THE EUROPEAN CANNABIS REPORT

7TH EDITION

PROHIBITION PARTNERS

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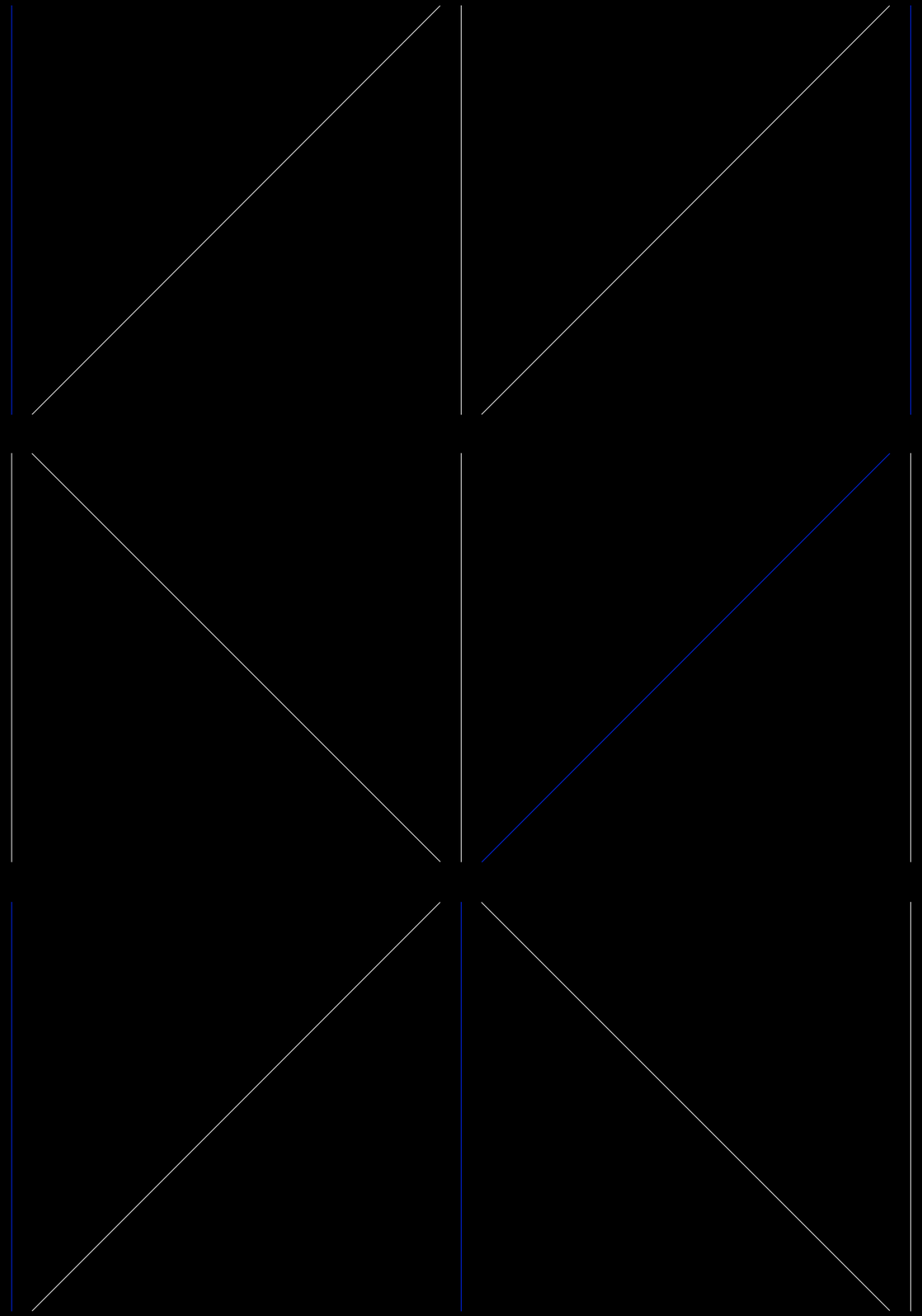

Our reports are the leading source of data and insights for the global cannabis industry.

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

The European Cannabis Report | ABOUT US

PROHIBITION PARTNERS TEAM

Stephen Murphy
CEO & Founder

Barbara Pastori
Head of Strategy and Data

Conor O'Brien
Industry Analyst

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SPONSORSHIP OPPORTUNITIES

Will Sloane
Head of Growth

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, sponsorship is an invaluable opportunity to put your brand front and centre in many of the industry's most influential reports.

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SPONSOR FOREWORD

Benedikt Sons
Co-Founder
Cansativa Group

Jakob Sons
Co-Founder
Cansativa Group

While the European cannabis industry continues to develop, its largest market, Germany, is on the verge of its most important breakthrough: the legalization of cannabis for recreational use. This is a logical consequence of the great success Germany has achieved in the medical cannabis sector and an impressive example of the overarching shift towards a progressive drug policy throughout Europe.

Cannabis was officially approved as a medicine in Germany as long ago as 2017. Since then, the market has grown significantly. As the exclusive distributor for German cannabis, granted by the Federal Institute for Drugs and Medical Devices, Cansativa has actively driven this development. Today we act as leading platform and one-stop shop for medical cannabis in the German market.

Legalization in Germany now marks a turning point. Issues such as cultivation and licensing must be clarified, dispensaries installed, and preventive measures institutionalized. With our sound network and expertise, Cansativa sees itself as a key enabler of German legalization.

With successful legalization for recreational use, Germany will pave the way for a progressive cannabis future. At Cansativa, we believe in the success of a European cannabis industry.

That's what we work to achieve every day.

Benedikt Sons and Jakob Sons
Co-Founders
Cansativa Group

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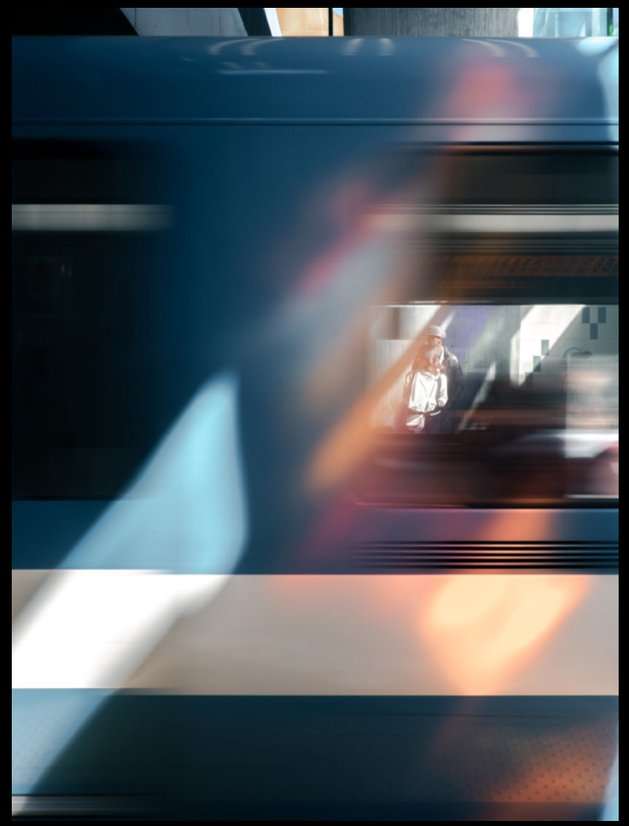
Definitions



The European Cannabis Report | 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. For a full picture of the legalisation of adult-use cannabis in Europe, see Prohibition Partners mini report Adult Use Cannabs in Europe™.

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. The common limit for Tetrahydrocannabinol (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.

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).

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).

Over-the-counter (OTC) drugs
Medicines sold directly to a patient without the need for a prescription from a healthcare professional, as opposed to prescription drugs, which are supplied only to patients possessing a valid prescription.

Minor Cannabinoids
Cannabinoids found in low concentrations in the cannabis plant such as Cannabigerol (CBG) and Cannabinol (CBN). Many have been shown to be bio-active though evidence for their therapeutic benefits is, as yet, lacking. Many researchers hope these will provide a host of new ways of modulating the endocannabinoid system.

Cannabis 2.0
Cannabis 2.0 products are cannabis derivatives that include cannabis infused edibles, beverages, topicals, concentrates and vapes. They arrived on markets later than products like oils and flower and are anticipated by some to be the future of cannabis.

Cannabidiol (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-arthritic and neuroprotective effects. Recommended by some as treatment for conditions such as epilepsy as well as pain and insomnia.

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.

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FEATURED INSIGHT

Timo Bongartz
General Manager
Fluence EMEA

LEDs are lighting the path toward a more consistent and profitable cannabis cultivation model

The days of static light intensities under HPS are quickly fading.

More and more research is showing that different cultivars respond to different lighting strategies at different stages of their maturation. More nuanced, customized lighting strategies have tangible benefits for nearly every layer of cultivation operations. The plants themselves will see improved aesthetic, enhanced aroma and taste, more pronounced cannabinoid profiles, faster cycle times and higher yields. Cultivators can achieve a level of consistency and production not possible under legacy lighting systems. Executives will benefit from improved business predictability, reduced operational expenses and consistent operational income. Ultimately, it becomes the go-forward business model in which each area of a cultivation operation is optimized to capture more revenue, reduce costs along the way and secure a competitive advantage in rapidly growing markets around the world.

Adopting such a model is contingent on an operation's ability to understand and better control environmental conditions, especially under high light intensity strategies. As LEDs increasingly become the standard for cultivators across nearly every crop and cultivar.

For those retrofitting facilities with LED fixtures or seeking to improve existing lighting strategies using LEDs, there are four major control parameters that LEDs enhance:

- **Vapor pressure deficit (VPD) management**
  HPS lights produced a significant amount of heat. When turned off, however, the resulting changes in the environment often left crops more vulnerable to condensation and pathogens as they cooled faster than other surfaces.

  Under LEDs, the environment is less affected by heat produced from lighting, relying instead on the more precise HVACD system designed exactly for the management of maintaining set points in temperature and humidity.

  This enhanced stability from LEDs ultimately translates to less condensation on plants, reduced water use and less dehumidification venting.

- **Temperature stability**
  Ambient temperature plays a major role in the physiological functions and pollen development of certain crops such as cucumbers and tomatoes. With HPS systems, it is far more costly and difficult to maintain adequate heat levels, leading to fluctuations that stress plants. While HPS lamps may perform two different tasks—both lighting and heating, they accomplish neither task particularly well and represent a far greater danger to plants should they fail. Ultimately, maintaining optimal temperatures should be the responsibility of the HVACD system.

  An LED retrofit may require the addition of a heating system, but growers will often see reduced heating loads overall and, more importantly, favor their increased control of their environments.

- **CO_2 stability**
  As PPFD increases, maintaining supplemental CO_2 levels is critical to maximizing photobiological responses and overall production. A concentration of 1,200 to 2,000 ppm is often the optimal range in cannabis production.

  However, growers who use HPS lights have to vent their facilities either to dehumidify or cool their environments, creating wild fluctuations in temperature, humidity and CO_2 levels.

  LED systems decrease the need for venting, which allows for better climate control, CO_2 preservation, increased photosynthesis, improved morphology and lower disease occurrence.

- **Higher PPFD levels and greater yields**
  Researchers studying the effects of LEDs are increasingly noting higher saturation points of many crops—including cannabis—creating new pathways to improve profitability for growers. An LED retrofit facilitates higher PPFD and improved production and growth.

  Studies show that increasing PPFD also increases crop weight until the saturation point. Fluence's own research has found that a 1 percent increase in photosynthetically active radiation (PAR) corresponded with a 1 percent increase in harvestable product up to light levels of 1,500 µmol/m2/s.

  When a facility replaces an HPS system with an LED system of similar wattage, supplementation capacity nearly doubles, assuming efficacies of 1.8 µmol/J for HPS and 3.5 µmol/J for LEDs.

  Cannabis has a near-insatiable appetite for light, and many researchers studying the effects of LEDs on cannabis are increasingly noting higher saturation points, creating new pathways to improve profitability for growers through high-PPFD, high-production lighting strategies.

Although projected savings drove early adoption of LEDs, their greater efficacy and ROI have emerged as principal factors in their sustained popularity. Increasing light intensity and spectral quality correlates to substantial increases in a crop's yield, morphology and health, when corresponding environmental conditions are adjusted and optimized. By optimizing facilities with LEDs and vertical racks, cultivators are realizing they can achieve profits that far outweigh the already meaningful savings.

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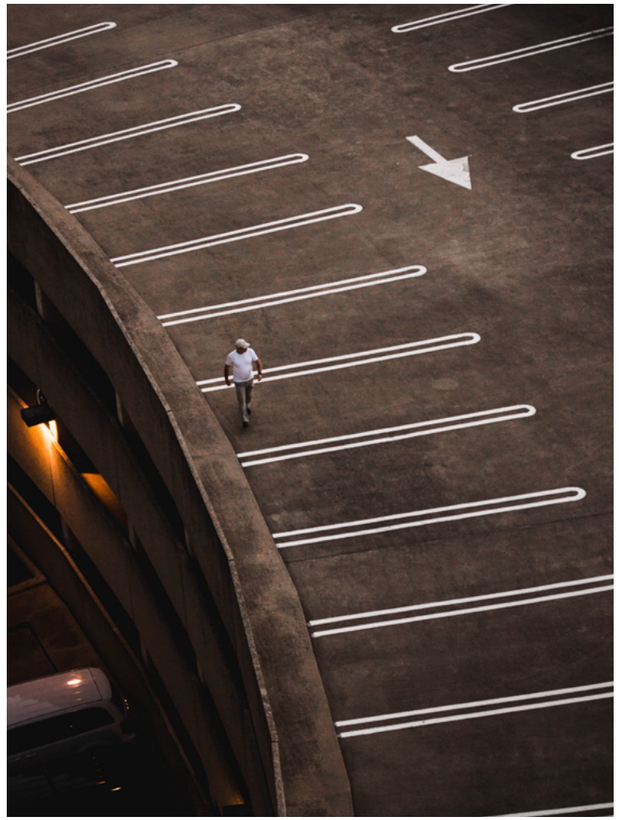
Methodology



The European Cannabis Report | METHODOLOGY

Market research

Prohibition Partners conducts research with industry experts to provide further information 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 then informs our writing generally and the results 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. Prohibition Partners' market sizing methodology for the European Report 2022™ involves calculations for the projected sales of cannabis products based on known data from existing markets which is used to form a model that is then adapted to project values for current and future markets which do not have such data. However, all the reported figures are very sensitive to the necessary assumptions of the model and there are several inevitable sources of uncertainty that come with such a modelling exercise in relation to: whether current markets will behave as they currently are, or have done, in the past; when and how legalisation will occur and finally whether future markets will behave in a predictable manner based on known data points from established markets.

A major factor in the progress of sales in cannabis markets is the progress of legalisation of the plant across the globe. Predicting the evolution of such regulations is difficult. We analyse the news and connect with our extensive network to keep track of political and regulatory developments, but the model can be very sensitive to even slight changes in the time frame or scope of measures being currently discussed, as well as any unforeseen macroeconomic, political or global transformations. COVID-19 and any related delays to supply and regulatory progress have been incorporated into our most recent model.

The main sources of information which inform our forecasting exercise are:

- Official data obtained from regulators, insurance companies and monitoring institutions.
- Company financial reports and news releases.
- Reviews 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, real-world data and literature reviews.
- Proprietary consumer research, public opinion and policy analysis.
- In-depth interviews with industry stakeholders and data-sharing agreements with key operators.

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Medical cannabis sizing

Our calculations for the European Report 2022™ use data on disease prevalence and patient penetration to assess the eligible population in each region covered. Our medical market sizing model then incorporates known data and estimates from existing markets on the sales of medical cannabis, patient numbers, product formats, dosages and pricing to establish an estimated market size for sales of medical cannabis. This model is applied to all regions, with more region-specific modelling carried out for the larger markets. For a full picture of the legalisation of adult-use cannabis in Europe, see Prohibition Partners mini report Adult Use Cannabs in Europe™.

Adult-use sizing

Our recreational cannabis market sizes are based on comprehensive data made available by public bodies in regions with legalised adult-use cannabis sales. These are used as the basis of projections for these regions, and they also inform our models for countries we believe will legalise adult-use cannabis within the relevant timeline. Also taken into account are the United Nations Office on Drugs and Crime (UNODC) yearly prevalence figures of cannabis use in order 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, thereby following the observed trends in Canada, the US and Uruguay.

CBD Sizing

CBD sizing was calculated for each country and for several categories of CBD products. Prohibition Partners' CBD sizing is based on data gathered by extensive surveys of tens of thousands of respondents across Europe, North America and Asia on their usage of CBD products. The surveys were commissioned by Prohibition Partners and carried out during 2020 by Attest, a renowned global survey firm. This data was modelled alongside real world sales data, where available, which provided the foundation for estimates in countries without such data.

EXPERT INTERVIEWS

Benedikt Sons
Co-Founder
Cansativa Group

Jakob Sons
Co-Founder
Cansativa Group

Starting a medical cannabis company was certainly not an obvious idea in 2017, let alone in Germany. How did you come to found Cansativa?

Jakob Sons: You could say that Cansativa is a genuine family business. Everything came together at a family event in 2017, when I was discussing the new cannabis law with my brother Benedikt and our father. The draft caused quite a stir in the law firm where I was employed at the time. Having Benedikt as a strategy consultant and our father as a medical doctor meant we had some very interesting points of view coming together. After intense discussion that went on late into night, we already had a rough concept for setting up the company: this was the start of our journey as cannabis entrepreneurs. Since its foundation in spring 2017, Cansativa has grown steadily, quickly becoming the market leader in the medical cannabis market.

What is special about Cansativa and has its huge success already changed the company?

Benedikt Sons: As one of the few first movers in the field of medical cannabis, we decided to consolidate crucial process know-how on an in-house basis. To this end, we opted for our own distribution and fulfillment center from the very beginning. Just one year after our launch in 2017, we started operating our first GMP and GDP certified facility. From there, we have vertically evolved from an importer and wholesaler to a pharmaceutical company and now to a cannabis platform, growing in terms of volume, capital and employees. Today, we are active at all stages of the value chain and are driving the professionalization of the industry at all levels.

Jakob Sons: But growth is not everything; more important are a shared vision and our very own ethos. We have remained true to our values since our founding: we want to professionalize the market, eliminate stigma and make it easier for people to access cannabis. Initially, this only applied to patients of medical cannabis – now we want to expand the scope of our mission to make cannabis available to everyone and provide professional support for legalization in Germany. We want to create an accessible ecosystem for industry-wide collaboration with government agencies, administrations and our commercial partners. Developing a reliable and diversified product and service landscape therefore requires above all knowledge, competence and perseverance.

Legalization in Germany is currently still subject to a great deal of uncertainty. Neither the timeframe, nor the regulatory framework, nor the processes have been clarified. How does this uncertainty affect the market?

Jakob Sons: It is true that many decisions are still pending. Yet we see this current market situation not so much as uncertainty but as a source of great potential. The legalization is an ambitious policy project where the government and science get together, along with legal and industry experts, to shape not only the German market, but also to a considerable extent the European cannabis industry of the future. It's clear that this future cannot be shaped from a single perspective. The German cannabis industry needs more creative minds and innovators in all fields – whether cultivation, research or local distribution.

Benedikt Sons: Cansativa Group is in an outstanding situation in that it has a business model that is already successful in the current market. We know that many potential innovators are holding back because of the uncertain schedule. That's why we are trying to push forward to create a strong ecosystem based on cooperation and industry knowledge to allow everyone to take a stake. But even though this current situation is a waiting game for potential founders and shop owners, there is a strong spirit of optimism. Once the government comes through with a roadmap, we can expect a much greater and far more diverse cannabis market in Germany.

The European Cannabis Report | EXPERT INTERVIEWS

What are your next steps as a business?

Benedikt Sons: As the central marketplace in the medical cannabis market and as the exclusive partner of the Cannabis Agency, we have shaped a young industry. Now we are applying this expertise to all areas of the cannabis industry and assisting a wide variety of players in gaining a foothold and growing to scale in this expanding market. With legalization comes a whole new set of challenges: we need a clear and uniform framework to ensure safety and transparency without stifling innovation or neglecting important social issues.

Jakob Sons: Once this has been accomplished, the rapid and widespread establishment of dispensaries and their legally compliant operation will be fundamental to ensuring effective legalization. We will develop a reliable and diversified product and service landscape in Germany as well as Europe. This will enable many new companies to participate in the German cannabis market. To this end we are establishing a strong accessible ecosystem for all stakeholders, be it government agencies, administrations or our commercial partners. Cansativa is ready to enable every partner or customer to start up fast with processes, products and services. The public market is ready for cannabis. And so are we.

Where do you see the German cannabis industry in 10 years and what role will Cansativa Group play in it?

Benedikt Sons: This is very difficult to predict, as many areas are currently seeing rapid development. The German market is the largest and fastest growing market for medical cannabis in Europe, and the future cannabis industry is becoming more diverse. And yet the potential of the cannabis plant is far from exhausted. We will do our best to make the many benefits of the plant available to society. At the same time, we will be vigilant in ensuring a safe, professional and healthy environment for all involved.

Jakob Sons: Our vision is to make Cansativa the leading platform for cannabis in Germany and Europe and to democratize the whole market continuously. In 10 years, all the doors will be open to young companies and consumers in a professional and secure European ecosystem. There will be more diverse products, new forms of distribution and all sorts of customer-oriented services.

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Takeaway Points

The European Cannabis Report | TAKEAWAY POINTS

Medical cannabis

Prohibition Partners estimate that around €354 million worth of unlicensed medical cannabis will be sold in Europe 2022, and we project this will grow to around €2.3 billion by 2026.

Pilot schemes for medical cannabis progressed across the continent. France began their pilot scheme in 2021 as Denmark voted to extend theirs, Ireland began their new access scheme in 2022 and the trial in Luxembourg is now due for a first assessment.

The German medical market continues to grow steadily, with a 43% increase in sales of cannabis to pharmacies in 2021, with the majority of growth coming from products sold to patients on private prescriptions. (see country focus section.)

In England, in 2021 the number of unlicensed medical cannabis products dispensed for private prescription grew by 425% to an annual 23,466 products (see country focus section).

North American cannabis operators remain heavily invested in Europe, with hundreds of millions of euros worth of assets on the continent. While slow revenues have caused some to divest hundreds of millions worth assets over recent years, others, like Curaleaf are now ramping up investment.

Canada remains the largest exporter of medical cannabis to Europe but this is changing as more and more countries around the world begin exports, and Canadian producers shift cultivation to Europe. Operators in at least 15 European countries are now cultivating medical cannabis for commercial purposes.

Product shortages continue to plague countries like Italy, Malta and Poland mostly due to efficient regulations and approvals processes.

CBD

CBD products are becoming more legitimised, as of February 2022, the European Commision has listed at least 12 valid applications for CBD as Novel Foods, with more expected in the very near future which will lead to the first legally protected ingestible products on the continent.

The CBD market remains fragmented and will remain so for some time. If regulations such as the Novel Foods Act are enforced, this could trigger the closure of many smaller producers and the beginning of a long-awaited consolidation.

Adult Use

In the realm of adult-use cannabis, Switzerland will likely begin their trials in 2022 followed by the Netherlands in Q2 2023. The German government has agreed to legalise the commercial sale of adult-use cannabis during this legislative term.

