just commenced or are about to commence adult-use sales. Since December 2022, adult-use sales have begun in Rhode Island, New York, and Connecticut (January 2023), Missouri (February 2023), and Maryland (July 2023). Minnesota and Delaware are slated to begin adult-use sales in 2024. Ohio and Florida could potentially see adult-use cannabis in upcoming ballots, and Pennsylvania could legalise via its legislature. These last three states, plus New York if well developed (the state regulator plans to issue licences for more than 1,000 stores), represent a combined population of almost 70 million.

All this said, the initial pace of growth in these markets could vary considerably owing to steep prices and/or taxes, a slow roll-out of adult-use dispensaries, and the prevalence of existing grey markets (in some cases, such as in New York state, the decriminalisation of cannabis has led to a number of unlicensed stores opening to sell cannabis).

Factors driving market development

The pace of store openings greatly drives market development. On the one hand, New York and New Jersey have been slow to issue licences for adult-use dispensaries, and this has been exacerbated by township restrictions (and, in some cases, by lawsuits that have hamstrung the states' regulators). On the other hand, Maryland and Missouri had over 100 stores ready to go from day one.

As a result, adult-use per capita spend varies widely across states. Annualising Q2 2023 sales, we calculate that Michigan has the highest adult-use per capita spend in the US, at US\$308 per person per year, followed by Colorado (US\$234) and Massachusetts (US\$224). The reason? Store counts and pricing. All of these three states have dispensary counts well above the national average. In Michigan, there are 84 stores per 1 million people, which is more than nine times the density of Illinois stores (Illinois per capita spend is only US\$125). Prices are also below other licence-restrictive states; flower-per-gram prices average US\$3.15 in Michigan and US\$3.40 in Colorado, compared with more than US\$12 in Illinois (Massachusetts US\$6).

On market consolidation and key players

The degree of market consolidation depends on the licence-restrictiveness of each state. Adult-use states such as Illinois and New Jersey are dominated by MSOs, while markets such as California and Colorado are significantly more fragmented – the Maryland market is somewhere in between. Most states tend to grandfather operators from medical programmes (often owned or controlled by the larger MSOs) into the adult-use market. Key determinants of adult-use market consolidation are the degree of consolidation in the medical market (to start with) and the speed at which the state's regulator issues adult-use licences. New York is a rare exception, as it has initially sought to limit the entry of medical operators (primarily owned by MSOs) into the adult-use programme.

Curaleaf and Green Thumb are the two largest MSOs by sales. MSOs do not split sales between adult-use and medical markets, but we calculate that Curaleaf and Green Thumb are the two largest operators in the US adult-use market (as already mentioned, though, their share varies widely by state). These two companies are on an annual run rate of total sales of US\$1.35 billion (adult-use/medical) and US\$1 billion (annualising Q2 2023 revenues), respectively. Trulieve is the only other MSO with sales over US\$1 billion, but we estimate that adult-use markets account for less than 10% of its sales (its two main markets, Florida and Pennsylvania, are still medical markets). These companies are in part vertically integrated (own stores and growth), with retail sales accounting for over 70% of sales, and net wholesale for 30%.

However, it is one matter with regard to predicting the growth of the adult-use markets, but quite another matter with regard to market structure and economics. In states such as New Hampshire and Pennsylvania, there have been proposals for retail (when and if adult-use sales are allowed) to be allowed only through government-owned stores (as is the case with liquor in some states). In New York, the regulator requires MSOs to pay an 'entry fee' of US\$20 million to participate in the adult-use market (cultivation and stores). Also, states may set 'caps' on the number of stores a company can own, or on the scale of their cultivation footprint. And then there is the matter of economics – cultivator spreads and retailer margins can vary widely, as can revenue per store (in New Jersey, some stores may be taking US\$50 million per annum, while in Michigan they may be taking US\$3 million or less).

Brand development (and concentration)

Given the silo-nature of most states, and only nascent brand licensing programmes, it is hard to speak of true national brands – this could change someday with interstate trade and further industry consolidation. In fact, brands with multi-state presence are few and far between; the exceptions, especially in vape, are Curaleaf's Select and Shryne Group's STIIIZY.

Investors often ask if the cannabis market will develop like the beer or wine markets (the latter being quite fragmented, and beer significantly more consolidated). Well, this may depend on the format. In mature markets, we observe that the flower category tends to be rather fragmented, while manufactured products (such as vape and edibles) tend to be more concentrated. For example, in California no flower brand has 4% share or above, and only five brands have more than 2%; but for vapes, STIIIZY has a 24% share (four times as much as the next player), and for edibles, two brands have a combined 52% share (Kiva and Wyld).

Also, house brand penetration (i.e. brands owned by the store owner) varies; in Colorado, flower house brands have a 34% share against 6% in California.



US Medical Market

A total of 38 states have legalised medical cannabis (with Georgia and Alabama being the latest), and more could be on the way (including Kentucky and Nebraska). Typically, the more conservative states, politically speaking, have been the last to allow medical cannabis.

As with adult-use cannabis, medical cannabis rules vary by state. That said, most states do not charge excise taxes on medical cannabis; they allow retailing only via licensed dispensaries (although, in a rare exception, Georgia will allow the sale of cannabis oils via pharmacies); and they are generally permissive on conditions (chronic pain, anxiety, and sleep disorders account for the bulk of sales). Also, most states allow 'open' recommendations from doctors (these are not Rx scripts/medical prescriptions), in which the patient and budtender can decide on brands and formats.

No state allows interstate trade of medical cannabis, and few allow telehealth.

Medical to adult-use

The initial jump from medical to adult-use can, on the one hand, lead to about two to three times more sales (in the case of Missouri and Maryland), but this can be as high as five times more if the medical market was not well developed to begin with (an example being New Jersey).

On the other hand, when states start allowing adult-use sales, medical sales tend to fall. In Illinois and Michigan, two states that legalised adult-use more than three years ago, less than 1% of the state's population is now part of the medical programme. The exceptions to this rule are states (e.g. Arizona) where medical excise taxes are much lower than adult-use taxes (or cases where medical cannabis taxes are non-existent).

Patient counts and basket size

Red tape, slow processing of patient applications, high costs (patient licences, doctor visits), and stricter controls on prescribing doctors are key factors driving medical market development. Typically, to begin with, medical programmes are fairly restrictive in format (Georgia only allows oils; Pennsylvania does not allow edibles or prerolls), conditions, and operator licences, and in the initial phases are slow in onboarding patients (Virginia being a case in point).

Also, the cost of patient licences, the restrictions on patient 'recommendations', and the length of the licences (for patients and prescribers) vary by state, and this impacts market growth and penetration. As a result, penetration regarding the medical cannabis population varies widely by state.

Oklahoma has the highest penetration in the US, with close to 8% of the state's population enrolled in its programme, followed by Florida at almost 4% (851,475 registered patients as of 6 October 2023). Enrolment for Ohio (close to 400,000 patients), Pennsylvania, and Arkansas is 3%, and Maryland 2.5%, while Virginia comes in below 1%.

Restrictions on the amount a patient can buy and/or for how long a prescription ('recommendation') can be used (and filled) also impacts basket size. As a result, this also varies widely across states. Based on public data, we estimate patients spend over US\$300/month in New Mexico, but only about US\$100 in Ohio.

In the future, insurance coverage may be a key determinant of medical cannabis penetration.

Potential for rescheduling of medical cannabis

President Biden ordered the Department of Justice (DOJ) to start a review of the 'scheduling of cannabis'. At present, cannabis is classified as a Schedule I drug (classified as having no medical use and being highly addictive); however, the US Department of Health and Human Services (HHS) has recommended that it should be moved to Schedule III. The Drug Enforcement Agency (DEA) must now issue its own opinion.

The final decision and timing of this 'review process' were not known at the time of writing this report.

It is not clear whether rescheduling cannabis to Schedule III would mean medical cannabis would be legalised at the federal level and whether a new set of rules would be implemented (greater FDA oversight; medical prescription (Rx script) required; end of open prescriptions; sales through pharmacies). Another school of thought has it that medical cannabis would remain federally illegal and that each state would continue to manage its own programme – but we would be sceptical of such an outcome, as every Schedule III drug is federally legal.

A move to Schedule III would have significant tax benefits for operators. Under Schedule I, cannabis companies pay taxes on gross profits (so they cannot deduct operating expenses and interest costs for income tax purposes). For those that generate positive profit before tax, this would mean moving from an effective >70% tax rate to the normal statutory tax rate of 21%.



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US CBD

The effective legalisation of hemp production resulting from the 2018 Farm Bill has resulted in increased production of hemp and hemp derivatives, but the lack of regulatory clarity (in the form of clear FDA guidelines) has led to low barriers to entry in the production of CBD. By the same token, although CBD cannot contain more than 0.3% of THC, the rise in hemp derivatives has further blurred the lines with CBD and has also represented a new form of competition for cannabis producers. In short, the CBD market remains stagnant, the profit pool has shrunk, and the market has fragmented across brands as well as channels, with CBD being sold in some cases in drug, speciality, and convenience stores; petrol stations; smoke shops and cannabis dispensaries; and online.

CBD in the US, for consumer use, was legalised as part of the 2018 Farm Bill, but the 'legal context' must be explained. Section 12619 of the Farm Bill removed CBD (and hemp-derivative products) from its Schedule I status, but the category is still in somewhat of a grey area. As a result, US exchanges have not uplisted US CBD companies, and the larger retailers do not stock CBD (this can vary by state, too). For example, large Food, Drug and Mass (FDM) chains (Walmart, Target, Costco, as well as Amazon), do not stock CBD. Drug store chains such as Walgreens only stock topicals (and only in some states), but do not stock ingestibles (edibles, oil extracts). Some of the speciality stores (natural channel, vitamin stores), especially the 'mom-and-pop' ones, however, have stocked CBD more liberally. As a result of this uncertainty, the market has not developed as originally expected. The CBD industry is lobbying for the FDA to classify CBD as a dietary supplement and regulate the industry. The new Farm Bill and/or specific legislation from the House of Representatives may address this - but it is far from certain at this point in time.

Sales and key players

We estimate retail CBD sales at US\$3.8 billion for 2023, but deflation and regulatory issues have resulted in a flat-to-down market. Also, no company has more than 3% market share in total (share by channel may be higher for some due to channel specialisation). In a fragmented market, notable brands include Charlotte's Web, SunMed, Medterra, JustCBD, PureKana, and +PlusCBD. The initial excitement regarding CBD led to mergers and acquisitions (M&A) activity, and several brands were acquired by larger cannabis and/ or consumer companies (JustCBD by Flora Growth; CBDistillery by Village Farms International (VFF); NuLeaf Naturals by High Tide; Garden of Life by Nestle). While tinctures/oils were once the dominant form, gummies and edibles (at a lower price point like for like) have been gaining share.

Future legislation

A new bill making the rounds in Congress seeks to classify CBD as a dietary supplement regulated by the FDA. By the same token, it is expected that the 2023 Farm Bill (a farm bill is introduced every five years, but it is possible the latest bill may extend into 2024) may tighten the regulations around hemp and CBD. It is not clear at this stage, however, if and when this legislation will pass.

Canadian Adult-Use Market

Canada commenced adult-use sales on 20 October 2018, and, if we annualise the latest data (July) reported by StatCan, the market is now nearing C\$5.3 billion in sales (US\$4 billion) in 2023. Still, poor economics (low prices, oversupply), various restrictions, high taxes, and several structural market challenges make the Canadian adult-use market a difficult one for operators. As a result, several have diversified away from cannabis and/or been forced to merge (or sell) to yield better economics. Although a five-year review is due, it is not clear if and when that process will be completed or if it will yield any favourable results for the industry participants (not government related).

Benchmarking with the US adult-use market

Year-to-date (YTD) growth of 13% is above the US adult-use pace (+9%), and only slightly below the +17% growth the Canadian adult-use market posted for all of 2022. Importantly, US growth is driven mostly by new markets opening adult-use sales, while in the case of Canada, the base of legal provinces is the same, so 13% growth is fairly good in that context. That said, the Canadian market has developed more slowly than in the US (Canada adult-use capita spend is below that of the state of California, which is not a leading state in the US per capita), so it could be argued the 'faster' growth is off a lower base.

Indeed, Canada underperforms the US in adult-use spending per capita metrics. At about US\$100 per person, adult-use consumption is well below that of even less mature US states (those that legalised adult-use cannabis after Canada): Michigan US\$308 (December 2019); Massachusetts US\$224 (November 2018, first stores); Arizona US\$181 (January 2022); Missouri US\$180 (February 2023); and Illinois US\$126 (January 2020). Why the difference, if Canada has as many stores per 1 million people as Michigan, and low prices (in line with Colorado and Oregon)? We believe this is

explained in part by a larger illicit market (compared with the US average), steeper taxes, marketing and packaging restrictions, restrictions on THC per unit (which have an impact on the sale of edibles), and retail stores that, on average, fall short of US standards across various metrics.

Factors impacting licensed producers

Three structural issues impacting Canadian licensed producers (LPs):

- Retail prices are well below US averages. Flower prices now average C\$5.32 per gram (US\$4.00) in Canada (Q2 2023 -2% Q-o-Q, -13% Y-o-Y, and -32% in two-year stacked terms), which is well below most US states. True, Canada's flower prices are above those seen in US states such as Colorado, Michigan, Oregon, and Washington (all between US\$3 and US\$4 per gram), but the price in California is US\$5.45 and in Massachusetts is US\$6.20.
- High excise taxes. The minimum tax in Canada is C\$1 per gram, which means average prices paid by the consumer are \$6.32 (C\$5.32 + C\$1) per gram for flower. But if we assume that an LP only keeps 30% to 40% of the C\$5.32 retail price, this implies excise taxes can be as much as 35% of total gross revenue generated at the LP level. When Canadian flower prices were C\$11/gram in Q1 2020, the minimum tax of C\$1/gram was less of an issue... but not now, with retail prices down more than 50%.
- The three-tier system (Canadian LPs sell to provincial boards that act as wholesalers, which then sell to retailers), combined with high excise taxes, means a typical LP only accounts for ~25% of the final price (including taxes) paid by the consumer. In contrast, in a vertically integrated state such as Florida (with no taxes on medical cannabis), a producer is able to keep 100% of the total amount paid by the consumer.

Leading producers and format penetration

Challenging economics, structural issues, and interstate trade have all resulted in a more concentrated market compared with that in the US. For example, the top five licensed producers have close to 40% national market share. But some of these have reached their market positions via organic growth while others have done so via M&A.

The market leader is Tilray (12% share), a company that via consolidation now includes more than four different operators: Aphria, HEXO, Redecan, and Tilray. Tilray has a wide range of brands and formats. Decibel (8% share) is now ranked second, growing mostly organically (sales are up close to 80% YoY); the company derives close to 70% of sales from pre-rolls. Village Farms International (VFF), a large-scale, low-cost producer based in British Columbia (the company has adapted tomato greenhouses into cannabis), is the third largest producer; flower accounts for 80% of company sales. Organigram (ground flower is a key part of the portfolio) and Auxly (vape is a key format) round out the group of the top five producers. As with most operators in Canada, these companies enjoy low EBITDA margins in cannabis, and in some cases are not profitable (Decibel and VFF are the main exceptions).

Sales growth and segment share vary widely across formats. Pre-rolls and vape are driving industry growth. Flower now makes up 39% of sales (compared with 43% in Q2 2022 and 60% in Q2 2020). Pre-rolls now make up 30% of sales (27% in 2022, and 17% in 2020); for context, in California pre-rolls make up only 17% of sales (and flower 34%). Vape makes up 15% of sales in Canada (26% in California). Edibles have low penetration in Canada (6% vs. 15% in California) due to packaging and potency restrictions.

Canadian Medical Cannabis Market

Canada's medical cannabis market has declined in recent years. Sales for the fiscal year ending March 2023 amounted to C\$401 million (U\$\$300 million), compared with C\$441 million the prior year, and C\$501 million for the fiscal year ending March 2021.

Active client/patient registrations amounted to 212,700 as of March 2023 (0.6% of the population), down 40% since October 2018 (adult-use sales commenced on 20 Oct 2018). Out-of-pocket patients (those not reimbursed) have switched to the adult-use market given generally lower prices and easy access (variety, supplies, formats, plenty of stores). In fact, between FY21 and FY23, sales to out-of-pocket patients fell 39%.

However, total reimbursements (mostly veterans) have continued to increase (+40% for FY23 vs. FY21) and accounted for 42% of sales in FY23. The medical market is more concentrated than the adult-use market in Canada; Aurora has a 24% share, followed by Canopy Growth with 13%, and Tilray with 8%.

Unlike the three-tier system in adult-use, Canadian medical cannabis companies can sell directly to patients, and/or directly to dispensaries.

Canadian exports of medical cannabis

Canada's exports of medical cannabis continue to grow. For the fiscal year ending March 2023, Canadian medical exports reached C\$160 million compared with C\$107 million in FY22 (March) and C\$39 million in FY21, as per StatCan. Canadian operators are on record indicating that medical exports can be as much as three times more profitable than domestic adult-use sales.

Compared with other producing countries, Canada has a first-mover advantage in the export markets, a larger production footprint, and more years of production expertise. While these advantages may be eroded over time, Canada for now remains the main supplier to key overseas medical markets such as Australia and Germany.

According to data shared by Health Canada, 44% of Canada's dried flower exports in FY23 March (of the 60 tons in total) went to Australia, followed by Israel (35%), and Germany (16%); Australia accounted for 90% of Canada's exports of extracts (9,300 litres in total).

CBD in Canada

CBD remains quite restricted in Canada, compared with the US market.

Only CBD oil is legal in Canada (derived from hemp, with a THC content of 0.3% or less), and it can only be sold via dispensaries selling THC cannabis. So, CBD edibles, vapes, concentrates, and topicals, are not permitted to be sold. Moreover, users of CBD need a prescription from their doctor to buy CBD in Canada.

The industry is lobbying for changes, but it remains unclear when, how, and if things will change in any meaningful way.





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Chris Murray
Founder,
FOXNRTH

Can you provide some context on FoxNRTH?

FoxNRTH is a cannabis-focused consultancy, mainly in the health-care cannabis sector. I founded it in 2020 after departing from Canopy Growth, where I had a seven-and-a-half-year tenure. At Canopy I was able to see up close what the transition from first to second-generation operators in the cannabis industry was going to look like. I got to see how alcohol and food and beverage were going to treat cannabis, and I just fundamentally did not think that they got it. So I started FoxNRTH with a few colleagues because we knew that there were going to be a lot of companies out there that could learn from our experience of the development of the Canadian industry, and Canadian companies which were going to need to diversify their product offering out of Canada. Furthermore outside of the US, cannabis is regulated by federal health systems, adding a layer of complexity which we happen to have a unique expertise in.

What are your thoughts on the current state of the US market?

The US has a legal-illegal cannabis industry which is broad-based at this point. In Texas (which doesn't have adult-use legalisation) you can go to a farmers market and buy THCA flower which is under 0.3% THC. But THCA is the precursor to THC - so they are selling cannabis under the auspices of the language of the Farm Bill, which essentially creates a loophole that allows them to do this. The only thing that is off the table is decarboxylated cannabis. So this is proliferating like crazy everywhere, even including in Texas - which has the most aggressive criminalisation around possession of cannabis. It's been a really interesting ecosystem to watch. Honestly, one of the biggest things that's shifted cannabis in the US with regard to criminalization has been the Farm Bill. Although the States legalising has helped as well.

The Farm Bill is commonly thought of as relating to CBD and hemp legalisation, rather than cannabis. Why do you say that it is so significant?

In the US, hemp is defined as a cannabis sativa plant with less than 0.3% delta-9 THC by dry weight. While crude extracts may have higher potency, finished or harvested products must adhere to the 0.3% THC limit. Some argue that crops with high THCA content are compliant, as THCA only becomes THC through decarboxylation. This interpretation has led to legal opinions suggesting de facto cannabis legalisation under current regulations, and some companies are really leaning into this.

This has significantly reduced law enforcement's ability to enforce cannabis laws, as probable cause elements like the smell of cannabis or the presence of leafy substances are no longer sufficient for probable cause. This aspect of the Farm Bill's impact on diminishing criminalisation is often underestimated.

One thing that is happening in both the US and Canada right now is that people are still accessing cannabis on the black market as well as through legal channels - how do you see this developing in each case?

I believe the illicit market in Canada will persist longer than in the United States because Canadian illicit cannabis is generally high quality. There's a significant culture of home production and cannabis trading among growers in Canada. Statistics Canada's estimates show legal sales surpassing illicit ones for the first time in 2022, so the transition to the legal system is slowly working, and I think it's working because of convenience and downward price pressure. There is still a significant flood of products, and part of that is that the government completely excluded all of the indigenous communities in Canada from being able to participate in the recreational system. So there's a huge proliferation of unregulated viable product that can't find a way into the legal system. You can purchase on reserve without a problem, but if you try to resell the product elsewhere, you'd be in a serious trafficking situation.

