

# The Cannabis Legal Report™

AUGUST 2019





# About Prohibition Partners





# Advancing the global cannabis industry.

## Data, analytics and business intelligence on the international cannabis industry.

### ABOUT US

Prohibition Partners was founded in 2017 with a mission to open up the international cannabis industry through reliable data and intelligence. Within two years, we have become the world's leading provider of market insights and strategic consultancy for this emerging frontier. We firmly believe that data, insights and education will unlock the societal and commercial potential of cannabis. Our research and content teams routinely share the latest legislative developments and key trends in the industry - information that is regularly cited by political leaders, investment banks and Fortune 500 companies. Our consultancy team works with investors, operators and regulators to identify and execute opportunities across multiple jurisdictions. We advise our private clients on licensing, regulatory and business opportunities.

### SERVICES

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#### Intelligence

Policy & Compliance, Market Analysis, Supply / Demand.

#### Strategy

Market Entry / Expansion, Regulatory Guidance, Licensing, Partnerships, Business Development.

## PROHIBITION PARTNERS TEAM:

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Our consultancy team works with investors, operators and regulators to identify and execute opportunities across multiple jurisdictions. We advise our private clients on licensing, regulatory and business opportunities.



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# PARTNERSHIP OPPORTUNITIES

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Prohibition Partners is the number one source for data and information on established and burgeoning cannabis markets. Read by over 150,000 global cannabis investors and entrepreneurs, and creating more than 6 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 sponsorship team on [info@prohibitionpartners.com](mailto:info@prohibitionpartners.com).

This is a unique opportunity to promote your business to key players in the cannabis industry, particularly those who have a keen interest in the cannabis market. As companies and investors scramble to get a foothold in the market, this is an invaluable opportunity to put your brand front and centre in one of the industry's most influential reports.





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A black and white photograph of an underwater scene featuring several jellyfish and coral. The jellyfish are translucent with visible internal structures and spots. The coral has a branching, textured appearance. The background is dark, creating a high-contrast image.

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**The transformative potential of what is emerging, as governments consider the public health and tax benefits, reaches far beyond the simple growing and selling of a plant, as cannabis promises to upend any vertical it comes into contact with.**

**Marco de Morpurgo,**  
Global Co-Chair, Life Sciences Sectors,  
DLA Piper

# INTRODUCTION

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In 2018, the cannabis industry enjoyed a breakout year with mainstream acceptance aiding significant advances in the market. In 2019, the global landscape is fracturing as traditionally conservative geographies embrace medicinal cannabis while more advanced territories hint at looser recreational laws.

**“Per the most recent UN World Drug Report, 188 million people, or 2.5% of the world’s population, used cannabis in 2017. Cultivation was reported in 129 countries.**

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There are significant opportunities for licensed producers and suppliers in the various global regulatory regimes, and firms are scrambling to comply with laws and, where possible, position themselves to benefit.

In this report, Prohibition Partners examines the increasingly complex legal and regulatory landscape shaping the future of the market. The report breaks down the regulatory matters governing the medicinal and adult-use markets, providing stakeholders, operators and investors with the clarity needed to succeed in the emerging global cannabis sector.

We hope you find the report a helpful guide to the shifting sands of global cannabis laws. If you have questions about the report or would like to discuss the many opportunities in the international cannabis market, please contact me directly.



**Daragh Anglim**  
**Managing Director**  
**Prohibition Partners**

# LEAD SPONSOR FOREWORD

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**C**annabis remains a controlled substance in most jurisdictions, but the demand for medicinal, wellbeing and recreational products and their derivatives is undeniable.

The transformative potential of what is emerging, as governments consider the public health and tax benefits, reaches far beyond the simple growing and selling of a plant, as cannabis promises to upend any vertical it comes into contact with.

Entrenched players in the food and drink, energy, tobacco and pharmaceutical sectors were the first to feel the impact. Now executives across industries as diverse as cosmetics and pet food are considering how cannabis is going to reshape their markets, and if they should acquire, partner or compete with these new entrants.

One thing is clear: they cannot be ignored.

The DLA Piper life sciences practice is a leading participant in the cannabis industry, from start-up to private and public fundraisings, acquisition and post-merger. We have observed a number of divergent streams materialising from the shifting tectonic plates of cannabis regulation across the globe. Uncertainty and service gaps are appearing as the forces of innovation and disruption clash with the variant maturity speeds of global regimes.

This report provides a snapshot of the trending regulatory issues businesses can ex-

pect to encounter in the cannabis space into 2020. The issues covered herewith provide a starting point for dialogue about future regulatory challenges and opportunities that can help executives stay ahead of evolving requirements and trends.

DLA Piper's team covers the range of corporate, intellectual property, technology and R&D, employment, regulatory and litigation services, and we are acting across every segment of pharmaceutical, biopharmaceutical, wellness and medical sectors around the globe.

High-growth industries with the breadth and scope of where cannabis can pervade come with an enormous regulatory burden. Smart firms must have a realistic plan to deal with the compliance dragnet that inevitably follows from a lack of geographical harmonisation.

Smarter firms scan the horizon and plan ahead of it and that's where DLA Piper can help.

Data, market intelligence and regulatory foresight are essential requirements for firms looking to navigate the cannabis landscape, and DLA Piper and Prohibition Partners are proud to present The Cannabis Legal Report™ as your guide.

**Marco de Morpurgo,**  
**Global Co-Chair, Life Sciences Sector,**  
**DLA Piper**

**Dylan Kennett,**  
**Corporate Senior Associate,**  
**DLA Piper**





# HOW IS CANNABIS DESCRIBED IN LAW?

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**E**very country has its own regulatory regime (and even vocabulary) for the control of cannabis, but definitions of what counts as ‘cannabis’ are taken directly from the international drug control regime. Here is how the 1961 Single Convention on Narcotic Drugs refers to the plant and its byproducts:

## 1 Cannabis:

‘the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated’

## 2 Cannabis plant:

‘any plant of the genus Cannabis’

## 3 Cannabis resin:

‘the separated resin, whether crude or purified, obtained from the cannabis plant’

Different laws were drawn up around the world to determine what behaviours involving the plant would be controlled, using the definitions as a platform. The regulatory prohibition of cannabis later included the central psychoactive component, tetrahydrocannabinol (THC), which is not mentioned above.



## TERMINOLOGY

Three similar terms are often used to discuss the varying legal status of cannabis around the world. Here is a quick explainer:

1

### Legalisation

Once prohibited behaviour (criminal or not) is now permitted. This is usually used to describe supply, rather than possession of cannabis.

2

### Depenalisation

Use remains a criminal offence, but is no longer punished.

3

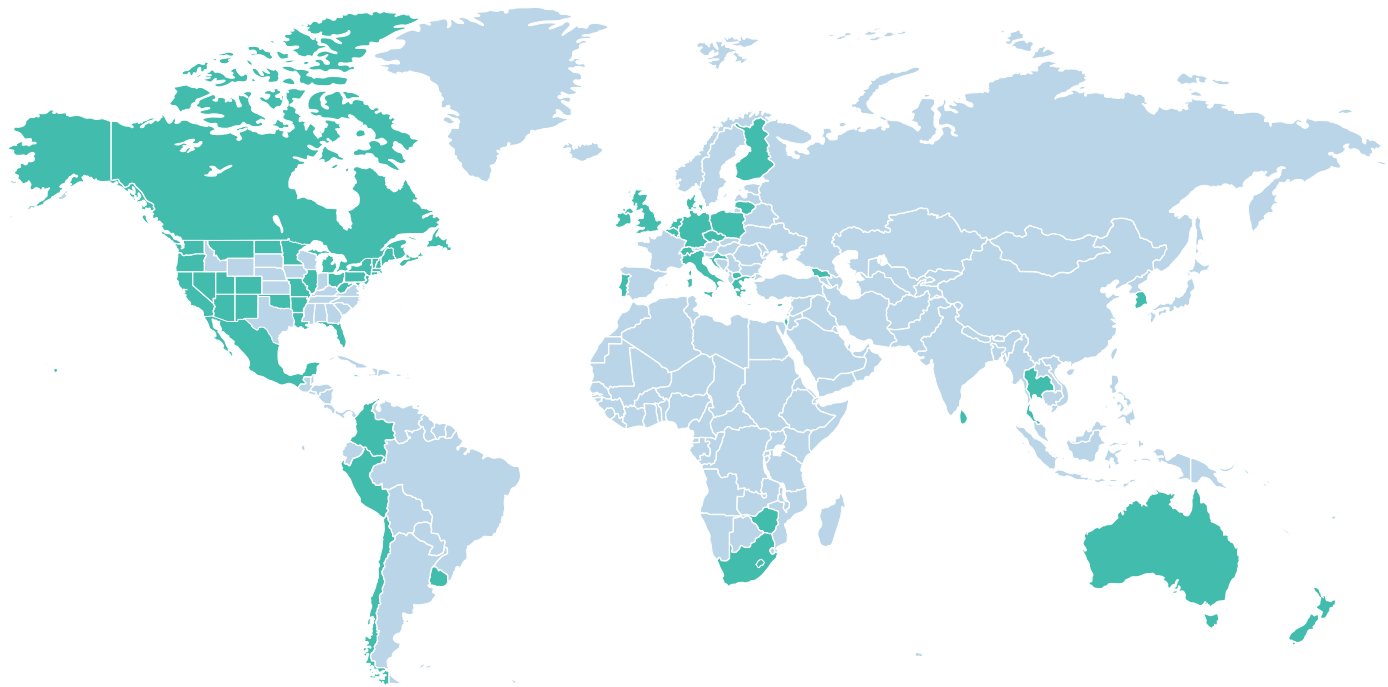
### Decriminalisation

The offence is reclassified from criminal to non-criminal. Usage remains an offence and may be punished by the police or other agencies, such as in an on-the-spot fine, rather than through court action.

## WHERE IS CANNABIS LEGAL?

### Medical cannabis legality\*

LEGAL



\*US remains illegal at the federal level

Some of the major countries that have legalised the medical use of cannabis include Australia, Bermuda, Canada, Chile, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Finland, Georgia, Germany, Greece, Ireland, Israel, Italy, Jamaica, Lithuania, Luxembourg, Macedonia, Malta, the Netherlands, New Zealand, Peru, Poland, Portugal, South Africa, Sri Lanka, Thailand, the United Kingdom, Uruguay and Zimbabwe.

In the US, the legality of medical cannabis varies by state. In Mexico, the THC content of

medical cannabis is limited to 1%.

The same limit applies in Switzerland; however, no prescription is required to purchase.

The most relaxed recreational policies are found in Canada, Uruguay, certain US states, and the Netherlands, where cannabis can be purchased without a prescription.



## RECREATIONAL-USE REGULATORY MODELS

In the last 18 months, four basic models of legal adult recreational cannabis production and supply have emerged.

Some jurisdictions allow multiple models.



### 1 Taxed commercial supply.

Many licensed growers supply many licensed retail outlets. This is the model in several US states, including Colorado, Washington State, Alaska and Oregon, and it is the model approved in 2016 in California, Maine, Massachusetts and Nevada.



### 2 Government supply.

The government contracts a limited number of growers and controls supply through outlets.



### 3 Permitting home grow, and providing small amounts.

No tax, no sales outlets. This is the only model in Washington, DC. Home grow is also permitted in a handful of US states with commercial supply models.



### 4 Social clubs.

A group of people grow cannabis in a collective and use it.

# GLOBAL THEMES AND HOT TOPICS IN 2019

## M&A ACTIVITY

Few new industries have emerged with the speed or potential size of the cannabis sector. Canadian enterprises, having capitalised on their home turf's maturation into a fully legalised domestic market, are leading an international pack. In almost every jurisdiction where cannabis is a business opportunity, Canadian firms can be found present. Should the US remove barriers to cross-state trade and reduce the threat of federal sanctions, that advantage could shift rapidly. Throughout 2018, Canadian firms bulked up with mergers and acquisitions across multiple continents, all the time observing matters in the US, and a quick route to large pools of capital. A wave of consolidation is likely in 2019 and 2020, cutting the number of big players in the sector. Speaking at an event earlier this year, Julius Kalcevich, Chief Financial Officer

of New York-based iAnthus Capital Holdings Inc said his company has completed 18 M&A deals in three years, as Canadian cannabis companies try to expand into the US to gain easy access to cheap growth capital.

'These Canadian guys are all waiting at the border and are figuring out how to get into these big states. If they want to get in there and put their balance sheets to work, it will create a huge amount of M&A, especially on the cross-border side,' Kalcevich said.

Most M&A activity in Europe, Asia and Africa involves Canadian firms buying up local producers; business is brisk, and there is little sign the next industry leader will emerge from outside North America.