Many countries continue to decriminalise cannabis without commercialising personal possession and consumption of cannabis, such as Malta who passed laws protecting users from prosecution in 2022, soon to be followed by Luxembourg.

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FEATURED INSIGHT

Rik Niemöller
Perfect Plants

The Advantages of Cannabis Tissue Culture

Perfect Plants is about giving Cannabis growers a competitive advantage in their market. Our company specializes in starting materials from Tissue Culture (TC). We have over 35 years of know-how in creating the best TC starting material which will help growers become much more successful in the global Cannabis market.

There are three ways to start, in growing cannabis. The first is with seed. This can be the cheapest and easiest, but the quality of the plants is not consistent as each seed is slightly different. Even within the same strain there will be differences between plants as they are all brothers and sisters. This lack of uniformity and predictability is not suitable for medical cannabis which needs absolute consistency and stability in order to achieve a reliable result. Starting from a seed cannot guarantee this.

The second method is by taking cuttings from a mother plant, which is currently a popular method. This is however not a sustainable process as the quality of the mother plants will deteriorate over time. The repeated harvesting of fresh cuttings induces a gradual loss of quality of the cuttings taken, and therefore results in lower yields and inconsistent plants. Furthermore, maintaining a mother plant department requires a lot of time, energy and space, which otherwise could be used to maximize the growing of profitable plants.

The third and best option is to start the growth process with tissue culture plants. These plants go through a strict initiation procedure, which takes place in the sterile environment of a laboratory. The cleanest and most consistent results are achieved by starting with Tissue Culture plants, making it the GOLD Standard for any grower, but especially in a medicinal production grade environment.

The European Cannabis Report | FEATURED INSIGHT

Working with tissue culture creates a genetic library that is of the highest biological quality. The cultures all originate from fully virus and viroid tested, carefully selected motherplants. Completed by strict initiation protocols ensuring all bacteria or molds are eradicated from the plants, this guarantees each plant is an exact genetic copy of its clean and tested original mother plant. Through this method Perfect Plants can provide growers with starting material which is totally consistent, tested for viruses and viroids, free of diseases or pathogens.

Recently the cannabis industry has been challenged with Hop Latent Viroid and other threatening pathogens. These pathogens can significantly reduce a grower's quality and yield. Tissue Culture is one of the few proven solutions to combat this situation.

Tissue culture also allows cultivators to reproduce harvests at lower cost than alternatives such as rooted clones or seeds. Tissue culture may cost a bit more to start with, however the quality of plants is much higher and the overall costs of propagation generally end up being lower.

Rik Niemöller, Product Manager Cannabis at Perfect Plants explains, "With diseases being a major issue, we see that cannabis growers are in need of a reliable source of consistent, clean starting materials. Perfect Plants experiences a very high demand for it's cannabis TC.

Cannabis growers have seen the devastating consequences that come from diseases, such as the Hop Latent Viroid. This is a pathogen which is smaller than a virus, hard to detect and easily spread by human interaction with plants. Whole facilities can easily get infected, greatly affecting yields and profit. With tissue culture we have an answer to this, by being able to supply clean stable genetics consistently. Especially for growers attempting to achieve GMP standards, the cleanliness and consistency is highly advantageous."

Perfect Plants receives genetics from some of the world's best breeders. They initiate these genetics into tissue culture and produce rooted tissue culture plants which are complete replicas of a specifically selected mother plant that has ideal properties. These tissues are maintained under strict sterile conditions ensuring a high quality, and mold and pathogen free start. Plants that are grown from TC are consistent to the mothers and are more energetic and vibrant, resulting in uniform harvests and significantly improved yields.

Perfect Plants maintains the highest possible pharmaceutical standards. As reliable and trusted providers of TC, we significantly reduce our partners' labor costs, save valuable growing space with the elimination of traditional mother rooms and deliver it all in a shorter production cycle.

We are the only global, commercial scale producer of Cannabis TC in the world.

Recently, some of our growers have expressed interest in setting up "Satellite" Tissue Culture labs in their facilities. There are significant advantages for a grower to have a satellite lab, operated by an expert company like Perfect Plants. There is a high cost in both equipment and expertise in setting up a satellite TC lab. However Perfect Plants is working on a business model which will

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support this strategy at a reasonable cost by taking advantage of the benefits that the scale of our global production brings.

Perfect Plants challenges the expectation that commercial growers must vertically integrate from "seed to sale". Setting a new global standard with a refined and proven Tissue Culture practice, we have proven that together with our growers, we can all achieve higher productivity, higher yields, and better financial results.

For more information:
Perfect Plants
Rik Niemöller
r.niemoller@perfectplants.nl
www.perfectplants.nl

The tissue culture media being created

Staff working on the cannabis tissue culture

Where the tissue culture is stored until it is ready for shipment

Where the tissue culture is stored until it is ready for shipment

Trends

Medical cannabis

As of 2022, the majority of people living in Europe are in countries who have some form of access to unlicensed medical cannabis products (e.g. flower and oil). However, the reality remains that most find it impossible to reach, either because of bureaucratic or economic hurdles. This situation is improving every year, be it through the introduction of new access schemes, the development of pilot programmes or the gradually evolving access, hard won, as a result of education in healthcare, public awareness raising and lobbying of European regulators.

Only a few countries have really begun to open up access to legal cannabis medications for their domestic patient population while millions of patients continue to use home-grown or street-bought products instead. Germany remains, by a distance, the leader in this regard in terms of legal patient numbers, followed by countries such as Italy, the Netherlands, Poland, Denmark and the Czechia. Many more countries have begun early efforts to increase access either through compassionate access or via pilot programmes such as in France and Ireland. Some countries such as Portugal and Greece have formally legalised medical cannabis but few patients are actively being prescribed, as the regulatory framework is not yet robustly established.

Some large, affluent countries such as Spain and Sweden have yet to really embrace medical cannabis and currently provide no route for obtaining medical cannabis outside of very limited allowances for pharmaceuticals like Sativex and Epidiolex. Several holdouts also remain in Central and Eastern Europe and in large countries like Romania and Ukraine, where conservative attitudes have meant that no single patient is obtaining medical cannabis products other than the few obtaining pharmaceutical products in Ukraine.

In Romania, a bill is being presented to Parliament in 2022 which woud liberalise medical-use cannabis. Alexandra Bivolu-Cârstea, president of patients association Victoria Mea told Prohibition Partners they are hopeful of the bill passing, but much taboo remains in Eastern Europe around medical cannabis e.g. from the Romanian Ministry of Health who have in the past blocked legislative reform.

Many who are new to the industry in Europe question why the number of patients being legally prescribed medical cannabis in Europe remains a fraction of that in North America, even for leading countries such as Germany. Part of this must be understood in the context that **medical cannabis in Europe has developed along a unique trajectory, quite different from its counterpart industry in North America**, or indeed from the CBD and adult-use markets in Europe. In Europe, medical cannabis has remained close to the existing healthcare system with courses of treatment being tightly controlled by regulators as well as the licensing of operators in the market.

This method of control for cannabinoid medicines has several advantages and disadvantages as compared to North America: on the one hand, patients are accessing medical cannabis with, at least, a normal level of medical supervision, obtaining products which have a high level of quality control and in many cases, are supported by national health insurance e.g. in Germany and Czechia. On the other hand, the tight control over prescriptions means that patients often have to contend with extensive bureaucracy to secure approval for the course of treatment and to obtain their medicines. Tight control of production and supply means that limited numbers of producers and distributors can operate in the field, therefore supplying a more limited number of products which means shortages and high prices are common on the continent.

As doctors in Europe rely heavily on the opinion of public health bodies, naturally, statements from these groups can have a large effect on patient access in Europe. In the UK, The National Institute for Care Excellence (NICE) has issued no support for medical cannabis treatment, curtailing, essentially, all public doctors from

prescribing unlicensed products. In the Netherlands, the National Healthcare Institute recommended against medical cannabis treatment, which saw a reversal of the growth in patient numbers after 2018. As a final example, in Belgium, the Committee for Medicines for Human Use recommended against medical cannabis treatment and as such, no unlicensed products are being legally prescribed in the country. Increased research by groups such as Drug Science in the UK are building the body of evidence which may at some point convince these institutes of the benefits of regulating medical cannabis products.

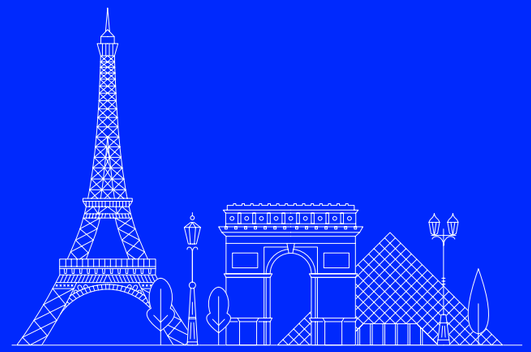
Pilot trials

Underlining the cautious approach Europe is taking to the liberalisation of medical cannabis are the pilot trial access schemes for medical cannabis currently in operation across several European countries including; Denmark, France, Ireland and Luxembourg. The purpose of these trials is explicitly to investigate the controlled distribution of medical cannabis products in each country and to assess the harms and benefits of such systems in their domestic settings. The trials are initially time-limited with a view to appraisal at the end of the trial period and the chance for further, more permanent developments. In reality, the purpose of these trials is also to soothe the worries of conservative regulators and politicians in Europe who would not agree to full initial legalisation but can accept this gradual implementation. Each of these trial access schemes made significant progress throughout the course of 2021 and they are showing early promising signs.

FRANCE

France approved a two-year pilot programme in 2019 which officially began on the 26 March 2021, after considerable delays due to the global pandemic, among other issues. The pilot access scheme in France is intended to treat 3,000 patients over the period, for conditions including neuropathic (chronic) pain, painful spasticity in multiple sclerosis, epilepsy and general oncology.

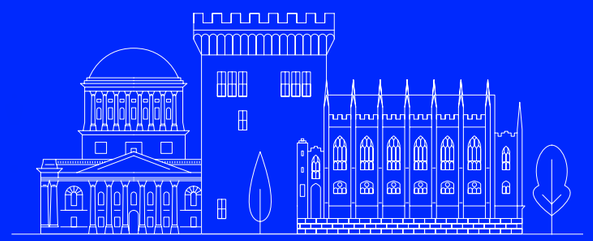
In the words of a spokesperson for the Ministry of Solidarity and Health, the results of the trial will allow regulators, 'to determine the framework that could be put in place for the creation of a system for the prescription and dispensing of such drugs in France' in case, 'it is desirable to introduce these drugs for use in common law'. The trial has several novel aspects which make it interesting, for example, medicines must be provided free of charge to patients from the six suppliers providing nine specific products overall to be distributed by six French pharmaceutical distributors. As of February 2022, 1,218 patients have received their initial treatment, with over 200 hospitals and 1,100 doctors signed up to participate in the experiment.



IRELAND

Ireland approved their five-year pilot programme in June 2019, and launched it in July 2021 with the first patient receiving medical cannabis in September of that year. The scheme will run for five years and has a similar purpose to the French trial, but it is more limited in scope, allowing only senior doctors to prescribe to patients for only the following conditions: spasticity associated with multiple sclerosis, intractable nausea and vomiting associated with chemotherapy and treatment-resistant epilepsy.

The scheme supplements the access via ministerial approval which saw just 67 patients treated up to the launch of the pilot scheme. Just six products from three producers are available on the scheme as of February 2022. All costs can be covered for patients on a case-by-case basis. The limited set of doctors prescribing medical cannabis and the five-year horizon for reappraisal means this scheme does not show promise that a permanent solution to cannabis access will be set up in Ireland in the short term.

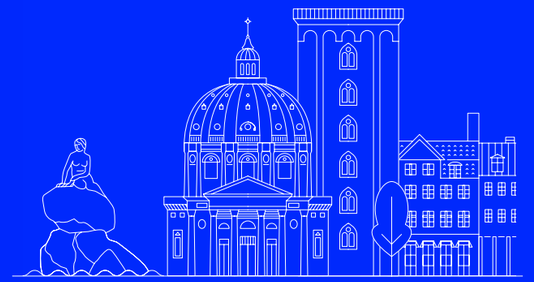


The European Cannabis Report | TRENDS

DENMARK

Denmark is home to the most well established medical cannabis pilot programme in Europe. Begun in January 2018, the programme currently serves around 500 unique patients per quarter in Denmark.

The scheme was initially conceived as a four-year project but in May 2021, a majority of parliament voted to extend the lifespan of the project for another four years, and it is now set to last, at least, until 2025. The trials allow any doctor to prescribe medical cannabis from a list of five flower and full-spectrum oil products for the following conditions: painful spasms due to multiple sclerosis or spinal cord injury, nausea after chemotherapy, and crucially, neuropathic pain, though some leeway is given for other conditions. Patients within the trial scheme have 100% of their costs covered by the government if their condition is terminal, and 50% in other cases. The pilot scheme has struggled since the CannTrust scandal and the instability of the supply of oil products which meant that many patients left this access pathway. In addition, it competes with a system of magistral distribution where medical cannabis isolates can be prescribed and bought at pharmacies.



LUXEMBOURG

Luxembourg authorised a two-year pilot trial in 2018, which began in February 2019. The scheme was due for appraisal early in 2021 but, at that point, a six-month review of the success of the treatment with patients had begun.

The scheme allows for any doctor to provide medical cannabis oil and flower from a restricted set of medicines and specifically for cancer-related conditions, palliative or chronic pain conditions and those related to multiple sclerosis. As of February 2022, a new appraisal of the scheme is in process and it is expected to be published soon. The scheme allows for full coverage of costs by the Ministry of Health. The latest data indicates 600 patients were prescribed medical cannabis in 2020, meaning Luxembourg has almost as many legal prescriptions per population as the leader in Europe; Germany.

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The amount of cannabis being exported from the Netherlands has not increased substantially since 2019

Supply chain

Imports to Europe

In 2021, there was the continuation of the decline of the duopoly over cannabis production held by Canada and the Netherlands, with the effects being visible in Europe more than anywhere else. These two countries were able to establish dominance in medical cannabis distribution mostly by virtue of having legalised medical cannabis a decade or so before other competing regions. This meant that producers like Tilray in Canada and the sole producer in the Netherlands, Bedrocan, had the opportunity to develop robust production systems. Aspects of these systems include: producing consistent genotypes and phenotypes in proprietary plant strains; large-scale production sites with efficient and compliant procedures and the reputation with regulators that comes from repeated passing of audits and spot tests.

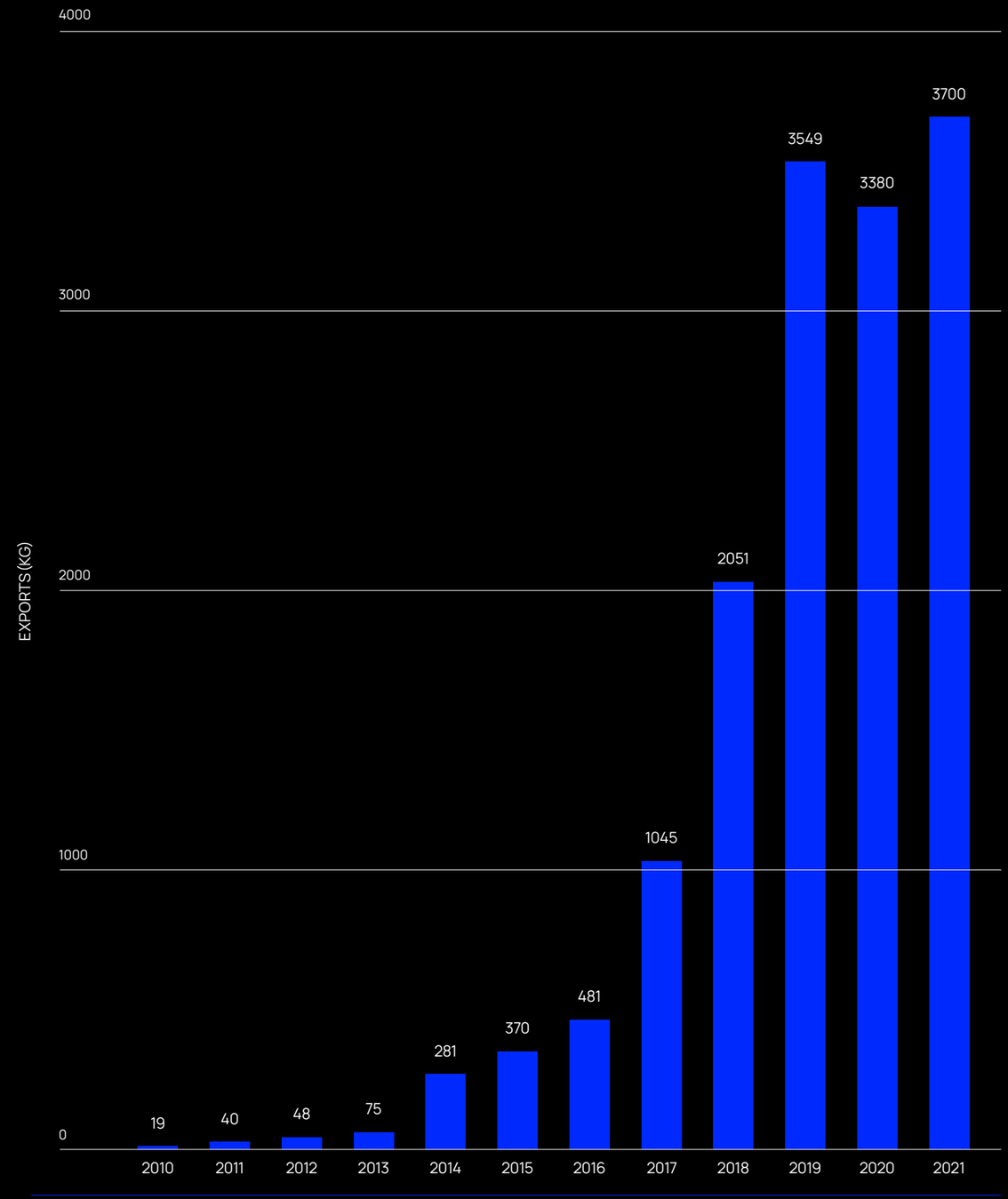
However, medical cannabis is now legal in many more countries around the world, and the lessons learned in early markets are being passed on to the new markets to enable producers to achieve scaled and compliant production in shorter and shorter time periods. While the market is leaning away from the geographic duopoly of the Netherlands and Canada, it should be remembered that much of the production is being shifted to new locations e.g. in Portugal and Denmark by large Canadian operators like Tilray and Aurora, meaning the same companies retain much of the market share.

Below, we review some exclusive and some public data detailing this evolving situation.

Dutch exports continue to stagnate

Prohibition Partners received an exclusive update from the Office of Medical Cannabis in the Netherlands which documented the quantity of product sold to domestic pharmacies and to foreign clients. The data showed a continuing trend, first reported on by Prohibition Partners in 2021, that the amount of cannabis being exported has not increased substantially since 2019. This raises the question; is there less demand for Dutch cannabis or is production not keeping up with demand? The answer probably lies with both.

Exports of Dutch medical cannabis flower



Source: OMC, Prohibition Partners

The Office of Medicinal Cannabis (OMC) has indicated to Prohibition Partners that the potential cause of the slowdown in exports from the Netherlands is related to the COVID-19 lockdown and disruption to the supply chain. This agrees with reports from various distributors and patient groups around the country who received word that production had been disrupted at Bedrocan during the lockdown.

It is worth remembering **the Dutch OMC is not intended to make large profits by exporting to many countries** on a long term basis. Their 2012 export directive dictates that countries should have a cap of 100 kilograms of exports per year, only enough so that they have time to set up their own production systems. Thus, the limit on growth of exports is in part by design. However, the OMC is aware that it may now lose out on sales to current clients, as the competition from international producers is heating up rapidly.

Medical cannabis production chain in Netherlands

Office of Medicinal Cannabis

↓

Production
^
bedrocan®

Control
^
OFICHEM GROUP

Packaging
^
Fagron

↓

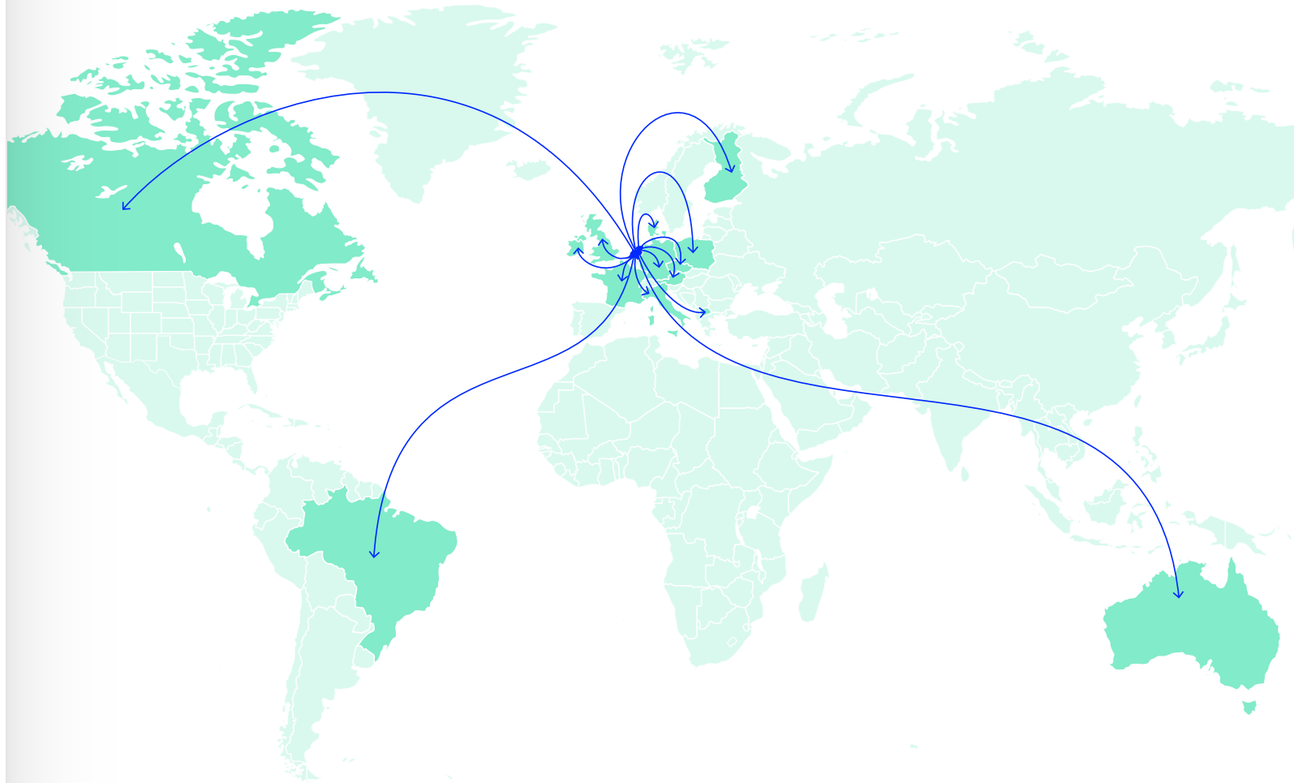
Research
Pharmacies
Export

Source: Bedrocan explanation of the medical cannabis supply chain in the Netherlands.

