

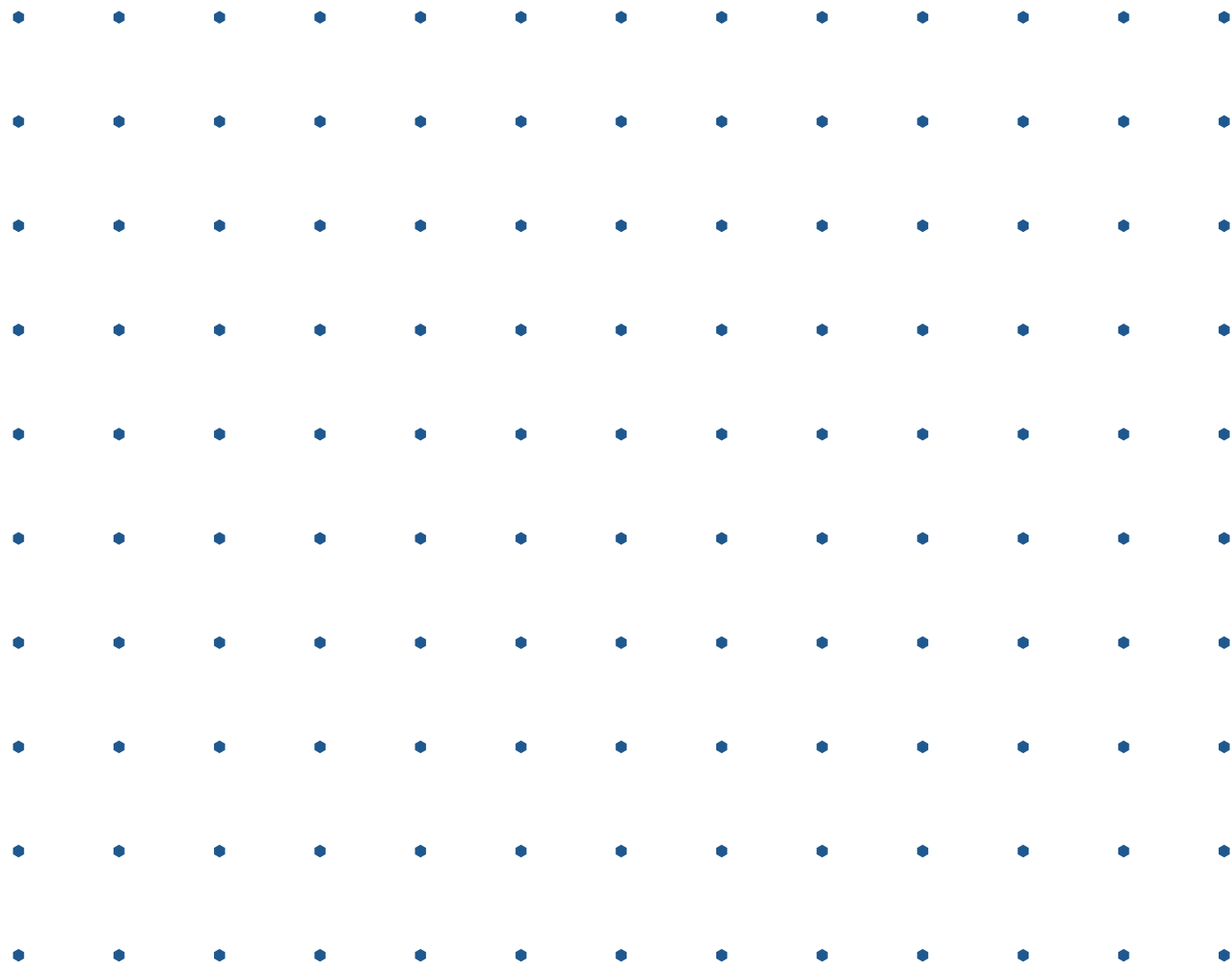
The European Cannabis Report

Edition 6





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, intelligence and strategy. We provide strategic solutions to an international client base of investors, operators, blue chip companies, FMCG brands and government bodies.

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



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EUROPE'S LEADING CANNABIS PHARMA EXPERTS



ADREXpharma® is the #1 independent German pharmaceutical company which is specialized in the development and distribution of medicinal cannabis and is the gateway into the EU-market. ADREXpharma developed several dosages (extracts, powder, resin, flowers) for the growing demand in the European cannabis market.

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LEAD SPONSOR FOREWORD



Mario Eimuth
Founder,
ADREXpharma GmbH

The European cannabis market is developing strongly. The latest projections indicate that the market is expected to reach €3.2 billion by 2025, growing with a Compound Annual Growth Rate (CAGR) of 67.4%. These are impressive numbers and they mirror the latest jurisdiction regarding CBD from the Court of Justice of the European Union (CJEU) that confidence and professionalism are at the heart of this growth. European countries are experiencing transformation in the regulations controlling the marketing of cannabis products.

At ADREXpharma® we strive to lead the way in product innovation and development in order to respond and participate fully in any potential market growth.

ADREXpharma® is the first independent German pharmaceutical company specialising in the development and distribution of medicinal cannabis and also providing a gateway into the European market. Our product portfolio consists not only of a wide range of cannabis flowers and extracts but also compounding products like dronabinol and pharmaceutical Cannabidiol (CBD) as well as innovative CBD-Cosmetic-Products. Due to our unique supply network, ADREXpharma® sets a new benchmark level by serving all of the approximate 19,000 pharmacies in Germany.

Our two collaborations with the German pharma companies, STADA and Neuraxpharm, for the GMP (good manufacturing practice) Full-Service and the distribution of Canadian and Israeli medical cannabis products has expanded our international footprint and has mirrored the tendency in the market for strategic collaborations within Europe and beyond.

We are proud to be one of the few German companies to hold all the necessary licences to operate in the German medical cannabis market. This will accelerate our growth potential even further over the next few years.

At ADREXpharma® we are committed to quality, authenticity and innovation, as well as to contributing to the growing body of evidence-based research regarding the benefits and efficacy of cannabis to validate new therapy options for patients. ADREXpharma® aims to provide the best possible treatment for medical cannabis patients - today and always.

Mario Eimuth
Founder
ADREXpharma® GmbH

EXPERT ANALYSIS

Mario Eimuth
Founder,
ADREXpharma® GmbH

How has the market in Germany evolved 4 years after its opening?

With over 300,000 statutory health insurance (SHI) prescriptions in 2020 and more than 120,000 patients treated with medical cannabis, Germany is the largest cannabis market in Europe. In 2017, we recorded 27,000 prescriptions – so within three years the numbers have increased tenfold.

How do you expect the market to develop midterm in Germany and Europe?

In Germany, the average cannabis expenditure per patient is €500 per month. With a permanent increase in the number of patients being treated with medical cannabis we will see 1-1,5% of Germany's entire population (82,8 million) being treated with medical cannabis within the next five years; similar to progress in other countries. All products are being reimbursed by the national health system according to the guidelines of German medical cannabis law. I expect more and more European countries to follow the German model as it is a well established system which is properly serving the needs of patients.

Can you tell us about the key factors for succeeding in the European market?

The most time consuming and challenging part is definitely to become a fully licenced company and to be in line with EU regulations. The regulatory framework is quite demanding. However, one of our partner's family has been in the pharmaceutical business for more than 200 years and this has made it easier for us. Building up and maintaining a

trusted circle of suppliers is key to success. In addition, we focused on hiring an experienced and highly qualified team which is not easy in a fairly new sector. Our GMP-certification specialist, for example, has decades of experience which has helped us in terms of support for our suppliers in all EU GMP part I and II guidelines, regulations, regulatory affairs, pharmacovigilance, research and development and hence to accelerate our procurement set-up.

What's the growth perspective that ADREXpharma® envisions within the next few years?

We are expecting a rapid growth in the overall cannabis market in Europe and believe that ADREXpharma® will outperform this organic growth significantly. We have all the necessary licences and the full cannabis product portfolio in place. From April 2021 we will offer all five of our product categories in 19,000 German pharmacies through our unique logistics set-up. We are expecting a CAGR of 61% in the next five years and have been cashflow positive since our first fiscal year in business. Profit margins will also continue to grow every year.

How about internationalisation?

This is the next step on our agenda and we are currently preparing our international growth strategy. We are permanently monitoring the regulative frameworks in all the other European countries and the most promising targets for now are; Austria, Italy, Luxembourg and Poland.

Any new projects on the horizon?

So far, 2021 has already been an exciting year. We have launched a range of products from Panaxia, the leading manufacturer of medical cannabis products in Israel. In Q1 we also started importing cannabis flos from Canada for STADA (one of the biggest pharmaceutical companies in Germany), a service that we are offering through our GMP-Full-Service unit.

What are your thoughts on the development of the recreational market in Europe?

Polls in most European countries show that the majority of the population is in favour of opening the market into this segment. It is obviously a more political question, however more and more parties are positioning themselves in the same direction. We will probably see regulatory changes here similar to those in the United States. This would clearly open up a second dimension for our business model – and we are well prepared!

Definitions

Adult-use or recreational cannabis

Adult-use cannabis refers to the use of cannabis for reasons other than medicinal, i.e. recreational purposes. The term adult-use is used to emphasise the fact that where cannabis is legalised, it is intended for consumption by adults of legal age only and for reasons more broad than recreation, including, for example, increasing physical performance, engaging in creative activities and for spiritual purposes.

CBD

Major cannabinoid extracted from cannabis sativa (mostly low THC hemp). Claimed to provide wide-ranging properties useful for health and wellness including anti-anxiety, anti-inflammatory, anti-pain, anti-arthritis and neuroprotective effects. Recommended by some as treatment for conditions such as epilepsy as well as pain and insomnia.

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. The common limit for THC content in hemp materials in Europe is 0.2% w/w but this varies and can be as high as 0.6% and 1% in Italy and Switzerland respectively. For the purposes of this report, industrial hemp includes hemp-derived CBD.

Medical cannabis

Cannabinoid-based medicine not holding marketing authorisation and therefore sold as an

unlicensed medicine that is supplied through health systems and prescribed by a doctor;

Or

Active Pharmaceutical Ingredient (API) to be manipulated and/or compounded by a magistral pharmacy in order to prepare a cannabinoid-based medicine without marketing authorisation (unlicensed).

Medicinal cannabis

Term used to indicate all cannabinoid-based therapeutic products (medical and pharmaceutical).

THC

Tetrahydrocannabinol (THC): the other primary cannabinoid, and the main psychoactive cannabinoid of cannabis. THC is considered the primary source of the 'high' produced by ingesting cannabis. Evidence suggests that THC exhibits medicinal properties that are useful in treating chemotherapy-related nausea, pain and spasticity. THC can also be synthesised and, in general, is more widely controlled than CBD.

Pharmaceutical cannabis

Formulated, processed or synthetic cannabis sold as a finished product, which has undergone full medical trials, and holds (in one or more geographical areas) a medical marketing authorisation e.g. Cesamet®, Marinol®, Syndros®, Sativex®, Epidiolex® and any derived generic medicines (such as dronabinol).

Or

Cannabinoid-based API (Active Pharmaceutical Ingredient), which is registered as an API in a medicinal product holding marketing authorisation in one or more geographies, to be manipulated and/or compounded by a magistral pharmacy to produce a cannabinoid-based medicine.

EXPERT INTERVIEWS



Susanne
Caspar
CEO,
Linnea SA

LINNEA

Why, given the challenges involved, has Linnea decided add Cannabis to its portfolio?

Over the last 40 years or so, Linnea SA has gained extensive experience in the manufacture of natural extracts for use as APIs, supplements and cosmetic ingredients. Working in different industries, whether pharmaceutical, food or cosmetics, we have a clear vision of the road to take to develop new products that are truly beneficial to people’s health and wellbeing.

To us, the challenges presented by Cannabis products are also an opportunity to apply the lessons learned and the expertise gained as we’ve grown as a company, focusing the skills and talent of our team of professionals on the creation of an innovative product that will help others.

What is important for a pharmaceutical Cannabis product?

Quality. Definitely quality. When I say quality, I mean an all-encompassing, 360-degree quality that starts from the selection of the raw materials and continues on to manufacturing and analysis.

Quality of course also means GMP; but at Linnea it means something more: passion and quality that isn’t just monitored, but built upon trust. At Linnea, we understand the importance of standardization, because once you become the supplier of a specific ingredient, you are also the warrantor and provider of reliable treatments for patients, not to mention measurable results in clinical studies.

What are the biggest hurdles faced in the development Cannabis products?

At first it can be hard to understand the general rules and legal status regarding Cannabis. Having a complete overview of the different national and local regulations is pivotal to the relationship between Linnea and the various regulatory authorities.

The next key step is to find a reliable supplier of raw materials that can guarantee a consistent product. Cannabis cultivations, like other cosmeceutical or pharma products, must comply with strict rules and require constant attention and care to generate a high-quality product.

No step can be taken for granted in the production of active ingredients in general, and Linnea has applied this same approach to Cannabis. We oversee and guarantee the entire process, from cultivation up to the final ingredient, applying excellence as our measure of quality in every phase. Moreover, Linnea is backed by experience and by a robust, talented team with the skills necessary to develop innovative extraction methods. In 2014, when we kicked off the project, we were pioneers in the market. Customers were perhaps a bit surprised when we first presented our Cannabis product, but good work is always rewarded.

In 2016, we became the first company in the cannabis market to receive GMP certification for our extract, giving us the boost we needed to continue on in the development and enhancement of our Cannabis line.

Today we are still working on new products, and we've applied to add two of our products to the Novel Food catalogue. We believe that this big step forward and other gradual changes to regulations in Europe make it a promising market.

Linnea has recently released its Cannabis Ready-Made forms. Why did you choose to add finished products to your portfolio?

It was a natural evolution. After almost 40 years of extraction, we embraced the challenge and started working on finished products.

Moreover, we've gotten the sense that there is a demand for high-quality finished products—we want to bring the quality of a pharmaceutical approach to cannabis products, and do so to meet the needs of our trusted customers around the globe. To date, some have launched products already, while others are still in the registration process. By meeting their needs, we will continue to serve our valued clients through our products (pharma, food and cosmetics), strengthening our ties with over 20 countries.

One such international client that we are proud to work with is BOD Australia Ltd, which launched Medicabilis in 2018, a prescription-only product based on our 5% Cannabis extract that is available in Australia under the national Special Access Scheme. Another respected client from Argentina, launched an interesting product within the national market in November 2020: Con-vupidiol, which contains our pure CBD.

These are all incredible achievements for Linnea, which after years of dedication and hard work is seeing collaborations with clients come to fruition, with both parties embracing the potential of Cannabis. And, perhaps most importantly, in the serious approach to Cannabis as a high-value pharmaceutical-grade ingredient.

What is your flagship product?

Without a doubt: our Cannabis extract 5% - CBD (CM05), a product developed thanks to incredible teamwork and Linnea's constant

pursuit of products that meet strict quality standards. As a full, standardized CBD extract, it's really taken off, with impressive sales and clinical results.

We continue to move forward with clinical studies in collaboration with some large independent research institutes, and with some of our customers. BOD Australia just recently conducted a clinical study that assessed the safety, tolerability and pharmacokinetics of Medicabilis. So far, the results have been incredible and it is quite likely that trials such as this one will give us the momentum to keep believing in the healing power of Cannabis.

What does Linnea have in store for 2021?

We're working on numerous different products and projects in terms of our Cannabis line. Be on the lookout for a 5% Cannabigerol extract, first as a food-grade ingredient and a pharmaceutical-grade product in the coming months.



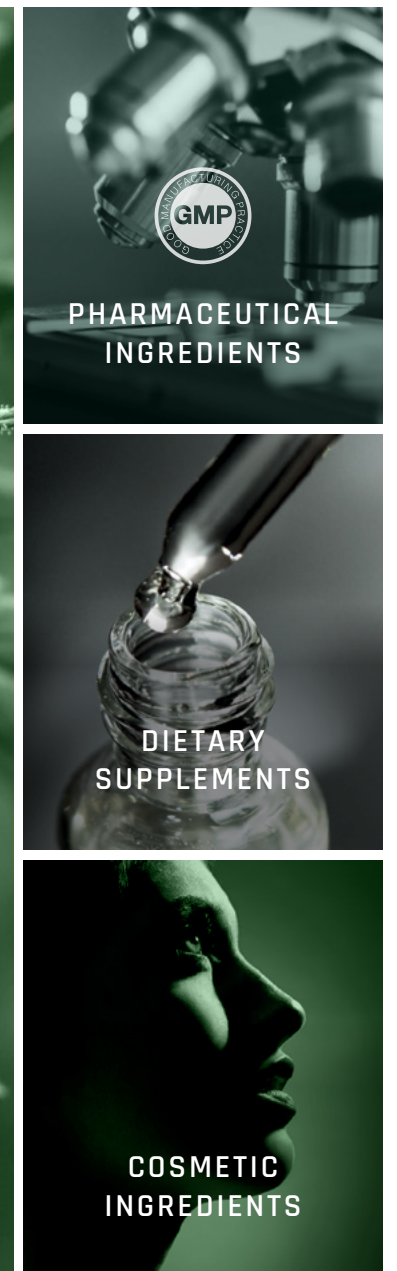
Improving lives with trustworthy
CBD and CBG compounds

Cannabis Therapeutic Solutions is a project by Linnea, a trusted name in the herbal extract industry since 1982. Linnea's therapeutic cannabis compounds are available as extracts, pure substances and dilutions, as customizable high-quality consumer-ready products.

// linnea.ch // linneacannabis.ch

QUALITY IS OUR MEASURE OF EXCELLENCE

Manufactured
in Switzerland



Linnea
CANNABIS
THERAPEUTIC SOLUTIONS

Methodology



Atalis

Atalis is Prohibition Partners' centre for data and insights on the cannabis industry. The data on which this report is built is largely extracted from the databases of Atalis, which themselves are built on continuously updated information provided by regulators, government agencies and industry-leading companies.

Market research

Prohibition Partners conducts research with industry experts to provide further detail on investment opportunities, technical detail, as well as market strategy and insider opinion on market challenges, opportunities and trends. Prohibition Partners conducts surveys at the international level, with tens of thousands of respondents internationally which inform our writing generally and are reported on extensively in our consumer report series. Responses to recorded interviews are published in full and represent the opinions and views of the individuals concerned. They do not necessarily reflect views held by Prohibition Partners. Industry experts are selected in accordance with their company or brand's activity within the selected market on which the report is written. Desk research is also conducted to inform the research and support the findings from our own research. We strive to ensure that all data referenced from other published sources is accurate and is the latest available at the time of writing.

Market sizing

All the figures contained herein represent an attempt at estimating the most likely scenario of development in each covered market. However, all the reported figures are very sensitive to the untested assumptions of the model and are based on historical data from the most developed international programmes, which do not need to necessarily correspond with the reality of the nascent or yet-to-be-born markets.

Prohibition Partners' approach to forecasting the cannabis industry has its foundation in the database of historical datapoints (sales, patients, volumes, imports, prices etc.), available in Atalis. The base-line delta curve in our models is based on the patient penetration of more mature markets, for instance Canada and Germany. Factors affecting the outcome include the size of the eligible population, the ease of prescription, supply restrictions and affordability. An assessment on likely date of legalisation (or new product format allowance) is also considered. Sales and consumption data is used to estimate the product split between oils and extracts. Prices and their likely evolution are inferred from the available datapoints and our insights on future supply-demand balance.

Cross-validation with historical datapoints to ensure robustness of the model is thoroughly conducted. However, in such a controlled market, the evolution of regulations is exceedingly difficult to predict. We analyse the news and connect with our network to

keep track of political and regulatory developments, but the model can be very sensitive to even slight changes in the timeframe or scope of measures being currently discussed, as well as any unforeseen macroeconomic, political or global transformations.

Our bottom-up approach draws from three main types of information:

- Historical granular data from our databases on sales, patients, prices, volumes and dosages for the concerned markets.
- Observed trends from the most mature markets in Europe and North America, e.g. patient penetration, user spending.
- Proprietary political and regulatory forecasting, including likelihood of regulatory change for product availability.

The main sources in order to conduct this forecasting exercise are:

- Official data releases by regulators, insurance companies, monitoring institutions.
- Companies' financial and news releases.
- Review of current clinical trials and patents in the cannabis space and likely impact of new products and indications.
- Assessment of prevalence, eligibility and dosing through clinical studies and literature reviews.
- Consumer research, public opinion and policy analysis.
- In-depth interviews with industry stakeholders and data-sharing agreements with key operators.

Medical cannabis sizing

Medical cannabis estimates include a forecast of patient penetration over time, as well as dosages, estimated from official and company data, where available. Eligible population 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. Prices of medicinal cannabis have been gathered where possible and estimated from price indexes in the geographies lacking products on the market. Evolution of prices has been modelled based on post-legalisation pricing trends from a number of markets.

Adult-use sizing

Our recreational cannabis market sizes take the United Nations Office on Drugs and Crime (UNODC) yearly prevalence figures of cannabis use to calculate the eligible population for a legal recreational scheme. Our assumption is that legal cannabis will increase its share of the market vis à vis the illicit market during the first few years, following the observed trends in Canada and Uruguay. Prices have been estimated from international bulk prices of cannabis, as well as the illicit market and our assessment on the current supply and demand balance in the international cannabis markets.

ATALIS^{BETA}

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Executive Summary

In Europe and across the world 2020 was a huge year for cannabis. The final quarter of 2020 saw several important developments internationally in the liberalisation of cannabis. November 2020 saw the passing of cannabis legalisation ballot measures in six US states. In the same month, the European Court of Justice ruled that CBD is not to be considered a narcotic substance under EU Law. Weeks later, the UN finally recognised the medical potential of cannabis by removing the plant and its derivatives from Schedule IV of the Single Convention on Narcotic Drugs. This was followed swiftly by the historic approval of the Marijuana Opportunity Reinvestment and Expungement (MORE) Act by the US House of Representatives which would federally decriminalise cannabis.

Already, 2021 has brought good tidings for cannabis globally. In January 2021, the Democrats won majority control of the US senate and therefore the full House, paving the way for potential federal decriminalisation. This will massively progress the normalisation of cannabis legality in Europe and elsewhere. February saw the largest acquisition in the history of the cannabis industry, with the purchase of the British company, GW Pharmaceuticals, by Ireland-based Jazz Pharmaceuticals for just under €6 billion. This was followed in March by the acquisition of EMMAC by US-based Curaleaf for €242 million, representing a huge vote of confidence in the European cannabis markets.

In Europe, COVID-19 delayed major regulatory reform at the national level. For example, France has delayed the beginning of the country's medical cannabis trial scheme, and Germany saw delays in the arrival of the first harvest of domestically produced cannabis. On the other hand, the necessity of medical cannabis has been underlined by COVID-related disruptions. In Ireland and the UK, special measures were set up to ease the process for obtaining cannabis medicines from the Neth-

erlands. In the Netherlands, access to cannabis via coffeeshops was deemed essential during 2020, not least in order to keep revenue and users away from the black market.

Despite regulatory delays, patient access to medical cannabis has progressed across the continent. We estimate that over 60,000 people were able to access cannabis medications for the first time in Europe during 2020, bringing the total to 185,000 patients accessing medical cannabis treatment in the region during the year. Overall, we estimate the value of the market for medical cannabis to be worth €230.7 million as of the end of 2020. Further, we expect the value of European cannabis to grow with a Compound Annual Growth Rate (CAGR) of 67.4%, to reach €3.2 billion in 2025. Part of this growth will be supported by the beginning of sales of adult-use cannabis in Europe which are expected to occur legally in countries like the Netherlands, Switzerland and Luxembourg during the forecast period.

The European cannabis supply chain underwent substantial change during 2020. Prohibition Partners exclusively report that exports of medical cannabis from the Netherlands, the main supplier to Europe together with Canada, decreased from 2019-2020 for the first time in a decade. The increasing import of cannabis into the main market of Germany means that it is very likely that the European supply of cannabis has begun to diversify away from the historic duopoly of the Netherlands and Canada, with the arrival of producers from regions like Israel and Uruguay.

As the patient access to medical cannabis advances across Europe, so too do the opportunities for businesses to embed themselves in niches of the value chain, before the market becomes more established. This report is designed to support businesses in doing so, along with the conferences offered by Prohibition Partners Live as well as our Consulting services for cannabis and psychedelic ventures.



HELPING THE WORLD GROW SMARTER

Fluence creates advanced lighting solutions for controlled environment crop production.

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Learn more at www.fluence.science

FLUENCE
BY **OSRAM**

IMPROVE QUALITY

INCREASE YIELD

PRODUCE YEAR-ROUND

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EXPERT INTERVIEWS



Timo Bongartz
General Manager,
Fluence EMEA

Pioneering European Cannabis Cultivation with LED Lighting Solutions: a Q&A with Fluence EMEA General Manager Timo Bongartz

The legal European cannabis industry is still young compared to its North American counterparts. As more operations pop up in Germany, Portugal, Italy, the Netherlands and elsewhere in Europe, cultivators will demand partners who can do more than sell products. They need proven advisers with the right combination of cultivation experience, market-specific knowledge and practical scientific expertise that helps them produce the highest-quality cannabis and ultimately grow top-line revenue.

Fluence by OSRAM: Cannabis Lighting Specialists

Fluence by OSRAM, a global provider of energy-efficient LED lighting solutions for controlled environment cannabis production, is pioneering lighting applications and research in the legal commercialisation of cannabis. Fluence has illuminated more than 325,000 square metres of cannabis canopy worldwide and approaches customer projects comprehensively to ensure the cultivation and financial goals of its growers are realised. It provides growers with the latest photobiology and applied scientific research and connects them to teams of proven horticulture experts with local market knowledge who can provide on-site guidance and consulting. With its regional headquarters in Rotterdam, the Netherlands, Fluence believes the only

way to truly help cultivators perfect their operational strategies and deliver the highest quality products is through collaboration, by being in the growers' greenhouses or indoor farms with them.

Based on Scientific Photobiology Research

Fluence is also committed to industry-leading research partnerships that explore how light influences crucial performance metrics like plant yield, biomass, consistency and quality. The company recently conducted a groundbreaking photobiology study, in partnership with the prestigious Wageningen University and Research (WUR) in the Netherlands, that examined supplemental lighting's effect on cannabis flower quality and yield in greenhouse production. The greenhouse study verified that while lower supplemental light spectra do not significantly influence cannabis yield, a lower percentage of red light correlates with an increase in cannabinoid concentrations in some cultivars, and that spectrum sensitivity is cultivar dependent. The findings reinforce what should be a core focus for cultivators around the world; cannabis cultivation is a top-line game. The cultivators most willing to embrace that philosophy and deploy lighting strategies that increase revenue—rather than cut costs—will be best positioned to compete and win in their respective markets for years to come.

Fluence's extensive cannabis research programme in North America is continuing to fuel the market with new findings that benefit

our collective understanding of how light impacts cannabis plant production. These findings are shared with the global network of cannabis growers and can be found at www.fluence.science/science.

