About Prohibition Partners
Unlocking the potential of cannabis. Empowering our partners to make better business decisions.

ABOUT US

Prohibition Partners unlocks the potential of cannabis through data, strategy and community. We enable our clients to make better business decisions that deliver transformational growth and disrupt mainstream verticals. We work with the industry’s most influential stakeholders, some of the world’s best known brands and an unrivalled network of analysts, innovators and advisors.

SERVICES

INTELLIGENCE

Unparalleled knowledge, market insights and proprietary data

CONSULTANCY

Corporate, new market and regulatory strategy

NETWORK

Advise and connect companies with capital and M&A opportunities
Our consultancy team works with Fortune 500 companies, industry-leading investors and global policymakers to identify and execute opportunities across multiple jurisdictions. We empower our partners to make better business decisions.

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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 Global Sponsorship Manager will.sloane@prohibitionpartners.com

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

Will Sloane
Global Sponsorship Manager
Introduction
As the legal European cannabis industry is at a nascent stage in its development, there is considerable opportunity for companies to establish their positions on the continent by filling niches in the market. Some progressive steps forward in the path to full legalisation were made in 2019, for example the announcement that the UK will undergo a trial which will supply around 20,000 patients, and Luxembourg’s plans to legalise recreational cannabis in the coming years. Generally speaking, regulators and lawmakers are taking a more cautious approach to legalisation than some of their counterparts in North America and reform is being hindered by the slow pace of regulators which are holding back the industry. Patients continue to lose out on access to the medication they need and uncertainty continues among consumers about the legality and quality of CBD products that are available owing to a lack of adequate regulations.

In 2020 we can expect progress with improved patient access to cannabis medications and for companies to continue to look for footholds in key countries, for example Germany and the UK. This report takes an in-depth look at the countries and companies that are leading the way in the nascent legal European cannabis space. In this report, Prohibition Partners provides you, the reader, with an in-depth analysis of what makes for successful cannabis policy. We analyse the companies at the cutting edge of the European cannabis space and what powers their success – be it integration or diversification – and look to the future to predict trends that will impact on the region going forwards.

In this, The European Cannabis Report: 5th Edition, we have used a new model to generate our market sizes. Taking into account the underperformance of the market leaders, the slow pace of the regulators and the high level of speculation that surrounds this market, we are now focusing on the short term and employing a bottom-up approach. This model is focussed on the current reality of the market and presents a more grounded and conservative view in order to promote and reflect realistic business investment.

We believe this new approach will help provide further clarity and accuracy for the global market. We hope you enjoy the report.

Stephen Murphy, Managing Director, Prohibition Partners
hen I founded Canna-
medical® back in 2016
my vision was to help
doctors and pharma-
cists provide critically
important medicine
to patients whose lives could significantly
be improved by medical cannabis. We are
persistent in the pursuit of our goal to improve
the lives of patients who have to live with the
+80 conditions for which medical cannabis is
prescribed in Germany (and the EU).

Europe is definitely one of the world’s most
difficult medical cannabis markets to enter,
due to the strict regulatory framework,
complex licensing and trading require-
ments as well as the very strict pharma sales
marketing limitations. However, Cannamedi-
cal® has positioned itself as an independent
market leader over the years by providing
free education to doctors as well as providing
the highest level of customer service in the
industry to approximately 22,000 pharmacies.
We successfully entered into exclusive
or preferred contracts with eight leading
suppliers of flowers and oils from Canada,
Europe and Australia, thus creating the
largest and most stable supply chain in the
EU cannabis market without vertical integra-
tion. Our expertise with regulators has yielded
six permits and licences, which provide the
broaderest range of import, refinement and
distribution on the market. To date, we have
supported four companies from around the
world to comply with all requirements and
ultimately receive the EU-GMP certification
for their cannabis facilities.

The product range of Cannamedical®
consists of 16 products with exclusively
homogeneous Indica-, Sativa-, Hybrid- and
Cannabidiol (CBD)-rich flowers, which are
separated into vita, light, medium and forte
categories. Next to this, Cannamedical® has
introduced pure EU-GMP certified CBD that
is sold in kits, so pharmacists can compound
preparations according to a doctor’s prescrip-
tion. The kits allow pharmacists to prepare
oils with either 5% or 10% CBD, depending on
the prescription.

This unique supply-chain flexibility and
multi-sourcing approach allows us to provide
the market with more precise and consistent
product formats, strains and THC/CBD con-
centrations, which means doctors are able to
refine treatment strategies more precisely.

David Henn,
CEO,
Cannamedical
THE MEDICAL CANNABIS EXPERT

Cannamedical® Pharma – Your leading partner for medical cannabis in Germany

We are Germany’s No. 1 independent and fully licensed pharmaceutical wholesaler with great experience and a broad international network of EU-GMP™ certified partners. The therapeutic care of patients, excellent customer service and informative educational work for medical professionals are the focus of our work.

With our varied range of Cannamedical® cannabis flowers, we offer innovative therapy options that meet the individual needs of patients.

KNOW-HOW
Our experienced team offers a 360° service for healthcare professionals.

INDEPENDENCE
We are the No. 1 independent wholesaler for medical cannabis in Germany.

HIGH STANDARDS
We operate according to GMP* and GDP** standards and distribute high quality pharmaceutical products.

FULLY LICENCED
We obtain all licences and support our international partners to receive EU-GMP status.

*Good Manufacturing Practice  **Good Distribution Practice

Interested in receiving more information?

T  +49 (0) 221 999 852 - 00
@  info@cannamedical.de
DEFINITION AND SCOPE

MEDICINAL CANNABIS

Medicinal cannabis refers to both medical and pharmaceutical cannabis products. Please see definitions below for more detail. Medicinal products may be referred to as CBPMs or cannabis-based products for medicinal use.

Medical cannabis

Medical cannabis refers to plant-based or plant-derived cannabis products prescribed by a medical practitioner for the treatment of a specific condition or disease (e.g. epilepsy, pain, multiple sclerosis (MS)). It should be noted that medical cannabis is an unlicensed medicine without marketing authorisation. Medical cannabis uses the whole unprocessed plant or the processed plant. It can include high-CBD and low-THC products, though CBD products may also appear as consumer goods, which are sold without prescription. Medical cannabis products are currently prepared in formats such as plant materials, oils, tinctures, edibles or capsules.

Pharmaceutical cannabis

For the purposes of this report, pharmaceutical cannabis refers to products that are formulated or processed using cannabinoids (either plant-extracted or synthetic) that have been through full clinical trials and that are licensed as a medicine with marketing authorisation. Examples of products include Sativex, Epidyolex (Epidiolex in the US), Cesamet, and Dronabinol (e.g. Marinol and Syndros).

RECREATIONAL CANNABIS

Recreational cannabis refers to any cannabis used for non-medical purposes, and this category includes black-market products. It ordinarily has a higher concentration of THC, the psychoactive and intoxicating compound of the cannabis plant, and is illegal in many countries and states. People tend to smoke (or consume via edibles) recreational cannabis. Regarding the statistics in this report, usage is assumed to be by people aged 15+. For the purposes of this report, recreational cannabis does not include CBD-only products.

INDUSTRIAL HEMP

Industrial hemp refers to cannabis plants cultivated for high yields of materials like seeds, fibre and oil, with low concentrations of psychoactive compounds. Materials derived from hemp have a wide range of uses as constituents in consumer goods, including paper, textiles, biodegradable plastics, building materials and fuel. Industrial hemp can also be used to produce CBD products such as oils, tinctures and food, whereas horticultural hemp is used to make health
food products. For the purposes of this report, industrial hemp includes hemp-derived CBD.

**CBD**

Cannabidiol (CBD) is one of the two main active cannabinoids in cannabis. CBD exhibits wide-ranging medicinal properties, including anti-anxiety, anti-inflammatory, anti-pain, anti-arthritic and neuroprotective effects. CBD is indicated for treatment of conditions such as epilepsy and is commonly used for conditions such as pain and insomnia. Whilst there is an emergent market for CBD-infused consumer goods, capsules and oils, these have been excluded from the market-size calculations for clarity.

**THC**

Tetrahydrocannabinol or THC is the main psychoactive cannabinoid of cannabis. THC is considered the primary source of the ‘high’ produced by cannabis ingestion. Evidence suggests that THC exhibits medicinal properties that are useful in treating nausea, pain, spasticity and loss of appetite. Weaker evidence exists supporting its use for neurological conditions such as anxiety, depression, ADHD, PTSD, Tourette’s and psychosis.
EXECUTIVE SUMMARY

While 2019 was a tough year for cannabis stocks, prospects remain strong in Europe so long as lessons learned in North America can be taken on board. 2020 is a big year for cannabis in Europe not least due to the fact that pilot access schemes are now on-going in key future markets, such as France, the UK and Denmark.

COMPANIES SEEK TO PROLIFERATE AND INTEGRATE

As with many emerging markets, the cannabis space is characterised by companies that leverage investor finances to obtain a foothold in markets before they become profitable. This has largely been the case since the inception of the cannabis market, and 2019 was no exception. This is especially true of the European cannabis market, which has the potential to become the most lucrative cannabis market in the world. To achieve a comprehensive foothold in Europe, overseas companies and growers need to navigate a patchwork set of rules and regulations in Europe before establishing a licensed system of supply, processing, distribution and retail. To this end, companies can either look to establish partnerships in key regions or can seek to set up branches of their own firms, either by acquiring native companies or beginning from scratch. For example, Canadian company Aphria has established a partnership with Danish company Schroll Medical to produce its own proprietary cannabis strains in Denmark, whereas Danish company Stenocare opted instead to source cannabis from licensed Canadian producers as part of a diversification strategy following the quarantining of products from Canntrust. In Germany, native company Demecan raised US$7.76 million (€7 million) in investments to establish distribution capabilities, whereas large Canadian firms Canopy Growth and Aphria acquired companies that already have these capacities in Germany. In 2020, acquisitions are expected to slow as the available niches are filling up and companies will try to control their expenditure a little more tightly, as seen in Aurora’s shelved Nordic II facility.

DIVERSIFICATION IS RAMPING UP

Acceptance of the benefits of medical cannabis legalisation is gradually spreading throughout Europe at the level of public opinion. Widespread acceptance of CBD in the consumer marketplace is occurring at breakneck speed. CBD is broadly seen as the acceptable side of cannabis, while the potentially intoxicating effects of THC now carry most of the stigma attached to cannabis. Cannabis companies are keenly aware of this and many are making moves to diversify their products within the European cannabis space. For example, in the past...
two years, Canopy Growth has acquired a CBD producer, This Works, in the UK; Tilray acquired UK CBD company Smith and Sinclair; Aurora acquired its own hemp agricultural business, Agropro in Lithuania (one of the larger hemp cultivation companies in Europe); while Aphria released its own range of hemp-based products: ‘Cannrelief’ for the German market, which initially included oils and has been extended to include creams, serums and masks. In many countries, regulation around CBD is not yet clear, and 2020 may see governments, such as those of the UK and Italy, implement more comprehensive regulations with no certainty around which products will remain legal. Still, companies are wasting no time in setting up shop in this growing market.

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>COUNTRY</th>
<th>COUNTRY</th>
<th>活動</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canopy Growth</td>
<td>This Works</td>
<td>UK</td>
<td>CBD skincare</td>
</tr>
<tr>
<td></td>
<td>Storz &amp; Bickel</td>
<td>Germany</td>
<td>Vape production</td>
</tr>
<tr>
<td>Aurora</td>
<td>Agropro, Borela</td>
<td>Lithuania</td>
<td>Organic hemp cultivation and production of hemp seed oil, hemp seed protein, hemp seed flour and hulled hemp seed.</td>
</tr>
<tr>
<td>Tilray</td>
<td>Smith &amp; Sinclair</td>
<td>UK</td>
<td>Infuses alcohol and CBD into food products</td>
</tr>
</tbody>
</table>

Source: Prohibition Partners.
*Produced in Canada specifically for Germany
RESEARCH IS KEY TO UNLOCKING EUROPE

As opposed to wide-scale medical legalisation within a short period of time, as has occurred in North America in recent years, many European countries are taking a more gradual approach to adopting cannabis medications. Countries such as Ireland, France and the UK have made use of various access schemes while the governments assess the medical benefits to be wrought from CBPMs (including Sativex and Epidyolex). Both doctors and national bodies such as the National Institute for Health and Care Excellence (NICE) in the UK cite a shortage of research and the high cost per prescription as deterrents to prescribing cannabis-based medications for the time being. Massive research efforts are currently underway across the continent to plug this gap in knowledge. As of February 2020, there are 17 active clinical trials investigating the efficacy of cannabis and cannabinoid medications against diseases ranging from schizophrenia to endometriosis. Even more importantly, massive trial schemes with increased access to medicinal cannabis are now underway in countries such as Denmark, France, the UK and Ireland. The largest is Project Twenty21 in the UK, which plans to supply medical cannabis to 20,000 patients. If the trials are successful and CBPMs are accepted in these economically developed regions, it makes it much more likely that the Domino Effect (a Prohibition Partners Trend) will take hold and full medical legalisation will spread across the continent.
Approved Cannabis-based Medical Devices for Europe

The two product lines - leafBasic & leafPro - contain oil with CBD concentrations between 4% and 30%. leafBasic is available in retail, while leafPro can be obtained exclusively in pharmacies.

Our CBD containing products are not novel foods, but legal medical devices according to EU classification of Medical Device Directive (MDD), 93/42/EEC. With leafPharma’s products we are pleased to introduce the first approved CBD containing medical devices to the European market.
In three years the Swiss CBD producer Pure Holding AG has become a leading player in the European cannabis market. With its 70 employees in Aargau, Switzerland, the company focuses on high product quality and the expansion of its research subsidiary, Pure Gene.

The cannabis industry is fast paced. What challenges are you facing?
The cannabis industry is fast paced. The time between a concept until market launch is extremely quick compared to any other industry. As an emerging market, it is not only a challenge, but it’s also the largest opportunity. Exactly these opportunities are what led to Pure’s current diversified structure. Just three years ago, Pure started out as a small production company in Switzerland. Initially focusing on tobacco substitutes, today we are a holding with six subsidiaries, completely vertically integrated. We cover the whole value chain of the cannabis industry. From variety breeding to raw material production, extraction, product development on to our own international distribution network. This is what gives us the flexibility to respond to client and market needs and allows us to have an active rather than a reactive role within the cannabis industry.

Is there an advantage being in Switzerland?
Switzerland is renowned for its quality and attention to detail and has one of the most mature hemp markets in the world.

The ‘Swiss Hemp Bill of 2011’ was a visionary move, which facilitated legal investments and innovation into the hemp industry, utilising the many experts and universities that are spread across the country. For this reason, Switzerland pursued innovation, knowledge, genetics and technologies in the cannabis field, cementing its role as an R&D hub for years to come. Let’s not forget the fact that the THC level is the highest in all of Europe, at 1%.

What needs to change in the cannabis industry?
Unlike other agricultural crop species such as soy and wheat, which have been bred for optimised industrial production, the current state of cannabis breeding limits its production potential. Furthermore, the number of unique valuable traits in cannabis is much more diverse than traditional row or greenhouse crops. For example, there is flower appearance, aroma, and cannabinoid content. Variety choice is the most important decision, towards a good return on investment, in order to have the competitive edge. There is a vast amount of varieties available in the marketplace, but with the current state of the cannabis industry it’s difficult to know what you’re going to get with the lack of reliable data.

Additionally, there is the legal uncertainty in the European market, which is currently providing frustration for all producers, retailers and consumers alike – regulations, and standards are absolutely necessary.
How do you plan on contributing to this change?
DNA is the blueprint of every living organism. With DNA, Puregene can decipher cannabis’ unique natural chemistry and all its valuable traits. For this reason, we have invested substantial sums to sequence the cannabis Super-Pan-Genome, gaining distinctive knowledge about cannabis and its DNA, which controls all its characteristics and traits, such as flavour, disease resistance, flower size, and yield. The genome is the entire DNA of a plant and every plant variety has a unique genome. Our goal is to remove the random guesswork plaguing cannabis breeding, and our extensive knowledge of the cannabis DNA is the foundation of what we do. Understanding the challenges in plant and cannabis breeding was a strategic step for the Pure group in founding Puregene AG, bringing breeding to the level of science-based and state-of-the-art research, as seen in major crops.

What distinguishes Puregene AG?
The high demand for variety in cannabis products (e.g. flavours, cannabinoids) has led to cannabis being one of the most genetically diverse cultivated crop species. We can now uncover the vast genetic diversity of cannabis in the highest possible detail that modern genomics technology allows. Puregene operates a research-first, data-driven, genomics-based molecular breeding programme designed for rapid and accurate development of robust, high-performance and tailored varieties in a non-GMO manner. Our genomics technology is maintained through our close partnership with renowned academic and leading industrial partners. Leveraging the investment in genomics and equipped with a cutting-edge molecular laboratory and breeding programme, dedicated breeding stations, and the expertise from a team of expert scientists, we have applied the most modern breeding toolset available to cannabis and are innovating elite varieties, variety ideotypes as well as testing and reporting methods. This has resulted in our headline variety for 2020 Pure CBG, which contains no other cannabinoids. These are available to clients internationally as seeds and clones. Our rapid development cycles and control of the breeding process enabled the creation of our CBDV, CBGV and THCV varieties, which will be available in 2021 and are opening entirely new applications in cannabinoid therapies.

We are the specialists in developing the best- performing varieties, but without the right partners and network it is difficult to impact change. Our close interaction with government entities across the globe has enabled us to perform the first legal import of live cannabis seeds and clones into the United States. Puregene has developed CBD and CBG genetics, perfectly suitable for this market. For this reason, we partnered up with one of the most established propagation and distribution companies – US Nurseries. We are collaborating to serve the U.S. market with clone orders of any magnitude.

What’s next for Pure?
Products containing CBD are trending everywhere in the world. Apart from THC, CBD is currently the most important cannabinoid containing cannabis. However, as products containing CBD are currently classified as ‘Novel Food’ and no approvals are granted, the market is facing unknown hurdles and legal uncertainty has developed throughout Europe. Pure has decided to take on this challenge head on and for this reason launched a new subsidiary PurePharma. Together with our partner, leafPharma, we are distributing the first and only CBD-containing medical devices in Europe. The legal certainty for consumers and retailers is now given. After many years of development work by both companies and within the scope of intensive clinical studies, a first product range will be available on the market in the next few weeks.

These CBD-containing products are not food supplements, but legal medical devices according to EU classification Medical Device Directive (MDD), 93/42/ECC.
MARKET TRENDS

OPPORTUNITY ABOUNDS

Here we analyse the key trends that are at play in the European cannabis space with many of the following trends identified as part of the Prohibition Partners Trends database, some of which are unique to Europe and some of which are part of the wider narrative shaping the global cannabis industry. Although the opportunity for recreational legalisation is much more limited for the short term in Europe, the potential for investment in a highly standardised medical product is high and in a region with a population twice the size of Canada. Furthermore, the receptiveness of European governments to the investment opportunity associated with medical cannabis in the region is also proving to be a driver of momentum, particularly in those countries that fall outside of the typical big European economies, such as Malta, Greece and Jersey. Europe, therefore, shaping up to be a continent of cannabis opportunity, with the varied regional stances and climates offering a range of different prospects to capitalise upon with the added bonus of the single market boosting the opportunity from which to scale-up and distribute.

EXPECT THE DOMINO EFFECT

The Domino Effect trend has been observed in other regions and is expected to be at play in Europe, with 2020 likely to mark the tip of the iceberg in the region. Observed by Prohibition Partners, the Domino Effect suggests a certain level of inevitability that in neighbouring countries to those legalising, barriers to cannabis legalisation will go down as both medical and financial benefits gain recognition.

As seen in the US, where legalisation typically comes in geographical clusters, it is probable that once legalised in Luxembourg, thanks to the influence of proximity and cultural similarity, its European neighbours may relax rules, or at the very least demonstrate an increased tolerance of Luxembourgers who travel with medicinal cannabis. This could create a ripple effect with legalisation following across the region.

The groundwork is already being done in some countries that are gathering evidence-based data to support a legal market, while countries such as the UK are creating studies to improve understanding and access.

- An initiative running in the UK could see up to 20,000 patients given medical cannabis over a two-year period with the aim of building the largest body of evidence on cannabis as a medicine in the region.
- Approval has been granted in France for a two-year trial to help doctors better understand the side effects and risk of addiction.
- Ireland has launched a pilot Medical Cannabis Access Programme, which will run for five years.
If successful, these schemes could significantly contribute towards a better understanding of medicinal cannabis by the medical community, lawmakers and patients alike. Depending on the outcome of the trials, they could also help to broaden the current scope of conditions for which cannabis could be prescribed, and this, in turn, could help to grow the patient base significantly.

**THE LEGAL LAG**

A dedicated cannabis agency is now recognised globally as being a key element in facilitating a successful medical cannabis programme.

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**Countries in Europe with Dedicated Cannabis Agencies**

- **NETHERLANDS**
  - **NAME**: Office of Medical Cannabis
  - **RESPONSIBILITIES**: Licensing, import, export, distribution
  - **YEAR ESTABLISHED**: 2001

- **CZECH REPUBLIC**
  - **NAME**: State Agency of Medical Cannabis
  - **RESPONSIBILITIES**: Licensing and distribution of medical cannabis (not import/export), reimbursement
  - **YEAR ESTABLISHED**: 2015

- **BELGIUM**
  - **NAME**: Federal Agency for Medicines and Health Products (FAMHP)
  - **RESPONSIBILITIES**: Licensing, import, export

- **GERMANY**
  - **NAME**: Cannabis Agency of BfArM
  - **RESPONSIBILITIES**: Licensing
  - **YEAR ESTABLISHED**: 2017

- **NORTH MACEDONIA**
  - **STATUS**: Proposed in current draft Bill
  - **RESPONSIBILITIES**: TBC

- **LUXEMBOURG**
  - **STATUS**: Planned
  - **RESPONSIBILITIES**: Production, distribution

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Cannabis remains illegal in some countries so please reference your local laws in relation to medical or recreational use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2020 PP Intelligence LTD.
Such agencies are able to simplify the process for becoming a licensed producer, to administer the applications and to oversee the imports and distribution of products coming into the country. Such agencies are also there to implement and adapt the systems whereby patients, or indeed consumers, can access licensed products from licensed producers and prescribers.