That is a significant portion of what they would quantify as the illicit market now. There is also some large-scale production in the interior of British Columbia and the West Coast because that's how it's always been out there.

If you go to any state in the US, cannabis is expensive by comparison. It's not anywhere near the Canadian price points. They've historically been way more dogged with their policing of cannabis trafficking, and the Canadian system was de facto legal for ten years before recreational came along, so people have been honing indoor production approaches for decades in Canada. And that was possible because the police weren't constantly kicking down doors the second they found a hotspot on a power grid. In the US, it's a very different thing. They were much more aggressive on cannabis. Overall from a product perspective, there is just not really a lot of quality illicit product available across the US and in some states they're trying well-grown cannabis for the first time.

What is the outlook for the SAFER banking actand federal legalisation more generally?

The big split is not actually on the question of legalisation itself, as a Republican vs Democrat discussion. It's actually an issue of the equity provisions and "reparations" from the war on drugs. The split on the SAFER bill is far more about what kind of social programs and social funding and actions would be happening with any taxation or any funds raised as a result. Then you've got Nancy Mace's bill (to remove cannabis from the controlled substances schedule and set a 3.75% federal excise tax), which is probably the most progressive cannabis bill from the Republicans. Her view is that the funding which would emerge as a result of this industry should be allocated to supporting police services. Rescheduling cannabis would actually achieve a reasonable amount of what the SAFER Banking Act would achieve with respect to 280E because the restrictions on expensing use of proceeds around the production of cannabis would change, although until these changes are tested with the IRS, the full scope is unclear.

What is your opinion on the outlook for North America more generally over the next one or two years?

I think both Canada and the United States are at significant inflection points. There's discussion about changing Canada's medical cannabis system and taxation structure. The Canadian government has even recently introduced farming subsidies which cannabis producers can qualify for. The current federal tax of 10% was based on a \$10 per gram price point, but the actual average price, around \$7-8 per gram, or lower in bulk or milled product categories, significantly affects the industry. When applied to finished products, the federal government's share amounts to approximately 25%, potentially impacting the industry substantially. Most

companies are well behind the payment schedule in terms of what they need to be remitting in terms of excise tax. So Canada is in this point of flux, which could see a lot of changes that could actually improve conditions for the Canadian market, and ultimately help a number of companies carve those paths towards profitability that they've been talking about for years.

On the US side, how the Farm Bill is currently being interpreted by legal counsel for a lot of companies is really opening up and broadening the types of products that are available. You're seeing a lot of the companies that have made state legal cannabis beverages to this point shifting their business model to hemp-derived beverages. So when you consider the beverage category, coinciding with the decline of alcohol consumption, I expect it to be defined and explode in 2024. So the Farm Bill certainly has this really significant bearing on what a THC market looks like going forward and that, coinciding with rescheduling, certainly changes the conversation about what a cannabis market could look like going forward.

I think there's also a lot of talk about pharma getting involved in cannabis, but my personal view is that pharma has been looking at cannabis for decades and it doesn't fit their business model. Alcohol and tobacco, on the other hand, have made substantial investments across both Canada and the United States. Many of these companies own pieces of US companies, hemp operators, Canadian licensed producers etc. These companies have a lot of money in their coffers, and they know how to play this game as a long-tail exercise.

I think right now is a really interesting point for the US and Canadian cannabis industries because I think these two inflection points could really open things up for producers. I don't think we're talking about a "green rush of 2015" scale event, but businesses having a much more viable path towards success and profitability.

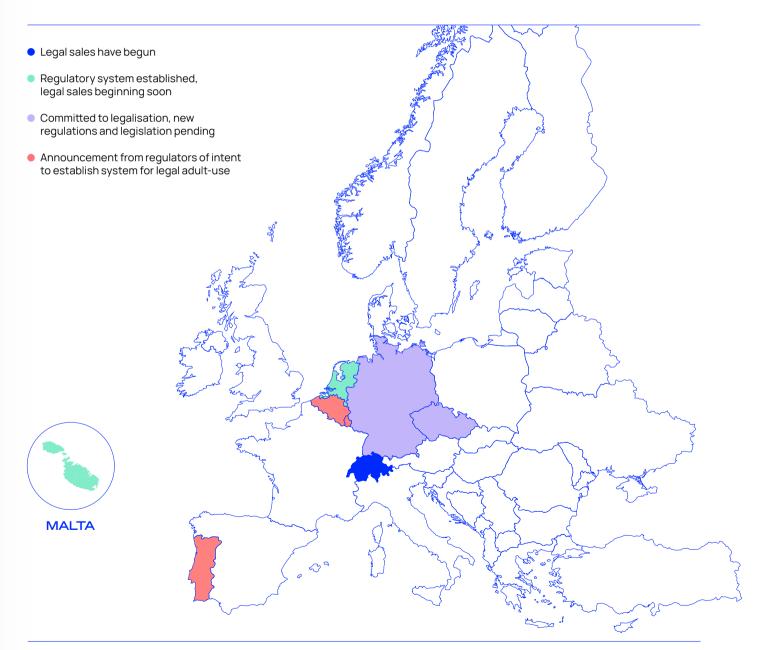
Europe & Israel



'I believe that the UK medical cannabis market is already on the right track and we will witness further market growth correlating with public awareness and scientific data.'

Rokshaw Laboratories

European Adult-Use Market



Source: Prohibition Partners, 2023

Europe's adult-use industry is still in its very early stages; however, significant developments continue to be made on a consistent basis in various countries across the region. Though only a small number of countries have reached advanced stages of developing systems for adult-use legalisation, there is already some variation in the approaches taken. Broadly, two models exist: one involving not-for-profit private organisations which will have a registered membership and handle cultivation and dispensation, with self-cultivation also permitted (e.g. Malta, Germany Pillar One); and the other involving spatially restricted and tightly controlled supply chains which will run for a set period of time, after which results will be evaluated (e.g. Netherlands, Switzerland, Germany Pillar Two). It is likely that in some cases versions of both models will be adopted, as is the current plan for development in Germany.

Adult-use markets coming online

The first fully legally compliant adult-use supply chains in Europe have already come online in Switzerland, which now has four active pilot trials, and a further two that have been given the goahead by the Swiss authorities. The four currently running (one in Zurich, one in Basel, one in Basel-Landschaft, one in Lausanne) have a combined total sample size of approximately 8,000 registered participants. When the other two trials come online in Geneva, Berne, Bienne and Lucerne in the coming months, approximately 10,000 registered participants will have access to legal adult-use cannabis through the system for the coming few years, with more trials expected to be given the green light soon.

The Netherlands has made the long-awaited announcement of when its first legal supply chains will come online - all coffeeshops in the Breda and Tilburg regions will be allowed to receive supplies by two licensed producers (a third is also eligible to supply but will not be ready in time for the kick-off date). The first six weeks will be a transition period, where coffeeshops can still source from existing illicit suppliers; afterwards, all cannabis sold in coffeeshops in the regions must come from licensed sources. From February, two additional licensed producers will begin supplying these regions. The trial is due to expand to other designated regions and suppliers (ten regions and suppliers have already been selected) but only after initial results from these opening stages of the trial have been evaluated. This is highly significant in a regional context. The combined population of the Breda and Tilburg regions is approximately 400,000, and studies have shown that the vast majority of cannabis users in the Netherlands buy their cannabis from coffeeshops. This, therefore, represents the first time that there will be a significant adult-use market in Europe which is supplied by a fully legally compliant supply chain, from seed-to-sale.

Legislative progress

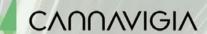
In Germany, progress is being made on getting legislation passed to implement the first pillar of the two-pillar system for adult-use legalisation (decided on by the traffic-light coalition government). Pillar One will include self-cultivation and not-for-profit associations, while Pillar Two will include trial projects, with registered participants accessing adult-use cannabis for sale through controlled channels. Despite opposition from some legislators, no significant barriers have been encountered thus far, with the bill for establishing the framework for Pillar One – which includes a proposition to remove cannabis from the Narcotics Act – having passed through the Bundesrat (the legislative body representing the 16 German federal states). The bill is now due to be reviewed by the government before ultimately being voted on by the Bundestag, the German parliament.

Likewise in the Czech Republic, expert groups have been busy fleshing out the details of a key cannabis reform bill, which proposes the authorisation of domestic and commercial cultivation of cannabis and the establishment of special clubs for adult-use. Various government departments are currently providing feedback and offering their comments on the bill before it is presented and put to a vote, which may take place before the end of the year. The primary barriers to getting the framework passed into law in the Czech Republic revolve around complying with rules set by the European Commission, which earlier this year curtailed Germany's ambitions for a wider legalisation and licensed production framework for adult-use cannabis. If these obstacles can be navigated successfully, the Czech adult-use market could quickly develop into a relatively large industry.

New countries announcing adult-use intentions

Elsewhere, Portugal's government recently announced its intention to develop a working group for adult-use legalisation, with support from all parties apart from Chega, a right-wing populist party. The working group, to be established within the parliament's health committee, will engage with experts and stakeholders to conduct a comprehensive analysis, and aims to conclude its investigation by the end of the year. So far little is known about the shape that regulation may take, but there is a consensus among all parties on the failure of prohibition.

Additionally, Belgium's Deputy Prime Minister and Minister of the Economy and Employment, Pierre-Yves Dermagne, has called for adult-use regulation to be considered in the country, pointing to the progress made on the topic by its three neighbouring countries, Germany, the Netherlands, and Luxembourg.



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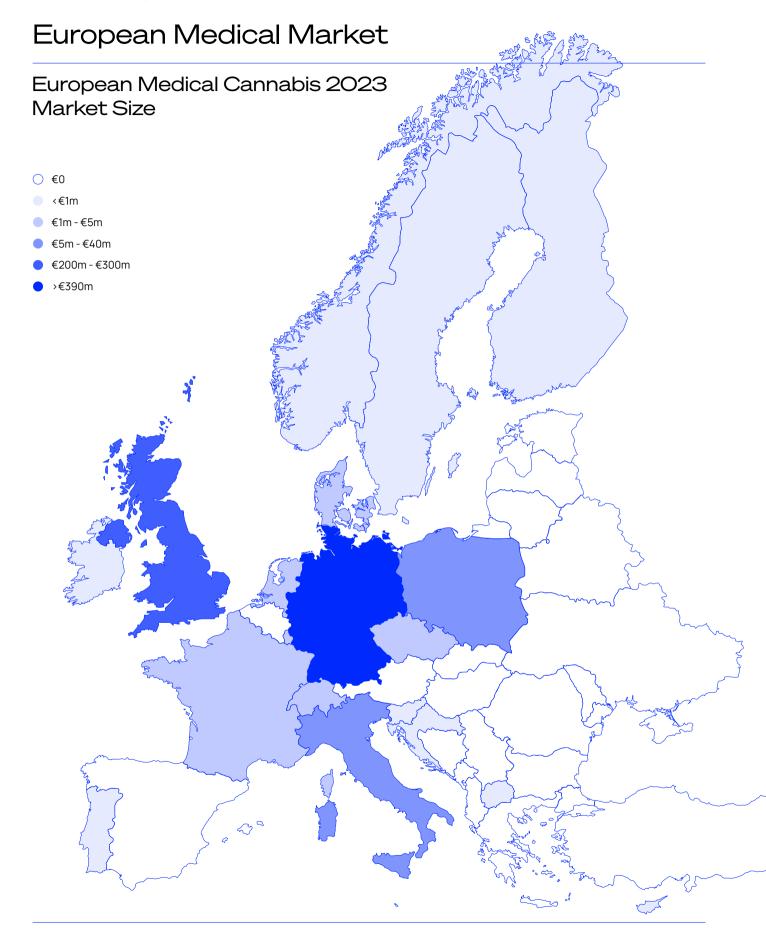
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Source: Prohibition Partners, 2023

Europe's medical market continues to see strong growth concentrated in key countries, with steady growth elsewhere, albeit often from a low base. Currently, 21 countries see patient treatment with medical cannabis; however, in most cases patient numbers are still very low, and the process for treatment can involve high costs and bureaucratic hurdles. Germany is the standout market, with 2023 sales of approximately €390 million to over 230,000 patients, comprising over 50% of the regional market. There are three other significant markets – the UK, Italy, and Poland – each with an annualised market size of between approximately €19 million and €222 million. Market sizes for other European countries for 2023 are below €5 million.

Meanwhile, Israel's medical cannabis market, valued at approximately €315 million for 2023, dwarfs any of the European markets. The country is introducing measures to make access to cannabis treatment easier for terminally ill patients, so will likely continue to see strong growth.

Despite legal medical cannabis programmes being reasonably widespread across Europe, a lack of willingness from regulators to take measures to expand patient access often restricts development. In general, progress is dependent on whether authorities are willing to raise eligible prescriber numbers, reduce red tape around prescription, allow greater competition and product variety, establish guidelines for treatment, and permit greater flexibility in cannabis treatment conditions. If some or all of these measures are taken, more doctors would be willing and able to prescribe, from a wider variety of different cannabis products, to a broader patient base, with costs reduced at the patient and wholesaler/distributor level.

Sources of growth

Germany and the UK are the two largest regional markets, as well as the fastest growing in real terms. The medical cannabis industry in both countries is stable, with no major regulatory changes so far this year, though there have been some developments of note. In Germany, the regulatory body for health insurance considered changing reimbursement regulations to make it harder for patients to have their treatment covered by health insurance, but the changes were ultimately rejected. In the UK, the House Affairs Committee (a cross-party parliamentary committee) published a report on 31 August 2023 that recommended the government allow for prescription of medical cannabis under the NHS – a move that would dramatically widen patient access – as well as supporting randomised control trials into the effectiveness of medical cannabis to treat chronic pain. The government has two months in which to respond to the recommendations, with potentially sig-

nificant consequences for the medium-term future of the market if one or both measures are adopted.

Italy and Poland are the next largest markets, and have seen reasonably similar growth trajectories over recent years. Both have seen shortages and inconsistencies in supply, though the issue is more chronic in Italy. Italian domestic supply in 2023 again fell dramatically short of target, with the military (which is responsible for cultivation) announcing a severe shortage of staff early in 2023. Imports are still tightly controlled by the Italian government, so product shortages are set to remain a key factor in the country. In Poland, high prices are a more significant factor in limiting patient numbers, with insurance not covering the cost of treatment for patients. Domestic production in Poland is in its early stages; however, progress on that front is a promising sign for the future of the industry there. If prices fall in Poland, or if a significant shift in reimbursement of patient costs for medical cannabis occurs, conditions are ripe for strong growth in the coming years.

Developments elsewhere

In the summer of 2023, Ukrainian lawmakers announced their intention to legalise medical cannabis access. The country had previously come close to doing so in 2019, and now in light of the potential of cannabis helping during the treatment of conditions such as PTSD and pain – rates of which are surging due to the ongoing conflict – medical cannabis legalisation is once again on the agenda. Significant progress towards this goal was made in October 2023, when cannabis legislation was finalised and approved in the National Health, Medical Care and Health Insurance Committee. All that remains is for the bill to be voted on in the Ukrainian parliament, and it will pass into law. The full details of the bill are not currently known, but it is expected that the range of conditions under which patients will be eligible to access medical cannabis will be broad.

In France, the budget for 2024 recently announced by the government did not include an allocation of funds for the generalisation and expansion of the ongoing medical cannabis trial. Having previously been extended, the trial was due to finish in March 2024, but will now be allowed to continue past this date according to announcements made by the French Minister of Health. Over 3,000 patients have been treated under the framework, with approximately 2,500 believed to be still receiving treatment on an ongoing basis. Given the lack of funding allocation and the extension of the trial, the 2024 medical cannabis market in France is expected to remain consistent with 2023, with expansion and normalisation delayed until further notice.

European CBD

The European CBD industry is fragmented, with the place of CBD in European (and most national) regulation not fully clarified. The progress of CBD regulation in the region has not always been linear, with some developments at times threatening to limit the market at regional or national levels – such as the suspension of novel food applications by the EU, or the back-and-forth decisions by the Italian regulator over the position of CBD as either a consumer goods product or a narcotic to be available under medical circumstances only. Regardless of the various machinations at the regulatory level, CBD consumption continues across the region, as the uptake of new products in different markets – in particular CBD flower, or 'cannabis light' – sees the overall market size continue to grow.

Normalisation and novel food progress

Due to the lack of legal clarity, the adoption of CBD products into mainstream consumer channels, and the entry of larger companies into the CBD industry, remains limited at a regional level. Products are still generally bought online or in dedicated CBD stores, rather than in supermarkets, though CBD products can also be found stocked in many wellness shops and pharmacies across the continent. The normalisation of CBD products within a given country still depends in large part on the approach taken by authorities – for example, in the UK, CBD can be found in many high-street retailers and even in some supermarkets, despite continuing regulatory confusion.

The primary obstacle to the normalisation and development of the CBD industry in Europe concerns its position as a novel food. The European Commission (EC) lists 14 separate ongoing valid applications for marketing authorisation of extracted CBD as a novel food ingredient, with many of these having been in process for several years. The EC stated in April 2023 that it had received over 190 such applications, with the 14 listed viable enough to be under consideration. There are parallel novel food processes in Switzerland and the UK, with ten unsuccessful applications listed by Swiss authorities, and dozens of ongoing applications in the UK system (though the official list of products linked to applications is no longer available). It is uncertain when CBD products will gain authorisation under any of these systems, though active engagement from the European Food Safety Authority (EFSA) in guiding applicants towards providing sufficient toxicological data earlier this year suggests that some progress is being made towards getting some of the EC-listed applications over the line. From the perspective of those involved, the pace of this progress is frustratingly slow.

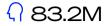
Further regulatory confusion

The legal status of CBD in Italy was thrown into question in August 2023, when the government issued a decree that would classify CBD as a narcotic, making it legally available only under prescription. This had previously been attempted by Italian authorities in 2020, only for the decree to be overturned the day after it came into effect. This time the change in the law came into effect on 21 September but was temporarily suspended until 24 October due to an appeal by cannabis association Canapa Italia Entrepreneurs (ICI), which argued that the decree failed to follow the proper legal procedures and violated wider European laws. In the brief period that the law was in effect, multiple raids and seizures took place involving retailers throughout the country which stock CBD products. With the matter still unresolved, the immediate future of the CBD industry in Italy remains uncertain.

The CBD industry in the UK also saw a setback in October 2023, as the regulator lowered the recommended daily intake of CBD from 70 milligrams to 10 milligrams. This decision was reported to be taken on the basis that there were 'important data gaps' and 'uncertainties' in the evidence provided by the industry thus far, with the regulator taking a cautionary approach in order to account for the lack of human-based long-term evidence in humans and potentially vulnerable groups. What the full impact of these measures will be depends on how events play out in the coming months, and while the recommended daily intake of products is not a legally enforceable guideline, the announcement may affect the number of major retailers that stock CBD products. The development further complicates the position of CBD in the country, which was already unclear due to the novel food issues.









LEGAL STATUS:	⊘ Medical cannabis	⊘ CBD	○ Cultivation	⚠ Adult-use	
EXPORT:	⊘ Flower and raw produc	⊘ Flower and raw product		⊘ Extracts and finished products	
IMPORT:	⊘ Flower and raw produc			⊗ Extracts and finished products	
COMPETITIVE ADVA Huge domestic market, strong	NTAGES: economy, large and growing pa	atient base, ongo	oing regulatory liberalisation	for cannabis	
BUSINESS CHALLE	NGES:				

Strong competition at every level, domestic production only under tender, regional variation under federal system

RELEVANT GOVERNMENT INSTITUTIONS:

BMG. BfArM. German Cannabis Agency

In the context of European cannabis, the German cannabis industry is of unparalleled significance. Its position as one of the de facto leaders of Europe in an economic and political context means that major developments for the German cannabis industry are also major developments at the European level. Aside from just determining the potential for the industry in the largest economy in the region, new cannabis regulations and their outcomes in Germany go some way to defining what is possible elsewhere. The mechanisms by which this can take place are varied, and identifying their causality is often not straightforward, but to a significant degree, Germany sets an example for others to follow.

When formulating regulations that test the boundaries of European law - such as the ongoing development of its adult-use regulations in consultation with regional authorities - Germany could set a template for a regulatory framework that could be used elsewhere. It was one of the early adopters of medical cannabis legalisation in Europe, and its quality standards for medical cannabis products are known to have been used as a benchmark elsewhere in the continent. Likewise in the adult-use context. Germany is the first European country to attempt to establish a fully fledged system for the licensed production, distribution, and sale of adult-use cannabis (as opposed to the pilot programme approach in the Netherlands). It has ultimately been unable to do so, and the scope of its final regulations will calibrate the ambitions of other countries looking to establish legalised adult-use systems - most immediately the Czech Republic. As the country moves closer to establishing the initial shape of its adult-use legalisation, it is important to be aware of the ripple effect this may have elsewhere.