### Cannabis M&A: Highest Value Deals 2018/19

ACQUIRER	TARGET	ANNOUNCED	TARGET JURISDICTION	ACQUIRER JURISDICTION	VALUE (US\$)
Canopy Growth	Acreage Holdings	04/19*	US	Canada	US\$3.4B
Cresco Labs	CannaRoyalty	04/19	US	US	US\$823.5M
Constellation Brands	Canopy Growth	08/18	Canada	US	US\$3.8B
Aurora	MedReleaf	07/18	Canada	Canada	US\$2.5B
Aurora	Cannimed Therapeutics	01/18	Canada	Canada	US\$825M

\*Contingent on federal US legalisation

Source: Prohibition Partners

# INDUSTRY EXPERT GUEST POST

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**Michael Corcoran**

*Partner,  
Hill Dickinson*

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## CANNABIS, A GLOBAL SECULAR TREND: M&A AND INVESTMENT IN EUROPE.

In 2001, Canada became the first country to adopt a system regulating the use of cannabis for valid medical purposes, and North America duly became the engine room for commercial expansion across the sector.

Those efforts peaked with new regulations in 2013 as the cultivation and distribution of medicinal cannabis throughout Canada was encouraged in a more conventional model of capitalist acceptability.

US firms were quick to emulate the Canadian model, with multi-state operators attracting huge valuations amid a booming market. By 2018, the North American industry alone had an estimated worth of more than US\$8 billion. There are clear indications that a lot of the early venture capital, freshly successful, is now focusing on Europe, investing seriously on the continent to develop a tangible footprint.

Analysts predict that the European legal cannabis market will be worth €123 billion by 2028. Considerable investment in the areas of research, development and manufacturing has created a window of opportunity for start-up businesses and entrepreneurs that simply did not exist in previous eras.

Moves to establish cannabis as a viable drug for medical purposes have led to significant recent interest and investment in the medicinal cannabis market throughout the region. Germany and Italy are powerhouses of the European cannabis market, which harbours the potential to be the world's largest in the medium-to-long-term future.

Closer to home, here in the UK, we have a complex interaction with the developing market. The number of patients is small, while doctors often encounter difficulty prescribing cannabis. Nevertheless, many medicinal cannabis companies place their flagship European offices in London, burnishing the UK's position as the likely centre for raising capital that will radiate across the continent.

Of course, Britain's impending exit from the European Union adds turbulence to the market. The shape and texture of Brexit will have ramifications for the country's medicinal cannabis sector, but the UK is likely to remain the beachhead for North American firms looking to acquire companies, assets and licences in Europe. Likewise, London remains the obvious hub for raising capital that will drive the expansion of Europe's medicinal cannabis industry. That is not likely to change any time soon.

As the European industry grows, the need for sound legal advice becomes more apparent. Due diligence at the outset of a venture or project can prevent crisis later on. Here at Hill Dickinson, we have been involved in the industry since 2017, advising on the first investment by a UK listed company in a Canadian LP (AIM listed FastForward Innovations in mid-2017), and the first IPO of a medical cannabis company in early 2018 (the first since GW Pharma in 2001). We have recently expanded our resources in this space, establishing an experienced team of dedicated lawyers in business services and healthcare.

If Hill Dickinson could invest in an industry, it would be medical cannabis, as it plays to all of our strengths. Our leading corporate team with extensive capital market and M&A experience in Europe is supported by our specialist healthcare, life science, licensing, regulatory, international trade and commodities teams. Our experience acting for public and private health groups in the UK, as well as for key European health regulators (including NHS England), together with our life sciences expertise, mean Hill Dickinson can assist and advise on the complete spectrum of medical cannabis transactions.

As a firm, we foresee a significant increase in the amount of cannabis-related mergers and acquisitions in the coming years. The next 24 months will be a time of significant investment by North American companies and funds in Europe. With an extensive network of partner firms and corporate advisors positioned strategically throughout the continent, we have our finger on the pulse, providing a one-stop solution for all of your legal needs.

Partnering with Hill Dickinson is essentially plugging into an established network of resource and expertise across Europe. A number of large global law firms offer support in medicinal cannabis matters, but we eschew the generic platitudes to deliver a scalable provision that works for you.

Our flexible allocation of resources allows you to access the appropriate level of guidance for

the most efficient price. Where others are just getting started, we have a proven record of accomplishment.

*For more information, please contact Michael Corcoran, Partner in Hill Dickinson's London corporate team.*

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**London remains  
the obvious  
hub for raising  
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will drive the  
expansion of  
Europe’s medicinal  
cannabis industry.**

**Michael Corcoran,**  
Partner,  
Hill Dickinson



## CONSUMER PROTECTION

Sitting on potentially the largest fully legalised global cannabis market, the European Union in January took baby steps towards a formalised set of laws for governing medicinal cannabis within the bloc. Members of the European Parliament's health committee adopted a resolution – the first step necessary to drafting legislation – designed to better support the industry.

Members of the directly elected legislative called for 'properly funded' scientific research in the non-binding motion, and will seek to incentivise member states to advance studies of medical cannabis, prioritising scientific research and clinical studies.

However, the move came at the same time the EU tweaked its regulations to ban the sale of products containing cannabidiol, better known as CBD. The European Food Safety Authority (EFSA) issued a memo stating CBD, the non-psychoactive compound in cannabis, was a 'novel food' additive and any product containing it must gain approval before being sold in the bloc. An appeal was lodged, as lobbyists pointed out the same EU Novel Food Catalogue states that hemp flower products such as hemp seed oil are exempt from the novel food classification, which would undermine CBD's novel food status.

Lawyers working on the appeal say they have been given little direction on when the outcome is likely; however, the legal wrangle sends a message to multinational firms that the rapid move to legalisation in the Americas is unlikely to be repeated in Europe.

In theory, retailers were meant to remove CBD items from sale immediately, but Europe's high streets have ignored the order. Throughout the first half of 2019, multiple 'cannabis lifestyle' stores have opened in London and across the EU.

One of the few comparable surveys of the strength of public opinion in the European Union is the Flash Eurobarometer, which interviews approximately 500 young people

(aged 15–24) in each country. In 2011 and 2014, young people were quizzed about opinions on drugs. More than half of the respondents were previously in favour of banning the sale of cannabis, instead of regulating it, but that number dropped over the period, from 59% to 53%.

In the US, support for cannabis legalisation is reaching a tipping point. A survey by US lobby group Drug Policy Allowance found two-thirds of Americans (64%) are pro-legalisation. Some 75% of US voters – across all party affiliations – oppose federal government enforcement of federal cannabis laws in states that have legalised cannabis for medical or adult use.

Researchers in the US, Canada and Uruguay are conducting ongoing studies into the health impacts of cannabis use, following the legislative changes that allow for adult use. All three areas will be test cases for public health officials in other countries seeking to weigh up the pros and cons of allowing adult consumption of cannabis recreationally.

## SUSTAINABILITY

Climate change, and its threats to the planet, has been one of the big stories of 2019. Governments all over the world are being challenged to show their green credentials, and the tide of public opinion is shifting, in part due to a large and very vocal youth movement.

Harmful environmental practices have long dogged recreational cannabis production, and the adoption of regulatory controls to drive sustainability are inevitable as new countries consider growing and researching the drug. The problems stem from intensive artificial lighting, temperature control and cooling, and are especially prevalent in black-market underground operations, contributing to high levels of power consumption and carbon intensity. Illegal grow sites in California have depleted over a billion gallons of water away from sources reserved for human consumption in cities such as San Francisco and Sacramento, it has been estimated.

A recent study published in Science Direct reported that cannabis growing could profoundly impact the environment, as planting for commercial production in remote locations was creating forest fragmentation, stream modification, soil erosion and landslides. Without land-use policies to limit environmental footprint, the impacts of cannabis farming could get worse, the study concluded.

Canadian regulations, for example, require anyone growing plants to hide them from the public, which would almost certainly mean indoor production. The indoor method uses the least amount of water, which helps growers in states and countries where water is scant, but it's also the most energy-sapping, with some cultivators having the lights on 18-hours straight per day.

Governments in Colorado, along with California and Massachusetts, have introduced policies that promote sustainability and try to reduce cannabis-related greenhouse gas emissions. A recent study revealed almost 4% of Denver's total electricity usage was down

to cannabis production. Boulder County and the cities of Denver and Boulder, which house around 350 grow operations, have started programmes to promote energy efficiency in an industry they see as a new challenge to their sustainability and climate-change goals.

Colorado is a global bellwether for indoor cannabis production and a test case for jurisdictions around the world hoping to learn how to harness a potentially massive local industry.

Cannabis grown indoors in the state is more than four times as carbon intensive as that in California and five times more carbon intensive as that in Oregon, according to reports. The jurisdiction is a magnet for vendors offering ever more sustainable lighting, heating and cooling, but is also home to an enormous black market; illicit growing accounts for around 75% of energy use. The state is a test case for how a government can make a legal market more efficient and cost-effective, competing with the black market, whilst hitting environmental targets.

## IP AND TRADEMARKS

On 17 April 2019, the US District Court for Colorado denied an attempt by Pure Hemp Collective to have a cannabis patent involving a liquid formulation filed by rival United Cannabis declared invalid, allowing the case to move to jury trial.

The case is notable for being the first, and so far only, cannabis patent infringement proceeding in the United States or Canada, and the eyes of the industry are watching the developments in the District Court. As the value of the global cannabis market soars, firms producing cannabis, associated products and devices, and R&D, will be increasingly driven to protect their intellectual property (IP).

Micheline Gravelle, partner at Bereskin & Parr law firm in Toronto, has warned European



firms that Canada's businesses have been battling each other over cannabis IP and trademarks for almost ten years, and these issues are certain to make their way over the Atlantic and beyond when the market for medicinal starts to become more competitive.

In the Asia-Pacific region, UK company GW Pharma and its subsidiary GW Research have the most granted patents filed for cannabis-derived products in New Zealand, much to the chagrin of local businesses.

The rocky legal landscape makes it difficult for firms to establish certain rights – for example, while cannabis remains illegal at the federal level, firms cannot trademark registration for products. In the EU, trademark registration is again limited due to prohibitions on registering products classified as immoral or illegal.

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HILL DICKINSON

## Your trusted legal partner

Our expert resource across the full legal spectrum allows us to provide timely, accurate and nuanced advice in all areas of the medicinal cannabis space.

From healthcare to regulation, licensing to mergers and acquisitions, you can trust our team to deliver tailored guidance that enriches your pursuit of strategic goals.

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# REGULATORY FRAMEWORK

## INTERNATIONAL DRUG TREATIES

For all the domestic regulatory cheer and liberal regimes, cannabis remains prohibited under three international treaties:

- 1 **The Single Convention on Narcotic Drugs, 1961**
- 2 **The Convention on Psychotropic Substances of 1971**
- 3 **The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988**

The gatekeeper of these treaties is the International Narcotics Control Board (INCB), an independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. The INCB does not have the power to enforce sanctions on countries that break the treaties, but it can pressure other countries to lobby each other.

## INTERNATIONAL REFORM

The UN's legal and institutional mechanisms have delayed several attempts to delist cannabis as a Schedule 1 drug. In December 2018, and then again in early 2019, the United Nations Commission on Narcotic Drugs postponed its vote on possible rescheduling. The group is due to reconvene in July where it will discuss the proposed softening of laws by the World Health Organisation on cannabis and cannabis-related recommendations.

In March, the INCB warned governments around the world who have supported the medical use of cannabis in their respective countries not to 'de facto legalise' cannabis for non-medical use. In the body's annual report, the INCB criticised Canada and the US, for 'skirting' international drug laws in developing domestic recreational cannabis markets.

'The legalisation of the use of cannabis for non-medical purposes in some countries represents a challenge to the universal implementation of the treaties, a challenge to public health and well-being, particularly among young people, and a challenge to the parties to the treaties,' wrote INCB president Dr Viroj Sumyai in the report. Sumyai said UN treaties only allow for medical and scientific use of cannabis. He added that medical cannabis programmes in Canada and the US are 'poorly regulated' and don't meet UN standards.



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**The UN’s legal and institutional mechanisms have delayed several attempts to delist cannabis as a Schedule 1 drug. In December 2018, and then again in early 2019, the United Nations Commission on Narcotic Drugs postponed its vote on possible rescheduling.**



Unexpectedly, the report was given short shrift by the global cannabis sector, and there is a sense the INCB is out of date and in dire need of reform. The report gained minimal press coverage despite its robust anti-cannabis sentiment, and its contents ran counter to the claims of other recent UN publications on cannabis.

## REGIONAL REFORM AND DIVERGING MARKETS

While cannabis remains a controlled substance at the international level, several jurisdictions, mainly in the Americas, have contravened the treaties to sketch out their own pro-cannabis regimes, by judicial approval, referendums and legislative tools.

As there is no international agreement, regulatory arbitrage is common given the myriad approaches taken by regimes looking to boost state finances by growing, selling and taxing the drug.

One of the biggest issues facing multinationals wishing to operate across continents is the lack of coordination between countries that have relaxed, or are in the process of easing, their laws.

Definitions of legality are not aligned; the wording of laws rarely translates with total accuracy, and each jurisdiction has an individual take on issues such as the length and cost of licensing applications, the number of licences allowed, growing experience, personal usage and amounts, strength and variety of strains, and import and export levels.