Q&A with a Horticulture Lighting Expert
Timo Bongartz, Fluence's General Manager for EMEA, shared his insights with Prohibition Partners on the European cannabis market and Fluence's work in the region.

What trends are you seeing in the development of European cannabis markets today?

Most growers in Europe are relatively new adopters of LED lighting and might not be as familiar with strategies to optimise yield and quality in their operations. European markets, however, have the added benefit of being able to draw on generations of proven expertise in other horticulture areas. I'm anticipating that a lot of experts in other crops will make the jump to cannabis as the market matures. For example, chrysanthemums are short-day plants similar to cannabis, so ornamental growers with a proven track record could make the transition to cannabis production and be successful. That's especially true when they have access to research and a team of experts—like we have at Fluence—who can be there with them on the ground to make that transition even easier. European growers are well known for their understanding of commercial crop cultivation. Though we can learn from our friends in North America, we can also apply techniques perfected by our generational growers here in Europe.

How does Fluence help European cannabis growers, specifically those searching for data-driven insights to improve their top-line growth?

We're focused on controlled environments in countries like Portugal, Germany, France, Italy and Denmark that are becoming hotbeds for medical cannabis production. These markets are still young, and cultivators are hungry for insights and best practices that can give them a competitive advantage. It's our job to help them do that. We have more

than 325,000 square metres of cannabis canopy under our LED lights. That's a huge install base, which gives us a wealth of knowledge and experience that cultivators can draw from. We're proud to have a skilled horticulture services team based in Europe that knows cannabis production, speaks the growers' languages, understands the nuances of the local markets and supports growers every day in their facilities. That's especially critical for cannabis growers because we know that each facility and operation is unique. There's no such thing as a one-size-fits-all approach to lighting or cannabis production in general. That's why we emphasise boots-on-the-ground partnerships with growers to adopt the right lighting strategy for each environment, whether that's a warm-climate greenhouse with a high daily light integral or a cold-climate warehouse that uses 100% supplemental light. We love working with growers who want data and analytics to understand highly tactical and operationally specific needs like photo acclimation, seasonal production and compressed cultivation cycles.

What are the top three insights or practices that the European market can take away from the North American market?

It's important that growers first take the time to understand their business models and products. Do you want to compete in the high-end flower market or will you focus on extracts and edibles? Do you want to enter the growing CBD market or produce well-rounded cannabis products that fit the needs of physicians and their patients? Identifying customer needs up front allows growers to tailor their strategies to deliver the correct products that meet market demand. Secondly, use research to inform those strategies at every opportunity. For example, our study with Wageningen University and Research shows that cultivators who focus on high-end flower production should apply high photosynthetically active photon flux density (PPFD) levels to enhance plant growth. Facility space is limited and expensive in Europe, so maximising capacity becomes even more critical. Growing under high PPFD and

broad-spectrum lighting can help growers produce consistent, high-quality crops with balanced cannabinoid and terpene profiles that are absent under legacy lighting systems like high pressure sodium vapour (HPS). Lastly, focus on year-round consistency. As markets become more saturated, cultivators competing in the high-end flower market, for instance, will need to meet the standards customers set for them regardless of the time of year. We see some growers cut back on supplemental lighting during the winter months, which leads to lower-grade plants. But as competition gets more intense, growers will need to deliver year-round consistency. Greenhouse growers in particular should ensure they maintain the same environmental conditions during the winter and summer. Otherwise they'll see different results and the end product will be inconsistent and unreliable for customers.

About Timo Bongartz

Timo Bongartz has spent more than a decade helping businesses transform legacy processes into interconnected digital strategies. His passion for accelerating business transformation—combined with a childhood affinity for cultivation—ultimately led him to the horticulture industry. Today, Bongartz serves as the General Manager for Fluence by OSRAM's EMEA region, empowering food, ornamental and pharmaceutical crop growers across Europe, the Middle East and Africa to achieve their cultivation goals through advanced horticultural lighting technologies.



Trends

THE MARCH OF LEGALISATION

The European cannabis industry faced a pivotal year in 2020. Despite the disruptions during 2020 caused by the COVID-19 pandemic, we estimate that 60,000 patients received cannabis medications in Europe for the first time. In November, the UN voted to recognise the medical potential of cannabis by removing it from Category IV of the Single Convention on Narcotic Drugs. The motion was supported by all European members who voted. The UN decision to reschedule cannabis is already bearing fruit, with the government of Morocco, the largest producer of illicit cannabis in the world, passing legislation to allow medical cannabis cultivation in March 2021.

In Europe, the Court of Justice ruled in November 2020 that CBD is not a narcotic under EU law, allowing for the commencement of application for marketing approval for CBD products on the continent. 2021 has started on a high, with the acquisition of the medical cannabis firm GW Pharmaceuticals by Jazz Pharmaceuticals for just under €6 billion. In the US, the promise of reform under the Democrats is helping to normalise cannabis across Europe, with incremental advances being made for patient access and the liberalisation of adult-use cannabis.

COVID-19 has caused some delays to broad regulatory reform in Europe. Switzerland has not yet changed its system to a more open-access one, France has not

begun patient treatment under its pilot programme (though it should by 31 March), and Romania has yet to see its draft law legalising medical cannabis use over 0.2% THC become adopted as official legislation.

Despite these delays on a regional scale, there has been progress within countries. Poland is rumoured to be on the verge of introducing medical cannabis extracts into their medical cannabis system, which has seen shortages in the supply of some products. Portugal has approved its first medical cannabis flower which will be on the market by March. Italy is taking steps to decentralise the dispensing of medical cannabis from a select few pharmacies to a broader network, and Germany has streamlined its pricing system to reduce the cost of medical cannabis to the taxpayer, while maintaining the same price for the patient.

As the COVID-19 vaccination process rolls out across Europe, we expect to see further delays in the emergence of new medical cannabis programmes, vaccination being rightly prioritised above all else in the focus of healthcare regulators. Legalisation timelines depend on the efficiency of this process, but the pace of cannabis reform is expected to pick up again as vaccination becomes less critical. When the region emerges from this crisis, new legalising countries will have more developed medical cannabis systems than Germany, Italy, Poland and France to draw experience from, so processes of implementation will be smoother as a result.

Timeline: Medical and adult-use recreational cannabis legalisation throughout Europe



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THE DIFFERENT PHASES OF MEDICAL LEGALISATION

The legalisation of cannabis medicines in Europe is an evolving process, both within the countries themselves and at the international level. The situation today is that each country takes its own approach to developing a regulatory framework which allows the treatment of patients using medical cannabis products. This is a complex undertaking, because these products mostly lack medical marketing authorisation and are classified as narcotics under national and international scheduling.

Until enough products gain medical marketing authorisation, like for instance Sativex® and Epidiolex®, we will not see full standardisation and harmonisation of the regulation of medicinal cannabis across the region. The majority of medical cannabis products on the market, being whole-plant extracts or even part of the plant itself, are not the type of products which normally gain these authorisations. Part of the market is currently moving towards more pharmaceutical-style products which would have greater eligibility for authorisation, though cannabis will, for years to come, remain an exceptional form of medicine in Europe.

The approaches taken by those European countries which have legalised the use of medical cannabis to some degree can be broadly categorised as:

Physician's discretion (e.g. Germany) vs List of specific treatable conditions (e.g. the Czech Republic)

Some countries allow certain authorised physicians to decide on a case-by-case basis whether medical cannabis treatment would be suitable for a patient's conditions. Conversely, some countries only allow medical cannabis treatment for a specific set of conditions.

Approved product formats (e.g. the Czech Republic) vs Specific list of approved products (e.g. Denmark)

Similar to the previous distinction, some countries have a list of specifically approved prod-

ucts which can be used, while others only specify approved product formats.

Public reimbursement (e.g. Germany) vs Private payment (e.g. Poland)

Some countries provide medical cannabis as part of subsidised public healthcare, whereas others exclude it from subsidisation, driving up the cost of medical cannabis to the patient. This categorisation is more of a spectrum rather than a dichotomy, with many countries at some stage of the process developing a system of subsidisation for medical cannabis treatment.

Permanent regulatory framework (e.g. the UK) vs Pilot programme (e.g. Denmark)

Some countries have allowed medical cannabis treatment as part of a pilot programme with a fixed period, whereby the programme will be reviewed at the end of the period and a decision made on the place of cannabis in the medical system going forward, whether the regulatory framework is updated and made permanent, or simply extended (or abolished). Conversely, other countries have put in place a system for medical cannabis treatment which continues indefinitely.

Normalised access (e.g. the Netherlands) vs. Case-by-case access (e.g. Norway)

Unlike in the US, where patients generally have to apply for a medical cannabis licence before being allowed to receive treatment, in Europe medical cannabis is usually prescribed through pre-existing procedures for treating patients with medicine which lacks medical marketing authorisation. Some European countries do however require application, generally by the doctor on behalf of the patient, to some level of health authority to receive permission on a patient-by-patient basis for medical cannabis to be administered as treatment.

Patient access (e.g. Italy) vs No patient access yet (e.g. Portugal)

The final categorisation is simple – some countries have legalised medical cannabis, yet for one reason or another no patient has yet accessed medical cannabis products via their domestic healthcare system. In this case, patients sometimes have to continue to receive imports under special allowance on a case-by-case basis from abroad.

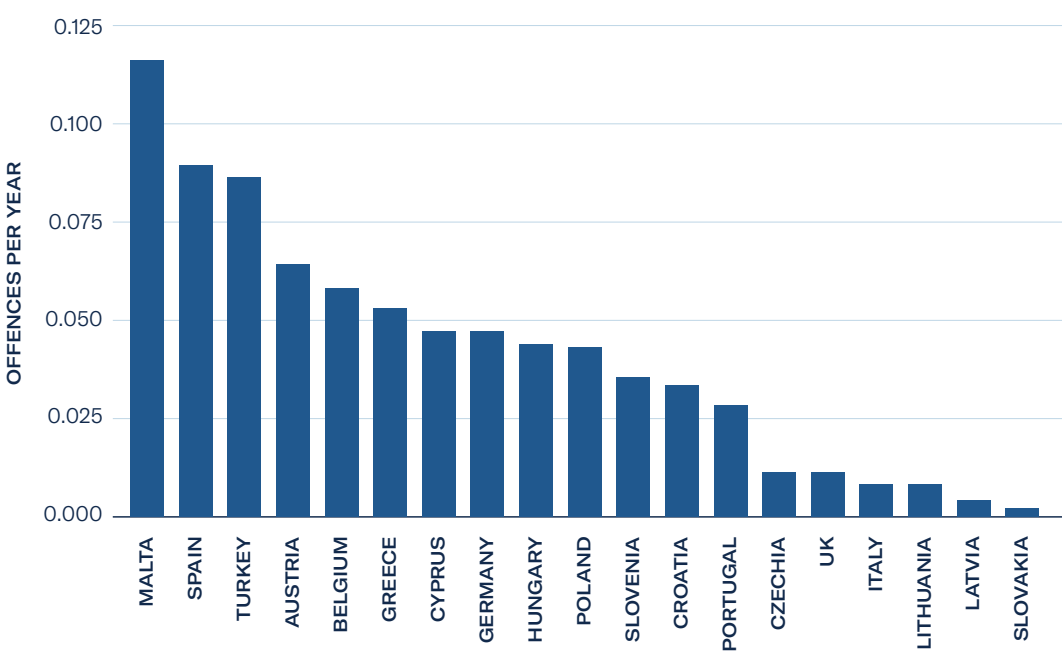
As legalisation of the medical use of cannabis spreads across Europe, so too will countries transition from one side of these categorisations to the other. Transitions will often happen simultaneously across categories. France and Ireland have both developed pilot programmes under which no patient has yet been treated. Portugal and Romania have legalised medical cannabis without having developed a means for patient access, beyond that of case-by-case allowances for imports.

ADULT-USE LEGALISATION

To date, no European country has legalised cannabis for adult-use purposes, and widespread legalisation is still years away. At the global scale, countries are slowly waking up to the benefits of legalising cannabis for adult-use purposes. These benefits include the billions raised in taxes, the lifting of unnecessary burdens from the justice system and the protection of people using cannabis who are otherwise criminalised. To date, only Canada, Uruguay and a selection of states within the US have legalised cannabis for adult-use purposes. These states are already reaping considerable rewards from these policies. Colorado, with a GDP similar to Norway (14th highest in the EU), sold over US\$1.7 billion worth of adult-use cannabis in 2020. Estimates are that the industry supports hundreds of thousands of jobs in the US in areas such as cultivation, distribution and retail. Legalisation of adult-use cannabis is spreading across the globe at a steady pace, with Mexico and Israel set to open their markets during 2021.

Despite its illicit status, adult-use cannabis is popular in Europe and more than a quarter of the population have at least tried it in their lifetime. However, due to outdated regulations, the market in Europe and the €11.6 billion in sales each year is confined to the black market. In this context, criminalisation of users of cannabis continues in many countries in Europe. In 2018, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) counted 1.2 million criminal offences for the personal use of cannabis. Using this data for offences and prevalence of use of cannabis, we can graph the amount of criminal offences per user in each country for which the data is available.

Criminal offences per cannabis user/year



Source: EMCDDA
Note: Data on number of users and offences is taken from the most recently available year. Definitions of offence are variable and available at EMCDDA's website.

As can be seen from the above graph, some countries are more active in enforcing regulations than others. Despite the relative tolerance of recreational cannabis use in Spain, there are ten times more cannabis offences recorded by the authorities per user each year than Italy.

Countries which are more progressive on cannabis policies such as Portugal and the Czech Republic expend relatively little resources on law enforcement for punishing cannabis users. These progressive countries may well be among the first to fully legalise adult-use cannabis.

The stigma attached to cannabis is steadily being chipped away and is being replaced by an acceptance of the low risk of harm and high medical potential. Below, we review the pioneering efforts of countries, provinces and cities that are experimenting with progressive adult-use cannabis regulations.

Luxembourg cautiously leading the way

In 2018, the Luxembourg coalition government agreed to legalise recreational cannabis. Luxembourg is home to just over 600,000 people, and would not represent a particularly large market if it were to legalise. However, the symbolic significance of being the first European country to legalise cannot be overstated. In addition, Luxembourg will be the first state on the continent to grapple with issues such as banking for legal cannabis businesses, as well as the challenge of reconciling national and international drug control laws.

At the time of the agreement in 2018, a draft law was set to be prepared for Autumn 2021, with an end date of Autumn 2023 set for legislation being put into effect. Early in 2020, the initial proposal for the regulated adult-use cannabis market was released and included the following points:

- A maximum of 30 grams of cannabis may be bought per month per person
- Buyers must be >18 years old
- No deliveries or online sales are allowed
- Only residents of over 6 months may purchase cannabis
- Consumption is prohibited in public places
- Cannabis products are to be produced exclusively in Luxembourg
- 14 points of sale across the country are planned in an initial phase
- Part of the annual turnover has to be paid to the State
- A maximum THC rate for cannabis flowers is not provided

As of early 2021, in the context of COVID-19, there is little sign of progress beyond early planning stages. Recently, a spokesperson for the Ministry of Health has indicated to the press that there is no specific deadline that the government will be adhering to in setting up the legal cannabis industry.

The Netherlands Experiment

For years, the Netherlands has been the poster child of liberal policies on cannabis by virtue of the law enforcement's 'tolerance' of cannabis sales in coffeeshops. Recently, the Mayor of Amsterdam has announced that there may be a ban on tourists from accessing cannabis in the city's capital, which has to date attracted as many as 1.5 million people per year. This policy has already been in place for years in other cities, such as Maastricht. Since 2017, the Netherlands government has been planning to institute a full, legalised cannabis supply chain on a trial basis. Under the current form of the plan 80 coffeeshops will be set up across ten municipalities including: Arnhem, Almere, Breda, Groningen, Heerlen, Hellevoetsluis, Maastricht, Nijmegen, Tilburg

and Zaanstad. Ten growers will produce cannabis for the experiment, which the government estimates will require 65,000 kilograms in total per year. The trial will notably exclude the capital city of Amsterdam. Participation in the trial requires that coffeeshops immediately abandon their illicit suppliers, which would threaten the existing ecosystem in Amsterdam, something shop-owners are reluctant to do.

The roadmap to the supply legalisation trial is as follows:

- 10 October, 2017
COALITION AGREEMENT
- July 12, 2018
CABINET SUBMITS BILL TO HOUSE OF REPRESENTATIVES
- 22 January, 2019
HOUSE OF REPRESENTATIVES APPROVES BILL
- 12 November, 2019
SENATE APPROVES BILL
- 28 November, 2019
LAW PUBLISHED IN THE OFFICIAL GAZETTE
- 1 July, 2020
PREPARATION PHASE BEGINS
- 3 December, 2020
PRODUCERS ARE CHOSEN
- First quarter 2021
PRODUCTION BEGINS
- When products are ready
EXECUTION OF THE EXPERIMENT
- At completion of trial (min 4 years)
FINAL EVALUATION OF THE EXPERIMENT
- After completion of trial
PHASE OUT EXPERIMENT

Source: Government Website



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EXPERT INTERVIEWS



Dylan Kennett
Corporate Senior Associate,
DLA Piper



Rahool Sarjua
Senior Associate,
DLA Piper

Hi Dylan & Rahool, thanks for taking the time to speak with us again. For readers who aren't familiar with you and DLA Piper, would you mind letting us know who you and DLA Piper are?

Dylan: Thanks so much for involving us again, always delighted to be working with Prohibition Partners. By way of background, I'm a corporate lawyer in the London office of DLA Piper. I predominantly focus on venture capital, private equity, M&A and taking companies into new jurisdictions as they go 'global'.

Rahool: Yes, thank you for having us. I'm in DLA Piper's London office focussing on intellectual property (both contentious and non-contentious) across a range of industries, but also work on commercial and regulatory issues affecting life science and cannabis businesses.

Dylan: DLA Piper is a global business law firm across 40 countries, with 90 offices globally. We are full-service in each of those jurisdictions we operate in and act for companies, investors and other stakeholders across the entire corporate life-cycle. By full-service it means we do everything from corporate, employment, intellectual property and litigation, just to name a few!

What has DLA Piper been doing in the cannabis space?

Dylan: We have been involved in the cannabis sector for some time now. Our Canadian practice traditionally led in this area, having been involved from medical to adult-use in the country. I hail from Canada as well, but am an English

qualified lawyer. In 2018 it was clear to us that a number of companies were looking to expand globally as capital flowed into this nascent sector and regulations started to liberalise. Our Global Cannabis Practice is now in over 20+ jurisdictions across DLA Piper actively advising across the globe, which is a reflection of the hard work and focus we have given the sector as a firm.

It has been a big year for cannabis in Europe to say the least, what have been some of the big news stories in your view over the last 12 months?

Rahool: The Court of Justice of the European Union's (CJEU) judgement in the Kanavape case is a very significant development for the CBD market, by clarifying that CBD by itself, cannot be considered to be a narcotic, no matter what part of the plant it comes from.

Dylan: From my point of view, with the green shoots in North America sprouting after a significant market correction, we are seeing that permeate into and across Europe. I would say that the listings on the London Stock Exchange, from a corporate lawyer's point of view was a massive advancement for the industry. For some time, it was somewhat unclear how, and importantly, what type of companies were going to be able to access the nexus for European capital markets. We were very pleased to see the statement from the Financial Conduct Authority in September 2020, which has provided clear ground rules. We're also quite positive that there are now pathways to build long-term businesses, through greater access to venture capital via

newly established funds, while also giving shareholders a path to liquidity through the recently opened public markets; founders no longer have to immediately sell their businesses prematurely to achieve an exit.

What about Brexit? What impact has this had on cannabis related businesses?

Dylan: As it pertains to the industry, we are yet to see how Brexit will shake out. There are real opportunities for the UK to be a hotbed for innovation, and the UK Government's last budget seems to have trended positively towards R&D and high-growth companies. On the other hand, patient access is still incredibly difficult, as I understand things. Therefore, we might end up in a scenario where a lot of great innovation takes place in the UK, but patients here struggle to benefit from it. The UK has good prospects to also be a 'best in class' in the hemp/CBD industry, but again, it will take significant government support to advance this part of the industry as well. We also see Brexit's more obvious negative consequences where patients were being supplied from the Netherlands and are now disrupted because of the changing import requirements.

Rahool: From a regulatory perspective, there were some differences emerging even before the end of the transitional period on 31 December 2020. For example, the UK Food Standards Agency (FSA) responsible for administering the Novel Foods framework, had already determined that it considered CBD products to be a novel food. When the European Commission suspended novel food applications for

CBD during the summer of 2020 (as Kanavape was still pending before the CJEU), the UK FSA had already firmly taken the view that CBD was not a narcotic and that it would support novel food applications despite the European Commission taking a more cautionary view until Kanavape was decided. This suggests that the UK authorities can move more quickly and decisively where needed. But I agree that we are yet to see how Brexit will affect the industry. English courts are still considering judgments coming out of the CJEU after the transitional period, even though the higher courts are no longer bound by it.

What European countries have you been most impressed with? Why? Which country has room for the most improvement?

Dylan: It's so hard to say what is going well and where, but from our point of view we were pleased to see the Dutch supply pilot programme in respect of certain cities. Historically, supply of the coffeeshops was illegal, yet consumption on premises tolerated – therefore, we had this weird lacuna in the law, which is now being addressed. Not all cities have signed up, but again, it's about steps that are being taken which should make the situation clearer for everybody.

France, probably the more conservative country with regard to this industry, is also moving forward with its pilot programme which is encouraging. However, there are no guarantees that the companies working with the government would be able or allowed to participate post-pilot. France is a potentially

huge market, but their cautious and conservative approach to cannabis presents challenges to the development of the industry.

We'll clearly continue to see growth in Germany as positive developments continue their momentum. It was worthy of note that STADA (one of the larger German pharma companies) declared that it would market medical cannabis in Germany in the future.

This is to our knowledge the first German traditional and big pharma player to do so. Germany continues to be a core focus of European cannabis, especially for those overseas players looking to expand into Europe.

I would also say that Denmark continues to punch above its weight. The government and related authorities are really making it attractive to set up a business there in this space with lots of events, meetups and venture capital available to pursue a business there. I think the concern remains with getting medicines approved for use under their pilot programme, but the innovation will no doubt be germinated there.

We also are keeping an eye on Malta as a gateway to Europe and now Morocco, as we understand they are looking to soon legalise for non-recreational use. As a country with such a deep history in cannabis, I'm curious to see how this develops.

Are you seeing a lot of corporate activity in the space yet?

Dylan: I would say the start to 2020 continued like 2019, as capital flows hadn't quite yet returned to the markets, but from autumn/winter 2020 things have definitely picked up and we're seeing signs of growth. We are now seeing consolidation, companies looking for overseas targets and, companies coming to the public markets. For example, we were delighted to see EMMAC and their tie up with Curaleaf at the beginning of March, as it validated the pan-European business model and the team there has been working hard for many years. MGC Pharma coming to market on the London Stock Exchange was also a

seminal moment for the European industry, so again, delighted to see this progress.

Can you help our readers (especially those who are non-Europeans) understand the Novel Food regime as it relates to CBD?

Rahool: A novel food is defined as food that had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel foods came into force. In order for a novel food to be authorised, it must satisfy the following three requirements:

- be safe for consumers;
- be properly labelled, so as not to mislead consumers; and
- if a novel food is intended to replace another food, it must not differ in a way that the consumption of the novel food would be nutritionally disadvantageous for the consumer.

In the UK, the Food Standards Agency (FSA) came to the view that CBD is a Novel Food in 2019. As a result novel food authorisations are now required in respect of CBD products.

What are the key issues keeping your clients up at night and/or the most common issues you are seeing them face?

Dylan: One of the main issues we continue to deal with is the application of the Proceeds of Crime Act (POCA) in the UK to cannabis businesses. The Financial Conduct Authority (FCA) guidance around this point gave a lot of clarity as to how such businesses would be considered and that, amongst other things, any business with adult-use in its portfolio would be precluded from going public – we basically knew that, but it was great to see it stated officially.

The POCA also created uncertainty in investors taking stakes in cannabis businesses and a lot of differences of opinion remain in the legal market, as to the application of POCA on this area. Nonetheless, everyone in the industry appreciates that regulatory uncertainty is

part of doing business in a novel sector such as this, but we're hopeful that more clarity comes in due course through the promised FCA guidance consultation or similar.

Our clients also remain concerned about patient access to the medicines that they're developing. It really varies across the continent and can often feel like two steps forward and one back.

Rahool: The patchwork of different regulations and the seemingly inconsistent application of some of those regulations, for example with respect to tolerance thresholds for THC, the interpretation of the Novel Food regulation or the UN Single Convention on Narcotic Drugs, 1961 by different countries is a significant burden for any CBD or cannabis business.

What further regulatory changes do you anticipate in the next few years?

There are still a number of areas that need to be addressed. For example, the use of CBD or other cannabinoids in pets is not yet authorised in the UK – this is due to a lack of safety data, so there is likely to be some change in this area as a number of pet-owners are keen to use cannabinoids to treat diseases in animals as more safety data becomes available. The fact that the UK doesn't consider CBD to be a narcotic, but still require extracts (when grown under a hemp licence) to come from the non-flowering parts of the plant does not reconcile with the approach taken by the CJEU.

At an international level, there obviously remains a lot more to be done under the Single Convention, so that businesses and the medical community can operate more efficiently. There is significant scope for research and development in this area, but the requirements for special research licences is slowing down scientific progress.

What transactions are you as a team most proud of this year?

Dylan: We've been really lucky to work with some amazing clients this year. Of particular note for our global practice was Chris Giordiano in the US and Russel Drew in

Canada advising Aphria in connection with its proposed CAD\$5 billion (USD\$3.8 billion) combination with Tilray Inc. The deal with Aphria and Tilray will create the largest company in the global cannabis industry based on reported revenue for the most recent 12 month periods of each company prior to the announcement of the deal. It really allowed our team to show its depth of expertise and ability as a firm, providing sector expertise across a number of jurisdictions globally, including the US, Canada, Portugal and Germany (among other jurisdictions).

I would also say, we were very pleased to work for Organigram as their European counsel for their transaction with BAT plc. That was an incredibly interesting transaction and we were delighted to be a part of such a fantastic transaction that validates the market.

Besides the 'mega' deals, we take great pride in assisting all clients in the sector look at new jurisdictions so that they can expand their footprint globally. Global regulations are complex and we're actively promoting solutions that help companies get their medicines or products to those who are in need of them.

We also are keeping an eye on Malta as a gateway to Europe and now Morocco, as we understand they are looking to soon legalise for non-recreational use.

Dylan Kennett, Corporate Senior Associate, DLA Piper

Switzerland

The government of Switzerland is also set to trial legal access to recreational cannabis. Multiple trials will be carried out across different cities. Each trial is meant for a limited number of citizens who already consume cannabis. Trials will be run by individual municipalities which can each supply up to 5,000 consumers at most. The purpose of the trials is to study the effects of legal access to cannabis for users in terms of health and socio-economic metrics. Volunteers will only be able to purchase personal amounts for a month's supply. As is the case in Luxembourg, only domestically produced cannabis will be permitted to be sold. In the case of Switzerland, cannabis must be both domestically and organically produced. Whether, and when, tenders will be released for this trial has not been disclosed.