For now, the Netherlands remains the second most prolific exporter of medical cannabis in the world behind Canada, exporting to at least 14 countries as of mid 2021, with smaller shipments to many other countries for individual patients and research purposes. In 2020, 65% of exported Dutch flower was sent to Germany, with the possibility that more was sent via other countries.

More exports should be expected though, with the appointment of two tenders currently being awarded for 5,000 kilograms production per year each (see section on domestic production).

Location of medical cannabis exports from the Netherlands as of 2021



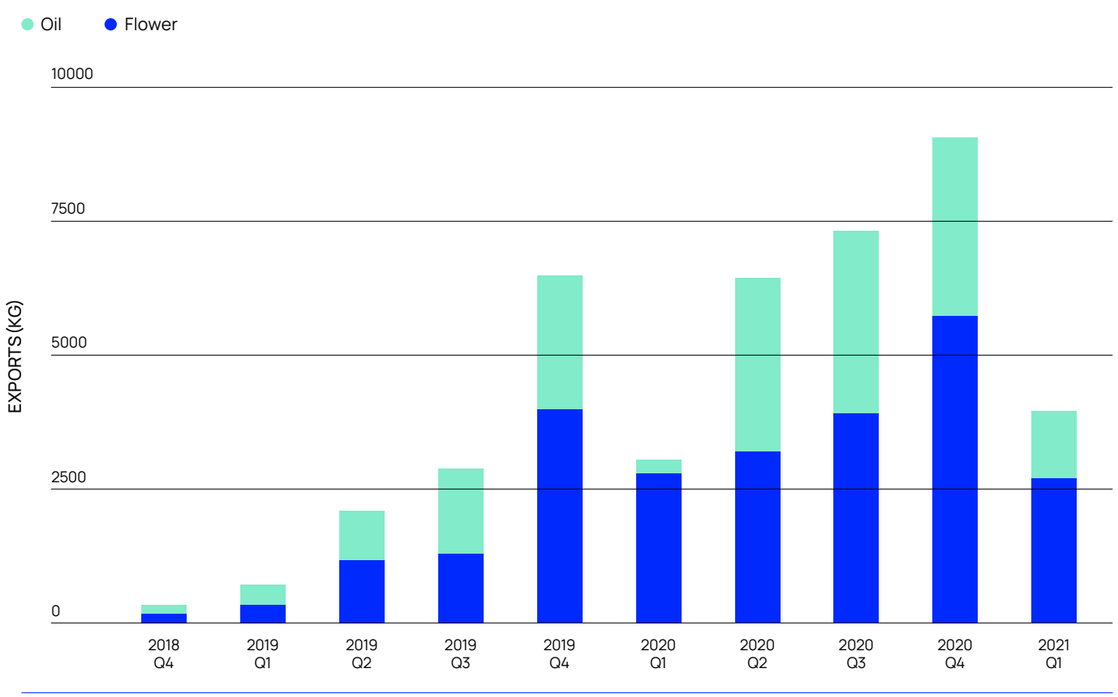
Source: Dutch Parliament (2021), Prohibition Partners

Canada remains the largest exporter to Europe

Canada is the single largest exporter of medical cannabis in the world and will remain so for the foreseeable future. Canada operates a free-market model for licensing and production in the country, with over 86 active pure-cultivation licences at the time of writing with many more mixed cultivators/manufacturing licences as well. Many states in the United States operate similarly open policies to production licensing for medical cannabis, but the illicit status of cannabis at the federal level means none can be exported in the same way that Canadian production can.

However, similar to the Netherlands, the threat of foreign production and the increasing trend for domestic production means that the growth seen up to 2021 may not continue. Already, 2021 was a slow quarter for the export of medical cannabis.

Exports of medical cannabis from Canada



Source: Health Canada, Prohibition Partners

In 2020, Israel was the largest importer of medical cannabis in the world, and the primary importer for Canadian cannabis, followed by Germany and Australia. Q1 of 2021 was a particularly poor quarter for Canadian cannabis exports. The reduction in exports from Canada can be mostly attributed to new rules in the Israeli import regulations around the Good Manufacturing Practices (GMPs) status of imports and the testing before release to the market, which caused large delays for many Canadian operators. The rules were relaxed in H2 of 2021 and statistics, from that point on, are likely to show a continuation of the 2020 trend. However, as seen below, there are now many countries vying to compete with Canadian exports, especially for Israeli and European buyers.

Shortages

The medical cannabis ecosystem in Europe is developing at a rapid pace, but is showing signs of growing pains, as inefficient regulation and supply chain development see frequent product shortages in several countries on the continent. This is especially true of several countries with highly centralised control of production tenders. This is a familiar story for many operators in North America, where intermittent shortages have been a consistent challenge for newly legalised markets. Currently, it is much more common for North American jurisdictions to run a surplus of adult-use cannabis. Medical cannabis shortages these days are mostly reported where a new adult-use market opens up and producers switch to this more lucrative market, leaving shortfalls in medical supply.

As reported in our recent Global Cannabis Report 2nd Edition™ and later in this report, the supply of compliant medical cannabis from around the world is developing steadily, both in quantity and variety. There is probably enough cannabis, currently being produced globally, to supply the current patient population that is legally accessing medical cannabis in Europe. Despite this, a variety of factors mean several countries are experiencing common shortages with some examples laid out below. Common threads are:

1. Production and distribution being controlled by tender with insufficient tenders being offered (e.g. Poland, Italy).
2. Sluggish regulatory approval e.g. for product approval and production/distribution licences(e.g. Poland).
3. Operators finding it difficult to navigate bureaucracies surrounding medical cannabis (e.g. Poland).
4. Limited numbers of products being approved meaning shortages in one product affects many patients, this is especially true of Dutch Bedrocan products (e.g. Malta, Poland).
5. Relatively low prescription numbers means operators have not established robust supply chains (e.g. Luxembourg, Malta).

As inefficient regulation and supply chain development see frequent product shortages in several countries on the continent.

Product shortages in Europe

ITALY

In Italy, supply shortages have been a frequent aspect of the medical cannabis supply chain since inception. The Italian government tenders all production in the country, and has only granted five companies with a licence to distribute. The country relies heavily on imports from the Netherlands, which have flagged throughout 2021. Alongside this, the military is tasked with the only ongoing domestic production, but it has been unable to supply sufficient quantities over recent years. As of February 2022, shortages are reported in 12 of the 20 municipalities in Italy, though this number hovered around 17 for much of 2021.

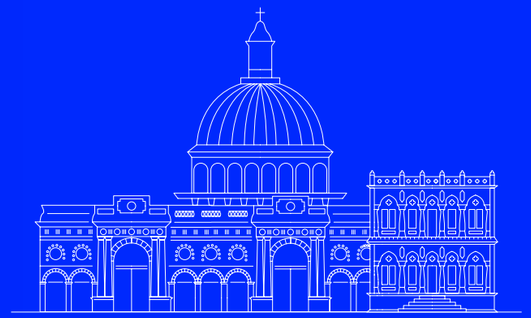
Dr. Ternelli, founder of Farmagalencia and advocate of medical cannabis in Italy told Prohibition Partners; 'An emergency tender is currently being offered which will, at best, meet the demand for a single month. A more permanent tender is rumoured to be on the way, as are more distribution licences, but it is unclear when these will be implemented. These shortages are completely predictable, and could have been dealt with by opening up licensing years ago, this will be welcome, but is long overdue'.

POLAND

Poland is one of Europe's fastest growing medical cannabis markets but patients there are often subjected to product shortages. Prohibition Partners reported late in 2021 on a months-long supply drought, where patients were unable to consistently obtain Aurora or Canopy Growth products in the country. When a 140 kilograms delivery arrived, it was used up within two weeks. The Polish government has approved just six products, of which only two are available in pharmacies as of February 2022. Maciej Konarowski of leading Polish cannabis legal firm, Can Advocare told Prohibition Partners that Polish regulators are currently processing 20 applications for new products, of which six have already been withdrawn by the producers.

MALTA

In Malta, the government has also approved only seven products. As of January 2022, four of these were completely out of stock across the country. The country has a reliance on Bedrocan imports which have been in short supply for months at a time during 2021. Andrew Agius, a Maltese specialist in cannabis treatment has told local media; 'The suppliers didn't realise what a huge demand Malta has for medical cannabis and went out of stock soon after products became available'.



LUXEMBOURG

Luxembourg suffers from similar problems to Italy, Poland and Malta in that a limited number of approved products has left the supply chain vulnerable to shortages within the small set of available strains. A parliamentary response in November 2021 revealed that one of two strains available in the country was completely out of stock at that time. The Ministry of Health placed the blame for the shortage at the feet of the producers, Tilray, for not sending adequate supplies.

EXPERT INTERVIEWS

Greg Dobbin

Chief Executive Officer
4C LABS

Let's start with a brief description of what 4C LABS does and why you and your team started the company.
We launched 4C LABS in 2019. Many of our team were directly involved in the development of the Medical Cannabis industry in Canada, as well as globally.

We founded 4C LABS because we believe that there is massive untapped therapeutic potential in cannabis based medicines. As a company we are very much driven by technology, clinical research, as well as practically changing the lives of patients for the better. This is very much reflected in the team of data scientists, clinical research experts and physicians we have assembled over the last few years.

Finally, we believe that regulated medicinal cannabis should be legally and easily accessible, via prescription, to patients in the UK – including children with epilepsy. This was the driving force behind us seeking a full medical cultivation license which was granted at the end of last year.

What stage are you at right now in setting up the operation?
We recently started our first capital raise to continue the development of our facility, as well as launch our virtual clinics and 4C product line. We anticipate our clinic and first suite of medical products will launch in Q3 of this year. While our high-tech cultivation facility in Guernsey will come online in 2023.

Why are you vertically integrated?
Vertical integration is the only way to obtain supply chain stability in this industry. As the industry evolves and patient numbers rise companies have to be able to address the supply chain pressures that will be created by increased demand.

Is tech important in this space?
Innovations in cultivation and IoT technology for facilities, as well as gathering clinical data are everything as they replace anecdotal evidence with a scientific approach to medical cannabis. Technology also drives improvements in the care that patients receive via virtual clinics, as well as our ability to understand what medicines work and why. Based on this technology underpins 4C LABS' virtual clinic workflows, cultivation, clinical research and entire supply chain.

On the cultivation side, 'crop steering' is the future. Crop-steering basically means we can gather data points from every single cultivation variable such as temperature, humidity, light intensity, soil conditions etc and then based on laboratory analysis of finished products replicate our most successful outcomes through automation.

What are some of the difficulties in the sector?
Banking is tough, we have corporate accounts at Barclays. The relationship took over a year to develop and we are very pleased to have Barclays as a partner going forward.

Compliance is also tough. We have been fortunate enough to secure a compliance team whose understanding of the sector is unparalleled as evidenced by their success in bringing over half a dozen international facilities online.

Why the UK?
The UK offers one of the best regulatory environments for Medical Cannabis in the world and sits on the doorstep to the EU. There are also a lot of endemic problems to be solved for patients and doctors and this offers an opportunity to enterprising companies.

The European Cannabis Report | EXPERT INTERVIEWS

How do you see the market for medical cannabis developing in the UK over the next 2-3 years?
In all likelihood UK market growth will mirror that of jurisdictions with similar regulatory frameworks.

Based on this, the existing 15,000 patients in the UK could conservatively reach 650,000 patients in the next seven years. This would imply a minimum gross market size of $1b USD.

By way of example, Canada's patient population went from zero to 370,000 patients in five years, or 1% of Canada's total population. The State of Florida has similar medical cannabis regulations to the UK. The Florida market has grown to over 440,000 patients in five years.

Where do you see the investment opportunity?
There are distinct opportunities when it comes to clinical research, cultivation, supply chain stabilization and investment in digital technologies.

In the last six months a number of companies have listed, or taken funds privately and there has been a recent uptick in interest in UK medical cannabis companies. We believe that our model offers a great opportunity to participate in this market.

Are there any concrete examples that support your investment perspective?
We have seen Akanda recently list on the NASDAQ and create a valuation north of US$200m. Celadon has also floated on AIM and at a valuation of £89m shows an increase in investor interest in the sector.

US investors are currently paying approximately 10 X sales for established companies, we expect the same to hold true for UK companies that capture market share.

Any other thoughts?
No, I think that covers it. Many thanks for the interview and I look forward to speaking again in the near future.

For investor inquiries or more information about 4C LABS contact greg@4CLabs.ca or https://4clabs.co/investor-relations/

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MODEL

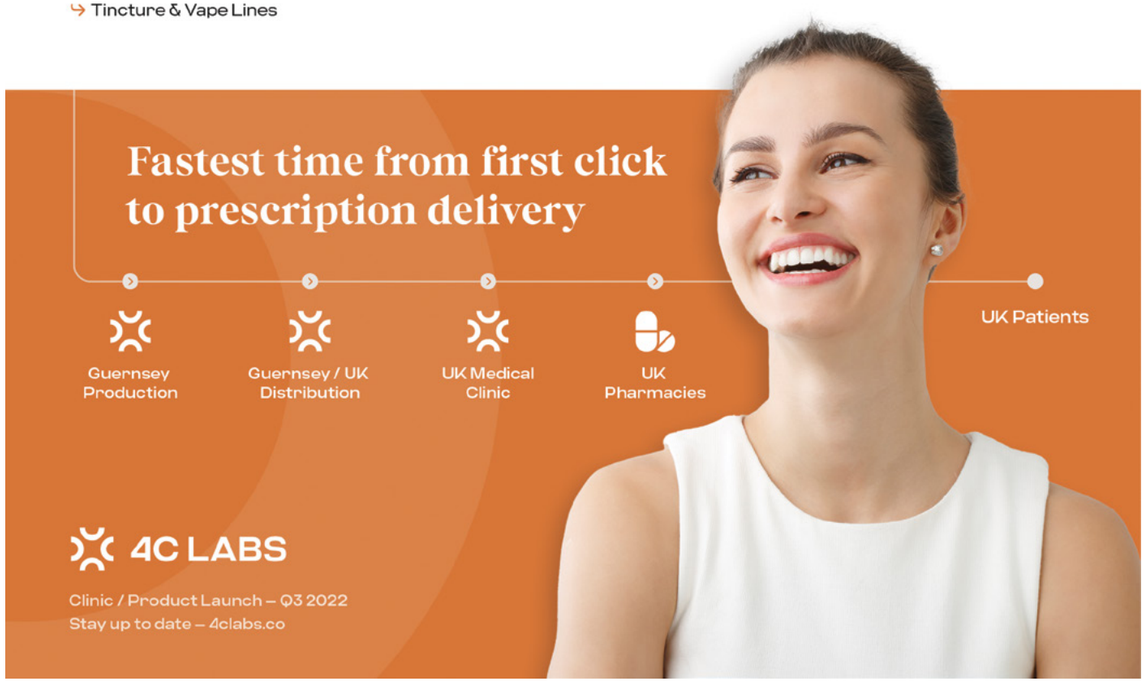
UK Specialist Medical Clinic
Guernsey Production + Distribution
UK Distribution Facility
↳ Craft & Premium Flower
↳ Tincture & Vape Lines

SYSTEMS

Step System™ Prescribing Framework
Step System™ Product Line
Colour-matched packaging
Best-in-class IT

MISSION

To deliver Craft
Medical Cannabis through
user-friendly technology



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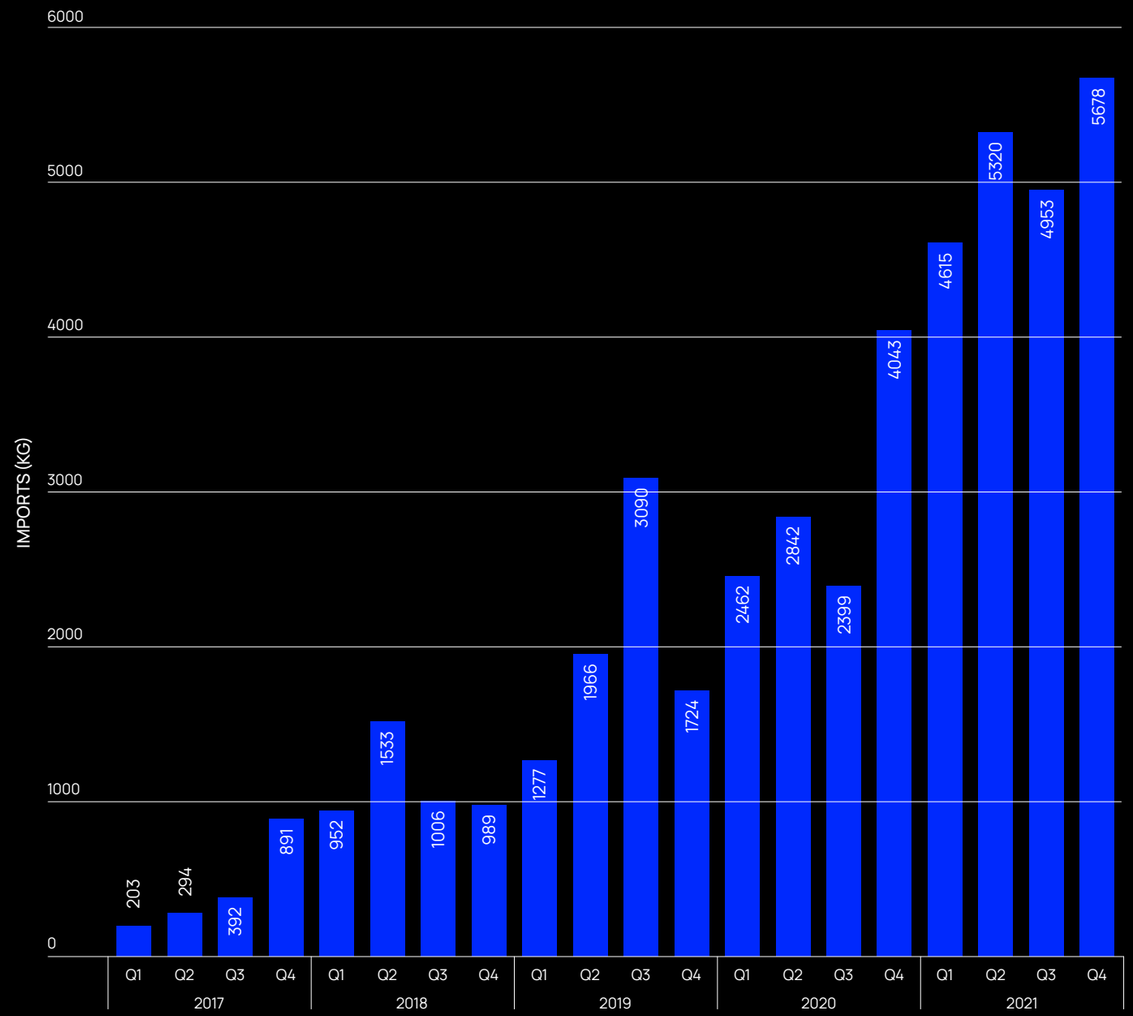
Imports to Germany

Imports to Germany have been increasing steadily since the inception of the market in 2017, on average, almost doubling each year up to the end of 2021. The German government operates a relatively free system of licences and product and import approvals, meaning any shortages that existed at the inception of the market have been overcome. Temporary shortages in product lines can also, in most cases, be substituted with another product of similar active ingredients and equal quality. The official statistics of the Federal Institute for Drugs and Medical Devices (BfArM) include some cannabis which is imported and subsequently re-exported but overall, it is clear that the trend is increasing.

Medical cannabis imports to Germany



Source: BfArM, Prohibition Partners

Note: data covers both extracts and flower

German imports of medical cannabis H1 2021

Canada	116	2882
Netherlands	-	1989
Denmark	2	1730

Portugal	426	1157
Australia	262	485
Uruguay	-	358

Spain	13	165
Austria	-	142
Colombia	97	-

Israel	58	-
Poland	-	50
Jamaica, N.Macedonia, Malta, Switzerland, Lesotho, New Zealand	6	7

Source: German Ministry of Health, Prohibition Partners

Operators from an increasing number of countries around the world are now exporting to Germany and elsewhere in Europe. This includes locations as disparate as Uruguay, Australia, Denmark and Uganda. In September 2021, the Health Ministry of Germany released data pertaining to the imports of medical cannabis per country. This showed, for the first time, the number of countries importing to Germany and the quantities of each. **Seventeen countries are recorded as having exported medical cannabis to Germany throughout the course of H1 2021.** While several countries only exported small quantities in these six months, the data still shows that the link in the supply network has been established and can be expected to grow in most cases.

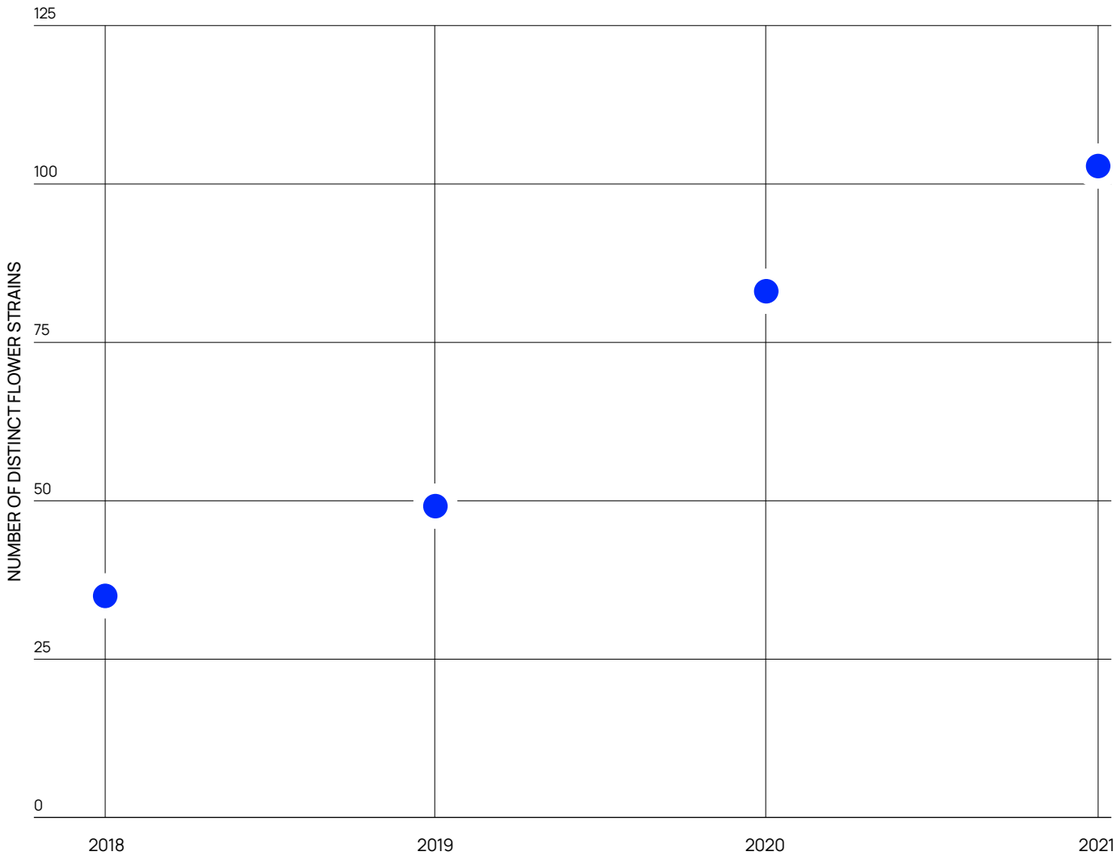
All medical cannabis in Germany must be EU-GMP compliant which legislates for a high standard for production and the testing of medicines. It takes time to construct the capabilities to produce at this level, and longer to obtain the certification via an inspector from the European Union (EU) or a proxy from domestic regulators. Part of this bottleneck has been avoided by companies who export medical cannabis to Germany from a variety of locations, and who produce to local standards. The cannabis is then processed in an EU-GMP compliant manner, making it suitable for the German and European markets. As one example, native German company Cantourage specialises in this manner of importation, thereby helping to increase the product variety for patients in Germany while opening the opportunity offered by the German cannabis markets to producers in many new regions.