In terms of market size, Germany's approximate €390 million in medical cannabis sales represents over half of the European total, with annual German sales figures expected to more than double by the end of 2026. The country's CBD sales of approximately €333 million makes it the leading regional CBD consumer. In both sectors it is supplied almost entirely by imports, though sometimes with final processing of products taking place within the country, and in both sectors there is market saturation in product supply. Medical cannabis cultivation is only undertaken by a select few companies under tender contracts, and accounts for only a small proportion of supply. Despite this, there are over 100 companies involved in the German medical cannabis supply chain, collectively selling just under 10 tons of cannabis in 2023. Reportedly, only 12 of these companies sell more than 20 kilograms per quarter, meaning that the majority are seeing insignificant sales revenue. The German medical cannabis sector is crowded with companies, and with funding difficult to come by in the current climate, a thinning of these numbers is likely to occur in the short to medium term.

Some recent developments in the German cannabis ecosystem:

- On 16 August 2023, a draft law was published by the German government providing for the removal of cannabis from the Narcotics Act. For adults, possession of 25 grams of dried product and private cultivation of a maximum of three plants would be permitted. Collective, non-commercial self-cultivation would be allowed in cultivation associations. Such associations would also be permitted to carry out controlled distribution of the cannabis they cultivate. Having passed through the Bundesrat, the final vote on Pillar 1 is loosely scheduled to take place in the Bundestag in January 2024. If passed, the law regarding decriminalisation and home cultivation is now planned to come into force in April 2024, while the law regarding cannabis associations will commence in July 2024.
- There is a growing trend of digital platforms allowing patients and doctors to track treatment and personalise prescriptions (e.g. Cannabisplatz, Copoeia), partly as a response to the overwhelming variety of products available.
- In September 2023, CBD of Denver announced that its wholly owned subsidiary, Luxora, had signed four Letters of Intent (LoI) to build production facilities for four Cannabis Clubs in Germany – a sign that companies are already taking steps to prepare to supply the new market there.

EXPERT INTERVIEW



Garvin Hirt CEO & Co-Founder, Copeia

How was Copeia founded, and why is it an important tool for the medical cannabis market in Germany?

We established Copeia to tackle the substantial unmet needs in the German medical cannabis market. Our team, composed of experts from diverse backgrounds, came together to recognise the persistent challenges in this sector and develop software solutions to tackle them.

Our focus is the patient's well-being and a commitment to supporting their healing journey. Our services are available free of charge to patients and physicians; particularly those interested in cannabis therapy but who are lacking in essential knowledge. These practitioners form a pivotal group in the traditional doctor-patient relationship, and Copeia tailors solutions to provide them with the tools and information they need to navigate the complexities of medical cannabis therapy.

Today many doctors in Germany and Europe are reluctant to prescribe medical cannabis due to a lack of clinical protocols and the unavailability of information supporting a cannabinoid therapy. The doctor's time and effort are required for unwieldy administration processes by having to submit data to health regulators and then dealing with insurance claims even though medical cannabis would prove beneficial in relieving many patients' symptoms.

Prescribing medical cannabis in Germany can be a complex and hideous process. Copeia's reimbursement tool serves as a valuable solution, by not only helping to grant patients access to their needed medication but also by alleviating the administrative burdens that doctors face with insurance claims. In Germany, 90% of patients are enrolled in statutory insurance with full coverage for their treatment expenses. Copeia's reimbursement tool has proven to be a significant success, being recognised and widely used among German patients, physicians, pharmacists and the medical industry. While its impact is widespread, the ultimate beneficiaries are the patients. However, there remain several ob-

stacles to be addressed on the path to streamlined reimbursement processes as many cases are still denied by the insurance companies. In addition, we're providing tools to help physicians with dosing and titration. This allows them to create individualised treatment plans, particularly for oral applications and extracts. We're also actively involved in supporting nationwide clinical studies with our innovative technology platform by partnering with pharma companies in Germany.

Furthermore, we are actively engaged in a range of projects, with an upcoming launch of an open patient registry. A significant challenge lies in the uncertainty surrounding medical cannabis therapy guidelines, with physicians often seeking reference cases for guidance. That's why we're developing, with a collective of industry partners, an open registry, providing physicians with a platform to compare cases, share experiences, and enhance their comprehension of medical cannabis treatments.

We are committed to making a positive impact in the realm of medical cannabis, striving to make the field more accessible, comprehensible, and efficient for all stakeholders.

How has the rate of medical cannabis prescriptions and prescribers evolved over the years in Germany?

In Germany, prescription rates are on a steady level, with flower prescriptions stagnating and an increase in extract prescriptions. However, a notable challenge lies in the limited increase in the number of prescribers. Despite the growing interest in cannabinoid therapy, many patients continue to struggle to find physicians willing and comfortable to prescribe it, particularly in rural areas. The highly regulated nature of the German healthcare system requires a significant commitment from physicians to enter this field. While there are specialised clinics focusing on medical cannabis, the number of prescribers remains stagnant, but there is still a lot of potential to grow once medical cannabis becomes a more established treatment option. The acceptance

rate for medical cannabis reimbursement claims in Germany has remained relatively constant, with approximately one-third of applications being denied. This rate can vary significantly depending on the patient's indications, age, medical history, and the individual insurance itself.

In your point of view, how will the planned removal of cannabis from the German Narcotics Act (BtMG) have an effect on medical prescriptions?

Assuming that everything proceeds as planned and we will see a declassification, the medical cannabis prescription process is likely to become easier. There are a number of German physician groups that do not have the capability to prescribe narcotics, so for them, it might become a new treatment option.

However, the primary challenge within the German medical cannabis system remains the cumbersome process of reimbursement claims. While it may become easier to prescribe medical cannabis, the issue of reimbursement remains a significant hurdle.

It may also affect the way patients acquire their medicines as it may be too exhaustive to go to the doctors and have the possibility of not getting their medicine reimbursed when they can purchase medical grade cannabis easier and cheaper as a private payer or even as a member of a social club or a home-grower with further applications and potential problems down the line.

How do health insurance companies view the reimbursement of medical cannabis? Are there certain German insurers that are more willing to do so over others?

There are currently some initiatives from health insurers that are collaborating with special groups of physicians to make the reimbursement process of medical cannabis easier. Physicians have to successfully complete a curriculum which would automatically grant them the right to treat their patients with cannabinoids without applying for the reimbursement process.

However, insurance companies in Germany, in general, are cautious and they often emphasise the costs associated with medical cannabis treatments. Many insurance companies also maintain a conservative approach toward cannabis, considering it an off-label medicine lacking specific rules and guidelines compared to other treatments and medical products.

Nonetheless, if a thorough analysis of real-world data is conducted to assess the potential cost savings of cannabis treatments in comparison to the expenses associated with other treatment options, insurance providers might better appreciate the potential for patients to reduce their dependency on other expensive or even harmful medications and regain a higher quality of life. This includes improved mobility and increased participation in the workforce, which could, in turn, make insurance providers more inclined to view cannabis as a viable treatment option.

In your point of view, what are the necessary steps the industry needs to take to improve the German medical cannabis market?

First of all, we need more evidence. Supporting physicians with real-world data is crucial, and that's precisely where Copeia aims to make a substantial contribution to advance cannabinoid therapy. Notably, we're observing the entry of major pharmaceutical players into the cannabis market, which is driving further product innovation. Germany stands out as one of the only true medical cannabis markets worldwide, thanks to its reimbursement schemes, in contrast to markets like the US where insurance companies rarely cover medical cannabis costs.

The industry requires a clear differentiation between pharmaceutical and adult-use sectors, given their unique characteristics. Cannabis companies must make a critical decision regarding their market positioning, either focusing on the adult-use segment or establishing themselves as pharmaceutical players. Making this distinction is a pivotal choice for the industry.



€ 67.3M

\$ 46.5K PER CAPITA

LEGAL STATUS:		⊘ CBD	○ Cultivation	⊗ Adult-use
EXPORT:	⊘ Flower and raw product		Extracts and finished products	
IMPORT:			⊗ Extracts and finished pro	oducts

COMPETITIVE ADVANTAGES:

Huge market potential, quickly growing patient base, watershed regulatory change on the horizon

BUSINESS CHALLENGES:

Bureaucratic obstacles to imports, strict licensing regime, strongly established networks of players under current regulatory regime, high cost of labour

RELEVANT GOVERNMENT INSTITUTIONS:

NHS. Home Office, DHSC, FSA, MHRA

The UK is the fastest-growing medical cannabis market in the region, and the second-largest behind Germany. Like Germany, the UK medical cannabis market is supplied primarily by imports, with some final product processing steps carried out by UK companies. Domestic cultivation is just starting, with only a small number of companies having been granted licences to grow. The process of importing products still requires a number of bureaucratic steps, which imposes costs, and despite a wide variety of different products being available, there are often problems with consistency of supply. Medical cannabis treatment is currently accessed almost exclusively through private channels, with patients bearing the full cost. Networks of private clinics, which are often linked to specific distributors and pharmacies, provide in-person as well as remote consultations, with prescriptions often delivered rather than collected. The major milestone that patients and industry alike are waiting for in the UK is the adoption of medical cannabis treatment by the NHS, the UK's public health system. Recent recommendations to the government by a parliamentary committee to consider medical cannabis use on the NHS and to initiate clinical trials for pain treatment with cannabis are very promising signs that authorities are moving towards this decision. Current annual growth rates in medical cannabis sales could be exceeded in the coming years if the NHS begins treatment, and if import restrictions are eased. Medical cannabis sales for 2023 are set to top €222 million, with significant room for more growth.

The UK's CBD market is lower than Germany's in size at €287 million for 2023 sales, and is considered the most mature in Europe, with a high level of product availability even in mainstream retailers like supermarkets and leading health stores. There is

very little cultivation or processing of CBD products in the country, with the overwhelming majority of the market supplied by imports. Despite the developed nature of the CBD market, uncertainty persists – with the regulator recently limiting the recommended daily intake for consumers to 10 milligrams of CBD, which is less than is in one single dose for a large proportion of the products on the market. This, together with the unresolved status of all novel food applications for CBD in the country, puts the industry in a state of uncertainty. While a reduction in CBD market activity is unlikely, these factors may delay normalisation and constrain growth in the short to medium term.

Some recent developments in the UK cannabis ecosystem:

- In August 2023, the UK's National Health Service (NHS) Research Ethics Committee approved the full-scale roll-out of a new clinical trial into medical cannabis and non-cancer chronic pain. The trial was designed in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA) to provide a data set that will enable the potential for prescription and reimbursement by the NHS and insurance companies.
- Also in August 2023, Ananda Developments announced that it would receive funding from NHS Scotland to carry out a Phase 1 clinical trial on the use of its CBD formulation for the treatment of pain associated with endometriosis.
- These trials are thought to be the first two cannabis randomised control trials (RCTs) in the UK since GW Pharmaceuticals' trials for Epidyolex® and Sativex®.

 In October 2023 the Home Office minister responsible for medical cannabis in the UK announced that approximately 24 tons of raw cannabis flower had been imported up until September 19th, more than triple the amount imported over the entire year of 2022.

'While France, Sweden, Poland the Czech Republic are interesting markets, however the German market remains the most compelling, not only in terms of the size of the medical market but also due to the shift towards adult-use legalisation.'

Rokshaw Laboratories







Jonathan Hodgson CEO, Rokshaw Laboratories

How long has Rokshaw Laboratories been involved in the medical cannabis industry and what services and solutions do you provide for your clients?

Rokshaw Laboratories was formed in 2012 as a 'Specials' manufacturer and importer of controlled drugs in the UK. As soon as we found out that medical cannabis would be rescheduled in the UK we began preparing ourselves for the upcoming market. Since the start of the medical cannabis market in the UK, we have been very well situated as we already held all the necessary licences to handle controlled substances. Regarding our services, we are predominately a manufacturer and importer of 'Specials' and 'Unlicensed Medicines', with medical cannabis being the vast majority of what we do.

Rokshaw manufactures and distributes the widest range of medical cannabis products in the UK, consisting of our own branded products and other major brands from around the world. Having a Schedule 1 Home Office licence allows Rokshaw to provide a best-in-class manufacturing and distribution service to help grow the market for both producers, patients and prescribers. We actively work with healthcare professionals such as specialist prescribers and pharmacists to help them enter the UK medical cannabis market with confidence.

Rokshaw is part of Curaleaf International, with the group also consisting of Curaleaf distance-selling pharmacy, where we directly provide patients with medical cannabis. Additionally, we also provide patient access through the Sapphire Medical Clinic which was one of the first Care Quality Commission (CQC) registered clinics for medical cannabis in the UK. Therefore, we offer a full spectrum of services towards patients also having cultivation and production facilities in Spain and Portugal.

How has the UK medical cannabis market evolved in recent years, what trends and developments are you witnessing?

In the first couple of years of the UK's medical cannabis market, progression was extremely slow, there was a lot of interest however prescription numbers were fairly low as it was difficult for stakeholders to understand the regulations regarding importing and prescribing medical cannabis products. One of the crucial points to make here is that although there was a rescheduling(to Schedule 2) some parts of the process are still technically classified as Schedule 1, which makes it difficult to import and process.

Rokshaw Laboratories holds a Schedule 1 licence, which meant that we could purchase starting materials and manufacture in the UK, which in our point of view is a much easier process. Although there was a slow start, we are now witnessing a strong acceleration in the market; around this time last year, it was estimated that there were 15,000 medical cannabis patients in the UK which are now estimated to be around 30,000. The doubling of patient numbers is very significant to the growth in the market. However, if we look at the bigger picture it can be argued that these patient numbers could reach the hundreds of thousands as around 2% of the UK's adult population could benefit from medical cannabis treatment.

Additionally, patient access has become much easier than ever before, as there are now many more clinics that have lowered their prices for appointments. We have seen medical cannabis prices drop and we are also witnessing a lot more variety and formats of these medicines.

As the range of products available to UK medical patients continues to increase, have you been witnessing any growing trends regarding specific formats, cannabinoid content, strains etc.?

Traditionally, the UK has been dominated by medical flower and oil products, however we are beginning to see some change in this instance. Just recently we have launched medical pastilles, also known as gummies, and we also offer liquid vape cartridges and produce capsules. All of these new product formats are being demanded by patients and clinicians as they provide a more accurate dose and are convenient for medical cannabis patients.

However, it must be noted that in the UK we have a diverse range of patients; some are looking for flower products with a high THC content, others are searching for strains with a richer terpene profile, and some are seeking strains that help them sleep or keep them sharp during the day. New strains and genetics are entering the market every month and it is very interesting to see which one works best for patients. Most patients do not just use one product but tend to purchase two to three medical products a month based on several factors. This can be based on convenience and dosage, as ingesting a 10mg oral product is much more precise and accurate when treating conditions than heating a medical dried flower product. So we are seeing patients take a hybrid approach in what medical products they purchase based on their lifestyle, health conditions and overall preferability.

What are the main challenges for cannabis brands that seek to operate in the UK's cannabis market?

The UK's medical cannabis market is highly regulated as it is a genuine medicinal market, thus for brands that do not have operations in the UK it is important to find partners that understand all of the complex regulations that currently exist. Looking into it, you have all of these different agencies in the UK such as the Medicines and Healthcare Products Regulatory Agency (MHRA), the Home Office, The General Pharmaceutical Council (GPhC), CQC, including the Advertising Standards Authority (ASA) which all have governing rules and frameworks which companies may trip themselves on, and that can hinder a product from entering the market or even fall under scrutiny.

Thus, it is extremely important to find the right partner who has experience when dealing with these bodies and frameworks. This is where Rokshaw Laboratories holds an advantage as we have been working with these regulators with other medicines prior to the launch of the UK's medical cannabis market. In one aspect it is a new and exciting area in terms of product format and there are some differences compared to other medicines such as the 'specials' prescriber model, however it is very similar other than that. Therefore if a new company is entering the market and is trying

to understand all of the regulations it can be difficult to navigate without an experienced partner as there isn't a centralised cannabis body a company can refer to.

In your point of view, how can the UK medical cannabis market improve and grow?

First of all, the market will improve if we continue to see quality products entering the market in tandem with high-quality service. We are already witnessing fantastic improvements with a range of clinics offering consistent and efficient services with prices for treatments and appointments dropping.

One factor that has to be mentioned, however, is that not many members of the public are aware of the legality of medical cannabis, they are still confusing it with CBD and are not aware that if they have one of the prescribable medical conditions, they are eligible for dried flower products with a high THC content. The lack of awareness by the public and the limitations set on medical cannabis players regarding advertising means the market relies on word of mouth.

However, I believe that as more data on cannabis patients, the market, and clinical trials continue to be collected we are going to see significant growth over the years. As chronic pain is one of the leading conditions for medical cannabis treatments I believe that many from the medical community may deem medical cannabis as a viable treatment over other drugs such as opiates which have serious side effects. Therefore, I believe that the UK medical cannabis market is already on the right track and we will witness further market growth correlating with public awareness and scientific data.

What international cannabis markets are you keeping your eye on and why?

The German cannabis market is very interesting, not only in terms of the size of the medical market but also the shift towards adultuse legalisation which seems to be more complex than anticipated. There is, however, a lot of progress happening there in terms of medical prescription numbers and updates in regulations. We recently launched the first products from our German sister company 420Pharma, in the UK, so we are very interested to see how the German market progresses. We have also just opened the Sapphire Clinic in Sweden and are excited about how the Nordic markets develop. We also have a close eye on the progress in Poland and the Czech Republic. France is another market which holds a lot of potential as the generalisation of medical cannabis could drive the growth of the overall European medical cannabis market as there is a massive patient base that could benefit from medical cannabis treatment. It will be exciting to see how all of these medical markets can learn from each other which can lead to further market growth and ease in patient access.



Switzerland (18.7M (9.92K PER CAPITA

LEGAL STATUS:		⊘ CBD	○ Cultivation	⊘ Adult-use
EXPORT:	⊘ Flower and raw produc	et	Extracts and finish	ned products
IMPORT:		et	Extracts and finish	ned products
COMPETITIVE ADVA	ANTAGES: gulatory infrastructure, liberalis	ed approach fror	n authorities, strong tax ince	entives
BUSINESS CHALLE High cost of labour, reasonabl	NGES: y small domestic market, small-	scale approach t	o building cannabis industry	,
RELEVANT GOVER	NMENT INSTITUTION	IS:		

FOPH, FSVO, FOAG, Swissmedic

Switzerland is the only country in Europe with legal commercial supply chains for adult-use cannabis currently operating. Six adult-use trials have now been approved, of which four are currently active. Upon activation over 10,000 users will be sourcing cannabis from legal supply chains in total, with more trials likely to be approved in the coming months. The country has the most developed regulatory framework for CBD products in the region, with maximum THC limits of 1% on products, hemp cigarettes regulated as tobacco substitute products, and licences available for the different steps of production and manufacture of CBD products and hemp cultivation. It shares the same regulatory uncertainty over CBD as a novel food as other European markets, however, and despite having its own novel food application process, no company has successfully achieved novel food status for a CBD product in the country. Switzerland also boasts a small-scale medical cannabis market supplied by both imports and domestic production. Reforms last year expanded patient access and are expected to drive modest growth over the next few years. The country could potentially reach up to €2.9 million in adult-use cannabis sales in 2023 (though it is likely to be less), with a CBD market size of €37.1 million and medical sales of over €31 million

Some recent developments in the Swiss cannabis ecosystem:

- The second phase of the 'Weed Care' adult-use trial in Basel-Stadt has begun, with the number of participants doubling from 180 to 374. Thirteen kilograms of cannabis products have already been sold via nine pharmacies, with demand greatest for those with the highest THC concentration. The Swiss manufacturer Pure Production supplies the trial.
- At the end of August 2023, another much larger study launched in Zurich, 'Züri Can'. This larger study will compare different models of procurement, enabling its 2,100 participants to choose to buy cannabis either from a social club, pharmacy or drug counselling service. The study will feature ten social clubs where participants can also consume cannabis, ten pharmacies, and one drug advice centre, and will be supplied by SwissExtract and Pure Production.
- In December 2024, Europe's first cannabis speciality store opened. Under the 'Grashaus Project' pilot project in the municipality of Allschwil in the northwestern Swiss canton of Basel-Landschaft. The project has a total sample size of 3,950 participants and the store sells a range of flower, hash, vape, edible and oral extract products supplied by SwissExtract. The project is funded by Sanity Group and will examine whether structured and controlled sales of high-quality and organically-grown cannabis in speciality stores will reduce harm to consumers affected by illicit sales.

- The pilot project Cann-L, which examines the feasibility of regulating cannabis 'through non-profit sales', began sales in December 2023, and is set to involve 1,600 citizens throughout the Lausanne municipalities.
- A fifth study, 'Script', is launching in three cities at the beginning of 2024, including Lucerne, Biel and the Swiss capital Berne, featuring another 1,091 participants. The study will compare one 'control' group of users, who will continue to purchase products on the black market, with those able to purchase controlled products legally through pharmacies. Pure is reportedly producing a number of different products, including an e-liquid, and an 'edible' product that is akin to a 'microdosing spray', which enables users to receive the effects much faster than with other edibles such as gummies. Any shift from smoking to other forms of cannabis consumption will be of particular interest to the study.