City wide trials and social clubs

Other manifestations of legal adult-use cannabis regulations are beginning to emerge across Europe, including city-wide trial periods and the social club model. Lawmakers in several regions have already volunteered to implement trial periods of legalised adult-use cannabis, including Copenhagen and several German cities such as Bremen, Berlin, Frankfurt and Hamburg. These attempts to introduce trials have not yet met with success. While cities and municipalities may be open to trialling adult-use cannabis, in most cases, this needs to be approved by the national legislature who have been reticent to do so.

Cannabis social clubs have also operated in Europe throughout recent years but these are largely non-commercial enterprises, which are tolerated rather than being legal. These clubs offer members the chance to cultivate cannabis, or delegate cultivation to other members of the club, and to consume it on the premises, or at home. A study run by the University of Leicester in 2020 found cannabis social clubs are operating in the vast majority of European countries. Spain is the

poster child for this form of adult-use cannabis access with municipalities and lone cities like Barcelona taking it upon themselves to regulate these clubs. According to a report by the Confederation of Federations of Cannabis Associations, as many as 1,500 clubs exist in Spain, with the majority operating in Barcelona. However, clubs are running into the same problem as cities like Copenhagen and Berlin by clashing with national legislatures. In November 2020, the Supreme Court of Spain ruled that the City of Barcelona did not have the right to regulate social clubs as the legality of the organisations is in question. This ruling underlines the fact that cannabis social clubs may not be long for the continent, and represent a short term solution to a continuing problem created by prohibition. In fact, there is a chance that the presence of social clubs could hinder the progress of full legalisation of cannabis by removing some of the impetus from advocates, and associating consumption with questionable legal practices.

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EXPERT ANALYSIS



Nick Davis
CEO,
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The firm is also the leading UK law firm on advising the emerging cannabis sector on capital markets, business set-up, mergers and acquisitions, private fundraising, licensing and commercial contracts. Following the newly published guidance by the Financial Conduct Authority (FCA), the firm advised on the first ever listing of a cannabis related business on London's primary markets.

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Wow, what a start to the year for the cannabis sector. London has been behind the curve on medicinal cannabis IPOs, how does it feel to finally have them on board?

We have been in discussions with the FCA for over two years now on behalf of MGC Pharmaceuticals (MGC), an Israeli pharmaceuticals company, so we are thrilled to finally have a positive outcome for medicinal cannabis companies. The market has been waiting for a high-quality cannabis company and in MGC they found just that. However, the true victory here is for the patients who so desperately deserve access to these life-changing medicines. By opening the London markets, these companies are able to raise money to fund vital research and in turn save lives – for me, the decision couldn't be simpler.

What does this mean for the future of cannabis companies?

At present, a Main Market listing for medicinal cannabis companies with UK only operations are likely to be the easiest to list from a regulatory perspective, followed by those which operate in jurisdictions whose regulatory environment is equivalent to that of the UK, such as EU countries, or Australia.

Beyond medicinal cannabis businesses, CBD companies who have successfully navigated the issue of "novel foods", or those who operate in the cannabis technology space (perhaps in extraction or vape technology), are likely to also be able to list on London Stock Exchange's Main Market. However, in all cas-

es legal due diligence and supporting opinions will remain vital for listings to proceed.

London's AIM has yet to see a cannabis company listing and therefore may remain challenging unless AIM is also able to set out its position as to cannabis companies.

What is keeping you busy at the moment?

Following MGC's listing, we have had a significant number of enquiries from cannabis companies considering a listing in London. Now is the time to maintain pressure with the investment industry to allow retail investors to participate in this huge growth sector.

Despite initial concerns, the London markets have remained incredibly strong during the pandemic, particularly in life sciences, those with COVID treatments, or med-tech products. Successive lockdowns have also seen the rise of tech companies and consumer brands that have developed a robust online sales strategy or those who have access to larger retailers.

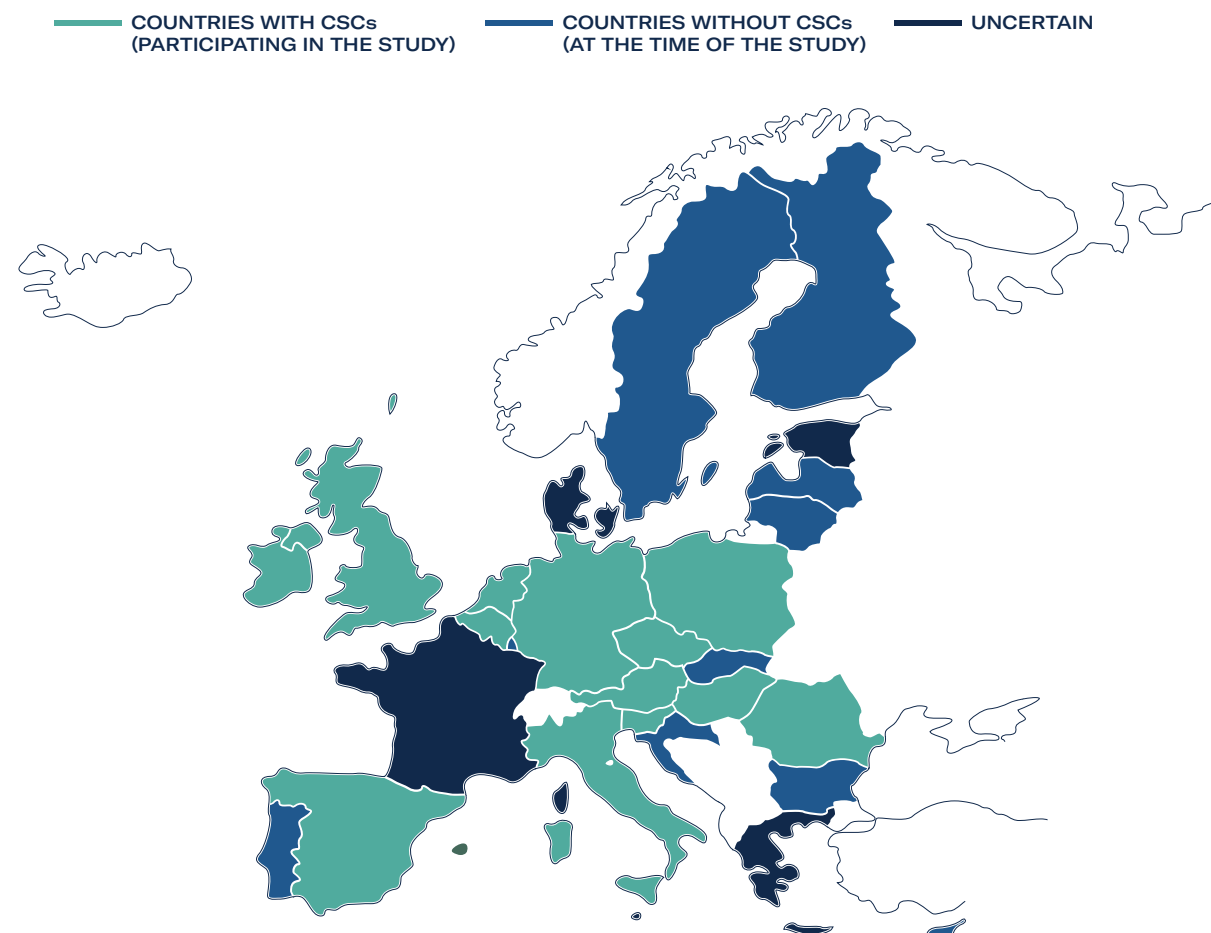
With the Main Market now being available, we are likely to see a steady flow of high-quality companies including CBD based businesses considering a London listing.

Listings aside, we recently advised on the UK aspect of the landmark \$285 million acquisition of EMMAC Life Sciences by US cannabis giant Curaleaf, which will be a huge milestone for the European cannabis market. The two leading companies combined create a global

platform that is poised to exploit the rapid pace of growth of the European cannabis market, especially in the potential shift from medical to more consumer-oriented.

This acquisition and the recent listings make for a very exciting time in the cannabis industry. Cannabis is still one of the world's fastest growing and most innovative industrial sectors and it is fantastic to be able to say that we at Memery Crystal continue to remain at the centre of it.

Overview of cannabis social clubs across the European Union



Source: Johansson et al.(2020)

DEVELOPMENT OF SUPPLY CHAIN

The supply chain of cannabis in Europe is currently in flux. Since the takeoff of medical cannabis in Europe in recent years, products in countries like Germany and Denmark have exclusively been sourced from more established cannabis markets abroad. The vast majority of medical cannabis imported to European countries to date has come from Bedrocan in the Netherlands and from Canadian producers like Canopy Growth, Tilray, Aurora and Aphria. However, as the legalisation of medical and adult-use cannabis progress-

es, the list of international players seeking to export cannabis products grows, and the emergence of domestically produced cannabis in several states is increasing the diversity of supply. The list of countries outside Europe where companies are now producing, or preparing to produce, with a view to exporting to the continent is extensive, including for example Colombia and Uruguay in South America, Uganda and Lesotho in Africa, the US, Canada, Australia and Israel.

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MOVING BOUNDARIES

PharmaHemp is at the forefront of innovative solutions in the rapidly expanding cannabis-related industry. The company produces a wide variety of hemp-infused products with the lowest THC level possible in Europe. Such products include oils, concentrates, cosmetics, and other hemp-derived products.

PharmaHemp's key competitive advantage on the market is the provision of complete solutions in the field of Phyto cannabinoids and commitment to continuous innovation, quality, transparency and full traceability of their materials and processes.

The company offers innovative development services, stability studies and customized formulations as well as certified supply, processing and distribution of Phyto-cannabinoid-based raw materials. All analyses are done in their accredited in-house laboratory.

Each step in PharmaHemp's production cycle or analytical task is closely monitored and documented in order to ensure full traceability of materials and processes involved. In other words, the company's team performs diligent quality control and quantitatively determines cannabinoid levels.

PharmaHemp offers a broad variety of products with the lowest possible THC level in Europe, which are produced to the highest quality standards within certified GMP production capacities.

Their dedication to quality is validated by independent and external supervisory bodies. PharmaHemp is certified with the GMP standard for Good Manufacturing Practice for food and cosmetics and is accredited under the ISO/IEC 17025, the highest standard for testing and calibration laboratories. This accreditation proves that the company operates with the highest competency level in terms of laboratory testing of hemp and hemp-related products for growers, producers and end users. Its accredited test reports are accepted globally without the need for further testing, which in turn improves international trade.

PharmaHemp also successfully passed an FDA audit in 2020, which further proves their products are safe and meet all regulatory requirements to export to the USA. Moreover, its business operations are in compliance with the following quality systems; GACP, GDP, GLP, GMP, ISO 9001 and certified under ISO 22000, ISO 22716 and ISO/IEC 17025.

Last, but not least, PharmaHemp commenced their new production facility initiative, including a new Active Pharmaceutical Ingredients (API) plant. The new facility is projected to be built by the end of 2022 and will combine all production, laboratory, R&D, warehouse and corporate efforts. PharmaHemp believes their expansion is an important chapter in their story and a vital step in their mission to continue to improve lives drop by drop.



”

PharmaHemp started to build an Active Pharmaceutical Ingredients (API) production plant in accordance with current European Union Good Manufacturing Practices (EU GMP), which will enable the company to expand into the medical cannabis market.

We are proud to be one of the few producers in EU that have an in-house cannabinoid profiling laboratory accredited under ISO/IEC 17025.

Andrej Sušnik,
CEO of PharmaHemp

The delayed diversification of supply

Over the past three years, it has been common knowledge in the European industry that the diversity of producers supplying medical cannabis to Europe was about to grow exponentially. Each week, a new supplier or set of licences to produce cannabis has been announced in various regions. Conventional wisdom has been that cannabis produced in the Netherlands and Canada would soon have a hard time from competition with product sourced from new suppliers. However, the massive influx of producers has not yet fully materialised:

- On a large scale, the cannabis industry underwent a slowdown during the 2018-2020 period, with opportunities for capital increases sporadically drying up as investors demanded to see better business fundamentals. Subsequently, an international pullback from Canadian producers over the past two years has postponed the prospects of a fully realised global cannabis supply chain. For example, in 2020, Canopy Growth announced it was ceasing operations in Lesotho and Colombia to 'improve efficiencies', incurring over US \$800 million in charges due to the restructuring. Similarly, Aurora pulled back from a large development in Denmark in late 2019 in order to stem outward cash flow, while Tilray cut 10% of its staff in February 2020. Late 2020 and early 2021 has seen a meteoric rebound for investment in cannabis owing to several legislative developments (see section on COVID-19 related developments).
- Setting up for production and distribution of cannabis to Europe has been more difficult than anticipated for international players. Navigating local regulations on the production of controlled substances is a difficult task in any nation. For example, while Colombia has had over 100 registered cannabis farms since 2019, only a few have registered cultivars of the plant which would allow for commercial growing. Beyond national legal challenges, compa-

nies have to connect with the European supply chain and ensure compliance with European standards like Good Agricultural and Collection Practices (GACP) and EU Good Manufacturing Practices (EU-GMP). This has led to a paradoxical situation wherein plans for the production of huge volumes of medical cannabis have seemed well underway, yet there has been a scarcity of approved EU-GMP products reaching patients on the continent.

- Local regulations have not progressed as quickly as anticipated. In Israel for example, issues with mutual recognition of EU-GMP standards has meant a costly delay in approval for export of products to European countries. In South America, international producer Auxly failed to deliver harvests from its Uruguayan subsidiary citing 'slower-than-anticipated pace of cannabis-specific regulatory development in Latin America'.
- Some delays have been caused by COVID-19. In Germany, the marketing of harvested cannabis was pushed from late 2020 to mid 2021. In Barbados and Jamaica, the development of regulations on the production and export of cannabis were delayed due to the pandemic.

Challenges to the Dutch/Canadian duopoly

In the long term, it will be difficult for more developed and northerly countries to produce bulk cannabis as cheaply as regions such as the Mediterranean and South America where land and labour are cheaper, and the climate is more conducive to cannabis growth. Historically, the Netherlands and Canada have produced the vast majority of cannabis used by European patients. However, there are early signs that this may be changing.

EU GMP-Certified Pharmaceutical Formulations Made To Order



With partnerships already in place with a wealth of licensed producers, we extract, purify and develop formulations of the highest quality, designed for the needs of the patient.

We're looking for Pharmaceutical partners to manufacture formulations of THC & other cannabinoids for the European medical market.

- EU GMP pharmaceutical certification*
- Registration of multiple APIs
- US cannabis know-how with full EU pharmaceutical team
- Large distribution network positioned for expansion

*Certification expected Q3 2022



For more information on formulations or the rest of our product range please get in touch:

Website: www.somaipharma.eu
Email: hello@somaipharma.eu
Instagram: [SomaiPharma](https://www.instagram.com/SomaiPharma)
Linkedin: [Somai Pharmaceuticals](https://www.linkedin.com/company/Somai-Pharmaceuticals)

EXPERT
INTERVIEWS



Michael Sassano
CEO,
SOMAí Pharmaceuticals

Who are SOMAí Pharmaceuticals?

SOMAí Pharmaceuticals is an international company focused on creating unique cannabis formulations for the EU market, developed and manufactured inline with EU GMP regulations for pharmaceutical products.

With a state-of-the-art extraction hub currently under-construction just 30 minutes from downtown Lisbon, Portugal, and numerous biomass and distribution deals already signed with future partners, SOMAí is well-positioned as one of Europe's largest cannabis manufacturers.

SOMAí Pharmaceuticals leadership has also been active in the American market through Solaris Farms. What inspired this move to Europe?

Over the next few years Europe is projected to become the one of the world's largest cannabis markets, second only to North America. And unlike North America, which is segmented state-by-state into patchwork of different regulations, the EU affords the potential for a much more unified market. US MSO's are already coming to the European market through merger and acquisition activity — exemplified by Curaleaf's recent acquisition of Emmac Life Sciences — and so by establishing SOMAí today in Portugal, we can be sure we will be ahead of the curve and be best placed to serve the demands of the EU marketplace as it expands.

What experience does SOMAí bring from the USA, and how advantageous is that for

operating in the European market?

Doing extraction on the West coast for over eight years, we have overseen huge advancements in technology, formulation science, and drug delivery systems. And having already managed successful roll-out and expansion in the United States, the SOMAí team has the real-world knowhow needed to create realistic development timelines that can flexibly adapt to the European market as it goes through its own period of development and expansion.

In terms of our operations, SOMAí comes with an expert knowledge base that has already learned how to optimise extraction operations to realise their peak efficiency, and crucially also their peak profitability. This is rare in the European market where many start-ups are learning the craft for the first time, and so SOMAí stands out.

Why Portugal, specifically?

Back in 2019, started off in Greece, but after visiting in Portugal in 2020 we saw just how progressive INFARMED — Portugal's National Authority of Medicines and Health Products — was, and it became clear to us that Portugal would become a leader within the EU cannabis market.

Portugal has some of the most advanced rules in the EU that allow for easy import of materials from non-EU countries to be used as biomass for extraction, and the Portuguese health ministry fully supports the

pharmaceutical advancement of cannabis. Portugal has also already awarded many licenses to cannabis producers, and large companies like Tilray continue to pave the way in terms of receiving marketing approval for medicinal cannabis products. For us, Portugal's sensible approach to regulation, it's geographical location as a doorway to Europe from the United States, an internal market and Lisbon's renowned pool of highly educated biomedical professionals makes it a perfect fit.

With the construction of this extraction hub in Lisbon, it would appear that SOMAí Pharmaceuticals is initially focussing on manufacturing rather than cultivation. Why is that?

Europe is already full of cannabis cultivators who, to their credit, do an excellent job. But the current European market does not have enough qualified manufacturers of pharmaceutical and medical cannabis product formulations, and that is where SOMAí can really demonstrate our skills.

By choosing to invest in manufacturing over cultivation, we are able to concentrate our spending on the development of innovative products and novel cannabinoid formulations, without the added capital drain that comes with implementing vertical integration. SOMAí with construction already underway on the Lisbon extraction hub, fundraising remains open to prepare for an uplisting. With this, SOMAí will be able to pursue even greater European expansion, and to invest more heavily in the development of advanced product lines.

Can you expand on the cannabinoid formulations being developed by SOMAí Pharmaceuticals?

At this early stage, the focus is on creating extracts for pharmacological applications, such as >90% THC distillate and 99% THCA isolate for the formulation of cannabis-based medicinal products. These are extracts that we are familiar with from our experience on the West coast, and we want to bring that manufacturing expertise to the EU market.

As our capabilities expand, we will leverage our expert manufacturing knowledge and strategic partnerships to create innovative, tailor-made cannabinoid formulations in the shape of oral drops, pills, topicals, and possibly edibles plus, vape oils in the future. As the EU market develops, SOMAí will respond in kind to meet the demands of this blooming industry.

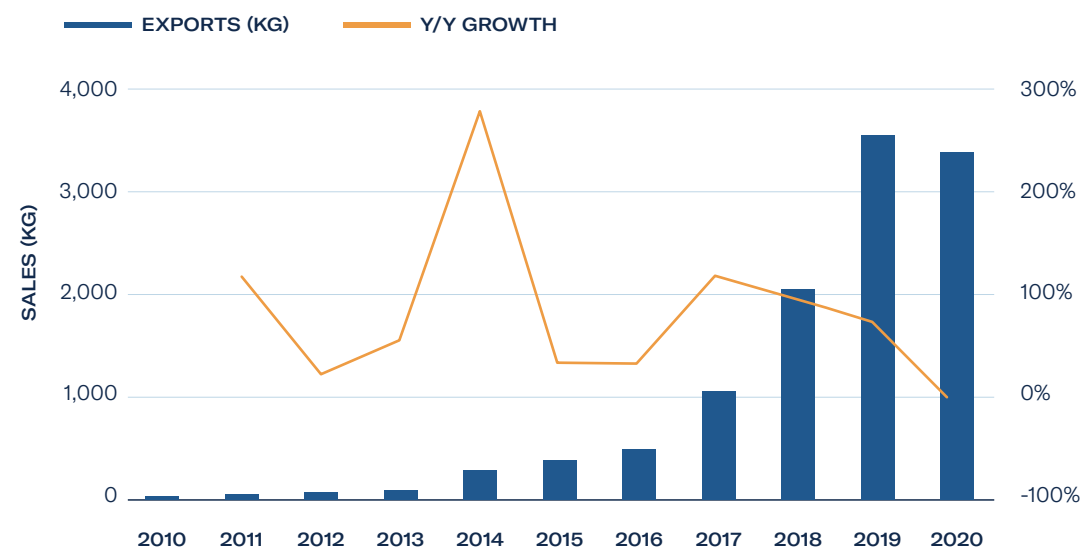
How do you see SOMAí Pharmaceuticals evolving over the next few years?

Presently we are looking for pharmaceutical partners that will allow us to manufacture more novel formulations for the future EU market. We anticipate that we will be able to start producing test batches in early 2022, with the site fully operational and EU-GMP certified soon after.

Our initial 3,700 sq m. facility in Lisbon has the availability to expand to up to 12,000 sq m. as the operation scales up, which would make it one of the largest manufacturing facilities in Europe. As the EU market broadens, we also plan to establish additional SOMAí extraction hubs in other promising locations around Europe.

All of this, in combination with our strategic partnerships and highly-knowledgeable staff means that SOMAí has the potential to dominate the market in terms of manufacturing and product formulation, and that is what we intend to do.

Exports of Dutch medical cannabis

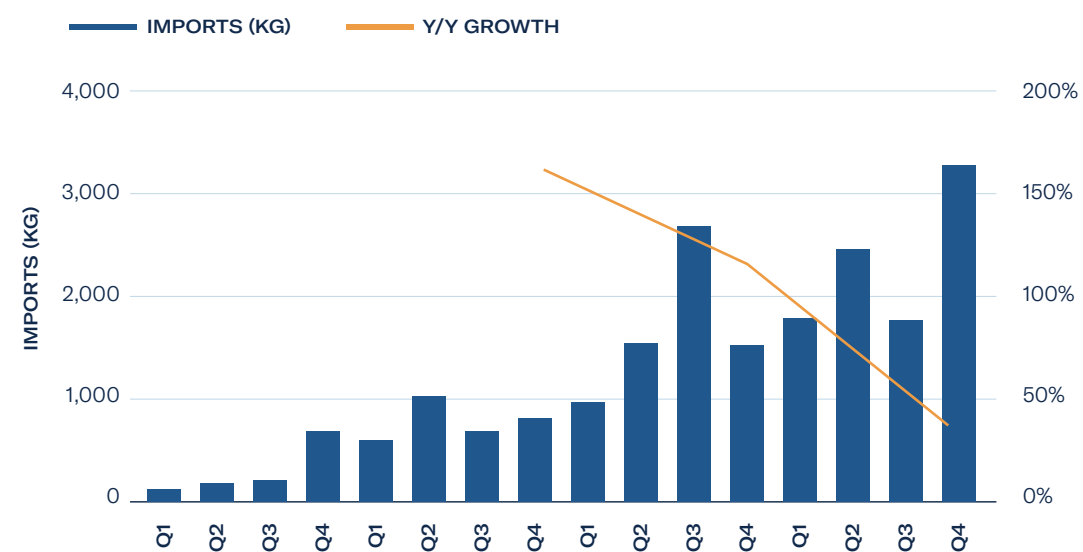


Source: OMC, personal communication

As Prohibition Partners exclusively reported early in 2021, 2020 was the first year on record in which Dutch exports of medical cannabis decreased as compared to the previous year. The average growth rate from 2015-2019 was 70%. In contrast to this, 2020

saw a decrease of 4.7% as compared to 2019. This may have been, in part, due to COVID-19 related disruptions. During 2020, medical cannabis imports increased in the largest market for Dutch cannabis; Germany.

Medical cannabis flower imports to Germany



Source: Atalis, BfArM

R.P GROW-TEC INNOVATIONS Ltd. Cannabis Drying & Curing Rooms WCD 380KG/560KG/760KG (Wet)

EU-GMP Ready



WeCanDry
ADVANCED HUMIDITY CONTROL

WCD CUTTING EDGE TECHNOLOGY SPECIFIC AND PRECISE PROTOCOLS FOR BEST DRYING & CURING

The room and all components are compliant with food and pharmaceutical standards.

The drying process leverages unique airflow technologies enables the achievement of high-quality flowers in a short time frame, minimizing loss, labor, and footprint.

The control system adjusts the climate conditions in the room, while tracking numerous variables, based on the flower's moisture content.

Real-time remote data-monitoring, eliminates room-entry and dramatically reduces pollution and energy loss.

✓ KEY FEATURES

- Consistent drying process based on laminar airflow
- Push alarms app
- Full climate control - air speed, temp & humidity
- Air filtration by HEPA & carbon filters
- Web based PLC control
- Optimal utilization of floor space
- Optional modular design
- No room entry required throughout all process

✓ GROUNDBREAKING TECHNOLOGY

- **Drying protocol**
Customized to ensure repeatability and stability
- **Weighing rack system**
Realtime monitoring flower's moisture content
- **Air sterilization**
Active Non-Thermal Plasma (NTP) system



**R.P GROW-TEC
INNOVATIONS Ltd.**



www.grow-tec.com

Imports of medical cannabis to Germany have grown each year on record, with well over 100% growth year on year from 2017-2019. 2020 saw the import market grow by 37%, with 9.3 tonnes being imported throughout the year.

Considering that German imports of cannabis increased while the Dutch exports decreased, and that no domestic cannabis was available to German patients in 2020, (notwithstanding the chance that large stores of medical cannabis from 2019 were used), the conclusion must be drawn that the supply of medical cannabis to the country has just begun to diversify. Below, we consider the countries who are vying to become the future suppliers of these medicines to European patients.