# Arnold & Porter

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- Leading multidisciplinary life sciences practice

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# INDUSTRY EXPERT INTERVIEW

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**Marco de Morpurgo**  
*Global Co-Chair,  
Life Sciences Sectors,  
DLA Piper*

## Prohibition Partners: How is DLA Piper set up to serve the cannabis sector?

**Marco de Morpurgo:** Early on we identified a very fast growth sector, triggered by changing legal regimes in a number of countries across the world. We have been doing a lot of work in both the medicinal and the well-being areas across EMEA. These are two of our focus areas in EMEA, as the recreational sector remains largely illegal in Europe. The DLA life sciences sector includes lawyers and groups active in corporate, IP, employment, and financial regulation, and covers the whole range of pharmaceutical, biopharmaceutical, medical and wellness sectors. It is a truly global practice; the team has been advising in the space for a long time across a number of jurisdictions, on everything from product to financial regulation and licensing in the medicinal, well-being and CBD sectors. In Canada, we are a market-leading practice and recently acted on the Acreage-Canopy transaction; by way of example, DLA acted on the highly complex Canopy Growth Corp acquisition of Acreage Holdings Inc for US\$3.4 billion.

**Dylan Kennett:** We saw the shift in Europe towards medicinal and wellness and decided to build out the EMEA practice to mirror what our Canadian team was already doing, leveraging their heritage, knowledge and know-how. I have a British passport and an English qualified lawyer, but am Canadian by birth, and spent some time over there watching how they did things and quickly understood the breadth and scope of the offering and the size of the opportunity.

## Prohibition Partners: Talk us through which areas are most exciting to you?

**Dylan Kennett:** Our heat mapping in Europe has led us to focus on the UK, Germany, Denmark, Italy, Spain, and perhaps France as we wait to see how they move; these are the big markets. We are waiting to see how jurisdictions progress into medicinal programmes and we position ourselves to assist.

Elsewhere, it has been surprising to see the regimes in Southeast Asia begin to look at medicinal. Australia and New Zealand are nascent but also busy. We are also very interested in Israel, which always punches above its weight.

In Africa, we operate in 20 countries, and there is a lot of interest in the continent; we are expecting a lot more work to come. Ultimately, if Africa wants to play in the pharmaceutical space, there are high barriers to entry at the moment, but on the hemp and CBD side there are big opportunities at the moment.

## Prohibition Partners: Is Europe (and the rest of the world) likely to follow the North American model?

**Dylan Kennett:** It may delineate, but I think we are unlikely to see Europe end up in the same place as the US and Canada, at least in the near to medium term. I would expect two distinct streams in future: the US and Canada will stay on the recreational path, while Eu-

rope, with its strong history of pharmaceutical knowledge and skills, will likely stay on the highly regimented medicinal regime. But, like any future-gazing, I very well could turn out to be wrong! Nonetheless, it will be interesting to observe the supply and value chains evolve. Southern European jurisdictions will grow due to climate and lower costs, and northern Europe may be where all the R&D is situated. The UK and Germany are particularly strong in this area. It is a clear way for places such as the Iberian Peninsula to improve their economy after the impact of the financial crisis.

There is a real opportunity for European companies to get into a new industry, create jobs and generate tax revenues. You can also provide a benefit to your population by providing access to a medicine that has not been on the market before, except in extremely limited instances. There is a barrier to entry for overseas companies coming to Europe. They need to ensure they meet the EU Good Manufacturing Practices (GMP) standard to sell products to Europeans. For Canadian firms, there is a Good Agricultural Practice (GAP) analysis to be done before they export into Europe. There is a window, a real opportunity for domestic companies to be built up and flourish, as it will take time for Canadians to get up to speed.

**Marco de Morpurgo:** We have seen this pattern in Italy; the government restricted ‘Cannabis Light’, and so it seems any recreational or CBD market is going backwards, while at the same time the medicinal opportunities are rising. There is increased demand, and inter-

est from the government, who recently put out a new tender.

**Dylan Kennett:** In the UK, media coverage around individual cases has pushed the issue of getting medicinal regime in place up the political agenda. There is a definite-use case for people with pain, epilepsy, MS, and even migrating patients away from opiate medicines. It’s clearly a pretty amazing plant and there is an argument to be using it for various ailments.

#### Prohibition Partners: What worries clients the most?

**Dylan Kennett:** The Proceeds of Crime Act is rightly a big concern for UK firms, and was something not many stakeholders were aware of. This does not just concern domestic European firms but those looking to invest abroad in Canada or the US, as it is a very real legal risk and they need to know how that affects them, their limited partners and other stakeholders. We have been conducting a lot of analysis on this and are keen that everyone knows of the risks of investing abroad. Even though it may be recreationally legal in Canada, you must look to mitigate your risk, where this is possible – in some instances, it may not be possible. What is definitely encouraging is that the smart cannabis companies we are working with are asking managing directors of pharma companies or those from other highly regulated industries to join their teams. There will be a significant regulatory burden in the near future that needs to be understood and

managed, and it should be done so sensibly. Smart companies are identifying these people and bringing them into the fold.

#### Prohibition Partners: What work is keeping you busiest?

**Marco de Morpurgo:** We are carrying out a lot of advisory compliance in Europe at a very granular level: kinds of products, components and ingredients. The supply chain needs to know how the product has been derived and where it is coming from and ensure quality assurance. In the CBD space, it was smaller companies at first, but now we are seeing a lot of activity from more traditional players, like the online payment service providers and large consumer goods companies. There is real diversity amongst the offerings: we have seen CBD used in products ranging from pet food to cosmetics. Everyone is waiting to see where this all goes. There is a lack of harmonisation across the EU, primarily with CBD, so we are working on a jurisdiction-to-jurisdiction basis to better understand the product offerings in greater depth.

#### Prohibition Partners: Which legislative developments should the industry be keeping an eye on?

**Dylan Kennett:** The EU is the big one and the general guidelines from the European Medicines Agency. On a jurisdictional level, France looks like the next big market, as there is an enormous appetite from a pharmaceutical point of view.

From a UK perspective, we would like to see legislation improved to help patient access. There have been approximately ten or less prescriptions granted on the NHS since November, and patients have to have exhausted all their available options before pursuing cannabis as a treatment. Perhaps there is a chance to revisit the legislation, both to improve such access and incentivise business to enter the market, thus bringing in R&D spend, which the industry will require.

**Marco de Morpurgo:** In Italy, we see a lot of uncertainty, which is never good for local companies or investors. Clarity is welcome. The current laws are from 2016, and very badly drafted.

**Dylan Kennett:** Germany is also very interesting to us; as it is an advanced market, there is a full insurance regime on their NHS equivalent. Denmark is another we are looking at with great interest. Similar to Germany, it is a good foothold in Europe to have your R&D and manufacturing facilities, and a great place to set up a business. In the coming year we expect to see a lot more private fundraising and capital markets activity, maybe even some public deals.

People are ultimately going to want to buy brands in this market, particularly on the CBD side. The financial regulatory aspect is very important, which very few law firms playing in the space have been looking at with depth. Ultimately, we would like to see harmonised European legislation for business certainty across the EU.

#### Prohibition Partners: What can we expect from the DLA life sciences team in 2020?

**Marco de Morpurgo:** We are strengthening the group of lawyers who cover life sciences and integrating that as one team.

**Dylan Kennett:** We have been cutting our teeth on the European side, while maintaining a very strong practice in Canada. Across our EMEA team we would like to continue building the practice out. Now it is more of the doing and assisting in building the market in a concerted and well-thought-out manner.

We want to be a market participant and bring maturity to the market. We have not actively taken on every client but those who we think bring the maturity and business acumen to build out the market. That has been an important focus for us to take a considered approach. Our motto is assist companies from start-up to exit, working with and alongside



companies and other stakeholders through the entire corporate lifecycle. It is important to get the base right, so we have created a 'start-up pack', freely available to download.

There is a very real frictional cost of capital for early-stage companies, which we have tried to address head-on. We openly provide documents addressing employment and IP issues, which we see as the pain points in early-stage companies. We have been trying to build the market across Europe by providing localised start-up packs in each jurisdiction. Again, we are trying to build out the market and do our bit to help where we can.

**Our motto is assist companies from start-up to exit, working with and alongside companies and other stakeholders through the entire corporate lifecycle. It is important to get the base right, so we have created a 'start-up pack', freely available to download. There is a very real frictional cost of capital for early-stage companies, which we have tried to address head-on.**

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# North America



## THE UNITED STATES

Several decades prior to the UN Treaties, the Marihuana Tax Act of 1937 was the beginning of the end of legal cannabis use in the United States, introducing a steep levy and triggering a wave of arrests that did untold damage to the hemp industry. Some 82 years and dozens of crusades later, the US is moving towards the end of prohibition, where a multi-billion-dollar industry awaits.

A regulatory domino effect is occurring across the country, and while cannabis remains a controlled substance at the federal level, many individual jurisdictions have legalised consumption in various forms, from medicinal to full recreational adult use.



**Medicinal cannabis is currently legal in 33 states, and in May, the Alabama Senate approved a medicinal cannabis bill, likely making it the 34th state to embrace change.**

As far back as 1996, California removed state-level criminal penalties on the use, possession and cultivation of marijuana by patients who possess a 'written or oral recommendation' from their physician that he or she

'would benefit from medical marijuana'. Patients diagnosed with any debilitating illness where the medical use of cannabis has been 'deemed appropriate and has been recommended by a physician' are afforded legal protection under this act.

On 9 October 2015, Governor Jerry Brown signed three bills to regulate California's medical cannabis industry: AB 243, AB 266, and SB 643. The bills cover licensing requirements for cultivation, transportation, distribution, and more.

Proposition 64, passed by 57.13% of voters on 8 November 2016, added five new medical cannabis statutes to the Health and Safety Code, including greater protection for patients and exemption from paying retail sales tax on cannabis for certain registered individuals.

As of 2019, California's medical cannabis programme website stated: 'Per Health and Safety Code Section 11362.77, a qualified patient or primary caregiver may possess no more than eight (8) ounces of dried marijuana per qualified patient. In addition, a qualified patient or primary caregiver may also maintain no more than six (6) mature or twelve (12) immature marijuana plants.'

California's experience was observed eagerly by other states, and sections of wording in California's original state law on medicinal cannabis were copied almost verbatim by others, including the State of Washington in 1998, and Alaska in 1999. A slow trickle of counties followed in the proceeding years, approving

their own domestic regulations to allow the prescription of medicinal cannabis.

Recreational cannabis is now legal in 11 US jurisdictions. The tipping point occurred on 6 November 2012, when Colorado and the State of Washington were the first two jurisdictions anywhere in the world to fully legalise cannabis for adult use. Two years later, the states of Alaska and Oregon, as well as Washington D.C., joined them.

In 2016, voters in four further states, California, Massachusetts, Maine and Nevada, also voted to legalise recreational cannabis. In January 2018, Vermont became the first state to legalise cannabis through a state legislature.

Despite their apparent similarity, the state laws are inconsistent and, coupled with federal criminalisation, make cannabis one of the most complex market verticals in which to operate. The industry throws up a daunting array of ever-evolving laws, policies and practical challenges.

## Recreational Cannabis in Illinois: a Snapshot



The Illinois General Assembly passed a cannabis legalisation bill the week of 26 May 2019, and Governor J.B. Pritzker has signed it into law.

### ON SALE:

Consumers will be able to buy cannabis for recreational use from licensed vendors as of 1 January 2020.

### WHO CAN BUY:

Consumers aged 21 and older will be able

to buy products from licensed vendors in Illinois – with or without a medical cannabis card.

### WHO CAN SELL:

Medical cannabis dispensaries will be the only legal sellers of cannabis for recreational use in January 2020. From mid-2020, Illinois will grant additional licences to new stores, processors, cultivators and transporters. County and municipal governments will have the power to decide whether to allow sellers to operate in their area.

### HOW MUCH:

Citizens will be able to legally possess 30 grams, or about an ounce, of cannabis flower. The legal limit for cannabis concentrate is 5 grams. The limit for cannabis-infused products, such as edibles or tinctures, is 500 milligrams of THC. Illinois visitors are allowed to possess half of these amounts.

### WHERE TO CONSUME:

It will be legal to smoke in one's own home and on-site in some cannabis-related businesses. Use is prohibited in any public place, such as streets or parks, motor vehicles, near and on school premises, near individuals under the age of 21, and near on-duty school bus drivers, police, firefighters or correctional officers.

### HOME-GROWN:

Medical cannabis patients can grow five plants at a time. Non-patients are not allowed to grow cannabis at home – this carries a civil penalty of US\$200 for growing up to five plants. Only Illinois' 20 existing licensed medical cannabis cultivation facilities will be licensed to grow cannabis initially. In 2020, 'craft growers' will be able to apply for licences to cultivate up to 5,000 square feet.