Without proper systems and infrastructure in place to facilitate accessibility to medicinal cannabis for patients, the markets will stall. This is encapsulated by the Prohibition Partners trend, *The Legal Lag*. This trend highlights how, despite the legalisation of cannabis, the lag in the legal infrastructure to supply a legal industry is creating shortfalls in legal supply. With legalisation nearly always implemented ahead of domestic cultivation schemes, European programmes are initially reliant on international supply from countries like the Netherlands and Canada until such time that they can draw from their own domestic cultivation. Anticipating patient numbers and creating a sustainable supply, both internationally and domestically, have proven to be persistent stumbling blocks for burgeoning patient programmes and should serve as a lesson to those countries about to embark on their own legalisation journey.

In Denmark, following a unanimous vote, a four-year trial began in January 2018 that legalised medicinal cannabis for select patients. However, opposition from Danish doctors, owing to insufficient clinical evidence about the effects and possible side effects of medical cannabis, blighted the trial. Patients reported finding it hard to identify doctors to prescribe cannabis and it was found that several medical associations advised doctors against the prescription of cannabis. This is one example of where the education and infrastructure simply wasn’t in place to facilitate medical cannabis accessibility.

Almost 12 months later and the UK followed in Denmark’s poorly planned footsteps, with access severely hampered by a lack of planning and infrastructure. It took 12 months following the initial legalisation for the first company (Canopy Growth) to be authorised to import medicinal cannabis in bulk directly into its own distribution centre in the UK. One year on from legalisation only 18 patients had been prescribed medicinal cannabis on the NHS, owing to a lack of recommendations from NICE in their prescribing guidelines in addition to the lack of qualified professionals able to prescribe.

A successful medicinal cannabis market in Europe is also dependent on medical professionals being fully trained in understanding product benefits so that they can be confident prescribing it and are fully aware of any contraindications.

Teaching academies such as TAOMC (The Academy of Medical Cannabis) have been used to fill the void until such time that clinicians receive training on cannabis as part of their medical school programme. However, it is the clinical trials and their results that are expected to truly unlock the full potential of the medicine in Europe, not only in terms of prescribing but also so that health authorities and insurance providers can be sure of the credibility of cannabis products, thus securing greater access for those patients across all financial backgrounds.

For 2020, we are likely to see a combination of trends playing out, including *National Character* (PP’s observation that domestic cannabis and CBD regulations are a reflection of a country’s national identity), *Blueprint Markets* (PP’s observation that the world is waiting to see which legalisation model works best), the *Crackdown* (the tightening and upholding of regulations on CBD and cannabis retailing) and *Testing, testing* (the growing importance of proving what a cannabis product is made of and whether it meets certain standards).

*Blueprint Markets* details how, with only a few states and regions that have full legalisation, the world is watching and learning and will pick and choose what does.
Customized solutions for cannabis analysis

Targeting the growing market of cannabis analysis, Shimadzu offers a wide range of analytical equipment and application support, including sample preparation.

Our solutions for cannabis testing serve the need for better quality control and standardization to fully leverage health benefits.

As widespread guidelines are introduced, it is likely that lower limits for harmful contaminants and stricter regulations will soon be established.

Shimadzu does not support or promote the use of its products or services in connection with illegal use, cultivation or trade of cannabis products. Shimadzu is not condoning the use of recreational or medical marijuana, and is merely providing a market summary of the cannabis testing industry.

www.shimadzu.eu/cannabis-testing-solutions
and doesn’t work in these early adopter markets. Towards the end of 2019, we heard that the EU was planning to align with Germany’s approach to medical cannabis regulation. Although a handful of countries in Europe have also amended laws to allow for medical cannabis treatments, in many cases access has been limited and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) now recognises both the medical and economic benefits to the region that come from a more progressive programme. With more than 142,000 prescriptions being issued since medical legalisation in 2017 and 60,000 patients obtaining prescriptions via health insurance, the German medical cannabis system combined with liberal recreational laws is looking like it could be one of the stronger blueprints for the rest of Europe.

In keeping with this theme we have seen Germany take a firm stand on the issue of CBD and the ‘grey market’ (PP Trend – The Grey Zone, which details the practice of operating somewhere between the law and illegality, born out of inconsistencies in regulation). In November 2019 the German authorities made a court ruling that CBD products must be considered as a prescription medicine or a novel food in line with the EC ruling in January 2019. While it could represent another example of a Blueprint Market, which could set into motion the much dreaded Crackdown (referring to the PP Trend, which details the beginnings of regulatory enforcement of the CBD market in the US and in Europe) across the rest of Europe, it may also be representative of the PP Trend National Character, which has come to define the way in which each and every country and state across the globe seems to have its own take on cannabis and CBD. For example, this decision in Germany to uphold the rules and plump for the highest level of regulation is very much in keeping with the way in which Germany functions across its economy and its broader society; in order for society to work smoothly, there is a general accord in Germany that a set of guidelines needs to be obeyed by the majority. The UK in contrast has not been bearing down as heavily on cultivators and retailers but is displaying stronger leadership in Europe on the matter. With international trade being a major driver in the decision-making process regarding cannabis legislation, it could be that the standards that come to be defined by one country’s CBD industry and the consequent demands in terms of trade and compliance prove to be a tipping point in either direction for the rest of Europe.

This brings us to another major PP trend that will play out in 2020 – Testing, testing. High standards and regulated products are the bedrock of the European medical cannabis movement, as safety and control have been the guiding principles of the legalisation process in the region. With Europe moving into the spotlight in 2020, compliance with the standards set by Europe will become paramount globally; meeting and proving these standards will therefore become ever more important. This is an issue that has already reared its head in the latter half of 2019, firstly with Denmark quarantining unlicensed products from CannTrust and secondly Aurora’s suspension from selling cannabis products in Germany after it was discovered that Aurora had used ionising irradiation on its products, the latter ban being lifted in early February 2020. The high standards associated with European cannabis trading will therefore become an international benchmark, with traceability at the core of this. For international players, the inefficiencies associated with having separate systems in place to meet varying standards around the world will likely see the vast majority of the major players adopting the kind of standards that are acceptable within Europe (although each country has its own standards due to Monograph and individual state rules). Furthermore, with Global Networking and Joined-up Thinking (both are Prohibition Partners’ Trends) also being key influences in the market, it is highly likely that an international universal standard will eventually be adopted to facilitate easier trading.
DOMESTIC SUPPLY

Another trend that has been evident not just in Europe but across the world is the trend for domestic supply, as it would seem the holy grail in legalisation is to ensure that a country has its own supply of domestically cultivated cannabis products that can be grown to domestic standards and benefit the local economy. For example, not long after Germany legalised the use of medical cannabis, demand soon outstripped the imported supply, and BfArM proposed a tender process for obtaining locally grown cannabis. Despite a legal hiccup in the initial tender process, which subsequently opened the door further to foreign supply opportunities, BfArM’s dedicated cannabis agency went on to create a one-step application process for tenders, and applicants need only have experience in growing and processing medicinal plants, which has opened up opportunities to many local agriculturists, and the limit has been raised on how much cannabis each licensed cultivator can produce. Germany hopes to cultivate 6.6 tonnes of cannabis domestically by 2022; however, the requirement that domestic cultivators have previous growing experience is proving to be a stumbling block for local players, given that cannabis cultivation has never been legal in Germany prior to the law change. It means that local commercial experience is thin on the ground within the region and prospective companies are finding it hard to navigate this prerequisite.

A similar situation is occurring in Italy following the recent announcement that the country plans to triple the quantity of medical cannabis being cultivated domestically. The health ministry is allowing the Stabilimento Chimico Farmaceutico di Firenze (SCFF) to produce 500 kilograms (1,102 pounds) of cannabis flower in 2020. The SCFF’s 2019 production is estimated to be below 350 kilograms. Medical cannabis sold in Italy comes from the Netherlands, where it is produced by Bedrocan and exported by the Dutch government Office of Medicinal Cannabis, while Aurora Cannabis is the only Canadian-based company supplying Italy, albeit a very small portion of the market. However, the Italian government has reduced the amount it has agreed to import from Aurora and instead has embarked on a three-year investment project of €1.4 million (US$1.5 million) for domestic production. Of that total, the SCFF will contribute €600,000 (US$660,000) and the region of Tuscany €795,000 (US$874,000), starting with €397,000 (US$436,000) in 2020 followed by €198,750 (US$218,760) in each of the following two years.

Denmark imports all of its domestic cannabis products and this has created issues with both supply and pricing. Under the Danish medical cannabis scheme, prescriptions are reimbursed at a rate of 50%, up to 10,000 kroner (US$1,500) per year. Terminally ill patients receive full reimbursements. However, for those who have reached their limit on reimbursement, the high costs have impacted their ability to access the medicine. The government hopes to bring down prescription costs through creating greater competition in the market through domestic supply. The quarantining of CannTrust’s products over the summer of 2019 also exposed the issue of standards, control and the interruption to supply from importing products. Despite the shelving of Aurora’s Nordic II facilities, as of September 2019, 34 companies in Denmark had permits to cultivate cannabis under strict guidelines, and the country hopes that this will be the key to ensuring a steady supply at an affordable price.
LESSONS LEARNED

Following the initial excitement of the Green Rush in North America in 2017 and 2018, some aspects of the market failed to perform as well as expected in 2019. Progress was more gradual than expected in Europe also. Legal roadblocks, inaccessibility to medicinal cannabis, and a lack of education amongst prescribers were the biggest factors delaying market potential for some of the region’s biggest nations, with the UK and France advancing very gradually.

- In the UK, just 177 prescriptions (nearly all of which were privately accessed) were issued in England in the 11 months following legalisation of medicinal cannabis according to the NHS Business Services Authority (NHSSBA), with the number rising to over 200 by January 2020. Furthermore, just a fraction of the UK’s 290,000 doctors have been trained to understand the endocannabinoid system.

- In France, prohibitively tight restrictions manifesting in price negotiations meant that a medicinal cannabis market failed to open up since Sativex was approved for use in 2014. However, a Temporary Specialised Scientific Committee (CSST) has been set up to investigate the introduction of medical cannabis into France. At the end of 2018, the CSST identified a wider range of conditions that would be suitable for the use of medicinal cannabis. These included chronic pain, severe and drug-resistant epilepsy, palliative care, MS and as a support for cancer treatment. A pilot scheme is now underway in France which is testing out new routes for patient access within the country.

This is in stark contrast to European neighbours such as Germany and Poland. By the end of the second year following legalisation, Germany saw 142,000 cannabis prescriptions issued (correct as of December 2019). The Polish Pharmaceutical Chamber has estimated that up to 300,000 patients may qualify for medical cannabis, and research undertaken for The Poland Cannabis White Paper highlighted that an estimated 10 million people in Poland are living with chronic pain. If just 1% of chronic pain sufferers in Poland were prescribed medical cannabis by their doctor, this would equate to an additional 100,000 medical cannabis patients and up to 400,000 medical cannabis prescriptions.

TIMELINE: MEDICAL, MEDICINAL AND ADULT-USE RECREATIONAL CANNABIS DECRIMINALISATION AND LEGALISATION THROUGHOUT EUROPE

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislative developments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1976</td>
<td>The Netherlands decriminalises possession of small amounts of cannabis for personal use and low volume sales via retailers that operate under strict licensing conditions</td>
</tr>
<tr>
<td>1992</td>
<td>In Spain, under article 368, consuming cannabis and growing it for personal consumption isn’t legal, but isn’t considered punishable as long as you can prove that you’re not growing to sell it or even help other people to smoke it</td>
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<tr>
<td>2001</td>
<td>Luxembourg decriminalises possession of small amounts of cannabis for personal use</td>
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<td>Year</td>
<td>Legislative developments</td>
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</tr>
<tr>
<td>2001</td>
<td>Portugal decriminalises consumption of all drugs</td>
</tr>
<tr>
<td>2003</td>
<td>Belgium decriminalises possession of small amounts of cannabis for personal use</td>
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<tr>
<td>2003</td>
<td>The Netherlands legalises medical cannabis</td>
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<tr>
<td>2004</td>
<td>The UK re-classifies cannabis as a Class C (less harmful) drug, before restoring it to Class B in 2009</td>
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<tr>
<td>2008</td>
<td>Austria legalises medical cannabis</td>
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<tr>
<td>2010</td>
<td>The Czech Republic decriminalises possession of small amounts of cannabis for personal use</td>
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<tr>
<td>2011</td>
<td>Denmark approves several cannabis-derived drugs for medical use</td>
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<tr>
<td>2012</td>
<td>Switzerland decriminalises possession of small amounts of cannabis for personal use</td>
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<tr>
<td>2013</td>
<td>The Czech Republic legalises medical cannabis</td>
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<tr>
<td>2013</td>
<td>Croatia decriminalises possession of small amounts of drugs for personal use</td>
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<tr>
<td>2013</td>
<td>Italy legalises medical cannabis</td>
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<td>2013</td>
<td>Romania legalises medical cannabis</td>
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<td>2013</td>
<td>France legalises the sale of medications containing cannabis derivative</td>
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<tr>
<td>2014</td>
<td>Slovenia decriminalises possession of small amounts of cannabis (up to 25g) for personal use</td>
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<tr>
<td>2015</td>
<td>Malta decriminalises cannabis</td>
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<tr>
<td>2015</td>
<td>Spain decriminalises consumption or minor personal possession of drugs in public places</td>
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<tr>
<td>2015</td>
<td>Croatia legalises cannabis-based drugs for specified medical purposes</td>
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<tr>
<td>2016</td>
<td>North Macedonia legalises medical cannabis</td>
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<tr>
<td>2016</td>
<td>Austria decriminalises possession of small amounts of drugs for personal use</td>
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<tr>
<td>2016</td>
<td>Poland legalises medical cannabis</td>
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<tr>
<td>Year</td>
<td>Legislative developments</td>
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<tr>
<td>2016</td>
<td>Norway makes allowances for medical cannabis</td>
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<td>2017</td>
<td>Germany legalises medical cannabis</td>
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<td>2017</td>
<td>Cyprus legalises the medical use of cannabis oil for advanced-stage cancer patients</td>
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<td>2017</td>
<td>Luxembourg legalises medical cannabis extracts</td>
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<td>2017</td>
<td>Greece legalises medical cannabis</td>
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<td>2018</td>
<td>The UK legalises medical cannabis</td>
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<td>2018</td>
<td>Denmark introduces a medical cannabis access scheme for cannabis-based medicines</td>
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<td>2018</td>
<td>Luxembourg introduces a medical cannabis pilot scheme</td>
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<td>2018</td>
<td>Malta legalises medicinal cannabis with a prescription</td>
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<td>2019</td>
<td>Estonia decriminalises possession of small amounts of cannabis for personal use</td>
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<tr>
<td>2019</td>
<td>Italy’s Court of Cassation decrees that the crime of growing narcotic drugs should exclude ‘small amounts grown domestically for the exclusive use of the grower’</td>
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<tr>
<td>2019</td>
<td>Cyprus legalises the cultivation and domestic use of the drug for medical use</td>
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<tr>
<td>2019</td>
<td>Ireland legalises medical cannabis as part of a five-year pilot programme</td>
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<tr>
<td>2019</td>
<td>France and Ireland introduce medical cannabis access pilot schemes</td>
</tr>
<tr>
<td>2019</td>
<td>UK introduces Europe’s first private patient registry (Project Twenty21)</td>
</tr>
<tr>
<td>2021</td>
<td>If approved, Luxembourg will possibly legalise adult-use recreational cannabis</td>
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Cutting-edge phytocannabinoid medical products

Seed to Pharmacy Pipeline

Global R & D

Patient Focus

Leading the way in Phytocannabinoid Derived Medicines with Seed-to-Pharmacy Strategy

mgcpharma.com.au
**HINDSIGHT IS 2020**

The North American market has been blazing a trail in the global cannabis industry and offers significant learnings for European nations (see *The North American Cannabis Report*). Learning from mistakes and oversights in more established markets should ensure that Europe’s path to a legal cannabis market is smoother by comparison.

Numerous publications have explored the impacts of legalisation in various American states on many areas, including the crime rate, employment, and the cost of cannabis. Nations and states looking to legalise are learning from these case studies, or are at least able to put measures in place to prevent certain outcomes, such as managing ‘narco-tourism’, ensuring in-country supply, limiting accessibility to residents only and undertaking law reforms that permit visiting medical cannabis patients to enter the country with their medication.

In April 2019, in Tennessee, bill SB 260/HB 234 was assigned to the General Subcommittee of the Senate Judiciary Committee. The bill proposes that patients who are registered to use medical cannabis in the jurisdictions that permit its therapeutic use may legally possess up to a half-ounce of cannabis while visiting Tennessee. Examples of law reform such as this could become a guide for European nations.

In 2020, preparations will be underway in Luxembourg for full legalisation of cannabis (although the law is unlikely to pass until 2021). However, concerns have been raised by neighbouring France and Germany about how legalisation of cannabis in Luxembourg could result in drug trafficking problems within their borders. Although ministers in Luxembourg have recommended that the sale of cannabis be limited to residents only, it does raise deeper issues that need to be addressed. Luxembourg’s health minister has lobbied its EU neighbours to relax drug laws in order to help smooth the course of legalisation. This demonstrates the imperative for integrated legislation across the wider EU bloc.

Nervous Neighbours is a PP Trend (detailing the anxiety that neighbouring states feel about legalisation and its impact) that is on the rise in the US. In January 2020, recreational cannabis became legal in Illinois. However, it remains illegal in neighbouring states such as Indiana and Wisconsin, with these states raising concerns over the impact of the legalisation of cannabis on their own states. There are reports of a significant rise in calls to Wisconsin state’s human resources hotline regarding employer drug testing, leading Wisconsin employers to consider amending their drug policies. This would also suggest that countries which share borders with countries that are legalising cannabis will need to consider law reform to accommodate their neighbours’ updated legislation.
CLARITY SHOULD BE A TOP PRIORITY

Around the world, legislation and regulation hit numerous stumbling blocks over a lack of clarity, which gives rise to legal loopholes and to businesses testing the limits of the law.

- In several European countries, such as Italy and Belgium, confusion over the legality of hemp and permissible THC concentrations have allowed for the creation of blossoming grey markets for low-THC cannabis or ‘cannabis light,’ which is sold and consumed outside of normal product regulations.

- In 2018 in South Africa, cannabis was decriminalised providing it was for personal use in a private space, yet policymakers and law enforcers are still wrangling over the definition of what constitutes ‘personal use’ and ‘private space’.

- In Illinois, the Cannabis Regulation and Tax Act came into effect in January 2020, which permits employers to adopt ‘reasonable’ zero-tolerance or drug-free workplace policies, but fails to address what a ‘reasonable’ policy looks like.

As this industry emerges from the black market, a significant amount of ‘grey areas’ remain to be considered. Learning from how other regions iron out these wrinkles could help European markets to fast-track their legislation, by using wording that has already been tried and tested, and to overcome initial ambiguities and pitfalls.

HIGHLIGHTING THE NEED FOR HARMONISATION

Although EU countries are still guided by international laws regarding the control of cannabis plants and products, permissions for medical and industrial use vary at country level. Cannabis-based medicines may have EU or national authorisation, but legislation is not harmonised among EU Member States. Luxembourg’s desire to press forward with full legalisation and the valid concerns flagged by its neighbours highlight the requirement for a harmonised approach to cannabis law across the EU. Full legalisation proposals have been presented to various parliaments in recent years, but tend to be devised by the opposition parties and most have been rejected.

In the US, the legal contradictions between federal and state present certain logistical issues, particularly for the supply and distribution of cannabis products across state lines. This highlights a further need for Europe to find workarounds to the issues experienced in the US to ensure that they have minimal impact on the developing European cannabis industry. Inconsistencies in inter-state regulation are creating new loopholes, which savvy medical cannabis users are exploiting. It highlights the need for joined-up thinking in Europe to prevent the need for legislative updates to close any possible loopholes.

For example, in the US, new regulations are being proposed in Rhode Island where residents have been trying to avoid in-state requirements (such as paying an annual renewal fee for their medical cannabis cards) by changing the address on their card to California. It is thought that some 6,500 Rhode Island medical cannabis patients (around one in three) have taken advantage of this opportunity. New laws would make it a requirement that out-of-state patients show ID proof of residency from their home states.
Can you provide a brief overview of the company?
MGC Pharma is a global leader in the research and development of pharmaceutical-grade phytocannabinoid-derived medicines within the biopharmaceutical industry. Our goal is to facilitate the transformation of phytocannabinoids into medicinal product pipelines, and to provide breakthrough solutions for prevalent health issues and to improve the quality of patients’ lives. The company’s activities revolve around an agenda consisting of three pillars – seed to medicine, global research and development, and patient focus. These three pillars have guided us to create a uniquely positioned company – producing pharmaceutical products from a phytocannabinoid-based pipeline, supported by experience and an understanding of the international industry that has continuously positioned us as a first mover with regards to standards, products and verticals.

Through our international distribution channels, we are already distributing products, the initial being CannEpil® into Australia, the United Kingdom, Brazil and most recently Ireland, all under early access schemes. We also recently passed the 2,000 prescription milestones in the UK, Australia, Brazil and Ireland with the number of prescribed products almost doubling month to month. Through clinical research in Australia and Europe, we are on the pathway for both CannEpil® and CogniCann™ to be granted conditional marketing authority in the EU, and approval in Australia, in the coming years.

When was the business founded?
The business was founded in 2014, when the founders realised the limitations of the Israeli cannabis industry, of which they had been formative members. Shifting IP and basing operations in Slovenia created an opportunity for an RTO by an Australian company, formerly known as Erin Resources, which then became MGC Pharma.

What is the business strategy and what are you trying to achieve?
The company’s ‘Seed to Medicine’ strategy comprises cultivation, to develop new strains of Cannabis spp., and preclinical and clinical research product manufacturing, at the group’s facility in Slovenia, and distribution.

The company’s mission is to produce ‘cost-effective, affordable, phytocannabinoid-derived medicines’ to improve the lives of patients. This mission is cemented by the company having established a GMP-certified facility in Slovenia, which develops and manufactures GMP-compliant phytocannabinoid-derived medicines following EU pharmacopeia standards.

Our main goal is to achieve product registration in various international territories, allowing broader market access, while taking advantage of early access schemes.

What are the main drivers behind the medical cannabis market?
As more research is being conducted on an international scale, medical
professionals and law-makers are becoming increasingly comfortable with prescribing phytocannabinoid-derived medicines. Alongside this, patients and carers are being educated on medicinal cannabis as a therapeutic option. This is not only driving legislation change around the world but driving demand for quality medicinal cannabis products.