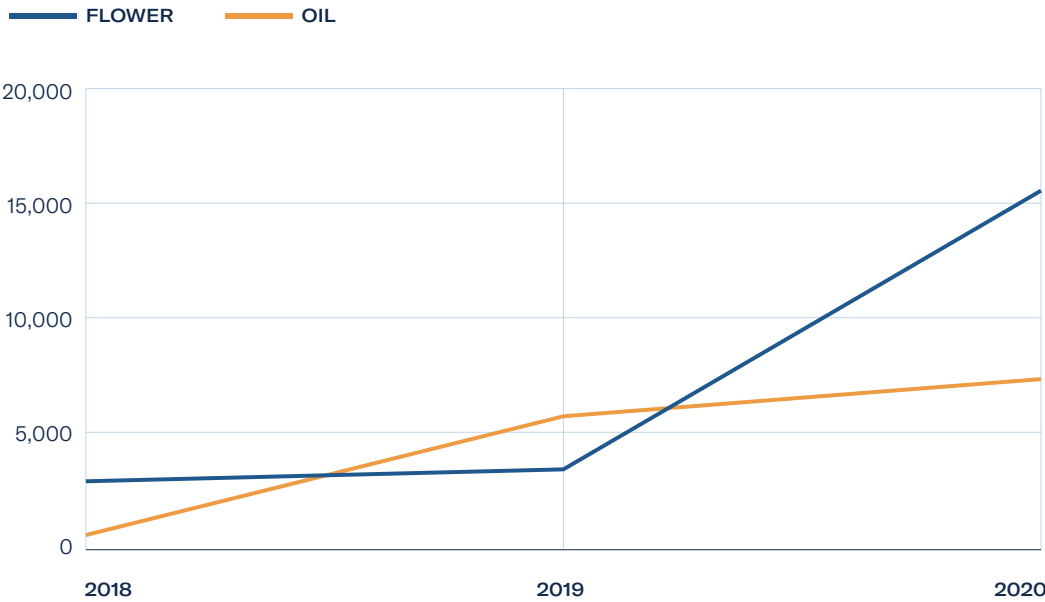
Imports to the EU

The European market for cannabis will be one of the largest untapped consumer packaged goods markets globally in the coming years. As lawmakers and health professionals increasingly recognise the benefits in terms of public health, justice and finance, legalisation of medical cannabis will open up market niches for those seeking to meet the needs of millions of patients on the continent.

Canada

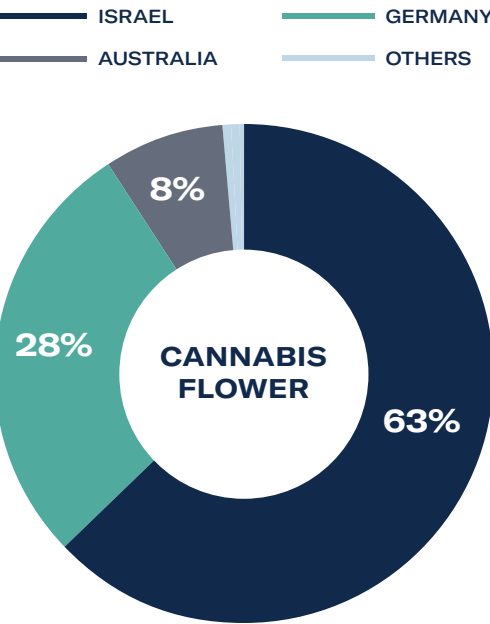
To date, the vast majority of legal cannabis imported into the EU has come from established producers in Canada. Prohibition Partners has obtained exclusive data on exports of medical cannabis from Health Canada displayed below. Exports of cannabis flower from Canada were briefly overtaken by exports of oil in 2019, but this trend was reversed due to large quantities of flowers being bought by Israel.

Exports of cannabis flower and oil from Canada



Source: Atalis/Health Canada

Export of cannabis flower from Canada 2020



Source: Atalis/Health Canada

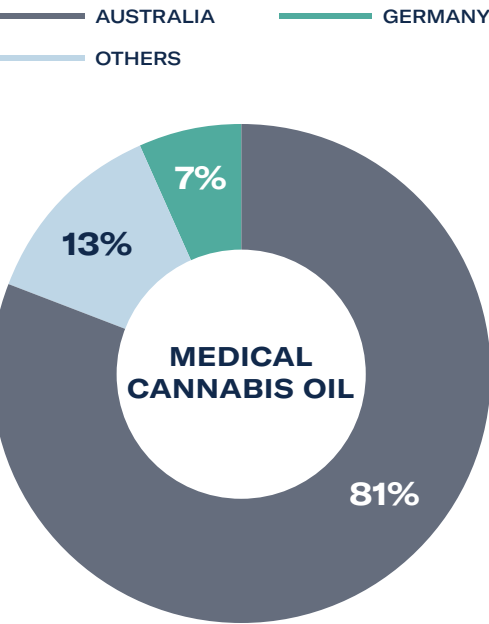
Up until 2020, the majority of exports of cannabis from Canada had been sent to European Countries. Exports of oil and flowers from Canada to Europe increased from 2019-2020 by 28% in terms of weight, but are now in the minority, with the majority of flowers being sent to Israel and the majority of oil being sent to Australia. Exports of oil to Denmark dropped from almost 1000kg in 2019 to 60kg in 2020 owing to the removal of Canntrust products from the market.

South America

Several producers in South America have been preparing to supply the European medical cannabis market for the past couple of years. However, only a few companies have managed to successfully ship any products and have them placed on the market.

Other producers in Latin America are 'hot on the heels' of Fotmer and Clever Leaves. For example, Khiron Life Sciences in Colombia have exported high THC cannabis extracts for sale in Peru, with the first delivery being

Exports of medical cannabis oil from Canada 2020



Source: Atalis/Health Canada

made in December 2020. Khiron have also secured agreements to supply the UK market with medical cannabis products for Project Twenty21, having already sold Khiron branded products in the country before this. Khiron also has a supply agreement in place with Nimbus Health to distribute their products in the German market and have already delivered high-CBD extracts to the country. Pharmaciolo is another leading cannabis group in Colombia with their sights set on Europe. Pharmaciolo has a supply agreement in place with XPhyto Therapeutics Corp. to distribute their products in Germany. Both companies are now among those in South America which are vying for EU-GMP certification which will enable exports to be sold on the European market.

Australia

Since late 2020, medical cannabis flowers and extracts produced in Australia have been available in the German market. Little Green Pharma became the first group to export commercially from Australia to Europe in November 2020, with a shipment of 600,000 units

of extract which were imported by Aphria and sold to pharmacies by AlephSana and Alternative Medical Products (AMP). The group also has an agreement with Demecan to supply 1,000 kilograms of dried flower, or 48,000 units of medicinal cannabis oil product per year. The first flower to arrive was produced by Australian Natural Therapeutics Group, and marketed in Germany by independent distributor Cannamedical. While the weights of export are not currently known, the flower is known to have a cannabinoid content of 22% THC with negligible CBD content. Australian group Little Green Pharma have also been successful in accessing the European market with their extracted products. As of February 2021, products exported from Althea have also reached UK and German markets.

Israel

Owing to progressive cannabis policies and a strong cultural acceptance of cannabis usage, Israel is now among the leading markets for medical cannabis in the world, and is the largest importer of any country. By June 2020, Israel had imported six tonnes of cannabis, which is more than the entirety of German imports up to the end of September, of the same year. As well as being a strong consumer market, Israel has the potential to be one of the leading exporters of medical cannabis anywhere in the world.

To date, regulation practices have hamstrung the Israeli medical cannabis markets. Domestically, changing compliance protocols and point-of-sale pricing issues have harmed patient access to medicines, by creating supply issues and decreasing affordability.

The export market has had similar problems, with Israeli regulators unable or unwilling to certify cannabis producers as EU-GMP compliant, which is a necessary precursor to exporting finished products. At the time of writing, no mutual recognition agreement has been made to establish the equivalence of the local Israeli Medical Cannabis GMP and EU-GMP. All firms wishing to export to Europe have had to invite European regulators to their facilities in Israel to certify EU-GMP compliance.

Potential Sources of Medical cannabis for Europe



Countries where governments or companies intend to produce medical cannabis for export to Europe

This has successfully been achieved by a small number of groups, including Panaxia, IM Cannabis and Breath of Life, though the latter only for API production. The first commercial exports of medical cannabis made from Israel to Germany came in December 2020. The shipment was made by Israeli Panaxia and their partners in Germany, Neuraxpharm. As of February 2021, Panaxia has also been chosen to supply medical cannabis to Cyprus and France as part of new government programmes. IM Cannabis export cannabis to Germany by purchasing EU-GMP flower and selling the product on to German wholesalers.

Africa

To date, production capacities in African nations are far behind those in markets such as North America and Europe. We do not predict any products from Africa reaching patients in Europe in 2021.

To date, no company in Africa has secured EU-GMP certification which would allow

large-scale commercial exports of medical cannabis products. Delays to the beginning of African exports have been caused by a number of factors, not least the fact that COVID-19 has prevented many regulators from travelling to inspection sites (see section above Delayed Diversification of Supply). Some medical cannabis has been exported from the continent in the past three years. In 2018, Medi Kingdom exported cannabis flower from Lesotho to Canada for research purposes. In April 2020, a Ugandan firm, Industrial Hemp (U) Ltd, began exporting cannabis to Israel, however, the company is yet to tap the European market. Early signs of the Afro-European supply line opening up came in August 2020. South African-based Felbridge claimed to be the first African producer to successfully ship to Europe, upon their delivery of medical cannabis to Swiss Puregene AG for research and development purposes.

AMP [logo]

WE ARE AMP

AMP provides German patients with the highest quality EU-GMP medical cannabis brands from around the world

amp-eu.com

Victory Column, Berlin, Germany

Alternative supply chain emerging

A route of medical cannabis supply not reliant on production in an EU-GMP facility developed over the course of 2020. This has been achieved by Fotmer Life Sciences, a Uruguayan subsidiary of Canadian Silverpeak Life Science. During 2020, Fotmer exported several large shipments of cannabis from Uruguay to an undisclosed location in Portugal. The total amount of cannabis flower shipped was probably in the region of four metric tonnes, equal in quantity to just under half the total consumption in the German market for the year. At least some of the cannabis which arrived on the continent was processed in EU-GMP facilities and sold on the German market by Tilray. This event sets a massive precedent for the industry in that cannabis can be cultivated in a facility without EU-GMP certification and subsequently processed in such a facility before being sold in Germany, and likely elsewhere in Europe. This process had in fact been carried out, in a way, by German dronabinol producers, Bionorica, who processed non-EU-GMP flowers from Austria in German EU-GMP certified facilities for the eventual sale of dronabinol on the German market.

To date, industry players are unsure whether this represents a legitimate route of supply within Europe. Whether Portugal is unique in accepting non-GMP cultivated cannabis in the EU is yet unclear. While cannabis sold in Europe has to be produced to EU-GMP standards, there is ambiguity around where in the supply chain the GMP process must start. If the good manufacturing practices have only to begin at the processing stage, then a new avenue of supply is opened up for the continent. Producers could cultivate cannabis destined for Europe at low cost in regions such as Africa, the Mediterranean and Latin America without first acquiring the onerous EU-GMP certification. Processing in a facility with EU-GMP, either within Europe or elsewhere, could then make the product compliant with European standards where it can be sold with a much higher profit margin than cannabis products produced in Euro-

pean greenhouses for example. In the near future, we expect the legal ambiguity to be cleared up, and/or for more companies to begin replicating this route of supply, though reputational and legal risks are present if this supply route is deemed illegitimate by European authorities at a later date.

Domestic production

The domestic production of medical cannabis has made some progress during 2020. European governments are still in the early stages of experimenting with the legal supply of medical cannabis. As cannabis is still a controlled narcotic under international law, the regulation and logistics of international trade is a taxing endeavour. As such, many countries are seeking to establish their own domestic production; to ensure stability of supply and control over quality assurance, to ensure local production is beneficial to the domestic economy, and to provide the basis for an export market, as seen in the Netherlands.

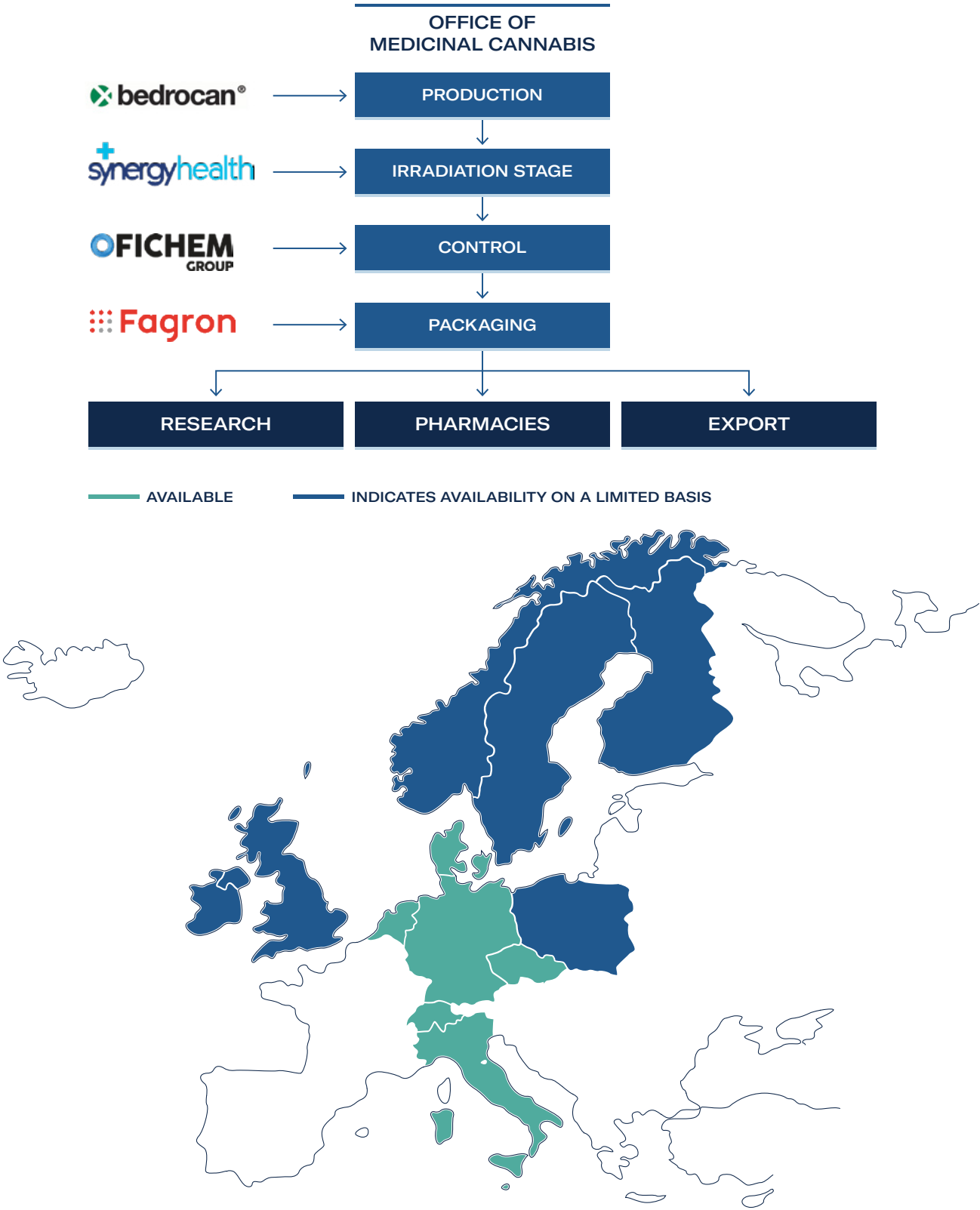
The Netherlands

The Netherlands has the longest standing production and export market for medical cannabis in Europe. The Dutch Government maintains strict control of the supply chain from seed to sale which means all opportunities arise from tender applications. Medical cannabis is regulated by the Office of Medical Cannabis (OMC), under the Corporate and Investment Banking Group which is part of the Ministry of Health, Welfare and Sport.

Since 2003, the local company Bedrocan has been the sole producer of medical cannabis for sale to the OMC in the Netherlands. In the early stages, this agreement facilitated supply for the domestic market predominantly. However, Bedrocan and the OMC have nurtured their market positioning over the years to become the main source of medical cannabis in Europe, holding the majority share of the most lucrative markets like Italy and Germany. Alongside tendering for the production of cannabis, the OMC also controls who irradiates, tests and packages cannabis products. See the diagram for an outline of the supply chain.



Medical cannabis ecosystem in Netherlands



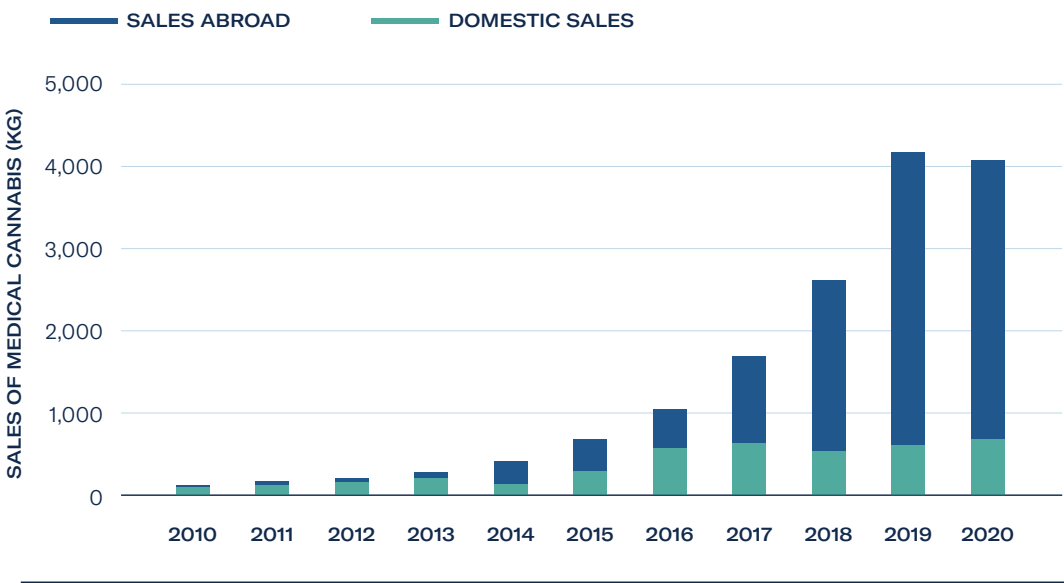
Source: Bedrocan
South Africa and Australia are on limited availability

As of early 2021, Bedrocan has stated that their products are available, at least on a limited basis, in 16 countries.

Cannabis produced by Bedrocan can be channelled to three routes; use in experiments, sales to pharmacies and sales to foreign markets. Since 2016, sales to foreign

markets have been the most lucrative for Dutch cannabis, being four to five times larger than the domestic market. The OMC controls the export process and agrees tenders with foreign countries, including 2,500 kilograms to Germany and ~700 kilograms to Italy in 2020.

Domestic sales and sales abroad of Dutch cannabis



Source: Atalis/OMC (personal communication)

The current recording period, which began in 2010, has only just, in 2020, seen the first reduction in overall sales. This has been driven solely by a 5% reduction in exports compared to 2019 figures. The amount of medical cannabis being produced and sold in the Netherlands continues to climb, with 685 kilograms being sold during 2020, a 13% increase from 2019. There are signs that the overall growth of medical cannabis sales in the Netherlands has slowed, with an average annual growth of just over 5% since 2016.

Germany

In April 2019, the Federal Institute for Drugs and Medical Devices (BfArM) announced that it was awarding the tender to cultivate cannabis domestically in Germany to three com-

panies exclusively for distribution in German markets. In total, the tender ensures that the BfArM will purchase 10,400 kilograms of cannabis from producers, split into 2,600 kilograms per year. This 2,600 kilograms is further split between the companies in the proportions listed below. The first substantial harvest grown under this tender is expected in Q1 of 2021.

Cultivation/production licence holders (winners of the three tendered lots) are as follows:

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

EXPERT INTERVIEWS



Lenny Karmiol
CEO,
Perfect Plants

With roots deeply embedded in the horticultural industry and over 40 years of biogenetic experience, Perfect Plants is a global leader in tissue culture production. Specialising in food and pharma crops, Perfect Plants has integrated cannabis into its list of starting materials available globally.

Tell us about the Perfect Plants advantage when it comes to the cannabis industry.

We believe that 80% of what it takes to achieve success in an agricultural-based industry is core competency, and only 20%, if that, is crop-specific.

Perfect Plants has headquarters in Honselersdijk, Netherlands - a town which has the highest level of productivity per square metre for agriculture in the world. A town illuminated by greenhouses focused on high intensity, technology integrated agriculture. Perfect Plants' facilities all have an extremely efficient level of skill and productivity - something that is quite rare in the cannabis industry.

We entered the cannabis industry with 40 years of experience behind us. We made sure to fine tune our core competencies; a solid production infrastructure and system, excellent human capital, experience at a commercial scale, and only then did we take on cannabis as an additional crop.

Between our automated greenhouse and our breeding and lab facilities in the Netherlands and in South Africa, we produce more than

15 million plants a year. These plant starting materials are distributed to every continent on the planet. As a result, we are now the only truly global producer of tissue culture for cannabis in the world.

What is the main benefit that tissue culture offers the cannabis industry?

Tissue culture provides the industry with starting material that is clean, reliable, and reproducible. Our plants are diligently processed to ensure that our customers receive exactly the plants they are expecting at exactly the quality they require - without exception.

Plant tissue culture seedlings significantly outperform conventional vegetative propagation materials in terms of uniformity, yield, pace, and quality. Rising global demand for high quality cannabis has boosted demand for micropropagation methods that yield superior performance, including tissue culture.

When our customers receive our plants, they can have 100% confidence in their growth - and that confidence is the key to producing high quality plants on a commercial scale.

What has been the main challenge of entering the cannabis industry?

One of the most difficult things about the cannabis industry is that it is such a young and immature industry compared to agricultural crops. In addition, the regulatory restrictions seem to compel companies to vertically integrate. Companies often feel they have no choice but to operate from 'seed to sale'

and on a commercial scale - something we believe is virtually impossible to accomplish while also maintaining the quality required at a large scale.

We challenge that paradigm by focusing on clean, stable starting material; a very specific category of the supply chain. By pouring all of our attention into this initial - but extremely important - part of the process, we set our customers up for success, so they have both the bandwidth and focus to excel in other areas of the growing process. This is where they can create a true competitive difference.

Was it difficult to pivot into cannabis?

Getting started in any new category as a tissue culture company that produces in the quantities that we do, requires a significant investment of time and capital. Just for context, we received our initial cannabis licence in the Netherlands in December 2017. Since then, we have been aggregating, stabilising, initialising and selecting genetics for more than 120 hemp and cannabis varieties. It has taken from then to now (over 3 years) to secure an inventory of starting material that allows us to produce on a commercial scale. Generally, the process for any new crop to be captured and initiated into in-vitro material, and then to be produced and sold commercially takes at least a year, if not longer.

We operate in the tens of thousands of units. If we do not set out with a plan to ultimately reach at least 5,000 plants for a given variety, it is not economically feasible for us to put that variety in vitro.

This high start-up cost is one of the reasons for significant barriers to commercial scale growth in the industry. Anytime I have conversations with principals of tissue culture companies in cannabis, my message to them is almost always the same: let's figure out a way to collaborate, because at the end of the day we will help build the industry and achieve much loftier goals through collaboration than through competition.

Where is Perfect Plant's future headed?

We believe that hemp and cannabis exist on a continuum of the larger category of Food and Pharma. Perfect Plants is a mature, diversified company able to deliver the highest quality starting material and plant genetics on a commercial/industrial scale. Over the next 40 years, we will continue to apply these essential ingredients of success to the Food and Pharma Industries.



The global standard in cannabis tissue culture production.

As the only global commercial scale producer of cannabis tissue culture in the world, Perfect Plants helps eliminate risks and variables of commercial cultivation. Applying over 40 years of horticulture industry experience, we are on a mission to raise the standard in the cannabis industry.

Perfect
Plants
perfectplants.nl

Now available in licensed jurisdictions throughout Canada, Europe & Africa

It is likely that the German government will end up buying more than the originally agreed amount. This is necessary to meet the rapidly growing demand but also, the BfArM are contractually obliged to purchase surplus cannabis up to 150% of the agreed upon amount. However, price reductions would apply to any plant material bought in excess of 120% of the originally agreed upon amount. This would reduce the estimated wholesale price per gram from around €2.3 to €1.87.

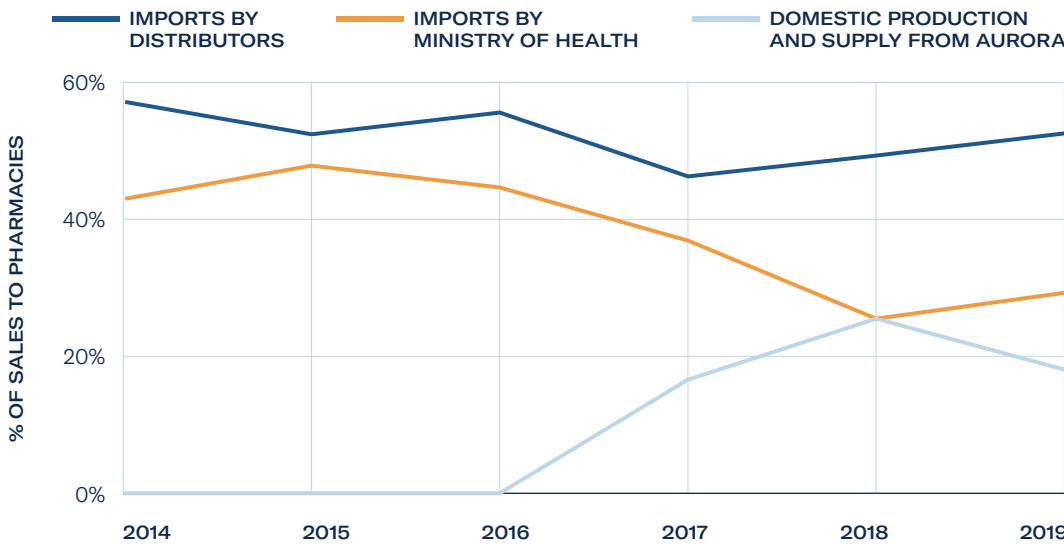
Italy

The Italian government also oversees domestic cannabis production. Cannabis cultivation

is under the control of the Italian Military division, the Stabilimento Chimico Farmaceutico di Firenze (SCFM).

The government of Tuscany have recently invested €1.4 million alongside the SCFM into a project to develop domestic production as well as towards providing evidence for safety and efficacy of medical cannabis in general. The project is planned to run from 2020-2022 but it may be extended. The health ministry permitted the SCFM to produce 500 kilograms (1102 pounds) of cannabis flowers in 2020. The SCFM's 2019 production was estimated to be below 350 kilograms.

Sources of medical cannabis in Italy



Source: Atalis/Italian Ministry of Health

The SCFM supplies cannabis sourced from its own production as well as through imports from Aurora. As such, it is unclear how much of the product sold to pharmacies from the SCFM is from each source though; it is thought that the split is roughly even over 2018 and 2019.



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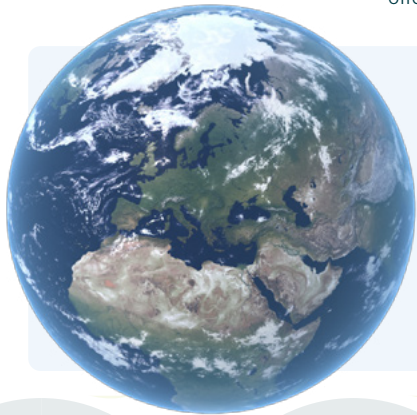
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Denmark

The Danish government is particularly proactive in supporting the development of medical cannabis production in the country. The 'Development Scheme' is led by the Danish Medicines Agency and aims to regulate the production of cannabis specifically for the four-year pilot project in the country. Progress has been much slower than expected due to prohibitively high quality manufacturing standards imposed on medical cannabis production by the regulator. No domestic products are yet approved for use in Denmark, despite production activity by many companies since 2018.