Increased competition in Germany

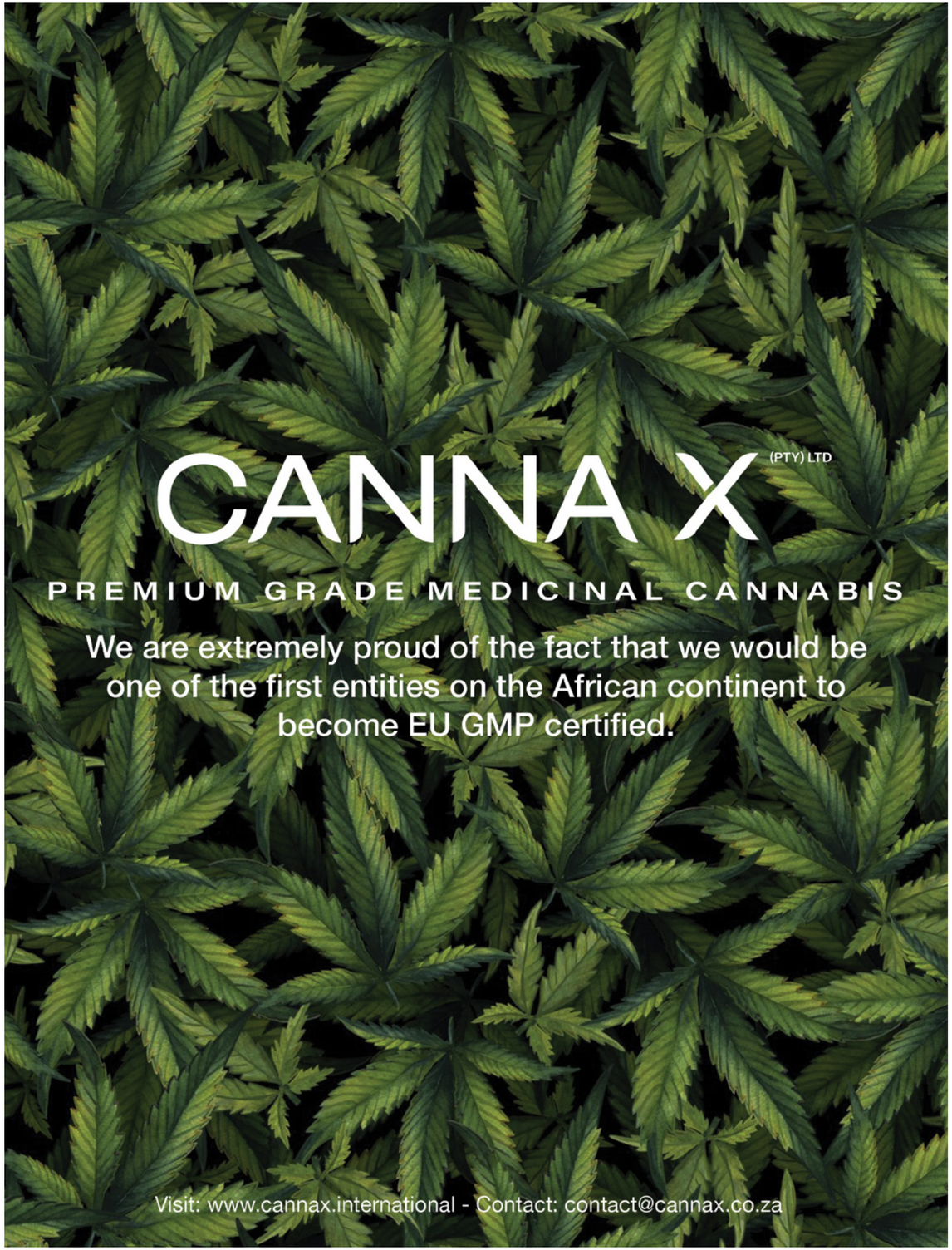
The price of medical cannabis across Germany has been on a decline since its inception in 2017. For several years, much of the medical cannabis flower in German pharmacies has been sold at a price of ~€20 euro per gram, roughly twice the wholesale price and several times higher than the price of the same strains in North America. This was understandable in the context of a scarcity of the medicine and the fact that regulators and public health associations were unprepared to accommodate this new product and control its price. Suppliers who had to meet heavy compliance burdens and pharmacies who felt vulnerable dealing with this new unlicensed medicine both took some liberties in charging a premium for products. However, as more and more suppliers have joined the market, and regulators have had the opportunity to grapple with this new product, prices are gradually coming down, to the benefit of patients and insurance companies.

As can be seen in the chart below, an increasing number of medical cannabis flower strains have become available in Germany, increasing the variety available to patients, but also decreasing the margins at which cannabis can be sold to pharmacies.

Number of medical cannabis strains in German pharmacies



Source: www.cannabis-aerzte.de, Prohibition Partners.



EXPERT INTERVIEWS

Warren Haviside

CEO
CANNA X

Unlocking Africa

Can African based companies meet the regulations and standards required to supply the EU market and if the stability within the political landscape poses any barriers to entry into the European market?

We caught up with CANNA X CEO, Warren Haviside who tackled some of these issues and believe his company, have the necessary geographic placement, team and strategy to overcome all of these challenges.

Tell us a bit about CANNA X and what will set you apart from other players on the African continent?

CANNA X is a start up, owned by 3 individual shareholders and is 100% self funded. Our journey started a few years ago. We've done extensive research, strategic planning and engaged with industry leaders both here and abroad to ensure that everything we commission in terms of our cultivation facility and processing facility meets the requirements of international markets. Most South African and African based entities are satisfied with being GACP certified, but we identified from a very early stage that becoming EU GMP certified was absolutely critical and would be a massive differentiator that would set us apart from other players on the African continent.

Do you think the certification you will obtain will be in line with the appropriate standards expected in the European and international market?

Our facility, which also includes a solar installation capable of generating 1mva worth of power (capable of powering our entire facility) will be completed by May 2023 and will undergo an inspection from the South African Health Products Regulatory Authority (SAHPRA), where we will be granted a GACP license, which will allow us to grow, cultivate and export medicinal cannabis. We are of the opinion, however, that this is a good starting point, but not satisfactory enough for where we want to take this business. That is why we will be embarking on ensuring that we obtain EU GMP certification. We are extremely fortunate to have people in our team that have walked the path of successfully obtaining EU GMP certification, which gives us a huge amount of confidence in the fact that we are not only on the right path in terms of our strategic thinking, but also have the necessary qualified people in our team to ensure we obtain our EU GMP certification. As you can tell, for us, being in line and on par with the appropriate standards expected in the European and international markets, is non – negotiable.

What is the South African governments' stance on the regulation around the cultivation and export of cannabis?

The first licenses to commercially grow cannabis in South Africa were issued in 2017, so the industry here in terms of being able to commercially grow cannabis is almost half a decade old. Our confidence has been boosted exponentially by the recent State Of The Nation address, by our President Cyril Ramaphosa in February 2022, where he publicly made it a top priority to fast track the growth and processing of cannabis in South Africa, as well as tie up any regulatory loose ends to ensure the industry is propelled onto the international main – stage. This is obviously great news for us.

Inspection is often delegated by European Authorities to local institutions, so there needs to be international trust in the national auditors and this is not always the case, what is your take on that?

The SAHPRA license is a GACP license, which belongs and falls within the guidelines of PICS (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme) So, from that stand point we feel very confident that international authorities can feel extremely comfortable with the level of our auditors and the process.

As in Europe, there is not a long history of cultivation in Africa, and some operators may be unsure that the companies in Africa have had the time to adapt to the know – how from established cultivars to produce premium products?

Our lead grower who has over a decades' experience, spanning from a few years in California to having successfully grown for about 3 licensed facilities here in South Africa. We are in the late stages of negotiations with the likes of a Canadian based, global

player (listed on the New York stock exchange) who intend partnering with us on genetics. Having being in the industry for over 15 years and being one of the biggest global players – we have full confidence in the fact that our world class facility, the experience of our team and the consultation and support we are receiving from partners abroad will ensure we meet the needs to produce premium product on a consistent basis.

Where to from here for CANNA X?

We are focusing our energy on the build of our facility and have various international trips planned to meet with potential partners. We will also be attending Cannabis Europa on 28 – 29 June 2022 and will have an exhibition booth at the event, so please feel free to come and meet us, or alternatively visit our website www.cannax.international should you wish to be in touch with us.

These numbers reflect the strains listed on cannabis-aerzte.de at the end of each year. It is possible that more strains went unlisted on this site as in 2022, Prohibition Partners are aware of 138 strains in total.

One major event in the price control of cannabis medicines in Germany is the agreement between the German Pharmacists Association (Deutscher Apothekerverband, DAV) and the National Association of Statutory Health Insurance Funds (Spitzenverband der Gesetzliche Krankenversicherung, GKV) reached in Spring 2020. Under this agreement, public insurers agreed to a set price at which they would reimburse pharmacies, in order to reduce the costs for insurers and by proxy, the taxpayer. he GKV now pays a set price per gram, depending on the size of the order of medical cannabis, for example, a 10 gram prescription costs €19.04/g whereas a 100 gram prescription costs €13.32/g. This incentivises pharmacies to purchase cannabis at a lower price from wholesalers, affecting both of their margins.

Another, more recent phenomenon is the agreement of open tenders between insurance firms and medical cannabis producers, where the insurers have agreed to insure certain medical cannabis products under certain conditions; if the producer offers a discounted price. The discounts are reported to be in the double-digit range, though specifics are not being widely shared. This has the potential to seriously impact the margins of distributors and suppliers in the European market, and could prompt some consolidation. Another important criterion is the holding of a narcotics manufacturing licence, which precludes many current suppliers in Germany. Towards the end of 2021, several German companies announced that they had already reached such agreements with insurance firms and now at least seven producers have made these deals including; Stada, Adrex, Cannamedical, Remexian, CanPharma, Eurox and Pohl-Boskamp. At least three public insurance companies have offered these open-ended tenders, but several of the largest ones have not yet done so.

Discount agreements are a common strategy for generic medicine producers in Germany, and are legally, usually, only applicable to such medications. Producers argue that this will help to shore up the roughly 33% of cases where patients are refused reimbursement for medical cannabis. However, some argue that this unfairly restricts the options for doctors and patients, as insurance firms are much more likely to reimburse products under such agreements. Whether these agreements are legal will be a matter of legal debate; the legal basis for them relates to generics, but many argue that the variety of active ingredients in cannabis means that patients cannot switch between products as they would with generics, and so they should not be treated similarly under law.

Domestic Production in Europe

Europe has relied heavily on imports of medical cannabis from Canada in the early years of medical cannabis regulations, however, there is an increasing trend towards cultivation within European borders and in countries beyond that of just the Netherlands. There are several reasons for this phenomenon. Firstly, most countries in Europe strive for a high level of control over medical cannabis products. In theory, this allows regulators an extra level of protection in terms of continuity and consistency of supply. This leads to the system of limited tenders such as the important markets of the Netherlands and Italy as well as countries who tender production but are open to imports, such as Germany and Cyprus. Another major reason for the shift from imports to European cultivation is the individual choices made by North American firms. In particular, Tilray and Aurora, have shifted much of their production for Europe from the Canadian facilities to Europe. Denise Faltischek, Chief Strategy Officer and Head of International at Tilray told Prohibition Partners of several reasons for this, including:

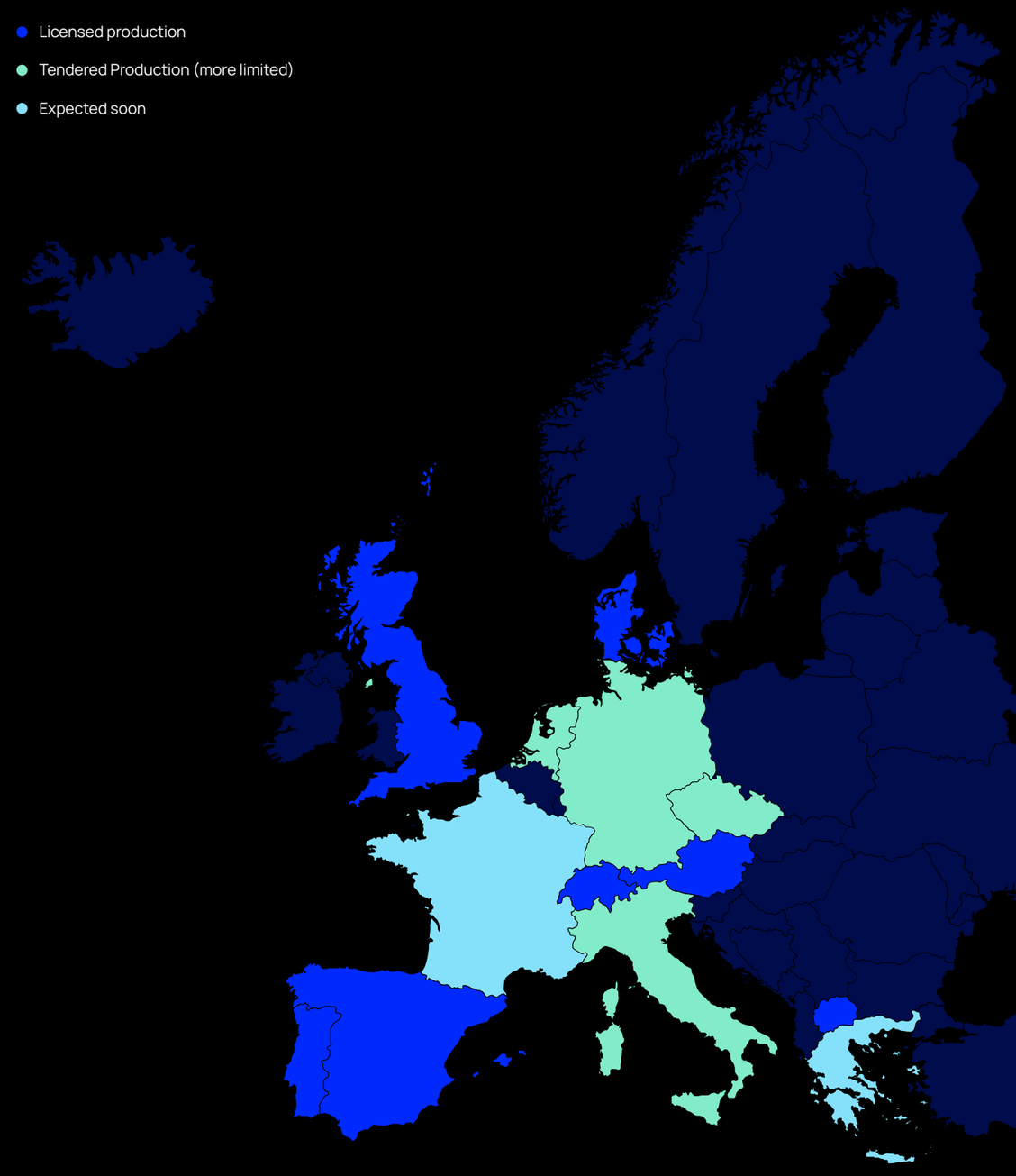
- Solidifying relations with regulators by investing in European assets and allowing for increased transparency in production.
- Shortening the supply chain which has several benefits for the quality of product and its shelf life as well as the environment.
- Taking advantage of more workable licensing systems e.g. in Portugal as compared to Canada.

There is also a long-term financial advantage for cultivating medical cannabis close to the site of consumption, as transport and the associated bureaucracy can be costly. In addition, the inputs such as land, labour and services can be cheaper in southern European countries such as Portugal, but also in other emerging production hubs like Malta and North Macedonia. **Operators in at least 15 European countries are now permitted to cultivate for commercial purposes in Europe, with more expected soon.**

The Netherlands

The Netherlands is currently in the process of increasing their production capacity and diversifying their supply. Up until 2022, only Bedrocan had been licensed to produce medical cannabis under a tender from the OMC. The tender between Bedrocan and the OMC is now concluded, so the government is introducing two new tenders, each at a capacity of 5,000 kilograms per year to two growers. Five selected shortlisted companies are currently producing test crops which will inform the government's final awarding of two tenders soon, though no dates have been made public.

Countries in Europe allowing medical cannabis cultivation



Source: Prohibition Partners, March 2022

FEATURED INSIGHT

Gabriel Newman
Cantourage UK

The Cantourage Effect

Transforming the pharmaceutical pathway for cannabis medicines in Europe

The founding team behind Cantourage have been trailblazers within the European medical cannabis sector since its inception. In 2015, when the total medical cannabis market in Germany consisted of around 250 patients, Dr Florian Holzapfel and Patrick Hoffmann founded Pedanios GmbH, Europe's first pharmaceutical wholesaler specializing in medical cannabis. To this day, Pedanios is one of the most widely distributed medical cannabis brands in Europe. Pedanios facilitated the German imports from Canada in 2016, enabling 5 EU-GMP certifications from the German authorities across Canada and Europe along the way. Pedanios, now formally known as Aurora Europe, was acquired by Aurora Cannabis Inc. in 2017.

In 2019, Dr Holzapfel, Hoffmann and Norman Ruchholtz founded Cantourage GmbH to be the first company to provide the European medical cannabis market with innovative and novel cannabis flowers, sourced from best-in-class LPs (Licensed Producers) from around the globe.

In July 2021, the team developed and implemented a groundbreaking operating model to broaden the potential for sustainable cannabis supply chains to be introduced into the European market. The 'Fast Track Access Platform' was designed to expediate the traditional complex and lengthy route to market. Cantourage prides itself on supporting licensed cannabis producers through the process of launching medical cannabis products into the European ecosystem. To date, Cantourage has 20 long-term strategic partnerships with cannabis cultivators, with many more currently undergoing their Quality team's comprehensive vetting processes.

The 'Fast Track Access Platform' consists of LPs from 14 different countries, the likes of Jamaica, Uganda, Portugal, Saint Vincent and the Grenadines, New Zealand, and Canada to name a few. The team at Cantourage envisage a symbiotic relationship with all their cultivation partners. An efficient pharmaceutical supply chain when handling herbal medicine plant materials such as cannabis is an intricate task. Cantourage allows partners to focus on what they do best, cultivating the highest quality cannabis. Cantourage takes care of the rest:

- necessary product registrations in multiple jurisdictions across Europe
- EU-GMP manufacturing in Germany, "Made in Germany" stamp of approval
- accomplished Quality team guides LPs through all necessary regulatory and compliance hurdles to enter the European medical cannabis ecosystem
- state of the art warehousing solutions offers real-time inventory management, ensuring stable supply for patients and optimized supply chain efficiency for partners
- sales and distribution via in-house pan-European infrastructure and long-standing partner networks

This presents LPs with a bona-fide opportunity to shift their supply chain solution to drive growth and save unnecessary capital expenditure by leveraging a cost-effective, asset-light alternative to contemporary global pharmaceutical supply chains.

Cantourage manufactures a broad spectrum of medical cannabis products at their GMP facility in Germany. Their product portfolio covers: Dried flowers, Extracts, Cannabidiol API and Dronabinol.

Cantourage is poised to offer one of the most diverse medical cannabis product portfolios in Europe consisting of dried flowers, extracts, Cannabidiol API and Dronabinol. With this extensive catalogue of EU GMP certified cannabis products, companies across the value chain are currently relying on Cantourage to deliver tailor-made private label solutions. The company's experienced marketing teams assist in creating compelling brands, developing education and communication materials for patients and prescribers, acting as the link between cultivators and patients. Cantourage boasts the opportunity for partners and clients to enter the multiple EU cannabis markets under a brand of their choice in 3-6 months, benefitting from the company's long standing distribution channels throughout Europe to drive revenues and aid growth (learn more on pages 47 and 48).

Each Cantourage-enabled cultivator has been working closely with the team during the onboarding process to highlight desirable cannabis strains for European patients, ranging from lower to higher THC strains and THC CBD balanced strains. Extract formulations follow the same methodology, offering a broad spectrum of solutions to treat eligible conditions such as chronic pain, neurological and psychological disorders.

Cantourage's experienced leadership team and pan-European infrastructure perfectly position the company to be a key player in the emerging European medical cannabis markets. In spring of 2022, Cantourage UK announced the receipt of pharmaceutical licences from Home Office and MHRA (Medicines and Healthcare products Regulatory Agency). The licences allow Cantourage UK to import and distribute cannabis-based medicines. Cantourage UK will provide patients its unique portfolio of products directly via its CQC (Care Quality Commission) registered clinic, offering patients and prescribers with an alternative to the existing UK medical cannabis clinics. Cantourage believes consistency of supply of quality cannabis flowers to be a key challenge in the UK, the company intends to focus on tackling in 2022, following the grant of the two pharmaceutical licences and clinic registration.

Cantourage's robust portfolio of products via the 'Fast Track Access Platform' has the ability to sustain key market developments in years to come. The recent announcements of the new coalition government giving the green light to a recreational market within Germany has caused a lot of excitement for key market players and investors. This year, Cantourage will go public, raising further capital to expand its operational footprint across Europe and further accelerating its growth.

Develop your medical cannabis brand in Europe

Cantourage's Private Label solution

Cantourage provides an extensive catalogue of EU GMP certified cannabis flowers via its global network of cannabis producers. All flowers are GMP manufactured and released in Germany, compliant with any global cannabis market. Cantourage supplies tailor-made solutions in line with clients requirements, providing support and expertise from seed-to-sale. Contact one of the team today to design your next offering.

E-Mail: sales@cantourage.com

1 Pick your flower

Dominance	Sativa ○	Hybrid ✓	Indica ○		
Origin	EU ○	OC ○	AF ○	CA ✓	SA ○
THC content	Low	Moderate	High	Intense	
Terpene profile	β-Caryophyllene ✓	β-Myrcene ✓	α-Pinene ○	D-Limonene ✓	Linalool ○

(and many more)

2 Create your brand (or simply use your existing one)

can tourage

- Brand Design
- Product names
- Labelling, info material, website

3 Define your go-to-market strategy

- Price points
- Sales channels
- Marketing activities

Portugal

Portugal is fast becoming a major centre of production of medical cannabis in Europe. This is buoyed by a government which is proactive about capitalising on the opportunity of medical cannabis in Europe. As of February 2022, 18 companies are licensed to cultivate and export medical cannabis products in Portugal, including international companies such as Tilray, Clever Leaves and Curaleaf. However, company regulators have already approved 80 facilities for construction, which need inspection before becoming fully licensed. Local expert Laura Ramos of CannaReporter has suggested that this could see over 100 companies licensed for production in the near future.

The UK

The UK is notable for having one of Europe's oldest pharmaceutical cannabis production sites under GW Pharmaceuticals, used for making Sativex and Epidiolex products. This remained as a lone production site for many years, up until 2021. During this time, new medical cannabis production facilities have been approved in the UK including a 2.5 hectare greenhouse for Glass Pharms in Southern England with preparations for several more in the UK.