### TAXED:

Purchases of cannabis flower or products with less than 35% THC carry a 10% tax. Cannabis-infused products such as edibles come with a 20% tax. Products with a THC concentration higher than 35% come with a 25% tax.

## SAFE Banking Act

One of the main roadblocks stymieing global cannabis trade is the inability of US banks to handle transactions or do business with cannabis firms without fear of federal prosecution, or worse, being locked out of the financial system under sanction.

Despite the moves at state level, cannabis is a Schedule 1 drug at the federal level, akin to cocaine and heroin via the classification system. Federally insured banks are forbidden from dealing with cannabis businesses, leading to problems all over the world where firms rely on either US capital, allow US dollars as a currency, or use the services of a lender based in the US.

The Secure And Fair Enforcement (SAFE) Banking Act was introduced to Congress in May 2017 under the sponsorship of Senator Jeff Merkley (D-OR). The legislation would limit the ability of federal banking regulators to interfere with the actions of a depository institution handling a legal cannabis business. Specifically, the act would stop regulators from ending or limiting either deposit or share insurance of such a financial institution for the single reason that it does business with a cannabis firm. The Act would also prohibit regulators from pressuring financial institutions to not do business with those companies.

The SAFE Banking Act was drafted to resolve issues faced by legal cannabis companies operating in the United States, and to eliminate the grey areas that exist between the legal standings of particular states who have legalised cannabis, and the non-legal status of cannabis at the federal level.

Firms doing legitimate business in states that have legalised cannabis have reported problems dealing with banks and lenders on account of concern among those institutions about punishment on the federal level. Businesses have found it almost impossible to obtain loans or acquire capital in order to expand, or obtain insurance to deal with incidents that impact their business or their employees.

The Act has not made its way through Congress without hiccups, having been re-introduced and re-written since its first appearance. Banking lobbyists and financial institutions have been pressing hard for approval, however, and the American Bankers Association, representing the US\$17 trillion US banking sector, testified to Congress in support of the bill. Banks, including Wells Fargo, HSBC North America, Key Bank, M&T Corporation, PayPal, and Prudential, are also supporting its passage.

While the US political landscape undergoes a sustained period of tumult, the advancement of states interested in exploring medicinal and recreational cannabis remains positive and constant.

The removal of vocal anti-cannabis advocate Attorney General Jeff Sessions following the 2018 midterms is seen as a huge boon to cannabis firms, given his replacement William Barr's moderate outlook on the sector and willingness to let punishments for banks interested in cannabis slide.

An updated version was reintroduced in March 2019, which the House Financial Services Committee approved. The vote passed 45–15 in support of cannabis banking, with 11 Republicans onside.

As of June 2019, the bill had 152 co-sponsors, making it the strongest supported of any cannabis reform legislation to date, but still short of the support required to pass it into law.

Additional lobbying efforts continue while the legislation returns to the House Judiciary Committee for further consideration.

'Thousands of employees, businesses and communities across this country have been put at risk because they have been forced to deal in piles of cash,' said Ed Perlmutter (D-CO) in a statement. 'The SAFE Banking Act is focused solely on taking cash off the streets and making our communities safer.'

## Other Notable Developments

A major regulatory initiative viewed as a huge step towards federal legalisation is the US Farm Bill, passed on 12 December 2018, and signed into law by President Trump on 20 December 2018.

The bill legalises production of hemp, which it defines as any Cannabis sativa plant with THC below 0.3%. It removes hemp from the Controlled Substances Act, ensuring it is not an illegal substance under federal law.

The US Food and Drug Administration (FDA) issued a statement on the regulation of cannabis-derived products on 20 December, stating it would take 'new steps' to clarify its public health obligation in this area.

### United States Medicinal Cannabis Due Diligence Summary



#### LAW:

State regulations.

#### DATE APPROVED:

1996–2019.

#### GENERALITIES:

Medicinal legal in 33 states and the District of Columbia.

#### PRODUCTION:

Some states only allow acquisition of pharmaceuticals, others allow cultivation for personal use, and others use a dispensary model.

#### PRODUCT:

Resins, extracts, oils, edible products or dried plant.

#### CONTENT/POTENCY:

Varies from 0.3% to 5% THC and 5% to 15% CBD, depending on the state; others may have higher degrees of THC.

#### RESTRICTIONS:

Medical prescription.

#### POINTS OF SALE:

Clinics, pharmacies.

#### REQUIREMENTS:

Prescription indicating recommended dose.

#### PROHIBITION/SANCTION:

Physician determines the amount that can be possessed.

#### REGULATORY BODY:

Food and Drug Administration (FDA).

#### OTHER:

Each state establishes its own regulations.



## CANADA

With the eyes of the world watching, the government of Canada legalised, regulated and restricted access to cannabis on 17 October 2018, becoming the second nation globally after Uruguay to do so, and the first of the G7 countries.

Under federal legislation:

- adults can possess up to 30 grams of legally produced cannabis
- adults can grow up to four cannabis plants per household
- the minimum age for purchase and use is 18 years of age, but provinces can increase the age limit
- licensed production of cannabis is controlled by the federal government
- distribution and sale of cannabis is controlled by the provincial government
- new provisions to address drug and alcohol-impaired driving have been established.

The total cannabis market in Canada, including medical and legal recreational products, is expected to generate up to US\$2.6 billion in total sales in 2019.

Alberta currently has the largest number of licensed recreational stores of any province, with 75 outlets.

Unlike its sister provinces, Alberta does not limit producer-affiliated stores, and enables each company to operate up to 15% of all brick and mortar cannabis outlets. In November 2018, the Alberta Gaming and Liquor Commission stopped taking new retail store applications due to a federal shortage, with media reporting that the regulator informed firms it may take as long as 18 months before the ban is lifted.

Supply not meeting demand has been the big story in Canada since the move to legalise full recreational use, causing some shops to close. Shortages have blighted an otherwise positive experience for the country. The problem has been blamed domestically on the regulatory licensing process of the Health Canada Licensed Processors and Cultivators. In response, the Canadian government in May said it will force applicants for cannabis cultivation, processing or sales licences to prove they have a fully functional site before they can apply, in hopes of easing the backlog. About 614 applications were stuck in the queue as of 31 March, according to Health Canada.

The regulator says it approves new licences almost every week, and there are 175 licensed sites across Canada. There are now more than 600,000 square metres of space under active cultivation, the regulator said, enough to produce about 1 million kilograms of cannabis per year, matching the quantity of cannabis consumed in Canada.

There are aspects of regulatory arbitrage between the Canadian provinces that businesses are advised to be aware of; although cannabis is legal all over the country, each district has its own rules on where it can be smoked. The only existing rules consistent in each province under the federal Cannabis Act are a possession limit of up to 30 grams of dried flower (or an equivalent) and a ban on consumption in vehicles.

The largest regulatory change in 2019 concerns the legalisation of edible sales, expected no later than 17 October 2019, 12 months on from the full legalisation of cannabis. Given edibles are more appealing to children, Canadian officials have issued robust guidance on regulation of sales.

## Canada Medicinal Cannabis Diligence Summary



### **LAW:**

Controlled Drugs and Substances Act, Access to Cannabis for Medical Purposes Regulations (August 2016).

### **DATE APPROVED:**

1999.

### **PRODUCTION:**

Health Canada grants licences for production.

### **PRODUCT:**

Edible products, tinctures, oils, concentrates, capsules and sprays, dried flowers.

### **POINTS OF SALE:**

Directly from a federally licensed seller, registration with Health Canada for home grow, provincial or territorial authorised retail outlets and through provincial or territorial authorised online sales platforms.

### **REQUIREMENTS:**

Medical prescription by authorised healthcare practitioner required, indicating the recommended dose, and a licence granted to the patient.

### **PROHIBITION:**

Production, distribution and sale outside of the regulated system carry criminal sanction. Sanctions vary from fines to up to 14 years in prison.

### **REGULATORY BODY:**

Health Canada.



**” In Canada, the support of the government to recognise the incredible opportunity we have as a country to be world leaders in cannabis would be a key factor in my mind. We have the chance to be world leaders in cannabis, but we need support to make this happen.**

**Megan McCrae,**  
Board Chair  
Cannabis Council of Canada



# LOCAL EXPERT ANALYSIS

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**Daniel Kracov**

*Partner and Co-Chair,  
Food, Drug and Medical  
Device Sector,  
Arnold & Porter*

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## CANNABIS DEVELOPMENTS IN THE UNITED STATES

In the United States, the landscape for regulation of cannabis products remains a patchwork. While cannabis remains scheduled by the Drug Enforcement Administration and thus unlawful at the federal level, thirty-three states and the District of Columbia have passed laws broadly legalising cannabis in some form, and 11 of those jurisdictions have adopted fairly expansive laws legalising cannabis for recreational use. While early in the Trump Administration the Department of Justice rescinded three Obama-era memos that had adopted a policy of non-interference with states that have legalised recreational cannabis, the Administration appears to have moved to a relatively more conciliatory position, under which it is not interfering with the states' decision to permit regulated cannabis within their jurisdictions.

The US Food and Drug Administration has approved prescription drug products derived from cannabis, including Marinol® (dronabinol) for anorexia, nausea, and vomiting in certain patient populations, and Epidiolex® (cannabidiol) for seizures in very young children with certain rare conditions. In addition, on December 11, 2018, Congress enacted the 2018 Farm Bill, which legalised hemp, a non-psychoactive varietal of the cannabis plant. While this step does not impact psychoactive medical

or recreational cannabis, it opens up hemp -- and constituents of hemp such as cannabidiol (CBD) -- to broader consumer and industrial uses, subject to other statutory provisions that may limit uses.

Recently, much of the attention in this area in the US has focused on the burgeoning market in foods and dietary supplement products containing CBD. While FDA currently takes the position that CBD is not lawful for use in conventional foods and dietary supplements due to the prior use of CBD in drug clinical studies and the Epidiolex approval, FDA has refrained from taking action against such food and dietary supplements absent disease-related claims, and the agency is being pressed to adopt an enforcement discretion-based approach or engage in rulemaking that would explicitly permit CBD as a food and dietary supplement ingredient. However, at this time it is unclear the extent to which FDA will ultimately continue to permit use of CBD in foods, and -- if so -- at what levels. While use of CBD in certain other products appear acceptable after the legalisation of hemp -- such as safe and suitable uses in topical cosmetics without medical claims -- FDA's position on inhaled non-psychoactive CBD, such as via vaping -- is unclear at this time.

**” While early in the Trump Administration the Department of Justice rescinded three Obama-era memos that had adopted a policy of non-interference with states that have legalised recreational cannabis, the Administration appears to have moved to a relatively more conciliatory position**

**Daniel Kracov,**  
Partner and Co-Chair,  
Food, Drug and Medical Device Sector,  
Arnold & Porter

# Europe





**E**urope's cannabis market is estimated to reach a value of about €123 billion by 2028 and will likely become the world's largest legal market over the next five years, according to our research. Several countries have announced new legislation, and over €500 million has been invested in European cannabis businesses.

The European Union abides by global standards on cannabis, and no national government in the bloc supports recreational sale of cannabis; all countries have prison sentences for illegal supply. However, several governments have drafted laws in the last few years, and there are certain cities hoping to buck the trend. **Spain, Portugal, Denmark, Malta, Luxembourg, Greece** and **The Netherlands** are the European states most likely to open a full recreational adult market in the coming decade.

Europe's most recognisable recreational cannabis environment is the **Netherlands**, where coffeeshops selling cannabis sprung up in the 1970s. They are licensed by the municipality, although two-thirds of Dutch municipalities do not allow them. There were 591 coffeeshops in 2014, with nearly one third in Amsterdam; numbers have been falling dramatically since 2000.

Sale and personal possession remain punishable by imprisonment under law, as elsewhere in Europe, but coffeeshops are tolerated provided they adhere to strict criteria published in a directive of the public prose-

cutor. Production of the stock is also illegal, although authorities acknowledge this has spawned a grey area, known in the Netherlands as the 'back door problem'.

Medicinal cannabis is firmly on the agenda at EU level, however, and talks in Brussels are underway as regards a harmonised set of laws that will apply across the bloc to enable easier access for funding and to provide a platform for research.

On 4 December 2018, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) published its first report on medical use of cannabis and cannabinoids. The report was pushed out along with a background paper on the impact of cannabis and cannabinoids when used to treat certain medical conditions.

The Netherlands has Europe's most mature medicinal cannabis programme, and is a recognised supplier to many other countries, including **Germany**.

In the last 18 months, the **UK, Greece, Portugal, Ireland, and Malta** have legalised medical cannabis products, while the Netherlands, **Denmark** and Germany have either issued cultivation licences or plan to introduce a tender for global cannabis producers. Key conservative markets, including France, Ireland and Italy, have also signalled their intent to review the legal status of medical cannabis.

Firms seeking to enter the EU medicinal cannabis market need to be aware of the fractured regulatory picture between states, but also the existence of the European Medicines Agency, which is the bloc's medicines supervisor. Firms can obtain certain permissions from the EMA, but will almost certainly have to satisfy domestic regulators in a state they wish to operate.