Establishment of production capacities by companies within Denmark is being built with a view to establishing a more permanent base, even after the pilot scheme ends. As of February 2021, 43 companies have active licences to produce cannabis, at least for research purposes, as part of the development scheme including local players such as, Stenocare and international giants such as Canopy, Aurora, The Green Organic Dutchman and Aphria, via their partnership with Schroll Medical. Aurora halted construction on their Aurora Nordic 2 facility in 2019 to save on costs. However, their Nordic 1 facility has already exported bulk cannabis products to the German market; the only commercial cannabis exports from Denmark, as of February 2021.

The UK

Despite the strict control of cannabis medications in the UK, it is home to the largest producer of cannabis for pharmaceutical purposes in GW Pharma. Since 1998, GW Pharma have been cultivating cannabis in the UK; first for research purposes and now also for the production of their marketed products Sativex® and Epidiolex®. GW's main facility is in Somerset, in the UK, with greenhouse facilities spanning over 182,000 m². Altogether, GW have leased over 566,000 m² to grow cannabis in the UK.

GW Pharma has taken a traditional approach to the development of cannabinoid drugs. Two

decades of research and development have now culminated in the production and sale of over half a billion USD in cannabinoid drugs around the world with the vast majority of sales coming from Epidiolex® in the US. GW Pharmaceuticals is now the poster child for the successful introduction of pharmaceutical cannabinoids to the market. In early 2021, GW was bought by Jazz Pharmaceuticals, headquartered in Dublin, Ireland, for just under €6 billion. (see section on CBD vs Epidiolex®).

GW may soon be joined by new producers within the UK and its dependencies. In May 2020, an investment firm, Artemis Growth Partners, acquired a cultivator with licences for medical cannabis production in the UK. The deal was worth €68 million and could produce large volumes of medical cannabis when up and running, as there is a claimed 60 acres of cultivation facilities available. In a separate development, January 2021 saw the finalisation of new regulations which allow the production, but not consumption, of cannabis on the Isle of Man. There are hopes that cannabis cultivation can contribute to the post-pandemic economic recovery of the British dependency. The Isle of Man will join Jersey and Guernsey in allowing the cultivation of medical cannabis in British dependencies. In January 2021, Jersey issued the first licences for cannabis cultivation on the island, with the recently formed Northern Leaf being a recipient of the licence. This is the first time anyone in the UK has received a licence to cultivate medical cannabis other than GW Pharma.

The Czech Republic

In the Czech Republic, a single company has the tender to grow medical cannabis which it supplies to the State Cannabis Agency (SAKL), similar to that of Bedrocan in the Netherlands. Throughout 2020, the company supplied 18.2 kilograms to SAKL, which was 27% of the amount consumed by patients. There are no plans currently to open the country up to new producers. The remainder of demand in the Czech Republic is supplied through imports from abroad facilitated both by private companies and SAKL.



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Intra-European Trade

In the recent past, the goal for most cannabis companies in Europe was to establish vertical integration. In some cases, this has proved to be more difficult and less efficient than was once thought. In the coming years, we expect to see the supply chain for medical cannabis develop significantly, with diversification of secondary services such as packaging and processing, agriculture and tech support as well as the development of a more international supply chain.

The main market European producers are seeking to export to is Germany, owing to the high number of patients with legal access to cannabis. However, there are still large swathes of patients who do not yet have adequate access to medical cannabis in regions across the continent. These markets such as the UK and France offer massive opportunities to the companies who can get a foothold and grow their presence in the country as the markets open up.

To date, very few producers have managed to establish vertical integration within Europe. One example of the successful establishment of a fully European supply chain is in the production of medical cannabis by UK-based EMMAC Life Sciences, recently acquired by US-based Curaleaf for €242 million. EMMAC are unique in that they are an independent firm who have established an all-European vertically integrated supply chain. EMMAC produce EU-GMP standard cannabis in their facility in Portugal, process the raw material in Portuguese and Spanish facilities and market final products in the UK, as well as Israel, with approvals already granted for the German market.

In response to a query on vertical integration, EMMAC told Prohibition Partners: 'To address the challenges presented by a fragmented and complex regulatory market, and to firmly establish EMMAC as the European cannabis leader, we believed it was essential for us to have complete control of our supply chain. In the past few years we have built a vertically integrated business model,

from our cultivation site in Portugal to our extraction facilities in Spain to our manufacture and distribution facilities in the UK. By owning the supply chain we are able to create cost efficiencies and allow the vertically integrated set up to pass these cost savings on to patients'- Antonia Costanzo, CEO of EMMAC

Tilray has also established a fully European cannabis supply route, in this case by partnering with German distributors Cannamedical. Alongside its Uruguayan imports, Tilray produce EU-GMP grade medical cannabis in Portugal and have transported it to Cannamedical for distribution in German pharmacies since early 2019. Tilray has also agreed to ship medical cannabis to researchers in Spain from its Portuguese facility.

Several other players on the continent are now either close to exporting, or have already completed exporting, their first deliveries of medical cannabis around the continent. In 2020 Alcaliber (Linneo Health) exported Spanish-sourced cannabis to the German market. Aurora Nordic has been granted the approval to export bulk cannabis produced in Denmark, which it hopes will soon become a main vein of supply for the German and wider European markets. North Macedonia based NYSK, a subsidiary of Pharmacann Polska, expects to soon be exporting EU-GMP certified medical cannabis products to Germany and Poland.

The government in Greece is also nurturing the production of medical cannabis in the country. Since 2018, new laws have been rolled out allowing the cultivation of cannabis for medical purposes. All cannabis produced in Greece must be exported or sold to the state agency for cannabis which maintains a monopoly on the licensing of cannabis related activities. To date, no Greek producer has yet reached markets with their products. In early 2021, new laws were introduced to the Greek parliament which would allow for the cultivation of cannabis for export without the need to observe the normal Greek laws on production of cannabis for consumption within the country.

Development of ancillary services

To date, the efforts of those involved in the medical cannabis industry in Europe have been firmly focused on increasing access to medicines by navigating regulatory hurdles to get cannabis legally cultivated and distributed to patients. Many companies have attempted to establish vertical integration; to control production, packaging, and distribution of medical cannabis. However, it is becoming increasingly obvious that the investment of human and capital resources makes this impractical to achieve with any efficiency, in many, but not all cases. As the market for medical cannabis products matures in Europe and more and more producers make it past regulatory hurdles and are offering medical cannabis products on the market, there will be increased competition especially at the upstream segment of the value chain.

We expect to see the movement of interest towards the downstream components of the medical cannabis value chain. These activities include agricultural and tech services, testing of products, manufacturing (extraction, formulation), packaging, logistics (transport, storage) and retail. As is the case with the production of cannabis; accessing downstream components of the value chain entail the navigation of patchwork regulatory frameworks. In the case of domestically produced cannabis, national agencies are usually in control of all aspects of the value chain, as is required by commitments to the UN Convention on Narcotic Drugs. For example, in Germany, the government has tendered the distribution of domestic produce to local company Cannsativa. In the Netherlands, the OMC tenders each stage of the process including testing and irradiation and packaging. International pharmaceutical firm Fagron are a good case study in establishing themselves in the ancillary services sector. While Fagron do not produce any cannabis themselves, they have successfully embedded themselves in the European medical cannabis value chain by becoming a licensed distributor of imported medical cannabis in Germany as well as the sole packager of medical cannabis produced by Bedrocan in the Netherlands.

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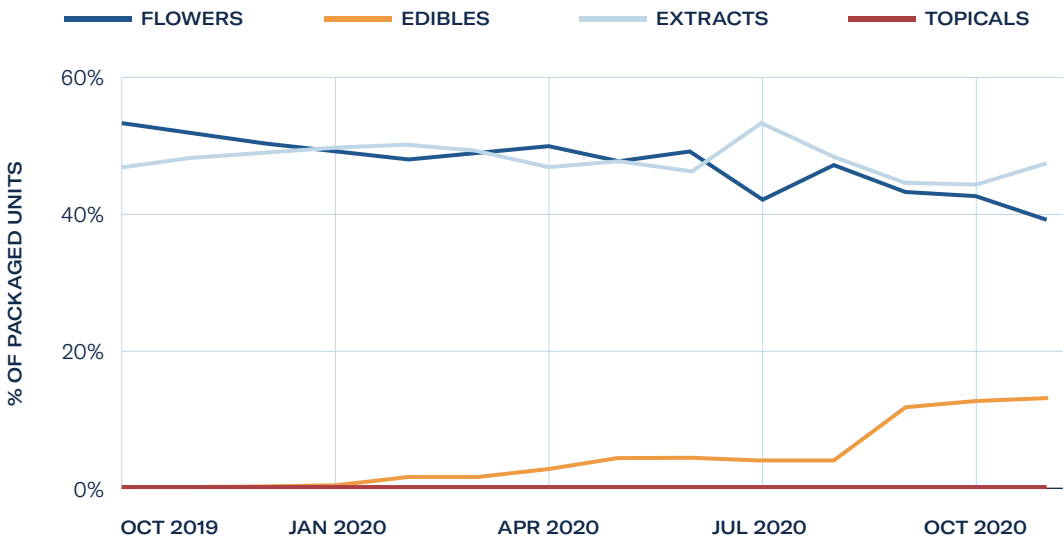
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The advertisement features a central image of a Boveda 58% humidity control packet and a Totem Farms cannabis box. The packet is labeled 'B 58% 1 GRAM 2-WAY HUMIDITY CONTROL'. The box is labeled 'TOTEM FARMS' and 'NATURAL UN...'. Below the main image, there is a smaller image of a Boveda 62% humidity control packet and a Boveda logo. The Boveda logo is labeled 'Boveda THE ORIGINAL TERPENE SHIELD™'. At the bottom, there are social media icons for Facebook, Twitter, and Instagram, followed by the text '@bovedacannabis | 952.522.8294'. On the right side, there is a vertical text: 'COPYRIGHT 2020 BOVEDA INC. ALL RIGHTS RESERVED.'

PRODUCT FORMAT:
THE TREND TOWARDS
EXTRACTS AND ISOLATES

Flowers have been the most commonly used form of medical cannabis in the healthcare of most nations with legal access. However, for several years now, it has been noted that the market for medical cannabis is moving away from flower products and towards more processed extracts and isolates. This is true in the newer markets in Europe like Denmark and Germany but also in the more established medical cannabis markets of Canada and Netherlands. We examine here the trends across several markets which show the rise in popularity of extract and isolate products.

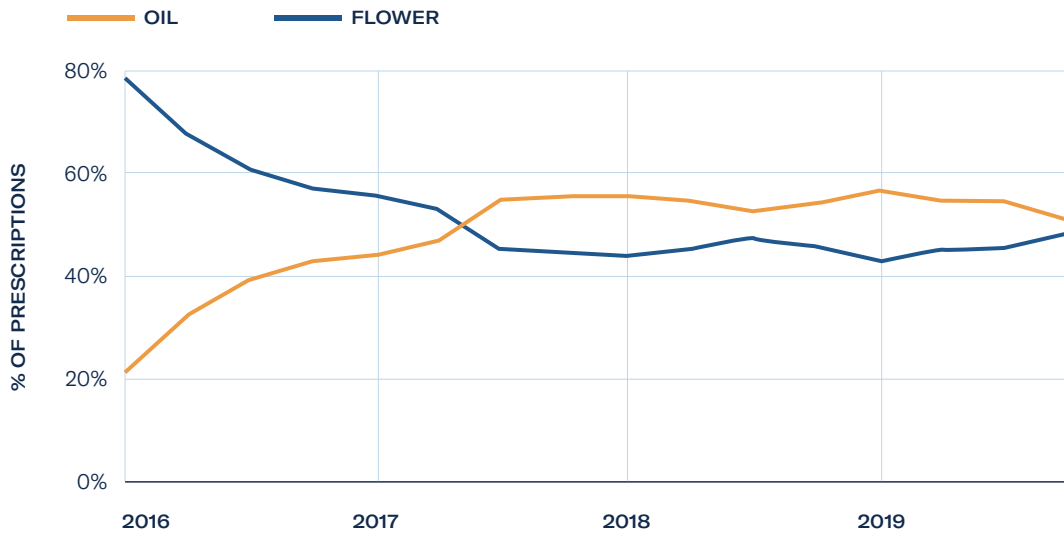
Sales of medical cannabis products in Canada



Source: Atalis/Statistics Canada

In Canada, the market for medical cannabis flowers continues to be replaced by more value-added products. Extracts have been the largest selling segment since June 2020.

Medical cannabis prescriptions in the Netherlands

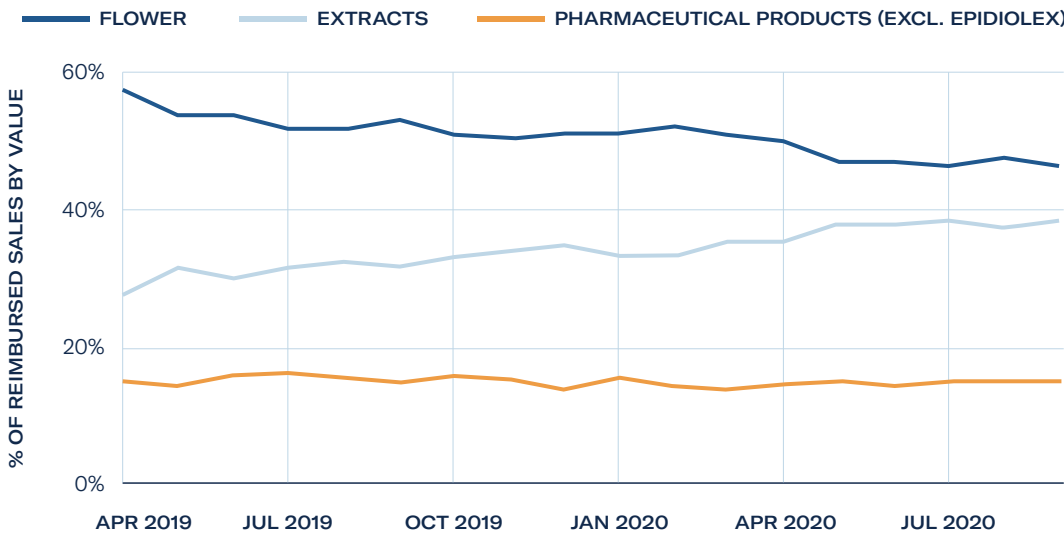


Source: Atalis/Dutch Pharmaceutical Key Figures Foundation (SFK)

Medical cannabis oil has been dominant in the Dutch market since mid 2017. This is according to data on the number of prescriptions from the Pharmaceutical Key Figures Foundation. The Netherlands is a special case

in that people have been able to avail themselves of cannabis from adult-use sources, meaning that many people who are using cannabis for quasi adult-use purposes are not present in these figures.

Sales of medical cannabis by category in Germany



Source: Atalis/GKV

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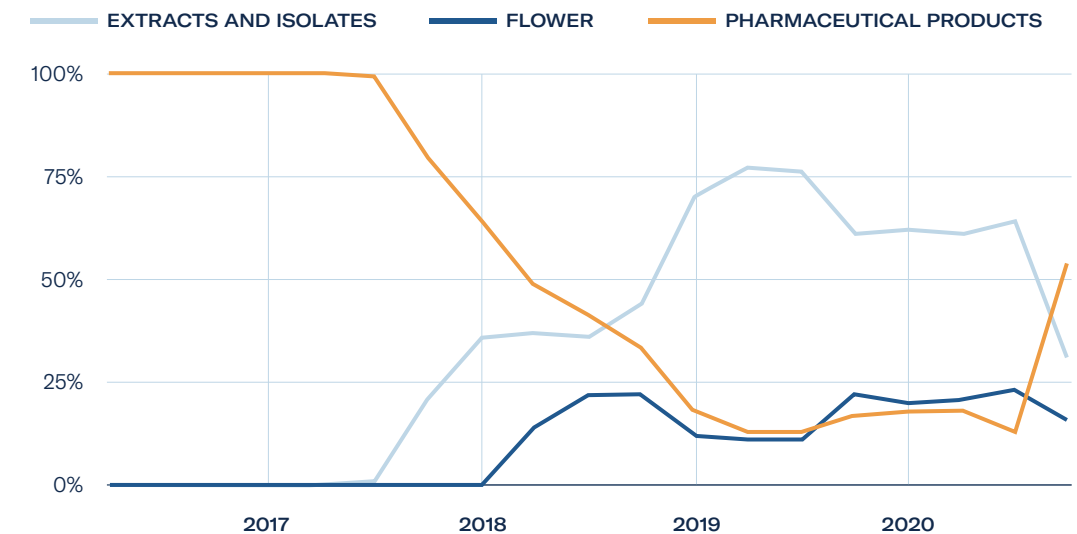
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As of early 2021, the German market is not growing at as fast a pace as in preceding quarters. However, according to data from the conglomerate of insurance providers, the GKV;

the market for extracts including magistral preparations and finished products continues to grow as a percentage of the market.

Sales of medical cannabis products in Denmark



Source: Atalis/Danish Health and Medicine Authority

In Denmark, medical cannabis flowers have never had the majority share of medical cannabis sales as seen, for example, in Germany. Extract and isolate products have been dominant, including during the more recent years of the medical cannabis trial scheme in the country. Notably, the introduction of Epidiolex® to the country in Q4 of 2020 saw the halving of sales for extracts and isolates and a massive increase in the sale of pharmaceutical cannabis products (see section on CBD vs Epidiolex®).

There are several reasons why this movement towards extracted products is occurring in Europe and elsewhere:

- Extracted and isolated active pharmaceutical ingredients are the standard for the pharmaceutical industry. The reasons for this are purely practical, for example; isolated products are more efficient, easier to dose and certify as free from contaminants. To date, regulators and insurance compa-

nies have been more inclined to see these products reimbursed than unlicensed or newly licensed products.

- On the patient's side; it is thought that orally dosed oil offers an ease-of-use not present with inhalation of flowers; with edibles and oils virtually no preparation is required on the part of the patient.
- Additionally; oral dosing of medicines is a more familiar process to both patients and doctors, and may be more appealing to new consumers. Patients and doctors are aware of the inherent harm in inhalation of any combusted or vapourised material.

To date, much of the appetite for extracted medical cannabis products in Europe has been met by magistral preparation of cannabinoid products in addition to pharmaceutical products like Sativex® and Epidiolex®. Going forward, Prohibition Partners see the market for magistral preparations being eventually re-

placed by products which are fully processed on arrival to the pharmacy. This process may take a considerable time to materialise. Some markets like the Czech Republic and Germany are more open to the use of flower and magistral preparations than novel finished products, and legislative change may be necessary to allow for these.



Aurora soft gel capsules as available in Denmark.
Source: ©Aurora Cannabis Inc.

Finished products offer ease of scaling of the production process. Instead of having many trained pharmacists processing products, value can be more efficiently added to cannabis products if extraction is performed in bulk and then supplied to pharmacies. Finished extract products such as Tilray’s oil and Aurora’s Sedamen capsules are on the rise in Europe and are the product type of choice for emerging markets such as France and Ireland who are at the beginning of their trial schemes for medical cannabis access. This is good news for producers of these products; processed extracts offer the opportunity to differentiate and add value to products as compared to raw flower sales. The success of Tilray’s oils is a good example of this, as Tilray have successfully placed these on the market in several European countries.



Example of Tilray medical cannabis oils.
Source: Tilray

Dronabinol

Dronabinol is a term for isolated THC, one of the main active components of cannabis. Dronabinol is one of the most popular formats for cannabis extracts and isolates. It is marketed in finished products like Marinol® or Syndros® as well as in oil extracted by pharmacists. Dronabinol can be obtained directly from the plant material of cannabis, from chemical synthesis, or it can be ‘semi-synthesised’ by altering cannabinoid molecules from the cannabis plant. Marinol® was first approved in the US in 1985 for anorexia associated with AIDS and also cancer induced nausea and vomiting. Marinol® is not produced in Europe and is instead supplied via imports from the US. In several European nations magistral pharmacists use isolated dronabinol dissolved in oil to produce capsules, oily drops, or an ethanol solution for inhalation. The main European markets in which dronabinol is currently sold are Denmark, Austria, Switzerland and Germany. Preparations in the latter three are formulated by pharmacists in line with instructions set out in the German Pharmacopoeia. Dronabinol used in these preparations must comply with regulations on ingredients in magistral preparations set out in the German monograph (D-100). The approved German formulations for dronabinol are:

- dronabinol capsules 2.5mg / 5mg / 10mg
- dronabinol oil drops 25mg / ml
- ethanolic dronabinol solution 10mg / ml for inhalation – used in Germany only.



As of late 2020, dronabinol makes up the majority of the cannabis preparations category of products in Germany which represent a third of the total market for reimbursed products in the country.

Canopy Growth dominates the dronabinol market in Europe through their subsidiary group Bionorica Ethics who have been operating in the space for years. An increasing number of groups are beginning to offer dronabinol in Germany such as Cantourage, Adrexpharma, Caesar & Loretz and Fagron. Tilray also began offering dronabinol on the German market in December 2020.



Example of dronabinol preparation kit from Bionorica Ethics



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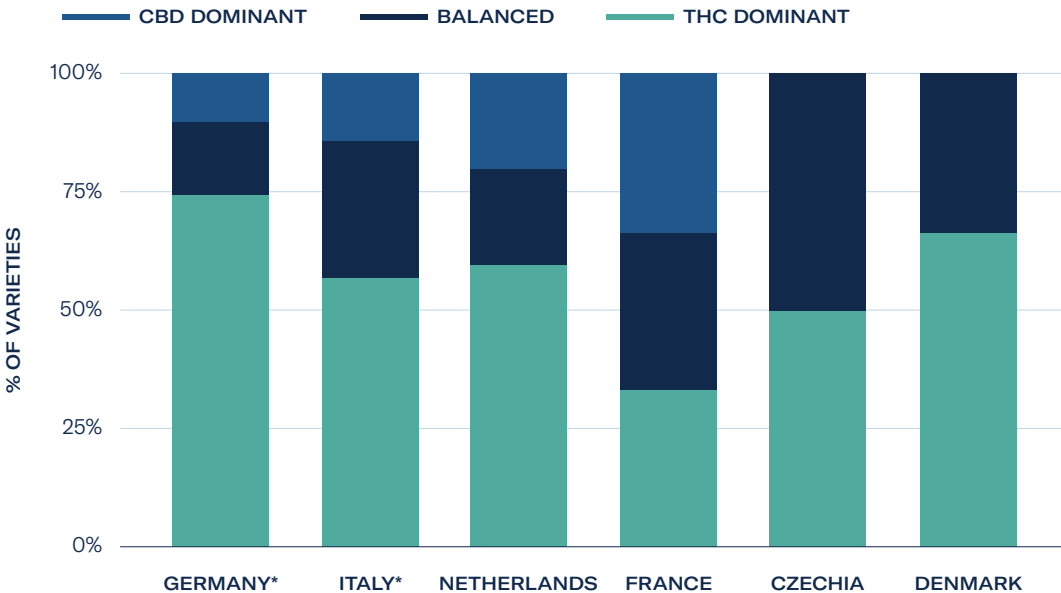
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THE MARKET FOR FLOWERS

While there is an ongoing trend in Europe of patients and doctors moving away from the use of medical cannabis flower and towards extracts and isolates; sales of flower and their

use in pharmacy-prepared extracts is still the norm in Europe. Below, we profile the cannabinoid content of cannabis flower varieties available in some European markets.

Cannabinoid balance of European cannabis varieties



Source: Prohibition Partners/State Agencies/local pharmacies

*Values for Germany and Italy refer to varieties available in these countries' pharmacies in early 2021. Other data refers to recognised or approved strains by the health regulators in each country. Source: Prohibition Partners, farmagalencia.it, cannabis-aerzte.de, government agencies

The majority of medical cannabis varieties available in the European market are THC dominant. This occurs for several reasons:

- Most patients are treating pain conditions and prefer a high THC content
- Some patients have a recreational side to their use of medical cannabis, for which THC content is more sought after
- CBD is commonly available in formats other than cannabis flower e.g. in over the counter preparations, over the counter flowers, and extracted products like Tilray oils and Epidiolex®



Examples of the flower strains produced in the Netherlands by Bedrocan and the OMC. Source: OMC

COVID-19

COVID-19 and the ensuing lockdown has disrupted almost every aspect of normal life for much of the world's population. Since breaking out in late 2019, over 100 million people have been infected with COVID-19, with over 2.5 million casualties and extreme pressure put on the healthcare system and frontline workers around the globe. The pandemic has had variable effects on the medical and adult-use cannabis industry around the world. While record sales were seen across North America, many patients in Europe had reduced access to their medicines. Coming out of the global lockdown, many nations will be seeking new sources of revenue to cover the effects of economic slowdown. Already, the governments of territories like Barbados, Jersey and potentially Portugal are factoring in liberalisation of cannabis into their plans for economic recovery.

Across the board, consumption of cannabis has increased in Europe, with the most recent Eurobarometer survey of European countries showing record numbers of respondents having consumed 'products containing cannabis', backing up similar findings by the European Monitoring Centre for Drugs and Drug Addiction. Below, we consider some other implications of the pandemic for the industry.

Patient Access

The pandemic caused a slew of disruptions to the medical cannabis supply chain in Europe, and laid bare its vulnerabilities. In the Netherlands, delays to cannabis exports from the OMC were seen during the Summer of 2020. While the OMC stated that this was due to additional testing, the event possibly occurred due to general disruption caused by the lockdown. Patients in nations which rely entirely on imports and travel to the Netherlands to maintain their supply were particularly affected. In Ireland and the UK for example, special arrangements were necessarily put in place by the Departments of Health so that patients could receive their cannabis medication by post, with minimal travel involved. In Spain, the closing of cannabis clubs across

cities such as Barcelona meant that patients who were already sourcing their medicine from a legally 'grey', and poorly regulated supply chain, had to turn to the black market to obtain their medicines.

Legal reform

Aside from physical disruptions to the supply chain in Europe, COVID-19 has stalled some progress of cannabis access and reform across the continent. In Germany, the introduction of domestically produced cannabis has been delayed in part due to the 'persistent consequences' of COVID-19 according to a response to a parliamentary question in the Bundestag in September 2020. In France, the need for deployment of extra health resources meant that the trial for medical cannabis access did not begin in 2020 as planned but was pushed into early 2021. In Denmark, regulators of cannabis production facilities halted the inspection of sites across the country in March 2020, hampering the ability of new suppliers to come online. Regulatory agencies in the UK and Germany have also scaled back the resources they are putting into inspections of facilities overseas, which may cause delays to the development of the supply chain for the coming quarters. In Switzerland, the rollout of legalised adult-use cannabis was delayed due to the pandemic and is now planned to begin in 2022.