18 companies are licensed to cultivate and export medical cannabis products in Portugal

On the British Isles of Jersey, Guernsey and the Isle of Man, yet more efforts are underway to establish production hubs. In January 2021, Northern Leaf secured the first cultivation licence on Jersey for a 75,000 sq. ft. facility. The first licence for cultivation was issued on Guernsey in September 2021. No unlicensed medical cannabis produced in the British Isles has reached the market.

Germany

In Germany, only three tenders for the production of cannabis have been released. The tenders are for a four year period and allow for the cultivation of 1,000 kilograms per year by Aurora and Tilray, and 600 kilograms per year from the German group, Demecan. German group Cansativa holds the only licence to distribute this domestic product, which they began doing in July 2021, upon delivery of product from Tilray, which remains the only company to have successfully brought domestic product to market in Germany. While domestic growers can exceed the tendered amount by 10%, the 2,600 kilograms/year does not come close to covering Germany's demand. In comparison 20,566 kilograms were imported in 2021.

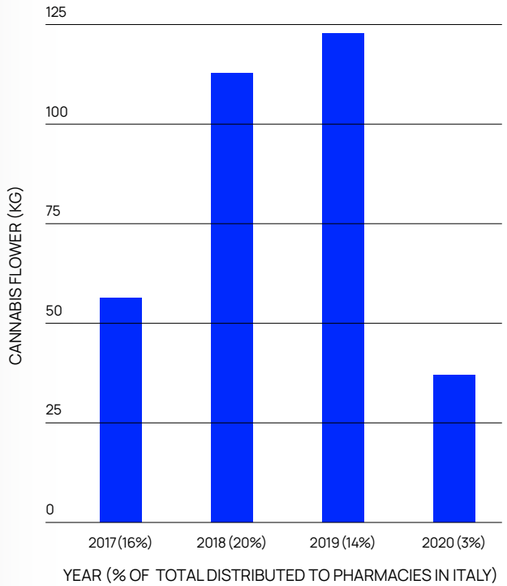
Malta, North Macedonia

Malta and North Macedonia are among two of the Mediterranean countries hoping to benefit from the growing demand for cannabis in Europe, having both exported small quantities (<5 kilograms) to Germany in H1 2021, potentially for testing purposes. In North Macedonia, as of late 2020, there were 55 companies licensed to produce medical cannabis, and the first commercial export licence was issued in December 2021. North Macedonia further bolstered their industry by introducing laws to allow for flower exports in July 2021. Malta allowed for cultivation and export of medical cannabis and has similarly attracted many companies, both foreign and domestic. Prohibition Partners is unaware of significant exports from the country, but at least two companies, Materia Ventures and Zen Pharma have domestically produced products on the market, as of 2022.

Italy

Italy tenders their entire domestic production to the Office of Stabilimento Chimico Farmaceutico Militare (SCFM). However, the site in Florence does not produce enough to cater for Italy's growing patient population and it is unlikely to do so in the near future. The drop in production of medical cannabis from the SCFM in 2020 is made up for by the tender of supply between Aurora and SCFM of 360 kilograms over a two year period and increased imports from the Netherlands.

Domestic production of medical cannabis in Italy



Source: Italian Ministry of Health, Fabrizio Dentini (Italian Journalist), Prohibition Partners

Czechia

To date, Czechia has also tendered their entire domestic supply to a sole cultivator, Elkoplast Slušovice, s.r.o. In 2018 and 2019, this production was sufficient in that it could have supplied the entire country without the need for imports. However, the pace of demand has quickly outstripped the scale of domestic production. Now imports from companies including; Tilray, Northern Green Canada, Spectrum Therapeutics and Bedrocan are distributed by pharmaceutical company, Phoenix. A new law allowing for licensed private companies to cultivate in Czechia should increase the quantities of domestic production.

EXPERT INTERVIEWS

Michael Sassano

CEO
SOMAÍ Pharmaceuticals

What is SOMAÍ Pharmaceuticals?

SOMAÍ Pharmaceuticals Ltd is a European pharmaceutical and biotech company with a manufacturing centre in Lisbon, Portugal and distributes EU-GMP-certified cannabinoid-containing pharmaceuticals throughout the European Union as well as globally. SOMAÍ emphasises scientific pharmacological applications with EU-GMP standards to deliver treatments to the endocannabinoid system, effectively and with consistency across all markets. SOMAÍ's product development knowledge was honed in the competitive American market and is the largest and most advanced cannabinoid manufacturing facility across legal European markets, producing medicinal products and registered APIs.

Where does SOMAÍ Pharmaceuticals get its know-how from?

SOMAÍ has brought together an all-star team of scientists and key opinion leaders (KOLs) from around the world with various types of clinical experience to guide SOMAÍ's product development and acceptance globally. SOMAÍ focuses on education and continual R&D, which started in the USA as transformative development, to help doctors and patients in the EU properly diagnose and treat individual indications by providing variable dosage choices.

What is SOMAÍ Pharmaceuticals' primary goal?

SOMAÍ's primary goal is to produce the most advanced products with the most innovative delivery methods, to create maximum bioavailability and healing for patients. SOMAÍ is fast becoming one of the most recognised and well-developed pharmaceutical brands in the EU. As a global biotech player concentrating on cannabinoids, SOMAÍ has a unique pipeline of current and future products that will be on the market from late 2022. The company already boasts one of the largest intellectual property (IP) vaults of APIs that weren't accessible to Europe until recently. SOMAÍ's near-term products conform to the highest standards of herbal medicine (ACM) and specialised cannabinoid APIs for R&D, but the company keeps a steady eye on the horizon of future clinical trials for its proprietary pipeline, so that it is well positioned for the next decade.

Tell us about your product launches.

All of SOMAÍ's products will be the 2.0 for Europe and will have increased bioavailability and faster absorption. We also believe in multiple formulations with diverse delivery devices to achieve relief for a variety of patients. The initial methods of delivery will be drops, oral mucosal sprays, transdermal patches, sublingual tabs, soft gel caps and vape oils. All will have research-based variable dosages to make it easier for doctors to prescribe the right formulation and delivery device for their patients. We do not believe in the one-size-fits-all pharma model, and relief comes in many ways based on the individual's interaction with cannabinoids. We provide the research and empirical data as a guide, but additionally provide follow-up with doctors so they can help their patients properly. Some of the fields we work in are gastrointestinal; psychiatric such as stress and anxiety; sleep-related such as apnoea; nervous disorders, both severe and mild; pain-related areas such as fibromyalgia and arthritis; and sports medicine just to name a few.

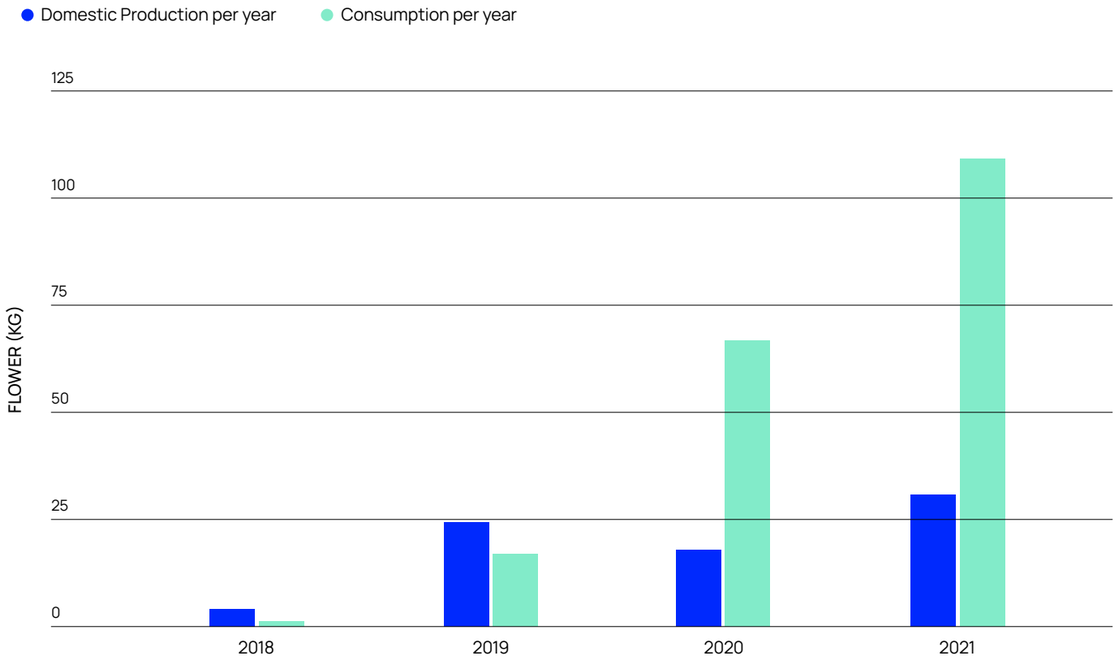
What does the future look like for SOMAÍ?

SOMAÍ has 12 significant initial product revenue lines that support the company starting in late 2022 and launching individually through till 2024. Cannabis rules for different countries allow us to obtain faster certification of herbal cannabinoid-containing products by demonstrating quality and stability. But the crown jewel of SOMAÍ is the API library that is being created for R&D in order to pursue clinical trials for the most innovative future cannabinoid-containing drugs. Our initial APIs besides pharma-grade THC distillate and CBD distillate are highly purified cannabinoids such as THC, THCv, THCa, CBD, CBDv, CBDa, CBC, CBG, CBL and CBN. But we will also be producing semi-synthetic cannabinoids such as CBC, CBG, CBN and newer semi-synthetic such as Delta-8, Delta-9, Delta-10, Delta-11 and Delta-O. As individual APIs, research has been carried out on the more common ones, but the majority of minor cannabinoids are under-studied or have not been studied at all. As SOMAÍ progresses, expect regular and continual announcements of product launches, research updates and, eventually, clinical trials as we accomplish near-term goals and long-term objectives.

The European Cannabis Report | EXPERT INTERVIEWS

Cannabis remains illegal in some countries so please reference your local laws in relation to medical or adult-use. This report has been compiled for informational purposes only. It should not be construed as a research report for investment, legal, medical, health or tax advice. © 2022 PP Intelligence LTD.

Domestic cultivation of medical cannabis in Czechia



Source: SAKL, Prohibition Partners

Denmark

As with Portugal, Denmark benefits from a proactive government, supporting companies to invest in production facilities for medical cannabis in Denmark. As of late 2021, 47 companies had applied for production licences in Denmark, of which 15 had been approved for moving on to the construction phase. International companies such as Little Green Pharma and Aurora have important centres of production in Denmark. In the past, as part of the refocusing of large North American companies, both Canopy Growth and Aurora pulled out of production facilities in Denmark at considerable cost. Products from Aurora's facilities arrived on German shelves in February 2021, marking the first international exports from the country.

EXPERT INTERVIEWS

Luc Richner
CEO
CANNAVIGIA

Philipp Hagenbach
COO
CANNAVIGIA

Vigilance Beyond Certification

CANNAVIGIA is a Swiss-based company with a foothold across four continents and some big plans for the near future. Their seed-to-sale-compliance software suite is taking a refreshing new approach to the current industry standards with a strong vision on how to create global market access. We spoke with two of the three founding fathers of the company, CEO Luc Richner and COO Philipp Hagenbach, about their software, their vision and why the Swiss government chose them to spearhead the traceability for its pilot project on recreational cannabis.

What are your backgrounds?

Luc: Coming from a logistics and international trade background I formerly worked in all areas of the supply chain. A passion project and one of the ventures that greatly inspired what we are doing now was a farm-to-table restaurant in Bali where we had our fair share of challenges in managing sourcing across the archipelago. I then went back to Switzerland to do an executive MBA to learn about the digital transformation of industries, specifically for this project.

Philipp: I come from a corporate commercial background. I worked in the development department of a big pharmaceutical company where I collaborated with doctors in the various phases of the clinical trials. I then went into chemical trading and specifically into industrial infrastructure. I have been working in high-compliance industries my whole life.

What was the idea behind CANNAVIGIA?

Luc: Having studied the cannabis industry from a distance we were getting ready to become involved at the point where there was a global industry to serve. When we looked at the international aspect, we realised that the global legal framework was so fragmented that supply chain management would be a strong challenge for longer than just the near future.

Seeing how there was no harmonised system for the various products on which to base logistics and trade, we started to look into what other highly regulated industries were basing their respective standards on and worked our way backwards from there. This clear overview of other industry standards, with the understanding of what the US and Canada were doing in regards to cannabis, led us to the conclusion that there was a strong opportunity to create something from scratch that was suitable for the European market and beyond.

Philipp: The compliance side of cannabis cultivation is complex because you need a regulatory framework that caters to a very wide range – from industrial to medicinal applications. We therefore created this software as a compliance guideline to aid the client in documenting their manufacturing process while also reducing workload and bringing a transparency to the eco-system. All these differing regulations and standards are usually set up in a way that is not user-friendly. We wanted to create something that is easy to use and accessible to everyone in the industry, from cultivators and manufacturers to distributors.

Luc: We knew what we wanted at the back end, so we created a user-friendly design from the bottom up, combining input from different industry players out of Switzerland with a good understanding of what the US is doing.

How does CANNAVIGIA work?

Luc: We created a process management system that allows you to track every single movement – from registering the seed to distributing to the end consumer or patient. CANNAVIGIA is essentially a complete digital twin of the environment that you work in; every single machine, every plant, every batch, every room, every employee – everything goes into the system and has an identifier. After that, every single movement throughout the facility is logged in a very straightforward way through the app or from the screen. We have created software that allows full transparency in the supply chain without adding to the many complications, with the mission to become an enabler of an economically sustainable industry.

Philipp: Additional to that we want to offer a management option in our system. So, on the one hand you have the regulatory framework where you need steps for traceability and quality, so-called track and trace, and on the other hand we wanted to give the user certain management tools for the value chain in their enterprises. We have implemented an overview planner, an inventory system, a task allocation system – and more – so you can end up managing your facility as well as your production. In combination, the client ends up with one tool that gives them insight into their chain of custody and their value chain.

Luc: We worked together with the Swiss industry association (IG Hanf) and approached the regulator in a process of open exchange. Working with various stakeholders along the supply network made us bring something forward that led to us winning the tender for the traceability of the entire Swiss recreational trial programme.

Philipp: We have also been involved in regulatory consultancies with various governments in cases where they were creating a new legal framework for the cannabis industry in their country and that is another way in which we ended up being part of the governmental pilot project for recreational cannabis in Switzerland.

What makes your system different from others in the market?

Philipp: Our system is very modular, and the software is built so you can adapt it to all the procedures in your production. The software is flexible and can adapt to match your processes. For me, this is the most important part of what we have. We want to bring transparency to the supply chain by splitting it up into different modules for the various stages and stakeholders involved.

Luc: The different modules have been created with a strong focus on a set of various regulations and standards . But we also believe it is not just reporting to a regulator or an internal structure that will be important in the future, but also the end consumer. Through the customer engagement module, the software enables end users to make a qualified decision on their purchase based on real and immutable data.

Our belief is that the times of capturing one moment in the supply chain and giving a certification for it is an outdated system. What we are setting out to do is to maintain a system that allows for full transparency throughout the supply chain hence our slogan: **Vigilance Beyond Certification.**

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Pharmaceutical players get involved

During 2021, several pharmaceutical companies spent hundreds of millions of euros investing in the medical cannabis sector in Europe. This was an unlikely event viewed from the North American perspective, where the line between pharmaceuticals and unlicensed medical cannabis remains sharp. In January, traditional narcotic pharmaceutical firm PS Pharma Service merged with leading European medical cannabis distributor, Cannamedical to form Semdor Group, backed by €40 million in fresh capital from Orkila Capital. In March, Stada, a German producer of pharmaceuticals and generics worth €6 billion, launched their own medical cannabis venture, 'CannabiStada' in Germany. In December 2021, branded pharmaceutical producer Dermapharm, worth €4 billion, acquired C3 - Cannabinoid Compound Company from Canopy Growth for a total of €120 million on the basis of certain milestones being achieved. Most recently, in February 2022, Indian pharmaceutical giant Dr. Reddy's, worth over €8.5 billion, acquired German medical cannabis distributor Nimbus Health GmbH for an undisclosed sum.

The involvement of pharmaceutical firms in unlicensed medical cannabis markets is unheard of in North America, where the separation between unlicensed medical cannabis products which have not undergone clinical trials remains quite separate from the pharmaceutical players involved in cannabis e.g. Arena Pharmaceuticals who are only interested in bringing fully-licensed pharmaceutical cannabis products to market. This underlines the degree to which the systems in Europe and North America differ, in that pharmaceutical expertise qualifies companies to participate in the European, but not necessarily the North American, medical cannabis markets.

These events do not necessarily represent the first movement of pharmaceutical players into the unlicensed medical cannabis industry in Europe. In the past, pharmaceutical distributor Fagron has been instrumental in the industry in the Netherlands and Germany, and German generics producer Klenk have had their hand in the market since 2018, offering their own branded medical cannabis strains. However, the recent increase in activity certainly demonstrates an increased interest from the traditional pharmaceutical sector. How many of these intend to remain solely in medical cannabis without moving into recreational cannabis upon legalisation remains unclear.

Private and Public reimbursement

The integration of medical cannabis into the established healthcare system in Europe has meant that insurance coverage is more relevant here than in most international markets, notably North America. Insurance coverage in Europe has allowed for increased access to medical cannabis for tens of thousands of patients, who could not otherwise afford it, especially considering the high prices, which far exceed those found in North America. Some countries such as Germany and Czechia mandate that public health insurance must cover the costs of medical cannabis, though enforcement of this has been somewhat lacking in Germany. Mandatory insurance is usually accompanied by price controls in order to ease the burden on insurance funds. In the United States, insurance coverage is precluded by the federally illicit status of cannabis. In Canada, around 10% of patients have some coverage for medical cannabis, but tax allowances exist for treatments. Below we provide a brief overview of the situation in selected European countries.

Czechia

Czechia has one of the most comprehensive regulations for public reimbursement of medical cannabis treatment. Since January 2020, 90% of costs of medical cannabis are covered for individual patients on treatments of up to 30 grams per month, and more in exceptional circumstances. The government also mandates price controls based on the size of the prescription, around €6 per gram with very slight discounts as the order size increases e.g. €5.90 per gram for 180 grams. Mandatory insurance cover was welcomed as the first step to a large opening up of the Czech market in January 2020, however, what has been seen is more gradual progress, as other aspects still hold the market back, such as; the single domestic grower, restrictive licensing and the fact that only specialised doctors can prescribe medical cannabis, meaning an extra layer of difficulty for patients.

The Netherlands

The Netherlands is a case study in the importance of insurance for medical cannabis in Europe, but also in terms of the opinion of public health bodies on the use of medical cannabis. Up until 2017, the quantity of medical cannabis sales from the OMC to pharmacies in the Netherlands was increasing rapidly, with 2017 seeing double the sales of 2015 at 640 kilograms. However, in 2018, the National Health Care Institute issued a non-binding recommendation against the prescription of medical cannabis on the grounds of a lack of evidence of efficacy. This had the dual effect of dissuading doctors from prescribing medical cannabis but also

stemmed the reimbursement of prescriptions from health insurers in the Netherlands. Since then, growth has stalled, and only 688 kilograms were dispensed in 2021. This is despite the fact that the government controls the price at which cannabis is prescribed to patients at a comparatively low price of €5.50 per gram excluding VAT and prescription fees.

Denmark

In Denmark, medical cannabis is covered as part of the country's ongoing pilot scheme. Cannabinoid medications from the official list of approved products are covered by the country's national insurance agency. Coverage of 50% of the cost is provided for everyone up to €1,340 per month. For patients with terminal illnesses, 100% of their costs are covered. Patients can also opt to obtain magistral cannabinoid isolates outside of the pilot scheme without reimbursement.

Germany

Upon liberalising medical cannabis in 2017, the German government stipulated that public insurance companies must cover the costs of medical cannabis treatment under certain conditions. The translated wording of the Narcotic Drugs Act is as follows: 'Insured persons with a serious illness are entitled to be supplied with cannabis in the form of dried flowers or extracts of standardised quality and to be supplied with medicines containing the active ingredients dronabinol or nabilone if:

1. a generally accepted alternative medical treatment
    a. is not available OR
    b. Cannot be used in the justified opinion of the attending panel physician. In individual cases, taking into account the expected side effects and the medical condition of the insured person, AND
2. The doctor can demonstrate a not-so-distant prospect of a noticeable positive effect on the course of the disease or symptoms.'

Insurance firms may reject applications for reimbursement 'in justified exceptional cases'.

The definition of 'serious illness' is not specified in this law but a working definition is provided by the Regulation on Medicinal Products from the German Federal Joint Committee as being, 'an illness that is either life-threatening or that will affect the quality of life permanently because of the severity of the resulting health problems'.

Despite the above, up to 40% of applications for insurance reimbursement are rejected by insurance firms. This has been a major issue for patients and the market in Germany and has stymied growth. Many patients opt to cover the charges themselves or have their private health insurance cover the costs, though the exact number of such patients is unclear. Local operator and expert in the field, Cansativa has indicated to Prohibition Partners based on their own surveys that currently **about half of the patients in Germany are obtaining medical cannabis on private prescriptions, rather than being reimbursed through public companies**. This proportion is supported by the survey findings of market specialist Copeia, who collected responses from over 1,000 patients accessing medical cannabis in Germany. It is likely that patients being denied coverage by insurance companies have been pushing the market towards private reimbursement over the past few years.

One sign that the situation is improving comes from the fact that insurance firms are making discount agreements, with the underlying message being that they are ready to accept reimbursements for medical cannabis under certain conditions. Additionally, the issue has been brought to court late in 2020, where the Berlin-Brandenburg State Social Court ruled in favour of a patient suffering multiple conditions having her costs for dronabinol covered by her insurance firm on the grounds that the conditions for 'an exceptional case' were not met.

The UK

The National Institute for Care Excellence (NICE) has offered no support for the use of unlicensed medical cannabis products in the UK on the basis of a lack of sufficient evidence. This dissuades doctors from prescribing unlicensed products in the UK. This is especially true of doctors working within the national insurance schemes in the National Health Service (NHS), where very few patients are now prescribed (<100). Instead, nearly all the patients in the UK must obtain medical cannabis with private doctors, and pick up the costs with private insurance or as is much more often, from their own pocket.

Italy

In Italy, medical insurance coverage for cannabis is largely dependent on regional rules, as are many aspects of medical cannabis law. Each of the regions has autonomy to decide which conditions medical cannabis may be insured for under national health insurance. Each region differs in terms of the conditions for which it chooses to reimburse. For example Basilicata does not allow reimbursement for use against pain, thereby ruling out coverage for the majority of patients there.

EXPERT INTERVIEWS

Ron Lipsky

VP Business Development and
International Relations, MGC Pharma

Can you sum up the past few years for MGC Pharma, and where it has led you?

In the past few years, our operations have been dealing with unprecedented challenges, a global pandemic, and now Russia's invasion of Ukraine. Like most businesses, this has been a challenge for us, both mentally and operationally. Against this backdrop, when I review our achievements, I am amazed at what we have been able to achieve in a short amount of time. Everyone at MGC Pharma has remained focused on our core goals and have made giant strides on achieving those targets.