The cannabis market is becoming increasingly competitive. What are MGC’s key strengths?
Our key strength and differentiator is that MGC Pharma is a biopharma company, not a medicinal cannabis company. Our focus is on the goal of creating the pharmaceutical quality medicines for as many patients as possible, at an affordable cost. Unlike the vast majority of companies in the medicinal cannabis industry, MGC Pharma is not focussed on the recreational market, rather investing in GMP manufacturing and the clinical research required for product registration.

In addition, our flagship products are targeting addressable markets with unmet medical needs, targeting large patient populations who currently have limited therapeutic options. The company has positioned itself as a bio-pharma manufacturer of phytocannabinoid-derived medicines to a GMP-certified pharmaceutical grade, under GMP certification. It is one of a few in Europe to manufacture and supply products to this level of quality, consistency and safety.

What products do you have in the pipeline?
Implementing a ‘Seed to Medicine’ core strategy, we currently have a pipeline of phytocannabinoid-derived medications and unique formulations, both proprietary and for third parties, all under GMP-certified regulations and facilities. Pre-clinical products in the pipeline are for the treatment of neurological disorders (cerebral palsy), autoimmune diseases (Crohn’s disease and colitis), oncological disorders (glioblastoma, melanoma and prostate cancers) and cancer-treatment side effects (cachexia).

In Australia, both CannEpil® and CogniCann™ are available to patients through the special access scheme, while CannEpil® is also available in the UK as a ‘specials’ medicines prescribed by specialists. CannEpil® is for the treatment of drug-resistant epilepsy, and CogniCann™ is for symptom management associated with dementia and Alzheimer’s disease. Both these products are in late stage development, and on the path for conditional marketing authority in the EU and approval in Australia. A Phase IIb clinical trial on CogniCann™ is underway with the University of Notre Dame Australia, while approval is being sought for a Phase IIb for CannEpil™ in Slovenia.

The company is actively pursuing a dual listing on the London Stock Exchange. What will this mean for MGC?
With our leading clinical and commercial position in Europe, and an increasing presence and patient uptake in the UK, it only makes sense to list on the LSE. This is an interesting time for us, as MGC Pharma could soon be in the highly enviable position of being one of the first medicinal cannabis companies to be listed on the LSE, or any major stock exchange in the UK, following the country’s introduction of medicinal cannabis legislation in November 2018. This has been an incredibly busy period for us where we have rapidly advanced the business, delivering material results through ground-breaking research and development, increasing our international distribution channels, opening new markets, strengthening our partnerships with academic institutions and widening our growing and manufacturing capabilities, demonstrated by construction having been authorised on a state-of-the-art 10,500m² manufacturing facility in Malta – the first of its kind. We definitely have exciting times ahead.
MARKET SIZE AND FORECAST

Although decriminalised in some countries, recreational cannabis is not currently legal in Europe; for this reason, medicinal cannabis dominates value sales in the region, and will continue to do so over the forecast period.

There is already established demand for medicinal cannabis in some of the Western and Central European countries (e.g. Germany and Czechia) and demand is expected to grow rapidly in Northern European markets (UK and Ireland) to 2024.

Recreational market estimates focus on the likely market value rather than previously published blue-sky estimates. As a result, recreational value is not expected to be realised in the region until 2021 following anticipated legalisation in Luxembourg.
TOTAL MARKET VALUE

Important note: Our new market size forecasts have been significantly revised since the publication of our Global Cannabis Report in December 2019. This is as a result of a decision to move to a more nuanced market sizing, which relies on a bottom-up approach, in order to deliver more realistic market estimates for a maturing market.

With regard to the recreational market, learnings from North America have shown that legalisation does not mean that all sales are legal. Although the gap is closing, a year on from legalisation in Canada, black-market sales still dominate. Please note that the market forecast calculations included in this report now pertain to legal product only, although the true value may be significantly higher.

Previous market forecasts assumed total legalisation and regulation of the recreational market across the region but, for the fifth edition of The European Cannabis Report, we have taken a more conservative approach and anticipate that this will not be the case. Instead, we expect just a handful of countries to legalise.

Source: Prohibition Partners
The market forecast expects to see a slow start over the review period with recreational cannabis only expected to come to the fore in 2022 following legalisation in Luxembourg. The Domino Effect is likely to see a number of neighbouring countries legalise within a year or two of law reform in Luxembourg, and our forecast assumes that Germany, Portugal and Switzerland will also contribute towards the value of the European legal cannabis market by the end of 2022.

Both the medicinal and recreational cannabis industries can expect to enjoy triple digit growth towards the end of the forecast period. However, whilst medicinal cannabis accounts for the lion’s share of value by 2024, recreational cannabis will grow twice as fast (albeit from a much smaller value base). Despite this, recreational cannabis will still account for less than 10% of value sales by the end of the forecast period.

**MEDICINAL**

The medicinal cannabis market is an amalgamation of pharmaceutical products (formulated products holding market authorisation, such as Sativex) and medical cannabis (whole plant-based cannabis that does not hold a marketing authorisation). Pharmaceutical products will account for a significant but minority share of the market value over the forecast period. Prohibition Partners forecasts that 2024 will be the first year where pharmaceutical grows faster than medical. This is largely owing to likely product roll-out dates (following lengthy clinical trials) and subsequently a rise in penetration of pharmaceutical products.

Medicinal cannabis is expected to break the US$1 billion barrier in early 2023 owing largely to the domination of Western Europe, thanks to a strong German market. However, over the forecast period, Northern Europe is set to grow its share of the market, at the cost of Southern and Western Europe. In Germany, Czechia and Poland there is already established demand for medical can-

**RECREATIONAL**

Europe’s recreational market is expected to open up over the forecast period with Luxembourg leading the charge. Europe’s legal recreational market is expected to be kickstarted by the small but pioneering country with a value of an estimated US$175,000 by the end of 2021.

Over the forecast period, Western Europe will drive growth of recreational cannabis with Germany and the Netherlands expected to account for the lion’s share of value to 2024. If successful, initiatives such as the coffee-shop trials in the Netherlands will help to address concerns over the legalisation of cannabis and possibly result in a domino effect amongst neighbours (something observed in The North American Cannabis Report).

In the next 2-3 years, Western European countries are expected to account for more than 95% of the recreational industry in the region, but legalisation in key Southern European markets such as Italy and Spain would reduce this dominance. Towards the end of the forecast period, some but not all Northern and Central European markets, such as the UK, Norway, Czechia and Poland would be expected to legalise, helping to bring the market value of recreational cannabis to some US$176 million by 2024.

For a more detailed analysis of market performance, please contact our consultancy team on info@prohibitionpartners.com
COUNTRIES TO WATCH IN 2020

1. Luxembourg moves from being a country with no medical cannabis programme at all to the country that is leading the adult-use conversation across Europe within the space of two years.

2. Opportunities are arising in countries both big and small, with many of the smaller economies looking to cannabis cultivation as a major economic stream.

3. Ireland and France are embarking on pilot projects to extend patient access and ensure the medical data are there to support long-term usage.

LUXEMBOURG LEADS THE EUROPEAN CONVERSATION ON ADULT-USE LEGALISATION

Luxembourg’s ministers are reportedly aiming to present a preliminary concept bill for cannabis legalisation by next autumn, though there is no similar projection for when the bill might be introduced to parliament. It is still the aim of the government to bring into force legislation for legalising cannabis during this term, which ends in 2023. If no other European country moves to legalise cannabis soon, Luxembourg will become the first European country to formally legalise the drug for recreational use in Europe. The Luxembourg government believes that legalisation of the drug would protect public health more effectively than decriminalisation, as it would help to stifle the country’s illegal cannabis market. Legalisation and the development of a regulated cannabis industry would also result in the generation of extra tax revenue, which ministers Schneider and Braz want to see reinvested in domestic drug education and addiction treatment programmes.
SMALL NATIONS SPEARHEAD THE ECONOMIC OPPORTUNITY

Malta is a prime example of a country that is looking to spearhead this new opportunity. Liberal cannabis policy and pro-business frameworks are helping position Malta as a market of interest for investors, operators and importers. Despite being a small domestic market, Malta is able to offer expertise in pharmaceuticals, cultivation licences and export potential to the rest of Europe, which is a lucrative opportunity for the international cannabis producers. However, a short supply of arable land is somewhat slowing progress on this front.

North Macedonia has embarked on a free-market approach to medical cannabis, rather than setting up productions under a state monopoly. Consequently there are no caps on the number of cultivation licences granted in the country. This strategy has been adopted to gain an early-mover advantage over other European states. North Macedonia legalised growing cannabis for medical purposes in 2016, and Prime Minister Zaev is a vocal supporter of the industry.

Greece and Cyprus have also adopted a similar stance on medical cannabis, having identified this as a major economic opportunity that plays to the region’s climate strengths. With 26 licences approved by the end of 2019 in Greece, producers are currently in the process of receiving their building permits if they have not already started work on their GMP infrastructure, with the first plants expected to be installed in the second half of 2020. More than 60 licence applications are still being considered. Greece is also proving to be more flexible about CBD production and selling than are many of its neighbours, with negotiations underway to raise the limits of THC levels in hemp to at least 0.3% and with a tolerance level of 0.8% for plants in the field.

The Channel island of Jersey appears to be punching above its economic weight in the cannabis stakes following its progressive legislation on CBD. The law allows CBD consumables to contain a 3% THC to CBD ratio, meaning Jersey hemp growers can legally extract and sell full-spectrum oil. If they wish to sell to foreign markets, they then need to extract the CBD to a higher purity. The island has granted several hemp licences and is expected to grant its first licences for medical cannabis in the first half of 2020, with strong interest from North American investors.
Unlocking the benefits of cannabinoids for health and wellbeing.

Our portfolio companies:

Sanatio
Fully licenced wholesaler for medicinal cannabis.

VAAY
Leading CBD brand for wellbeing products.

sanitygroup.com
CULTIVATION AND SUPPLY

In February 2019 in the UK, the first bulk shipment of medical cannabis was brought into the country, and advances such as this are helping to reduce the bottlenecks in supply, with Canopy bringing in more from its German and Danish distribution/greenhouses. In Germany, Aurora, Aphria and Demecan will be delivering their first harvest by the end of 2020 with production of some 10,400 kilograms expected by 2023. This should help reduce reliance on imported products and boost access to domestically cultivated cannabis for Germany’s 60,000 patients. The Netherlands is also gearing up to allow more small tenders for cannabis cultivation, ending the monopoly that Bedrocan has maintained for years. Similar plans have been hinted at in the Czech Republic, where, to date, just a single company, Elkoplast, has been producing cannabis domestically. Many other nations, including Portugal, Denmark, Malta and North Macedonia have their eyes on supplying the European market. Some care will be needed that cultivation does not outpace the growth of the licit market as happened in some regions of North America. One lesson learned here is that the legal market will take over gradually from the illicit market and the demand will not shift instantaneously from black to white markets.

ACCESSIBILITY IN PILOT SCHEMES

France’s medical cannabis pilot scheme means that medical cannabis will become available for certain patients in France after the Assemblée Nationale authorised a two-year trial of the drug. Patients who are not responding to existing treatment could be eligible to be prescribed cannabis on a ‘therapeutic’ basis. It will allow doctors to gather evidence of any possible side effects, and to review the risk of addiction. The government voted through the trial on 25 October 2019 as part of the 2020 social security proposals.

In Ireland, legislation allowing people access to medical cannabis on a limited basis over the next five years has been signed into law by Minister for Health Simon Harris. Similarly to France, it is a last-resort scheme and is limited to just three conditions: severe treatment-resistant epilepsy, spasticity in MS sufferers, and CINV. In the UK, November 2019 saw the launch of Europe’s first medical cannabis patient registry – Project Twenty21. The project is being led by drug reform campaigner and former health minister David Nutt and has seen 20,000 patients suffering from a variety of conditions enrol on the scheme. The private project is designed to create the largest body of evidence for the effectiveness and tolerability of medical cannabis – with an aim to demonstrate to policymakers that medical cannabis should be as widely available, and affordable, as other approved medicines for patients who would benefit from them. Similar pilot schemes are being successfully conducted in Luxembourg and Denmark, which are granting access to patients who otherwise would have no legal alternative.
EXPERT INTERVIEW

We sat down for a short interview with Alvit’s CEO Yona Levy to discuss his company’s plans to begin shipping EU-GMP certified flowers into Germany during Q2, 2020.

I hear there is some news coming soon from Alvit on the sales front; can you elaborate? Sure, it’s an exciting time at Alvit. One of the cannabis manufacturing facilities we are constructing in Malta is expected to receive final EU-GMP certification in April. This means that we’ll already be shipping flowers from Malta into Germany in May of 2020.

If the German market needs an influx of 10-20 tonnes of cannabis flower this year, we’re here to ensure those needs are finally fulfilled.

Who will you be working with in Germany to distribute your flowers? We’re currently in discussions with multiple distributors in Germany and the rest of Europe. Some distributors are discussing multiple ton orders for 2020, and others only several hundred kilogram orders. Some discussions are quite advanced, and others are in the early stages. The way things are looking now, it’s possible we might sell out our entire 2020 capacity before we even receive the EU-GMP certification in April.

Why are companies chasing you guys for your flowers? What other companies are there? There’s only a handful of EU-GMP certified facilities around the world that can produce medical cannabis flowers for sale in Europe. Enter Alvit with a brand-new, state-of-the art, EU-GMP certified cannabis manufacturing facility in Malta that can easily supply a large portion of the market needs over the coming years, and it’s right here in the EU. Suddenly there is an EU-based supplier with tens of tonnes of high quality, consistent, locally cultivated and supplied EU-GMP certified medical cannabis for sale. Wouldn’t you want to make sure you were one of the companies locking up that supply instead of relying on 250 kilogram handouts from the current handful of companies supplying the market?

Are you producing only flowers? We’re starting with flowers, but we’ll be doing a lot more than that going forward. Flowers will be Q2, oils will be Q3, and our larger 12,000 square metre facility will be completed in Q3 and EU-GMP certified in Q4. That facility has the ability to produce pharma-grade cannabis products such as tablets, sprays, suppositories, creams and more. So, we’re starting with flowers and fulfilling that market need, but we’ve spent five years developing drug delivery technologies for cannabis that we believe the market will be moving towards over the coming years.

Any message you want to leave with our readers? We’re open for business. Get in touch with us sooner rather than later if you want to ensure supply from our Maltese facility. It wouldn’t surprise me if five tonnes or more are already accounted for by the time this report goes to publication. Distributors across Europe are beginning to realise they can get a steady supply of EU-GMP certified flowers from a local EU supplier, and as such we expect our production capacity for 2020 to be entirely accounted for before we begin production in May. So, email us at info@alvitpharma.com if you’re serious about 2020.
European countries are moving towards legalisation, but at very different paces. In this section we probe deeper into the selected countries, which we consider to be influential, rapidly-moving or of high value in the region.
# Germany

## Key Stats

<table>
<thead>
<tr>
<th>Population</th>
<th>Min. State Purchase of Domestic Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>82.8 M</td>
<td>650kg/year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year Medicinal Cannabis Legalised</th>
<th>Imports of Medical Cannabis Flower</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>6.7 tons</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Medical Cannabis Patients</th>
<th>Wholesale Cost Per Gram</th>
</tr>
</thead>
<tbody>
<tr>
<td>60,000</td>
<td>€2.30</td>
</tr>
</tbody>
</table>

## Conditions Treated

- **Pain**: 71%
- **Spasticity**: 11%
- **Anorexia**: 8%
- **Other**: 10%

Cannabis remains illegal in some countries so please reference your local laws in relation to medical or recreational use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2020 PP Intelligence LTD.
Since the legalisation of medical cannabis in March 2017, Germany has quickly developed into Europe’s leading medical cannabis market by some distance, with an estimated 60,000 active patients. Aside from population size and Germany’s GDP, this primacy is down to the progressive approach towards medical cannabis taken by the federal regulator, BfArM, as well as high (and rising) reimbursement rates for treatment by public insurers. With the exception of dentists and veterinarians, any physician is authorised to prescribe medical cannabis, and there are no limitations on which conditions are eligible for cannabis treatment. Together with the affordability granted by reimbursement and relaxed regulations around distribution and dispensation, this means that patient access is greater than anywhere else in Europe, resulting in huge demand. These high levels of demand in the market have seen supply come from a variety of sources, with six companies currently supplying 35 approved products, and, with the recent granting of production licences to three companies, a domestic supply chain will soon be in operation. In the meantime the German market will continue to rely on imports primarily from the Netherlands and Canada, with confirmed shipments also coming from Australia, Colombia, Portugal and Uruguay as of December 2019.

**Licence holders**

Cultivation/Production licence holders (winners of tendered lots):

- Aurora – 1,000kg/year for 4 years
- Aphria – 1,000kg/year for 4 years
- Demecan – 600kg/year for 4 years

**Patient data**

**Conditions treated**

No list of indications has been published by the regulator; most prescriptions so far have been given for pain (71%), followed by spasticity (11%) and anorexia (8%).

**Legality**

In January 2017 a law was passed through the lower house of the German parliament, to be put into effect in March of that year, allowing the use of medical cannabis to treat serious illnesses, and requiring public health insurers to cover the costs of treatment. Under previous legislation, use had been tightly restricted, with approximately 1,000 patients having received medical cannabis treatment in the country up until that point. According to an amendment made to the German Federal Narcotics Act in 1992, those found in possession of only ‘a small amount’ of cannabis would avoid prosecution. What this constitutes is left at the discretion of the regional governments, and so varies across the country: up to 15 grams in Berlin, up to 6 grams in most regions.
Format prescribed
No exact figures on cannabis prescriptions are available; however, a proxy may be obtained from government sources for prescriptions made for pain.

Percentage of market

<table>
<thead>
<tr>
<th>Medication</th>
<th>Percentage of market</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRONABINOL</td>
<td>64%</td>
</tr>
<tr>
<td>CANNABIS FLOWER</td>
<td>21%</td>
</tr>
<tr>
<td>SATIVEX</td>
<td>13%</td>
</tr>
<tr>
<td>CANNABIS EXTRACTS</td>
<td>2%</td>
</tr>
<tr>
<td>NABILONE</td>
<td>1%</td>
</tr>
</tbody>
</table>

Source: Prohibition Partners/BfArM

Prescriptions granted
According to the German Institute for Drug Use Evaluation, in 2017, from March to December, 27,000 prescriptions were processed. In 2018, this number jumped to 95,000. Between January and March 2019 alone, around 60,000 cannabis prescriptions were issued by doctors.

Demographics
No direct information is available. However, statistics on pain patients, which make up a significant portion of cannabis patients in Germany, indicate that it is the elder age categories which are using the most CBPMs, with the over 50-year-olds consuming around two thirds of all pain-prescribed CBPMs.

Age categories of pain patients in Germany

<table>
<thead>
<tr>
<th>AGE GROUP</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–29</td>
<td>4.4</td>
</tr>
<tr>
<td>30–49</td>
<td>24.5</td>
</tr>
<tr>
<td>50–69</td>
<td>43.9</td>
</tr>
<tr>
<td>70–89</td>
<td>24.6</td>
</tr>
<tr>
<td>90+</td>
<td>0.7</td>
</tr>
</tbody>
</table>

Source: Prohibition Partners/BfArM
**Recent news**

In attempts to meet growing demand, the German federal government recently announced it will buy at least 650 kilograms of medical cannabis flower from domestic producers for approximately €1.5 million (US$1.66 million) per quarter, which sets the average wholesale price at €2.3 per gram. The government also mentioned the option of buying 325 more kilograms per quarter, also at €2.3 per gram. Australian medicinal cannabis company Althea has signed an agreement that will see the first shipment of its medicinal cannabis products arrive in Germany in the first half of 2020. On 13 January, Europe’s first cannabis exchange-traded fund (ETF), the Medical Cannabis and Wellness ETF, dubbed CBSX, was launched in Germany. A joint project of Purpose Investments, a Canadian asset manager, and HANetf, a British ETF platform, the fund will invest in listed businesses that grow, make and distribute medical cannabis products.
What were the drivers for founding Cannamedical Pharma?

When I founded Cannamedical® back in 2016, my vision was to help doctors and pharmacists to provide critically important medicine to patients whose lives could significantly be improved by medical cannabis. We are persistent in the pursuit of our goal to improve the lives of patients who have to live with the +80 conditions for which medical cannabis is prescribed in Germany (and the EU). In addition to that, members of my own family had to rely on opioids for years and have had to deal with the steadily increasing side effects which develop over the years. Hence I started to look for an alternative, natural form of medication and I came across the medical cannabis opportunity. Cannamedical today generates a double-digit-million revenue and employs around 50 people in Cologne, Germany.

The German cannabis market is becoming increasingly competitive. What advantages does Cannamedical have in comparison to the rest of the market?

Cannamedical® provides reliable medication of the highest quality and creates new standards through product transparency in the market for patients, doctors and pharmacists alike. Our product range is comprised of twelve products with exclusively homogeneous Indica-, Sativa-, Hybrid- and cannabidiol (CBD)-rich flowers. There are three different categories of flowers: light, medium and forte, which were developed together with experts to set new standards for transparency and therapy. We are also the industry’s first mover and leading independent player in the German cannabis industry and hold exclusive or preferred contracts with six leading suppliers of flower and extracts, which is creating the largest and most stable supply chain in the EU cannabis market and follows a de-risking approach. Our expertise with regulators has yielded six permits and licences, which provide the broadest range of import, refinement and distribution activities in the market.

Lastly, Cannamedical has the highest level of customer service in the industry with multiple customer touchpoints that gives us a direct commercial access to all 22,000 German pharmacies. Our team serves an increasing and recurring number of patients every month, which stimulates cash flow and growth of the company.

The regulatory and commercial landscape within the cannabis industry is continuously changing. What has been the biggest challenge when operating in the cannabis industry?

Europe is one of the world’s most difficult medical cannabis markets to enter due to the strict regulatory framework. This includes complex licensing and trading requirements, the strict pharma sales/marketing regulations and prohibition on consolidating certain medical practices and pharmacies. People often think of cannabis as a commercially traded good, whereas reality is far more regulated and difficult when acting within
Cannamedical has recently released a CBD compounding kit for pharmacies. Which problem does it solve?