Innovation

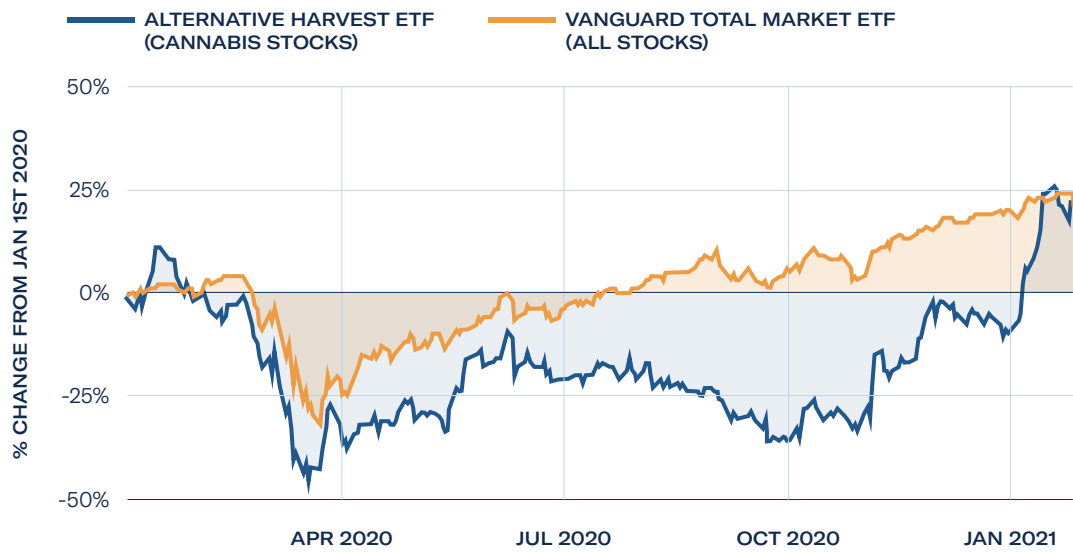
As with many disruptive events, the global pandemic has prompted innovation in a number of sectors. Similar to other markets, much of the innovation in the cannabis sector has focused on accessibility and digitisation while movement has been restricted for many. In Ireland for example, patients with a prescription for medical cannabis can now send the prescription to a pharmacy in the Netherlands and have their medicines shipped to their homes. This is a first for patients in Ireland, and the Minister for Health has indicated that this may well become a permanent feature of medical cannabis access in the country. In the UK, the government released an emergency measure

which meant that patients no longer have to travel to see their physician in person. Instead, patients in the UK can now consult with their doctors via teleconference and receive their prescribed medications by post. These events mirror developments in the US, where

more than two dozen states began allowing teleconference for the prescription of cannabis. The deployment of telemedicine will be a welcome improvement to the accessibility of medical cannabis wherever it is made available on the continent.

Stocks

Stock markets during 2020

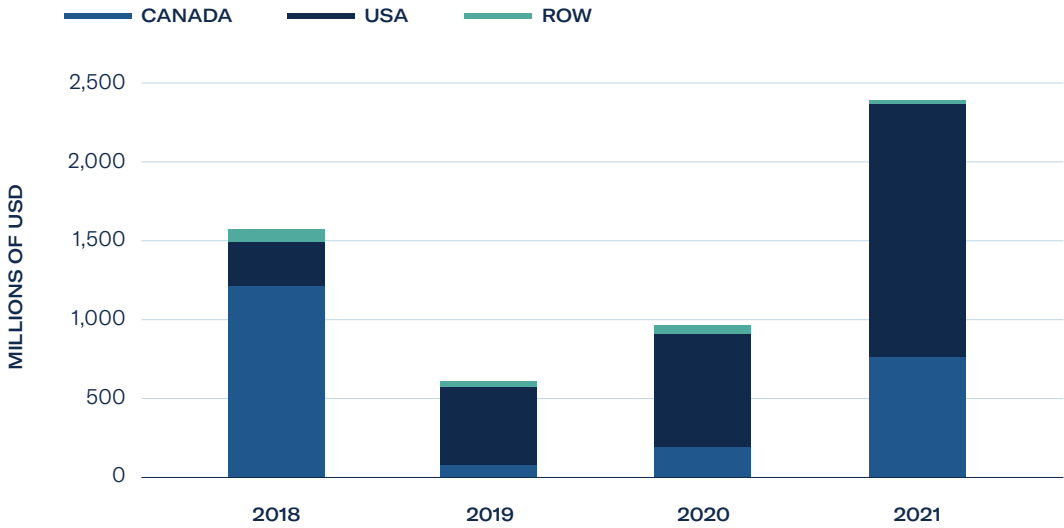


Source: Prohibition Partners/Yahoo Finance

The pandemic precipitated a steep decline in global stock markets. At the lowest point, the Vanguard Total Stock Market Index which can be used as a proxy for the general market, saw a 30% reduction in share prices compared to 1 January 2020 levels, and took ~six months to recover from the blow. Cannabis stocks took an even larger hit, as proxied by the Alternative Harvest ETF, with more than a 40% drop which took nine months to recover from. Since the beginning of the pandemic, the markets have recovered to pre-2020 levels. As reported by Prohibition Partners midway through 2020, cannabis stocks have shown signs of stronger recovery than the market average. On a broad scale, the introduction of massive fiscal stimulus packages in March 2020 contributed to turning the

momentum of the markets around at the end of Q1. Cannabis advocates then held their breath during the 2020 US elections, hoping for a Democratic government for the incoming presidential term. The subsequent Democratic presidential victory, re-categorisation of cannabis by the UN, and the securing of the US House by the Democrats has seen a meteoric recovery for cannabis stocks as of February 2021, with stock values at all time highs and capital increases worth tens of millions of USD occurring frequently. The first quarter of 2021 is set to be historic for cannabis, with record amounts of capital being raised.

Capital Raises in Cannabis Companies



Source: Viridian Capital Advisors, Prohibition Partners

EUROPEAN STOCK EXCHANGES

On 18 September 2020, the UK’s financial regulator, the Financial Conduct Authority (FCA), announced that UK based, and overseas medical cannabis and CBD companies are eligible to float on the London Stock Exchange (LSE). However, the companies must comply with the Proceeds of Crime Act (PoCA), meaning that they must not conduct any activities that are deemed illegal under UK jurisdiction, such as activities in the adult-use cannabis market. As the LSE is one of the world’s stock exchanges and the largest European capital market holding a combined market cap of £3 trillion, there has been excitement in the industry as many cannabis-related businesses (CRBs) have been looking to list on the reputable exchange. On 10 February 2021, MGC Pharmaceuticals, the Australian listed biopharma phytocannabinoid medicines company, dual-listed on the exchange, to gain European and international investment. This was closely followed by the initial public offering (IPO) of Kanabo, a medical cannabis and CBD company, on 16 February 2021. Both companies saw successful IPOs on the LSE. Kanabo’s share price tripled from £6.5 pence per share to £20.8 pence per share on opening

day, whereas MGC Pharmaceuticals saw its share increase by 60% from £1.47 pence per share to £2.38 pence per share. With these successes on the LSE, market analysts and advisors are expecting the London Stock Exchange to see further listings from the cannabis industries in the coming months.

In Europe, the Frankfurt Stock Exchange, the world’s 12th largest stock exchange by market cap (roughly US\$1.8 trillion), is currently known as Europe’s cannabis capital hub. Approximately 130 CRBs have their stocks cross-listed on the German stock exchange. The Frankfurt Stock Exchange has been very popular for cross-listings, dual-listings and triple-listings for overseas CRBs looking to expand into Europe and gain capital from international investors. Large North American cannabis companies such as Aphria, Aurora and Canopy Growth all trade their shares on the Frankfurt Stock Exchange while being listed on the North American capital markets (NYSE, CSE, TSE).

Although there have not been any cannabis IPOs on the Deutsche Börse, in January 2020 the first European medical cannabis and CBD Exchange Traded Fund (ETF), 'Medical Cannabis and Wellness UCITS ETF' (CBDx),

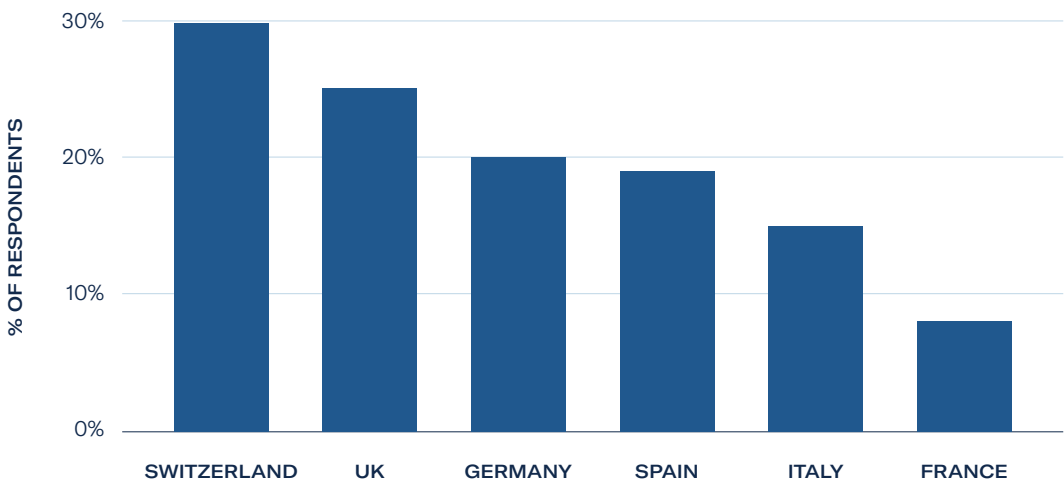
launched on the German electronic trading platform XETRA as well as the London Stock Exchange and the Six Swiss Exchange. The CBDx fund, which is domiciled in Ireland, consists of publicly listed companies conducting legal activities across medical cannabis, hemp, and CBD industries. The medical cannabis ETF currently has US\$58.3 million assets under management and holds companies including GW Pharmaceuticals and Charlotte's Web in its portfolio. CBDx has seen significant growth since its launch in January 2020 and has seen a yearly return of ~31.75%. In February 2020 the second ETF was launched on the European markets, Rize's FLWR ETF, a medical cannabis ETF that focuses on those sectors similar to CBDx. Rize's FLWR ETF currently holds GW Pharmaceuticals, cbdMD and Charlotte's Web in its portfolio. As Rize's FLWR and CBDx share similar holdings in identical sectors, its growth has been comparable with assets under management reaching US\$50.2 in one year.

For more information regarding cannabis listings on London's capital markets please visit: <https://www.cannabis-europa.com/londonisopen/>

CBD

In recent years, the CBD market has been flourishing across Europe. Regulation of CBD in Europe is still patchy, with different countries on the continent controlling CBD in different ways, with variable law enforcement levels. To date, the CBD industry has developed in Europe in spite of the sparse regulations rather than according to them. Specialist and mainstream shops in most European countries now stock CBD consumer packaged goods including foods, drinks, cosmetics, nutritional supplements, flower, oils and vape cartridges. Prohibition Partners currently estimates the market size of CBD at just over €2.8 billion, even before taking into account food and drink infused with CBD and all smokable products. When considering all CBD product categories, our own research indicates that between 9% and 30% of Europeans had tried CBD products in the past 12 months as of early 2020, equating to tens of millions of consumers each year.

"Have you used CBD or CBD/hemp infused foods in the past 12 months?"



Source: Prohibition Partners/Atalis, based on responses from 10,543 adults. For more in-depth CBD consumer data see the CBD Consumer Report

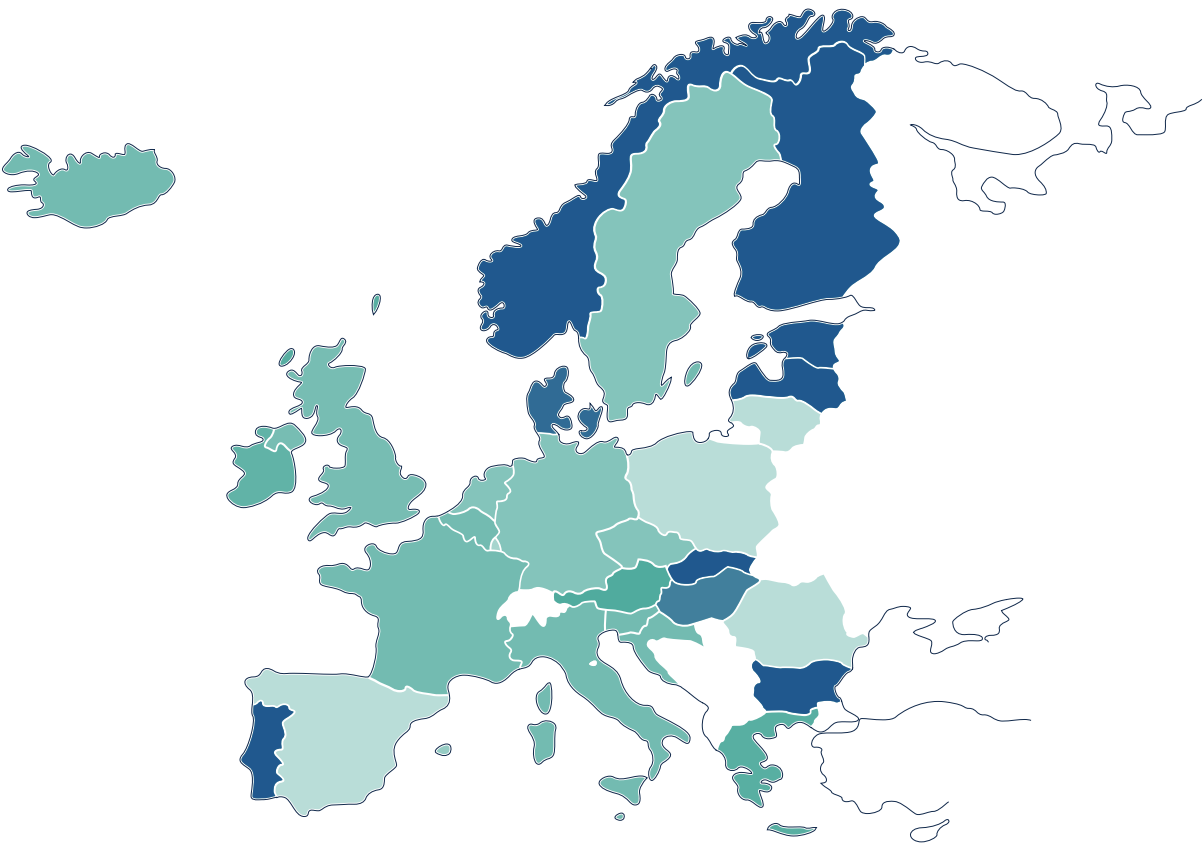


This data indicates high usage rates of CBD in European countries at the outbreak of the pandemic. There is every reason to believe that usage rates have increased in the midst of the COVID-19 lockdowns. Evidence has shown that use of medical cannabis has increased during the pandemic across the globe

and it is likely that increased stress has led to increased consumption of CBD products. CBD is currently being investigated for use against stress brought on by COVID which could solidify the role CBD has to play in the current lockdown and beyond.

Diversity of CBD products available in Europe (2019)

0 6



Source: Prohibition Partners/EMCDDA

In 2019, the European Monitoring Centre for Drugs and Drug Addiction recorded advertising of CBD products in all EU countries with the exception of Estonia, Finland, Latvia and Norway. Since then, CBD has become available for sale in all locations except Finland where the government is actively removing

CBD products from shelves. The diversity of product formulations such as flower, oil, edibles and e-liquids can give a proxy as to the progress of the CBD market in each region.

Regulations

The European CBD market largely operates inside a legal grey area, though Europe-wide regulations are beginning to emerge. While multiple CBD products are sold in high street stores across the continent, this often happens with disregard to local regulations which remain unenforced by authorities. A key aspect to the regulation of hemp products is the permissible level of THC. Different countries set their own limits on the THC content, with CBD friendly nations such as Switzerland and Italy allowing 1% w/w and 0.6% w/w respectively. Many states allow just 0.2% THC in hemp products, with even lower levels in the UK and the Netherlands being offset by similarly low levels of enforcement.

CBD was the focus of several developments of international law throughout 2020. These include:

- **November 2020** - European Court of Justice (ECJ) ruling on Kanavape. This ruling was the climax of a legal case taken against CBD company Kanavape by the French government. Kanavape had imported CBD into France which had been legally produced in the Czech Republic. The ECJ ruled that France could not infringe the free movement of Kanavape’s product. This ruling hinged on the interpretation of the UN Single Convention on Narcotic Drugs not to include CBD within its scope as CBD lacks ‘psychotropic effect or any harmful effect’.
- **December 2020** - UN vote not to exempt CBD from international control. In December 2020, the UN commission on Narcotic Drugs voted on a set of recommendations made by WHO on the rescheduling of cannabis and its constituents. While the Commission voted to reclassify cannabis to a less restrictive category under International Law, they also voted against adding a footnote to the Single Convention which would remove control from CBD. The motion was rejected by a large majority of 46:6 with four abstentions. All nine EU member states voted against the motion, not necessarily in principle as some only

had issues with the specific wording. A representative for Germany said the wording ‘does not offer the necessary legal certainty’ on the issue. The US also voted against the motion but on the grounds that they do not consider CBD to be under international control currently.

- **Development of Novel Foods regulations** regarding CBD. In 2019, the European Commission took the position that CBD constituted a Novel Foods ingredient meaning CBD joins a list of specially regulated products now marketable as foodstuff only after case-by-case approval. This ruling has caused upset in the industry as Novel Foods applications can cost producers a considerable amount, in the vicinity of US\$327,000+ depending on the type of product and the national authorities involved in the process. EU regulators froze the Novel Foods applications of over 50 companies in July 2020 while the Kanavape case was being considered. In December, a spokesperson from the European Commission confirmed that the application process has now resumed, on the basis that the ECJ does not consider CBD a narcotic. The European Industrial Hemp Association (EIHA) is currently spearheading a campaign to repeal the Novel Food status of CBD on the grounds of historic consumption on the continent. As of early 2021, it is unclear whether the campaign to repeal the status will be successful.
- **February 2021** - addition of CBD to the list of recognised cosmetic ingredients in the EU. In February, the Directorate General of the Internal Market, Industry, Entrepreneurship European Industrial Hemp Association (EIHA) to update the EC Cosmetic Ingredient database to include CBD. This request was granted on the basis of the November 2020 ECJ ruling that CBD is not a narcotic. CBD is now recognised on the list of cosmetic ingredients of the EC. The functions which CBD is listed for are as; an anti-sebum, skin conditioning, a skin protecting agent as well as being an antioxidant.



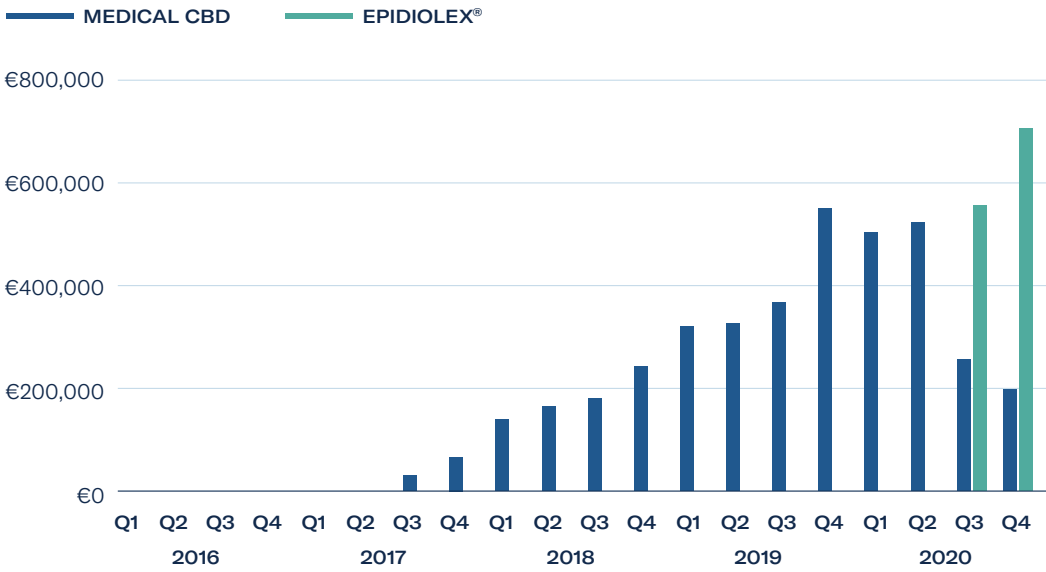
CBD vs Epidiolex®

There is inevitably going to be market competition between OTC CBD, prescription CBD and CBD extract with pharmaceutical CBD, namely Epidiolex®. CBD has been shown to be a powerful anti-inflammatory agent with low risk of abuse and a strong safety profile. However, the specific inflammatory conditions for which CBD is useful, and in what way CBD is best applied, is still an active field of research. Currently, OTC and prescribed CBD is being used for a wide range of conditions including dermal conditions like psoriasis, psychological conditions such as anxiety and internal conditions like arthritis.

The most vetted use of CBD to date comes from the clinical trials of Epidiolex® run by the patent owner GW Pharmaceuticals. GW Pharma have pioneered the use of cannabinoids in the pharmaceutical setting by guiding CBD through the regulatory process to become an approved product in the US as of 2018 and the EU as of 2019 for the treatment of Lennox-Gastaut syndrome (LGS) or Dravet syndrome. GW Pharma now has annual sales of over half a billion US dollars, mostly owing to sales of Epidiolex® in the US. These sales will undoubtedly grow as the medicines are rolled out across more European countries.

The presence of Epidiolex® poses competition to similar CBD products without marketing authorisation. The normal practise of physicians and healthcare systems across Europe is to prioritise treatments which have passed clinical trials. Even where countries allow the prescription of non-approved products, reimbursement of medicines from insurance providers also favours regulated pharmaceutical products. Illustrating this, the introduction of Epidiolex® to Denmark in Q3 of 2020 saw a large reduction in the prescription of magistral CBD.

Sales of CBD and Epidiolex® in Denmark



Source: Atalis/Danish Health Authority. The Danish statistics do not differentiate here between magistral CBD and THC.

It should be noted that the introduction of Epidiolex® to the market in Denmark also brought in a large swathe of new prescriptions, quite possibly from patients who had not yet used cannabinoid medicines. Epidiolex® flourishes as it is a traditionally regulated pharmaceutical product, which is a more familiar fit to global health systems.

There will remain a huge market for magistral and OTC CBD for the foreseeable future. CBD has a wide range of uses, and Epidiolex® does not challenge many of these domains. CBD can also be produced relatively cheaply and marketed with little processing, meaning the end product can be sold at affordable prices while maintaining profit margins. Epidiolex® on the other hand is expensive, roughly US\$32,500 a year, meaning sales will rely on patients, national welfare or insurance providers picking up the cost which may deter some uptake. In addition, many see CBD as an alternative to traditional pharmaceutical products. CBD is seen by many consumers and patients as a natural, plant-based alternative to 'chemical' pharmaceuticals produced by large companies and these patients and consumers will probably prefer CBD marketed as more 'natural' and organic than pharmaceutical products.

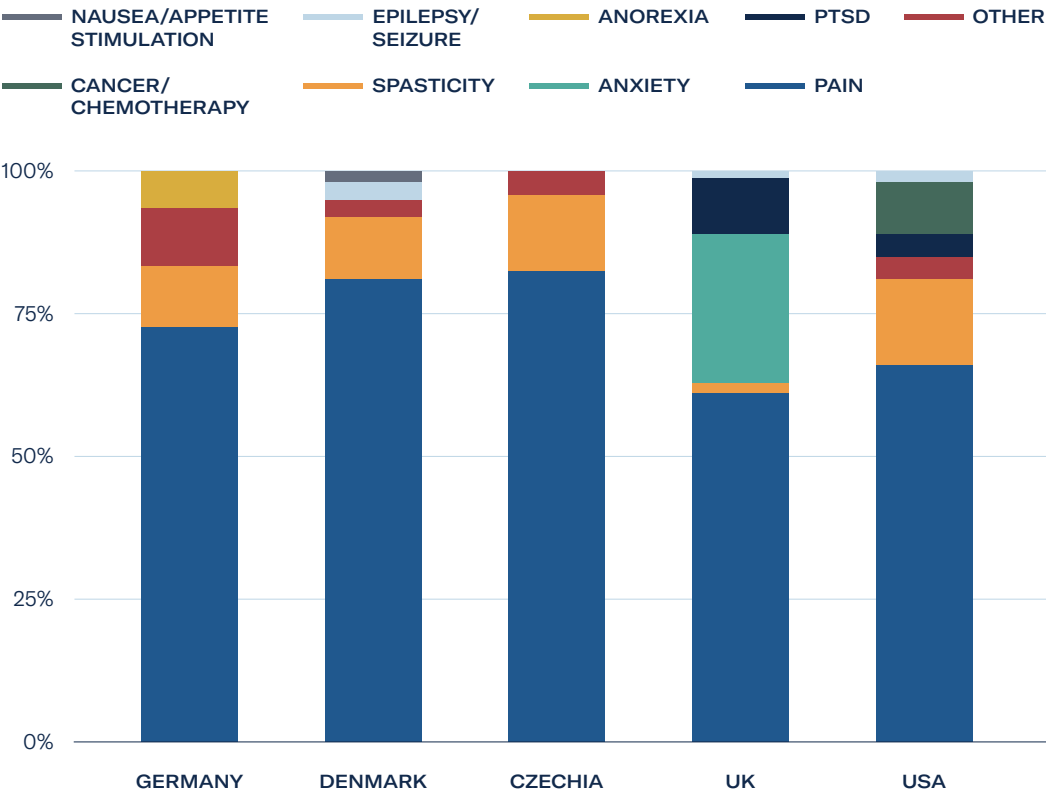
WHO ARE THE MEDICAL CANNABIS PATIENTS?

INDICATIONS

Producers of medical cannabis for the European market should take note of the conditions for which cannabis is being prescribed on the continent. The needs of patients vary widely by condition e.g. where CBD/Epidiolex® is

more useful for epileptic patients, THC is more often needed for reduction of nausea. Below are the indications for which medical cannabis products are prescribed per country.