When Covid-19 hit, we were given the opportunity to develop a product, CimetrA™, in a very compressed timeline, that has helped us to shape the focus of our company. CimetrA™, now in Phase III clinical trials has been proven to arrest the cytokine storm, which is the leading cause of death throughout this pandemic. It also has the added benefit of being able to treat other viruses and diseases, where the cytokine storm is a symptom. Significantly, this product is a non-phytocannabinoid, but still plant based treatment. Working on CimetrA™, alongside our Cannabinoid pipeline, demonstrated to us the intersection of these two worlds that we now see as the company's true calling – as a Plant based biopharma, with a focus on creating affordable treatments for underserved indication. This places us in a very narrow market segment that we see growing significantly over the coming years. Working with cannabinoids for so many years opened our minds to the power of plants of all types, and our work on CimetrA™ cemented that belief.

Additionally, achieving our landmark LSE listing, which did not come without struggles of its own, gave us further support to the idea that we are market leaders, establishing new opportunities for the industry as a whole as we advance our agenda across rapidly changing global markets.

We are now in pole position to lead the plant based biopharma market, while at the same time making more inroads for the cannabis industry every day in various geographies, operating at the highest level of clinical efficacy and regulatory oversight, to ensure our patients will have the best and most consistent treatments available to them for years to come.

What is the vision of MGC Pharma for the coming years?

Our vision is simple, to be one of the leading plant-based biopharma companies in the world. We are confident that we have the clinical pipeline, and the expertise within the business to achieve this. We have already made strides towards achieving this, by building a strong pre-clinical and clinical pipeline, the core of a pharma business. We know we still have a long way to go, but we have a clear path that we are on, and I fully expect us to continue to make significant progress both on the cannabinoid and non-phytocannabinoid sides of the business.

What products are leading your pipeline today, and what is planned for the future?

In 2022 and 2023 we will see most of our efforts focused on CimetrA™, CannEpil©, and CogniCann©. These are three products already in advanced clinical trials with promising results treating severely underserved indications:

- CimetrA™, as previously mentioned treats the cytokine storm, a cause of death associated with Covid-19 and a host of other conditions.

- CannEpil© is a phytocannabinoid product treating refractory epilepsy, which is now available in Ireland on their national health insurance scheme.

- CogniCann© is another phytocannabinoid which has undergone Phase II clinical trials for the treatment of patients with mild dementia and Alzheimer's disease.

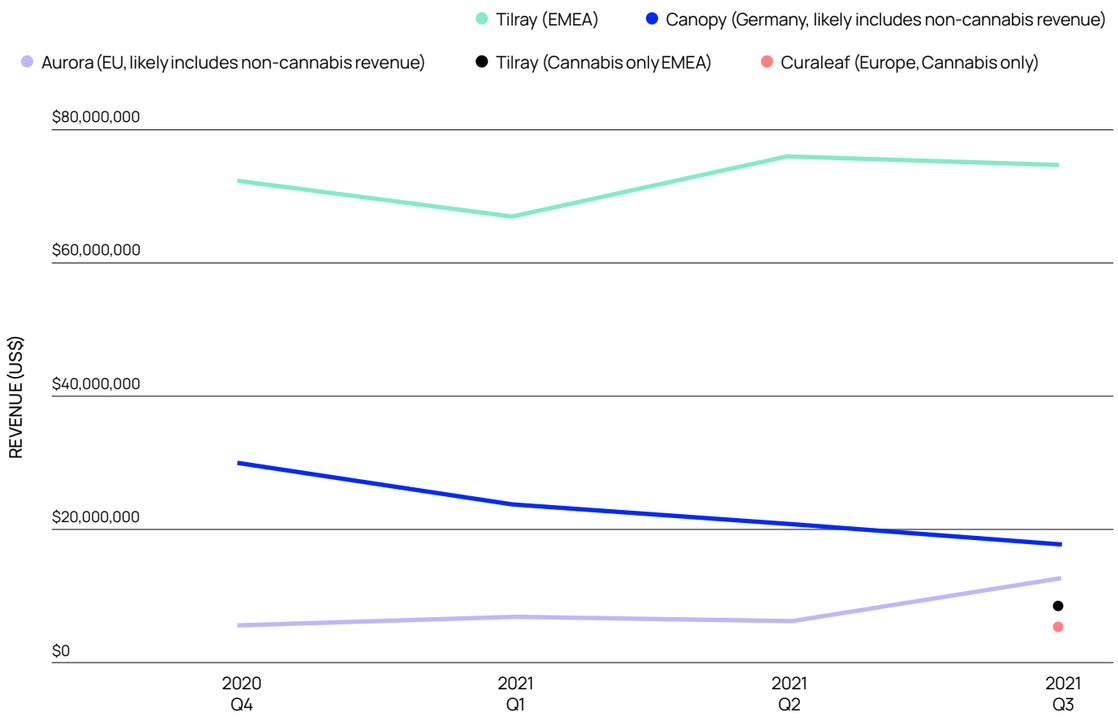
We fully anticipate achieving market authorization for these products, cementing our position as a plant based biopharma with significant impact on patient wellness, pushing the acceptance of what are currently still considered "alternative" treatments, and doing our part to impact global public health. We are also building a robust pre-clinical pipeline guaranteeing years of products to sustain the growth we anticipate and to ensure we remain at the cutting edge of the industry we feel we have been so involved in building and growing.

Positions of North American Players in Europe

Over the past five or so years, North American cannabis businesses have invested hundreds of millions in staking a claim on the European cannabis market. Tilray, Aurora, Canopy and Curaleaf, have combined non-current assets in Europe of ~US$620 million as of Q3 2021. These investments have been justified based on the large addressable base of medical and recreational cannabis users and the fact that sales to these patients and consumers are transitioning towards a fully legal, regulated market worth billions of euros. For several years, only Canadian companies such as Tilray, Canopy Growth and Aurora have had significant positions in Europe. However, they have been joined by US-based Curaleaf who purchased vertically integrated EMMAC Life Sciences. Each company is employing a slightly different strategy in building their presence in Europe as explored here.

This graph charts the revenues of North American cannabis operators and their subsidiaries in regions covering Europe and Israel. It is vital to bear in mind differences in reporting when reading this chart, as companies have apportioned their revenues to different geographical regions and, especially in the case of Tilray, they can include non-cannabis based revenues from other activities, such as pharmaceutical distribution, CBD and hemp products.

Revenues of North American players in Europe and other regions



Source: Quarterly Financial Statements, Prohibition Partners. Note the different regions reported on in brackets and the fact that not all companies necessarily report on their revenues in the same manner. Curaleaf had just one quarter of data available while Tilray's results covered the period when they merged with Aphria, whose results accounted for values before August 2021.

Tilray

Tilray is the company most heavily invested in the international and European cannabis market. The vast majority of the revenue Tilray makes in Europe is related to CC Pharma's non-cannabis activity. Most of Tilray's assets in Europe came from merging with Aphria who in turn had acquired vertically integrated European operators e.g. Nuuvera, Italian distributor FL Group, and German pharmaceutical distributor CC Pharma, among others. Tilray has the widest reach of any international cannabis company in terms of the number of countries which have approved or who stock cannabis products. It also has, by far, the most stock keeping units (SKUs) on European shelves, and has more than 40 oil and flower products on sale in Germany. Tilray also has the largest portion of their revenue generated outside of North America, with 48% of Q3 2021 revenue coming from Europe, the Middle East and Africa (i.e. Germany, Israel, Italy and other smaller markets). Central to their operations in Europe are their production and distribution operations in Portugal and their production unit in Germany.

Canopy Growth

Canopy Growth has invested considerably in the European and especially German markets over recent years. Notable acquisitions include; pharmaceutical distributor C3 pharma (since divested), Spanish producer Cafina, Czech distributor Annabis, British CBD company This Works! and industry leading German vape-producers Storz & Bickel. In Q3 2021, ~20% of Canopy Growth's revenue came from German operations. The company has around 10 SKUs on the German market. Canopy Growth has divested considerably from Europe over 2021 (see below). The declining revenues for Canopy in Europe are likely due to the shrinking market share of the isolated THC market previously held by C3 pharma, which has since been spread out across the newly arrived competitors.

Aurora

Aurora also entered Europe quite early, and has products on shelves in virtually all open markets on the continent. Notable acquisitions include, vertically-integrated operator Pedanios, in addition to building considerable production and distribution facilities in Denmark and Portugal. Aurora has about 20 medical cannabis products on the German market. Central to Aurora's strategy in Europe are its production facilities in Denmark and Portugal, its successful tenders to supply the Italian market with cannabis and to also produce domestic cannabis in Germany. Aurora has also divested considerably from European assets, with the closure of a large second production facility in Denmark.

Curaleaf

Curaleaf entered the European market by way of a large acquisition of vertically-integrated operator EMMAC Life Sciences in 2021 for €300 million. Before this deal, EMMAC had acquired a number of operators across Europe such as Portuguese cultivators Terra Verde, British manufacturers Rokshaw and Spanish manufacturers Medalchemy . Including these acquisitions, Curaleaf now owns a cultivation facility in Portugal, processing facilities in Spain and the UK, a pharmacy licence in the UK, as well as wholesale operations supplying Germany and Israel from Spain and Portugal.

Next wave of Investment in Europe

In late 2019 and 2020, a major shift occurred for large Canadian cannabis producers, when investors lost confidence that the expansionist strategies being employed by the management of several operators were leading towards a profitable business in the foreseeable future. Indeed, the cumulative losses to this point for the top Canadian companies were several billion euros. For many companies, and especially Canopy Growth and Aurora Cannabis, this forced a considerable refocusing of their operations, entailing the closure of facilities across the globe, changes of management and considerable job losses. The years 2020 and 2021 saw several divestments from these companies in Europe. Aurora closed one of its two large facilities under construction in Denmark. Canopy Growth sold a facility in Denmark to Little Green Pharma, roughly €15 million below fair market value, and considerably less than Canopy had invested in the facility. In 2022, Canopy also divested from C3 Pharma who developed and produced dronabinol products for Europe for 120 million, again at a loss of about 60% of the price the company paid in 2019.
Simultaneously, a new wave of investments started to flow into the European cannabis sector, prompted not least by the promise of a legalised German adult-use market. The largest such example in 2021 was the purchase of vertically-integrated player EMMAC by Curaleaf, as mentioned previously. The deal was worth, in total, €300 million and represented a huge vote of confidence from the large US multi-state operators (MSOs) in the near-mid term prospects for European cannabis. An additional ~€180 million was spent by another handful of North American players. Another notable deal was the acquisition of vertically-integrated operator, Eco Equity by Virtual Medical International for €114 million. North American players are also lining up to claim a stake in the emerging European adult-use market, as shown by the acquisition of Dutch cultivators Leli Holland by Village Farms and Growery B.V. by Aurora. Despite the considerable losses taken on by North American players in recent years, there can be little doubt of the eventual value of the European cannabis markets and so, it is a question of timing and whether investments can be justified with due diligence. This would illustrate that the risks are worth taking, considering the pace of legislative reform, current supply and demand and the chances of being 'locked out' after the market matures.

Patients & Products

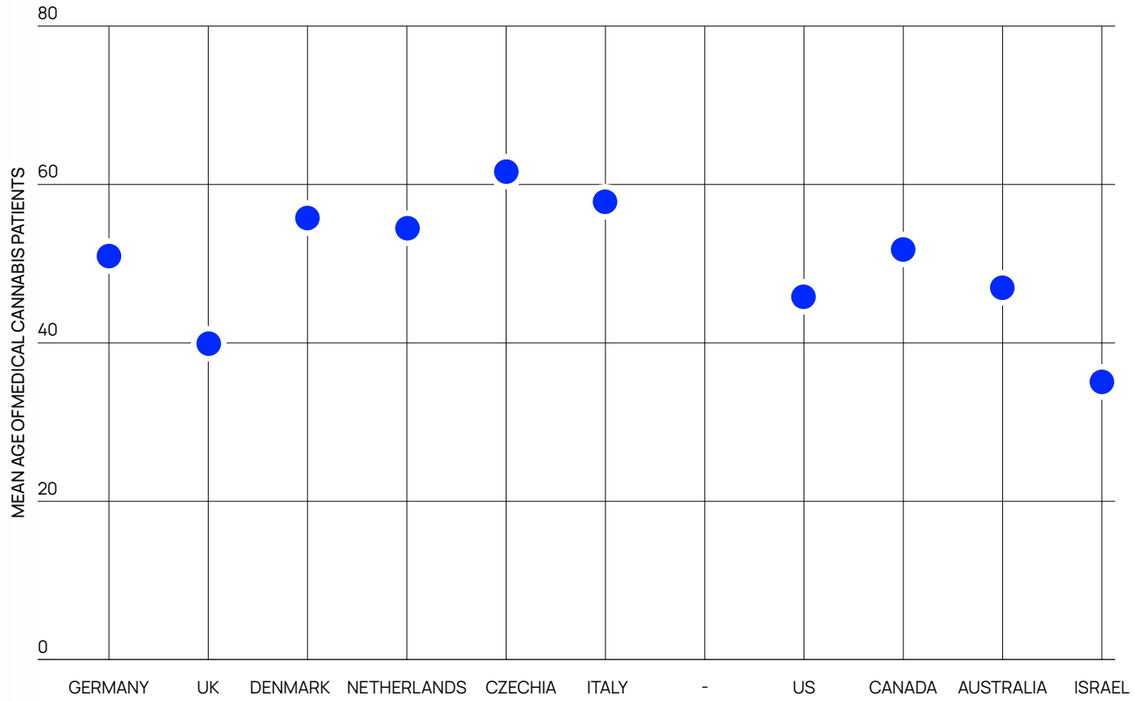
The relatively close integration of medical cannabis into the European healthcare systems has contributed to a patient population and purchasing patterns distinct from developed markets in North America or indeed developing markets elsewhere in the world. The medicalised nature of cannabis distribution in Europe means the balance of patients who are using for purely medical purposes rather than mixed medical/adult-use is lower. More familiar product formats such as oils and capsules are more common in Europe than most other medical cannabis markets. Here we provide one of the most comprehensive views on the characteristics of medical cannabis patients and products available anywhere.

Age

The average age of medical cannabis patients in Europe is slightly older than in most developed markets, especially those which have a large prevalence of patients using for mixed medical and adult-use purposes. In the Global Cannabis Report 2nd Edition™, we demonstrated that it is likely that younger patients are the first to transition out of the medical market and into the adult-use market upon legalisation.

The average age of patients in Germany stands at around 56, as recorded in the mandatory reports on patients covered by national health insurance. However, it is likely that the precise average age is lower, due to underreporting of young male, flower-using patients and the predominance of these cases not covered by national health insurers.

Mean age of medical cannabis patients



Source and most recent period covered by data: BfArM (2020), Project Twenty21 (2022), Danish Ministry of Health (2022), De Hoop et. al (2016), SAKL(2020), Italian Ministry of Health (2019), Boehnke et. al (2018), Health Canada (2021), TGA (2022), Israel Ministry of Health (2022).

Data for the United Kingdom comes from Project Twenty21 which is a national register for patients which subsidies treatment and also publishes aggregated data. The average age of patients to date is 40, though it is unclear why this population is more similar to that of the US or Israel.

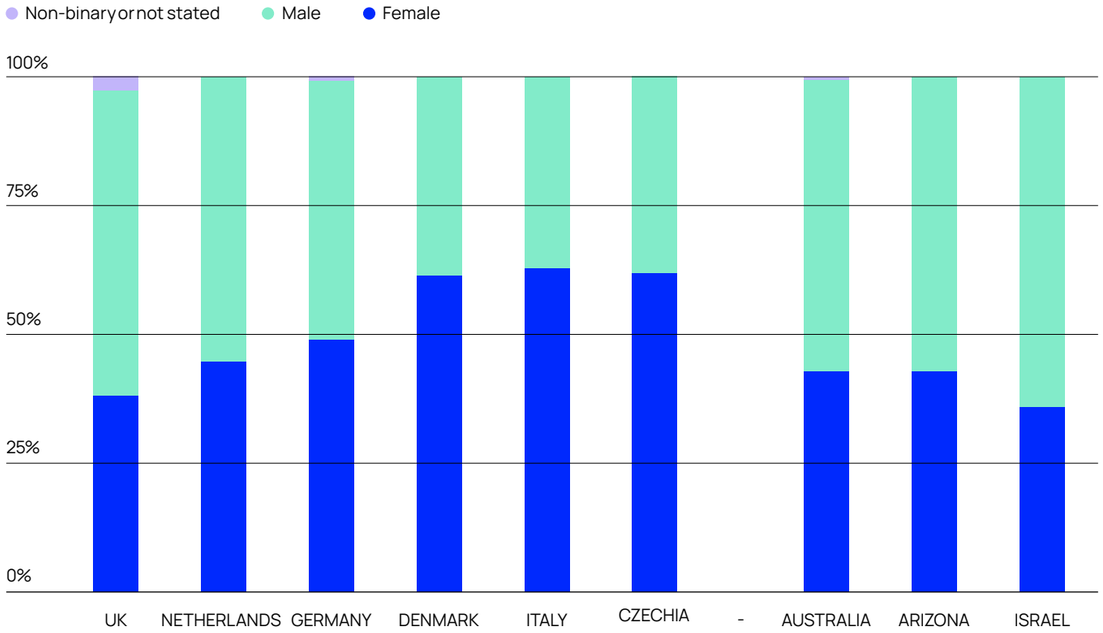
Denmark, Czechia and Italy all operate somewhat restrictive medical cannabis policies. This probably contributes to an older patient population, as more mixed medical/adult-use patients find it more difficult to obtain medical cannabis. The average age for these countries is between 55-60, considerably older than the more liberal markets in the US and Israel. Patients in the Netherlands have access to adult-use cannabis via the network of coffeeshops in the country which might suggest that the younger users might migrate to the adult-use market. However, it is likely that the younger patient population has never made much use of legal medical cannabis, owing to the relative difficulty of obtaining medical cannabis, as is the case with the three countries mentioned previously.

Gender

The medical cannabis patient population in Europe has a predominance of females not exhibited by other markets. Czechia, Italy and Denmark all have patient populations which are above 60% female, a phenomenon not exhibited by any other large market for medical cannabis with publicly available data. As with age, the gender breakdown of patients in the UK is closer to the more liberal markets of Israel, Australia and the US.

The medical cannabis patient population in Germany, covered by the survey mentioned earlier, shows that about 51% of patients are male, however, this is likely to be more skewed than this appears due to the underreporting of young, male, flower-using patients covered by the national survey.

Gender of medical cannabis patients in Europe



Sources and most recent period covered by data: Project Twenty21 (2022), Key Pharmaceutical Statistics Foundation (2022), BfArM (2020), Danish Ministry of Health (2022), Italian Ministry of Health (2019), Arizona Dept. of Health Services (2022), SAKL (2020), TGA (2022), Israel Ministry of Health (2022).

Medical Indications

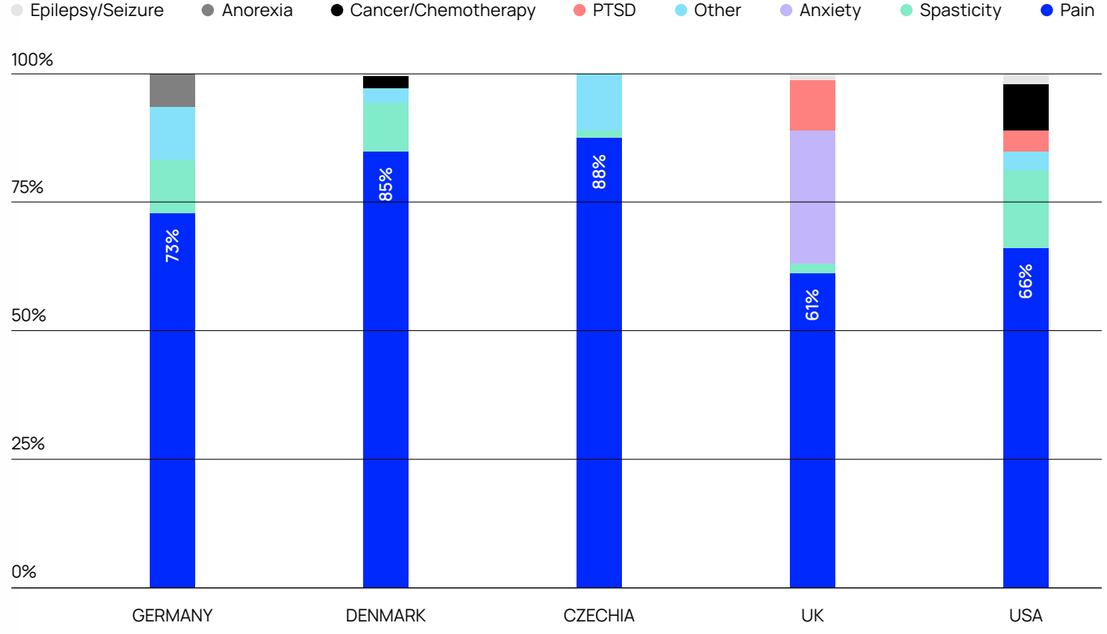
European countries are in line with all other markets for medical cannabis in the world in that the predominant primary condition for which medical cannabis patients are prescribed medical cannabis is for severe pain related conditions including e.g. chronic pain and neuropathic pain. This is unsurprising given that pain affects as many as one in three people in developed countries, and that evidence is relatively strong for the potential of medical cannabis in treating various types of pain. Indeed, in many cases, where a condition such as cancer or spasticity is listed as the primary condition, the treatment of pain is a central reason for the prescription of medical cannabis.

Spasticity, most often caused by multiple sclerosis (MS), is another of the more common conditions for which medical cannabis is prescribed in Europe. While the prevalence of MS is far less than for pain conditions, the current medications for controlling these symptoms are insufficient for many patients, and there is good clinical data for the effectiveness of THC and CBD, hence the development and approval of Sativex.

Patients using medical cannabis for epilepsy represent a relatively small percentage of the population in Europe. This is probably due to the fact that the prevalence of intractable epilepsy is relatively low and that the licensed medication Epidiolex is now in widespread use and is probably preferred by many health professionals.

Individual countries have their own peculiarities in prescribing for other conditions, especially for neuropathic issues such as anxiety in the case of the UK and Post-Traumatic Stress Disorder (PTSD) in the case of the US. This does not necessarily reflect a larger prevalence of these conditions in these countries but rather an artefact of the prescription practices of doctors in those countries.

Conditions of medical cannabis patients in Europe



Sources and most recent period covered by data: BfArM (2020), Danish Ministry of Health (2022), SAKL (2020), Project Twenty21 (2022), Boehnke et. al (2018)

EXPERT INTERVIEWS

Susanne Caspar

CEO
Linnea

An Emerging Beneficial Cannabinoid

What is the newest cannabinoid Linnea is selling and why did you decide to sell this?

We have created a CBG isolate that is 99% pure and a GMP certified standardized CBG extract with 5% Cannabigerol. According to scientific research and studies CBG is a powerful cannabinoid that has the potential to be very beneficial and therapeutic for a variety of conditions. Therefore we invested in this new cannabinoid because our mission is to improve people's lives with our quality standardized ingredients.

What are the most interesting indications for CBG?