Cannabidiol is the non-psychoactive component of the medical cannabis plant and addresses a wide variety of health issues such as childhood epilepsy syndromes and chronic inflammatory diseases, which typically don’t respond to anti seizure medications. Recent studies show that CBD was able to reduce the number of seizures and increase life quality tremendously. As an effect of the reclassification of cannabidiol (CBD) in the EU as a Novel Food, food and dietary supplements containing CBD must no longer be marketed in Germany without regulatory approval. With this product extension, we responded to the high demand on the German healthcare market for licensed CBD products, which is expected to triple this year compared to 2019.

Cannamedical has released a CBD formulation kit according to the new German formulary (NRF 22.10) for the preparation of cannabidiol oil solution. All quality standards and certifications are complied with according to the guidelines for use as a medicinal product. Patients receive a high-quality product from controlled, GMP-certified CBD isolate.

What is Cannamedical’s growth strategy?

Our supply chain allows us to run all processes out of Germany, including primary and secondary packaging, quality testing and product release. We are fully licensed and thus able to export into any EU member state that can present us an import permit, either from an integrated subsidiary or external and third-party contractual partner. The first half of 2020 Cannamedical will primarily be focused on educating doctors and pharmacists about our product portfolio together with a strong field sales service team that covers any queries within Germany.

At the same time we are targeting to introduce THC oils and extracts to the market by the second half of 2020 to complete the largest portfolio of medical cannabis products in Europe. The Cannamedical science and product development team are currently focusing on exploring new options in alternative mediational forms such as oils.

Cannamedical has also established a subsidiary in the UK, which is currently in the licensing process and expects to start operations within 2020.
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# UK

## KEY STATS

<table>
<thead>
<tr>
<th>POPULATION</th>
<th>NUMBER OF PRESCRIPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>66.87 M (2019)</td>
<td>177*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>YEAR MEDICINAL CANNABIS LEGALISED</th>
<th>COST OF PRESCRIPTION (3 MONTHS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>US$3,268 (£2,500)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NUMBER OF MEDICAL CANNABIS PATIENTS</th>
<th>PERCENTAGE OF MEDICAL CANNABIS FOR UK PATIENTS, IMPORTED FROM ELSEWHERE</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPROX. 100 (MOSTLY PRIVATE PATIENTS)</td>
<td>100%</td>
</tr>
</tbody>
</table>

*England only, up to September 2019

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Medical cannabis has been legal in the UK since 2018. Despite this, government progress on access and prescribing recommendations lags behind much of Europe. As of November 2019, around one hundred patients are thought to have successfully accessed medical cannabis in the UK. However, this has largely been via private clinics rather than via the NHS. Despite changes in the law, barriers to patient access remain, including having to engage a specialist doctor who will accept liability for treatment, or paying the fee for a private prescription, which can cost around US$3,268 (£2,500) for a three-month supply depending on the clinic and size of prescription. Other large-scale factors that are slowing the progress of medical cannabis access in the UK include the lack of doctors who are trained in understanding the endocannabinoid system, the lack of UK sourced research on the efficacy of CBPMs and the reluctance of groups such as the British Paediatric Neurology Association (BPNA) and NICE to recommend physicians to prescribe medical cannabis. The most promising response is coming in the form of Project Twenty21, which will see 20,000 patients supplied with subsidised medical cannabis before the end of 2021. This will be used to lobby policymakers and make a case for NHS funding and evidence-based legislative reform and should pave the way for more widespread patient access in the coming years.

The UK is home to the single largest exporter of medical cannabis in the world: GW Pharmaceuticals. The International Narcotics Control Board (INCB) reports that the UK contributed 69% of the total reported global CBPM and held 94.6% of cannabis in storage in their most recent report of 2017. Despite this, due to strict regulations on cultivation and medical cannabis production in the UK, currently all CBPMs are imported. Since legalising medical cannabis, consistency of supply has been a challenge for UK cannabis providers. This is set to change in the near future, as recently we have seen the increase in large imports by companies such as Canopy Growth, Lyphe Group and Aurora.

### Legality

#### Medical cannabis status

In June 2018, the Home Office reviewed the legislative stance on medical cannabis and began a two-part review to examine the scheduling of cannabis-related medicinal products under the *Misuse of Drugs Regulations 2001*. In November 2018, medical cannabis was legalised. In practice, restrictive prescription guidelines limit patient access for products other than Epidyolex, though this should improve with the recent NICE recommendations for Nabilone and Sativex for intractable nausea and MS spasticity respectively.

#### Recreational cannabis status

Illegal

### Patient data

#### Conditions treated

NICE recommended:

- Intractable chemotherapy-related nausea
- Intractable spasticity due to MS
- Lennox-Gastaut syndrome and Dravet syndrome

Also in the upcoming Twenty21 trials:

- Chronic pain
- PTSD
- Anxiety
- Tourette’s syndrome
- Substance use disorder

### Licensed products

- Sativex
- Nabilone
- Epidyolex
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Founded in 1978, Memery Crystal is an independent, full service, partner-led law firm based in Fleet Street, London. The firm’s practice areas include Corporate, Real Estate, Banking & Finance, Dispute Resolution, Commercial, IP & Technology (CIPT) and Employment. The firm is also the leading UK law firm on advising the emerging cannabis sector on business set-up, capital markets, mergers and acquisitions, private fundraising, licensing and commercial contracts. At Memery Crystal, our intelligent and tailored approach makes us a more attractive proposition than the ‘one size fits all’ service offered by many other law firms. We are commercially aware, entrepreneurial in spirit, international in outlook and pragmatic in approach. For more information, visit www.memerycrystal.com.

How is Memery Crystal set up to service the cannabis sector?
Memery Crystal has been engaged in the emerging cannabis sector for over two years now and from that has gathered significant insight as to who is active in the space, both as investors and promoters. We acted on the listing of one of the first cannabis investment companies onto the NEX Exchange, Ananda Developments. Being involved in the sector early on has meant that we understand the market and the legal challenges it’s facing and how those are evolving. As a firm, we have been part of the Centre for Medicinal Cannabis, which was established to engage with stakeholders in the cannabis-based medicinal products and cannabinoid wellness space. From this we have obtained a lot of market intelligence and are close to what is being discussed in the market. More broadly, we, as a firm, understand the language of the industry and are able to apply that to our existing legal expertise across all of our practice areas.

Talk us through which areas of the sector are most interesting at the moment.
There are very few things in this space that are not exciting at the moment, although perhaps not all of them in a positive way. The CBD market is crying out for regulation, and the implications of the EU position with respect to cannabis as a Novel Food remain a challenge. Cannabis-based medicinal products are now available for prescription in the UK but prescriptions remain low, which makes widespread distribution of these medicines economically challenging, and can make scaling difficult for companies at present, but this will start to change.
We are moving into the world of cannabis 2.0. Having been through the initial wave of cannabis company promotors and products, companies are now looking at other cannabinoids such as CBG, CBA, as well as the implications technology can have on how cannabis is produced, developed or used. We are also now seeing companies develop to support the operation of the cannabis sector, including recruitment companies, invoice financing groups, and extraction providers. Cannabis will for the most part become a commodity, like coffee, so being able to develop cannabis beyond its most obvious parts will be where greater value is generated.
Is Europe (and the rest of the world) likely to legalise recreational or adult-use cannabis?

Across the EU, certain states are already taking a more liberal approach to recreational cannabis, but 'legalisation' is coming in different forms. For example, the Netherlands have a system of toleration of recreational cannabis; in Spain it is illegal for public sale and consumption, but can be consumed in private or in 'cannabis clubs'; Portugal takes a similar approach, allowing limited personal use; in Italy, a court ruling at the end of 2019 confirmed that growing and using a small amount of cannabis at home was no longer a crime; in Germany, recreational cannabis use remains illegal, although there is ongoing debate and anticipation that it could be made legal shortly. In the UK, recreational cannabis use remains illegal; however, there is a body of public support towards some form of decriminalisation. Whether the UK is actually ready for this step, it’s hard to say. The narrative around cannabis in the CBD wellness or medicinal space is often confused or mixed in the public psychology of recreational cannabis use. More education is needed so that people understand cannabis is more than a recreational drug.

What is the biggest concern for your clients?

There are two main areas we have people contact us about from a legal perspective. Firstly, CBD and the regulatory status (or lack of it) in the UK, and the implications of EU Novel Food. Secondly, we regularly get asked to advise about the implications of the Proceeds of Crime Act 2002 (POCA). Under POCA, conduct which takes place in an overseas jurisdiction, which would be criminal conduct if it took place in the UK, can be money laundering, and the parties involved subject to the sanctions under the Act. From a non-legal perspective, because the sector is still emerging in the UK, many companies are struggling for further funding and spend a lot of time looking for investors. At present, investment is mostly coming from high-net-worth private investors and family offices.

Institutional money remains hard to find due to the legal and regulatory issues across the sector. The disconnect between global and EU approaches to cannabis is also creating confusion and delaying companies being able to scale and operate efficiently.

What work is keeping you busiest?

It’s a range of things. We have been working on a number of stock exchange listings, assisting with the various stages of funding rounds, advising on M&A transactions, as well as either providing or facilitating advice on the existing regulatory regime, including co-ordinating advice from jurisdictions across the EU. We have lots of calls where we are simply discussing some of the issues the market is facing and knowledge sharing.

Which legal developments should we be keeping our eye on?

We would like to see clarity being given around POCA and its interpretation in the context of investments being made into overseas cannabis companies, or funds being invested by overseas cannabis companies (particularly those from North America) into UK cannabis businesses. While a number of cannabis investment companies have come onto the privately operated NEX Exchange, the London Stock Exchange is yet to truly embrace the cannabis sector and POCA issues are complicating that process. Once a few true cannabis companies are listed on the main London exchanges, access to the larger pot of institutional money will become available, which should kick-start the sector, particularly medicinal.
MemeryCrystal

The original doobie brothers
Memery Crystal takes you higher
Blunt talking legal advice

The leading UK law firm advising the cannabis sector


Nick Davis
Chief Executive
nick.davis@memerycrystal.com
Prescriptions issued
177* (in the 11 months following legalisation, 90% were issued via private clinics, according to the NHSBSA)

Key companies
Share prices for the majority of companies listed here have fallen steadily since December 2019, owing to uncertainties in the global market.

Public companies: as of Jan 2020

<table>
<thead>
<tr>
<th>COMPANY NAME</th>
<th>EXCHANGE</th>
<th>SHARE PRICE</th>
<th>MARKET CAP [million]</th>
<th>STOCK PERFORMANCE [3 months to Jan 2020]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sativa Group Plc</td>
<td>NEX</td>
<td>US$4.68 (£3.60)</td>
<td>US$28.14 (£21.63)</td>
<td>-13.76%</td>
</tr>
<tr>
<td>World High Life</td>
<td>NEX</td>
<td>US$15 (£11.50)</td>
<td>US$23 (£17.6)</td>
<td>-4.35%</td>
</tr>
<tr>
<td>Zoetic International</td>
<td>LSE</td>
<td>US$9 (£6.85)</td>
<td>US$13 (£10)</td>
<td>27.78%</td>
</tr>
<tr>
<td>Spinnaker Opportunities PLC</td>
<td>LSE</td>
<td>US$6.10 (£4.65)</td>
<td>US$1.9 (£1.4)</td>
<td>N/A</td>
</tr>
<tr>
<td>Ananda Developments Plc.</td>
<td>NEX</td>
<td>US$0.31 (£0.24)</td>
<td>US$1.3 (£1.0)</td>
<td>-17.24%</td>
</tr>
<tr>
<td>Freyherr International Group Plc</td>
<td>NEX</td>
<td>US$127.40 (£97.50)</td>
<td>US$32.8 (£25.1)</td>
<td>-43.48%</td>
</tr>
<tr>
<td>GW Pharma</td>
<td>NASDAQ</td>
<td>US$100 (£76.55)</td>
<td>US$3,075.37 (£2,352.68)</td>
<td>-29.32%</td>
</tr>
</tbody>
</table>

Currency conversion correct as of 21/01/2020 www.xe.com

Recent news highlights (Past three months)
Many recognise the need for dedicated medical cannabis clinics in the UK in line with other mature medical cannabis markets. Progress came in October with the approval of Sapphire Medical Clinic. This is set to be built upon with the approval of further facilities such as the Medical Cannabis Clinics, which already have doctors active in seven regions within the UK. There is already huge support for increased access to cannabis, both from the patients accessing via the black market and from the general public. Supply is also beginning to ramp up after London-based Lyphe Group signed an import deal to bring Israel’s first cannabis exports in the country in January 2020. A survey run by the Centre for Medicinal Cannabis (CMO) and the Cannabis Advocacy and Support Services (CPASS) made headlines in November 2019 with the finding that around 1.4 million people living in the UK are using street-bought cannabis for a diagnosed condition. Major news outlets picked up on a poll run by the Conservative Party in the summer of 2019 which found that twice as many UK residents support legalisation of recreational cannabis as oppose it. The question this raises is will government policy catch up with public opinion and, if so, how long will this take?

*England, Nov 2018 – Sept 2019
## Key Stats

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>60.5 M</td>
</tr>
<tr>
<td>(2018)</td>
<td></td>
</tr>
<tr>
<td>Year Medicinal Cannabis Legalised</td>
<td>2013</td>
</tr>
<tr>
<td>Distribution of Medical Cannabis to Pharmacies in 2018</td>
<td>578.5 KG</td>
</tr>
<tr>
<td>Year Recreational Cannabis for Personal Use Decriminalised</td>
<td>2019</td>
</tr>
<tr>
<td><strong>Market Value of Cannabis Light Industry</strong></td>
<td><strong>US$187 M</strong> (€170 M)</td>
</tr>
<tr>
<td><strong>Exclusive Cultivation Rights</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Italian Ministry of Defence</strong></td>
<td></td>
</tr>
<tr>
<td>Domestic Cultivation Expected in 2020</td>
<td>500 KG</td>
</tr>
</tbody>
</table>

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The sale or supply of cannabis in Italy for recreational purposes is illegal; possession for personal use can incur penalties; however, this is rarely enforced. The laws regarding medical cannabis have been updated a number of times, most notably in 2007 when medicinal cannabis was legalised, and in 2013 when its medical use was expanded. Policies on medical cannabis vary by region, with reimbursement and authorised prescribers under regional control. Regarding recreational usage, in December 2019 Italy’s highest court ruled that growing a small amount of cannabis privately and for personal use is not a crime.

Owing to legal reform, hemp has been widely cultivated in Italy without the need for a licence since 2016. This has allowed the blossoming of a low-THC ‘Cannabis Light’ industry. This industry is encouraged by an unusually high tolerance of up to 0.6% THC concentration for hemp in Italy, as opposed to the normal 0.2% limit used by most other countries. Research from Erasmus University Rotterdam indicates that revenues which have been diverted from black-market cannabis suppliers to the cannabis light industry amount to as much as €170 million per year. A bill that would have legalised cannabis light in Italy was blocked by the Italian Senate in December 2019, which may prolong the existence of the grey legal zone.

Italy operates a strict centralised policy of supplying cannabis aimed at protecting patients, which does, however, limit the scope for commercial opportunity. Currently the military has the only licence to cultivate cannabis within Italy, which it does at a facility in Florence. The remainder of the demand is met by imports from Bedrocan in the Netherlands and Aurora in Canada. Cannabis is then distributed by five licensed wholesale distributors to pharmacies within the country, but Italy has faced a shortage of cannabis supply in recent years. In an attempt to alleviate this, the Health Ministry has announced two measures; in July 2019, Aurora was awarded a tender to supply a massive 400 kilograms of product over two years, and in December the Ministry announced it would almost triple domestic cultivation up to 500 kilograms of cannabis in 2020.

### Legality

**MEDICAL CANNABIS**  
Legal since 2013

**RECREATIONAL CANNABIS**  
Illegal; private cultivation was decriminalised as of December 2019

### Conditions treated

(Guidelines only, not restricted to these conditions)

- Chronic pain
- Multiple Sclerosis
- Spinal cord treatment
- Lack of appetite due to HIV/AIDS
- Cachexia
- Anorexia
- Glaucoma
- Tourette’s syndrome
- Chemotherapy-related side effects
**Format prescribed**
Sativex, Flower, Magistral preparations

**Prescriptions granted**
No details on the number of prescriptions granted in Italy are publicly available; however, the government has released data on the sale of cannabis to pharmacies, see below.

### Key figures on medical cannabis wholesale in Italy (kg)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sale (distribution) of wholesalers to pharmacies</th>
<th>Total imports authorised by the Ministry of Health to ASL (DM 1997)</th>
<th>Total sale (distribution) of Italian-produced cannabis to pharmacies</th>
<th>Grand total sale (distribution) of cannabis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>300</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>400</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: Prohibition Partners/Italian Ministry of Health*

### Key financials

**REIMBURSEMENT TRENDS**
Currently 14 autonomous regions reimburse patients for medical cannabis, and this policy varies between regions.

**PHARMACEUTICAL COST PER GRAM**

**RECREATIONAL COST PER GRAM**
US$9 (€8.2) (black market)

**Company data**
Aurora and Bedrocan products are supplied to Italy.

**Recent news**
Italian hemp company Canapar made headlines throughout 2019 in relation to the building of its extraction facility in Sicily. The plant is expected to have the capacity to process 600 tonnes of hemp per year, making it the largest such facility in the EU. In addition, a number of significant investments were made in Italy’s cannabis and hemp market from international players during 2019, with EMMAC (UK) establishing a partnership with distributors Farmalabor; Khiron (Canada) acquiring hemp company Canapalife; Canopy Rivers (Canada) completing a €17 million investment in Canapar; and Elixxer (Canada) receiving GMP status for its new hemp facility in Pavia.
GMP compliant importer of medical cannabis to EU

Synoptis Industrial provides pharmaceutical import and batch certification services to the European Union fully compliant with GMP

CONTACT:
Tomasz Nawrocki
e-mail: tomasz.nawrocki@synoptisindustrial.pl
# Czech Republic

## Key Stats

<table>
<thead>
<tr>
<th><strong>Population</strong></th>
<th><strong>Government Subsidy</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>10.65 M (2019)</td>
<td>Up to 90% cost from 01 Jan 2020</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Year Medical Cannabis Scheme Introduced</strong></th>
<th><strong>Exclusive Production</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>ElkoPlast Slusovice S.R.O.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Number of Medical Cannabis Patients</strong></th>
<th><strong>Year Recreational Cannabis Possession Decriminalised</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2,050 (2019)</td>
<td>2010</td>
</tr>
</tbody>
</table>

Cannabis remains illegal in some countries so please reference your local laws in relation to medical or recreational use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2020 PP Intelligence LTD.
The Czech Republic has a small but steadily growing cannabis industry, which is attracting the attention of local entrepreneurs as well as international cannabis giants. This progress is backed by a strong history of liberal attitudes towards cannabis within the country. There has never been a strong criminalisation of cannabis within the Czech Republic and currently personal possession is decriminalised for up to 5 grams of cannabis resin and 15 grams of herbal cannabis. The medical cannabis scheme in the Czech Republic was introduced in 2013 for a very limited number of patients. This was expanded in 2015 with Decree No. 236/2015 Coll2, which allowed for specialists to prescribe cannabis for many conditions, including chronic pain, MS and chemotherapy-related side effects. The Czech Republic has a strict but transparent system of regulation in place that is helping its market to grow in a stable manner. Medicinal cannabis can be prescribed only as Sativex magistral formulas and the dry flower format, with a maximum 20% content of THC with a 20% variation in concentration between what is declared and what is measured in other labs. To date, only one company is licensed to produce cannabis within the country: Elkoplast. Elkoplast sells its product to the State Institute for Drug Control from where it is distributed. Production within the country is reportedly set to diversify as the government opens up the licensing regime in 2021.

---

**Legality**

**MEDICAL CANNABIS**

legalised August 2013

**RECREATIONAL CANNABIS**

STATUS
decriminalised January 2010

---

**Cannabis grams prescribed per year**

<table>
<thead>
<tr>
<th>Year</th>
<th>Grams Prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>836</td>
</tr>
<tr>
<td>2016</td>
<td>2577</td>
</tr>
<tr>
<td>2017</td>
<td>1227</td>
</tr>
<tr>
<td>2018</td>
<td>4800</td>
</tr>
<tr>
<td>2019</td>
<td>17000</td>
</tr>
<tr>
<td>January of 2020</td>
<td>3010</td>
</tr>
</tbody>
</table>

*Source: Prohibition Partners/State Agency of Medical Cannabis SA*
The rate at which cannabis is being prescribed in the Czech Republic is increasing rapidly (see graph above) due in part to the announcement during 2019 that the government would be subsidising 90% of the costs of medical cannabis for all qualifying patients for amounts up to 30 grams per patient per month from 1 January 2020.

Key financials

90% of all costs associated with cannabis to be reimbursed for approved conditions

Recent news

The most significant development of the past year was the announcement from the government that 90% of cannabis medications would now be subsidised. The implications of this are hard to overstate. In the coming year, we can expect that patient access will be significantly eased, and the market for supplying these needs will continue to grow at an exponential rate. This presents companies with very attractive opportunities to begin exporting and distributing products to the Czech market.

BRINGING TOGETHER THE STRENGTHS OF TWO MEDICAL CANNABIS LUMINARIES

Canada, with its track record of business expertise, cannabis leadership, good governance and international collaboration, and

Jamaica, with its long medicinal cannabis history, unique indigenous cultivars, ideal sustainable growing climate and stringent medical cannabis regulatory system.

A Canadian-Jamaican company with nearly one million square feet of cultivation and processing operations in Jamaica, JMCC is poised to achieve its mission of becoming the leading provider of GMP-certified, Jamaican medical cannabis to the world in 2020.

Learn more at jamaicanmedicann.com

WHERE NATURE MEETS SCIENCE™

JMCC
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## Denmark

### Key Stats

<table>
<thead>
<tr>
<th>Population</th>
<th>Mediterranean Cannabis Program Introduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.8 M (2019)</td>
<td>2018</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical Cannabis Prescriptions 2018 to 2019 Q2</th>
<th>Land Being Cultivated Under a Development Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>15,607 G</td>
<td>280,000 M²</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Medical Patients 2018 to 2019 Q2</th>
<th>Government Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>4,300 (Approx.)</td>
<td>50% of cost or 100% for terminal patients</td>
</tr>
</tbody>
</table>

Cannabis remains illegal in some countries so please reference your local laws in relation to medical or recreational use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2020 PP Intelligence LTD.
Denmark has established itself as one of the main players in the emerging European medical cannabis industry, with many of the world's leading cannabis companies gearing up to use it as a launchpad to access the wider continental market. Low energy costs, a wealth of experience in horticulture and pharmaceuticals, and a clear and transparent regulatory framework have seen large-scale investment, with approximately 280,000 square metres of cultivation space currently under development. First harvests are expected in 2020, and will represent the beginning of a Danish supply chain that will grow to far exceed the demand of the domestic market, providing a significant boost to Danish exports.