Cannabis remains illegal in some countries so please reference your local laws in relation to purposes only. It should not be construed as a research report for investment, legal, medic





Susanne Caspar CEO, Linnea SA

Why are sustainability initiatives important at a company?

It's vital that companies create their own sustainability initiatives and ESG policies in order to practice a strong commitment to the community and environment in which they operate. In addition to those changes mandated by government regulations it's important businesses take further steps to ensure ongoing progressive changes. Making these investments mean increased efficiencies and productivity for your business, long term cost savings, positive cultural and diversity shifts in your personnel and a greater symbiotic relationship with the community both small and at large. Forward thinking actions in the area of sustainability create longevity in your business relationships, encourage innovation, foster a genuine positive impact of your brand for patients and consumers, and bring substantial rewards for our environment.

What are some concrete ways to make ESG improvements and how has Linnea taken these steps?

Some important ESG improvements that companies can make that have substantial impact are reducing scope 1 and scope 2 emissions. At Linnea we voluntarily adhere to the Swiss energy strategy program (ENAW) to reduce carbon dioxide emissions and energy consumption. Since 2016 we have reduced our scope 1 carbon emissions by almost 30%. Part of how we accomplished this was by optimizing our processes to have more efficient insulation in pipes and buildings, changing our steam generators and investing in more efficient equipment. We have also been able to reduce our electricity consumption scope 2 emissions by 30% with more efficient machinery and optimizing our processes. Additionally, since 2017 all of our bio waste is used to produce electricity and heat for the local community. Our biogas installation runs 24/7 fermenting biowaste in a closed environment with zero emissions turning this organic waste into energy sources. We have also installed solar paneling in all places of our facilities where it is possible to further reduce energy consumption.

While many of these steps require substantial investment upfront, they yield even bigger positive returns over time for your business, your consumers and partners and the community.

Are there other ways a business can make investments in ESG and the environment outside of manufacturing?

Businesses can take further day to day steps within their company work environment such as reducing the use of plastic and paper. Also participating in local community initiatives, such as world cleanup day as we do at Linnea, can help create a stronger connection to the local environment and the people served by our businesses.

Social responsibility is another important area of focus for companies to make additional investments. The dedication, passion and experience of a company's employees are at the heart of every business. Making investments to help your internal community to grow and flourish is as vital as those made externally. Respecting diversity, ensuring equity in compensation, creating a safe and healthy work environment and providing ongoing professional developmental training are all ways a company can enhance their social responsibility commitment. Creating a code of conduct and a culture handbook for employees and contractors to follow also ensures an environment with respect and care for peers and external partners.

Are there any unique reasons why cannabinoid companies should make these environmental commitments?

Since the cannabinoid industry is still fairly new and emerging it's crucial to create the right foundation of business practices. When companies are new or expanding this is an opportune time to make investments in sustainability and ESG-related changes to ensure consistent efficient growth. Also, the cannabinoids industry is under intense scrutiny from the community, regulators and medical providers and patients so it's critical to contribute to the

long term health of the communities your business serves. Our mission at Linnea is to improve people's quality of life and this mission is accomplished not only with high quality products but also with sustainable processes and a strong environmental commitment. Businesses in a growing industry like cannabinoids have the potential to make a greater positive impact on the environment compared to individuals so it is integral businesses consider how they operate in the ecological, social and economic environment.



€ 37.8M



LEGAL STATUS:		⊘ CBD	⊗ Cultivation	⊗ Adult-use	
EXPORT:	⊗ Flower and raw produ	⊗ Flower and raw product		⊗ Extracts and finished products	
IMPORT:		○ Flower and raw product			

COMPETITIVE ADVANTAGES:

Low labour costs, strong economy, significant potential for reform, large domestic market

BUSINESS CHALLENGES:

Relatively uncertain political environment, lengthy bureaucratic processes, highly regulated market

RELEVANT GOVERNMENT INSTITUTIONS:

CPI, MOH, ORMP, ChPhI, KOWR

Poland has seen steady growth in its legal cannabis industry over the last number of years without implementing significant regulatory change. While there are still no indications of any intention to develop a legalised adult-use system, CBD consumption remains strong, with a reasonably large cultivation and manufacturing base for CBD products in the country (though limited to only a few companies). Medical cannabis is the area that is seeing the most growth and new activity, while also representing the greatest opportunity for significant growth in the short to medium term. Despite the long bureaucratic process required to get products approved by the regulator (reportedly 18-24 months), new products continue to appear on the market, with approximately 30 distinct products having been used for prescription and treatment so far. Arduous bureaucracy is currently the most significant factor restricting growth in the market - in addition to the product approval process, a separate import permit is required for each batch of products imported, and considerable additional expertise, knowledge and documentation are required of pharmacies and doctors choosing to engage in medical cannabis treatment. Due to the difficulty and complexity involved in getting products approved, imported, and prescribed, there have been issues with consistency of product supply since the beginning of the market which persist to this day. Of the 30 or so products that have been on the market, many are no longer stocked by pharmacies where they were once available. Compounding these difficulties in patient access, the cost of treatment is paid entirely by the patient, with no reimbursement available on private or public healthcare. Treatment costs are often significant due to the bureaucracy involved, and by extension the lack of market competition. The market is supplied entirely by imported products, with few companies involved in distribution. No cultivation is allowed in the country, and the only domestic production is small-scale limited to repackaging of imported raw materials. There are plans

from at least one company for some future processing of imported raw materials to manufacture extract-based products. The market is dominated by flower products, though some extract-based products are also available. A new coalition government likely to be formed and take office in 2024 is a promising sign for the industry, as it is expected to hold a more progressive stance on social and health issues. Whether this translates into reform for the medical cannabis sector in the country remains to be seen, but if so, growth for the industry and more affordable and consistent treatment for patients could follow.

Some recent developments in the Polish cannabis ecosystem:

- The results of the Polish parliamentary elections held on 15 October 2023 were unexpected. The right-wing populist party PiS has held power in Poland since 2015, and looked set to remain in government; however, the vote saw it lose its parliamentary majority. This has cleared the way for the centre-right Civic Coalition, led by former Prime Minister and European Council President Donald Tusk, to form a coalition government with two other opposition parties. While medical cannabis was legalised under the PiS, no significant regulatory progress has been made for several years. The stance of the incoming government on cannabis reform is unknown; however, the outlook for positive change is certainly more promising than if the status quo were to remain.
- According to data released in April 2023 by the health regulators, in January and February alone, Poles bought 270 kilograms of medicinal cannabis in pharmacies. This figure is higher than for the entire consumption of 2021, when sales amounted to approximately 250 kilograms.

'The volume of imported medical cannabis to the Polish market is limited by the government. Starting at 3 tons, the limit was gradually raised to 5 tons, which will still not cover patient needs for 2024.'

Michael Simon, Vice President Commercial, Aurora Europe

'We must manage a complex regulatory process. The system for issuing permits by the Main Pharmaceutical Inspectorate (GIF) is crucial for companies to import medical cannabis. We believe it would be meaningful to see an easier and quicker registration process for new cultivars, as well as unlimited volume for import licences. These changes would alleviate the Main Pharmaceutical Inspectorate (GIF) and result in a more scaled and responsive market.'

Michael Simon, Vice President Commercial, Aurora Europe

'Specific medical cannabis cultivars may remain unavailable despite an oversupply. This challenge is primarily attributed to the regulatory policy, which does not fully acknowledge the significance of individual cultivars in therapeutic applications.'

Michael Simon, Vice President Commercial, Aurora Europe





Israel



\$ 54.9K PER CAPITA

LEGAL STATUS:		⊗ CBD	○ Cultivation	⊗ Adult-use	
EXPORT:	⊘ Flower and raw product				
IMPORT:	⊘ Flower and raw product		⊗ Extracts and finished products		
COMPETITIVE ADVANTAGES: Strong R&D, agriculture-tech expertise, high VC funding					
BUSINESS CHALLENGES: Regional conflict, strict export regulations, differences in international standards/practices					

RELEVANT GOVERNMENT INSTITUTIONS:

MOH, IMCA

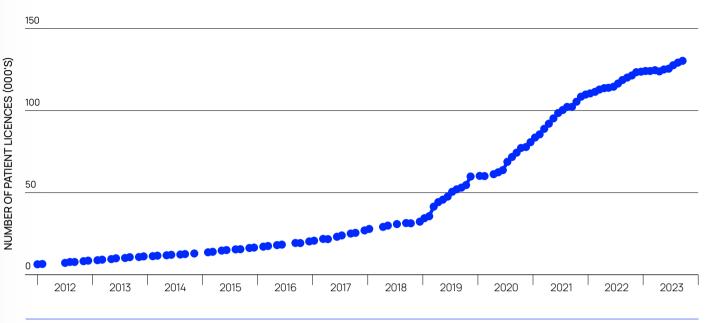
Israel has been at the forefront of the international cannabis industry with Israeli public sentiment about cannabis use becoming more normalised due to its growing medical market, R&D projects, and the decriminalisation of cannabis for those aged over 18 in 2019.

The Israeli medical cannabis industry is one of the most advanced globally, as the country benefits from several advantages, including a first-mover advantage, the legalisation of medical cannabis back in the early 1990s, an evolving framework that is continuously updated to make patient access easier, and strong expertise in the fields of R&D and agritech, making it one of the leading medical cannabis hubs globally.

Medical cannabis has been legal in Israel for the past three decades; however, only in recent years has the country witnessed strong growth in the sector due to regulatory reforms that have benefited patient access. Following the establishment of the Israeli Medical Cannabis Agency (IMCA) in 2011, and regulatory amendments in 2019, which made patient access easier through the loosening of permit approval procedures, the country witnessed dramatic growth, boasting an active patient base of 129,836 as of September 2023 (IMCA, 2023). These numbers, which are currently stagnating, are expected to increase following new reforms announced in August 2023 that come into force in December 2023. The new reforms would transition medical cannabis from a 'treatment of last resort' to a 'first-line treatment', and would eradicate the need for terminally ill patients to obtain a governmental medical cannabis licence. The announcement also included a review of potentially removing CBD from the Controlled Substances Act, as it is currently only available through the medical framework, and seeks to ease restrictions on raw imports for research purposes.

Although Israel has held a proactive approach in developing its domestic market, hoping to become a significant exporter globally with a positive trade balance, its vision has not come to fruition, with exports being few and far between. This has been driven by internal conflicts with domestic producers and the Ministry of Health (MOH), restrictive regulations on production and exports, low-level THC products, domestic supply shortages, and easier access to high-quality imported products, leading many domestic companies to discontinue their production activities. The country is currently the largest importer of medical cannabis internationally (16.8 tons in H1 2022, primarily from Canada and Portugal), as in 2019, supply shortages led to a temporary opening of medical cannabis imports which became permanent. This became a struggle for domestic producers as patients have been favouring high THC strains from international producers, whereas Israeli products with lower levels of THC are favoured less. Additionally, Israeli companies are allowed to export products only if domestic supply shortages are met. This has led to many challenges for domestic companies as they are faced with stringent production and export regulations as well as competing with international importers that have a competitive edge over the market. All of these factors have contributed to an over-saturation of the market with dozens of companies competing for market share, the majority of Israeli-listed companies operating at a loss, and the closing of domestic cultivation and manufacturing operations.

Israeli Medical Cannabis Patient Licences (2012-2023)



Source: Israeli Medical Cannabis Agency 2023

At the time of writing (October 2023), Israel declared war on Hamas, creating uncertainty in all economic aspects of the region, including the medical cannabis market. It has been reported that the Canndoc cannabis farm owned by InterCure situated in the Kibbutz Nir Oz has been damaged by Hamas and that two employees have been kidnapped and taken to Gaza. However, Israel has made a dedicated effort to support patients, with the Israeli MOH extending medical cannabis prescriptions by three months and domestic producers providing free medical products to patients affected in the region. How the war will affect Israel's medical cannabis market remains unclear as security is at an all-time high, which may cause barriers in terms of imports, supply chains, and levels of investment.

Recent events related to cannabis in Israel:

- In October 2023, following the conflict in the Gaza/Israel region, the Israeli MOH extended patients' medical cannabis prescription licences by three months.
- In August 2023, the IMCA announced regulatory reforms, which seek to ease patient access, review the eligibility of removing CBD and other non-THC related cannabinoids from the Controlled Substances Act, remove import barriers of raw cannabis for research purposes, and add restrictions on packaging and advertising. These reforms are expected to be rolled out in December 2023.
- In July 2023, the international tobacco giant Philip Morris announced plans to acquire Syqe Medical, an Israeli-based medical cannabis technology company focused on metered-dose inhalers, with the potential of the deal reaching US\$650 million if the product receives FDA approval.



EXPERT INTERVIEW





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Alon Hershkovitz
CEO & Co-Founder,
IMCI Pharmaceuticals

Avi Yakobovich
Executive Director
& Co-Founder,
IMCI Pharmaceuticals

How is IMCI involved in the medical cannabis industry on a global scale?

IMCl is a biopharmaceutical company focused on developing pharmaceutical-grade and innovative medical cannabis products that comply with the diverse regulations governing magistral preparation and final dosage form markets in various countries worldwide.

By taking a global perspective, IMCl ensures that its products meet the highest quality standards required by various markets including Israel, the DACH region, the UK and Australia. It provides ease to patients with final-dose products, and pharmacies with compliant easy-to-prepare magistral preparations. This strategy allows IMCl to navigate the unique regulatory landscapes of different countries and deliver compliant medical cannabis solutions to patients and healthcare providers globally.

Through its commitment to quality and adherence to international regulations, IMCI strives to contribute to the advancement of the medical cannabis industry on a global scale.

What aspects of the medical cannabis industry in Israel have changed while IMCI has been operating, and are there any significant recent developments or trends?

In recent years, the medical cannabis industry in Israel has witnessed significant changes and developments. One notable development is the comprehensive reform introduced by the Israeli Medical Cannabis Agency in 2019 with the "Medicalisation" reform that grew the number of patients from about 30,000 to over 132,000. Lately, a new reform has been announced which aims to simplify direct supervision, promote research, and encourage innovation in the industry.

Here are some key changes that have taken place:

Clinical Indications Licence Exemption: Starting from December 2023, 10 clinical indications no longer require a special licence and can be prescribed solely by physicians. After a

year of this implementation, the regulator may expand this exemption to include additional clinical indications. This change is expected to increase the access of new patients seeking medical cannabis treatment.

Prescribing as First Line of Treatment: The regulator is currently reviewing its position on allowing physicians to prescribe medical cannabis as a first-line treatment before resorting to opioids. This potential shift highlights a focus on exploring alternative treatment options and reducing reliance on potentially addictive medications.

These changes are expected to have a positive impact on the accessibility of medical cannabis treatment for patients, increase acceptance among healthcare professionals and contribute to the growth of the medical cannabis market as a viable option alongside conventional treatments.

Where do you see the global medical cannabis industry heading?

We anticipate that the medical cannabis industry will continue to face challenges of oversupply and low differentiation, especially in the most popular product category of dried flower. This will result in price decline and financial hardship for many companies that cannot compete in the crowded market.

We also expect that new entrants will have to provide clear therapeutic value and differentiation in order to be adopted by professional healthcare providers and patients. This will require high-quality, standardised, and reliable products that target specific indications and demonstrate clinical efficacy and safety.

We believe that IMCI products are well-positioned to meet these requirements and provide clear therapeutic value and confidence to professional healthcare providers and patients.

Can you tell us about IMCl's advantages in technology and innovative products?

IMCl's technology and innovative products are at the forefront of the medical cannabis industry. Our products are formulated using iCann technology, a nanoparticle drug delivery system clinically proven to function on humans. This technology enhances therapeutic benefits, reduces dosage regimens, and minimises side effects. The iCann technology combines active pharmaceutical ingredients (API), innovative formulation, and a delivery system. Each product contains a unique cannabis profile that encompasses the full cannabis spectrum, providing a comprehensive therapeutic effect for relieving chronic indications.

We are focused on creating clinically proven pharmaceutical-grade products that enhance the patient experience in a holistic manner. This includes safety, precision, discretion and easy dosing. We provide various flavours to cater to a diverse range of patients. Our goal is to create products that improve patient treatment compliance and enhance their overall quality of life.

We offer three products within our first line:

iCann Fast: A sublingual tablet with a fast onset mechanism, providing relief of about 2.5 hours, designed mostly for daycare settings.

iCann LA: A mucoadhesive tablet with a long-release mechanism, providing relief of about 8 hours ideal for patients seeking relief throughout the night.

iCann Oral: An orally administered capsule with rapid release, which can complement the iCann Fast product providing relief of 3-4 hours.

These innovative products provide patients with effective and tailored solutions for managing chronic symptoms and improving their overall quality of life.

Which emerging medical cannabis markets in your point of view are most exciting in terms of growth and potential?

In our opinion, there are several emerging medical cannabis markets that are exciting in terms of growth and potential. The following stand out due to their favourable regulatory environment and potential for further growth:

Israel: Israel has been at the forefront of medical cannabis research and innovation for decades. The country has a well-established medical cannabis industry and a supportive regulatory environment which encourages research and development. With recent regulatory changes aimed at simplifying direct supervision, promoting research, and encouraging innovation, the Israeli medical cannabis market is poised for significant growth.

Germany: Germany is the largest medical cannabis market in Europe and has been rapidly expanding in recent years. The country has a well-established healthcare system and a growing patient population seeking alternative treatment options. The German government has also been supportive of the medical cannabis industry, creating a favourable regulatory environment for growth.

Switzerland: The potential for growth in the medical cannabis market in Switzerland has been significantly boosted by the country's revision of its narcotic legislation in August 2022. This revision aimed to streamline and simplify access to medical cannabis for patients, making it easier for them to obtain the treatment they need, leading to increased demand and potential growth in the market.

The UK: The United Kingdom has recently made significant strides in its medical cannabis market. While still relatively new, the UK has shown a willingness to explore the therapeutic benefits of cannabis-based medicines. The government has taken steps to improve access for patients and streamline the prescribing process. With a large population and a growing acceptance of medical cannabis, the UK market holds great potential for growth in the coming years.

Australia: Australia has a relatively small medical cannabis market but is poised for significant growth in the coming years. The country has a supportive regulatory environment that encourages research and development, and there is growing patient demand for medical cannabis as an alternative treatment option. With recent regulatory changes aimed at streamlining the importation process for medical cannabis products, the Australian market is expected to grow rapidly in the near future.

What's on IMCI's roadmap for 2024?

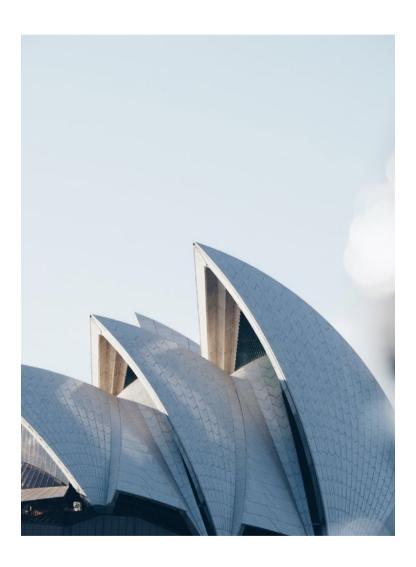
In 2024, IMCI has several key goals in mind. We are focused on completing the final stages of technology transfer for the commercial production of our iCann Relief product line. We anticipate launching this product line during the second half of 2024.

Additionally, we are committed to developing new and effective cannabis-based API's to be incorporated into our iCann platform products for the treatment of specific chronic indications. This will allow us to expand our product offerings and provide patients with even more tailored solutions for managing their conditions.

In terms of business development, we plan to leverage our strong footprint in Israel, including our solid distribution and marketing network, to expand our operations into emerging medical cannabis markets. We are currently in discussions with leading pharmaceutical and cannabis companies that have a dominant position in their markets and possess a large sales force. Additionally, we are open to achieving expansion through strategic collaborations with well-positioned and established cannabis and biopharmaceutical companies that share our product vision and market potential. These collaborations would allow these companies to leverage IMCl's innovations and products in order to enter the rapidly growing cannabis therapy market. Our goal is to continue growing and provide patients with the highest quality of medical cannabis products available.



Oceania



The cannabis industry in Oceania is developing quickly, and the region already represents the third-largest medicinal cannabis market globally, after North America and Europe. The vast majority of commercial activity is concentrated in Australia and New Zealand's industry, while some low-level activity is also seen in some island nations and overseas territories in the region.

The industries in Australia and New Zealand share many similarities - both countries are primarily import-supplied medicinal cannabis markets, with a focus on domestic production for exports and future domestic supply. Australia's production is at a more developed stage, and some of its companies are already seeing significant export volumes to Europe. New Zealand's producers meanwhile have managed initial commercial exports successfully; however, export volumes so far have been low. Both countries are currently implementing regulatory updates that are favourable to domestic producers - in Australia, imports will be subject to Good Manufacturing Practices (GMP) requirements, making imported products comply with the same quality and safety standards as domestic production, which should level the playing field for producers aiming to supply the domestic market. In New Zealand, stringent quality standards are being loosened for certain categories of exported products, such as raw materials, which are intended to facilitate easier exports for producers.