CBG (Cannabigerol) is the biosynthetic precursor of THC and CBD as well as many other cannabinoids. CBG is non-psychoactive, like CBD, so it does not cause a high. Research into the positive effects of CBG is ongoing and what has been seen so far is exciting. Studies show CBG has the potential to treat glaucoma and reduce intraocular pressure. It's also shown to benefit symptoms of Irritable Bowel Syndrome and Inflammatory Bowel Disease, and related pain and gastrointestinal ailments. It can provide supportive care for dental plaque and gum health, as well as treat skin irritation and extreme conditions of dryness. Studies have also shown CBG has anti-inflammatory and antioxidant properties, increasing the body's antioxidant defenses and inhibiting cellular aging and cell death. Initial studies indicate that CBG may help combat multiple sclerosis, motor neuron disease, Parkinson's disease, Alzheimer's disease, and Huntington's disease. So you can see the potential therapeutic benefits of this cannabinoid are incredible and we are excited to be able to provide pharma grade and food grade CBG to companies across the globe looking to create formulations with this compelling cannabinoid.

What markets do you anticipate this cannabinoid being sold and used in this year?

We can already see in more established markets that customers are looking for non-psychoactive cannabinoids that can target specific conditions. In the EU and the UK, where we have some of the most sophisticated customers and a growing cannabinoid market, we already see quite a few CBG products in the market. As customers get to know the benefits of CBD first hand they become more interested in additional non-psychoactive cannabinoids that can bring even greater benefits to their lives. CBG is also regulated similarly to CBD in some markets so it is possible to sell products containing this cannabinoid to some of the same customers and markets buying and selling CBD. The U.S. is an additional large market that is well established, and growing rapidly, where we are seeing consumer demand for CBG products grow in the market as well.

What is next for Linnea and cannabinoid products?

Two exciting developments we are working on are a standardized blending of CBD and CBG extracts as a new API or a blending of CBD/CBG pure components. We have seen that these cannabinoids have significant therapeutic benefits and when combined together can be a powerful ingredient for finished products. We are also anticipating being able to produce and export a high THC full spectrum standardized extract ingredient in the near future, as there is a law change in Switzerland coming up for consideration later this year. Also currently our applications for natural CBD extract and CBD isolate in the UK and in the EU were validated and we hope to have final approval very soon.

The products

As with the 'patient population' the medical cannabis products being used in Europe vary somewhat from markets elsewhere in the world. This is a direct result of the treatment of medical cannabis similarl to existing pharmaceuticals but also, the constraints placed on the market by regulators. In general, observation of other markets shows that, given access to a full range of product formats e.g. flower, oil, edibles, vaporisers, high THC, balanced and low THC products, flower is always the single most popular product, and it usually occupies between 30-50% of the market with some clear exceptions. High-THC products are always the most popular when the market is given free rein to supply these. This makes sense due to the fact that the majority of patients are being treated for pain conditions, for which THC is the most sought after, rather than CBD alone.

Format

As stated above, **flower is the single most popular medical cannabis product format in Europe and will be for some time due to popularity in key markets like Geramny, Italy and the UK**. As with patient demographics, the UK is similar to more liberal markets e.g. in Israel or in the US, in that flower is the dominant product format being prescribed, by far. Regulations constrain the availability of this product in Europe, whereby virtually no country allows for medical edibles and few prescriptions are written for cannabis intended for vaporising, as opposed to US markets. Products such as edibles, beverages and vapes are not as recognised by regulators in Europe primarily due to the medicalisation of cannabis on the continent compared, for example, to the US.

In Germany, medical cannabis flower remains the single most important product format, but it has been losing ground to pharmaceutical formats, such as pharmaceuticals. With the exclusion of pharmaceuticals, flower is also losing ground to extracts in the unlicensed medical cannabis sector. At the beginning of 2020, flower accounted for 60% of the unlicensed market and this has declined slightly to 56%. However, it should be noted that these figures for Germany have two drawbacks. The first is that these reports are recorded in terms of value and not in terms of weight. As oil products are generally more expensive per treatment, this means that a higher percentage of patients are utilising medical cannabis than the value portion would suggest. Secondly, the figures omit medical cannabis prescribed on private health insurance, or where the patient pays for the product themselves. It is likely that the majority of these sales are of flower products, which would further push the product balance towards 'flower' for Europe's largest market. Market specialists Copeia surveyed over 1,000 patients and found that as much as 75% of the public and private prescriptions were written for flower products, with the remaining 25% covered by extracts, dronabinol, Canemes and Sativex, exclusive of Epidiolex.

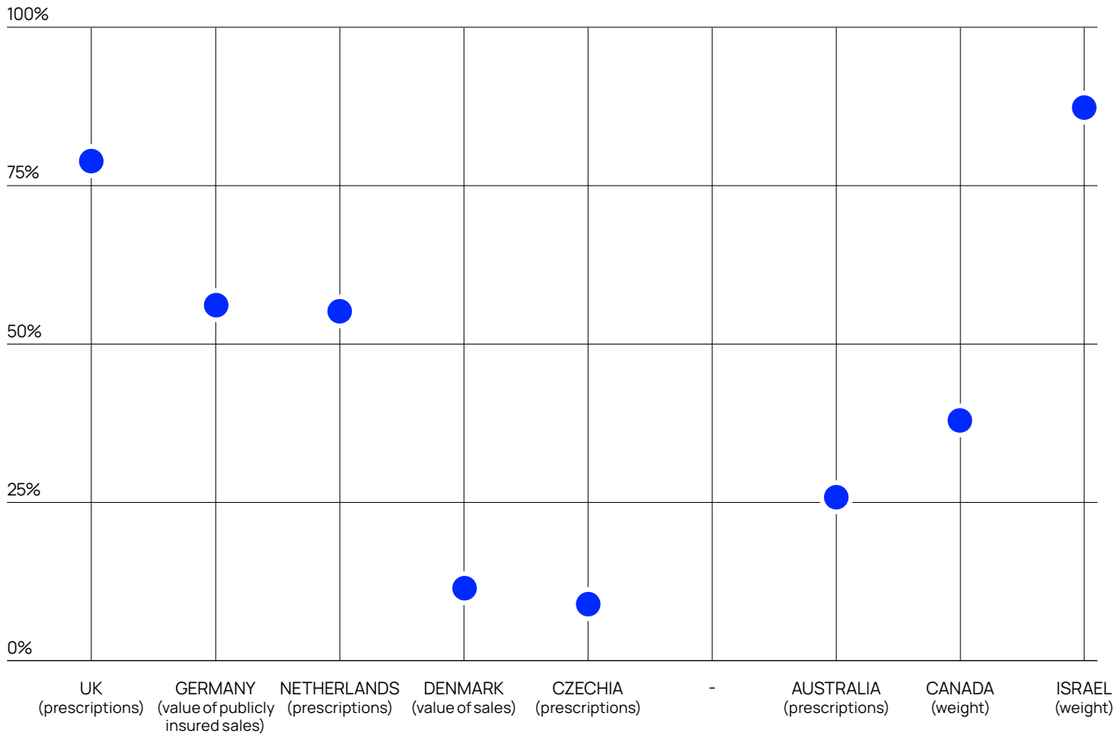
In the Netherlands, prescriptions for oil products have been on the rise, going from 45% of the market in 2016 to 55% in 2020. However, 2021 saw a swift reversal of this trend, and the latest data indicates that flower is now prescribed in 55% of cases, rather than oil products.

Glueberry OG flower from Together Pharma, cultivated in Uganda, manufactured under EU-GMP conditions in Germany and distributed by Cantourage

Example of medical cannabis extract manufactured by Tilray and distributed by Cansativa

Czechia and Denmark represent two markets where the constraints of regulations dictate for a large part, the medical cannabis format choices. While some flower products are available in each country, there is clearly a strong preference for derivative products. In Czechia, 91% of prescriptions for unlicensed medical cannabis are for capsules, 3% for herbal tea products, and just 6% for dried flower. In Denmark, the majority of the market share is in single substance extracts, both THC and CBD, with flower accounting for just 12% of the overall unlicensed market.

Percentage of European market dominated by flowers



Sources and most recent period covered by data: Project Twenty21 (2022), BfArM (2021), SFK (2021), Danish Ministry of Health (2022), SAKL (2020), TGA (2022), Health Canada (2021), Israel Ministry of Health (2022).

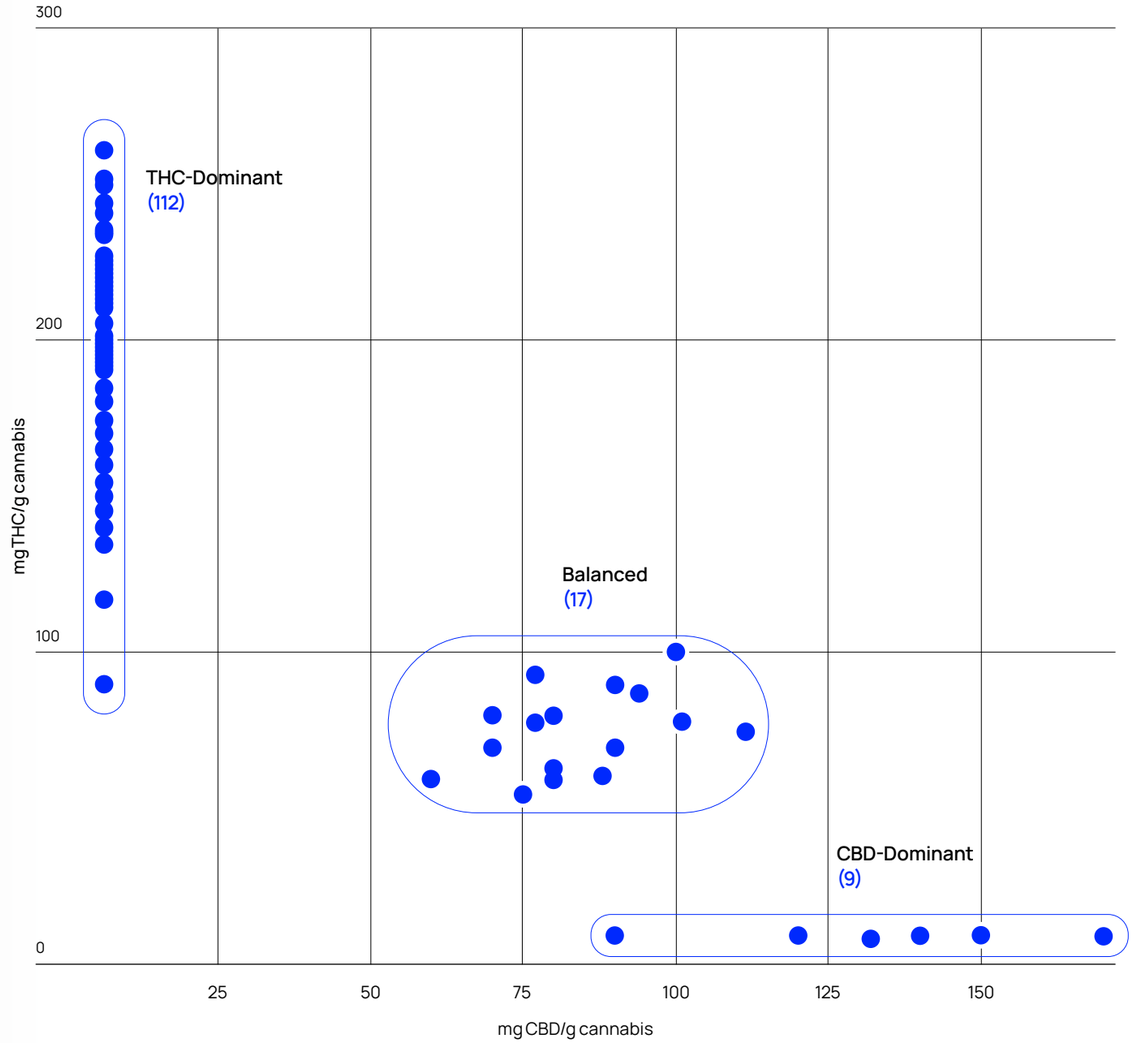
THC:CBD

In virtually every market in Europe, high-THC products are the most sought after. This mirrors trends in every other medical cannabis market, as well as adult-use markets in North America. Germany is the only market which has a relatively free-market approach to the approved products, with many products from different producers available on German shelves.

In Germany, around 140 strains of medical cannabis flower are currently available, though stocks, of course, may vary between strains. The vast majority, around 80%, are high-THC strains, with very little CBD in them. Around 12% have relatively balanced quantities of CBD and THC while just a few prescription CBD flowers are available; around 7% of the total. The reason for

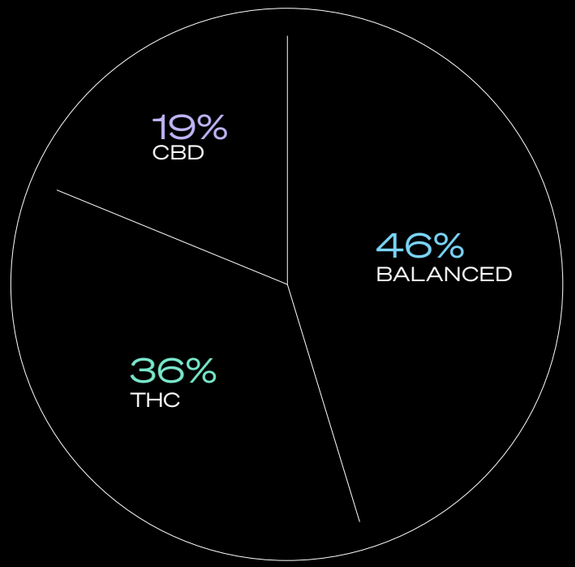
the low diversity in CBD flowers is of course due to the fact that many CBD products, including flower, are sold in stores across the country, as in most central and western European countries. This reduces the impetus for patients to seek out professional medical advice in obtaining CBD products. However, it can be assumed that given free access to any medical cannabis product, the balance would still be skewed towards high-THC products, as these are preferred by patients suffering from pain and other prevalent conditions.

CBD/THC profile of flower in Germany

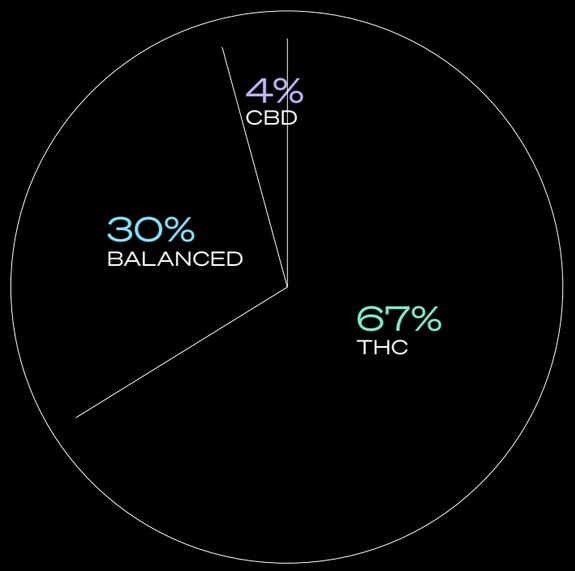


Source: Cannabis Ärtze 2021, Prohibition Partners

High-THC products dominance in Europe

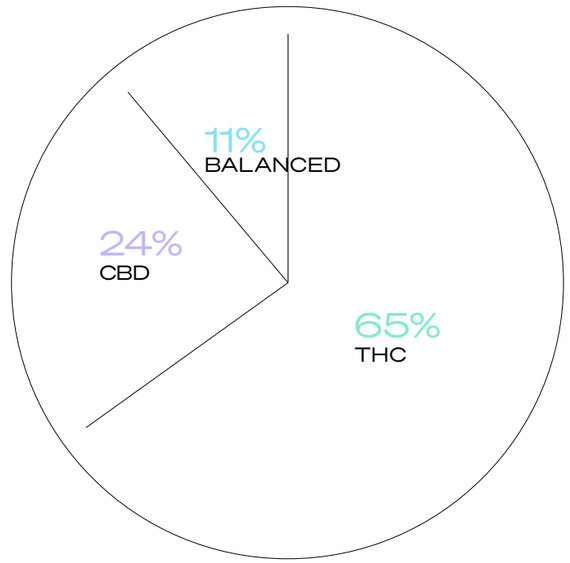


CZECHIA (2020)
(prescriptions)



UK (2022)
(prescriptions)

Source: SAKL, Project Twenty21, Danish Ministry of Health, Prohibition Partners



DENMARK (2021)
(sales value)

Source: SAKL, Project Twenty21, Danish Ministry of Health, Prohibition Partners

High-THC products are most often prescribed in both the UK and Denmark. This is known from the number of prescriptions in the UK under Project Twenty21, as well as the official sales figures published by the Ministry of Health in Denmark. Czechia bucks the trend somewhat, in that a large quantity of medical cannabis prescriptions are of balanced THC and CBD products, loosely defined here as strains where neither active ingredient is more than twice the concentration of the other.

CBD

Fragmented European markets

The European CBD market remains fragmented, there are many companies seeing success in multiple markets, but with few clear leaders in the region as a whole. European production is competing with imports from the USA, of CBD isolate in particular, from the likes of Mile High Labs; large scale cannabinoid extractors selling bulk ingredients. In many cases these US producers are able to sell products at lower prices than their European counterparts. There are multiple reasons for this, but one with particular relevance is the access of US extractors to biomass with a far higher CBD content that which is available in Europe. European extractors are mostly limited to biomass from hemp varieties listed in the EU catalogue of approved agricultural plant varieties, which were bred and selected for their industrial use rather than their cannabinoid content.

The proliferation of CBD brands continues in Europe, with certain brands and CBD retailers becoming established in the more developed national CBD markets (e.g. UK, Germany, Italy, Switzerland, Netherlands), while the earlier stage markets (e.g. France, Spain, Portugal, Ireland) still have many independent operators, with small CBD-focused stores selling own-brand products, or smaller (often local) brands. The UK remains, for now, the only market where CBD products are stocked by multiple mainstream non CBD-focused high street retailers. Established brands seen across multiple markets in Europe include Endoca, Reakiro, Nordic Oil and Cibdol.

CBD legislation in Europe

CBD has had an easier path towards acceptance in Europe than that of high-THC cannabis. The market has been gradually establishing itself over the past 10 years or so, first via legally 'grey' supply chains and points of sale but increasingly, with the full protection of the law and with increasingly normal treatment by regulators on the continent. The tide of international opinion on CBD has turned over the past five years, with the World Health Organisation (WHO) calling for the descheduling of CBD as far back as 2017. Late in 2020, the United Nations' Commission on Narcotic Drugs voted to remove cannabis and its derivatives from Schedule IV of the Single Convention. However, the council also voted against the removal of CBD from control under the Convention.

Recently, the UK and the European Court of Justice have acted similarly to the US in interpreting that CBD is not to be considered a controlled substance under the International Convention. The key court case occurred in France, where distributors were being charged for importing CBD made from hemp flowers which was compliant with Czech laws, but not French. The case was eventually passed to **the European Court of Justice who ruled in November 2020 that CBD should not be considered a narcotic under the 1961 UN Convention**, as CBD does not, 'have any psychotropic effect or any harmful effect on human health'. The Court ruled that while CBD could technically have been included in the legislation set out in the UN convention, banning CBD would be, 'contrary to the general spirit of that convention and to its objective of protecting 'the health and welfare of mankind''. Furthermore, the court ruled that EU states cannot ban the marketing of CBD legally produced in another member state unless a risk to public health 'appears sufficiently established'. As such, CBD is no longer considered a narcotic substance under French, EU or subsequently, UK law. Below we review the current legal status of CBD under different guises.

CBD as a cosmetic

The use of CBD in cosmetics is now fully regulated and protected by law in the European Union. The 'de facto' descheduling of CBD by the European Court of Justice (ECJ) has opened the gate for regulators of cosmetic products to recognise and control the substance. In February 2021, CBD was included in the CosIng database. The CosIng (Cosmetic Ingredients) is the European Commission database for information on cosmetic substances and ingredients. Inclusion in the database does not have legal value, but it is a clear indication that EU regulators recognise the legitimate nature of CBD products. CBD products are now available in major online marketplaces, retail outlets and speciality stores across Europe.

CBD Face Serum by Berlin-based VAAY

CBD as a medicine

Any CBD which is obtained with medical supervision via prescription is treated by Prohibition Partners as a medical cannabis product and included in the relevant sections above. Different countries in Europe treat prescription CBD in different ways. Many countries have some access to CBD in pharmaceutical products e.g. Sativex and especially Epidiolex, CBD being the only active ingredient in this medicine. Thousands of patients use CBD in the form of Epidiolex in Europe, and GW Pharma saw sales of €20 million in Germany alone in the 12 months ending March 2021. In addition to pharmaceutical CBD, unlicensed CBD products are available in several European countries. For example, in Germany, at least nine CBD-dominant flowers are available on the market and several extract oils. Even in restrictive countries such as Ireland, Bedrocan flowers with a low-THC and a high-CBD content are available via special access pathways. Finally, CBD can be obtained on prescription as an unlicensed magistral product, where a doctor prescribes the isolate on the basis of a national formulary which describes the allowed formats for isolates, and pharmacies then produce the extract for the patient in line with the instructions set out in the formulary, or monograph.

Epidiolex, the most popular licensed pharmaceutical form of CBD, used on label to treat Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex.

The European Cannabis Report | CBD

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Ingestible CBD and the Novel Foods Catalogue

Ingestible products are potentially the most important category for CBD, given the popularity of oils, gummies, edibles, other supplements, drinks etc.. However, producers in this product category are currently wrestling with EU legislation en route to becoming a fully compliant Consumer Packaged Good (CPG). In January 2019, the European Food Safety Authority (EFSA) released a disputed guidance on handling cannabinoid-infused food products:

Without prejudice to the information provided in the novel food catalogue for the entry relating to Cannabis sativa L., extracts of Cannabis sativa L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient.

As such, most ingestible CBD-containing products are considered Novel Foods in Europe and are subject to special regulation. This does not apply to hemp seeds, seed oil, hemp seed flour, or defatted hemp seed. Many hemp products are available on shelves around Europe and are considered fully legal CPG products.

During the Kannavape court case, the question of whether CBD should be considered a narcotic was still alive in the minds of regulators and as such, the >50 applications for plant-derived CBD as a novel food were frozen, with no applications being deemed valid. This situation has progressed as of 15 February 2022 and the European Commision has now listed at least 12 valid applications, with more expected in the very near future. The EFSA must now perform a risk assessment for each product before each application is finally approved for marketing by the Standing Committee on Plants, Animals, Food and Feed.

Under EU law, food that has not been consumed to a significant degree by humans in the EU before 15 May 1997 is considered to be a 'Novel Food' and cannot be placed on the market until the EC has: processed an application for the authorisation of the Novel Food; has adopted an implementing Act that authorises its placing on the market, and has updated the EU list of Novel Foods. This has not occurred yet for CBD therefore, in theory under EU regulations, no plant-derived CBD products, other than full spectrum or cold pressed hemp products, may be marketed for human ingestion in the EU. Enforcement of this is variable but is in general relatively light, with such products available in retail locations in most countries.

There has been a mixed reception to the Novel Foods ruling as this ruling benefits some, while harming others. Specifically, the high cost of the applications may lock-out smaller players who cannot afford the time and money to apply. The cost of individual Novel Foods applications has been estimated at between €300,000-400,000 and can take three to four years. On the other hand, many in the industry also welcome the ruling with the opinion that having some kind of barrier to entry and a set of regulations ensures that only quality CBD products reach the market. The importance of the

latter point is underlined by the frequent findings by inspectors of non-compliant CBD products, with supra-threshold THC levels, or nominal CBD concentrations. Approval of one CBD product as a novel food will not necessarily benefit other producers, as the approval is specific to the given product and applicants.