Conditions for medical cannabis prescriptions



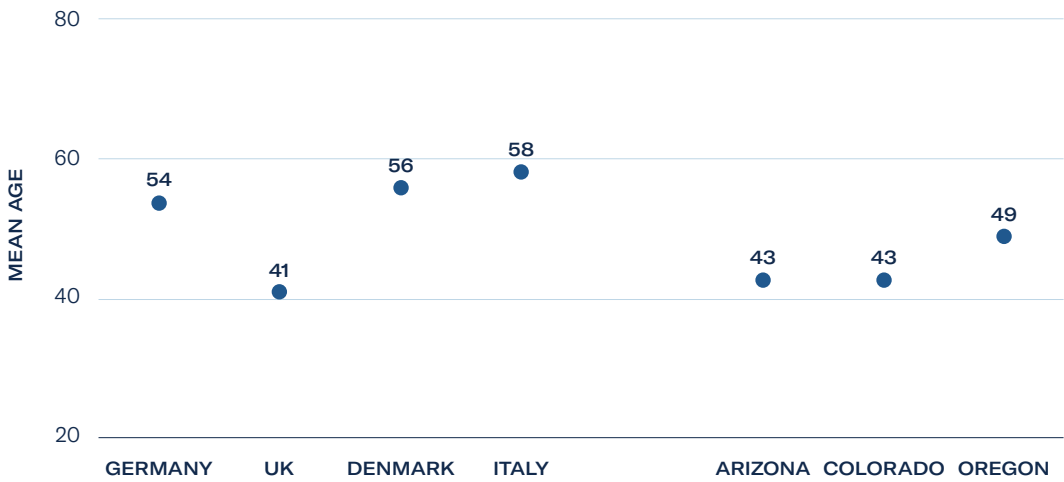
Source: Atalis/Government agencies/ Project Twenty21/Boehnke et al. (2019).

Pain is by far the most commonly cited reason for doctors to prescribe medical cannabis and this will be the case for the foreseeable future. Chronic pain affects as many as 1 in 3 people in developed countries, usually defined as pain occurring most or every day for six months. European countries are comparable with North America in prescribing medical cannabis most often for pain. Medical cannabis patients seeking to treat pain differ in their need depending on intensity of pain and frequency of use.

Generally speaking, patients with pain prefer cannabinoid medications with high and balanced quantities of THC and CBD, with heavier users preferring high THC and lower CBD. This complements the type of medical cannabis currently available in Europe, with most countries having a wider array of medications with high THC and balanced THC:CBD than high CBD alone (see section on Types of cannabis).

DEMOGRAPHICS

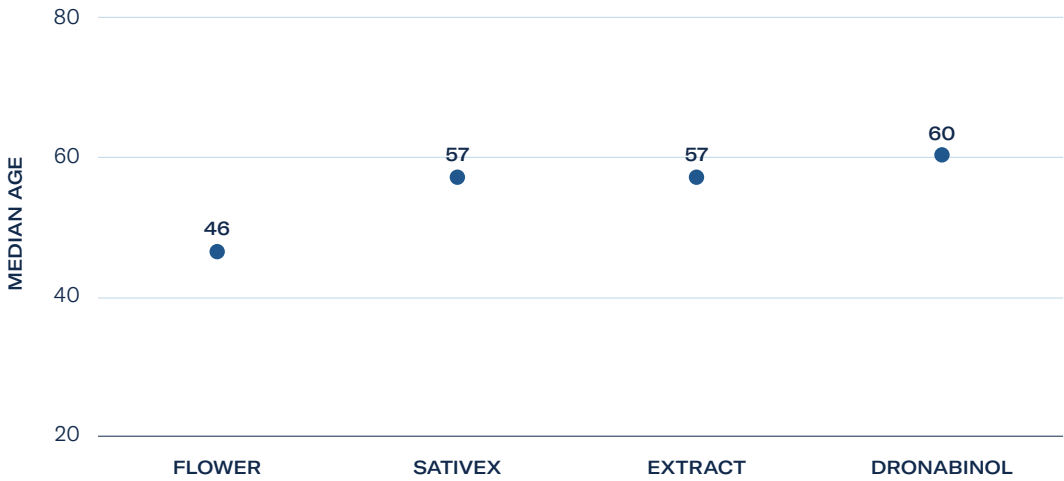
Mean age of international medical cannabis patients



Source:Atalis/Government and state agencies/Da Cas et al. (2019)

The average age of medical cannabis patients in Europe is similar to those of the North American patient population. The mean age of medical cannabis users in Germany is 54, but the medical authorities suspect an under representation of young patients accessing medical cannabis flower to be skewing this datapoint. Denmark and Italy are notable for having an elderly population of medical cannabis patients at an average of ~56 and 58 respectively.

Age of German medical cannabis patients by product



Source: Atalis/BfArM

People of different age groups are known to prefer different medical cannabis products. Data from the official survey of German patients indicates that younger demograph-

ics prefer flowers, whereas dronabinol and other extracts are predominantly used by older age groups.



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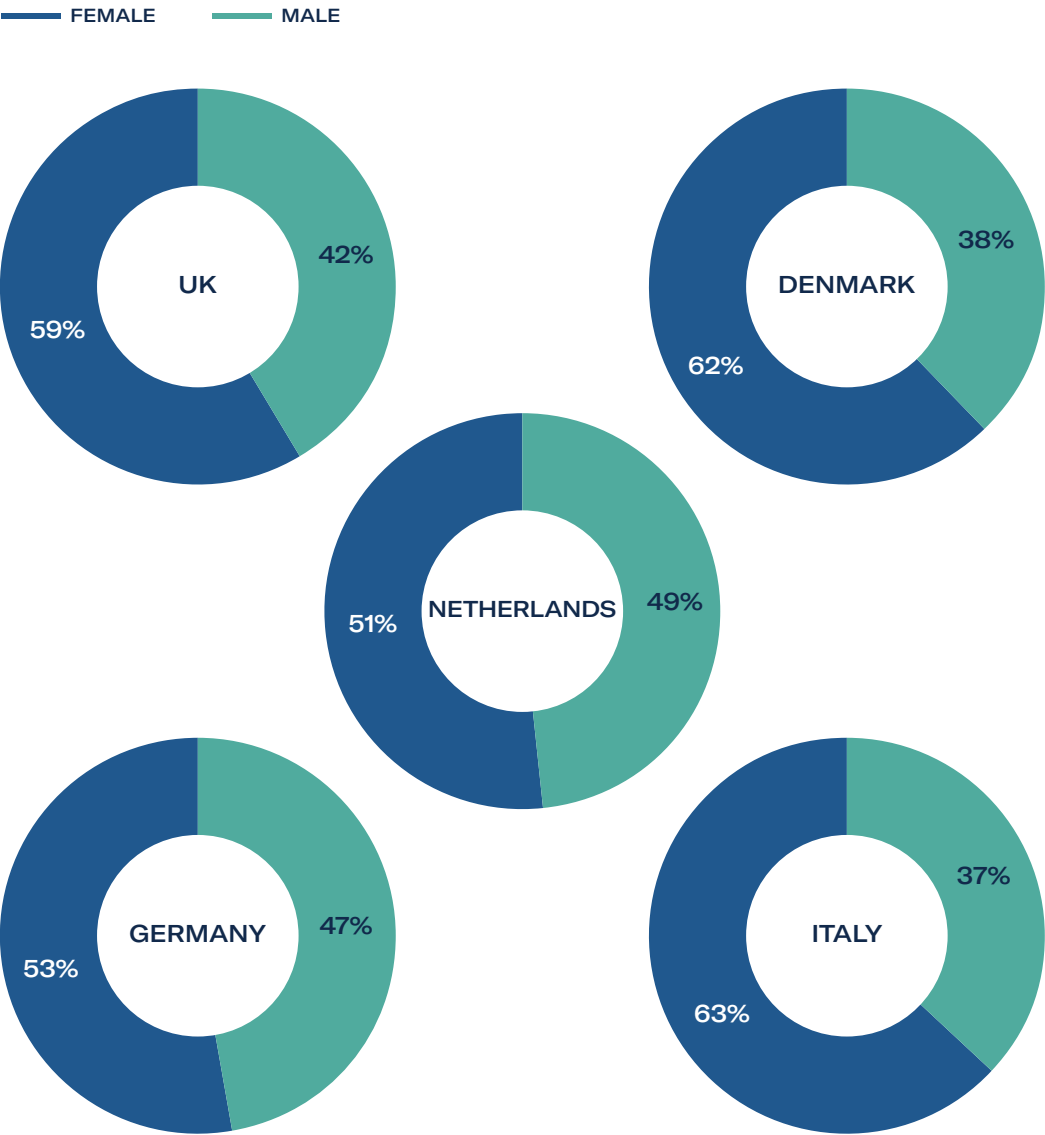


GENDER

The data on medical cannabis usage to date shows that the European population of cannabis patients is tipped towards being female-led. In the Netherlands and Germany, the gender divide is not large. There is strong evidence that medical can-

nabis patients in the UK and Denmark are predominantly female, nearing 60% in each case. Germany recorded 0.1% of patients as neither male nor female and it is the only country in Europe with such data available.

Gender of medical cannabis patients

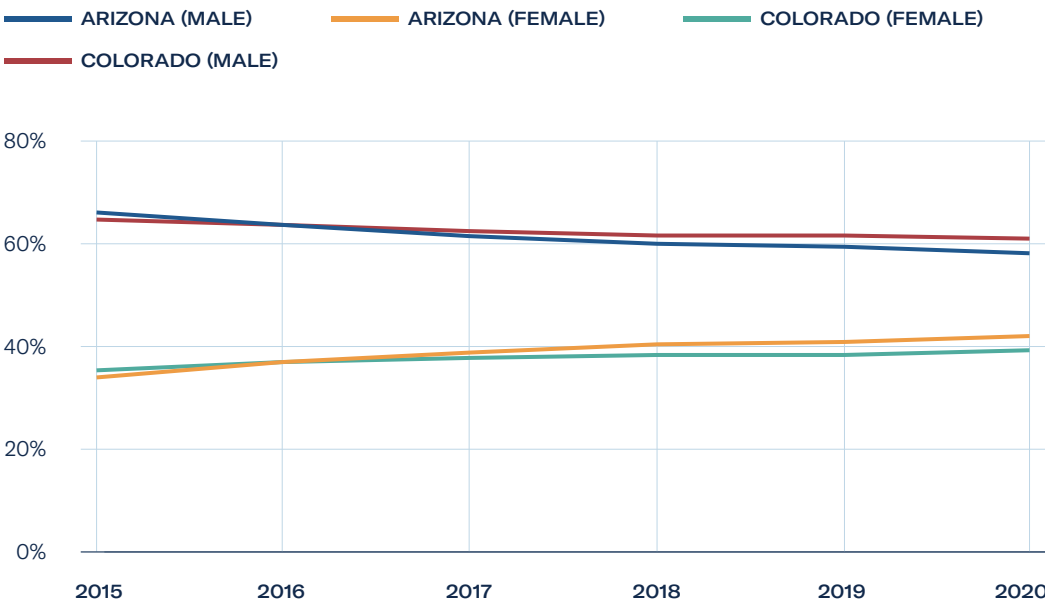


Source: Atalis/State Agencies/Da Cas et al. (2019)



The trend of predominantly female patients in Europe differs from the trend found in North America, where for over a decade, the majority of patients have been male. While the share of the patients who are female has been growing in the US, the balance still remains around 60:40 male to female.

Gender of medical cannabis users in US



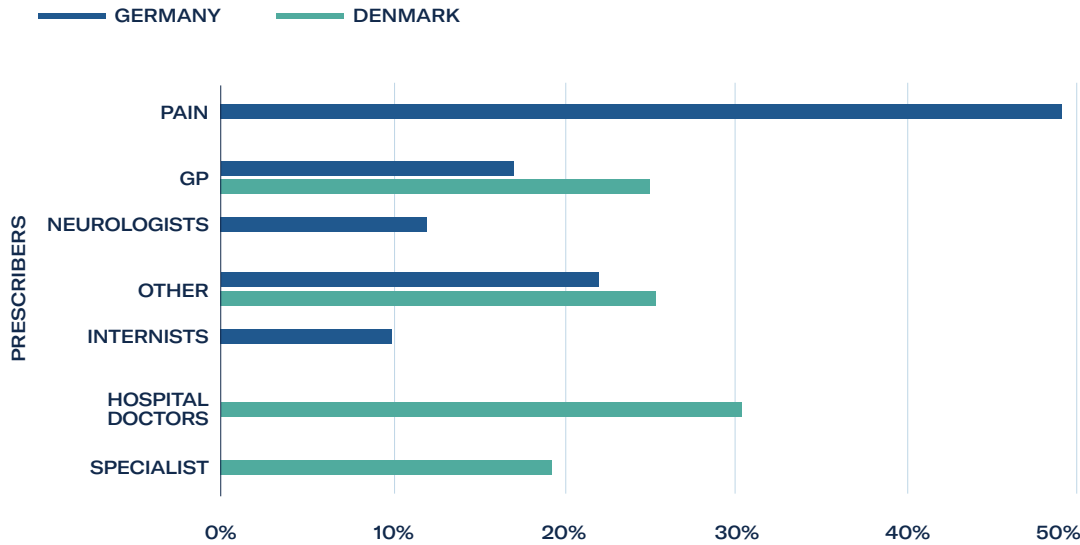
Source: Atalis/State Agencies

Gender plays a role in patient product choice. In Germany for example, 68% of patients receiving flower are male, while females dominate the use of dronabinol (58%), Sativex® (54%) and extracts (54%) as defined in the surveys of the BfArM.

WHO ARE THE PRESCRIBERS

Germany and Denmark release data on the doctors who are prescribing medical cannabis in their countries. The majority of medical cannabis in Germany and Denmark is currently being prescribed by specialists in pain management. In addition to the figures shown in the chart below, many of the general practitioners in Germany carry a secondary specialisation in pain management and palliative care. In Denmark, it is probable that many of the undefined specialists and some of the ‘hospital doctors’ are experts in pain treatment. The BfArM also predict there is an underreported prevalence of general practitioners prescribing in Germany, primarily for pain conditions.

Percentage of cannabis prescriptions by doctor speciality



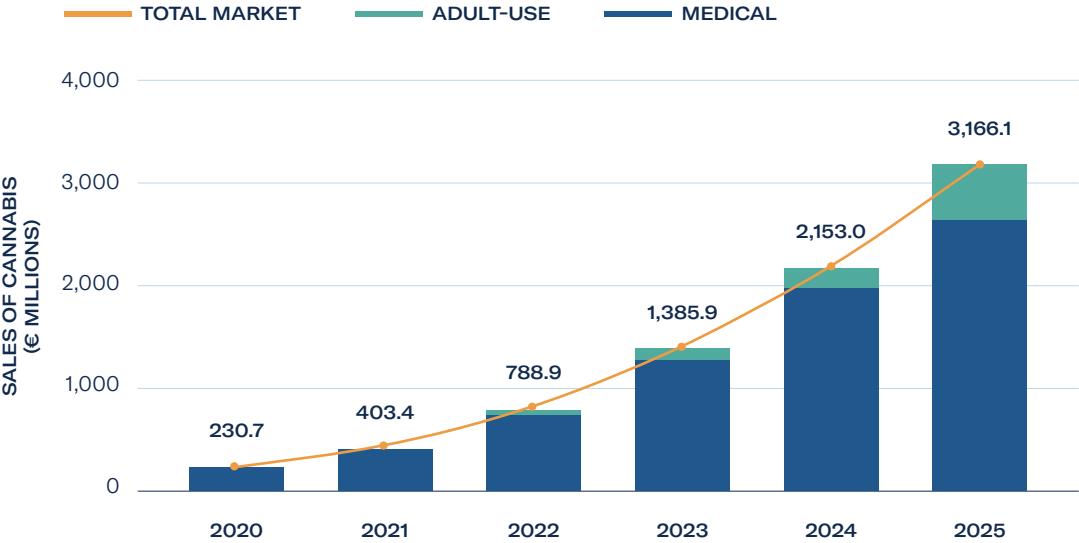
Source: Atalis/BfArM, Danish Health Medicines Authority

Market Sizing



- 1** The European cannabis market will be worth €403.4 million by the end of 2021. We expect the market to grow with a CAGR of 67.4% from 2021 to reach €3.2 billion by 2025.
- 2** Recreational cannabis is not yet legalised anywhere in Europe and so the market for legal cannabis products in Europe continues to be entirely medical. This balance is expected to shift by the end of the forecast periods as more countries open up to legalised adult-use cannabis.
- 3** Germany has by far the largest number of medical cannabis patients as of 2021. By 2025, countries like France and the UK will have developed their patient access considerably, and large nations like these will represent a significant share of the European market.

Projected growth of European cannabis market

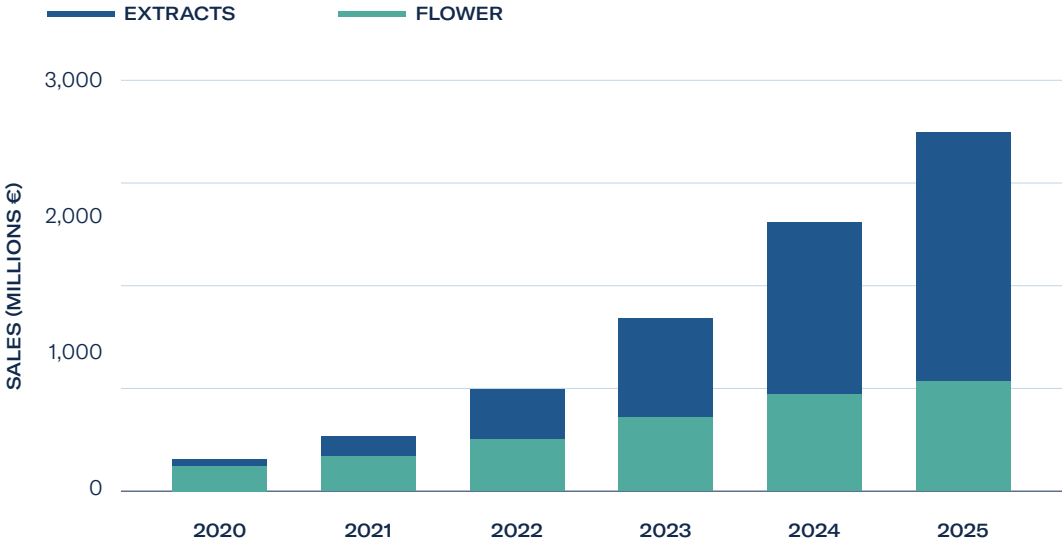


Source: Prohibition Partners/Atalis

Medical

For the next five years, we expect that medical cannabis will remain unique in the healthcare systems of Europe primarily because unregistered products will be the dominant forms of prescription medication owing to the limited set of conditions for which registered products are approved. Germany will be the country with the most patients, and most in need of medical cannabis in the coming years. We predict Germany will constitute over half of the European market until 2024 and will be worth over €840 million by the end of the forecast period. If regulations progress as we predict in the UK, this country will show the most impressive growth over the forecast period, and will have begun to catch up with the primary market of Germany. Some pioneering nations like Denmark and the Czech Republic currently hold a relatively large market share but these will be overtaken in terms of sales by larger nations such as France and Poland before long, owing to the progress of legislation and the large potential patient populations in these countries.

Projected sales of medical cannabis in Europe



Source: Prohibition Partners/Atalis

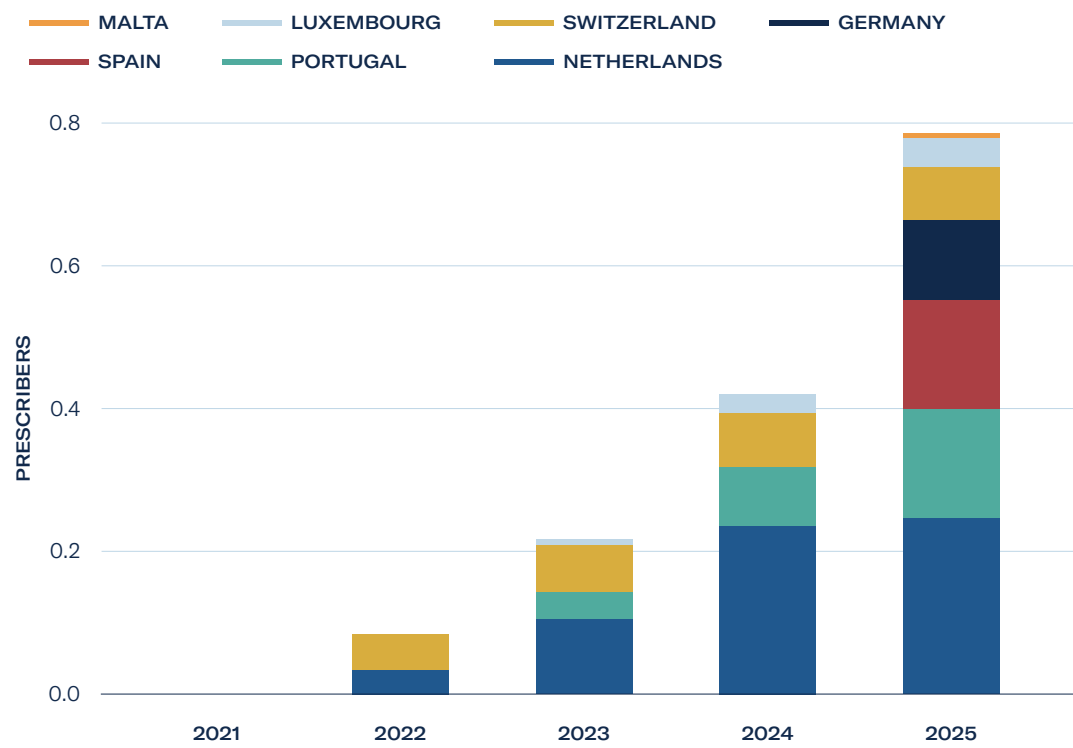
Adult-use

Owing to the increasing popularity of extracts in the key market of Germany, and in Europe generally, we predict that the value of sales of extracts and isolates will overtake the sale of medical cannabis by the end of 2023. This represents an opportunity for companies to introduce value added products to the market, as the price per gram of active substance is known to increase when offered as oils and isolates as compared to flowers.

The value of the market for adult-use cannabis products in Europe is entirely dependent on progress made in the political and regulatory sphere and as such these forecasts should be recognised as ‘models’ rather than certainties. Based on current information and trends, and the stance of various governments, we predict that several nations such as Spain, Portugal, the Netherlands, Luxembourg, Germany, Switzerland and Malta will introduce legal access to adult-use cannabis, at least on a trial basis, by 2025.

The most lucrative market during the forecast period will be the Netherlands, owing to the existing culture of acceptance around adult-use cannabis and the upcoming trial scheme involving coffeeshop supply. It should be noted that the trial scheme, which will be introduced to the Netherlands, will regulate the production, supply and sale of cannabis to consumers, leaving consumption in a legal grey space of ‘tolerance’ rather than full legalisation.

Projected sales of adult-use cannabis in Europe



Source: Prohibition Partners/Atalis

Note: The above is an estimated, forecasted value of adult-use cannabis sales in Europe, subject to regulatory changes. Countries like the Netherlands and Switzerland are implementing trial access to adult-use cannabis, which could be reverted at the end of the trial periods. In addition it should be noted that while supply and sale of cannabis will be legal in the Dutch trial, consumption remains in the legally grey definition of 'toleration' rather than legalisation.

Switzerland will also be a market of interest as they are open to beginning trial access for potentially tens of thousands of users during the forecast period. Trial access to adult-use cannabis in Germany and Spain is contingent on political developments during the forecast period e.g. the 2021 federal elections in Germany. However, with the large population of cannabis users and the established market for cannabis clubs in Spain, we predict these will grow rapidly following the introduction of even limited legalisation.

To put the figures for adult-use cannabis in context; the black market revenue for cannabis in Europe was an estimated €11 billion in 2019. Upon legalisation in Canada, the black market for cannabis was worth €800 million. It took just two years for the legal adult-use cannabis industry in Canada to take away

over half the market share from the black market. While Canada has had a headstart with the early legalisation of medical cannabis and decriminalisation of adult-use cannabis, they serve as an example of how quickly adult-use markets can develop.



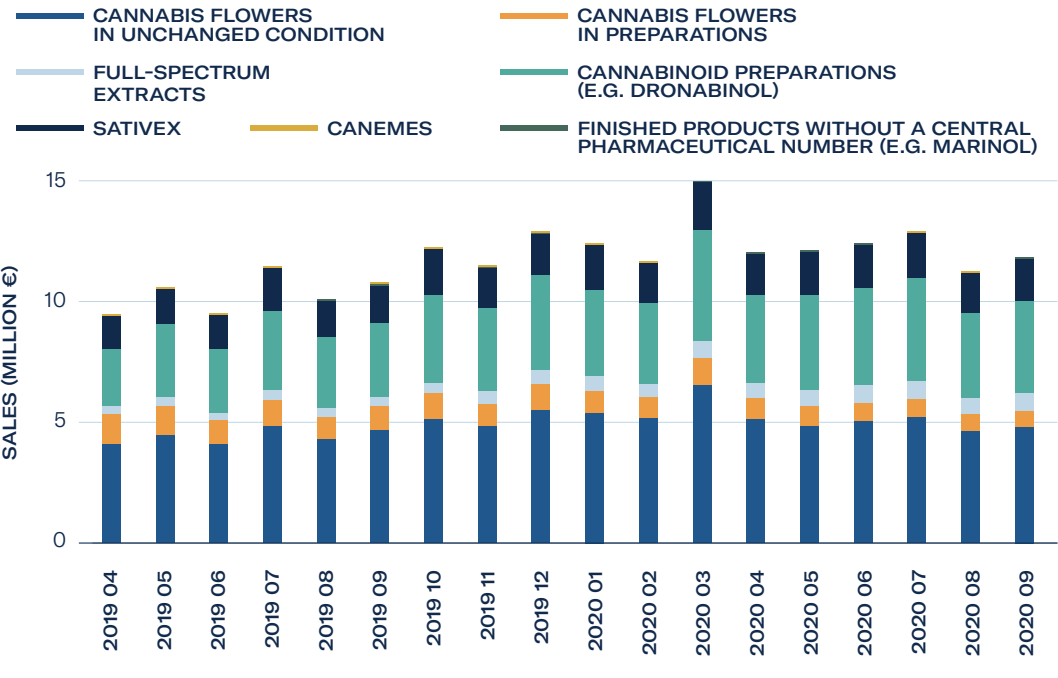
Countries in Focus

GERMANY

Germany is the focal point of Europe’s medical cannabis market, with over 128,000 patients treated in 2020 for a wide range of conditions. Reimbursement rates are high, and prescription regulations are not overly strict, allowing many physicians to prescribe at their own discretion. The main thing to note in Germany this year is the fruition of the domestic supply chain, which was expected to come online earlier last year,

but has been delayed by the pandemic. Germany will continue to import products from a variety of sources however, and it is normally the first place any product appears on the European market. Development of the medical cannabis system is still ongoing, with the streamlining of wholesale pricing regulations being an important step, and the move towards more extract-based medicine instead of flower-based products ongoing.