Having reached the midway point of Denmark's four-year pilot programme for medical cannabis, it can so far be judged a resounding success. The numbers for prescribing doctors and patients treated have so far exceeded expectations, with the most recent figures showing treatment levels well above those forecasted at the beginning of the programme. This can be attributed to many factors, including the wide range of conditions eligible for prescription, the lack of restrictions on doctors who can prescribe, the variety of products available on the market, as well as the affordability granted by a straightforward and generous system for reimbursement.

In contrast to the open nature within the Danish market, significant barriers exist to market entry. Chief among these are stringent regulations with regard to quality control in agricultural and manufacturing processes. The potential advantage to this is that medical cannabis produced in Denmark which supplies the Danish market will be perceived as a high-quality product, which should fuel demand for it elsewhere.

The shockwaves that reverberated around the global cannabis industry in late 2019 were certainly felt in Denmark, as Aurora suspended construction on its Nordic 2 facility, which at 93,000 square metres was set to be the country's largest medical cannabis cultivation facility by some distance. Additionally, revelations about CannTrust’s dubious cultivation practices in Canada saw its imports into Denmark halted, leaving Danish patients temporarily without access to oil products. Despite these considerable stumbling blocks, the industry continues to thrive, and, with exports seemingly around the corner, the future looks bright for Danish cannabis.

**Legality**

In 2017, two relevant pieces of legislation were passed: an executive order for the growing, manufacturing and distribution of cannabis and cannabis products, and a law passed in parliament for the establishment of a trial programme for medical cannabis to begin in 2018. Prior to this the only cannabis-based medicinal products available to Danish patients were pharmaceuticals.

Recreational cannabis status – Illegal

**Licence details**

January 2018 saw the introduction of two parallel programmes related to the legalisation of medical cannabis, which will run for four years; these are:

- The Development Scheme, under which companies can gain authorisation for the cultivation and handling of cannabis with a view to producing cannabis suitable for medicinal use, potentially for use in the Pilot Programme; and
- The Pilot Programme, under which companies can gain authorisation for the cultivation and production of cannabis and cannabis products for supply to patients via prescription.
Approved products
There are currently four products on the market:

- Bediol, Bedica and Bedrocan (Bedrocan) – Flower ingested via herbal tea or vapour inhalation
- Sedamen (Aurora) – Soft capsules ingested orally

Patient data
The average patient in Denmark is using cannabis for pain-related conditions and is between the ages of 42 and 64. The prevalence of usage for pain is similar to other countries that prescribe CBPMs for pain, such as Germany, Canada and Australia.

Medical conditions for which cannabis is prescribed in Denmark, 2019 (%)

- PAIN-RELATED: 69%
- EPILEPSY: 9%
- MS-RELATED: 3%
- CANCER-RELATED: 1%
- OTHER: 1%

NB: Around 67% of prescriptions are reported to the Danish Health Agency without the condition being treated so these numbers are considered indicative.
Source: Prohibition Partners/Danish Health Data Agency
Prescriptions granted
From the beginning of its medical cannabis scheme in 2018 up until Q2 of 2019, Denmark made out 15,607 prescriptions to 4,300 unique patients. The figure had been growing steadily with an average quarterly increase of 14%; however, growth slowed at the beginning of 2019. This may be due to the high cost of cannabis medications, which may be remedied as the domestic supply of cannabis increases.

Demographics
While most consumption takes place in the 42–64 age group, Prohibition Partners calculates that the 65+ age group are most likely to use CBPMs. The tendency for older age groups to make use of pain-relieving cannabis products mirrors the mature markets in Canada, where the 65+ age bracket is the fastest growing segment of the market. This is likely due to the benefits of decreasing stigma surrounding cannabis medications as well as the fact that chronic pain is more common in older age.

<table>
<thead>
<tr>
<th>AGE CATEGORY</th>
<th>0–17</th>
<th>18–41</th>
<th>42–64</th>
<th>65+</th>
</tr>
</thead>
<tbody>
<tr>
<td>PENETRATION (% of age group using CBPMs)</td>
<td>0.003</td>
<td>0.036</td>
<td>0.104</td>
<td>0.151</td>
</tr>
<tr>
<td>TOTAL PATIENTS</td>
<td>35</td>
<td>574</td>
<td>1,980</td>
<td>1,743</td>
</tr>
</tbody>
</table>

Source: Prohibition Partners/Danish Health Data Agency
Recent news

Denmark has been forthright in its intentions to generate a cannabis export industry. In January 2019, Denmark made waves by announcing it had legally paved the way for bulk exports of cannabis produced within the country. Copenhagen made global headlines multiple times throughout the year with attempts to introduce a trial legalisation of recreational cannabis. Though not yet passed by the national government, if the bill is established, the city could become an ideal testbed for the benefits of legalised recreational cannabis.
# Luxembourg

## Key Stats

<table>
<thead>
<tr>
<th>POPULATION</th>
<th>RECREATIONAL CANNABIS POSSESSION DECRIMINALISED</th>
</tr>
</thead>
<tbody>
<tr>
<td>600,000 (2019)</td>
<td>2001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>YEAR MEDICAL CANNABIS PILOT INTRODUCED</th>
<th>LEGALISATION OF RECREATIONAL CANNABIS FOR ADULT USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>PLANNED FOR 2021</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NUMBER OF MEDICAL CANNABIS PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>270</td>
</tr>
</tbody>
</table>
Small in size but punching above its weight in the cannabis conversation, in just two years, Luxembourg has transformed from being a country without a medical cannabis programme to one that is leading the European cannabis discussion on implementing a fully integrated medical and recreational policy.

More than half a year into the two-year pilot programme that followed Luxembourg’s legalisation of medical cannabis in 2018, it was reported that in excess of 270 patients (as at August 2019) were being treated with medical cannabis, ahead of the Ministry of Health’s initial expectations of 200. This represents 0.045% of the population in the small Duchy of 600,000 residents.

While patient numbers have exceeded expectations, critics of the bill feel that more conditions, such as HIV, should be added to the law when it comes up for review in June 2020. During the review period that has followed the law change, medical cannabis has been prescribed only under strict conditions and has normally been limited to terminal or advanced illnesses where chronic pain is a key feature. However, some legislators argue that for many patients this help comes too late and that the full potential of the medicine is not being used to alleviate suffering across a wider remit of ailments.

Following the implementation of the medical cannabis bill, Luxembourg set up supply agreements for oils and capsules with Canada. In December 2018, Aurora became the first producer of medical cannabis to supply Luxembourg with dried flowers for medical purposes, with the deal extended in May 2019 to a second national delivery of 20 kilograms. However, as with all burgeoning cannabis programmes, supply has proved to be an issue and, in August 2019, doctors were asked by the Ministry of Health to suspend adding any more patients to the programme even though the INCB approved a new quota to Luxembourg of 183 kilograms up to the end of 2019. Following a government procurement review, the country appointed the German branch of the Canadian business Canopy Growth to supply the region’s therapeutic cannabinoids, such as Dronabinol and CBD, with the contract expected to last until the end of 2020.

With Health Minister Etienne Schneier describing Luxembourg’s trial programme as ‘very successful so far’, the next phase of the operation has been implemented. In November 2019 the Luxembourg Department of Health announced an increase in the budget for doctor training and medical cannabis purchase from US$389,000 to US$1.52 million (€350,000 to €1.37 million) in 2020.

**Legality**

**Medical**

The law to allow cannabis to be prescribed and used for patients in Luxembourg who suffer from chronic pain, nausea relating to chemotherapy, or muscle spasm resulting from MS was passed unanimously on 28 June 2018. Although the original draft of the bill limited prescription authorisation to specialists, a ruling by the Council of State made a crucial step in facilitating wider access by allowing any general practitioner to prescribe cannabis (following successful completion of a one-day training course) in the final version of the bill.

Medicinal cannabis was initially only available in Luxembourg via prescription from hospital pharmacies; however, with only four hospital pharmacies in Luxembourg initially providing access, this made it more difficult for consumers in rural areas to collect their prescriptions. Consequently, the next phase of the pilot in 2020 has seen medical cannabis available from all pharmacies.
Recreational
Possession of small amounts of cannabis for recreational use was decriminalised in 2001 after the substance was reclassified as a Category B controlled substance, meriting only a fine for a first offence. Prosecution depends on the amount of cannabis the offender has been caught in possession of, with monetary fines ranging from US$278 (€250) to US$2,780 (€2,500). At the start of 2020, the purchase, sale and production of cannabis remains illegal in Luxembourg, though this is unlikely to remain the case for much longer, after November 2018 saw Luxembourg announce plans to legalise adult-use cannabis.

Adult-use legalisation
Adult-use cannabis was pushed into the government’s agenda in 2018 after a public petition secured the necessary number of signatures to trigger a parliamentary debate on the issue. Following the November 2018 announcement, Luxembourg’s coalition government released a 250-page document detailing the Duchy’s plans to introduce recreational legalisation of cannabis by 2021. Key objectives of the plan include:

- removing consumers from the black market
- reducing psychological and physical harm
- reducing criminal activity at the supply level
- regulating production, purchase, possession and consumption within Luxembourg’s borders, which likely would not allow for exports or imports.

The state has also revealed plans to regulate production and distribution through a cannabis agency. Luxembourg intends to follow Canada in legalising the possession of 30 grams of cannabis, with tax revenues being reinvested in drug education and addiction treatment programmes. Legislation is likely to include a ban on non-residents buying cannabis in order to dissuade drug-tourism. Home-growing is also likely to be prohibited.

Minors aged between 12 and 17 would not be criminalised for possessing five grams or less of the drug, but those who break the more generous laws will be hit with harsh penalties under the plan. It still remains to be seen as to whether usage will be banned in all public places or allowed in specific public areas.

Licence details
Relevant licences
No cultivation or production licences have been issued yet, as the Duchy has still to confirm its commitment to domestic production. However, it does intend to follow the Canadian model in this respect and so production and distribution licences are eventually likely to reflect those issued by Health Canada. The law currently states that the manufacture, import, export and marketing of cannabis medicine are subject to a general authorisation to be issued by the Ministry of Health. At present the German arm of Canopy Growth holds the contract to import cannabis medication into Luxembourg. As part of its recreational legalisation plan, Luxembourg intends to establish a dedicated cannabis agency, through which licensing applications will likely go through.

Patient data
- In the first three months of 2019, 120 patients had been prescribed medical cannabis amounting to an estimated 7 kilograms of medical cannabis.
- Up until July 2019, 270 patients had been prescribed medical cannabis and around 20 kilograms was prescribed.

Key companies
Cannad’Our is the only hemp company in Luxembourg and is based in Kalborn, in the north of the country. It has 3,000 customers, mainly in Luxembourg, and exports products to countries such as Poland. The company produces flax, sunflower and rapeseed but also industrial hemp.
The production of its CBD oil is controlled by the National Health Laboratory (LNS).

Following the announcement that Luxembourg will pursue recreational legalisation, Cannad’Our contacted the Ministry of Health to offer to produce cannabis in Luxembourg. Although no permissions have been granted at the time of writing, Minister of Agriculture Romain Schneider (LSAP) said that if cannabis production in Luxembourg is confirmed in the coming months, Cannad’Our would certainly position itself as a player in the sector. Canopy Growth is currently the only company supplying medical cannabis for Luxembourg’s pilot access scheme, an agreement that will last until the end of 2020.

Recent news
The closing session of parliament before Christmas 2019 saw the approval of a National Agency for Medicines and Health Products, in the form of a public establishment called Luxembourg Agency for Medicines and Health Products (ALMPS). As one of the few European nations without a health agency, the agency is being implemented to help the country monitor the quality and safety of medicines on the market, in order to prevent harmful, substandard or counterfeit medicines from reaching the public.

In January 2020, Nicolas Henckes, the head of the Luxembourg Trade Confederation (CLC), reported that domestic companies were already positioning themselves for the sale and distribution of cannabis in Luxembourg and that he would be in favour of the establishment of a coffeeshop model of sale and consumption. This would bring heavy regulation to the system and standardised framework where resellers are ‘duly trained and qualified’. The CLC has said that it is looking to create a system in which the distribution of recreational cannabis is controlled within ‘defined places’.
Recognition of the medical and commercial benefits of cannabis is spreading across Europe by the day. 2019 saw many countries make moves to introduce more broadscale access to medicinal cannabis. Here we take a brief consideration of the status of cannabis in each country across Europe. For more information on the rules and regulations as well as licensing and business-related queries for the countries below, contact our consultancy service at info@prohibitionpartners.com.
Decriminalisation of Recreational Cannabis

YEAR STATUS CHANGED

| 1976 | 2019 |

NORTHERN EUROPE

Channel Islands
Cannabis is a Class B drug under Schedule 1 of the Misuse of Drugs (Bailiwick of Guernsey) Law, 1974. It is a criminal offence in the Bailiwick to possess, cultivate, supply or import cannabis. However, it is possible to apply for a licence (to the Office for the Committee for Health and Social Care) that would authorise the cultivation of cannabis and associated activities for the manufacture of industrial hemp and any other product. The licensed production and manufacture of products can be legally marketed in Guernsey. Licences are granted for a period of up to 12 months.

The Channel Islands are also home to Jersey Hemp, the first company in the British Isles to be awarded a licence to harvest hemp flowers for cannabis oil. Hemp started to be grown in 2017 with the island producing an estimated 35 tonnes of hemp seed (around 13,000 litres of hemp oil). In early 2019, Jersey began to issue licences to grow medicinal cannabis.

Denmark
Danish drug laws are based on international UN conventions. Cannabis falls under the 1955 Euphoriant Substances Act, which is used for minor offences (punishable with a prison term of up to two years) and the penal code’s §191 from 1969 (aimed at the suppliers rather than users). The Danish judicial framework does not distinguish between cannabis and other illegal drugs, including hard drugs such as heroin.

Denmark has been a pioneer in Europe in big-scale cannabis production. It is a signatory to the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 United Nations Convention Against Illicit Traffic of Drugs and Psychotropic Substances.

Medicinal cannabis is legal. In 2018, medical cannabis became legal and was regulated for a trial period of four years. Following a unanimous vote in favour by the Danish parliament, a four-year trial period legalised medicinal cannabis for a select group of medical patients. The trial began on 1 January 2018 but was blighted by inaccessibility to medication, with patients struggling to find doctors who would prescribe. Indeed, a number of medical associations advised doctors against it.

Prior to 2018, Sativex was available on prescription. The producers of medical cannabis can now import and promote their products, and doctors are allowed to prescribe it but, as the products are not approved as medical products, there are no prescription guidelines and nor is there sufficient research on the effects and side effects of medicinal cannabis. As a result, and with doctors having to take full responsibility for the prescription and dosage, few doctors are willing to prescribe cannabis products.

Estonia
Cannabis in Estonia is controlled under The Act on Narcotic Drugs and Psychotropic Substances and Precursors Thereof. Under this law, unauthorised consumption of narcotic drugs or psychotropic substances without a prescription, or illegal manufacture, acquisition or possession of small quantities are illegal and punishable by a fine or prison sentence.

Medical cannabis is legal and the Estonian State Agency of Medicines (ESAM) may authorise use based on an application by a doctor on a named-patient basis. However, the market has been slow to take off, largely because the country does not have a medical cannabis programme. It was reported that eleven years after legalisation, as of 2016, just one patient had been prescribed cannabis in the country. By 2018, just three applications for Sativex had been submitted (two were approved). There were no further applications in 2019. Dronabinol and Nabilone are available to Estonian patients through the unauthorised medicinal products procedure, but data from ESAM show that they have not been used in recent years. Regarding
the supply of medicinal cannabis, medicine wholesalers must submit an application (evaluated by the ESAM) to import.

**Faroe Islands**

The Faroes constitute a self-governing community within the Kingdom of Denmark. Although cannabis is illegal in the Faroe Islands, in the first half of 2019, the local government in the Faroe Islands approved a programme based on the Danish approach to medicinal cannabis.

Medical cannabis that is registered in Denmark is also registered and legal to use on the Faroe Islands, when prescribed by physicians. The Medical Registration Board approves enquiries from physicians to prescribe cannabis and adapt the medical instructions accordingly. However, physicians can freely prescribe any extempore products.

On the Faroe Islands the medical registrations are not limited in time. The Faroese Minister of Health has ordered the Medical Registration Board to register the same medical cannabis preparations as are registered for the experimental scheme in Denmark. This means that medical cannabis preparations registered in Denmark are also available on the Faroe Islands.

The Faroe Islands do not follow the Danish experimental scheme and there are no patient trials currently being carried out on the Faroe Islands.

2019 figures supplied by the Faroe Islands Ministry of Health suggest that there are currently around 60 patients being treated with medical cannabis.

**Iceland**

With exception to special cases, cannabis is prohibited (Habit-forming and Narcotic Substances Act No. 65/1974). Sativex has a marketing authorisation in Iceland and can be bought in a pharmacy with a prescription from a physician who specialises in neurological diseases. CBD can be imported for personal use, provided it has been manufactured as a medicinal product.

Despite its illegality, it is estimated that in 2017 almost 6% of adults used the drug recreationally. This marks a rise from just over 3% in 2007 (a change in research methodology may account for some of this increase).

**Ireland**

Cannabis is illegal for recreational purposes in Ireland. Despite this, data from the UNODC World Drug Report shows that the annual prevalence rate amongst 15–64-year-olds stands at almost 8% (2015).

In 2019, Ireland introduced a five-year Medical Cannabis Access Programme (MCAP). Under the scheme, medicinal cannabis could be prescribed as a drug of last resort for just a handful of conditions (spasticity associated with multiple sclerosis, CINV, and treatment-resistant epilepsy). Commercial medical cannabis suppliers whose cannabis products meet the specified requirements set out in the legislation:

- have been listed in Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations;
- are in line with the clinical guidance for the scheme; and
will be able to supply these products to the Irish market via an Irish-based authorised wholesaler, for use under the MCAP.

Until listed cannabis products become available and the MCAP becomes fully operational, doctors may continue to use Ministerial licensing to prescribe medical cannabis for their patients.

The Health Service Executive (HSE) covers the cost of prescriptions for patients with the CBPMs being dispensed through pharmacies. Sativex was authorised for use in Ireland in July 2014, and Epidyolex was authorised in September 2019. There is currently no information available on the estimated number of patients expected to participate in the scheme.

The number of Ministerial Licences granted to medical practitioners in Ireland for medical cannabis is 72 (31 patients). Licences are valid for three months at the initiation of treatment, with subsequent licences valid for six months. There are no forecast projections for 2020.

Isle of Man

Medicinal cannabis is legal in the Isle of Man. Changes in legislation in the UK impacted on the Isle of Man with the Department of Health and Social Care (DHSC) consulting residents on whether they wanted legislation to follow that of the UK or to take an alternative approach. Some 4% of residents completed the survey with more than 99% supporting the introduction of medicinal cannabis. Respondents were in favour of cannabis being directly available to the public as a quality assured product for self-medication through accredited dispensaries or as a framework similar to the Netherlands. A total of 95% would support the cultivation and manufacture of medicinal products in the Isle of Man subject to a suitable regulatory framework.

The legal position echoes that of the UK, in that CBPMs can be prescribed by doctors on the GMC specialist register; however, they are not necessarily funded on the NHS. Any specialist wishing to prescribe medicinal cannabis would be expected to have regard to the current guidance from NICE and other relevant bodies such as the Royal Colleges.

The Isle of Man’s Department of Health and Social Care is currently considering the recent guidance from NICE in respect of Epidyolex for Lennox-Gastaut and Dravet syndromes and the revised guidance on Sativex in MS. This will lead to a decision on NHS funding but, at the time of writing, no cannabis-based medicinal products are routinely funded on the NHS.

Currently, any CBPMs with a marketing authorisation can be prescribed by an appropriate medical practitioner and would require a private prescription. There is no register of patients accessing CBPMs (either those with a marketing authorisation or those that would be obtained as ‘pharmaceutical specials’ on a named patient basis).

Recreational cannabis is illegal. Since 2018, there has been debate as to whether cannabis should be decriminalised but, at the time of writing, there have been no changes to legislation. A petition on change.org to decriminalise cannabis in the Crown dependency had garnered some 1,500 signatures (around 2% of the island’s population).

Latvia

It is illegal to cultivate, sell or possess cannabis for recreational or medical use in Latvia. However, research from one of the country’s best-known research suppliers, the SKDS research centre, has found that although almost 8/10 (78%) residents in Latvia do not believe it is worth legalising cannabis, this figure has fallen from almost 9/10 (87%) in 2014.
Lithuania
In October 2018, Lithuania’s parliament voted unanimously to approve the use of medicinal cannabis, giving doctors the authority to prescribe cannabis for certain health conditions. This resulted in the amendment of Lithuania’s Pharmacy and Narcotic Drugs and Psychotropic Substances laws. The Act entered into force in May 2019 and medical usage is permitted for patients suffering from MS, severe epilepsy, HIV/AIDS and/or cancer. Licensed companies may import, manufacture (but not cultivate), retail or export medicinal cannabis products.

Norway
Under Norwegian law, the use and possession of minor quantities of drugs fall under the provision of the Act on Medicinal Products. There are no separate laws for illicit drugs. As of 2018, doctors who have been approved by the Norwegian Medicines Agency can prescribe medical cannabis to patients on a case-by-case basis. Conditions treated include debilitating pain or discomfort, cancer, epilepsy, conditions that cause spasms, such as Tourette’s syndrome and MS. There is currently no publicly available information on the number of state-scheme medicinal cannabis patients.

Sweden
Dronabinol and Sativex are available with special permission on a case-by-case basis. Other than this, Sweden operates a very restrictive policy on cannabis medications. In June 2019, the Supreme Court ruled that any product marketed as a CBD or wellness product with any THC at all was to be considered an illicit drug, making Sweden one of the more restrictive countries in the EU on cannabinoid-based products.