In each country there is a reasonably wide variety of products available, though there is little reimbursement for cannabis treatment, so costs are high for patients. CBD has been considered medicinal up until this point in both countries, so has only been available under prescription (though is expected to change soon in Australia), meaning there is no over-the-counter (OTC) CBD industry as in other regions. In New Zealand, a move to legalise adult-use cannabis was rejected via referendum in 2020, with little movement on the subject since, while in Australia momentum around the question of legalisation is beginning to build.

Oceania has the potential in the coming years to become a major exporter of medical cannabis globally, and this is one of the primary goals of both regulators and industry in the region. Regulators are taking positive steps to encourage producers, and significant progress has already been made. If the balance between high production standards and ease of export can be struck successfully, then companies in the region can become suppliers to emerging cannabis markets the world over, as well as becoming fully self-sufficient in supplying their own domestic markets.



Australia



(\$) 61.4 PER CAPITA

LEGAL STATUS:		<u> </u>	○ Cultivation	⊗ Adult-use	
EXPORT:			Extracts and finished pro	oducts	
IMPORT:					
COMPETITIVE ADVANTAGES: Clear and detailed regulatory framework, high product safety standards					
BUSINESS CHALLENGES: Highly commoditised, strict requirements for product approval, no public reimbursement					

RELEVANT GOVERNMENT INSTITUTIONS:

Australian TGA, Office of Drug Control

Australia legalised medicinal cannabis in 2016 and set up a regulatory framework to allow its production. Since then it has grown into a significant consumer and producer of medical cannabis. Each federal state in Australia has some discretion over the implementation of regulations, and therefore over the extent of patient access and commercial activity, so the industry is mainly concentrated in east coastal regions such as New South Wales, Queensland and Victoria. Until recently, CBD has been available under prescription only; however, recent regulatory changes are expected to see some OTC CBD products becoming available in pharmacies soon. Adult-use cannabis is illegal, though some states have relaxed personal possession and cultivation regulations, and there is growing support for further regulatory progress on the matter at the federal level, with the first cannabis legalisation bill being introduced to the parliament in August 2023.

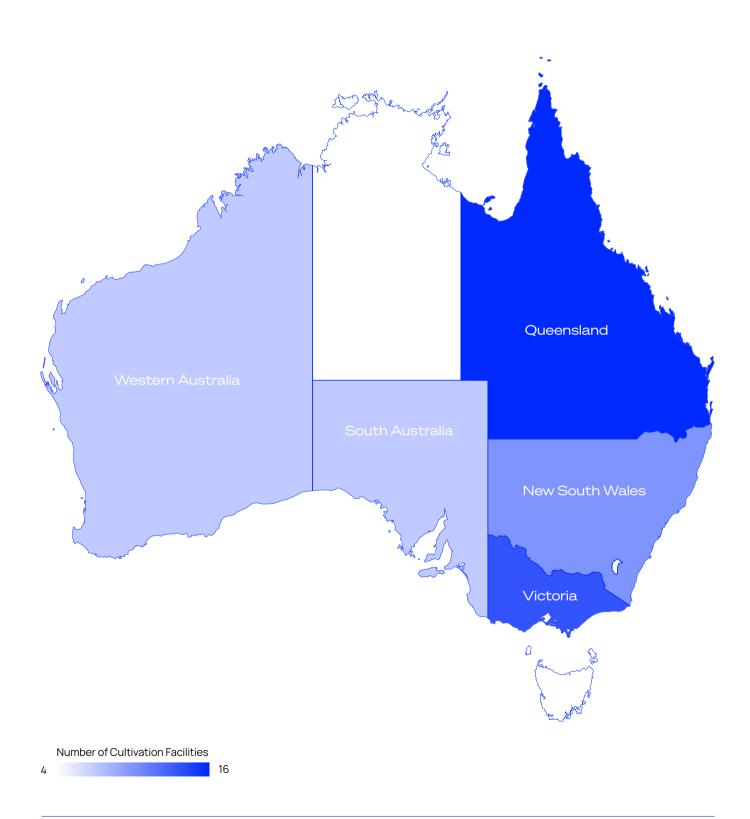
Australia currently remains an import-reliant medicinal cannabis market with 35 licensed importers, importing medicinal cannabis products primarily from Canada and Israel to meet the growing patient demand. The slow roll-out of production in the country has hindered the supply of domestically produced products on the market thus far; however, a recent tightening of import requirements, particularly around GMP requirements, together with expanding domestic production capabilities is expected to see domestic producers gradually take market share. Exports of finished medical cannabis products have been legal since 2018, with regulations allowing the export of plant material introduced in 2020. A number of Australian companies, including ANTG, Little Green Pharma and ECS Botanics, now export manufactured and plant-based medicinal cannabis products to countries such as Germany and the UK.

As of October 2023, Prohibition Partners has identified 48 companies with cultivation and production licences, and 44 with manufacturing licences in Australia. The majority of cultivation and production sites are situated in Queensland (16), followed by Victoria (14) and New South Wales (11). The east coast of Australia is where most cannabis cultivation and production occurs in the country due to its favourable regulations, sunny climate and expertise in horticulture and agriculture production. There are still no medicinal cannabis cultivators in the Northern Territory as the state only issued its first commercial hemp licence in 2020, and has been fairly slow in regard to adopting medicinal cannabis laws.

Although medical cannabis is not covered by Medicare or the Pharmaceutical Benefits Scheme in Australia, the country has been witnessing a significant increase in patient numbers and unapproved medicinal cannabis prescriptions over the years, with annual patient numbers exceeding 110,000 in 2022.



Concentation of Medicinal Cannabis Cultivators by State



Source: Prohibition Partners 2023

Recent events related to cannabis in Australia:

- In March 2022, the minimum quality requirements for unapproved medicinal cannabis products that are imported into and supplied/manufactured in Australia were updated, making it mandatory for medicinal cannabis imports to meet GMP requirements as of 1 July 2023. Before 1 July 2023, imports were not required to meet GMP standards, which created an unfair playing field for domestic producers as they had to compete with cheaper medicinal cannabis imports that potentially could be inferior in quality.
- In November 2021, the TGA made amendments to its medicinal cannabis access framework in order to improve patient access. Following the amendments, the TGA now accepts submissions for medical cannabis products from practitioners by active ingredient rather than trade name, categorising products by cannabinoid content and low- to highrisk categories. Products classified as low risk (CBD ≥98% (of total cannabinoid content), CBD ≥60% and <98%, CBD <60% and ≥40%) became easier for Authorised Prescribers to prescribe to patients.</p>
- In February 2021, the TGA down-scheduled low-dose CBD (CBD ≥ 98%, THC ≤1%) from Schedule 4 (Prescription Medicine) to Schedule 3 (Pharmacist Only Medicine). Although the down-scheduling came into effect on 1 February 2021, there are still no low-dose OTC CBD products available in Australian pharmacies, as the requirements for becoming an Australian Register of Therapeutic Goods (ARTG)-listed product are very strict and costly for companies to undertake.
- In January 2020, the Australian Capital Territory legalised the possession (50g dried and 150g fresh) and home cultivation (max. 4 plants per household) of adult-use cannabis.



Is Australia poised to become the largest medical cannabis market in the world?

New figures have revealed Australia could already be the world's largest federally legal medical market, with growth experienced down under not seen anywhere else in the world.

An international survey from CannaMonitor has released data indicating Australian Natural Therapeutics Group (ANTG) is among the top Australian companies leading domestic export sales, with key markets including Germany and New Zealand. Earlier this year, ANTG CEO Matt Cantelo told Business News Australia the company continues to experience 'massive growth'. He says the medically driven market in Australia is a result of making significant investments in research 'giving the Australian doctors and patients more confidence. Medicinal cannabis is now used by tens of thousands of Australians, with patient approvals through authorised prescribers in the first half of the year, more than double the amount last year.

Get in contact: info@australiannatural.com www.antg.com.au









ANTG



New Zealand () 5.12M (§ 48.8K PER CAPITA

LEGAL STATUS:		⊗ CBD	○ Cultivation	⊗ Adult-use
EXPORT:	⊘ Flower and raw product			
IMPORT:	⊘ Flower and raw product		⊘ Extracts and finished products	

COMPETITIVE ADVANTAGES:

Clear and detailed regulatory framework, high quality standards for production

BUSINESS CHALLENGES:

Strict quality requirements for exports (pending regulatory change), small domestic market, high capital requirements for production, no public reimbursement for cannabis

RELEVANT GOVERNMENT INSTITUTIONS:

Medicinal Cannabis Agency, Pharmac

New Zealand's cannabis industry is exclusively medicinal. CBD products are available only under prescription, and legalisation of adult-use cannabis is not a possibility in the short to medium term, after a referendum on adult-use legalisation was held in 2020, with the results seeing the New Zealand population rejecting legalisation by a narrow margin. Medicinal cannabis access began in 2016, when patients were first granted access to imported non-pharmaceutical cannabis products, and expanded in 2020 to allow domestic production and easier patient access. Though New Zealand is still primarily supplied by imports, domestically produced medical cannabis products became available to patients in 2022; however, patients face high costs for treatment, as there is no public reimbursement, and little private reimbursement (if any), for cannabis products.

The cannabis industry in New Zealand is concentrated, with only a small number of commercially active importers and distributors, and even fewer cultivators and manufacturers (though there are also some that have not yet reached commercialisation). Until now, high-quality requirements for exported products have prevented producers from exporting large volumes of products abroad; however, incoming changes to regulations expected in 2024 should ease these requirements, and make it easier to export finished cannabis products as well as raw materials from New Zealand.

There are a small number of key players in the New Zealand cannabis landscape, the most significant of which are Puro, Helius Therapeutics and NUBU. Puro is currently the largest cultivator in New Zealand, with two large cultivation sites in Marlborough. In 2022, Puro received a NZ\$13 million grant from the government, contributing to an overall NZ\$32 million project to scale up its facilities and

activities. Puro supplies Helius Therapeutics and has signed future supply agreements with others. Helius Therapeutics is a GMP-certified extractor, manufacturer and distributor of medicinal cannabis products and is the only company to have fully domestically produced products on the market. The company also has cultivation facilities, as well as research and analytics, though it currently sources all flower for its products from Puro. NUBU is an importer and distributor of medicinal cannabis products in New Zealand and currently holds the licence for seven products on the market, which are all imported from ANTG in Australia. The company has a number of supply agreements negotiated with other companies, including the New Zealand-based companies Organic Greenz Group (OGG) and Kalyx. It is also the sole distributor of Canopy Growth's medically approved vaporiser products in New Zealand.

Recent events related to cannabis in New Zealand:

- Incoming changes to the medicinal cannabis regulations will also see an update to the minimum quality standard, which all products must meet in order to be used for patient treatment in New Zealand. These changes will involve incorporating by reference the European Pharmacopoeia 11th edition (in its entirety), as well as elements from the US and UK pharmacopoeias.
- Commercial exports continue to grow under existing regulations, with three companies seeing successful shipments as of September 2023.
- New regulations that ease export regulations for New Zealand producers are also expected to lead to a reduction in prices for patients, as domestic producers are able to realise economies of scale in supplying the national and international markets simultaneously.

Other Countries and Territories

There have been recent medical and adult-use cannabis regulatory and commercial developments in the smaller nations within Oceania and its surrounding Pacific islands. The majority of these are still within their developing stages as regulatory frameworks and issuance of licences are still being finalised.

Vanuatu

Vanuatu passed the Medical Cannabis and Industrial Hemp Act in 2021 and in February 2023 signed off regulations making it legal to cultivate medicinal cannabis and hemp for export. Within the regulations, companies seeking to cultivate are required to have at least ten years of experience and are required to purchase a ten-year production licence, of which only five are available (three for hemp and two for medicinal cannabis) with annual fees amounting to A\$125,000.

French Polynesia

In November 2022, a local law approving the medicinal use of cannabis was approved by the French Polynesian assembly. The law also authorises the agricultural production of cannabis and hemp for industrial purposes, in particular pharmaceutical, within the framework of regulations under the International Narcotics Drugs Convention.

Guam

In Guam, medical cannabis has been legal since 2015, and patients may register as medical cannabis patients through the Department of Public Health and Social Services, which requires proof of ID, approval from a licensed physician and an initial fee of US\$15. In April 2019, the Governor of Guam signed the Guam Cannabis Industry Act, which legalised the possession and home growing of adult-use cannabis. In September 2022, the government approved the first adult-use licences for responsible officials to Pacific Cultivation and Green Flash Guam.

Northern Mariana

In September 2018, the Commonwealth of the Northern Mariana Islands passed the CNMI Cannabis Act of 2018, which legalised medical and recreational cannabis in the country. The country has its own Commonwealth of the Northern Mariana Islands Cannabis Commission, which regulates the nation's industry. The first commercial licences began rolling out in 2021, with companies including Slider Marianas and Saipan Select LLC receiving the country's first production and retail licences.

Cook Islands

In August 2022, the Cook Islands held a legally non-binding referendum to legalise medical cannabis, which passed with a 62% majority. The government has since created a committee to look into rules, regulations and availability of medicinal cannabis.



EXPERT INTERVIEW



Carmen Doran CEO, Helius Therapeutics

What are the main barriers in New Zealand that restrict medicinal cannabis patient access?

In terms of patient access, we've seen medical cannabis patient growth happen very quickly in New Zealand over the last two years since the medicinal cannabis scheme went live. Basically, in 2021, there were 30,000 prescriptions in New Zealand. In 2022, this doubled to approximately 60,000 prescriptions. At Helius, we first expected that the number of prescriptions in 2023 would reach 120,000 but now looks to be more.

This upward trajectory is faster than expected; however, we knew that based on the NZ Drug Foundation 2020 Survey there was demand, as there are around 270,000 users who purchase their products from the illicit market, likely many of them using cannabis for medical reasons, so actually there should be more than 100,000 patients on medicinal cannabis by now. It is great to be able to offer medicinal cannabis products that are free from contaminants and that hit consistent potency profiles every time, all under the guidance of healthcare professionals under the medicinal cannabis scheme, with patients entering the scheme both from the illicit market and as brand new patients for medicinal cannabis.

The increase in demand is patient-driven. Due to New Zealand regulations, medicinal cannabis companies cannot advertise products, so what we are witnessing is patients talking to other patients and to their doctors and asking about medicinal cannabis and if it could be a good option for them.

Any doctor in NZ can prescribe medicinal cannabis for any condition, and any pharmacy can dispense. Doctors are showing curiosity to learn more about medicinal cannabis at conferences and events, which is great! We actually want doctors to be a little risk-averse because we don't want them to prescribe something they are not educated about or don't understand. Therefore, a big part of what Helius is focused on is healthcare professional education, removing barriers patients face when they visit their doctor. This

way, a doctor either feels comfortable to prescribe, or if they don't feel they understand the medicine well enough, they can refer the patient to a specialist at a medicinal cannabis clinic. The barrier of doctor awareness is currently reducing; however, we still sometimes receive stories from patients who are still denied access by their doctors, meaning there is more education work to be done.

As in many countries, cost is a barrier. Since medicinal cannabis products are not covered by insurance, patients must pay for them themselves, which can be a significant barrier for some of our patients in NZ. At Helius, we prioritise patient access and affordability, and we have always made it a focus to help kiwi patients first. Fortunately, as more locally grown and manufactured products have become available (driven by Helius, as we're currently the only supplier in market), we have seen prices decrease dramatically.

Do you reckon that there will be a reimbursement system for patients in the near future?

We are seeing the first small steps and good progress from our insurance companies. There are currently two insurance companies in New Zealand that will cover the costs for medicinal cannabis consultations, though they do not reimburse for medicinal cannabis products yet. I think covering consultations is already a great step in the right direction.

In New Zealand, we also have something called the ACC, which is the Accident Compensation Corporation, which is a no-fault accidental injury scheme for New Zealand which covers the medical costs of eligible patients. Based on the latest data, we have learned that 101 medical cannabis patients have been approved through this scheme to date. New Zealand is still in its early stages, and we believe that there are a lot more patients who could and should have their medicine costs covered through the ACC, and at least it is already happening and we are seeing some progress there. The first steps are always the hardest, and these developments are a really good indicator that things are moving forward for our patients.

In your point of view, how is medicinal cannabis education for healthcare professionals progressing?

In New Zealand, there are two General Practitioner education conferences happening every year, one held in the North Island and another in the South Island. Helius has attended each of those conferences since the medicinal cannabis scheme was introduced. I think that this has been a great way of providing more information for doctors who are curious and want to learn more. We are definitely seeing a pull there and more openness than the early days. Now doctors approach us with various questions because their patients have asked them about medicinal cannabis treatment and they want to provide an informed opinion on what is best for their patients.

What changes do you hope or expect will come into effect with the new regulations from the NZ Medicinal Cannabis Agency? How will this affect Helius and the industry as a whole?

The planned changes by the Medicinal Cannabis Agency are really significant for the whole industry in New Zealand. When the medicinal cannabis scheme was first developed, there were barriers put in place that were unintentional but have slowed the industry growth. This has been acknowledged by the Ministry of Health, and through Helius's collaboration with the New Zealand Medicinal Cannabis Council and other government departments, we have been able to work with the New Zealand Medicinal Cannabis Agency to make these changes happen.

None of these changes impact patient safety with our same highly stringent rules applying; however, these new regulations do remove some barriers to export. Where in the past only products which are registered in New Zealand as meeting the minimum quality standards could be exported, now products that are made under GMP standards can be exported. This means Helius can cater and tailor medicinal cannabis products to international customer needs in the market, meeting all of the registration rules for their country.

Another important benefit of the new regulations is that they allow us to expand our R&D practices, which is a big focus for us at Helius. It will allow us to work with more research partners including universities which will be able to utilise cannabis for their research in a much easier way. I expect this to accelerate innovation in the field as well as provide Helius with more information and understanding of the cannabis plant and its medicinal properties.

At Helius, we are really excited about these new changes, as exports and research & development are two areas that are near and dear to our hearts.

How does the import market compare to the NZ domestic market? In terms of products, prices, quality, and supply?

In New Zealand, until 2021, all products were imported. However, since then, Helius has been the only company supplying New Zealand-grown and New Zealand-made medicinal cannabis products. Currently, the New Zealand medicinal cannabis market is skewed towards international imports with 24 of the 30 products available coming from overseas. With the new regulatory changes, I expect to see the domestic industry ramp up, and companies like Helius will be able to bring more New Zealand-grown and -made medicines to our patients.

Helius is a vertically integrated company built for supplying medicines on a global scale. We always knew that there was an export potential for high-quality NZ-grown medicinal cannabis. We are committed to supplying our New Zealand patients first and foremost, but we are a company that is built for scale and global growth, and I think that New Zealand can be a world leader in this space.

What are the similarities and differences between the New Zealand and Australian cannabis markets?

Australia is a larger market and began its medical cannabis programme a couple of years before New Zealand. In New Zealand, we watch the trends in the Australian market very closely in terms



of products and patient growth because it has been a really good proxy for what happens in New Zealand, but at a different scale. One of the differences between the two markets is that until the 1 July 2023, imports into Australia were not required to meet EU-GMP standards, which put Australian producers on the back foot compared to importers, but now with the new regulations in place, it is a level playing field and is much fairer for Australian producers.

In terms of prescriptions, in Australia there are a few extra steps required for doctors as they need extra approvals, whereas in New Zealand any doctor can prescribe medicinal cannabis for any condition. Another difference is that in Australia regulations may differ in different states and territories as well as federally, similar to what we see in the US, whereas in New Zealand, as a smaller country, our regulations are at a national level.

CBD is considered a medicine in both markets, Australia and New Zealand, whereas globally we are witnessing a rise of CBD as a cosmetic or novel food ingredient. Do you expect this scheduling of CBD to change in the region?

In New Zealand, CBD is classified as a prescription medicine, and in terms of the safety profile of CBD, it can be seen as over-the-top and restrictive to patient access. However, on the other side, I do appreciate that at least the regulation is clear compared to other regions such as Europe, where it is extremely difficult to navigate through CBD regulations.

One of the advantages of CBD being classified as a prescription medicine in New Zealand is that it has brought some of the GPs on the journey of understanding cannabis as a medicine in a nice, safe way. CBD is a great introduction to cannabis as a prescription medicine and it is helping a lot of patients. Some patients, due to other factors, may not want to use THC medicines.

At Helius, we explore the whole potential of the plant focusing on producing full-spectrum extracts – allowing us to explore the medicinal potential of minor cannabinoids and terpenes and the effects of those components of the plant. The extracts we make are from single strains which are all exclusively grown for us, ensuring that we are providing patients with a consistent and standardised product every time, which really matters when producing a medicine.