The EU operates on a regulatory passporting scheme for certain services, whereby firms can obtain permissions in one state that will allow them to serve another EU jurisdiction without having to jump through multiple costly regulatory hoops in each area they want to operate. Businesses cannot passport medicinal cannabis services around the bloc as yet; however, officials in Brussels are laying the groundwork for a harmonised approach to supporting research into medicinal cannabis, the first necessary step.

The Netherlands legalised the medicinal use of cannabis in 2000, launching the Bureau for Medicinal Cannabis (BMC) to support a strong pharmacological industry. Bedrocan Medical Cannabis has the monopoly of all medicinal cannabis production and distribution in the Netherlands. All cannabis passing via the BMC is produced by Bedrocan – which developed and standardised domestic demand and exports five types of pharmaceutical cannabis flos (flower) medications prepared with different percentages of THC and CBD.

Medicinal cannabis in the Netherlands is produced and controlled by the Medicinal Cannabis Agency, and can be purchased in pharmacies only when the patient is in possession of a medical prescription. Medicinal use has increased dramatically over the past decade, with over 50,000 patients now being prescribed cannabis in the Netherlands.

Across Europe, 'cannabis social clubs' have begun to appear, purporting that if cultivation of one cannabis plant is tolerated for one person's use, then 20 plants together might be tolerated for a club of 20 people. The principle runs contrary to European law

and no national government recognises the clubs; however, some regions in Spain have attempted to pass regulations to stem the proliferation of such clubs.

In 2015, the Spanish Supreme Court said that 'organised, institutionalised and persistent cultivation and distribution of cannabis among an association open to new members is considered drug trafficking'.

## GERMANY

Germany's standing as the top European market makes it a key jurisdiction for firms looking to become the number one global cannabis company, and it has attracted significant attention from Canadian businesses.

Medicinal cannabis was legalised by a 2017 law that also established the German Federal Institute for Drugs and Medical Devices (BfArM), in part to oversee the delivery of the tendering programme that all potential licensees would have to satisfy.

Two years and multiple delays and court cases later, Germany finally appears ready to hand out licences to three firms: Canada's Aphria and Aurora Cannabis and Germany's Demecan. There has been no official announcement from BfArM, due to impending legal action from one of the many unsuccessful firms.

Provisionally the three companies will split a four-year tender to grow 10,400 kilograms between them. Aphria won 5 of the 13 lots, with Aurora Cannabis and Demecan handed 5 and 3 lots respectively. The tendering process was cancelled in July 2018, only to be restarted a week later. Eventually, the 3 companies were selected from a field of 79 entrants. Firms were graded on domestic cultivation, based on a points system focused on infrastructure, quality standard, security plans and price.

**In the last 18 months, the UK, Ireland, Greece, Portugal, Malta, and Belgium have legalised medical cannabis products, while the Netherlands, Denmark and Germany have either issued cultivation licences or plan to introduce a tender for global cannabis producers.**

Cannamedical Pharma, one of the top German suppliers, estimates 30,000 patients were served in 2018 with imports of 22,000 kilograms. Given the legal limits of the new licensing system, it is unlikely enough cannabis will be grown to meet the demand. Observers see this as the government testing the water to calculate the depth of a future, more liberal, market. Germany has been dependent on cannabis imported from Canada and the Netherlands, and will continue to import in the coming years to compensate for the domestic shortfall.

## Germany Due Diligence Summary



### LAW:

Narcotics Law.

### DATE APPROVED:

19 January 2017.

### GENERALITIES:

Access to medicinal cannabis products for ailments such as epilepsy, multiple sclerosis, chronic pain or nausea, and for research.

### PRODUCTION:

Importation of cannabis from other countries until it can be replaced by domestic industrial production. Self-cultivation prohibited.

### PRODUCT:

Pharmaceutical products, cannabis extracts or dried flower buds.

### POTENCY:

Same as contained in existing medications.

### POINTS OF SALE:

In pharmacies.

### REQUIREMENTS:

Medical prescription with recommended dose, by a licensed physician.

### PROHIBITION:

Limited to amount indicated on prescription.

### REGULATORY BODY:

National Ministry of Health and Federal Institute for Drugs and Medical Devices (BfArM).





## UNITED KINGDOM

Another systemically important European market alongside Germany is the UK, which is home to one of the world's largest cannabis firms by market capitalisation, GW Pharmaceuticals.

As a global financial capital, London is the top European destination for business, and only New York ranks higher anywhere else in the world for stock exchanges, access to capital via its concentration of public and private banks, and trading and insurance companies.

Domestically, it took a high-profile public health campaign running in the British media for the status of medicinal cannabis to be changed. From 1 November 2018, specialist doctors could for the first time in history prescribe medicinal cannabis. The government announced a two-part review into the use of cannabis-based products for medicinal purposes, and stated that synthetic cannabinoids should remain in Schedule 1 to the 2001 regulations pending periodic review.

On 31 October 2018, the NHS sent a letter providing support and guidance following the rescheduling of certain cannabis-based products for medical use to clinicians in the UK. The letter set out the expectations of what this regulatory change will mean in practice for clinicians working in the NHS and in private practice in England. Despite the initial fanfare, and with around 80,000 people on the waiting list, British doctors have been loath to prescribe medicinal cannabis.

Efforts at local level have begun to improve the situation, with the launch of the Beeches Consulting Rooms – Britain's first medical cannabis clinic. The Medical Cannabis Clinics (Britain's first chain of specialist medical cannabis clinics) is set to open two more clinics in the summer of 2019. This has helped achieve a historic milestone by enabling the importation of the UK's first bulk shipment of cannabis-based medicine since the 2018 decision.

Britain's government is currently gridlocked due to Brexit, with little chance of any major

legislative initiatives making their way through parliament, and the Conservatives in their current state, having made concessions on medicinal cannabis in 2018, are unlikely to entertain more liberal policy changes. However, the Boris Johnson administration has hired senior advisers with a background in pro-legalisation groups or who have expressed support in the past, most prominently adviser Blair Gibbs and political secretary Danny Kruger.

However, the impending exit from the European Union single market would remove the right of firms to gain a licence in the UK and passport across into other EU states, should medicinal cannabis attain the status of such a service.

Cannabis investors have been warned to consider any potential changes to the UK's Proceeds of Crime Act 2002 when investing in jurisdictions where the legal status of cannabis differs from that of Britain, such as in Canada.

Under the act, 'proceeds of crime' means any known or suspected benefit won from criminal conduct. Offences are broadly drawn and often unclear. There is a carve-out for criminal conduct that is illegal in the UK but legal in the country in which it occurs: the so-called 'Spanish Bullfighter' exception.

Some UK companies have leaned on the Spanish Bullfighter exception in dealing with overseas cannabis-related businesses. The exception only applies to offences that in the UK would result in a maximum custodial sentence of 12 months or less, whereas the maximum sentence in the UK for supplying or being concerned in the production of cannabis is 14 years.

More material changes to the POCA concern the reform of the suspicious activity report (SAR) regime. The aim of SARs is to improve the prevention, detection and prosecution of money laundering and terrorist financing in the UK, but the system has long been recognised as not fit for purpose.

Since the introduction of the POCA there have been various proposals to amend the SAR regime, and it was a surprise to many that in July the Law Commission – the statutory arm-length body charged with keeping the UK's legislation in check – recommended retaining the current SAR regime. It has suggested minor refinements aimed at easing pressures encountered by banks.

The Commission declined to recommend a move towards corporate, rather than individual liability, a source of concern for Money Laundering Reporting Officers, and firms have been advised that further changes may come from the Ministry of Justice, which is seeking to introduce a broad corporate offence of failing to prevent economic crime, similar to US bribery laws.

## OTHER NOTABLE DEVELOPMENTS

On 1 March 2018, **Greece** adopted the bill 'Provisions for the production of end products of medicinal cannabis', and has been working to fast track a regulatory licensing system for medicinal cannabis firms.

It is noteworthy that the majority of parliamentary political parties supported the bill, although opposition parties voted against the bill in the final vote. The bill proposes that Greece's medical patients can access medicinal cannabis products, in recognition of their benefits for specific illnesses. It also proposes that individuals can cultivate cannabis for the sole purpose of producing medicinal cannabis products in the country. Finally, the bill recognises the economic potential of medicinal cannabis, with the creation of new jobs and the potential of exporting products to the international market. In other countries, medicinal cannabis is limited to pilot projects.

In **Denmark**, cannabis for therapeutic purposes is still illegal, but a pilot programme was launched on 1 January 2018 for a limited number of patients with specific health problems (i.e. multiple sclerosis, chronic pain and nausea). It has proved so successful some commentators are calling on the government to end it early and launch a full-blown programme. As of June 2019, Denmark had received applications from 12 companies for licences.

Italy's diametrically opposed positions to recreational CBD product and medicinal cannabis were thrust into the spotlight when the country's highest court outlawed the sale of cannabis light products, in a landmark ruling handed down in May. The Supreme Court of Cassation said existing laws do not permit the sale or transfer, for any reason, of products 'derived from the cultivation of cannabis', and that products currently on sale including oil, leaves, inflorescences and resin must be removed from shelves.

The decision was a heavy blow to Italy's burgeoning 'cannabis light' industry, and came amid a right-wing government push that may derail the country's attempt to re-establish itself as a global hemp superpower. Weeks later, Italy surprised the market with a tender announcement, calling for firms to supply it with medical-grade cannabis, following a shortfall.

The Italian Ministry of Defence (MOD), which has the only licence to grow domestically and controls the country's production, opened a four-week window for firms to bid. It hoped to address Italy's growing demand for medical cannabis but also to diversify away from Bedrocan, which supplied around 450 kilograms in 2018 (around two-thirds of Italy's supply). On 15 July, the MOD announced that Aurora Deutschland had landed a government contract to supply medical cannabis to the Italian government, after the other three firms left in the running were eliminated over paperwork errors.

A medical cannabis trial was announced in Ireland in June 2018, following several delays related to supply. A bill was first passed by the Dail (Irish parliament) in December 2016. The pilot is set to last five years.

Ireland's Health Ministry has unveiled a plan to decriminalise possession of small quantities of narcotics, provided the substance is for personal use and it is a user's first offence. Health Minister Simon Harris called this a Health Diversion Approach, whereby arrestees would be initially given a mandatory medical appointment and check up on the first offence, followed by the possibility of a police warning on the second offence, and on the third, a punitive judicial response. Irish policy makers have been trying to adopt a health-focused approach to narcotics since 2015.

**Poland** legalised medicinal cannabis in 2017, but it took 12 months for the first non-state company to gain approval to import medical cannabis into the country, and not until 2019 was cannabis available for sale in pharmacies. In a landmark move for business, on 25 October 2018, the Polish Ministry of Health granted Aurora Deutschland GmbH the green light for its first shipment of medical cannabis to Poland.

**Romania's** Health Ministry has reportedly created a commission to analyse the potential for legalising cannabis for medical use in the country. Currently derivatives and extracts are permitted for medical use for specified conditions, as controlled by The Narcotic Drug Regulations, but local pharmaceutical operations have been slow to market and distribute cannabis medications to date. The new commission will investigate the potential for the use of cannabis flower for medical use. This could reinvigorate the country's once robust hemp cultivation and production industries.

**The Netherlands** has begun looking at revamping its laws surrounding cannabis production and distribution for recreational use. Paradoxically, while the country has long been at the forefront of the cannabis world, to date retail of cannabis has been licensed in the Netherlands, while production and dis-

tribution have not. This has meant grey areas, without quality assurances.

The new process has begun with pilot schemes, whereby a variety of models are being tested on a small scale with participating retailers. This will seek to determine the suitability of production and distribution models, varying from small-scale producers who are registered by the retriailer, to the state monopoly model that is used for production and distribution in the Netherlands for medical cannabis.

Politicians from **Luxembourg's** ruling coalition have suggested that the country will be the first in Europe to fully legalise and regulate the entirety of the cannabis market. The Health Ministry will unveil the legislative path the country will take this autumn, and aim to fully legalise within two years. So far policy makers have suggested that non-residents may be barred from purchasing cannabis, to prevent drug tourism as approximately 200,000 people cross the border to work in the Duchy, daily. Further, home growing may be proscribed to enable regulators to ensure quality. There is an expectation that small, wealthy Luxembourg's bold move will set off a "domino effect," encouraging reticent EU neighbours to follow suit.