United Kingdom
Medical cannabis has been legal in the UK since November 2018. Despite this, government progress on access and prescribing recommendations lags behind much of Europe. As of November 2019, around one hundred patients are thought to have successfully accessed medical cannabis in the UK to date. One major reason is the reluctance of national health groups to recommend prescription of cannabis, such as the British Paediatric Neurology Association (BPNA) and NICE, who cite a lack of UK-sourced research on the efficacy of CBPMs.

The most promising response to this slow progress is coming in the form of Project Twenty21, which will see 20,000 patients supplied with subsidised medical cannabis before the end of 2021. Recently, we have witnessed the granting of import licences to companies such as Canopy Growth (bulk licence) and Aurora. Cannabis clinics have recently begun opening up, with a highlight being the approval by the Care Quality Commission of the Medical Cannabis Clinics network in January of 2020. The success of the UK cannabis industry will largely depend on new ventures such as these, which improve patient access, as well as the results of Project Twenty21.
**SOUTHERN EUROPE**

**Albania**
Cannabis and hemp are both banned substances in Albania. The transport, selling and possession of quantities over ‘a single dose’ are criminal offences, which can incur years of jail time for offenders. Possession of ‘a single dose’ as arbitrated by authorities is not a punishable crime (*Criminal Code*, Art. 283). By some estimates, Albania is the lead producer of illicit cannabis (at around 1,300 tonnes in 2016), dwarfing the current licit cannabis market, in the EU. There is currently no clear sign that the country will move towards legalisation as politicians try to demonstrate a strict policy on drugs in attempts to help their accession to the EU. As Albania is opened up to new markets, if legalisation were to occur, the significant experience of cultivation in the country could feasibly be channelled to the benefit of licit production and provide jobs in a country that currently has 17% unemployment.

At present, there is no medicinal cannabis programme in Albania, and cannabis is not available on prescription from doctors.

**Andorra**
Cannabis and hemp are currently illegal substances in Andorra for both medicinal or recreational use. The region has approximately 2% arable land and so is not a good prospect for the cultivation of cannabis. However, Andorra has a history of tobacco production as well as a strong tourism industry buoyed by nominal tax rates. As such, if legalisation were to occur, it’s not unlikely that a cannabis-related tourist industry could develop within the principality.

**Bosnia and Herzegovina**
Cannabis and hemp are currently illegal substances in Bosnia and Herzegovina (BiH). The region has a low consumption rate compared with neighbouring countries. One study, using similar metrics, noted that just 10% of adolescents in Bosnia used cannabis compared with 30% in neighbouring Croatia. There were whisperings of legalisation coming to BiH in 2016 when a task force was set up to investigate the feasibility of legalisation but there has not been any significant shift in policy since.

**Cyprus**
Cyprus is on a path towards broadscale medical legalisation of cannabis. This is backed up by a trend of increasing acceptance of cannabis and a reduction of associated stigmas. In 2016, laws were adopted in Cyprus that allowed for treatment of personal drug users rather than criminalisation, with personal amounts of cannabis set at 30 grams or lower. Cyprus legalised the medical use of cannabis oil for use by cancer patients in the advanced stages of illness in January 2017. Medical access was expanded in February 2019 with the law being changed to allow for import, export, cultivation and prescription of medical cannabis for a wider range of conditions, including HIV, degenerative diseases of the motor system, rheumatism, neuropathy and glaucoma, as well as Tourette’s syndrome and Crohn’s disease.

Cyprus is taking a restricted approach to licensing, with plans to grant just 3 cultivation licences within the first 15 years in an attempt to attract financially stable countries. Each licence will cost €500,000 to acquire, with more costs applicable for the duration of cultivation.

**Gibraltar**
Gibraltar is a small territory of the UK on the south coast of Spain and has 33,000 inhabitants. Gibraltar’s cannabis policy is now maturing at a fast pace. The territory green-lighted Sativex in February of 2017 in response to calls from health activists within the region that year.

Throughout 2018, the Chief Minister of Gibraltar supervised a consultation process on medical cannabis legalisation. This culminated in a June 2019 announcement that the country would be creating a ‘bespoke licensing regime’ to enable certain
licensees to cultivate cannabis domestically and a legal route of patient access to medical cannabis. This promise was expanded on in October of 2019 when the government announced that any doctor with specific training could prescribe medical cannabis for refractory MS, epilepsy, CINV and life-altering pain. Each product must be approved by the Gibraltar Health Authority before being prescribed to patients. Once fully functional, Gibraltar’s developing industry could prove to be exceptionally important to the region as the effects of Brexit take their toll on importation of cannabinoids to Britain, a hole in the market Gibraltarian producers may look to plug.

**Greece**

A trend of pro-legalisation sentiment has been on the rise in Greece over recent years, both due to the needs of Greek patients and the need for the Greek economy to recover from its financial crises, with hemp and cannabis production offering an attractive new export product. In May 2016, the country legalised and reintroduced hemp to Greek agricultural markets. Then in June 2017, the government announced it would be legalising medical cannabis. Less than a year later, Greek leaders approved Law 4523 and Joint Ministerial Decision No. 51483, which permitted farming and production of low-THC medical cannabis. However, no medical cannabis has been harvested and product hasn’t been made available to the patients yet. This is set to change soon; in August 2019, Greek authorities spoke with Prohibition Partners, confirming that 26 licences for vertically integrated cannabis facilities had been granted since legalisation. The administration also said they hoped that licences granted at the time would bring in €360 million of investment and create up to 2,250 jobs. Industry sources report that up to February 2020 35 new licences have been issued by the new government, elected in July 2019. As companies navigate Greece’s comprehensive licensing system and complete all stages of licensing, it can be expected that Greece will not only sufficiently meet its domestic market but also begin to supply the growing markets in neighbouring European countries, such as Germany and Poland, which industry experts forecast happening as soon as the end of the current year.

To deliver on all that cannabis has to offer and gain its place as a major European hub of medical cannabis Greece may need to cut some of the red tape that producers are currently wrestling with. Greek business consultancy VK Premium has been involved with the Greek government in attempting to streamline the process in response to complaints about the process from some interested parties. At the time of writing, possible law amendments are being discussed to allow for bulk exports of flower and private distribution to pharmacies, in addition to the previously envisaged monopoly. In the realm of CBD, a similar complaint was lodged by Kannabio, a cooperative of hemp farmers in Greece. Kannabio are working to increase the current limitation of 0.2% THC for hemp products, which they say is restrictive, to between 0.3 and 0.8%. They are also currently working with the government to produce clearer provisions for licensing around beauty and food products containing CBD. When these licensing issues are cleared up, the country’s cannabis and CBD markets will be freer to develop and diversify, providing new products, jobs and medicines.

**Italy**

The sale or supply of cannabis in Italy for recreational purposes is illegal, while possession for personal use can incur penalties; however, this is rarely enforced. In December 2019 Italy’s highest court ruled that growing a small amount of cannabis privately and for personal use is not a crime. Since 2016, hemp is effectively a legal substance, which has allowed the blossoming of a low-THC ‘Cannabis Light’ industry. This industry is encouraged by an unusually high tolerance of up to 0.6% THC concentration for hemp in Italy, as opposed to the normal 0.2% limit used by most other countries.
The legal framework for punishment and prohibition regarding illicit substances is laid down in Law nº 162, 26 June 1990, approved with a presidential decree known as the DPR 309. The laws regarding cannabis have been updated a number of times, most notably in 2007 when medicinal cannabis was legalised; in 2013 when its medical use was expanded; and in 2014 when it was reclassified as a less dangerous substance under Italian law.

Medicinal use of cannabis varies by region, with reimbursement and authorised prescribers under regional control. Italy has seen significant rates of medicinal cannabis prescription since 2014, and it is currently the second largest market for medical cannabis in Europe at approximately 20–25,000 patients. According to reports, supply has not met demand for a number of years, so the market remains in shortage.

**Malta**

Malta is fast becoming a hub of cannabis cultivation in Europe. Cannabis was decriminalised in the state in 2015 and further progress was made in March 2018 when medical cannabis was officially legalised under amendments to the Drug Dependence Act, which allowed for prescriptions for chronic pain, MS-related spasticity and chemotherapy-related side effects. Just a month later, the Production of Cannabis for Medicinal and Research Purposes Act paved the way for companies to produce, import, export and distribute medical cannabis within the country. Aurora, Aphria, MGC Pharma, Alvit, MPX International, Supreme Cannabis and EMMAC Life Sciences are just some of the international companies that are setting down roots in Malta. This success in attracting outside investment has been due in part to sustained efforts from lawmakers, the Malta Medicines Authority and Enterprise Malta, each of whom have made efforts to streamline the process of obtaining licences within the country. Exports of Maltese cannabis are expected to begin in the first quarter of 2020, with Prime Minister Joseph Muscat announcing his expectation that export revenue will be ‘more than one billion Euro and that 900 jobs will be made available’ within the next three years.

**Montenegro**

Both medical and recreational cannabis are illegal in Montenegro. The most recent attempt at legalisation was launched in 2014 with the introduction of a medical cannabis bill, which the parliament rejected, and recent surveys indicate just 6% of people have a favourable attitude towards legalisation. However, licensed cultivation of hemp for nutritional and industrial purposes has been legal within Montenegro since 2011. As recently as January 2020, this has attracted outside investment; for example, Organigram-backed Canadian firm Eviana plan on investing €10 million into the creation of a cannabis extraction facility in conjunction with local company Montenegro Bio Science and Ramel Ltd. If this operation is successful, it could open up the Montenegrin market for further cannabinoid-based industries.

**North Macedonia**

Medical cannabis was legalised in the country in 2016, and now medicinal cannabis is available by prescription for conditions such as cancer, epilepsy, HIV and MS. Cannabis containing less than 0.2% THC, i.e. hemp, is legal to produce, and to procure over the counter. Since legalising medical cannabis in 2016, the government has granted licences to over 29 companies for the growth and production of cannabis oil. The market is still in its nascent stage, with few producers obtaining full licensing that meets all the required criteria for marketing approval, such as extensive security requirements for production facilities as well as the regular Good Manufacturing Practice (GMP) approval. To date, the government has instituted a free-market solution to the licensing of cannabis companies for
Cannabis remains illegal in some countries so please reference your local laws in relation to medical or recreational use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2020 PP Intelligence LTD.
cannabis oil and not to dried flowers. Going forward, expect North Macedonia to be at the cutting edge of the European market, especially when it comes to production and export. This progress has been bolstered by strong public support for legalisation (70% in 2015). How cannabis regulation will progress will depend largely on attitudes of the incoming elected government in April 2020.

Portugal
Possession and consumption of personal amounts of all drugs, including up to 25 grams of cannabis, were decriminalised in Portugal in 2001 by Law 30/2000 in order to combat a growing addiction problem. Punishment for activities involving larger amounts are still controlled by Decree Law 15/93 of 22 January 1993 and remain severe, with lengthy jail terms imposed. The success of these policies has made Portugal a role model for other countries wishing to turn a new leaf regarding policy in the post ‘War on Drugs’ world.

Cultivation of cannabis for medical purposes has been taking place in Portugal for a number of years, primarily by GW Pharmaceuticals for the production of its pharmaceutical cannabis products. Recent years have seen many more companies clamour to take advantage of Portugal’s ideal climate and cheap labour; and large-scale cultivation and production projects by Canadian multinationals make it a main player in the nascent European medical cannabis industry. Despite this growing industry, and despite introducing legislation in 2018 to allow for medical cannabis treatment of Portuguese patients, there have been no reports as yet of a domestic market for medical cannabis products.

San Marino
San Marino has a mature medical cannabis programme, begun in 2016, which provides access to medical cannabis products, for example Sativex and Bedrocan strains, to patients with conditions such as neuropathic pain and MS, as well as making provision for licensing of production of cannabis. In September of 2019, the parliament passed a citizens’ proposal by 18:13 that would regulate the recreational use of cannabis within the country. The proposal needs to pass before a Committee board before being confirmed or negated but, if passed, will pave the way for legal adult-use of cannabis within the country as well as for establishments along the lines of Amsterdam’s cafés.

Spain
Consumption and possession of cannabis are illegal in Spain, but only in public places. Under the Law on the Protection of Citizens’ Security (Art. 36), public possession of cannabis, even of a personal amount, constitutes an offence punishable by a fine of up to €30,000. Private cultivation, possession and consumption are allowed to varying degrees depending on the region. Catalonia is by far the most liberal region in Spain regarding cannabis laws, and has overseen the establishment of a network of ‘cannabis associations’, which work on a membership basis. Restrictions on cultivation, distribution and sale (which are illegal) are often ignored, leading to closures and crackdowns on some offenders.

A number of pharmaceutical cannabis products are legal but virtually inaccessible due to pricing and limitations on conditions for use. Otherwise there is no distinction made in the law between cannabis for recreational use and cannabis for medical use. Most users of cannabis for medicinal purposes access cannabis through associations, either self-prescribing or seeking consultation with patient organisations regarding treatment.

Hemp is legal in Spain, and the country has a thriving industry based on hemp-derived textiles and other products. The regulatory
turmoil, which has arisen as a result of the EU Novel Foods regulation, has engulfed Spain’s CBD industry however, and the official stance is that CBD can no longer be sold for human consumption. Despite this stance, a CBD industry still exists, as does an industry for non-consumable products such as topicals, balms and creams, primarily through online retailers.

EASTERN EUROPE

Belarus
There is no distinction made in Belarusian law between cannabis and hemp, and any activities involving either are severely punished. There is no medical usage of any cannabis product. Import of cannabis is technically possible, but only under the permission of a number of departments and only for scientific purposes.

Bulgaria
Strict laws and harsh penalties characterise Bulgarian drug policy. Consumption and/or possession of a minor amount of cannabis are punishable by a fine of €1,000 to €2,250, while crimes involving larger amounts will see offenders facing incarceration. These laws are laid out in the Narcotic Substances and Precursors Control Act, which allows for the production of up to 30,000 grams under special licence for medical, scientific or laboratory research, for educational purposes, as well as for maintaining the ability of dogs uncovering narcotic substances.

Cultivation, production and sale of hemp are legal under licence in Bulgaria, and it is the first and only country in the EU so far to have issued formal permission to a company for the sale of CBD products intended for human consumption since the new EU regulations were published concerning the status of CBD as a novel food. The permission was granted on the grounds that CBD is a traditional food in Bulgaria consumed before 1997, and therefore the regulations are not applicable to it.

Republic of Moldova
Cannabis is illegal under Article 85 of the Public Convention Code of the Republic of Moldova, which was passed in 2008. Under Article 85, it is illegal to procure, store or consume narcotic or psychotropic substances without a doctor’s prescription. Despite its illegality, cannabis is the most-used illegal drug in the country (ahead of Ecstasy) with latest available data putting lifetime prevalence rates at around 4% and prevalence rates for the previous 12 months of less than 1% (2010 household survey).

Cannabis, cannabis resin, cannabis oil and THC are included in Table 1 of Narcotic substances and psychotropic substances not used for medical purposes (Government Decision number 1088, 2004 and The Law number 382, 1999) meaning that they have no medical value and no medical use. However, in recent years, several state officials, such as MP Vladimir Hotineanu, have become more accepting of the medical benefits of cannabis. Dr Gheorghe Brega (Deputy Prime Minister for Social Affairs of Moldova until May 2017) proposed a law in 2013 that would permit the medical use of several psychotropic substances including cannabis. The proposition was rejected.

Romania
Since the adoption of new legislation in 2014, Romania’s approach to drug control has been relatively nuanced. Punishments for offences are linked to the type of drug involved, and the level of risk it is considered to pose. There is no penalty specified for consumption, and convictions for possession of amounts intended for personal use can result in anything from a fine up to three years’ incarceration.

In 2013, lawmakers legalised the medical use of cannabis derivatives containing under 0.2% THC in the form of pills or oil. In March 2019 it was announced that discussions were taking place around the further legalisation of medical cannabis, and on 4 July a bill bearing the signature of 100 Romanian MPs was introduced proposing...
the legalisation of cannabis painkillers for patients with chronic terminal illnesses via a special access procedure.

**Russia**

Medicinal and recreational cannabis are illegal in Russia. Although recreational use was decriminalised in 2004 (Government Decree No. 231 of May 6, 2004), the limit of cannabis that would be tolerated was decreased from 20 grams in 2004 to 6 grams in 2006 (Federal Law No. 11-FL of January 5, 2006).

However, attitudes towards medicinal cannabis are softening. In 2018, the organisers of the FIFA World Cup in Russia permitted football fans to bring medical cannabis and cocaine prescriptions to the country during the championship.

In 2019, the government approved the changes made to the annex of the Decree of the Russian Government dated 22 June, 2009 No. 508 to legalise the import of cannabis for research purposes. This was in light of ongoing studies being conducted by the WHO and UN. Nonetheless, although research might be ramping up, cannabis, for the moment, remains a Schedule I drug, meaning that it cannot currently be used for medical purposes.

**Ukraine**

Medical and recreational cannabis are both currently illegal in Ukraine. This is not expected to change in 2020 but very possibly within the next three to five years. Medical cannabis was the subject of a press conference in November 2019 with the Ukrainian president being quoted as saying medical cannabis is ‘not a priority’ at the moment. If legalised, Ukraine could utilise some of its state-owned 8 million hectares of arable land for low-cost cultivation.
Austria
Austria legalised the production and prescribed consumption of CBPMs in 2008 by amending its Narcotic Substances Act. The same act gave individuals the right to cultivate low-THC (<.02%) cannabis at home. Then in 2016, Austria decriminalised possession of cannabis for personal use (below 20 grams THC). All of this has had the effect of increasing the amount of cannabis that is being grown in the black market and supplied to domestic users as well as producing a huge ‘clone’ market whereby Austrians sell hundreds of thousands of cuttings and seeds to customers in and around the country.

Access to medical cannabis remains restrictive in Austria; while Dronabinol, Nabilone and Sativex are available, due to restrictive policies they are rarely prescribed. CBD was banned from cosmetic and food products in 2019 under sitting right-wing chancellor Sebastian Kurz. As Kurz was re-elected in January of 2020, it is unlikely that cannabis laws will be progressed in the short term.

Belgium
Belgium was an early adopter of the ‘support don’t punish’ doctrine that saw the lawmakers advise against criminal prosecution for personal quantities of cannabis in 2003. Some cities such as Antwerp have gone against national legislation by issuing on-the-spot fines for any amount of cannabis, so users and patients need to be observant of local laws. The country legalised the prescription of CBPMs, which received authorisation from the Health Ministry in 2015, as well as magistral CBD-based preparations. In reality, the only medicinal cannabis product that is currently approved is Sativex. Since 2019, a loophole has been made use of in Belgium that allows for the sale of hemp products including dried flower when they aren’t marketed as CBD. This has allowed for the creation of a large grey market in Belgium.

Despite this creation of a grey CBD market, access to medicinal cannabis remains low in Belgium, though this may soon change. The parliament passed an amendment in 2019 that provides for the creation of a dedicated cannabis office, which will oversee access to cannabis as well as research. It is expected that the office will release a tender for cannabis cultivation, the produce of which will be sold to the cannabis office for distribution within Belgium. This represents a significant opportunity for the winner of the tender, as Belgium is a relatively populous nation with a high GDP and middling prevalence of cannabis use. A draft resolution has also been presented to the Belgian government that would allow for the use of CBPMs.

France
Until recently, France was known for having some of the harshest policies relating to cannabis in Western Europe. New regulations released in 2018 reduced fines for possession of personal amounts to approximately €200; however, punishment for activities involving larger amounts remains severe. Hemp is legal and grown in quantities larger than in any other European country, although, its use in France is restricted to the textile industry.

The legal framework for cannabis is described in Law No. 70-1320 of 31 December, 1970, and new regulations were introduced by the National Assembly on 23 November 2018 to reduce penalties for possession of personal amounts. A law allowing for the restricted use of medical cannabis in France was implemented in 2013.

Until now the only cannabis-based medicinal product approved in France has been Sativex; however, it has not been supplied under French healthcare due to pricing disputes between the distributor and French authorities. A two-year trial programme expected to treat up to 3,000 patients is in a six-month implementation phase, with treatment expected to begin during 2020.
Germany
Legislation for the allowance of medicinal cannabis treatment was first implemented in Germany in 1998 with Dronabinol becoming available for prescription. Various subsequent regulations gradually widened patient access until March 2017, when full legalisation of medical cannabis treatment for severe illnesses opened the floodgates. Since then, patient numbers have seen a dramatic rise from approximately a thousand to an estimated sixty thousand making it Europe’s leading medical cannabis market, despite reports of significant supply shortages.

As in other Western European countries, non-medical cannabis is illegal in Germany with the exception of the possession of small amounts for personal use, 6 to 15 grams depending on the region. The Narcotic Drugs Act outlines the federal position on cannabis, though a certain discretion is exercised by the regional governments in exactly how the policies are interpreted and enforced. Hemp is legal in Germany, and while cultivation is low there is a large industry for the processing of hemp, grown elsewhere, into white-label products. The once-thriving German CBD market took a hit in 2019 as a result of the government crackdown in response to the new EU Novel Foods regulations requiring marketing authorisation for CBD products meant for human consumption; nevertheless, the export of white-label products to countries that take a more lenient view of the EU regulations, such as the UK and the Netherlands, continues apace.

Liechtenstein
Liechtenstein was incorporated in the 2019 European Commission decision to approve Epidyolex for a limited number of conditions and the country also allows Sativex on a restricted basis. Cannabis substances with 1% of THC or above are strictly illegal in Liechtenstein. Despite this, Liechtenstein is home to some innovation in the cannabis arena; for example, blockchain company Aeternity is developing a cannabis supply-chain management application.

Luxembourg
Luxembourg has recently announced plans to fully legalise the production, sale and consumption of cannabis within two years. If successful, it will be the first EU country to do so. This announcement comes soon after the country allowed full legalisation of cannabis for medical use (June 2018), and if carried out would represent a significant milestone in the march towards legalisation for the broader European context. As the law stands, possession for personal use is decriminalised, with fines being issued for possession of larger amounts.

Monaco
Cannabis is a tightly controlled substance in Monaco. Cultivation, production, possession and distribution are possible for research purposes only, and only under an exemption granted by the Minister of State. Otherwise, possession of even small amounts is considered a criminal offence, and there is no medical use except for the pharmaceutical cannabis product Nabilone, which was legalised in 1999 and can be prescribed only in restricted circumstances.