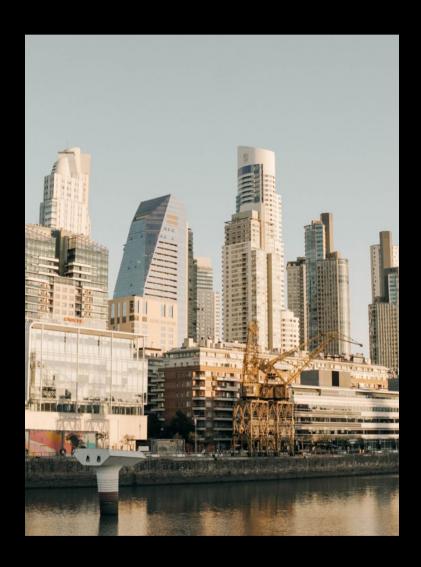
What's the future for the New Zealand medicinal cannabis market?

As mentioned earlier, with the regulation changes, especially the ones concerning R&D and exports, I think this is going to be a significant game changer for New Zealand. In New Zealand, we have a great agricultural and horticultural background with expertise in breeding and genetics in industries such as kiwi fruits and apples,

which I think will transfer across to the medicinal cannabis market. We have a strong research space in New Zealand, where some of the worldwide clinical trials for various medicines are performed in the country due to the diverse ethnicity in our population base. I can absolutely see New Zealand in the future creating medicines that are specific for indications, and providing the data and science evaluating the entire value chain, from breeding and genetics right through to the dosage forms. I think all of the pieces are there – we just have to put them together – but I think New Zealand from a medical perspective can contribute to helping patients all over the world.



LATAM



As other emerging regions join the international cannabis ecosystem, Latin America is trying, with some degree of success, not to miss the closing window of opportunity to gain and consolidate a key position in this emerging industry by leveraging its competitive advantages while solving its many supply chain, bureaucratic and political challenges.

In 2013, Uruguay made a bold move by pioneering the legalisation of adult-use cannabis, which yielded positive outcomes in terms of access and a developing exporting industry, although there was some legal consumer stalling in the process. The decade that followed witnessed other countries in the region becoming open to legalising access paths not only for medical cannabis patients but also for entrepreneurs to invest in the field.

The region's largest market, Brazil, has experienced substantial medical cannabis consumption growth in the last few years, which continues today, with a 72.8% increase in import authorisations from September 2022 to September 2023. Most of the local demand is supplied by imported extracts as in-country cultivation is not yet allowed – a reality that has a narrow but real possibility of change in 2024 under a new, mostly pragmatic government. Colombia, land of genetic diversity, joined the green wave in 2016, legalising medical cannabis, cultivation, and exports, but has suffered from a lack of specialisation, unfulfilled expectations for local producers, and a small, still developing local consumer market. However, exports grew 96% in 2022 compared with 2021, a result of the country's resilient entrepreneurial attitude and the work of public entities such as ProColombia, which has been trying to get Colombian output into the hands of consumers worldwide.

Despite great potential for the market in Mexico, legislative and regulatory uncertainty, politicisation of the debate, and a powerful illicit market ecosystem have created barriers that prevent the country from becoming the world's largest adult-use market. Argentina, despite its constant economic turmoil, has made some legal prog-

ress in 2022 aiming to take advantage of its competitive advantages for production. With the Argentinian ecosystem having a strong government hand, long-term success is a matter of pragmatism.

Uruguay, the trailblazer, shows signs of a growing but struggling sector, with a 35% drop in exports in 2022 compared with 2021 in US dollars despite exporting similar amounts of cannabis in kilograms. Patient access shows timid growth, with little over 50,000 registered consumers as of 2023, close to 20% of the total estimated consumers in the country, mostly due to the competitiveness of the illicit market with regard to THC product thresholds.

Taking a look at other markets in Latin America and the Caribbean, we see, for example, patient associations dominating the developments in Chile, with no significant immediate local business opportunities apart from two pharmacies selling imported Canadian products. Costa Rica, Ecuador, Jamaica, Panama, Peru, and Trinidad and Tobago have made efforts to evolve a legal framework, exploring the potential of commercial cultivation and supporting medical patient demand. Meanwhile, Paraguay has surprised the region with fast-growing hemp production with participation from local, rural and indigenous communities that is thriving, which is a great example of conscious production, aligned with an environmental, social strategy of cannabis and hemp entrepreneurship.

'Panama has one of the highest costs of medicines in the region due to a monopoly of pharmaceutical companies; however, 20% of the population suffers from chronic pain.'

Gabriel Menasche, ACAPAN

'Paraguay is leading in LATAM's industrial cannabis sector, with 23 foreign companies established in the country from Brazil, Spain, the US, Uruguay and others. We are becoming a major local hub in terms of cultivation and processing with an inclusive approach.'

Marcelo Demp, VP, LAIHA

'In Chile, we can expect relevant changes by 2024. In addition to the modification of the Chilean Drug Law, this year the first export of CBD flowers from Chile to Switzerland was allowed, by the company MA Botanics, which produced 600 kilos of flowers and has the support of the government institution to the promotion of Chilean businesses abroad, Pro Chile.'

Simon Espinosa, ENVOLA

'In Peru, consumption has been growing at a CAGR 280%+ since 2019. As of July 2023, 42k+ patients were registered. Our estimates indicate that, in Peru, around 1.5 million patients could benefit from cannabis treatments.'

Jose Escalante, CEO, Futura Farms.

The region has several competitive advantages for becoming a major player in the global cannabis industry, but clearer seed-to-product regulatory pathways, access to capital, reduced red tape, and depoliticisation of the cannabis debate are prerequisites for success.

TABLE 1 LATAM Medical Cannabis Legal Landscape

Country	Medical commercial production	Imports (medical cannabis)	Exports (medical cannabis)	Patient access to commercial medical cannabis
Argentina	Emerging	Yes	No	Yes
Brazil	Emerging	Yes	 No	Yes
Chile	No	Yes	No No	No
Colombia	Yes	Yes	Yes	Yes
Costa Rica	No	No	No	No
Ecuador	Emerging	Emerging	No	Emerging
Jamaica	Yes	Yes	Yes	Yes
Mexico	No	Emerging	No	Emerging
Panama	No No	Emerging	No No	Emerging
Paraguay	Emerging	Emerging	Emerging	Yes
Peru	Emerging	Emerging	No	Yes
Trinidad & Tobago	No	Emerging	No	No
Uruguay	Yes		Yes	Yes



Argentina 9 45M



(\$) 10.6K PER CAPITA

LEGAL STATUS:		⊗ CBD	⊗ Cultivation	⊗ Adult-use
EXPORT:	⊗ Flower and raw product		⊗ Extracts and finished products	
IMPORT:	⊗ Flower and raw product		⊗ Extracts and finished pro	oducts

COMPETITIVE ADVANTAGES:

Outstanding cultivation potential, developed agricultural and pharmaceutical industry, high levels of social cannabis acceptance, skilled workforce

BUSINESS CHALLENGES:

Political instability, economic turmoil, complex regulatory landscape, outdated infrastructure, lack of historic cannabis expertise

RELEVANT GOVERNMENT INSTITUTIONS:

ANMAT, ARICCAME, INAME, INTA, MOH, SEDRONAR

The Argentinian cannabis industry, which benefitted from a major legal regulatory evolution in 2022, exported hemp as a raw product in 2022 to countries such as Chile and Uruguay, while Argentina imported medical cannabis and medical CBD, mostly as finished products, from countries such as Canada and the US, with the latter only exporting medical CBD products to Brazil due to the existing restrictions on THC exports. This signals commercial expansion in a sector that has so far been dominated mostly by limited public initiatives and R&D projects in a few provinces such as Jujuy. As of July 2023, about 20 hectares of land for medical cannabis cultivation were reported as being concentrated in Jujuy, Salta, and Buenos Aires provinces. Patients can access medical cannabis via home cultivation, purchase or via the public healthcare service.

The left-wing government that approved the regulation in 2022 expects this industry to add 10,000 job opportunities, serve over 6 million local consumers, and create a US\$500 million national industry as well as US\$50 million in exports. The Argentinian Chamber of Cannabis (Argencann) sees these figures as conservative, proposing a US\$1 billion export potential alone. According to some experts, these figures will largely depend on the overall economic performance in the next few years, in Argentina, in which a -3% drop in GDP is expected for 2023, with a cumulative inflation rate of 115%, and with the country seriously considering the dollarisation of its economy.

On a more positive note, Argentinian pharmaceutical exports grew 82% in the first half of 2023 compared with 2022, while agricultural exports grew 8.5% in 2022 compared with 2021.

Some recent developments in the Argentinian cannabis ecosystem:

- In September 2023, the Argentinian Health Ministry reported planning the distribution of 3,000 cannabidiol 15 millilitre droppers, of which 1,000 would be freely distributed, and opening 30 specialised cannabis clinics in the Santa Fe province.
- Also, in September 2023, the use of hemp seeds in food products was approved, including its derivatives such as flowers, fibres and oils.
- Right-wing ultra-libertarian President Javier Milei declared in August 2023 as being in favour of cannabis and legalisation of controlled substances.
- The Public Research and Development Cannabis Programme was launched in December 2022 and had invested in 23 R&D cannabis projects as of July 2023.
- In November 2022, the country's first public production plant, Cannava, in the northern province of Jujuy, started production with public funding.

'Currently, there is a considerable degree of uncertainty due to the lack of clarity in the regulations regarding the requirements for obtaining licences. This process is in its early stages and is likely to be subject to developments in the upcoming presidential elections, adding an additional factor of uncertainty.'

Pablo Fazio, President, ArgenCann





√ 210M

(\$) 8.8K PER CAPITA

LEGAL STATUS:	⊘ Medical cannabis	⊗ CBD	⊗ Cultivation	⊗ Adult-use	
EXPORT:	⊗ Flower and raw produc	ct	⊗ Extracts and finish	ned products	
IMPORT:	⊗ Flower and raw produc	ct	⊗ Extracts and finish	ned products	
COMPETITIVE ADV	/ANTAGES: ced agricultural and pharmaceut	tical industry, ava	ilable land for cultivation		
BUSINESS CHALLENGES: Regulatory setbacks, dominant conservative politics					
RELEVANT GOVER	RNMENT INSTITUTION	IS:			

Brazil is the largest country and market in Latin America and the southern hemisphere, therefore it comes as no surprise that it boasts a large consumer market, particularly in the relatively affluent southeast but also in the south and centre-west regions, as well as having vast agricultural lands suitable for cannabis and hemp cultivation. Together with a developed medical-industrial complex, and a sophisticated agricultural industry, the country has all it needs to become a major player in the cannabis business. However, this potential has not yet been fulfilled due to conservative, overly cautious approaches from the government and regulatory bodies in Brazil.

'Brazil still frames cannabis as a moral agenda. There is an interference contrary to the cannabis agenda that does not take into account scientific facts, experiences from other countries or even the economic potential and positive social impact that good regulation could have. Today, Portugal already benefits from the cultivation and export of cannabis and is beginning to discuss adult-use as part of a regulatory proposal. Brazil still needs to find the political maturity to adequately make plans for this plant that is present in the daily lives of its population, even though it is not properly regulated.'

Viviane Sedola, Brazilian cannabis expert, currently based in Portugal

Despite this conservative approach to cannabis, patient associations have been growing in the country. In addition, cannabis imports have been increasing steadily, with a 93% increase from July 2022 to July 2023, and the yearly total for import authorisations of medical cannabis jumped from 17,812 in 2020 to 80,413 in 2022, and was counted at 66,159 up to June 2023, according to local regulatory body ANVISA, mostly benefitting producers in the global north, and translating into higher prices for the average consumer.

In terms of production, important events unfolded in 2023, with the country's pioneering commercial producer of medical cannabis Prati Donaduzzi a Parana-based pharmaceutical company already producing and commercialising medical CBD, signing a partnership with Brains Bioceutical, an international active pharmaceutical ingredient (API) leader, to expand and diversify production. Another interesting development in 2023 came from Ease Labs Pharma, a specialised cannabis producer based in Minas Gerais, which received about £2.5 million financing from a major national bank, to purchase a Colombian company specialising in cannabis genetics, and which has plans to open a new production facility for 2024.

In the context of a new executive government this year, with a less conservative view towards cannabis, political discussions are heating up in Brasilia, with projects ranging from approval of commercial cultivation of hemp and cannabis to cannabidiol distribution in the national public healthcare system, serving about 190 million people nationwide.

'In the market, the trend is to understand the need for social impact in cannabis initiatives, to be consistent with Brazil's historic process. We also see a trend for specialisation in the cannabis ecosystem, from marketing to labs and law firms.'

Emilio Figueiredo, Brazilian cannabis expert

'For 2024, I believe that the next review of ANVISA's RDC 327 will take into account the volume and/ or absence of cannabinoids, meaning that products with a low cannabinoid or derived from hemp seed oil will be regulated and sold without the need for a medical prescription.'

Gustavo Maia, Director and Founder, Cannabis Monitor Brazil

Some recent developments in the Brazilian cannabis ecosystem:

- President Lula and his Minister for Agrarian Development,
 Paulo Teixeira, declared in September 2023 that they were in favour of national cannabis cultivation and processing.
- In September 2023, the largest cannabis event so far in the country took place in São Paulo: ExpoCannabis Brasil 2023 lasted three days with over 140 companies attending the event.
- In August 2023, the country's supreme court, STF, started voting to decriminalise cannabis for personal use. Voting resumes in November 2023 with a positive outlook.
- In July 2023, ANVISA prohibited the short-lived authorisation to import cannabis flowers for medical use, a decision that surprised investors and over 5,000 patients receiving treatment with flower products.
- In the first half of 2023, the country witnessed a trend whereby several states of the federation approved cannabis distribution through the SUS, Brazil's public health system. This occurred mainly in São Paulo, home to 45 million people, but was only applicable for some conditions.
- In June 2023, Brazilian researchers at the Federal University of Rio de Janeiro (UFRJ) discovered CBD in the trema micrantha tree.
- In March 2023, a national bill to bring medical cannabis distribution to the SUS was introduced. The bill is being analysed and discussed, and if approved, the Brazilian market potential would increase exponentially.





(\$) 6.6K PER CAPITA

LEGAL STATUS:		⊗ CBD	○ Cultivation	⊗ Adult-use		
EXPORT:	⊘ Flower and raw produc	et	Extracts and finish	ned products		
IMPORT:		et	Extracts and finish	ned products		
COMPETITIVE ADVA	ANTAGES: egislative and regulatory suppo	ort, growing ecos	ystem, suitable land for cultiv	vation		
BUSINESS CHALLENGES: Hurdles with regard to exports, lack of business specialisation in the industry, lack of capital for cash-intensive developments						
RELEVANT GOVERNMENT INSTITUTIONS:						
CND, INVIMA, ICA, MINISTRY OF H	lealth and Social Protection, Mir	nistry of Law				

The Colombian cannabis industry has undergone significant evolution in recent years, from being a major producer of illicit cannabis to becoming a burgeoning legal industry with the potential to be a major economic driver for the country. Since decriminalisation in 2009 and cultivation legislation in 2015, the country has gained international attention for its rapidly growing cannabis industry, with over 100 licensed companies now cultivating and processing cannabis. Despite the frenzy, local producers still struggle to fulfil expectations, and major lessons are now being understood in order to become more competitive internationally.

Despite the challenges, the outlook is positive. According to data from ProColombia, cannabis exports totalled US\$8.4 million in 2022, a 96% increase compared with 2021 – almost 60% of that figure is exported within LATAM, with Bogotá and Cundinamarca representing almost 80% of total production.

Local consumption of CBD products shows slow growth, mostly due to the lack of non-medical CBD regulations, contributing to an uncertain commercial environment. Yet, signals are positive despite being modest, with a cannabis clinic in Bogotá, named Zerenia, treating over 30,000 patients in 2022, setting a new record. At the same time, the city's public health insurance organisation Capital Salud signed an agreement with Zerenia, allowing at least 280,000 chronically ill patients to benefit from medical cannabis in the near future, with Khiron Life Sciences acting as the main provider for the treatments, another example of a regional trend of combining private with subsidised cannabis treatments for patients with specific conditions.

Some recent developments in the Colombian cannabis ecosystem:

- In October 2023, Colombian company Terra Cann exported genetic material to Costa Rica, opening a new market in the region for alternative Colombian exports.
- In August 2023, the second edition of a major cannabis and hemp summit was announced for November 2023 in the Valle del Cauca region.
- In July 2023, a commission from Brazilian regulator ANVISA made an official visit to Colombian companies and regulators, aiming to learn from the country's industry and to strengthen the potential exchanges between the two countries.
- Colombian company Santa Marta Golden Hemp, a subsidiary of Avicanna, exported CBD and CBG as APIs to Paraguay in July 2023, another successful international export after exporting seeds to Spain in January.
- In June 2023, the Colombian Senate voted down, by a close margin, the adult-use sale of cannabis, and proponents plan to try again in early 2024.
- In February 2023, INVIMA authorised four food items containing CBD-free hemp oil.
- In June 2022, Allied Colombia SAS, the Colombian branch of Allied Corp., received authorisation to perform the first export of low-THC cannabis flower (0.3% THC, 18% CBD) to international markets, exporting 200 kilograms initially, within a 500 kilogram monthly export contract. Destinations include Switzerland and the US.

'The main trend is that the industry matured and we understood that the key is not in verticality but in specialisation. We went from having many licensees to a few active ones committed to preparing to serve international markets.'

Juan Camilo Vargas, Partner at Cinnetico

COFEPRIS, CONADIC, Secretariat of Health





(\$) 10.5K PER CAPITA

LEGAL STATUS:	<u> </u>	⊘ CBD	⊗ Cultivation	⚠ Adult-use		
EXPORT:	⊗ Flower and raw produc	ct .	⊗ Extracts and finish	ed products		
IMPORT:	⚠ Flower and raw produc	et	⚠ Extracts and finish	ed products		
COMPETITIVE ADVANTAGES: Large internal market, developed pharmaceutical industry, know-how and genetic diversity, competitive labour costs, proximity to the US						
BUSINESS CHALLENGES: Unclear legal and regulatory framework, lengthy approval processes, illicit market influence						
RELEVANT GOVERNMENT INSTITUTIONS:						

The Mexican cannabis industry has been characterised by an intricate, complex back and forth among governmental institutions in terms of its legalisation and regulation, influenced by several aspects, including the strong presence of illicit operators working in clandestine production aiming to supply the internal market as well as its affluent northern neighbour, the US. Despite these hurdles, the country has made some legal progress in the last decade, with the medical cannabis bill being approved in 2017 and attempts to legalise adult-use cannabis in 2018, with a 2021 Supreme Court ruling demanding that the Chamber of Deputies approve its legalisation, a decision that has been in limbo, reflecting the national scenario, but remains of interest due to approximately 1.5% of the population consuming cannabis frequently and a growing population.

The lack of regulation and the conservative approach from the regulator means a lack of medical awareness and prescriptions, with medical activity being nonexistent as of 2023.

'The changes have had no practical effect, because comprehensive regulation is needed. The only areas that are growing are the illegal medicinal and adult-use markets, without any control from the authorities. Importing CBD in any of its forms is very complicated for companies due to the lack of clarity in the regulations that were published in 2019.'

Jorge Rubio, Mexican cannabis expert

Some recent developments in the Mexican cannabis ecosystem:

- Many Mexican farmers, activists and entrepreneurs gathered in June 2023 at the Toquefest celebration, one of the many cannabis-related events taking place in the country, aiming to bring life to an industry that seems at a standstill as of mid-2023.
- In March 2023, Canadian company Xebra received authorisation from the national regulatory office, COFEPRIS, to operate in the country, after two years of attempting to do so. The regulatory office is now trying to remove this permit arguing it was obtained through force by the Second District Court.







(§) 18.2K PER CAPITA

LEGAL STATUS:		⊘ CBD	○ Cultivation		
EXPORT:	⊘ Flower and raw product		⊗ Extracts and finished pr	oducts	
IMPORT:	⊘ Flower and raw product		⊗ Extracts and finished pr	oducts	
COMPETITIVE ADVANTAGES: Developed cannabis industry, legal and regulatory clarity					
BUSINESS CHALLENGES: Competition from illegal markets, increasing extreme weather					
RELEVANT GOVERNMENT INSTITUTIONS: IRCCA, DGA, MOH					

Uruguay, a pioneer in cannabis regulation back in 2013, still faces challenges in establishing an efficient supply chain and financial access for an emerging industry. Legal sales began in 2017 after initial full legalisation in 2013. Nearly a decade later, obstacles persist, including banking restrictions influenced by the US federal stance on cannabis. Additionally, the number of pharmacies is limited with a relatively low THC offering (now a maximum of 15% THC allowed), and high product prices hinder market growth compared with the illicit market. Additionally, the number of registered patients has stalled at around 50,000. In terms of exports, Uruguay exported a total of 16 tons valued at US\$5 million from 41 companies in 2022. These exports were similar in terms of weight to those in 2021 but significantly less in price compared with the US\$8 million exported in 2021 - this was due to international price variations. As of April 2023, exports were already at US\$3 million for 1.7 tons, with high-THC medical cannabis products holding a bigger share.