*For a more in-depth look at the European market, download the Prohibition Partners 4th European Cannabis Report™.*



# “ Analysts predict that the European legal cannabis market will be worth €123 billion by 2028.

**Michael Corcoran**

Partner,  
Hill Dickinson



# LOCAL EXPERT ANALYSIS

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**Ian Dodds-Smith**

*Partner and Co-Chair,  
Food, Drug and Medical  
Device Sector,  
Arnold & Porter*

## DEVELOPMENTS IN THE UK RELATING TO CANNABIS-BASED MEDICINAL PRODUCTS & PRESCRIPTION UNDER THE NHS

### INTRODUCTION

In November 2018, when cannabis-based products for medicinal use (CBPMs) were re-scheduled under the UK's Misuse of Drugs legislation, it became legal for specialist doctors, to prescribe and for pharmacists to dispense, CBPMs without holding a licence from the Home Office. This was so even where such products did not have a marketing authorisation issued as, in principle, such products could, thereafter, be supplied under the UK's national medicines legislation governing supply of unlicensed medicines. In summary, this allows supply of "specials" which are products that may be manufactured in the UK or imported to the order of a doctor (and certain other categories of persons) to enable the doctor to meet the special therapeutic needs of an individual patient that cannot be met by a licensed product. However, although there has been considerable publicity concerning the establishment of special clinics able to prescribe on private prescription, less than 10 NHS prescriptions were issued for CBPMs between November 2018 and March 2019, according to the NHS Business Services Authority.

The dearth of prescriptions arises for two principal reasons. First, the prescribing doctor

normally had to be on the Specialist Register of the General Medical Council and associated prescription guidance was fairly restrictive. Secondly, the relevant authorities controlling the purse strings for NHS funding had to agree to fund the cost of such an unlicensed product. In practice, it is notoriously difficult for doctors to obtain approval for so-called Individual Funding Requests. Local arrangements vary, but the opinion of the doctor wishing to prescribe may be "second-guessed" having regard to the assessment by others of the available evidence of safety and efficacy and of the relationship between the perceived benefits and risks and the costs of funding, particularly on a long term basis.

### A REVIEW OF PROCEDURES

This situation has dashed the high expectations of many patient representatives who thought that the change in the law in 2018 would ease substantially the pathway to prescription. This led, in March 2019, to an intensification of lobbying by such representatives and the Secretary of State for Health responded by asking NHS England to review the practical barriers to patients accessing clinically appropriate cannabis-based products in the NHS and to recommend how these barriers might be overcome.

## THE REPORT

The Report by NHS England and NHS Improvement that followed this review was published on 8 August 2019 and its conclusions on the major barriers to NHS use are said to be:

- The reluctance of clinicians to prescribe CBPMs because of the lack of evidence of efficacy and safety, for any of the indications under consideration, derived from good quality randomised controlled clinical trials (“RCTs”).
- The reluctance to fund prescription given the costs involved for sourcing imported products. NHS Trusts had reported that, in the absence of quality evidence of efficacy and safety, it was unlikely that the prescription of CBPMs would be routinely funded.

The Report makes various proposals on how improved information and guidance on prescription of CBPMs can be made available to doctors and patients, but this does not go to the core of the problem which concerns therapeutic evidence and cost.

## CLINICAL EVIDENCE AND QUALITY

The Report emphasises the absence of RCTs of the type normally required to obtain a marketing authorisation and states that the evi-

dence currently available largely consists of small observational studies which are not a reliable basis for general prescribing of any medicine. The Report also concludes that better information is required on imported products to establish they have been manufactured to GMP standards and have consistent ratios of CBD to THC, between batches. The Report encourages exploration of the options for UK manufacture.

## NICE GUIDANCE

The reluctance to fund the prescription of CBPMs is likely to be enhanced by the recommendations of the National Institute for Health and Care Excellence (“NICE”) due in October 2019. Their draft advice was issued for consultation in August 2019. This does not recommend use in the NHS of CBD or THC to manage chronic pain in adults or to treat spasticity, unless as part of a clinical trial. NICE said it was also unable to make a recommendation on use of CBMPs in treatment resistant severe epilepsy because of lack of good quality evidence, but an express recommendation against use was also not made as “this would restrict further research in this area and would prevent people who are currently apparently benefiting from continuing with their treatment”. It, therefore, made only research recommendations.

## CONCLUSIONS


The Report recommends that the National Institute for Health Research should support extensive research in this field, while noting the possibility of useful evidence being developed outside the framework of a RCT (such as through a national patient registry for all patients prescribed a cannabis-based product). However, it is questionable whether there will be any real change in the status quo without the conduct of RCTs and there is no prospect of the results of properly designed RCTs being available for some time to come. The design of such studies and the clinical endpoints adopted are not straight forward and the costs are very high.

If the results of studies are favourable there will be a strong pharma-political and financial incentive for sponsors to seek a marketing authorisation. After grant, the further supply of unlicensed products for the relevant indications will not be authorised because there will no longer exist a “special need” that cannot be met by a licensed product. In the meantime,

private prescription is likely to remain the only avenue to access, despite the Report noting that this imposes on families “a very considerable and unsustainable financial burden”.

The Report’s conclusions will disappoint many. The Chair of the Medical Cannabis Clinicians Society has said that the Report is more promising and inconsistent with NICE’s approach. He states that NICE’s position represents “a sad day for many thousands of people in the UK who are benefiting from, or who would benefit from wider availability of cannabis medicines”. He argues that the “pharmaceutical model of the [RCT is] not an appropriate methodology for the assessment of cannabis efficacy”. However, both reports are a reminder that the UK regulatory framework and increasingly the practice of medicine, is built on the assumption that public health is best protected by use of products with marketing authorisations granted following independent assessment of their quality, safety and efficacy based on standardised particulars relevant to those criteria. Widespread prescription on the NHS of costly products available outside this framework is unlikely.





**” The UK regulatory framework and increasingly the practice of medicine, is built on the assumption that public health is best protected by use of products with marketing authorisations granted following independent assessment of their quality, safety and efficacy based on standardised particulars relevant to those criteria.**

**Ian Dodds-Smith,**  
Partner and Co-Chair,  
Food, Drug and Medical Device Sector,  
Arnold & Porter



# Latin America





**S**outh America has been at the heart of the 'war on drugs' since the 1970s, and has long taken radical approaches to dealing with social problems caused by the illicit trade. Cannabis worth US\$125 million was sold legally in the region in 2018, according to our research, and we predict sales will increase to US\$12.7 billion over the next decade. Latin America has some of the most progressive attitudes to recreational cannabis use anywhere in the world, and has become a favourite destination for large international cultivation companies to expand into.

## URUGUAY

In 1974, Uruguay legalised drug possession for personal use, and in 2013 it became the first country in the world to pass legislation to legalise the entire supply chain of cannabis. The most recent statistics from the government department responsible for regulation of cannabis, Instituto de Regulación y Control del Cannabis (IRCCA), show there are 43,694 registered cannabis users from a total population of 3.5 million in Uruguay.

The thrust of the legislation is a series of restrictions that ensure users can only access cannabis through one of three methods:

- Home cultivation; registration of individuals through the IRCCA began on 27 August 2014. Home cultivation allows for a maximum of six flowering female plants per household with a maximum total yield of 480 grams per annum. Any excess cannabis produced is seized by the IRCCA.
- Cannabis clubs; registration opened on 30 October 2014. The clubs must contain between 15 and 45 members and they can grow up to 99 plants per year. No individual member may take more than 480 grams of the drug per year. Similar to home cultivation, clubs must register with the IRCCA and hand in any excess cannabis produced.
- Purchasing through pharmacies; individuals who are registered with the IRCCA can buy up to 40 grams a month, with a 10-gram weekly limit, through a fingerprint ID scan.

Uruguay became a test case for the rest of the world to observe the impact on public health, and business, as the first country to fully legalise cannabis. However, four years on from the first sales (and two years since it started selling in pharmacies), there are only about 14 pharmacies with permission to sell cannabis in Uruguay, almost all of them in the capital, Montevideo.

Pharmacies have reported a resistance to selling cannabis due to the financial headaches involved. Uruguay's economy is dollar-based, and transactions are routed through US banks, which are forbidden from servicing accounts that 'involve the manufacture, importation, sale, or distribution of a controlled substance'.

US lenders sent notes to Uruguayan customers informing them their accounts would be shuttered if they got into the cannabis business. Cash-only transactions became the norm, similar to the situation in the first US states to allow sales of cannabis, deterring more pharmacies from entering the industry.

Production has also been dogged with issues as there are only two suppliers contracted by the government. Farmers are also inexperienced, with early batches being rejected. The IRCCA reports a black market that is around the same size as the regulated sphere, with about half a million cannabis users, not including tourists, who acquire cannabis by other means.

Although an early mover, the future of cannabis in Uruguay is heavily dependent on links to events at the US federal level and any easing of sanctions for the banks that take on cannabis business clients. Many Uruguayan pharmacies and dispensaries are holding talks with Canadian banks following Canada's move to decriminalise cannabis use, and experts believe this could be one way around the issue.

## Uruguay Medicinal Cannabis Due Diligence Summary



### LAW:

Article 5 of Law 19172 and Decree 46-015.

### DATE APPROVED:

7 January 2014.

### NOTES:

Cannabis for scientific and medical purposes permitted.

### PRODUCTION:

Institute for the Regulation and Control of Cannabis issues licences for research purposes or pharmaceutical uses. Self-cultivation allowed.

### POTENCY:

THC lower or equal to 9%; CBD greater or equal to 3%.

### RESTRICTIONS:

Max. 40 grams a month. All forms of direct or indirect advertising, promotion or sponsorship are prohibited.

### POINTS OF SALE:

Clinics and pharmacies, or through the recreational system (self-cultivation and social clubs).

### REQUIREMENTS:

Medical prescription.

### PROHIBITION/SANCTION:

Warning, fines, administrative sanctions and possible criminal charges.

### REGULATORY BODY

Institute for the Regulation and Control of Cannabis.

## MEXICO

In 2017, a bill supporting the use of medicinal cannabis was passed into law in Mexico, but it took until 30 October 2018 for Mexico's regulatory agency Cofepris to publish regulatory guidelines on the legal status.

The new laws were considered strict, stating only imported cannabis products that contain less than 1% THC are approved for use. Cultivation is restricted solely to scientific research.

Shortly afterwards, Mexico's Supreme Court set a binding precedent, that the country's ban on consuming cannabis – both medicinally and recreationally – was unconstitutional, following rulings from two separate cases. As the two high-court judgments followed three similar previous rulings, under Mexican law, when chambers of the Supreme Court rule the same way five times on a subject matter it becomes binding precedent.

Lawmakers are thrashing out a cannabis regulation bill during the summer months, in the hope of passing the legislation ahead of an October deadline. Until the legislation is approved, there is a regulatory grey area, as the court ruling applies only to personal possession and private use, and cultivation in the home for small amounts of sharing, similar to some US states.

It is widely expected that later in 2019, Mexico will join Uruguay and Canada in opening a fully legal adult cannabis market.

Senate Social Affairs Committee passed a draft bill to legalise cannabis cultivation for personal medical use, but the legislation is facing multiple hurdles.

While the right-wing President Jair Bolsonaro is at the helm, it is unlikely that Brazil's reforms are likely to go beyond medicinal, given the premier once tweeted that legalisation would benefit 'traffickers, rapists and hostage takers'. Since taking office, Bolsonaro has amped up the war against drugs, doubling down on punitive measures and stating the military will increasingly have a role in punishments for dealing narcotics.

## BRAZIL

In Brazil, Article 28 of Law 11.344 of 2006 states that holding, storing, transporting or carrying cannabis for personal use does not carry a jail sentence. The acts are still considered crimes, but are subject to warnings and community service. Individuals who grow or harvest plants for personal use are in the same situation, according to the first section of that article. On 28 November 2018, Brazil's



## OTHER NOTABLE DEVELOPMENTS

Continuing the theme of mostly liberal approaches in Latin America, **Argentina** and **Peru** have made minor regulatory changes to cautiously welcome medicinal cannabis, on the back of pressure from activists and patient groups.

- In October 2017, Peru approved its 'Law regulating the medicinal and therapeutic use of cannabis and its derivatives', which entered force in November 2017. The law granted use of registries for groups who wish to access cannabis, such as patients, researchers, importers and public bodies. It also introduced a system of government licences for research, importation, commercialisation and production. Peru's government has issued studies acknowledging the benefits of cannabis for the treatment of symptoms caused by cancer and multiple sclerosis; however, the regulatory regime to ensure correct legal access is still being worked through.
- In 2017, Argentina issued a decree granting patients the right to import their medication while the state initiates the local production of medicinal cannabis for the domestic market. The laws decriminalised the use of cannabis for certain illnesses but did not allow for domestic growing of cannabis for medicine or medical purposes.
- In March 2019, Argentina announced further deregulation guidelines and approval of seed imports to a cultivation location in Jujuy Province; however, the chances of domestic production remain slim. Canadian firm Aphria is the exclusive supplier to the Argentinian medical cannabis market.

*For a more in-depth look at the Latin America market, download the Prohibition Partners Latin America Report™.*

## CARIBBEAN

The CARICOM Commission, an intergovernmental group consisting of 15 Caribbean countries, said in a 2018 report that the ultimate intention of all groups is to end prohibition of cannabis in all forms. The commission called for a 'strictly regulated framework similar to that for alcohol and tobacco, substances which are harmful but not criminalised.'