Reimbursed cannabis sales in Germany



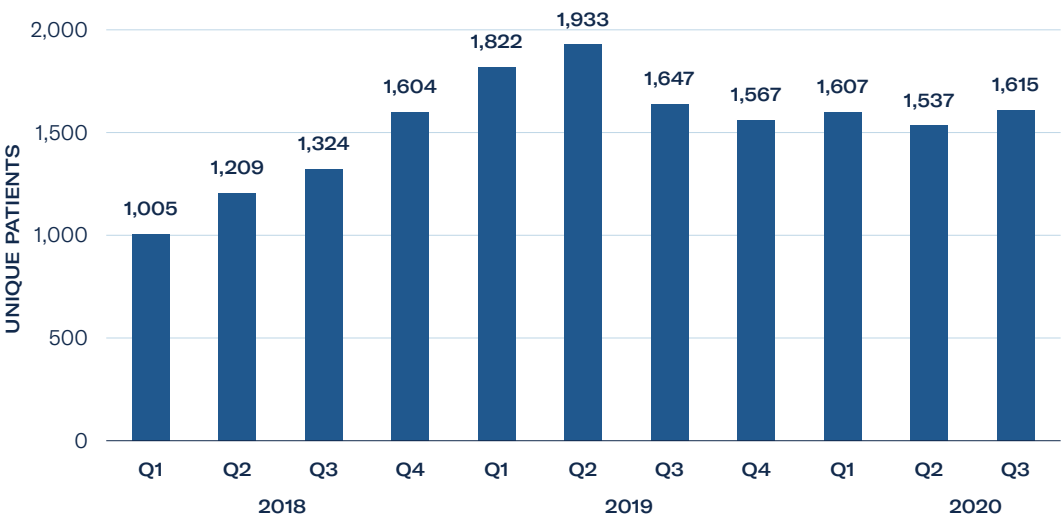
Source: Atalis/BfArM



DENMARK

Denmark’s medical cannabis system is heavily regulated, with incredibly high quality standards. This applies both to products used to treat patients in the small domestic market, as well as those produced by companies operating within Denmark, with limited exports so far. All products require official approval from the health authority before they can be used for patient treatment or exported, and though many companies have tried, none have yet been able to supply the Danish market with products manufactured on Danish soil. Aurora is the sole company so far to successfully complete exports. A review of the pilot programme is due to take place soon, so some reform may be forthcoming, though it is unlikely to affect supply regulation obstacles faced by producers.

Unique medical cannabis patients per quarter in Denmark

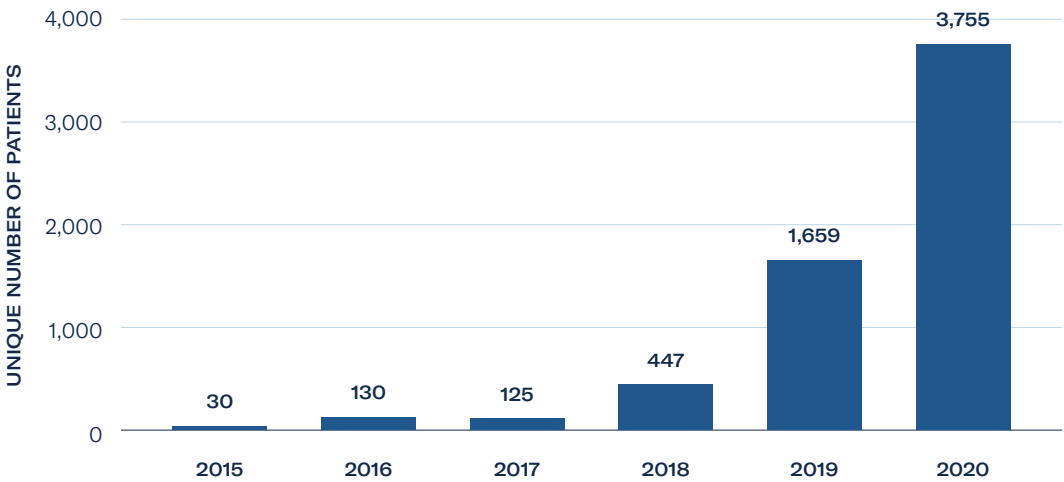


Source: Atalis/Danish Medicines Authority

THE CZECH REPUBLIC

The Czech Republic medical cannabis system treated approximately 3,700 patients in 2020, with a number of different suppliers, including one domestic producer. Only flower products are used for patient treatment, and the list of conditions approved for medical cannabis treatment is relatively limited. The country is rumoured to be preparing to establish a larger production capacity for export purposes, however there have been no official reports indicating this at the time of writing. Patient numbers increased significantly from 2019 to 2020, partly due to the introduction of a reimbursement scheme, which drastically reduced the cost of medical cannabis to patients.

Cannabis patient number in the Czech Republic



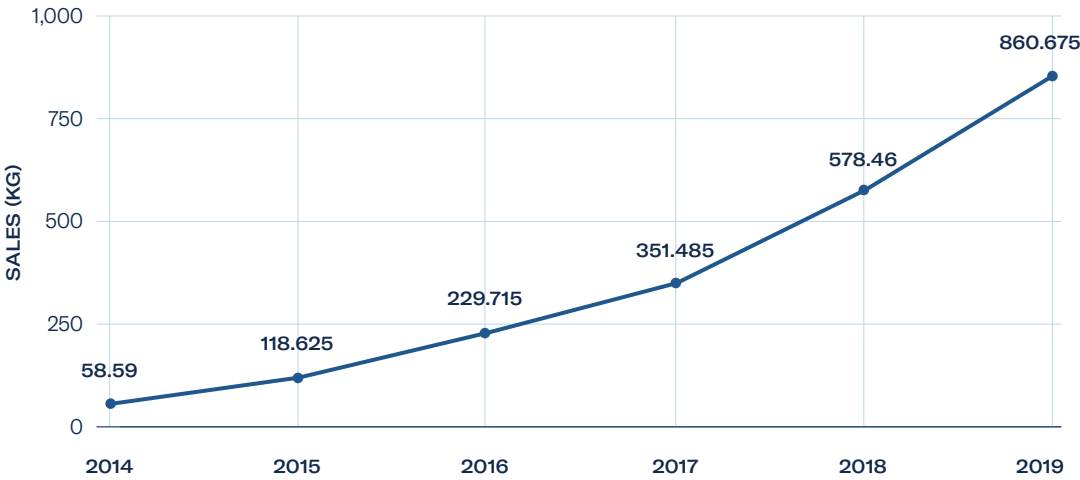
Source: Atalis/SAKL



ITALY

Italy is Europe's second-largest medical cannabis market by patient count, with 29,000 patients treated in 2020 and a system which varies by region in terms of prescription/reimbursement regulations. It is relatively closed to new producers, as the market is supplied via tendered imports, official agreements with the Dutch Office of Medical Cannabis, or from its military-controlled domestic production. Domestic production targets have repeatedly never been met, so the market has often seen shortages in supply. In late 2020, Italy introduced a measure which banned the delivery of medical cannabis prescriptions, known as telemedicine. While aimed at decentralising the dispensation of medical cannabis from a few pharmacies to a greater number around the country, the measure drew criticism for its timing, in that in-person prescription filling should be minimised rather than expanded, at least temporarily during the current crisis.

Sales of medical cannabis in Italy



Source: Atalis/Italian Ministry of Health



FRANCE

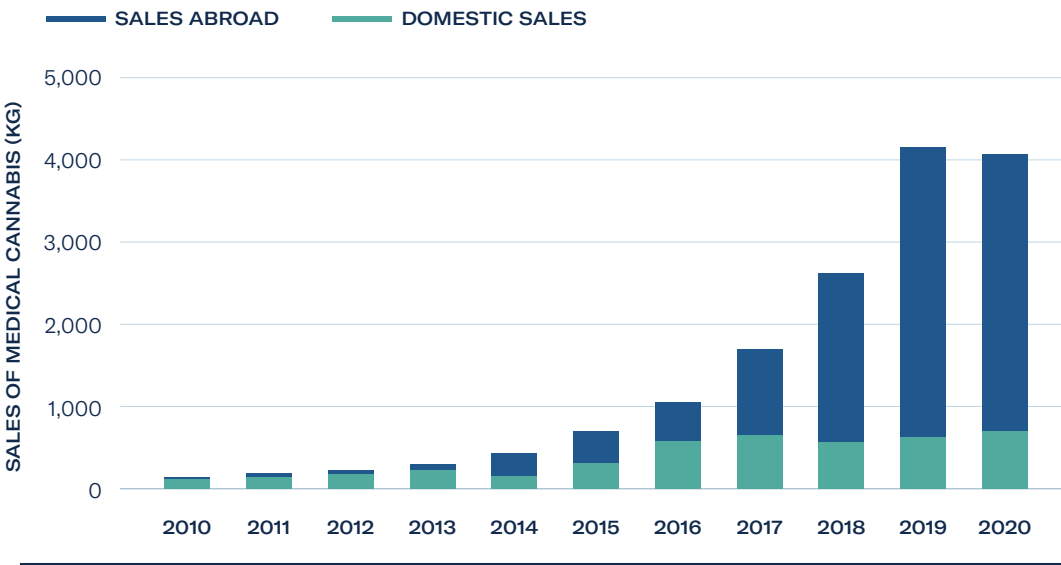
France has continuously delayed its two-year medical cannabis pilot programme, which was initially due to begin in 2020, and is expected to treat 3,000 patients. There is now a more concrete deadline of 31 March 2021 for its beginning, as regulators have decided that the trial programme will end two years from this date, regardless of when patient treatment begins.

The regulator released a statement in October 2020 announcing the opening of the application process to secure tenders to supply the programme, specifying a number of THC:CBD ratios as well as a variety of permitted product formats. Formats can be dried flower, capsules, oils and liquids for vaporisation. Producers have now been chosen to supply - Panaxia (Israel), Althea and Little Green Pharma (Australia) - and are expected to provide products to the patients taking part in the programme free of charge. At the end of the two-year period, the programme will be reviewed, and a widening of accessibility to medical cannabis is expected.

THE NETHERLANDS

The Netherlands is Europe’s oldest medical cannabis market, having legalised medical cannabis treatment in 2003. During this time, annual patient numbers grew to approximately 11,000 in 2019, dropping to 9,000 in 2020, possibly due to supply chain issues from the country’s sole supplier, Bedrocan. All doctors are allowed to prescribe cannabis, and there is no specific list of approved treatable conditions, though there are some official recommendations. The Netherlands has been Europe’s largest medical cannabis exporter for over a decade, but it is now facing stiff competition from Portugal. It is currently expanding its production capacity, allowing an additional cultivator alongside Bedrocan, with commercial sales from the new harvest expected to come online in 2021.

Domestic and international sales of Dutch cannabis



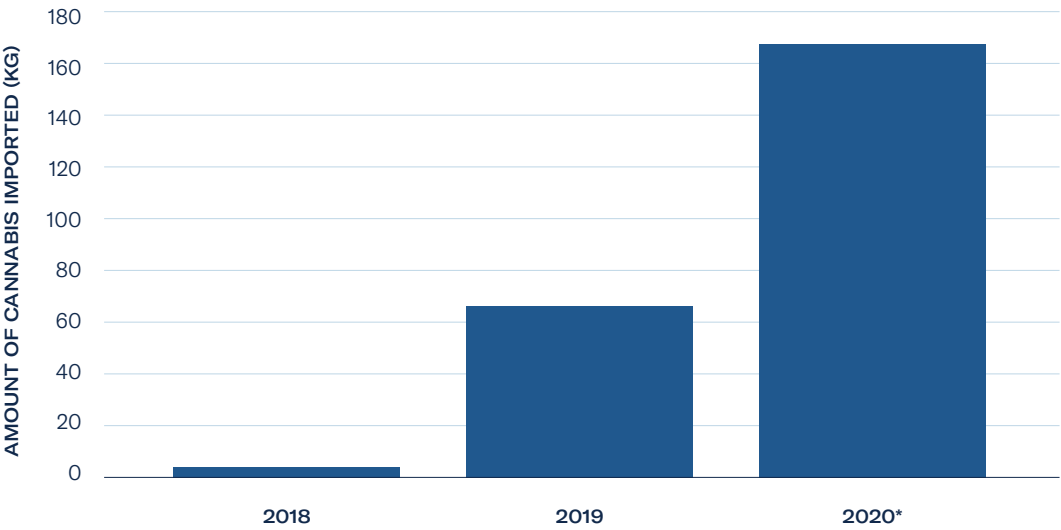
Source: Atalis/SFK



POLAND

Poland is Europe’s fourth-largest medical cannabis market by patient count, with over 5,200 patients treated in 2020, and it has the potential to grow significantly, due to its large population. Regulations around prescribable conditions and authorised prescribers aren’t too strict, but the lack of a framework for patient reimbursement holds back market growth. Additionally, products have to be approved by the regulator, which so far only allows dried flower products for treatment. This is reportedly due to change soon, in a press release last year a North Macedonian subsidiary of the Polish pharmaceutical company Pharmacann Polska stated its expectation to supply the market with extract-based products, though there have been no updates on this since November 2020. The country is currently facing supply chain issues for the limited number of products which are approved, making access to treatment difficult for the patient base.

Polish imports of cannabis flower



Source: Atalis/ MjBiz
* Through August 2020 imports that were subsequently re-exported are not included.



THE UK

The UK currently has very restrictive policies on medical cannabis access. While prescription of medical cannabis has been legal in the UK largely since 2018, still less than 3,000 patients have been able to access these medicines. This is set to change, with the introduction of the country’s first registry for medical cannabis patients set up in 2019. Project Twenty21 aims to enrol 20,000 patients by the end of this year. These efforts are also boosted by the presence of dedicated clinics for cannabis patients such as those run by The Medical Cannabis Clinics which connect patients with physicians and suppliers of these medicines. A major obstacle for the industry currently is that the National Health Service does not reimburse the cost of medical cannabis prescriptions, and private insurers will be reluctant to do so either, which limits the incentive for patients

to seek their medicines via prescription from a health professional. Regarding Brexit, many relevant product regulations have parallels and mutual recognition in the EU and UK such as the Novel Foods approvals for CBD and recognition of medicines approved by the European Medicines Authority in the UK. However, logistical issues for medical cannabis entering and leaving the UK cannot be ruled out in the coming year.

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SWITZERLAND

Switzerland is one of the largest markets for medical cannabis currently. While the country has a relatively small population of patients at just over 2,000 for 2020, high prices in the pharmacy and a predominance of high-value extracts means the overall value of sales in the country is comparable to the larger markets on the continent. The country has progressive cannabis policies when compared to many of its European neighbours. For example, the limit of THC in CBD products is 1% instead of the common 0.2%, which supports the existence of thriving 'cannabis light' sales which are available at most tobacconists in the country. Medical cannabis has been available by authorisation from the Health Ministry since 2011. Switzerland will also be a pioneer in the legality of cannabis for adult-use purposes, with the first trials within individual municipalities set to be operational in 2022.

EXPERT INTERVIEWS



**Marianne
Hundtofte Nielsen**
*VP Business Development
& Medical Affairs, Aurora Europe*

AURORA EUROPE

Extracts of cannabis are on the rise in Europe and North America. In the case of Europe why do you think this trend is occurring?

In contrast to North American markets, manufacturing and formulation activities have grown significantly in Europe due to demand for dosable, pharmaceutical-style products. Adherence to the relevant regulations and, in particular the GMP criteria during manufacture, are an indispensable prerequisite for guaranteeing patient safety and must not be circumvented by open interpretations. Aurora plans to launch in the course of the year more extracts (high-THC and balanced) from our facility in Denmark, in numerous markets in Europe.

Where do you see the balance of cannabis flower vs. extracts and isolates going in Europe in the coming years?

Developments in manufacturing techniques further enable targeting of specific conditions, in line with growing research for conditions medical cannabis can be prescribed for. This will influence the market preference for formulation types. There is a growing preference for oils and extracts in Europe, due to the need for precise dosing and targeted formulations. However, despite an increasing demand for liquid cannabinoid formulations, we believe that flowers will always have a place in the portfolio of cannabis medicines. The absorption mechanism and pharmacokinetics of cannabinoids from flowers and liquid formulations are different and each have their specific field of application based on a patient's indication.

Overall, the entire medical cannabis market will grow substantially, due to the huge gap between patient needs and current prescription possibilities. More importantly, we hope that European countries not allowing medical prescription of pharmaceutical quality / GMP cannabis for patients, fill this treatment gap and give physicians the tools on hand to improve patients' lives. France is a good example, where a two-year pilot programme will commence at the end of March 2021. Aurora, together with its local partner Ethypharm, will be the sole supplier of dried flowers (high-THC, THC:CBD-balanced and high-CBD) in the programme. Other countries are investigating an access programme, which starts hopefully very soon.

What role do you see magistral preparations playing in the future, will they be replaced by finished products?

Several key European markets allow pharmacists to prepare patient-specific magistral preparations in accordance with national monographs, offering doctors and patients a greater choice of formats and strengths. Magistral preparations are prepared using active pharmaceutical ingredients (e.g. isolated THC and CBD) rather than the alternative method of performing in-house extraction using plant material. Pharmacists play an important role in preparing formulations. This allows for the provision of personalised medicines to patients. The focus is therefore less on off-the-shelf cannabis products, and more on targeting a patient's specific need.

In Germany for example, medical cannabis supplied to pharmacies must be a 'bulk intermediate product' rather than a finished product, and compounding is a compulsory step. The DAC/NRF (New German Formulary) states the types of cannabis medicines pharmacists can formulate, including oils and capsules, by using dried flower or dronabinol. For dried flower, weighing and re-packaging are the required processing step by pharmacists.

Understanding country specific regulations and healthcare practitioner perceptions is vital to success in bringing new products to market in Europe. Developments in manufacturing techniques will enable this further, in line with growing research for conditions medical cannabis can be prescribed for. This will influence the market preference for formulation types.

What is Aurora focused on currently in the European context, are there any developments that you find particularly important?

It is very important for the individual and patient-specific therapy that the required supply of medical cannabis products is guaranteed (in accordance to EU-GMP standards) and available in the various presentations. We address the growing demand and need to reduce time to market with Aurora's first greenhouse facility on European soil – Aurora Nordic. In less than two years, we outfitted and licenced this high-tech cultivation and production facility in Odense, Denmark. With more than 9,200 m² production space and an output of approximately 10,000 kilograms of high-quality medical cannabis per year, we are positioned to service European and international markets in accordance with local medical cannabis regulations.

Aurora also supports medical education in opening and growing markets. We are one of the lead sponsors of the Clinical, Scientific & Regulatory Cannabinoid Conference by the Centre for Medicinal Cannabis UK in April. The event focuses on key aspects relating to research and clinical evidence. Leading figures across the UK regulatory and clinical sectors will be speaking at the event. The

attendance of such senior policy makers and researchers promises to make this a landmark event and highlights the importance of research and evidence in the UK medical cannabis policy debate. www.thecmcuk.org/events/scientific-conf

What would Aurora like to see in the European cannabis space in the near future in terms of regulations or policies?

It is very important to us that we always focus on the well-being of the patient. To this end, existing barriers to access must be further dismantled, more education and research must be available to doctors and patients about the effects of medicinal cannabis, and prejudices must be fought further. However, this must not happen by generous interpretations of regulations. So regulators should continue – for the safety of patients – to very carefully watch for compliance with EU-GMP regulations.

Additionally, there are numerous patients left out by the existing guidelines and regulations for cannabis medicine. Emerging data indicates that there are various areas where medical cannabis shows a positive effect, in addition to those for which it is prescribed for today.

My hope is that the countries where medicinal cannabis is not yet legalised will look at the success of the programmes in countries with legalisation and legalise them as well, so that gaps in supply are closed and patients have access to a better quality of life.

EXPERT INTERVIEWS



Jordan Lewis
*CEO and Founder of Fotmer
Life Sciences*

FOTMER LIFE SCIENCES

What is Fotmer currently focussed on in terms of international development?

We are currently focusing on entering and growing our brand in three primary markets: Israel, the EU and Brazil.

Israel - We have recently signed an agreement with Israel's leading medical cannabis company Canndoc, where we will be supplying up to 3,000 kilograms of high-quality bulk dried flower per year for a four-year period. The flower will be processed into finished products and co-branded under the Canndoc and Fotmer brand names.

We are very excited with this agreement and with being able to bring much needed medicine to patients across the country and the EU. We look forward to seeing the market grow in the near future.

Israel sits at the forefront of technological and agricultural innovation in cannabis. The country has recently overtaken Germany as the number one importer of medical cannabis flower in the world. The systematic development of the Israeli medical cannabis market over many years has been made possible by relatively rapid regulatory progress in comparison with the rest of the world. The government is constantly promoting the local medical cannabis market and it is considered one of the most attractive geographies to conduct clinical trials and at a much lower cost than the US.

Europe - We have identified various strategic partnerships within the EU and will continue to leverage our first mover advantage, as the high quality low cost producer, to achieve value throughout the supply chain by moving closer to the consumer in terms of brand and margin.

Germany represents a promising opportunity within the EU, where it has emerged as the third largest market behind the US and Canada. Not only is it a culture bearer for pharmaceutical research throughout Europe, but German lawmakers have been establishing a simple framework consisting of doctors prescribing, pharmacies dispensing and insurance companies covering most prescriptions.

Brazil - Currently Brazil presents itself as the most attractive market in LATAM. As the largest Latin American market with about 15,000 patients authorised to import individually as of mid 2020, Brazil is expected to reach 4 million patients in three years. The new regulation in place since March 2020, opens the market for companies to import and distribute medical cannabis products in bulk without the need for proven efficacy through clinical trials.

Fotmer have made headlines for exporting unprecedented quantities of medical cannabis from Uruguay to Europe. Can you tell us how this came about, and how easy or difficult it was?

Uruguay was the first country in the world to fully legalise cannabis in 2013 and Fotmer was the first company in the country to

receive the licence to produce and export high THC medical cannabis. This first mover advantage gave us the opportunity to develop the relationships, track-record, accreditations and knowledge of a very complicated international regulations that have enabled our success. Fotmer has achieved a pedigree of consistency and accomplishment which is not too common in this fledgling industry. In addition to being the first company in Latin America to export THC products, we have also sent the largest shipment of high THC medical cannabis in history. We are a trusted global counterparty who has demonstrated that we can meet the most stringent regulatory requirements and deliver a consistent safe product that the consumer likes.

These achievements were extremely difficult. There was no road map to follow. There were countless unexpected events. We had to build the plane as we were flying. It has been a remarkably difficult and rewarding process.

Do you have ongoing partnerships with European wholesalers i.e. will you continue to supply the European market into the near future?

Yes, it is within our goals to improve the lives of patients who have to live with the +80 conditions for which medical cannabis is prescribed in the EU.

Fotmer is working on three new different supply strategies in Europe for Fotmer cultivated flower, and we have identified strategic partnerships with European entities for each strategy.

On the topic of compliance, are Fotmer aiming to obtain EU-GMP certification or will the GMP processing always be carried out elsewhere?

All of our processing facilities have been purpose built to the highest GMP standards. We achieved our Uruguayan GMP certification in 2019 and aim to achieve our EU-GMP certification this year. We believe that in order to be nimble and successful as a global supplier of cannabis, the more pathways we can establish the better. Every country is establishing their own regulations and requirements. We

will continue to work with strategic partners and enter into the supply chain at various points to ensure that we have the flexibility to pursue as many commercial opportunities that present themselves.

What advice would you give to producers of cannabis around the world seeking to supply foreign markets like Europe?

Familiarise yourselves with the local regulations. The European medical cannabis market lacks a common regulatory framework. This means despite the opportunities that cannabis presents, marketing cannabis products in the diverse European market is a complex challenge.

Are there any legal or regulatory developments anywhere in the world which will have a big impact for you or that you are anticipating?

We anticipate that changes in US policy will rapidly accelerate the global legalisation of cannabis. Normalisation of banking in the US seems inevitable in the near term and it would not be unrealistic to think that legalisation on the federal level may also be achieved some time soon. We see this as the single biggest near term catalyst. When the money flows, the industry grows.

EXPERT INTERVIEWS



Jonathan Nadler
*Co-founder | Managing
Director at LYPHE GROUP*

LYPHE

Do you see a trend away from vertical integration in the European cannabis supply chain. If so, why do you think this is occurring?

No, not at all. Far from it, I see companies that are building new functions, and spreading across the supply chain. Vertical commerce is not just impacting on our industry, it is common and admired in many other industries.

We are very much behind the curve. But let's be clear about what vertical integration actually means in our market – owning the supply chain from seed to sale is the usual definition in jurisdictions like Canada but here in Europe due to the lack of grows in-country, the verticality usually starts from product finishing, and ends with sending a medical cannabis or wellness product to the consumer.

The mindset of the majority in Europe is that the grow is not a huge loss from the vertical, the product is commoditised, the price is tumbling, here in the UK medical cannabis is cheaper per gram than the black market – that's more than 1.4 million potential medical users here that might now turn to legal medical cannabis.

Vertical integration for LYPHE is as follows: importing own label NOIDECS from multiple manufacturers, patients then meeting with out doctors online and finally cannabis being sent by our dispensary to the patient's door.

When looking at the individual companies in the vertical for medical cannabis in Europe, you

must pay attention to the profit margins. There are levers that generate demand, and there are levers that generate revenue – it's a fine balance to have them all working in unison.

Many companies market cannabis produced in several locations and from different seeds as the same strain/brand. Does this introduce a level of variance in the branded product, taking into account a possible entourage effect?

Lots of brands get their genetics from the same place, so they have the same name. Medical cannabis usually focuses on showing the THC and CBD levels. These are the active ingredients that doctors care about. The ratio of the active ingredients is how doctors medicate their patients.

If it is EU-GMP that is fine, the name of the strain is not a prerequisite at all, that said, if the strain name is there for the patient that is fantastic. We know that there are some patients that have been self-medicating for a number of years – they usually know more than the doctors when it comes to the strains that work best for them.

Is there anything else you would like to add about Lyphe, what you're focused on or regulatory developments you are looking forward to in the European context?

This is a golden age for European cannabis. We are opening the door to a completely different approach to medicine, and it will be felt deeply and for generations to come.

Acronyms

AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
BfArM	Federal Institute for Drugs and Medical Devices
CAGE	Compound Annual Growth Rate
CBD	Cannabidiol
CEO	Chief Executive Officer
CIBG	Centrael Informatiepunt Beroepen Gezondheidszorg
CRBs	Cannabis related businesses
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ETF	Exchange Traded Fund
EU	European Union
EU-GMP	EU Good Manufacturing Practices
FCA	Financial Conduct Authority
GACP	Good Agricultural & Collection Practices
GDP	Gross Domestic Product
GKV	Gesetzliche Krankenversicherung
IPO	Initial public offering
LATAM	Latin America
LSE	London Stock Exchange
MORE	Marijuana Opportunity Reinvestment & Expungement

OMC	Office of Medical Cannabis
OTC	Over-the-Counter
PoCA	Proceeds of Crime Act
SAKL	State Cannabis Agency
SCFM	Stabilimento Chimico Farmaceutico di Firenze
SFK	Dutch Pharmaceutical Key Figures Foundation
THC	Tetrahydrocannabinol
UN	United Nations
UNODC	United Nations Office on Drugs and Crime
USD	United States Dollar
WHO	World Health Organisation



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