Netherlands
Cannabis exists in a legal grey area in the Netherlands. Technically it is still an illegal substance; however, consumption is decriminalised and it is permitted to be sold within coffeeshops. Possession of over five grams is an offence outside of their premises, and cultivation of over five plants is illegal anywhere, necessitating a ‘back door’ black-market route of supply for these establishments. Hemp is legal, and the Netherlands boasts a thriving hemp-derived CBD industry despite low levels of cultivation.

Cannabis falls under the jurisdiction of the Opium Act, while there have been a number of regulations and amendments delineating the permissions granted to coffeeshops. An experiment trialling a legitimate supply chain for coffeeshops is soon to get underway, which could end the heavily criticised ‘back door’ route of supply currently in operation.
Pharmacy sales of cannabis produced in the Netherlands, 2010-2019

Source: Prohibition Partners/The Dutch Bureau for Medical Cannabis

Medical cannabis has been legal in the Netherlands since 2003. It is the largest exporter of medical cannabis in Europe and there are an estimated 10,000 patients currently being prescribed cannabis treatment in the country. All production of medical cannabis is undertaken by the company Bedrocan and supplied to the Office of Medical Cannabis (OMC) for distribution and export. Whether Bedrocan maintains this monopoly depends on the outcome of the recent tender put out by the OMC.

Slovenia
Slovenia decriminalised the personal consumption of cannabis in 2014 in response to a public petition, which gained over 11,000 signatures. Currently, the only medical cannabis products that are permitted are Dronabinol and Sativex, and on a very limited basis – around 160 patients – the last time public figures were published in 2017. Historically, public opinion has strongly backed legalisation in Slovenia, with large pushes for widespread medical cannabis access resulting in bills being presented to parliament in 2016 and, in 2018 but to date no such bills have been passed. Slovenia has recently implemented the EU directive to classify many CBD substances as ‘novel food products’, effectively banning them from being sold within the country as approval for this classification is stringent and costly. Despite these policies, Slovenia has been open to both hemp and some cannabis production, attracting massive international players, for example MGC Pharmaceuticals, which is producing GMP-standard CBPMs for clinical trials and distribution to locations such as New Zealand and Australia, as of January 2020, as well as Freyherr, which is headquartered in Slovenia and is producing hemp on 20 hectares.

Switzerland
Recreational cannabis is illegal in Switzerland; however, possession of up to 10 grams is decriminalised. Punishment for amounts exceeding 10 grams ranges from a fine to a sentence of up to three years. Consumption is punishable by a fixed 100CHF penalty. Cannabis in Switzerland is defined as having over 1% THC concentration, unlike most countries where the limit is 0.2% THC. Under
this 1% limit it is classified as hemp and is legal. As in Italy, this unusually high tolerance for THC in hemp has led to the development of a ‘Cannabis Light’ industry, whereby hemp is used to make a variety of different products for consumption, including many CBD products that are exported all over Europe.

The Federal Act on Narcotics and Psychotropic Substances is the official document relating to the control of cannabis. An amendment to this act was passed in 2011 by popular vote, allowing for the use of cannabis for medical purposes under special authorisation on a case-by-case basis.

Since 2011, the number of patients being treated with cannabis has risen steadily, with an estimated 3,000 patients currently receiving medical cannabis treatment. Due to rising demand, the government released a statement with a commitment to facilitating easier patient access to medical cannabis, and in summer 2019 proposed to allow doctors to directly prescribe medical cannabis treatments to patients with cancer, MS and other serious conditions. New regulations are expected to be approved during 2020.

CENTRAL EUROPE

Croatia
Croatia is a strongly progressive country in terms of its cannabis regulation. This is buoyed by its popularity amongst the population; Croatians between the ages of 15 and 35 have the sixth highest consumption rates of cannabis in the EU. In 2013, the country decriminalised personal possession, with the only possible punishment being a fine between €650 and €2600. This was followed in 2015 by legalising the import and prescribed use of medical cannabis. Up until 2019, cannabis could legally be sourced only outside of Croatia. This will change soon, however, as licensed production of low-THC medical cannabis was made legal within Croatia in April 2019. As with each place that legalises domestic cultivation, two major benefits will be reaped: firstly, patients will be able to access medicines at a lower cost and from a more consistent source, and, secondly, companies can include Croatia itself when considering locations for cultivation of cannabis products to supply Croatian markets.

Czech Republic
The Czech Republic is slowly but surely turning into a hub for cannabis cultivation within Europe. Since the establishment of the country in 1993, the Czech Republic has not had a strong criminalisation of cannabis, and currently personal possession is decriminalised for up to 5 grams of cannabis resin and 10 grams of herbal cannabis. The medical cannabis scheme in the Czech Republic was introduced in 2013 for a very limited number of patients. This was expanded in 2015 with Decree No. 236/2015 Coll 2, which allowed for specialists to prescribe cannabis for many conditions, including chronic pain, MS and chemotherapy-related side effects.

Hungary
Cannabis is a tightly controlled substance in Hungary, although personal possession under one gram of active compound (THC) is not considered a criminally punishable offence.
The situation is unlikely to change soon, with the country facing the rise of increasingly right-wing governments and challenges associated with refugee intake. However, polls indicate that around 60% of the population would support the legalisation of medical cannabis versus just 20% who would oppose it and a further 20% who ‘do not know’. Hungary is not considered to be a region that will allow access to medical cannabis or cultivation thereof in the near future.

**Poland**

Although not technically decriminalised, as of 2011 charges for possession of cannabis can be dropped in Poland if the prosecutor deems the amount for personal use only. Under the Act on Counteracting Drug Addiction possession of an amount beyond that deemed for personal use is punishable by up to three years in prison. Medical cannabis was legalised in late 2017, allowing for cannabis treatment of any condition, provided there is clinical evidence to prove its effectiveness. Hemp cultivation, production and sale are all legal in Poland, making it a leader in the European CBD industry as it is one of the few countries with significant activity at all levels of the value chain.

So far the market for medical cannabis has been limited in Poland, with reluctant prescribers and unaffordable pricing for treatment restraining patient access. These issues are by no means exclusive to Poland; similar patterns of development have been seen across European medical cannabis markets, with a lack of clear guidelines or training preventing medical professionals from prescribing unfamiliar medicines, particularly those with a stigma attached as is the case with cannabis. Pricing issues are not uncommon either, with no framework for reimbursement and, in Poland’s case, high taxes driving up the cost of cannabis medicines. Nevertheless, most of the largest global cannabis companies have a foot in the door, with confirmed deliveries to Polish patients, and with Poland’s population size and broad indications for cannabis treatment, there is huge market potential.

**Serbia**

Serbia has made strides in recent years on the hemp and CBD fronts yet has been slower to accept medicinal cannabis. Serbia is home to one of the strongest pro-legalisation movements in the EU, but this is unfortunately being ignored and opposed by more conservative views within the country. As of early 2020, Nabilone and Dronabinol are available on prescription but access remains restricted. Hemp has been enjoying a small renaissance within Serbia, led by companies such as Konoopa and Eviana. For example, Eviana’s Serbian subsidiary Intiva Plus d.o.o. is in the process of selling over 97 tonnes of hemp worth €1.75 million to a Montenegrin third party. There is, however, a chance the Serbian parliament could put the brakes on this growth too. In May 2019, the Commission for Psychoactive Controlled Substances shared an opinion recommending against the distribution of cannabis within Serbia and also the production of CBD. Whether this opinion will be backed by legislation is yet to be seen.

**Slovakia**

Slovakia maintains restrictive policies around cannabis and CBPMs. Sativex for treatment resistant MS-related spasticity is currently the only form of medicinal cannabis that is registered for use in Slovakia. This is unlikely to change in the near future as the sitting parliament voted down an amendment to remove CBD from the list of controlled psychotropic substances as recently as December 2019. While neighbouring countries are developing their cannabis markets, it seems Slovakia will take a following role, rather than a leading role.
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European Guest Experts

In this section, we consult with some of the leaders of the cannabis space within Europe to get their take on how the industry is developing.
**PROFESSOR MIKE BARNES,**
**CHAIRMAN,**
**THE MEDICAL CANNABIS CLINICS**

The Medical Cannabis Clinics were recently CQC approved and are expanding rapidly; how do you feel about this and what do you see as the result for cannabis patients in the UK?

I’m really pleased that the Medical Cannabis Clinics can get going. We have 5 doctors actively prescribing and over 700 people on the waiting list. This demonstrates the huge demand for medical cannabis. I would still like to see greater availability through the NHS for all who need it as sadly the private route is out of reach for many people due to the ridiculously expensive supply chain. The government need to tackle the supply issues urgently.

How would you like to see legislation and regulation progress in the next couple of years in the UK?

I would like to see GPs able to prescribe, and not just specialists. Above all, we need to see cannabis available through the NHS, and that actually does not need legislation but a change of attitude from the over-cautious medical bodies, like NICE and the Royal College of Physicians, who have done a serious disservice to those who need this product.

**NICE has called for more research to be conducted on medicinal cannabis before allowing greater patient access; what are your thoughts on this, do you agree with this position?**

Of course I agree that more research is needed, but we already have a vast array of studies from observational and ‘real world’ data. NICE ignored this valid evidence and have totally relied on double blind trials. This is a very narrow and misguided approach that may suit a pharmaceutical product but does not suit a multi-faceted plant product like cannabis.

**Project Twenty21 is set to treat around 20,000 patients; what are your thoughts on this? Do you foresee the trial being extended or leading to more broadscale medical access in the UK?**

This is a great project and I hope it succeeds. My only worry is that it will need many more trained doctors to deliver the target than we currently have. We must focus on training programmes like those provided through The Academy of Medical Cannabis (taomc.org).

**Where do you feel are the main areas of opportunity in the UK cannabis space at the moment?**

I think a great opportunity for the UK is to establish a UK cannabis industry so we can supply our own products rather than relying on foreign import. That will reduce cost and provide jobs and tax revenue. Let’s also make importation easier and cheaper so that many tens of thousands of people can benefit from medical cannabis.
How do you feel about patient access to medical cannabis in Italy at the moment?
The access process is as follows: the patient goes through a physician exam first, who will forward the prescription to a pharmacy that will link up with an importer (such as our company) and acquire the amount of cannabis that patient needs. The cannabis is delivered as flower and the pharmacist will make a magistral preparation out of it. We currently have two channels by which cannabis can be acquired: one is from the importers, of which there are six overall in Italy, who can only import from the Dutch OMC; and the second one is the military facility in Florence, who are the only ones to hold a cultivation licence in Italy.

Are there any main bottlenecks to patient access at the moment? If so, how do you feel this could be improved?
The whole system is a little convoluted and, for patients in need, the access is not as fast as it could be. But cannabis is a market that will keep on growing, and our ability to meet patient needs is growing all the time; we will solve any of the administrative issues that we may currently have.

Is there any other aspect of regulation of cannabis in Italy you feel could be improved?
I am generally quite happy with the progress the Italian cannabis market has made over recent years. Back in 2015 the importation limit was 30kgs when in 2019 we reached 750kgs. Owing to the work from those patients in need of medication and the work of the Italian Ministry of Health, I’d say the market has rapidly expanded, but it might be improved. I don’t know for how long the importation system will work, indeed as the demand continues to rise, I hope there will be a chance to increase the local cultivation.
How do you feel about patient access at the moment?
Patient access to medical cannabis in Czech is steadily progressing, but still does not provide access on the level needed to meet the demands of our ageing population patients in chronic pain.

Are there any particular bottlenecks in patient access, e.g. supply, doctors, retailing?
With regards to supply, Czech has hopefully overcome issues we were facing a few years earlier, when we had no supply for up to several months in a row. A combination of local supply and import meant that last year at least one strain or ‘chemovar’ of medical cannabis was in distribution at any given time. Unfortunately, patients and physicians cannot rely on the availability of specific chemovar and this also hinders our ability to test the potency of different strains on specific conditions. Also, physicians now have to report anonymised data annually on their cannabis patients’ treatment. Prescribing physicians have raised concerns that this places extra administrative burden on cannabis-prescribing physicians and, in fact, 90% of this data is already collected in electronic prescriptions.

With just one company licensed for cultivation within Czechia, how has this affected the commercial opportunity and patient access?
Local production currently supplies two chemovars to the Czech system. Patient organisations, physicians’ associations as well as cannabis industry associations have repeatedly requested state authorities to open the licensing procedure for at least three parallel licence holders, as the original medical cannabis law clearly requires. The Czech FDA has for the last four years been tendering one licence at a time as per their interpretation of the cannabis and opioid legislation.

We have heard this licensing will be opened up in 2021; have you heard anything about this?
The multiple licensing does not need legislative changes and can work within current legislation. The Czech FDA is claiming to be introducing as yet unspecified legislation changes to enable the multi-licensing model. The process of new legislation being adopted can take years. The Czech Republic will have our regular parliamentary election in 2021 or sooner, so it is hard to predict when proposed legislative changes will make it through parliament.
The government is currently subsidising the cost of cannabis medications up to 30 grams per patient per month. How has this affected the cannabis space in Czechia? This change was valid from January 2020, thus there is yet no data to compare effects on medical cannabis access. The overall expectation is that there will be year-over-year increase in prescribed total monthly dose as well as the number of patients in cannabis treatment. However, it is already clear that dozens of physicians interested in prescribing cannabis have postponed registering new electronic prescriptions until it is more clear how these new rules affect medical practices.

Where are the opportunities for companies in Czechia, e.g. cultivation, distribution, processing? The Czech Republic is one of the most liberal drug-policy countries with some of the best outcomes on public health figures. Dozens of cannabis/hemp companies have selected the Czech Republic for cultivation, distribution or manufacturing of their products. The Czech Republic also has a long and successful tradition of research and development in multiple areas of cannabis.

Is there anything else unique about cannabis space in Czechia you would like to share? The cannabis community in Czechia as well as in the EU and globally should get more educated in scientific facts about potential cannabis health benefits but also on risks of various contamination and improper manufacturing processes containing cannabis products. There are many examples from the boom of CBD oil markets, where companies ignore safety standards to protect their revenues; some products ended up containing no CBD at all. Using different ways to avoid novelty foods registration with CBD-rich products leads to products making it to market which harm the industry but, more importantly, jeopardises customer access to products they choose to use to support the well-being of themselves and their loved ones.
How do you feel about patient access in Denmark at the moment?
We are pleased that over 2,000 patients have received a prescription through the trial programme, but it is still too difficult to get a prescription from a doctor. We do have around 400 doctors who had prescribed medical cannabis in the period, but many of them have only prescribed once or twice and very few of them will 'admit' it in public. The result is that most patients try in vain, unless they can afford to go to a private clinic. Around 80% of the prescriptions are from private clinics. We get calls from patients every week asking if we know a doctor who will prescribe and we can’t help them because we don’t know the names of the doctors. Unfortunately, the situation makes desperate patients turn to the illegal market. We need more education for doctors and a list of doctors in different areas of the country or a centre for medical cannabis, so access is equal to all. Medical cannabis should not only be available for the wealthy or dependent on which part of Denmark you live. The lack of product variation is also holding back access. At the moment, we only have three imported flower products from Dutch Bedrocan, and both doctors and patients want oils, not flowers. The suspension of CannTrust products in July 2019 will probably have caused a decrease in prescriptions in Q3 2019. We will know for sure when we get the updated data from the Danish Health Statistics Agency.

The third obstacle is the price. We have a limit of 10,000 DKK reimbursement per patient per year all-in-all and we can see that the products are so expensive that most of the patients will pay full price after three or four months.

What do you think will happen in Denmark after the four-year trial ends?
We would find it very odd if the pilot programme did not become permanent eventually, possibly already at the end of the trial period. The Danish Health Minister Magnus Heunicke has already made it clear that he expects the trial to continue after 2022. And it is important that we continue. There are no Danish products on the market yet. This makes it impossible to evaluate properly. Furthermore, the research being done currently is not using products from the pilot programme. It would be a disaster for both patients and the industry to end the pilot programme in just two years. We are just getting started.
Which do you think are the main commercial opportunities in the Danish cannabis industry, e.g. cultivation/extraction/distribution?

Extraction will most likely be among the main opportunities. As mentioned earlier, most patients and doctors prefer the oil products over the flowers as they are easier to dose and the intake method is more familiar than vaporising. The medical cannabis industry is huge in Denmark and, of course, this is not just because of the tiny market in Denmark – it is because of the opportunity to develop medical cannabis for other countries in Europe. So, you will find that it’s the European demand that dictates the commercial opportunities in Denmark.

How do you feel about Copenhagen’s attempts to legalise all adult-use of cannabis? Do you think they will be successful at any stage?

This is the third time Copenhagen tried to legalise adult-use. It is also the third time a majority in our parliament turns it down.

We don’t work with adult-use at Cannabis Danmark. It is not part of our agenda. We only work with prescribed medical cannabis. However, we do have an opinion. In Canada, according to our sources, there are signs that adult-use legalisation has caused medical cannabis to be less interesting for doctors and scientists. We want to make sure that if adult-use were permitted, it would not hurt the patients who want the medical cannabis on prescription. It is important that medical research continues and that doctors continue to prescribe. It is important to keep the two separate and that should be a focus area for all stakeholders.

Is there anything unique about the Danish cannabis space which you feel would be interesting to share?

The most unique about the Danish cannabis space is probably the strict yet unbureaucratic legislation and the fact that we constantly try to improve it with good communication with politicians and authorities. Also, we have high standardisation of demands and a rapidly emerging research community in medical cannabis in our universities. Therefore, it is attractive to be a part of the business in the whole value chain from plant to research and development. On top of that we have a steady political environment behind our pilot programme.
COMPANIES TO WATCH IN 2020

1. Firms that have found success in North America are now using their funds to power their success in Europe.

2. Companies are diversifying into the booming CBD and consumer goods industries.

3. Companies will slow down acquisitions in 2020 and focus on setting their roots firmly in their respective niches.

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KEY CANNABIS COMPANIES

The European cannabis market is still maturing in 2020, so there is time for companies to entrench their positions on the continent before all market niches are filled within this emerging space. While some successful cultivators and distributors are operating in Europe, the name of the game for most companies is full integration from seed to retail. The companies profiled below are some of the largest companies leading the way in the nascent European market. While each company is taking a unique strategy to achieve success, certain key trends are emerging. Four of the six companies profiled here are Canadian giants that have found massive success in Canadian and American markets over the past decade. They have an automatic advantage over newcomers to the European industry in terms of experience in the cannabis space and in their liquid assets, which can be leveraged to set up new facilities in Europe and also to buy up established and licensed firms in key markets. The majority of these companies are also using their considerable purchasing power to diversify into the CBD and consumer markets. Companies such as Bedrocan and GW Pharma have a different tack in the European cannabis space. Each of these rely on strong proprietary products: pharmaceutical cannabis in the case of GW Pharma and strictly standardised medical cannabis strains in the case of Bedrocan. Neither of these companies are as yet diversifying into other cannabinoid markets, which again sets them apart from the standard Canadian company model. All companies profiled are expected to be key players in the European cannabis market for the foreseeable future as the industry finds its feet in the new decade.
Canopy Growth

MARKET CAP:
US$6.64 b (€6.08 b)
(As of 10 FEB 2020)

REVENUE
(3 months ending September 2019):
US$64.9 m (€58.9 m)
(+228.43% Y/Y)

PROFIT/LOSS
(3 months ending September 2019):
-US$283.9 m (-€257.8 m)

Canopy Growth is the powerhouse of the cannabis industry both at home in Canada and globally. Canopy has a market cap twice that of any competing company, and has put down roots deep into the emerging cannabis markets in Europe. Canopy is establishing a main centre of production in Odense, Denmark via its subsidiary Spectrum Therapeutics. This facility already has a reported 27,500m² of licensed greenhousing and is set to be the cornerstone of Canopy’s European distribution chain. To date, Canopy or its subsidiaries have received the necessary approvals to export product to key European markets such as Germany, the UK and Denmark as well as Czechia, Poland, Luxembourg and Spain. In Germany, Canopy has acquired German cannabinoid company C³ for US$251 million (€225.9 million), which already has had much financial success with its licence for marketing of Dronabinol, one of the most popular active ingredients in pharmaceutical cannabis.

Canopy also broke ground in the UK in 2019 by obtaining a licence for mass storage and distribution of cannabis; this promises to bolster UK supply, which has lagged behind demand despite low patient numbers. It can be expected that wherever legalisation occurs in Europe, Canopy Growth will be among the first movers and, with such strong financial backing from major investors Constellation Brands, the company has the capacity to back long-term investments in new markets, helping to secure its relevance in the future European markets.

Canopy is among those leading the charge to diversify assets within the cannabis space. For example, Canopy boasts the leading producer of medical vaporising technology Storz and Bickel within its portfolio after a US$161 million (€145 million) acquisition in December 2018. 2019 saw Canopy Growth move into the CBD space with purpose, acquiring This Works for US$55.6 million (€50 million) in May. This Works is a UK company that produces CBD products. It focuses on health and well-being such as topicals and sleep supplements, which are sold in over 35 markets. Canopy has further strengthened its production capabilities with the acquisition of Cáñamo y Fibras Naturales, S.L., which has both cannabis and hemp production licences in Spain. This expanded portfolio will help to stabilise Canopy’s position in the European cannabis space after a rocky 12 months for medical and recreational cannabis stocks.
Aurora

MARKET CAP:
US$1.75 b (€1.6 b)
(As of 10 FEB 2020)

REVENUE
(3 months ending September 2019):
US$57 m (€51.7 m)
(+153.57% Y/Y)

PROFIT /LOSS
(3 months ending September 2019):
-US$7.9 m (-€7.1 m)

Aurora is another giant of the cannabis industry. Similarly to many in the space, Aurora was negatively affected by the slump in 2019, with stocks tumbling around 50%. Still, Aurora is on the leading edge of the advance of big players into Europe, with at least seven subsidiaries active on the continent. Aurora has shown the industry the value of supply deals with government agencies. As of July 2019, Aurora was the sole owner of a tender to supply the Italian medical cannabis market, via a two-year deal with the Italian Ministry of Defence, which will distribute roughly 360 kilograms of cannabis over the time period.

Even more importantly, Aurora has obtained a deal to supply the German medical market over the next four years, after securing the rights to produce at 5 of the 13 grow sites allotted by the government. This entails a total of 4,000 kilograms of cannabis over the course of the agreement.