Given the region's dependence on US trade, it is unlikely any ruling party within the bloc of countries will move out of step with the US. Early in 2018, Jamaica updated its laws to state that possession of up to two ounces, or cultivation of five household plants, would no longer be a criminal offence.

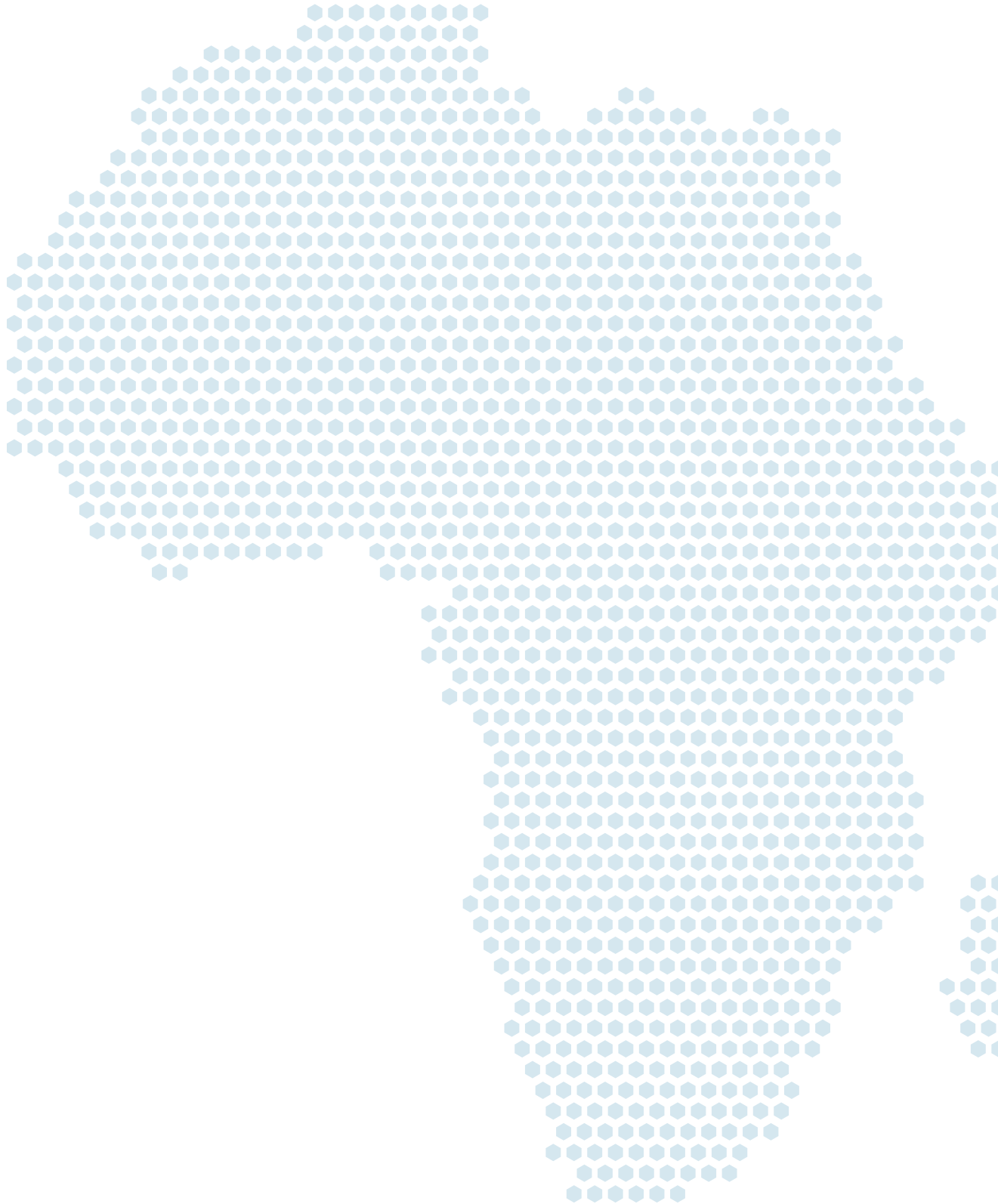
Cannabis for medicinal or therapeutic purposes must be recommended or prescribed by a registered physician or a health professional certified by the Ministry of Health. Tourists or persons who do not reside in Jamaica can apply for a permit that allows them to purchase and possess up to two ounces, or 56 grams.

It is broadly expected that the rest of the Caribbean will follow Jamaica's route, but will go no further until US federal changes are wrought.

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**In 2019, the global landscape is fracturing, as traditionally conservative geographies embrace medicinal cannabis while more advanced territories hint at looser recreational laws.**

# Africa



**A**frica's many ideal climatic locations, agricultural growth potential and under-served economies make it the perfect incubator for cannabis firms, and the continent is emerging as a key market in the global industry. Prohibition Partners research has identified nine African states moving towards some form of regulated market, which are **South Africa, Zimbabwe, Lesotho, Nigeria, Morocco, Malawi, Ghana, eSwatini, and Zambia.**

No state other than South Africa, which has legislation to be worked through in 2020, allows any form of recreational use by law; however, the region has been central to black-market supply globally for decades, and is sitting on a wealth of growing experience, which, if harnessed correctly, could be converted to legitimate medical product for exporting, or for aiding the supply-hit recreational market in Canada.

Our research estimates the potential value of Africa's legally produced cannabis to be worth >US\$7.1 billion annually by 2023 – the bulk of which will come from the recreational market.

## SOUTH AFRICA

In September 2018, the Constitutional Court of South Africa went against government opinion and ruled that in private the use and cultivation of cannabis, known locally as dagga, should not be punished.

Legislators have until September 2020 to write the bill into law and thrash out the details. On the advice of the court, adults may, for their personal consumption, use, possess and cultivate cannabis in any place that is private and not public. The judgment also appears to suggest that adults may carry cannabis on their private person while passing through a public space, provided that it is concealed and is intended to be used for personal consumption in private.

Local experts feel the move to a recreational model may hit the same bureaucratic snags that South Africa's medicinal cannabis sector has endured.

The country's licensing process has been described as onerous and difficult to navigate, and the ruling party's anti-drug stance has limited the availability of permits for private companies seeking permission to produce medicinal cannabis. Experts believe recreational licences could endure the same bureaucratic headache unless the ruling executive fully embraces reform.

## LESOTHO

The tiny state of Lesotho, surrounded entirely by South Africa, made global headlines in 2017 when it became the first African state to legalise production of medicinal cannabis.



The kingdom's black market has been a major supplier to South Africa and other nations for many years, and the government made the decision to support legitimate business in the hope of reversing the social decay caused by the illicit drug trade.

The constitutional monarchy, home to 2 million people, soon welcomed a wave of Canadian firms hoping to take advantage of cheap local labour and the perfect growing conditions of high altitude, and fertile soil. Canopy Growth, Supreme Cannabis, White Sheep Corporation and Halo Labs were amongst the first movers into Lesotho. The local government has also granted Namibian businessman Knowledge Katti a licence to cultivate, manufacture and supply cannabis, indicating wider interest than solely big Western names.

## ZIMBABWE

In 2018, Zimbabwe became the second African state to legalise the production of cannabis (known locally as mbanje) for medicinal purposes. Previously, the country had taken a hardline stance, with prison sentences of up to 12 years for production and possession. While recreational cannabis remains illegal, Health and Child Care Minister Dr David Parirenyatwa announced in a *Government Gazette* statement that individuals and corporations can apply for licences to grow cannabis, and must be licensed by the minister.

Earlier in 2019, Zimbabwe's government said it had approved about 40 applications. Local sentiment is cautious, and legal experts have expressed private doubt about the validity of statements coming from official sources. The total price of a licence is rumoured to hover around US\$50,000 (£40,000). On top of that sum, the annual return fee costs US\$15,000, an application to renew a producer's licence will cost US\$20,000, and a licence to conduct research on cannabis is priced at US\$5,000. An application for an import or export licence is US\$5,000, and an inspection licence, US\$2,500.

Lands, Agriculture, Water, Climate and Rural Resettlement Deputy Minister Vangelis Haritatos said as of March 2019 more than 200 foreign and local investors had applied to begin producing cannabis in Zimbabwe. The licensing process is carried out via Statutory Instrument 62 of 2018 (Dangerous Drugs Production of Cannabis for Medicinal and Scientific Use Regulations). Successful applicants are granted a 12-month permit and are subject to a moderate level of oversight.

There are unlikely to be any further legal and regulatory developments this year in regards to the adult market, as the government concentrates on supporting the new medicinal cannabis industry. Corruption is endemic in the country's political and business networks, and concerns over supply to the black market are hanging over production in Zimbabwe.

## NIGERIA

Although all forms of medicinal and recreational cannabis are illegal in Nigeria, the country has the third highest use rate amongst adult populations in the world at 14.3%, the equivalent of about 15 million users.

A fully legal adult cannabis market in Nigeria would be worth more than GB£3 billion annually, ranking it alongside South Africa as the most lucrative in the entire continent.

There has been little sign of flexibility from the federal government in easing the total prohibition of cannabis, despite several calls in recent years from outspoken domestic figures. In May, the influential Ondo State Governor Rotimi Akeredolu said the government should encourage the cultivation of medicinal cannabis, also known as Indian hemp, and proclaimed that his state would begin to explore the possibility. Akeredolu said it would create thousands of jobs, and boost the economy. In response, Nigeria's drug enforcement agency destroyed 3,900 hectares of cannabis sativa in Ondo State, and reiterated the government's unwillingness to bend.



**The region has been central to black-market supply globally for decades, and is sitting on a wealth of growing experience, which, if harnessed correctly, could be converted to legitimate medical product for exporting, or for aiding the supply-hit recreational market in Canada.**



The country's staunch opposition to legalising cannabis was reaffirmed at a national forum roundtable talk on narcotic drugs held in Vienna in March 2019.

The National Drug Law Enforcement Agency (NDLEA) polices drug activity in Nigeria. The general powers of the Agency are contained in Section 3 of the NDLEA Act. Under the NDLEA Act, which came about via Decree Number 48 of 1989, the possession or smoking of cannabis, or even allowing one's premises to be used for dealing in cannabis, can result in a prison sentence from 15 years to life. Its precursor, the Indian Hemp Act, was even tougher, carrying the death penalty as punishment.

## OTHER NOTABLE DEVELOPMENTS

**Morocco** is considered an 'emerging player' in the global pharmaceutical market due to key factors such as its location and political stability. Despite this, all forms of cannabis are currently illegal. Moroccan cannabis is a popular strain in the coffeeshops of Amsterdam, and is the top global source of cannabis resin according to the UN Office for Drugs and Crime. All attempts to ease domestic laws have been torpedoed repeatedly over the last decade. Under Moroccan law, the sale and consumption of cannabis is outlawed, but tens of thousands of farmers still grow and sell it to tourists who have visited Morocco since the 1960s, hippie movement. Chefchaouen, the 'Blue Pearl' city, is considered Morocco's main hub of cannabis production.

In March 2017, **Zambia's** Minister of Home Affairs, Stephen Kampyongo, said under existing national laws, the cultivation of medicinal cannabis was permitted under Section 9 of Zambia's Narcotic Drugs and Psychotropic Substances Act. However, as it stands, the production, sale and possession of cannabis in any form, medical or recreational, remains illegal in Zambia. In May 2017, Dr Chitalu Chilufya, the Health Minister, said he would not

allow the issuing of any licence for medicinal cannabis. He stated there was no additional benefit medicinal cannabis could bring to patients that was not available from ready-approved drugs within the country. Following the remarks, the Drug Enforcement Commission of Zambia issued a statement proclaiming that cultivation of hemp would remain illegal and that individuals would risk prosecution. 'We wish to clarify that cannabis cultivation is still illegal in Zambia unless one has lawful authority to cultivate for medicinal purposes as indicated in the Minister's statement,' said Theresa Katongo, in a statement on behalf of the agency.

The contravention of the anti-drug law attracts a substantial fine and an imprisonment term of up to ten years.

**Africa's many ideal climatic locations, agricultural growth potential and under-served economies make it the perfect incubator for cannabis firms, and the continent is emerging as a key market in the global industry.**

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# APAC



**H**ome to more than half of the world's population, the Asia-Pacific regions encompass a dramatic mix of some of the most-developed and competitive nations, from **Singapore, Australia** and **New Zealand**, to many of the poorest and most remote island nations anywhere on earth.

Contrary to the direction of regulatory travel in the West, areas such as **Thailand, Singapore, Indonesia**, and the **Philippines** carry severe punishments on trade and possession of even small amounts of cannabis.

Much of the region, including areas such as **Japan, Vietnam, Pakistan, Nepal** and **Cambodia**, maintain the repressive approach to cannabis and other drugs drawn up by the United Nations almost 60 years ago. In 2018, a Malaysian citizen was given a death sentence for selling cannabis oil.