Despite challenges in the national context such as severe weather events and challenges with cannabis financing that the country experienced early on, as a first-mover internationally, the country's industry keeps advancing with an ecosystem that includes about 100 companies in 2023 according to the Uruguayan Institute for the Regulation and Control of Cannabis (IRCCA), and with an increase from three exporting companies in 2019 to 41 in 2023.

Uruguay is witnessing an increase in exports not only to Latin America but also to Europe. The country exports to Portugal, which acts as a logistics hub for European distribution, with Uruguayan exports growing over 400% from 2021 to 2022 in Europe (IRCCA, 2023). It will be interesting to monitor how Uruguay adapts to, profits from and competes with the emerging Argentinian industry,

with its complex pharmaceutical market, and the competitive exports from Colombia.

Some recent developments in the Uruguayan cannabis ecosystem:

- In September 2023, local company Pharmin secured a deal to supply medical cannabis for the Australian market in partnership with Australian company Breathe Life Sciences (BLS).
 The deal includes a 25% THC lemon sherbet strain.
- Aurora Cannabis Uruguay reported in September 2023 a deal with a Brazilian commercial partner to export 3% full spectrum medical CBD to Brazil.
- In July 2023, the six-year anniversary of cannabis sales in pharmacies, a total of 10.7 tons of cannabis was officially sold, though this figure is still far from illicit market sales.
- In June 2023, it was reported that one of Uruguay's largest cannabis production centres, Boreal Uruguay, was closing down amid conflicts with former employees.
- In the first months of 2023, the IRCCA requested a withdrawal of licences from 19 cannabis companies due to a lack of production – a sign of the country's cannabis production stalling.

'In order to overcome the excessive supply of Uruguayan production, Brazil seems like the natural destination in the years to come. Additionally, the introduction of a higher THC variant, with 15%, aims to compete with existing illegal market supply.'

Rodolfo Perdomo, Uruguay cannabis lawyer and expert





EXPERT INTERVIEW



Gustavo Maia Director and Founder, Cannabis Monitor Brazil

From your perspective, what have been the main trends in the world of cannabis in Brazil over the last year?

Brazil has been building this market based on a pharmaceutical vision for cannabis products. Despite starting out with flexible regulations, we are seeing regulatory bodies pressurising companies that manufacture cannabis-based products to adapt or direct their efforts towards developing products that follow good pharmaceutical manufacturing practices and protocols.

What are the main challenges in the sector from a patient and entrepreneur perspective?

For the patient, despite the growing access to cannabis-based products, the cost is still very high and the form of access is still very bureaucratised and elitist. Prices, when compared with the US, for example, are up to four times more expensive, taking into account the need for a doctor's consultation and import taxes.

From the entrepreneur's perspective, the unclear rules and abrupt changes create instability that undermines the development of initiatives that could expand access to these products. In addition, the fact that there is inefficient inspection means that entrepreneurs who try to follow the rules to the letter are at a disadvantage compared with competitors who circumvent the rules and take the risk.

Thinking about the long term, do you think we could see significant legal/regulatory changes in 2024?

I believe that the next revision of ANVISA's RDC 327 (cannabis product regulation) will take into account the volume and/or absence of cannabinoids, so that products with a low cannabinoid content or products derived from hemp seed oil will be regulated and sold without the need for a medical prescription. This revision could also include authorisation for the sale of cannabis food products, such as seeds, flowers, fibres, and oils.

The supreme court trial debating the decriminalisation of cannabis possession for personal use, which depends on just one vote out of five remaining to declare Article 28 of the drug law (restricted to cannabis) unconstitutional, will also open up an important milestone for broader regulation in the legislature, despite the current parliament's configuration not being at all favourable to any civilisational advance on this issue.

Africa



The African continent boasts a fast-growing population, a rapidly developing economy, and large areas suitable for farming, including cannabis and hemp, with very low production costs in terms of land, transport and labour. It comes as no surprise that several countries and investors are paying close attention to the region, with countries entering the global cannabis playground in the last few years. Considering both medical cannabis and industrial hemp, the first country to legalise cultivation in the region was Lesotho back in 2017, followed by South Africa and Zimbabwe in 2018, Malawi in 2020, Morocco and Rwanda in 2021, Ghana and Uganda in 2023, and others expected to follow in 2024.

With a low regional consumer potential, relative to countries in the global north, Africa aims to leverage its competitive advantages to become a long-term exporter to Europe and potentially to the emerging, complex and eager Asian markets. To do so, scarce access to capital, lack of a skilled workforce, and complex bureaucracy have to be overcome.

As of 2023, the continent's commercial activity remains fairly limited, focusing on production aiming to export to richer markets. Countries such as Lesotho, Malawi, South Africa, and Uganda have successfully exported cannabis, with Lesotho pioneering in terms of exports to the EU since 2021, while North Macedonia is a common destination across the board. In terms of local consumption, only South Africa shows signs of an evolving consumer base and ecosystem; in Nigeria, the largest regional market, cannabis remains illegal, and the same goes for Egypt, the second largest market in Africa, where, despite lax attitudes towards adult-use cannabis enforcement, discussions about medical cannabis are yet to emerge.

Therefore, the African medical cannabis industry is outlining itself as a potential competitor to other developing economies. Access to capital, bureaucratic agility, and oiled and specialised supply chains will be key in determining its likelihood of success.



TABLE 2

Africa Medical Cannabis Legal Landscape

Country	Medical commercial production	Imports (medical cannabis)	Exports (medical cannabis)	Patient access to medical cannabis
Morocco	Emerging	No	No	Emerging
Ghana	No	No No	No	No
Malawi	Yes	No No	Yes	No
Rwanda	No	No No	No	No
Lesotho	Yes	No	Yes	No
Zimbabwe	Emerging	No	Emerging	No
Zambia	No	No	No	No
South Africa	Yes	Yes	Yes	Yes
Uganda	Yes	No	Yes	No





South Africa (1 59.9M (5 6.7 K PER CAPITA

LEGAL STATUS:		⊘ CBD	○ Cultivation	⊗ Adult-use	
EXPORT:			Extracts and finished pro	oducts	
IMPORT:	⊗ Flower and raw product		Extracts and finished pro	oducts	
COMPETITIVE ADVANTAGES: Cultivation potential, developed pharmaceutical industry					
BUSINESS CHALLENGES: Lack of proper legal and regulatory frameworks, illegal markets					
RELEVANT GOVERNMENT INSTITUTIONS: Department of Health (DoH), SAHPRA, DALRRD					

In 2018, the Constitutional Court of South Africa decriminalised cannabis use. Nonetheless, South African law maintains a prohibitionist stance against cannabis use in public spaces or around minors and non-consenting adults. Cultivation and sales are only allowed for medical purposes. Despite the 'dagga belt' offering excellent cultivation conditions and there being over 100 LPs in mid 2023, only about 5% have the scalability to supply large quantities.

The South African government is actively crafting a regulatory structure for the cannabis sector, with an anticipated completion date by the close of 2023. Once this framework is established, comprehensive legislation and regulation of both medical and adult-use cannabis are expected in South Africa. Despite being the largest consumer market for cannabis and CBD products in the region, with OTC CBD being legal since 2019, medical cannabis patient figures still remain low, being estimated at about 1,000 patients as of December 2022.

'With only one certified EU-GMP medical cannabis facility in South Africa at this stage, the route to the German market is complex and costly. With pricing more attractive than the Australian market, cultivators are exploring ways to access this market. With more processing facilities coming on line, offering the conversion of GACP cultivated flowers to EU-GMP compliant packed products, the high cost of this process should decrease, based on competition.'

Greg Beadle, Founder & CEO, Farmer 2 Pharma

Some recent developments in the South African cannabis ecosystem:

- In July 2023, South African police agreed to put a stop to cannabis-related detentions, finding alternatives such as penalties and fines to bring possible offenders before justice.
- SafriCanna received EU-GMP Part I certification in May 2023.
- In May 2023, the Iqela Lentsango, also known as the Dagga Party, fiercely opposed the proposed Cannabis for Private Purposes Bill, declaring that it criminalises users.
- In 2022, a cannabis-growing academy opened a brick-andmortar centre after two years operating online, investing in potential future opportunities.







Greg Beadle Founder & CEO, Farmer 2 Pharma

What are the current challenges faced by medical cannabis producers in South Africa?

One of the main challenges producers in South Africa are facing concerns consistency. With the majority of licensed cultivators in South Africa using different forms of greenhouse technology, most of the cultivators are realising it is difficult to maintain the consistent results required by international markets through the seasons. In winter, there may be less UV radiation, and colder temperatures, resulting in a fluffier, less-dense flower with lower levels of active ingredients, for example THC. By working with the cultivators to better understand the global market's requirements, we are seeing an improvement in achieving more desirable results, ensuring that the revenue generated by these licensed cultivators is increasing overall.

Another challenge is the fact that we are seeing a downward pressure on pricing in the Australian market. This is due to a few reasons, including alternative low-cost supply options and major players possibly attempting to control the market by steering pricing to a level that lowers the amount of competition in the market. This affects South African producers.

Are there South African companies seeing success in exports? What is the situation with South African medical cannabis exports?

There are definitely great opportunities for export from South Africa. Farmer 2 Pharma currently facilitates sales and shipments of approximately 250 kilograms of medical cannabis flower per month from Southern Africa to Germany and approximately 150 kilograms per month to Australia. We also facilitate the supply of GMP manufactured medical cannabis products from South Africa to global licensed importers.

The dynamic nature of the regulations which exporters must navigate is challenging. As Germany cautiously navigates the ice-breaking process of how to not contravene international con-

ventions and other historic agreements while attempting to allow easier access to cannabis, Australia is raising its quality standard on imported products, and Israel is constantly managing its political landscape, trying to keep both local cultivators and importers happy. Cultivators and manufacturers need to ensure they are focusing on the right markets relevant to which required standards they can comply with.

The route to the German market is particularly complex and costly. There is only one certified EU-GMP medical cannabis facility in Africa at this stage. Pricing there is more attractive than in the Australian market, so cultivators are constantly exploring ways to access it. With more processing facilities coming on line, offering the conversion of GACP cultivated flowers to EU-GMP compliant packed products, the high cost of this conversion process should decrease, based on competition. This may make it easier for South African companies to access the German market.

There are many medical cannabis companies active in South Africa – what has been the experience of cultivators and manufacturers in the country so far?

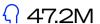
The cultivators and manufacturers who are succeeding in the South African market are those who have invested for the long term. Generally, this means large capex investments into setting up a facility, investing more capex each year to upgrade equipment as optimisation is sought out. The entrepreneurs who expected profit from the first harvest are, unfortunately, not meeting their expectations.

With 100 cannabis cultivation licences having been issued in South Africa, I believe it's time for the industry to consider the feasibility of issuing more licences. Many cultivators are operating marginal businesses with limited futures. Issuing more licences to eager entrants to the market will not improve this situation.





Uganda



(§) O.9K PER CAPITA

LEGAL STATUS:	⊗ Medical cannabis	⊗ CBD	○ Cultivation	⊗ Adult-use
EXPORT:	⊘ Flower and raw produc	et .	Extracts and finis	hed products
IMPORT:	⊗ Flower and raw product		⊗ Extracts and finis	hed products
COMPETITIVE ADVA	NTAGES:			
BUSINESS CHALLEN	GES:			
Legal uncertainty, lack of capital, limited internal market				
RELEVANT GOVERNMENT INSTITUTIONS: MAAIF, NDA, UPF				

The Ugandan approach to cannabis has evolved since 2020 when the country went from full prohibition to allowing cultivation and processing for exports. Aiming to take advantage of the global growing appetite for the plant and its derivatives, the country quickly saw significant exports to countries such as Israel and Germany taking place from 2021, originating from Together Pharma (an Israeli company in Uganda) and Industrial Hemp Uganda Ltd, which is owned by a former congress member. These exports include several tons of flower to Israel, at first making up for a shortfall of Israeli domestic production, as well as a major 400-kilogram export to Germany in the midst of the COVID-19 pandemic in 2021, which affected the emerging business in the country according to local experts.

Some recent developments in the Ugandan cannabis ecosystem:

- In August 2023, the Ugandan parliament passed a new law with strict penalties related to cannabis use outside the medical and export frameworks. This came as a response to a court ruling that some interpreted as fully removing all prohibitions.
- In July 2023, the director of a major reference hospital in the country called for a full prohibition of the plant, citing unknown long-term effects.
- In August 2022, it was announced that Cantourage would bring Ugandan medical cannabis to Germany's pharmacies in partnership with Israeli Together Pharma.





Lesotho

 Ω 2.3 M

\$ 1.175K PER CAPITA

LEGAL STATUS:	⊗ Medical cannabis	⊗ CBD	○ Cultivation	⊗ Adult-use
EXPORT:			Extracts and finished pro	oducts
IMPORT:	⊗ Flower and raw product		⊗ Extracts and finished pro	oducts
COMPETITIVE ADVANTAGES: Cultivation conditions, competitive operation costs				
BUSINESS CHALLENGES: Lack of infrastructure, small cannabis ecosystem, upfront costs				
RELEVANT GOVERNMENT INSTITUTIONS: Minister of Health (Nkaku Kabi)				

The small and mountainous country of Lesotho, landlocked in South Africa, has gained some attention in recent years for its incursion into the cannabis industry. However, the experience so far has come with mixed results, one of the reasons being that to plant matekoane, as cannabis is known locally, farmers need a licence that costs approximately 400 national minimum salaries, keeping the vast majority out of the game.

Meanwhile, companies operating in the country, largely with foreign capital (primarily from North America, Germany and Israel), have been able to build EU-GMP facilities, creating jobs in the nation as well as exporting medical cannabis to countries such as Germany, the Netherlands, Switzerland, North Macedonia and Israel. These capabilities and exports have provided the nation with international visibility, as companies such as MG Health, which have received an EU-GMP licence and export flower and extracts as APIs, received US\$18 million in further funding in 2021 to scale their production in order to provide more international markets with their products.

Some recent developments in the Lesothian cannabis ecosystem:

- In June 2023, it was announced that local producer MG Health planned to triple its capacity, in order to target further markets including Israel, Australia, Europe, particularly Germany.
- In August 2021, Lesotho-based medical cannabis producer Highlands Investment completed an 8.5 ton shipment of THC and CBD flowers to North Macedonia.



Morocco

√ 37.4M

(§) 3.5K PER CAPITA

LEGAL STATUS:		⊗ CBD	○ Cultivation	⊗ Adult-use	
EXPORT:			⊘ Extracts and finished pr	roducts	
IMPORT:	⊗ Flower and raw product		⊗ Extracts and finished pr	roducts	
COMPETITIVE ADVANTAGES: Cannabis cultivation expertise, competitive operation costs					
BUSINESS CHALLENGES: Strong illegal market, upfront costs, complex bureaucracy					
RELEVANT GOVERNI ANRAC, DMG, MAPMDREF, MSPP	MENT INSTITUTIONS	S:			

The North African country has a strong connection with cannabis cultivation, considered by the UN Office on Drugs and Crime (UNODC) in 2022 as the world's largest cannabis resin producer and the main source of illicit cannabis in many Western European countries, thanks to its proximity, cultivation conditions and developing economy. The country embraced cannabis legalisation in 2021, in an attempt to take advantage of the widespread cultivation culture in the Rif region and compete with Israel. Despite hopes, the new legal framework has not been translated into desired interest and adoption by farmers, due not only to loyalty to illicit organisations but also to the investment needed to enter the legal supply chain. Despite challenges, over 450 farmers have obtained cultivation licences; meanwhile, about 80 organisations have received operational licences for activities such as processing, extraction and exporting, giving hope to Al Maghreb, where a recent study by the Economic, Social, and Environmental Council (CESE) suggested that 86% of the population support the move.

Some recent developments in the Moroccan cannabis ecosystem:

- In mid-2023, Morocco's state news agency MAP reported on the government's plan to supply 10% of Europe's demand for cannabis by 2028.
- In May 2023, Morocco's government provided clearer export and import regulations.
- In March 2023, construction began on the first formal cannabis laboratory for medical and industrial uses in the country, in Chefchaouen, a city in the Rif Mountains of northwest Morocco.

'Morocco's approach to cannabis remains fraught with caution, even if there is a desire to progress towards progressive policies. The willingness to take advantage of the benefits of a legal market still faces the challenges of a restrictive approach regulating this same market. Hope remains that regulations evolve and adapt as the national and export markets start and expand in the coming years.'

Dr Khalid Tinasti, researcher at the CCDP, Geneva Graduate Institute and David F. Musto visiting scholar at the ICDPS, Shanghai University



Asia



Cannabis is an indigenous plant in Asia, with historical evidence of uses in countries such as China, where it likely originated, and India, where it is mentioned in Hindu sacred texts. After the plant's prohibition in most Asian countries in the 20th century, with hemp remaining legal for industrial uses in some countries, cannabis is having a slow yet evolving comeback in several Asian economies for diverse uses. This comeback is not always linear, with Thailand planning to reverse its decision on adult-use cannabis decriminalisation as well as the recent efforts from countries such as Japan and South Korea exerting stricter control over the emerging and growing demand for cannabis products that are often in a legal grey area.

Further west in India, a brighter scenario dawns in a country where the plant has very different statuses in its many regions, due to its traditional uses, where we witness attempts towards more R&D and understanding about the agricultural potential of the plant.

Meanwhile, besides Thailand, other Tiger Cub economies of Southern Asia – those who show similar signs of outstanding economic growth to the original Asian Tigers – show some signs of not being indifferent to global cannabis trends. The Philippines, a country with a 2022 GDP growth of 7.6% and a population over 110 million, shows signs of potential medical cannabis approval for 2024, inspired by the Israeli model of medical cannabis. Further south, Indonesia's constitutional court rejected a medical cannabis legalisation request in 2022, but it is worth noting that the request was pushed by the parents of children with severe medical conditions, following a pattern of grassroot, bottom-up social movements that have ended up in medical cannabis legalisation elsewhere.

All of the above create an interesting scenario in Asia, and this mix of countries with high purchasing power and developing economies, plus a large appetite for beauty and well-being products, could see good opportunities for the CBD segment.

China remains a huge untapped market for the medical cannabis industry, which is appealing not only for its massive population and growing purchasing power, but also for its US\$1.2+ trillion healthcare industry, a figure that has been growing over 10% yearly since 2016. Hopes for pragmatism and well-being over ideology give hope for Chinese patient access in the long run.

TABLE 3

Asia Medical Cannabis Legal Landscape

Country	Medical commercial production	Imports (medical cannabis)	Exports (medical cannabis)	Patient access to medical cannabis
India	To some extent (only via Ayurveda, using stem and seeds, varies by state)	No	No	To some extent (only via Ayurveda, using stem and seeds, varies by state)
China	No	No	No	No
Thailand	Yes	Yes	Yes	Yes
Japan	No	No	No No	No
South Korea	No	No	No No	No
Malaysia	No	No	No	No
Vietnam	No	No	No	No
Indonesia	No	No	No	No
Philippines	No	No	No	No
Pakistan	No	No	No	No
Bangladesh	No No	No	No	No No
Myanmar	No No	No	No	No No
Laos	No No	No	No	No No
Cambodia	No No	No	No	No
Mongolia	No No	No	No	No No
Taiwan	No	No	No	No No
Sri Lanka	To some extent (only via Ayurveda, using stem and seeds, varies by state)	No	No	To some extent (only via Ayurveda, using stem and seeds, varies by state)
	To some extent (only via Ayurveda, using stem and			To some extent (Ayurveda, using:





71.6M

\$ 7.6K PER CAPITA

LEGAL STATUS:		⊘ CBD	○ Cultivation	⊘ Adult-use*	
EXPORT:	⊘ Flower and raw product		⊗ Extracts and finished products		
IMPORT:		⊘ Flower and raw product		⊗ Extracts and finished products	
COMPETITIVE ADV. Liberal cannabis stand, touris	ANTAGES: sm, competitive operation costs				
BUSINESS CHALLE Unstable regulatory landscap					
RELEVANT GOVER Thai FDA, MOAC, MOPH, ONCE	NMENT INSTITUTION	IS:			

Cannabis has been present in Thailand's history for many generations with diverse uses ranging from gastronomy to fabric and medicine. After years of full prohibition, in 2019 the country approved cannabis for medical use. In 2022, a major liberalisation took place, which involved removing cannabis and hemp from the Category 5 list of narcotics, allowing many uses of cannabis in the country, attracting both global investors and tourists, mostly from more conservative Asian countries, who were aiming to take advantage of the liberal legal stance.