One challenge Aurora grappled with in 2019, and one that all cannabis companies must face as industry matures, is compliance. November 2019 saw Aurora suffer two setbacks in supplying its patient base. The first came in Italy with the cancellation of one of the three lots it had been awarded. The reported cause was non-compliance with the EU-GMP standards of production around assessing shelf-life of products. This should not worry investors too much as the cancelled lot amounted to only 10% of the total licensed production and did not affect any of the high-THC growing capacity. More serious was the announcement later in the month that Aurora products were being pulled from pharmacy shelves in Germany, the largest market outside of North America. The hiccup was caused by a proprietary step in Aurora’s production line that irradiates cannabis to sterilise it. This process requires a permit in Germany, which the company had not received. Sales of Aurora products were permitted to resume in Germany as of early February 2020, after what could amount to millions in lost profits for the company. As the medical market matures in Europe, compliance and standardisation of products will be key to ensuring trust between producers and policy-makers as well as patients.
GW Pharma

MARKET CAP:
US$3.96 b (€3.62 b)
(As of 10 FEB 2020)

REVENUE
(3 months ending September 2019):
US$90 m (€81.8 m)
(+3691.6% Y/Y)

PROFIT / LOSS
(3 months ending September 2019):
-US$13.8 m (-€12.5 m)

GW Pharmaceuticals is a leader in the European cannabis market as well as in the global pharmaceutical cannabinoid market. Headquartered in Cambridge, GW Pharma is a prime example of the value of proprietary pharmaceutical products. In Germany, which has the most mature medical cannabis programme, GW Pharma’s Sativex is prescribed for 8.6% of pain patients using CBPMs, pain being the primary symptom of 70% of the cannabinoid patient base. According to the national German insurance provider, Sativex accounted for 16.7% of total CBPM sales for the twelve months ending March 2019. The other flagship product, Epidyolex, is set to take off in Europe following EU commission approval, which makes the CBD-based oral solution a market-authorised product across the region. The medicine is currently approved for the treatment of Dravet syndrome and Lennox-Gastaut syndrome, which together affect around 129,000 patients across Europe. As shown above, GW Pharma products have secured approval in all corners of the globe, including North America. As of September 2019, the company reports over 12,000 patients are being prescribed Epidyolex in the US and sales revenue is increasing rapidly, rising 25% to €77 million in Q3 of 2019.
Regional approval of GW Pharma products

Revenue Generation as a Percentage of Total for GW Pharma in 2018

Source: Prohibition Partners/GW Pharma
**Tilray**

**MARKET CAP:**
US$1.6 b [€1.4 b]
(As of 10 FEB 2020)

**REVENUE**
(3 months ending September 2019):
US$48.2 m [€43.8 m]
(+379.45% Y/Y)

**PROFIT/LOSS**
(3 months ending September 2019):
-US$35.7 m [-€32.4 m]

Tilray is yet another Canadian giant that is betting big on the European medical cannabis market. Tilray has set up its centre of European production in Cantanhede, Portugal via its wholly owned subsidiary Tilray Portugal. The facility includes over 10,000m² of greenhousing, 3,000m² of processing facilities as well as 200,000m² of outdoor cultivation area, which was added in August 2019. The facility has EU-GMP approval and made its first successful medical cannabis harvest in March 2019. The company is also looking to lead the advance of Cannabis 2.0 in Europe, with the acquisition in July 2019 of UK company Smith & Sinclair, which will begin to produce CBD-infused edibles and drinks.

Tilray has already established its access to the key medical markets of the UK and Germany. In August of 2019, Tilray Portugal announced it had signed a €3 million deal to supply medical cannabis to Germany, the first supply of which arrived in September 2019. The company has also begun to entrench itself in the UK, with six approved medical products and a licence to import bulk quantities of product from its Canadian facility. As of December 2019, the company also has supply channels in Cyprus, Croatia, Czechia, Ireland and Switzerland. As the European medical market matures, Tilray is well placed to take full advantage of growing patient bases, increasing acceptance and legalisation across the continent.

**Aphria**

**MARKET CAP:**
US$1.09 b [€0.999 m]
(As of 10 FEB 2020)

**REVENUE**
(3 months ending September 2019):
US$55.7 m [€50.6 m]
(+239.6% Y/Y)

**PROFIT/LOSS**
(3 months ending September 2019):
-US$81.9 m [-€74.5 m]

Aphria is yet another Canadian giant that is contending for a place in the European cannabis market. The company is setting up multiple production centres across the continent, as well as diversifying into the nascent CBD market. In January 2020, Aphria announced its production facility in Canada had acquired EU-GMP status, which will allow it to begin shipping cannabis to the EU, feeding its distribution network there.

Aphria is establishing centres of production both in Germany and Denmark. Since September 2018, Aphria has been partnered with Danish company Schroll to produce medical cannabis. Under the agreement, Schroll will be producing Aphria’s proprietary strains of cannabis for export, the first of which were transported to Denmark from Canada in February 2019. It can be expected that Aphria products will soon be distributed from Denmark as Schroll received final approval for production in its GMP facility in November 2019. Even
more significantly, Aphria was one of three victors of the tendering process for medical cannabis production in Germany. Similarly to Aurora, the company won the maximum 5 of 13 licences, each entitling the companies to produce 200 kilograms per year for the 4-year contract period. The establishment of this tender has secured Aphria’s place in the most lucrative cannabis market outside of North America for years to come.

Beyond production, Aphria is developing a widespread and diverse distribution network across Europe. Central to this is Aphria’s acquisition in January 2019 of CC Pharma for between €19 and €42.5 million (exact amount depends on company performance). CC Pharma specialises in the distribution of pharmaceutical products in Germany, having access to over 13,000 pharmacies in the country. Beyond medical cannabis, Aphria will use this network to market its CannRelief CBD nutraceutical products. With this acquisition backing up its production tender, Aphria is one of the most well-placed companies to take advantage of the developing German markets. Beyond this, Aphria has secured some exclusive distribution deals. In Italy, Aphria owns one of only seven import and distribution licences in the country via its wholly owned subsidiary Fl-Group. In Malta, a GMP-certified lab has been established via ASG Pharma, which the company intends to use as a base for the development of production and packaging facilities.
Bedrocan produces medical cannabis strains of highly standardised quality. The company has been doing so for over two decades and is the sole supplier to the Dutch Office of Medical Cannabis (OMC), which has a monopoly on Dutch pharmacies as well as import and export of medical cannabis in the Netherlands. This exclusive arrangement is the backbone of Bedrocan’s success to date, supplying more than 2,600 kilograms of cannabis to the OMC in 2018, 2,050 kilograms of which were exported, and 550 kilograms of which were sold in the Netherlands. The OMC states that a typical 5 gram package of cannabis is sold for €29. If this is applied to all of the 2,600 kilograms of Bedrocan
product sold in 2018, before accounting for wholesale discounts, pharmacy mark-ups and VAT, the net amount would equal €15.08 million. Via the OMC, Bedrocan is currently the primary source of cannabis imported into Germany, which was aiming to import 2,500 kilograms of Bedrocan products in both 2019 and 2020. Bedrocan is tapping other key emerging markets such as Italy, to which it exported ~400 kilograms of cannabis in 2018 and a planned 700 kilograms in 2019. Bedrocan was among the earliest entries to the European cannabis space, the first to set up GMP-certified production capabilities and is therefore the company with the strongest track record on the continent.

Some challenges face Bedrocan in the coming years. Central to this is the efforts of several countries to increase domestic supply. In Italy, Aurora has won the sole tender to supply 400 kilograms of cannabis over the next two years (40 kilograms has since been cancelled). In Germany, Demecan, Aphria and Aurora will supply the country with 2,600 kilograms of cannabis per year for four years. The Netherlands is also looking to diversify the supply of cannabis in the country; the OMC published a tender for new producers in July of 2019. It is likely that Bedrocan will obtain a renewed licence but also that it will no longer be the sole supplier to the OMC. As such, there is a chance that Bedrocan may have to look at diversifying into other cannabinoid markets such as CBD and wellness products, something the company has historically been reluctant to do.

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KEY MEDIUM-SIZED COMPANIES

The European market is very much in its infancy and is open not just to established North American players but also to native innovative European ventures. The companies profiled here are an example of the pioneering companies that are making waves across the European cannabis space. Key to company success is obtaining footholds in key emerging European markets such as Germany and the UK. To do this, companies are setting up subsidiaries or partnerships in relevant markets to obtain the necessary licensing. As with the larger companies, many smaller companies are beginning to diversify into the CBD space, either by acquiring companies, as in the case of EMMAC, or by releasing new products, as in the case of Cannamedical. It will be interesting to see if these companies will maintain their independence, go public or be acquired as the European market matures and consolidates.

EMMAC Life Sciences

COUNTRIES ACTIVE IN:
France, Germany, Italy, Malta, Portugal, Spain, Switzerland, UK

HEADQUARTERS:
London, UK

STOCK PERFORMANCE:
Private (Float possible in 2020)

London-based EMMAC is one of the largest cannabis companies based in Europe, and possibly the largest to remain unlisted. EMMAC is well on its way to establishing a network of production and distribution of cannabis products across Europe to rival that of any large company. EMMAC is setting up hubs of production in Malta and Portugal. In June 2019, the company announced it had begun construction of a 2,800m² EU-GMP production facility in Malta. In July, the company announced its acquisition of Portuguese producer Terra Verde, which reportedly cultivates on 80,000m², both outdoors and in greenhousing with GACP licensing. EMMAC will look to channel these production capabilities into: Germany, via subsidiary About Nature’s distribution agreement with CC Pharma, which distributes pharmaceuticals to over 13,000 pharmacies; the UK, via subsidiary Rockshaw Ltd; and Italy, via its 50% owned subsidiary Fontana JVCo. EMMAC is also diversifying into the CBD space with the acquisition in 2019 of French CBD and wellness company Greenleaf and Swiss company Blossom.

Emmac is well placed to take advantage of developments in the European cannabis market. This opinion is apparently shared by investors, who backed the company in funding rounds during 2019. During the 12 months ending October 2019, the company raised around €40 million. The latest
successful funding round pitched convertible loan notes of the company at 50 British pence per share, which gave the company an implied value of about €175 million. The next test the company faces is the challenge of turning a profit on its new medicinal products, which were launched in December 2019 for the UK and EU.

**Cannaray**

**COUNTRIES ACTIVE IN:**
Germany (planned), Ireland, Poland (planned), UK

**HEADQUARTERS:**
London, UK

**STOCKS INFO:**
Private (Float possible in 2020)

Cannaray is a London-based company that is seeking to break into the European cannabis and CBD markets by establishing production facilities in the UK and distribution networks across the UK, Germany and Poland. Cannaray made waves in the European cannabis space in late 2019 after a series of significant deals. In July, Cannaray closed its Series A round of funding, which the company reports was oversubscribed even after raising €9.2 million. This is reported to be just the beginning of a planned 2020 float for the company, which would raise a further €35.2 million and would put the company’s value at €117.5 million, making it one of the largest cannabis companies on the London Stock Exchange. On the same day, Cannaray announced it acquired UK pharmaceutical distributor Therismos for an undisclosed figure. Therismos will be pivotal to Cannaray’s success in Europe as the company already has licences to handle and distribute controlled drugs in the UK, Norway, Switzerland and Iceland. To feed this growing distribution network, Cannaray has allied with Newey, one of the largest horticultural companies in the UK, which is currently pending licensing. Cannaray fulfilled its first prescription in the UK in January 2020 in conjunction with Canadian group Aphria. 2020 is set to be a huge year for Cannaray; beyond their possible market flotation the company plans to begin distributing medical cannabis as well as proprietary CBD products, with the main target markets being the UK, Germany and Poland.

**Demecan**

**COUNTRIES ACTIVE IN:**
Germany

**HEADQUARTERS:**
Berlin, Germany

**STOCKS INFO:**
Private

Demecan is a pioneering company in the German domestic cannabis market. The company has been operating outside of the limelight since 2017. This changed during late 2019, largely thanks to Demecan being awarded one of three tenders to produce medical cannabis within Germany by the BfArM in May. This agreement will see the company produce at least 2.4 tonnes of dried cannabis over four years. It is likely that this was obtained in part due to Demecan’s joint venture agreement with Canadian company Wayland Group Corp., who can provide expertise in obtaining licences and in breaking into growing markets. The joint venture agreement permits Wayland to purchase 50% of stock pending ‘certain conditions’, though it is unclear what stake is currently owned. Demecan also has GMP licensing for wholesale import and distribution of cannabis and has signed a deal to import 10 tonnes of cannabis over 5 years from Canadian producers Invictus MD.
Demecan had secured several other significant investors and partners by late 2019. In October 2019, Demecan announced it had closed a funding round after raising €7 million. The funding round attracted first-time investors in the cannabis sector in the form of venture capital firm btov Partners, who contributed half of the investment, with the other half coming from German brewing company Krombacher. This mirrors developments in North America, where tech investors as well as brewing companies are becoming involved in the cannabis industry. If Demecan can channel the expert experience and distribution capabilities of Krombacher in marketing consumer goods in Europe, it could give Demecan a competitive edge as the market develops.

Lyphe Group

COUNTRIES ACTIVE IN:
UK

HEADQUARTERS:
London, UK

STOCKS INFO:
Private

Lyphe Group has developed a patient-focused ecosystem of medical cannabis companies, with a focus on building infrastructure for the UK market. The group made headlines several times in late 2019 and early 2020, for example with the announcement of a partnership with medical technology company JAYEX Technology Ltd in a venture that will seek to streamline patient access issues in the UK and further afield. The group manages a portfolio that helps to build out a number of firms focused on access, imports, education and distribution, including:

• The Medical Cannabis Clinics – the UK’s first chain of clinics focused on medical cannabis treatments, providing patient access and capturing scripts. The clinics were recently approved by the UK’s Care Quality Commission.

• Dispensary Green – the UK’s first cannabis-focused pharmacy, fulfilling scripts for patients as well as the broader market and more general NHS scripts.

• Astral Health – Import and distribution of EU-GMP-certified medical cannabis into the UK and other European markets. In January of 2020, the group successfully imported its first delivery of GMP-certified cannabis from BOL Pharma in Israel into the UK. This was the first such commercial export from Israel since cultivation began.

• The Academy of Medical Cannabis – Online education platform on medical cannabis for health professionals.
**Stenocare**

**COUNTRIES ACTIVE IN:** Denmark, Ireland

**HEADQUARTERS:** Randers, Denmark

Danish company Stenocare was the first company in Denmark to receive authorisation from the Danish Medicines Agency after trial legalisation in January 2018. The company is now a leader in the European market; its production and distribution network in Denmark was profitable in 2018 and is currently expanding to Ireland among other emerging markets. This is notable as even large companies have struggled to produce a profit in the early years of the industry. It was the first company to obtain licensing for three imported cannabis oil products. Stenocare is now working on re-inventing its business, creating partnerships with Solural Pharma Aps. and Pharmaceutical Research Corp. to develop novel medicinal products. The company has also expanded from its core market in Denmark to Ireland, via Stenocare Ireland Ltd.

As with Aurora, 2019 presented Stenocare with challenging issues in compliance. Its Canadian supplier Canntrust Inc. has been Stenocare’s most important partner with 19.03% of total equity. In July 2019 Stenocare’s products went into quarantine in Norway and sales were halted. This was the result of an audit of Canntrust’s production process by Health Canada, which deemed that the products were not fully authorised and licensed at the time of production. In November of 2019, Stenocare signed a supply deal with Canadian company Emerald Health Therapeutics. As of early 2020, the two companies are working to get Emerald Health Therapeutic products approved by the Danish Medicines Agency and presumably the Irish Health Products Regulatory Authority (HPRA). How quickly Stenocare can recover from this hiccup in supply will largely determine whether they return to being a profit-generating company, as they were in 2018.

**Cannamedical**

**COUNTRIES ACTIVE IN:** Canada, Germany, UK

**IMPORTS FROM:** Australia, Canada, Portugal

**HEADQUARTERS:** Cologne, Germany

Cannamedical is the largest private distributor of cannabis in Germany. The company commanded roughly 11% of the German pharmaceutical cannabis flower market in 2019, with access to over 2,200 pharmacies in Germany. The company is Good Distribution Practice (GDP) certified and licensed for cannabis import into Germany, and distribution and export to the EU. The company also has GMP-certified storage in Germany. 2018 and 2019 saw Cannamedical sign several huge supply agreements with companies in Europe and North America. In October of 2018, Cannamedical announced it had secured a supply deal with Canadian firm Wayland for a minimum of 9,000 kilograms of cannabis over three years. In September of 2019, the firm reported it had processed the largest ever shipment of cannabis from within the EU to Germany. While the company has not yet gone public, it has received considerable sums of investment, the largest coming in January 2019 when the company received a €15 million investment, with a further round of investing expected to open in 2020, this time for an estimated €30–€50 million. Cannamedical is now well situated within the German market, with the potential to begin exporting to other EU destinations. Furthermore, partnerships with some of the Canadian and European giants like Wayland and Bedrocan mean the company is well placed to begin expanding around Europe; Cannamedical is currently in the process of obtaining a licence for a planned 2020 incursion into the UK and is diversifying its products to include not just high-THC cannabis but also CBD oils and CBD production kits for pharmacies.
METHODOLOGY

The market sizing contained within this report has been based on a variety of official sources including United Nations (UN) population projections by country, World Bank forecasts of inflation (GPP), UN price change data, and the United Nations Office on Drugs and Crime (UNODC) figures on prevalence of annual cannabis use by country. Calculations were then made using quantitative analysis of socio-economic data, consumption trends, cannabis requirements and pricing informed by a wide range of reputable datasets including, but not limited to, the World Bank, the Organisation for Economic Co-operation and Development (OECD), the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the International Narcotics Control Board. To generate these regional estimations, Prohibition Partners’ proprietary market-sizing model accounts for every country within the region as an individual entity and aggregates country-level estimations at the final stage. For situations where data were not available for a particular country, reputable data from the most comparable geography were utilised (with appropriate statistical adjustments applied as necessary).

Medicinal

The medicinal market-size estimates and forecasts contained within this report include both medical and pharmaceutical products. The year of legalisation of medicinal cannabis (both medical and pharmaceutical) is key to our methodology. Estimates represent a calculation of price per gram of cannabis (or a calculation of the average where specific data points are unavailable) multiplied by the expected usage, multiplied by assumed dosage and multiplied by the estimated potential patient population. Price per gram of medicinal cannabis differs to street value prices, and the price per gram has been modelled based on post-legalisation pricing trends from a number of markets. This has been factored into the market-size calculations with price modelling incorporated into the year-on-year forecasts.

Patient numbers have been modelled on existing markets where medicinal cannabis has already been legalised and regulated. It is not calculated as the sum of patients who suffer from qualifying conditions, primarily because patients may suffer from multiple qualifying conditions for which cannabis can be prescribed. Value forecasts can include pharmaceutical and CBD medical products.
Recreational
While models for the medicinal market rely on established market values, more inferences have been drawn on for projections on the recreational market in Europe. Our team of dedicated analysts have assessed each country individually and come up with a likely timeline for legalisation of recreational cannabis across Europe over the next five years. Upon legalisation, we recognise that the shift of sales from black market to legal dispensaries is gradual and have calculated legal market size based on the rate this shift has occurred in other legal markets. Once this has been taken into account, we measure the size of the market based on the known number of users of cannabis in each country, by the average price of cannabis in those countries and the dosage at which recreational users tend to consume cannabis. Where data were not available for certain countries, inferences have been made for those countries based on regional averaging.

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### Glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADHD</td>
<td>Attention Deficit Hyperactivity Disorder</td>
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<tr>
<td>BfArM</td>
<td>Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)</td>
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<tr>
<td>BIH</td>
<td>Bosnia and Herzegovina</td>
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<tr>
<td>BPNA</td>
<td>British Paediatric Neurology Association</td>
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<tr>
<td>CBD</td>
<td>cannabidiol</td>
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<tr>
<td>CBDV</td>
<td>cannabidivarin</td>
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<tr>
<td>CBG</td>
<td>cannabigerol</td>
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<tr>
<td>CBGV</td>
<td>cannabigerivarin</td>
</tr>
<tr>
<td>CBPM</td>
<td>cannabis-based product for medicinal use</td>
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<tr>
<td>CHF</td>
<td>Swiss Franc</td>
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<tr>
<td>CINV</td>
<td>chemotherapy-induced nausea and vomiting</td>
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<tr>
<td>CMC</td>
<td>Centre for Medicinal Cannabis</td>
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<tr>
<td>CPASS</td>
<td>Cannabis Advocacy and Support Services</td>
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<tr>
<td>DKK</td>
<td>Danish Krone</td>
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<tr>
<td>EMCDDA</td>
<td>European Monitoring Centre for Drugs and Drug Addiction</td>
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<tr>
<td>ESAM</td>
<td>Estonian State Agency of Medicines</td>
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<tr>
<td>ETF</td>
<td>exchange-traded fund</td>
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<tr>
<td>GACP</td>
<td>EU Good Agricultural and Collection Practices</td>
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<tr>
<td>GDP</td>
<td>Good Distribution Practice or Gross Domestic Product</td>
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<td>GMC</td>
<td>General Medical Council</td>
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<td>GMO</td>
<td>genetically modified organism</td>
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<tr>
<td>Abbreviation</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>INCB</td>
<td>International Narcotics Control Board</td>
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<td>IP</td>
<td>Intellectual Property</td>
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<td>LSAP</td>
<td>Luxembourg Socialist Workers’ Party</td>
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<td>LSE</td>
<td>London Stock Exchange</td>
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<td>M&amp;A</td>
<td>mergers and acquisitions</td>
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<td>MCAP</td>
<td>Medical Cannabis Access Programme</td>
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<td>MP</td>
<td>Member of Parliament</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NHSBSA</td>
<td>National Health Service Business Services Authority</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>OMC</td>
<td>Office of Medical Cannabis</td>
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<td>POCA</td>
<td>Proceeds of Crime Act</td>
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<td>PTSD</td>
<td>post-traumatic stress disorder</td>
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<td>RTO</td>
<td>Reverse Takeover</td>
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<td>SCFF</td>
<td>Stabilimento Chimico Farmaceutico di Firenze</td>
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<td>THC</td>
<td>tetrahydrocannabinol</td>
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<tr>
<td>THCV</td>
<td>tetrahydrocannabinvarin</td>
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<td>UNODC</td>
<td>United Nations Office on Drugs and Crime</td>
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<tr>
<td>VAT</td>
<td>Value Added Tax</td>
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<td>WHO</td>
<td>World Health Organization</td>
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