Despite this, there are some signs the region is beginning to thaw its hardline approach to cannabis, led by an unlikely candidate.

## THAILAND

On 25 December 2018, Thailand became the first country in Southeast Asia to legalise medicinal cannabis. The Thai National Legislative Assembly approved a bill to legalise the medi-

cal use of cannabis with a caveat that the legislation is scrutinised after five years. Notorious for its strict penalties for any form of drug use, the move was considered a surprise, and occurred after an extra parliamentary session was arranged to push bills through before the New Year's holidays, according to Reuters.

Users will be allowed to hold specified amounts for medicinal purposes, if they have a prescription or recognised certificate, issued by the state. An amnesty was held in May to allow users to apply.

Attempts to review the status of cannabis in Thailand have increased in recent years, and in 2016 a public forum was held regarding the removal of cannabis from Category 5 of the country's drug legislation. Government agriculture officials were commissioned to draw up proposals for the decriminalisation of the substance, under consideration of the government. In January 2017, hemp was decriminalised in 15 districts and 6 provinces of the northern region. Around 32,000 people applied for the cannabis amnesty that ran from 27 February to 21 May 2019. By August 4,000 patients had successfully registered, compared to patients in the U.K. (where cannabis was legalised for medical use before Thailand) which were in the single digits at the time of writing. Thai authorities have not yet ensured regulated, domestically grown supply, so are instead are using a mix of imported oils and producing medical products from cannabis seized by the police, whilst legal supplies are being grown.

Progress, production and quality control are being driven by a specially instituted research outfit at Rangsit University, and supplies distributed to the public health system by Thailand's Government Pharmaceutical Organisation. The reforms have been driven by the political will and pro-legalisation stance of health minister, Anutin Charnvirakul, who campaigned to promote it as a new cash crop for Thailand's large agri-business sector. There is further hope that Thailand can cash-in on a first mover advantage and already regional powerhouse status for wellness tourism in the coming years.

## INDIA

Cannabis and its various forms have been banned in India since 1985 when the Narcotic Drugs and Psychotropic Substances Act came into effect. Per the act, cultivation, production, possession, usage, and transportation of cannabis are prohibited. An edible form of hashish, known locally as bhang, is permitted in a handful of states.

Public opinion has swung towards legalisation of medicinal cannabis, however, and in 2018 the government approved a pilot programme through the Indian Institute of Integrated Medicine in Jammu, to cultivate cannabis for medical research and drug development.

Existing Indian law distinguishes two types of cannabis products: 'ganja', the flowering tops of the cannabis plant; and hashish, cannabis resin. The former is more tolerated. In 2015, the Phytopharmaceutical Act was passed to accelerate research into plant-based medicines, including cannabis, which has in turn sparked great interest from investors and overseas businesses.

With government backing, scientists in India are building a strong research case for the therapeutic properties in treating the symptoms of diabetic neuropathy, cancer, epilepsy and sickle cell anaemia.

## PHILIPPINES


The Philippines is another area that carries some of the strictest anti-drug penalties anywhere, but has now embraced medicinal cannabis. On 29 January 2019, House of Representatives legislators voted 163-5-3 to approve on its third and final reading House Bill 6517 or the Act Providing Compassionate and Right of Access to Medical Cannabis and Expanding Research into its Medicinal Properties and for Other Purposes.

The bill would make it legal for patients suffering from debilitating medical conditions to use medicinal cannabis. Bill 6517 defines this as any disease that causes wasting syndrome, severe and chronic pain, severe nausea and seizures (including those that are characteristic of epilepsy, or severe and persistent muscle spasms).

House Speaker Gloria Macapagal Arroyo had previously told the parliament she uses cannabis patches to ease her illnesses whenever she visits a country that permits use. Arroyo, a former Philippines president, suffers from multiple cervical spondylosis or the degeneration of the intervertebral discs, causing spinal pain.

Representatives from the Department of Health had previously stated medicinal cannabis research was already allowed by the Comprehensive Dangerous Drugs Act of 2002. The law classifies cannabis as a dangerous drug, but Section 16 allows medical use.

The Dangerous Drugs Board must prescribe the implementing guidelines for the proper cultivation, culture, handling, experimentation, and disposal of these plants and materials, however. The Philippine Drug Enforcement Agency is responsible for the regulation and dispensation of medicinal cannabis.



**“  
The Philippines  
carries some of the  
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world, but has now  
embraced medicinal  
cannabis.”**



## Philippines Due Diligence Summary



### LAW:

Philippine Compassionate Medical Cannabis Act

### GENERALITIES:

The law prohibits the use of cannabis in its raw form. Patients need prior authorisation from a doctor, and treatment will be delivered in dedicated centres with a special licence from the Department of Health.

### POINTS OF SALE:

Medical Cannabis Compassionate Centre.

### REQUIREMENTS:

Can only be prescribed by a qualified medical cannabis physician, who has a personal knowledge of the use of medical cannabis, a licence to prescribe drugs, a doctor's degree in medicine and a relationship with the patient. Medical cannabis can only be accessed via a Medical Cannabis Compassionate Centre, which is a licensed centre located in a hospital.

### REGULATORY BODY:

Department of Health.

### SANCTION:

Cannabis is a controlled substance, and possessing and smoking cannabis remains criminalised in the country. Any violation of the Act is punished by a fine and revocation of licences.

## AUSTRALIA

Australia's efforts to advance its cannabis industry have been rapid and well supported by both private and public sectors.

The country amended its Narcotic Drugs Act 1967 to allow for the domestic production of medicinal cannabis, in 2016. This was required under Section 26A of the act, with a review report to be tabled in Parliament by 29 October 2019.

Three types of licences relating to the supply of medicinal cannabis products are available:

- 1 **Medicinal cannabis licences authorising cultivation or production or both;**
- 2 **Cannabis research licences authorising similar process for research purposes, and**
- 3 **Manufacturing licences authorising the manufacture of a drug or product.**

As of May 2019, the Department of Health has granted 64 licences to cultivate, produce and manufacture cannabis. The department has also approved over 4,200 Special Access Scheme (SAS) applications for medicinal cannabis, with more than 700 approvals in February 2019 alone.

A new domestic regulator was created in 2016 to issue licences to growers and to regulate medicinal cannabis crops so that medicinal marijuana can be cultivated. Medical practitioners can supply a medicinal cannabis product to patients after alerting the relevant regulatory authority and gaining prior permission from either the state or territory government department.



Some of the most seismic changes in Australia have been observed at state and territory levels. The state of New South Wales first instigated wide-ranging medicinal cannabis trials and provides police with the power not to prosecute terminally ill patients using cannabis for medical purposes, while the state of Victoria was the first to create a state-based medicinal cannabis scheme allowing children with severe epilepsy to be provided with the drug. Every state and territory in Australia now has schemes to access medicinal cannabis via prescription for a range of conditions. Queensland drew up the first guidance documents for health practitioners in March 2017, while in December 2017, the Commonwealth produced the national guidelines for five conditions.

Australia's federal government is under increasing pressure to allow states to decriminalise recreational use of cannabis, but the issue is not on the immediate agenda. Several states have discussed the matter within their parliaments and the most likely outcome is a situation similar to the US, where individual territories open their own domestic recreational markets individually.

## Australia Medicinal Cannabis Due Diligence Summary



### LAW:

Narcotic Drugs Act 1967 as amended by the Narcotic Drugs Amendment Act 2016

### DATE APPROVED:

30 October 2016.

### GENERALITIES:

Access to medicinal cannabis can be granted by a medical practitioner on a case-by-case basis, subject to regulatory and state and territory government approval.

### PRODUCTION:

At federal level, licences for cultivation are administered by the Office of Drug Control (ODC) within the Department of Health. Sponsored import of medicinal cannabis products is via a licence.

### PRODUCT:

Rules relating to medicinal cannabis products vary between states and territories. A variety of products are currently available through import including raw (botanical) cannabis, which is vaporised but not smoked, cannabis extracts in oils, and solvent extracts such as tinctures, and oral sprays.

### RESTRICTIONS:

Patients cannot purchase medicinal cannabis or import it themselves. They must obtain it via a prescription from a medical practitioner.

### POINTS OF SALE:

Must be prescribed by a medical practitioner and obtained via a pharmacy or hospital (arranged by the medical practitioner).

### PROHIBITION:

Cultivating, distributing and selling cannabis outside of the legal system carries criminal penalties.

### REGULATORY BODY:

Office of Drug Control within the Federal Department of Health and the Therapeutic Goods Administration.

## NEW ZEALAND

During the 2020 national elections, a referendum on recreational cannabis use will be held, with a binding result, confirmed the Minister of Justice of New Zealand in December 2018. A year earlier, the country introduced the Misuse of Drugs Amendment Bill in December 2017 with the aim of making medicinal cannabis available without threat of criminal punishment.

## OTHER NOTABLE DEVELOPMENTS

The first Asian country to legalise medical cannabis was South Korea, having updated the Narcotics Control Act in November 2018. The Korean National Assembly passed an amendment to allow the medical use of cannabis under strict conditions. Prior approval is necessary and granted on a case-by-case basis. The Ministry of Food and Drug Safety will establish specific implementing regulations setting out procedures for applicable patients to follow.



# Conclusion



# THE STATE OF PLAY

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**T**he global cannabis industry is at a crossroads at the mid-point of 2019, with a multitude of legislative actions and key regulatory trends set to crystallise in the coming months.

Previously hard-line and authoritative Eastern states with strict anti-drug laws, such as the Philippines and Thailand, are launching or advancing medicinal cannabis programmes, while liberal Western jurisdictions are inching toward adult recreational markets.

The freedom of the US banking system to support and lend to businesses without fear of federal punishment is perhaps the most important forthcoming legislative development to monitor, given the enormous knock-on effect that would be felt far outside the US.

Hope is already growing that the European Union's new lawmakers will take a more proactive approach to cannabis regulation than previous administrations have done.

Groundwork has been laid with a promise to divert cash and resources to a formal study of how medicinal cannabis can be supported across the bloc and where regulations that apply across borders can be smoothed over.

What regulators will hope to avoid is a wider fragmentation of European Union markets, with some areas such as Greece and Spain seeking to plug budget deficits with hastily assembled cannabis programmes. Brexit also

promises to complicate matters, causing a reduction in spend towards harmonised projects. Given that the UK will eventually split from the European Medicines Agency, a regulatory body set to play an important role in bloc-wide overseeing of medicinal cannabis, there will be structural adjustments that may distract from progress on medical cannabis resolutions.

As it stands, the maturity of the Canadian regime has given its firms a clear advantage in the global race, as they develop a clear leadership role in markets for both medicinal and recreational supply.

The support and experience gleaned from working in a fully regulated adult market have enabled Canadian firms to penetrate strategically important foreign jurisdictions such as Germany, the largest European Union state. Although Germany's domestic licensing scheme is in its infancy and is beset with legal wrangling, its medicinal market alone promises to be larger than Canada's medicinal and recreational markets combined, making it an essential outpost for ambitious firms.

While cannabis remains federally outlawed in the US, there is also a reluctance from multinationals to enter the market, as they cannot as yet carry out cross-state trade. A smooth passage into law for the SAFE Banking Act may dramatically shift the environment, however, putting large US firms into play.

The regulatory environment for cannabis across the globe today is undergoing a significant shift, powered by a kaleidoscope of forces including widespread political upheaval, technological innovation and new societal norms.

To succeed, firms must have a clear compliance strategy to navigate the increasingly uncertain regulatory waters, allowing them to execute strategy confidently and effectively in times of relentless ongoing change.

**The freedom of the US banking system to support and lend to businesses without fear of federal punishment is perhaps the most important forthcoming legislative development to monitor, given the enormous knock-on effect that would be felt far outside the US.**

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# GLOSSARY

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<b>ABA</b>	American Bankers Association
<b>APAC</b>	Asia and Pacific
<b>BfArM</b>	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
<b>BMC</b>	Bureau for Medicinal Cannabis
<b>CARICOM</b>	Caribbean Community
<b>CBD</b>	cannabidiol
<b>CND</b>	Commission on Narcotic Drugs
<b>EFSA</b>	EFSA
<b>EMA</b>	European Medicines Agency
<b>EMCDDA</b>	European Monitoring Centre for Drugs and Drug Addiction
<b>EU</b>	European Union
<b>FDA</b>	Food and Drug Administration
<b>INCB</b>	International Narcotics Control Board
<b>IP</b>	intellectual property
<b>IRCCA</b>	Instituto de Regulación y Control del Cannabis (Institute for the Regulation and Control of Cannabis)
<b>M&amp;A</b>	Mergers and Acquisitions
<b>NDLEA</b>	National Drug Law Enforcement Agency
<b>ODC</b>	Office of Drug Control
<b>R&amp;D</b>	Research and Development

**SAFE (Banking Act)** Secure And Fair Enforcement

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**SAS** Special Access Scheme

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**THC** tetrahydrocannabinol

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**UN** United Nations

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**US** United States

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**WHO** World Health Organization

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