This openness to the plant is now being reviewed, with plans to revise adult-use cannabis regulations, mostly due to a perception of rapid widespread use among nationals and tourists, with over 12,000 official dispensaries opening to 2022, an exponential growth accelerated with the post-COVID-19 touristic rebound. The plan is to focus on medical cannabis access, rather than adult-use, a move that could influence, and likely slow up, flexibility in cannabis in the region. The country also registered as of 2022 about 1.2 million individual reported cannabis growers, the vast majority with a focus on high-THC varieties, impacting heavily on prices, dropping from an average of 350 Thai baht per high-THC gram in June 2022 to an average selling price of 120 Thai baht in August 2023, a figure that explains consumption peaks.

Notwithstanding that the main goal of the cannabis flexibilisation was to counterbalance the strength of the illegal market, the globalised economy brought a surprise, with entrepreneurs in the Thai cannabis ecosystem complaining about the market being flooded with cheaper illegal imports from the US, with prices as low as 50% less than local produce.

An interesting market to monitor is that of CBD products in the country, particularly around food and cosmetics. The country is known as a destination for healthcare and beauty procedures – the beauty industry has shown consistent growth and it is projected to grow at a CAGR of 5.5% up to 2027. Yet surprisingly, at the Cosmoprof CBE ASEAN 2023 event, where major beauty brands met in Bangkok, only one CBD-based Thai brand was present – Dr. CBD.

Recent events related to cannabis in Thailand:

- In September 2023, the new Thai Prime Minister, Srettha Thavisin, called for more restrictive cannabis-related laws, a view shared by several other political parties.
- In August 2023, a New York Times article suggested that, despite legal uncertainty and limitations for foreign investment, the Thai cannabis industry is growing.
- In mid-2023, many tourist operators, a large part of the country's economic activity, declared being in favour of stricter cannabis laws due to recent incidents

^{* (}ending soon)

'The Thai cannabis market is becoming increasingly competitive. Entrepreneurs need to differentiate themselves through product quality, branding, and innovation to stand out. Thailand also encountered a tremendous amount of illegally imported flowers being sold domestically, which had an extremely negative impact on the domestic market. Access to financing remains challenging.'

Mikhail Kornievsky, Regenerative Cannabis Farming Specialist

'CBD is definitely on the rise with a greater volume of the Government Pharmaceutical Organisation (GPO)'s product line being dispensed at higher numbers Q-o-Q and Y-o-Y. However, the number of recreational local cannabis users, I believe, has matured; we are definitely seeing a great reliance on sales from tourists and the tourism seasonality. On the supply side, there are fewer illegal imports available, cheap PGR cannabis is on the rise, but we also see an amazing improvement of local craft small-batch grows.'

Nadon Chaichareon, CEO & Founder, Teera Group Holding

'Destigmatisation is a big issue. I suppose this is worldwide because of the decades of anti-cannabis sentiment since the 6Os. That said, because of the already-existing Traditional Thai Medicine (TTM) industry, CBD and the health aspects of cannabis have been somewhat welcomed by both the public and the government.'

 ${\it Gaurav Sehgal}, {\it Co-Founder \& COO} \, at \, {\it Siam Green Cannabis Co} \,$





Nadon Chaichareon CEO & Founder, TEERA GROUP HOLDING

How would you describe Thailand's current cannabis industry?

Open but unstructured. We witnessed a cannabis industry that turned 180 degrees from 9 June 2022. It is quite a phenomenal change from a country that had strict regulations, to becoming such an open market – open to home growers and attracting substantial local and international investments from across the world. In tourist towns, cannabis shops are seen with greater regularity than even 7-Eleven convenience stores. With local politics being a fundamental theme to the narrative in Thailand, cannabis was once again targeted in recent political campaigns. I personally believe that the uncertainties of the current situation, at the time of writing, will most definitely be addressed soon. The new government has announced its intention to make cannabis 'medical', and Phum Jai Thai, the political party who pushed for decriminalisation of cannabis last term, is once again a part of the coalition.

What are the main opportunities and challenges for local entrepreneurs? Are there any expected changes with the new government?

The opportunities are becoming more evident around higher adoption of CBD as we see a greater availability of products being approved by the FDA, but also the adoption of cannabis by clinicians for patients, which essentially reflects the new government's announced intention to make cannabis 'medical'. The challenges for local entrepreneurs have become even more evident – with no real regulations to govern the industry, there are many international players, small and large, partaking in the opportunities along the supply chain.

I do expect the government to become successful in passing the by-laws for medicinal cannabis with a greater emphasis on safety protocols within late 2023/ early 2024.

In terms of national market potential, do you have any figures or estimates for medical cannabis, CBD and recreational?

CBD is definitely on the rise with greater volume of the Government Pharmaceutical Organisation (GPO)'s product line being dispensed at higher numbers quarter-over-quarter and year-over-year. However, the number of recreational local cannabis users, I believe, has matured; we are definitely seeing a great reliance on sales for tourists and the tourism seasonality. On the supply side, there are fewer illegal imports being available, and cheap PGR cannabis is on the rise, but we also see an amazing improvement of local craft small-batch grows.





China

√ 1.425 M

§ 12.7K PER CAPITA

LEGAL STATUS:	⊗ Medical cannabis	⊗ CBD	⊘ Cultivation (hemp)	⊗ Adult-use	
EXPORT:	⊗ Flower and raw produc	ct	⊘ Extracts and finished p	oroducts (CBD)	
IMPORT:	⊗ Flower and raw produc	⊗ Flower and raw product		⊗ Extracts and finished products	
COMPETITIVE ADVANTAGES: Large internal market, evolving pharmaceutical industry					
BUSINESS CHALLENGES: Strict governmental interference, IP related challenges					
RELEVANT GOVERN CFDA, GACC, NMPA, MARA	MENT INSTITUTION	NS:			

China is a pure hemp market, with adult-use and medical cannabis being strictly prohibited. In the recent past, the country witnessed a growing CBD market, purely in CBD cosmetics; however, in May 2021, China's National Medical Products Administration (NMPA) decided to ban CBD as a cosmetic ingredient.

Currently, the People's Republic holds itself as the largest cultivator of industrial hemp globally, representing almost 50% of hemp production worldwide and is seeking to expand its production output for its domestic fibre market as well as its raw material export markets. According to the country's 13th Five-Year Plan, which was set in 2016, China aims to cultivate hemp over 1.3 million hectares (3.2 million acres) in order to produce 2 million tonnes of textile fibres by 2030.

Regulations regarding hemp cultivation in China are very opaque and differ by province, as on a national level, cannabis cultivation regardless of its THC content is illegal under the country's Drug Control Law. However, in 2018 the Ministry of Agriculture and Rural Affairs issued standards on industrial hemp seeds (THC limit less than 0.3%). On a provincial level, the Yunnan province provides licences for hemp production under the definition that it includes all cannabis plants and extracted products with a THC content of less than 0.3%. with no mention of CBD. In the province of Heilongjiang, industrial hemp growers have to be certified by the provincial government's agricultural department; however, under its regulations, the plant may be used for fibre, food, health products, medicines and construction materials. All of these differences create an unclear picture of the legality of hemp in the country, especially as, in 2019, China's National Narcotics Control Commission issued a circular reiterating that its production should be limited to fibre and seeds only.

Despite the extremely conservative approach and unclear regulations, the fact is that Chinese hemp farmers have been benefitting from the increase in CBD demand worldwide, particularly in the Yunnan province, with a handful of companies allowed to, under strict supervision, extract and process cannabidiol for international export.

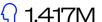
Recent events related to cannabis in China:

- In February 2023, Hong Kong province banned the production, commercialisation and use of CBD to align with mainland prohibitionism classifying the plant as 'dangerous'.
- Strict surveillance in China has pushed illegal-market investors to eye the US, where several Chinese-funded illegal centres have been discovered recently.









\$ 2.4K PER CAPITA

LEGAL STATUS:	<u> </u>	⊘ CBD	<u> </u>	⊗ Adult-use
EXPORT:	⊗ Flower and raw produc	ct	⊗ Extracts and finis	shed products
IMPORT:	⊗ Flower and raw produc	⊗ Flower and raw product ⊗ Extr		shed products
COMPETITIVE ADVANTAGES: Growing internal market, society's acceptance of cannabis				
BUSINESS CHALLENGES: Unclear legal status, lack of federal regulation, bureaucracy				
RELEVANT GOVERNICMR, Ministry of Ayush, MoAF	NMENT INSTITUTION W, MOHFW, NCB	IS:		

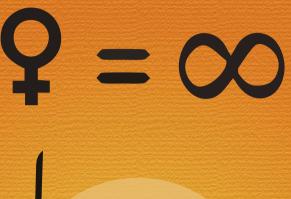
The connection between cannabis and India has a long history and many names, including charas, vijaya (medical), the worldwide-famous ganja, and bhang, according to how it is consumed. The plant survived the British Empire's attempts to diminish its relevance, but it was after the country's independence that prohibition came into effect with the 1985 Narcotics Drugs and Psychotropic Substances Act prohibiting some uses of the plant such as flowers or resin but not leaves and seeds. Indian states also created regional laws pertaining to cannabis in the last few decades, all contributing to a complex legal and regulatory landscape with CBD being legal with some elements from the plant but advertising being fully illegal. Meanwhile, medical cannabis, vijaya, part of ancient Ayurvedic medicine, is enjoying increasing official support, such as the 2022 Delhi High Court decision regarding medical cannabis as legal. Medical cannabis treatment still takes place as part of traditional Ayurvedic medical practices in the country today, with abundant cannabis growing wild in the northern parts of the country, particularly around the Indian Himalayas.

Despite the challenges, the country's connection to the plant and growing economy are promising for the cannabis sector, with a growing appetite for CBD in e-commerce platforms, and with states such as Uttarakhand, Uttar Pradesh, Madhya Pradesh, Rajasthan, and Odisha taking the lead.

Recent events related to cannabis in India:

- In July 2023, it was announced that the city of Jammu would pioneer the first medical cannabis research project, with national government support, in a public-private partnership with a Canadian firm.
- In June 2023, the state government of the Himachal province formed a committee to research people's perception of cannabis cultivation, with favourable initial outcomes.
- A mid-2023 article reported that, according to the Pan India Medical Cannabis and Hemp Association (PIMCHA), over 50 cannabis-related startups have been created since 2020, most of them working in the fields of hemp and CBD for now.
- It was reported in April 2023 that the Indian government destroyed about 82,691 acres of cannabis cultivation in the country, contradicting other recent trends.
- In October 2022, it was announced that HempStreet, the
 Indian producer of hemp-based medicines, has partnered with
 Amrita School of Ayurveda to conduct a year-long randomised
 clinical trial to examine ayurvedic treatments for the treatment
 of menstrual cramps.







BRAVELY MADE IN INDIA FOR WOMEN OF THE WORLD



SCAN HERE



Japan

123.9M

\$ 33.8K PER CAPITA

LEGAL STATUS:	⊗ Medical cannabis	⊘ CBD	⊗ Cultivation		
EXPORT:	⊗ Flower and raw product		⊗ Extracts and finished pro	oducts	
IMPORT:	⊗ Flower and raw product ⊗ Extracts and finished products		oducts		
COMPETITIVE ADVANTAGES: Highly developed economy, high purchasing power					
BUSINESS CHALLENGES: Conservative legal framework, synthetic product competition					
RELEVANT GOVERNMENT INSTITUTIONS: MAFF, MHLW					

Japan has a millennial connection with cannabis. Its prohibition in the 20th century was a peculiar one, representing the main differentiator of Japanese regulations pertaining to cannabis, as it is formally prohibited unless the products are made from the plant's stem or seeds or from synthetic cannabinoids. This is the root cause of current challenges in the Japanese cannabis industry, as the market has been flooded with products containing synthetic cannabinoids such as THC-O and 9beta, with little research on long-term impacts on human health. This is causing Japanese authorities to try to catch and regulate new trends, while pushing for a political debate around legalisation of some forms of cannabis as other world economies are doing, a move expected in the next few years.

Although Japan has a long history of hemp use for fibre, textiles, paper and foods, domestic production is extremely low and is limited to its traditional fibre production. Thus there is no legal domestic CBD production and the country relies on international CBD imports in the form of retail-packaged goods and bulk CBD materials (isolates and distillates). It is estimated that there are between 120 and 150 companies (USDA, 2023) that either import, manufacture or distribute a range of CBD products in the country, with sales channels including online shops, speciality retailers, and health & wellness boutiques.

All considered, the Japanese CBD market is growing and is promising, due to its high purchasing power, and its per capita investment in wellness, beauty and health-related problems such as lack of sleep, which could be addressed by 'real' cannabis products.

Recent events related to cannabis in Japan:

- In August and September 2023, Japanese society became divided over cannabis-related arrests that took place in two Japanese universities and among media celebrities, sparking debate around increasing youth cannabis consumption.
- In December 2023 the Japanese parliament approved a bill to legalise the medicinal use of cannabis-based products, while reinforcing strict laws around recreational cannabis possession and use. The new regulations have not been fully defined yet, however they are believed to be geared towards allowing only approved pharmaceutical cannabis-based products like Epidyolex[®].
- In December 2022, it was announced that UK firm Jazz Pharmaceuticals PLC would start Phase III clinical trials with 84 participants in Japan for Epidyolex®.

'The CBD market is growing in Japan, but most of the sales are happening online on Rakuten or Amazon.

There are a few CBD oriented shops popping up, but mostly centred in Tokyo. We're seeing a cat-and-mouse dance with regulators and sellers of semi-synthetic cannabinoids that mimic the effects of THC.'

Mike Eidlin, Founder & CEO, Balanced, Inc.





South Korea () 51.8M (§) 32.3K PER CAPITA

LEGAL STATUS:	⊗ Medical cannabis	⊘ CBD	⊗ Cultivation	⊗ Adult-use	
EXPORT:	⊗ Flower and raw product		⊗ Extracts and finished pro	ducts	
IMPORT:	⊗ Flower and raw product ⊗		⊗ Extracts and finished products		
COMPETITIVE ADVANTAGES: Large internal market, high purchasing power					
BUSINESS CHALLENGES: Conservative views on cannabis					
Conservative views on Carmabis					
RELEVANT GOVERNMENT INSTITUTIONS: KIDES, MFDS					

Cannabis has been present in South Korea for millennia with different uses. In the 20th century, heavily influenced by US presence in the country, cannabis experienced partial prohibition, followed by popularity and full prohibition in 1976. Half a century later, in 2018, some forms of medical cannabis became legal for patients with severe health conditions, trailblazing this trend in Asia, and in 2020, the Gyeongbuk province, in the south of the country, obtained authorisation to cultivate hemp. The country is strictly conservative regarding THC, similar to Japan. As tends to happen in Asian countries with cannabis, legislation has specific permissions that need to be observed. For instance, in South Korea, despite CBD not being legal (unless for medical reasons), hemp seed oil is legal, and often sold as containing CBD despite lacking the cannabidiol.

Regardless of the liberalisation, access to cannabis remains limited. Medical cannabis can only be accessed for very specific medical conditions in authorised hospitals. Meanwhile, the country's strong expenditure on beauty, particularly skin-care, estimated at being +800% higher than the global average, promises fertile soil for those investing in the country's future.

Recent events related to cannabis in South Korea:

- Amid the growing appetite for cannabis and CBD in the country, August 2023 witnessed news relating to the illegal entrance of cannabis into the country both via flight attendants and supposedly via US soldiers serving in the country.
- In an attempt to reduce the misleading of consumers and international marketing influence, the South Korean regulator announced plans to prohibit the term 'CBD' in January 2023.

- Yuhan Care and Inventage Lab announced in October 2022 the development of an injectable cannabis-based medicine.
- In August 2022, the government announced in its '100 Food and Drug Regulatory Innovation Tasks' that it would allow for national production and import of cannabis-based medicines in 2024, with the goal of treating rare and incurable diseases.

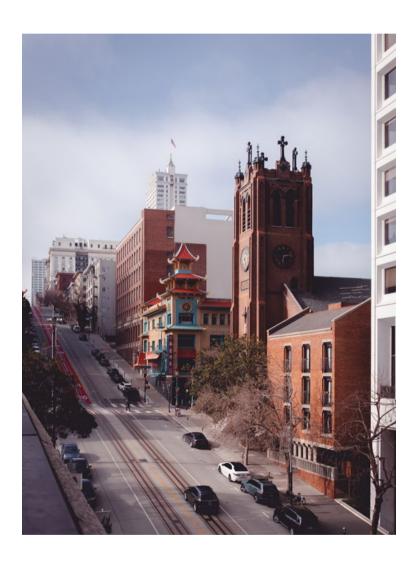


Conclusion



In a difficult global economic environment, businesses and regulators alike are taking a pragmatic approach to the cannabis industry. On the part of businesses, this is the result of multiple constraining factors - the requirement to work within certain regulatory limits, the difficulty in accessing funding or expanding sales channels, the ongoing recalibration of targets as the outlook for the industry shifts, and changes in response to developments at different levels. For regulators, pragmatism is reflected in cannabis reform that is shaped by past experiences and insights from other regions and countries - the failure of prohibition as a means to control cannabis usage, the benefits of approaching cannabis regulation from a health-oriented perspective, and the economic potential of nurturing cannabis-related industries. Significant milestones such as the opening of legal adult-use markets in Europe, or the potential for the same in Australia, are not met with the exuberance shown during the initial spread of medical cannabis markets across the globe. This is partly a reflection of different economic circumstances, but also speaks to a more measured outlook from participants in the cannabis sector, and those looking to join it. Promising developments in multiple areas show progress towards a larger, more sophisticated and more internationalised global cannabis industry. Based on past experience, companies and investors are able to navigate the industry based on a more realistic assessment of its pace of growth.

Acronyms



ANVISA	Brazilian Health Regulatory Agency	CPI	Chief Pharmaceutical Inspectorate
ANMAT	The National Administration of Drugs, Food and Medical Devices	DGA	General Directorate of Customs
ANRAC	The National Agency for Regulating Cannabis	EC	European Commission
7440	Related Activities	ESG	Environmental, social and governance
API	Active pharmaceutical ingredient	FDA	Food and Drug Administration
ARICCAME	The Regulatory Agency of the Hemp and Medicinal Cannabis Industry	FDM	Food, drug and mass-merchandise
ARTG	Australian Register of Therapeutic Goods	FSA	Food Standards Agency
BMG	Federal Ministry of Health	FOPH	Federal Office of Public Health
BfArM	Federal Institute for Drugs and Medical Devices	FSVO	Federal Food Safety and Veterinary Office
CBD	Cannabidiol	FOAG	Federal Office of Agriculture
		GACC	General Administration of Customs
CBG	Cannabigerol		of the People's Republic of China
CESE	Economic, Social and Environmental Council (Morocco)	GACP	Good Agricultural and Collection Practice
CFDA	China Food and Drug Administration	GMP	Good Manufacturing Practices
ChPhI	The Chief Pharmaceutical Inspector	ICA	The Colombian Agricultural Institute
	·	IMCA	Israeli Medical Cannabis Agency
CND	National Council on Disability	INAME	National Institute of Medicines
COFEPRIS	Federal Committee for Protection from Sanitary Risks	INVIMA	National Institute of Drug and Food Surveillance
CONADIC	National Commission Against Addictions	INTA	National Agricultural Technology Institute

IRCCA	Uruguayan Institute for the Regulation and Control of Cannabis	NCB	Narcotics Control Bureau
KOWR	National Support Contro for Agricultura	NDA	National Drug Authority
KOWK	National Support Centre for Agriculture	NHS	National Health Service (UK)
LP	Licensed producer	NMPA	National Medical Products Administration
M&A	Mergers and acquisitions	NWI A	(China)
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries	ONCB	Office of the Narcotics Control Board
MACE	Ministry of Assistable so Forester	ORMP	Office for Registration of Medicinal Products
MAFF	Ministry of Agriculture, Forestry and Fisheries of Japan	отс	Over-the-counter
MAPMDREF	Ministry of Agriculture and Fisheries	PGR	Plant growth regulators
MARA	Ministry of Agriculture and Rural Affairs	Q-o-Q	Quarter-over-quarter
MFDS	Ministry of Food and Drug Safety of the Republic of Korea	SEDRONAR	Secretary of Programming for the Prevention of Drug Addiction
			and the Fight against Narcotrafficking
MSPP	Ministry of Public Sector and Privatization	SAHPRA	South African Health Products
MHLW	Ministry of Health, Labour and Welfare of Japan		Regulatory Authority
MHRA	Medicines and Healthcare products Regulatory Agency	DALRRD	Department of Agriculture, Land Reform and Rural Development
MoAFW	Ministry of Agriculture & Farmers' Welfare	TGA	Therapeutic Goods Administration
MoHFW	Ministry of Health & Family Welfare	THC	Tetrahydrocannabinol
MOAC	Ministry of Agriculture and Cooperatives	UNODC	UN Office on Drugs and Crime
МОН	Ministry of Health	UPF	Uganda Police Force
MOPH	Ministry of Public Health of Thailand	VC	Venture capital
MSO	Multi-state operator	Y-o-Y	Year-over-year





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