UK-Based Goodrays range of CBD-infused beverages.

CBD flowers

Hemp flowers have been under particularly stringent regulations in Europe and elsewhere owing to the specification of the Single Convention on Narcotic Substances that defines cannabis as: the flowering or fruiting tops of the cannabis plant. This has meant that for the most part, European regulators have been more accepting of CBD products including cosmetics and oils which have been produced from leaves and stems, rather than CBD flowers (to the extent that they can tell the difference in the starting material). CBD flowers are, of course, higher in CBD and other cannabinoids than the leaves or stem material, and are suitable for smoking, which adds another layer of complexity for regulators. Hemp flowers can be used as tea but are more often smoked or a vaporiser is used for the ingestion of CBD and/or as a tobacco substitute. While regulations for CBD cosmetics and ingestibles are progressing, courts and legislators are still trying to pin down hemp flowers as a retail product.

CBD flower, produced by Dr. Feuerstein Medical Hemp is in Austria and marketed in various European countries.

Hemp flowers have already been established as a common product in several European countries. In Switzerland, Czechia, Luxembourg, Austria and Belgium, hemp flowers are traded openly as in many other countries where products are sold in legally 'grey' supply chains. Belgium has set the bar for the legitimisation of CBD flowers by regulating in 2019, that 'products destined to be smoked and in which the THC content is less than 0.2% are considered as tobacco products and will therefore be taxed as such'. This has had the dual effect of legitimising the industry but also reducing its extent, as it ate into the margins of the many small operators in the country. In Italy, the hemp flower or 'cannabis light' industry thrived for years after the Italian government left a legal loophole open which allowed marketing of hemp flowers. This caused a huge reduction in illicit market activity and pharmaceutical drug usage where economists estimated that the illicit market lost up to €200 million in annual revenue, and sales of anxiolytic prescription medication reduced by 11.4% (Principe et. al 2020).

As with many issues surrounding cannabinoids in Europe, regulation of CBD flowers is now being dealt with at the national level by legislators and the courts. In Italy, in January 2022 the State Regions Conference accepted an inter-ministerial decree which declared that regardless of the THC content, all cannabis plants, not intended for industrial use, are considered medicinal and should be regulated as such. The implications for CBD law at the national level have not been firmly established and some operators hope hemp plants will still escape the definition of a medicinal plant.

At the time of writing, Luca Marola, the so-called initiator of the cannabis light market in Italy is awaiting his trial for distribution of the flowers. In Germany, the Higher Administrative Court of Lower Saxony is currently examining a case involving expert cannabinoid lawyer, Kai Niermann, and his clients who distribute cannabis flowers. The case will likely hinge on whether CBD flowers can be treated as a tobacco product, and whether the EU laws of free movement of goods will apply, as the products are legal in other EU countries. In France, following the Kanavape case, the courts maintained a ban on hemp flowers. A French interministerial decree had declared that hemp flowers 'may only be harvested, imported or used for the industrial production of hemp extracts'. However, in light of the ruling by the ECJ and a subsequent ruling in French law against the narcotic status of CBD, the French Administrative Supreme court ruled in late January 2022 that 'it does not follow from the investigation […] that hemp flowers and leaves with a THC content of no more than 0.3% would be harmful to health to such an extent as to justify a general and absolute prohibition on their sale'.

Testing

A recent trend in the European CBD industry is the increased attention being given to the standards of testing in the CBD industry. The consistency and comprehensiveness of testing in CBD currently varies widely based on producer and geography, for a variety of reasons. There is a lack of awareness of the parameters which define legality and quality in CBD products, common to consumers, regulators and even some commercial operators. There is a lack of clarity regarding what constitutes an accept-

able, or even a required, level of testing. Many producers make the claim that their products are tested by independent third-party laboratories, however which parameters are being tested for, and on what recurring basis, can often be difficult to quantify.

The reason that CBD products are under more scrutiny than other products in similar categories is due to the significance of the quantity of THC present in products. The maximum legal limits vary by jurisdiction, and in many cases the permitted limits in products are not clear (even at the EU level). Since products are most commonly derived from cultivated plant material, achieving total standardisation in production is exceedingly difficult. The legal consequences of solely handling a product with THC levels over the permitted limits are generally far more serious than those for selling a product with, for example, too much heavy metal content, whatever the disparity in health risks.

Based on Prohibition Partners' research into over 35 brands supplying retailers in Europe, the CBD players which currently full-panel (i.e. comprehensively) test their products on a batch-by-batch basis are almost exclusively the ones with internal laboratory facilities, which brings testing costs down. For the majority of producers in Europe, particularly the smaller companies, full-panel batch-by-batch testing of all products by independent third-party laboratories is unaffordable, with costs of €700 and above for fully testing one batch. This level of testing is only manageable by producers creating large batches of products, and even amongst these larger players, consistent testing on more than three parameters is not common for producers without internal laboratories.

The test which operators and regulators place most emphasis on is the measurement of cannabinoid content in a product, also known as the 'cannabinoid potency' test. It is crucial that the cannabinoid content of products is tested because a product's THC content defines whether it can be legally available for sale. Since the legal limit of THC in products varies by jurisdiction, it is necessary both to have visibility on the THC content of products being sold, as well as a clear understanding of which limits apply in which countries. The other reason that cannabinoid content testing occurs is to verify the level of CBD present in the product, thereby ensuring that the content on the product label is accurate.

If a CBD product is tested for cannabinoid content, then a retailer and consumer can at least determine whether the most essential components of the product are in line with what is claimed. Beyond this parameter, the more products are tested for contaminants and other content, the more accurately their quality and their safety for use can be measured.

A number of groups including Cannabinoïden Adviesbureau (CAN) in the Netherlands have been working towards developing guidelines for CBD testing in Europe; frequently discussed parameters include:

Contaminants

- Microbiology
- Heavy Metals
- Pesticides
- Solvent Residues
- Polycyclic Aromatic Hydrocarbons
- Mycotoxins
- Dioxins & Polychlorinated Biphenyls (PCBs)

Content

- Cannabinoid Potency
- Terpenes
- Peroxide Value

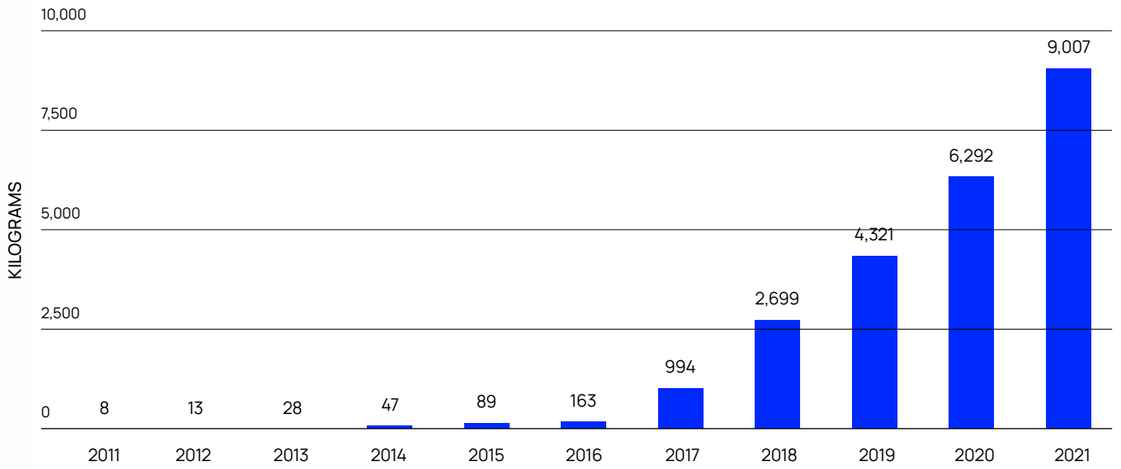
Country Focus

Germany

Germany remains Europe's leading example for the liberation of medical cannabis on the continent. A number of regulations have helped achieve this including: mandatory reimbursement of medical cannabis from national health insurers, the ability of any doctor to prescribe medical cannabis for any condition and a relatively open policy on product approval and imports. Last year, 2021, saw the arrival of domestic production of medical cannabis from Tilray, one of three producers licensed to distribute domestically grown cannabis for the BfArM which is then distributed by the single licensed distributor Cansativa, though the majority is still being imported from abroad. The single most financially important development for cannabis in Europe is the recent announcement of the incoming German government coalition who have promised to regulate the sale of adult-use cannabis in Germany within their legislative term. See the mini-report 'Adult-use Cannabis in Europe™' for more details.

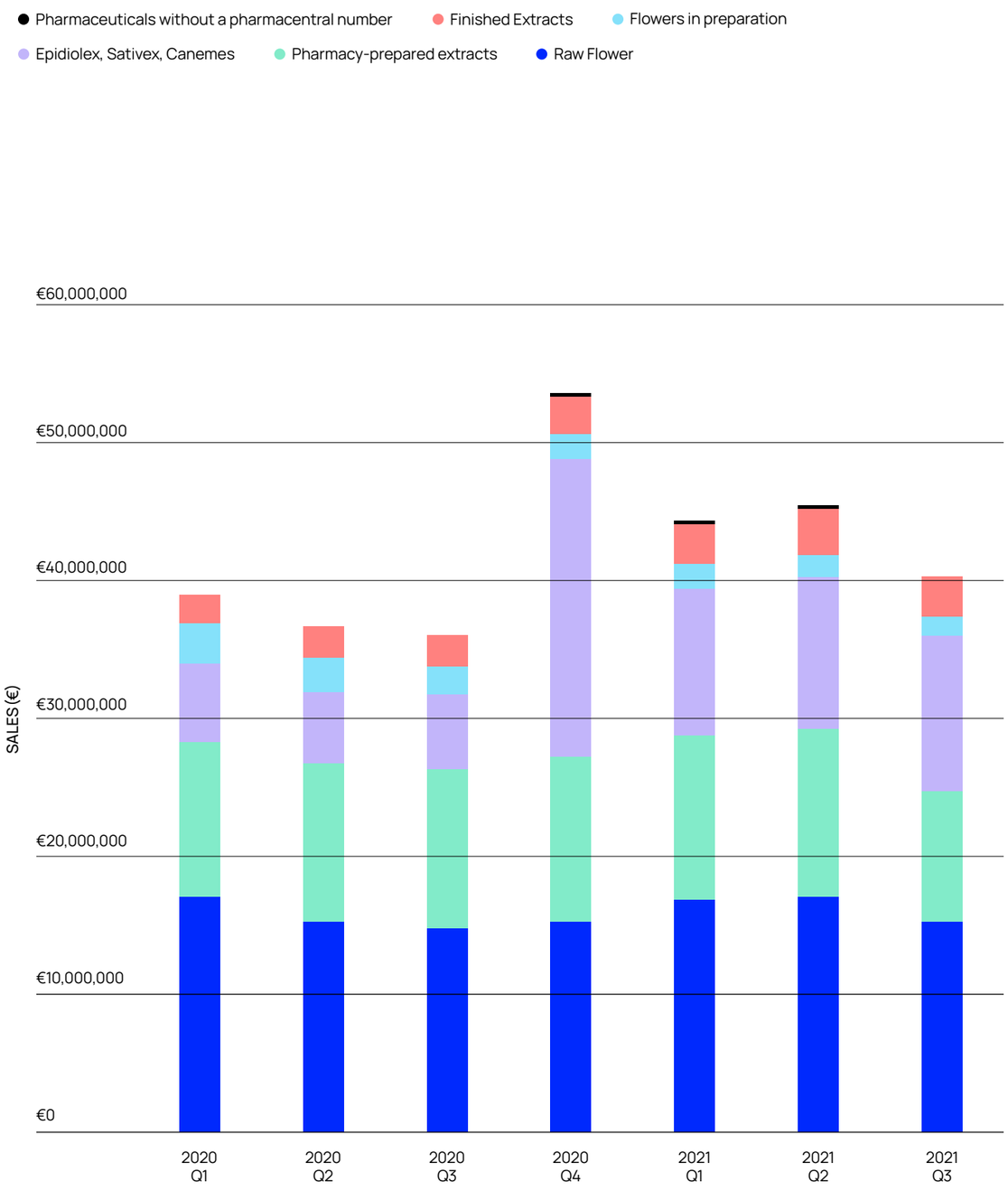
In 2022, the German Parliament released Health Ministry data detailing the amount of medical cannabis distributed to pharmacies for each year to 2022. The volumes are considerably lower than those for imports each year. This is likely due to the fact that not all imported stock of flowers sold to pharmacies actually makes it to patients by the end of their shelf lives; some flowers are re-exported rather than being sent to pharmacies, and the import figures account for extracts while it is likely (but not certain) that the figures for sales to pharmacies do not. When more details on the figures for pharmacy supplied cannabis is known, Prohibition Partners will update its audience. The figures for pharmacy sales show a clear growth of about 43% for 2021.

Medical cannabis sales to pharmacies in Germany



Source: Deutscher Bundestag, Prohibition Partners

Publicly insured sales of medical cannabis in Germany

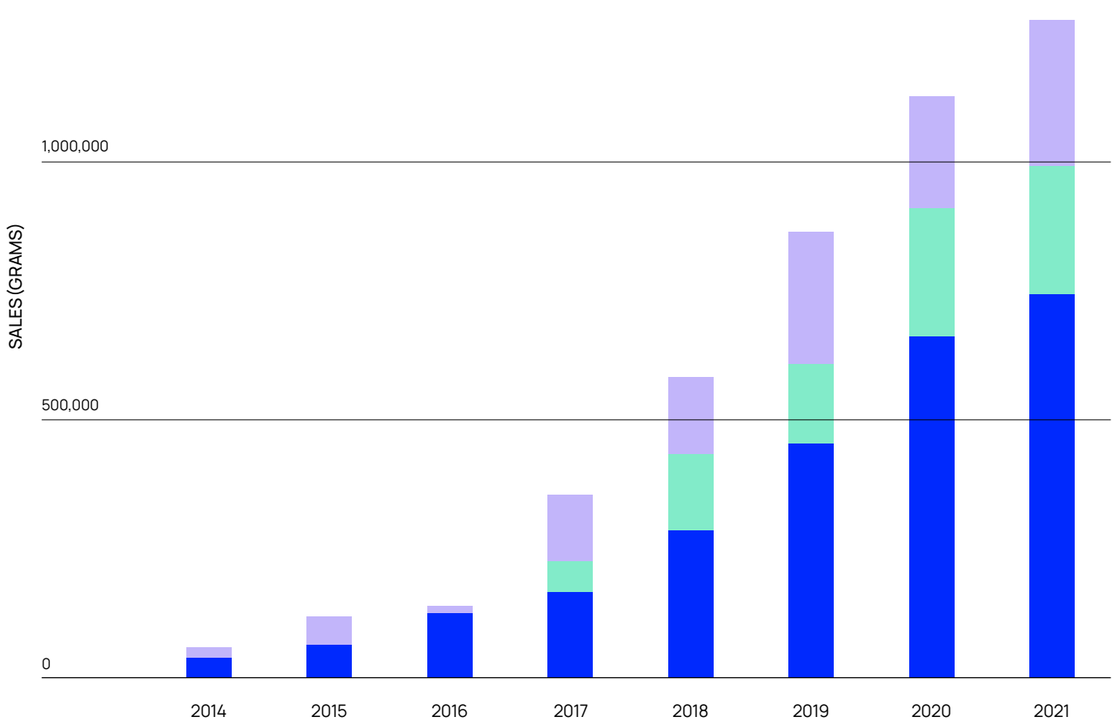


Source: BfArM, Prohibition Partners

Italy

Italy remains one of Europe's most important and fastest growing countries for the use of medical cannabis in Europe. Despite the obvious surge in demand over the past five years, the monopoly control over distribution of medical cannabis in Italy by the government has seen large gaps in the supply chain leaving many patients without their medicines for weeks on end. The Ministry of Health controls tenders and licensing for cannabis in Italy, and allows just five distributors to operate, importing cannabis only from the Netherlands, while the ministry imports from Canada also, and tenders cultivation to the Ministry of Defence in Florence. One major recent event is the awarding of an emergency supply tender to Australian operator, Little Green Pharma. However, the emergency tender will probably only cover one month's or so worth of supply. Patients and advocates will be hoping for the Italian government to do a lot more in 2022 to ensure adequate supply, whether it be through new import tenders, distribution authorisations or increased domestic cultivation.

Distribution of medical cannabis to pharmacies in Italy

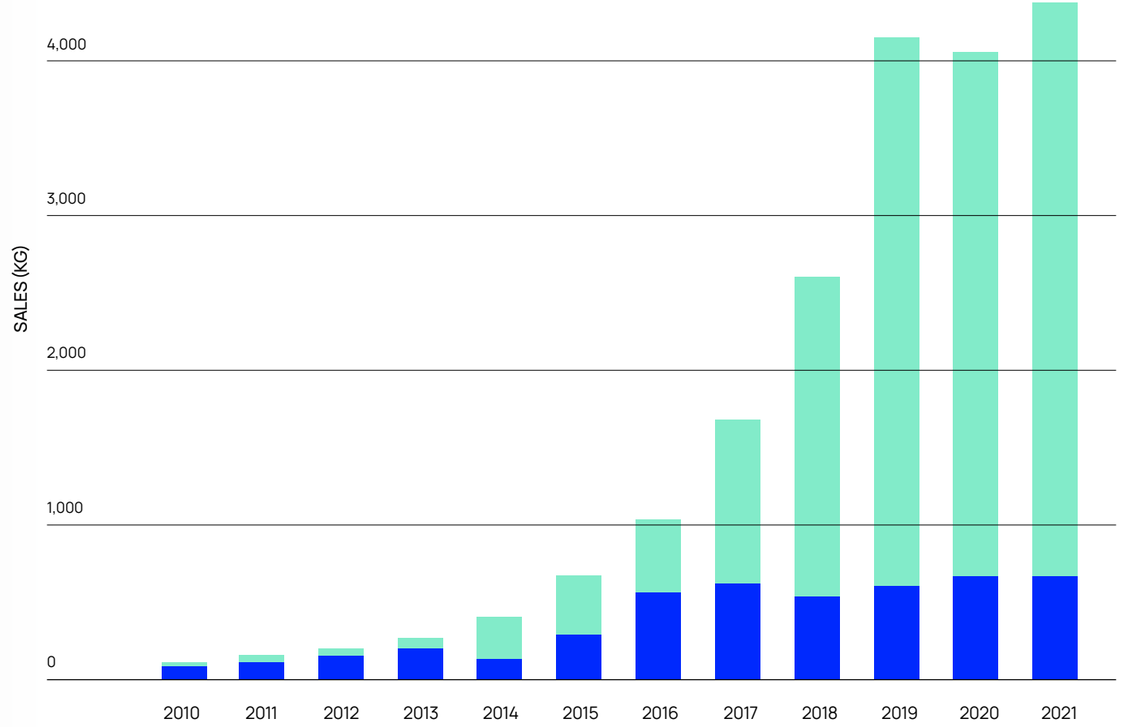


Source: Italian Ministry of Health, Prohibition Partners

The Netherlands

The Netherlands is a central hub of activity for cannabis in Europe, being home to one of the largest patient populations, the coffeeshops and adult-use pilot trials, as well as Bedrocan, who are the largest European producer and exporter of unlicensed medical cannabis. However, the domestic market in the Netherlands has not grown considerably since 2019, after a negative recommendation from the National Healthcare Institute on these treatments, and the subsequent discontinuation of public insurance reimbursement for medical cannabis, except in rare exceptional circumstances. The country continues to be a source of medical cannabis for many nations around the world, and could feasibly expand production and increase revenue from production if the Office of Medical Cannabis were inclined to do so. While Bedrocan has been the sole producer of medical cannabis for years, a new tender for production is expected soon, after being delayed by COVID-19.

Sales of Dutch medical cannabis flower



Source: OMC, Prohibition Partners

Poland

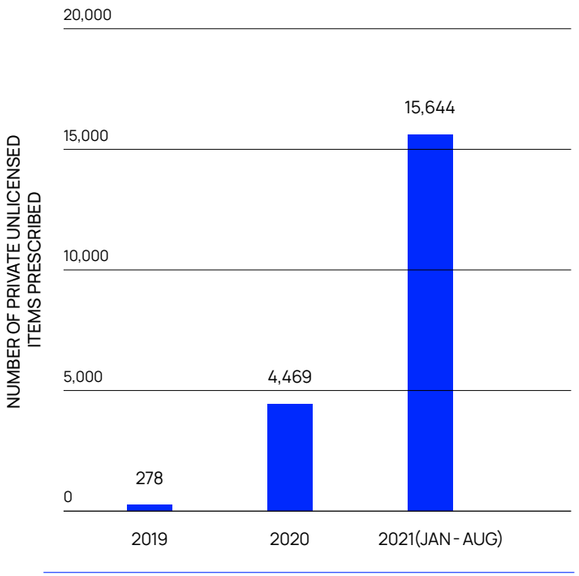
In early 2022, Prohibition Partners published new data showing the size of the patient population in Poland for the first time. In the first three quarters of 2021, physicians in Poland issued 28,076 prescriptions to 9,261 patients, of which 22,029 prescriptions were filled. This would mean about 7,270 patients collected their prescriptions during the period. In total, 197 kilograms of dried flowers were dispensed to patients. This places Poland amongst the largest markets for medical cannabis in Europe. However, severe shortages of medical cannabis have been common throughout 2021. As with Italy, the government places stringent control on imports of medical cannabis, and has approved just seven products to date. One trend to watch out for which would signal the potential for further patient access and market growth in 2022 is the approval of some 14 products currently awaiting approval from the Office for Registration of Medicinal Products (URPL). In late 2021, the first approval for a cannabis extract product was given. Advocates hope that the restrictive process for obtaining individual shipment authorisations might also be streamlined in the near future. As of January 2022, the Polish Parliament is considering a draft bill which would allow for domestic cultivation of medical cannabis under the authority of the Minister of Agriculture.

The United Kingdom

The UK is one of Europe's most promising markets for medical cannabis in terms of the sheer number of patients who could benefit from increased access. Some major regulatory hurdles remain before this can become a reality. Two main issues are; the lack of reimbursement, meaning pricing can be prohibitive for many patients and secondly, the fact that only specialist doctors can approve a course of treatment for medical cannabis patients. This drastically increases the time and effort necessary for a patient to obtain medical cannabis in the country, and may prevent many of the estimated 1.4 million current patients from migrating from the illicit to the legal market.

The NHS Business Services Authority released data in response to a request from Prohibition Partners detailing the number of privately prescribed, unlicensed medical cannabis items dispensed each year in England covering the period January 2019 until August 2021. Private prescriptions refer here to those prescriptions not covered by the NHS. One item here refers to a single product on a prescription e.g. if a patient is prescribed 3 packages of Tilray 25:1 oil and one of Noidecs 20:1, these would register as just two items. The data shows a massive increase each year since 2019, albeit from a low base. Based on Prohibition Partners' calculations which conservatively assume all quarters in 2021 are equal, the annual number of products for last year, amounted to 23,466 a 425% increase on 2020. Things are moving more quickly elsewhere in the UK. On Jersey island with a population of just over 100,000 inhabitants, over 2,000 prescriptions were filled from January 2019 to late 2021.

Privately prescribed items of medical cannabis in England



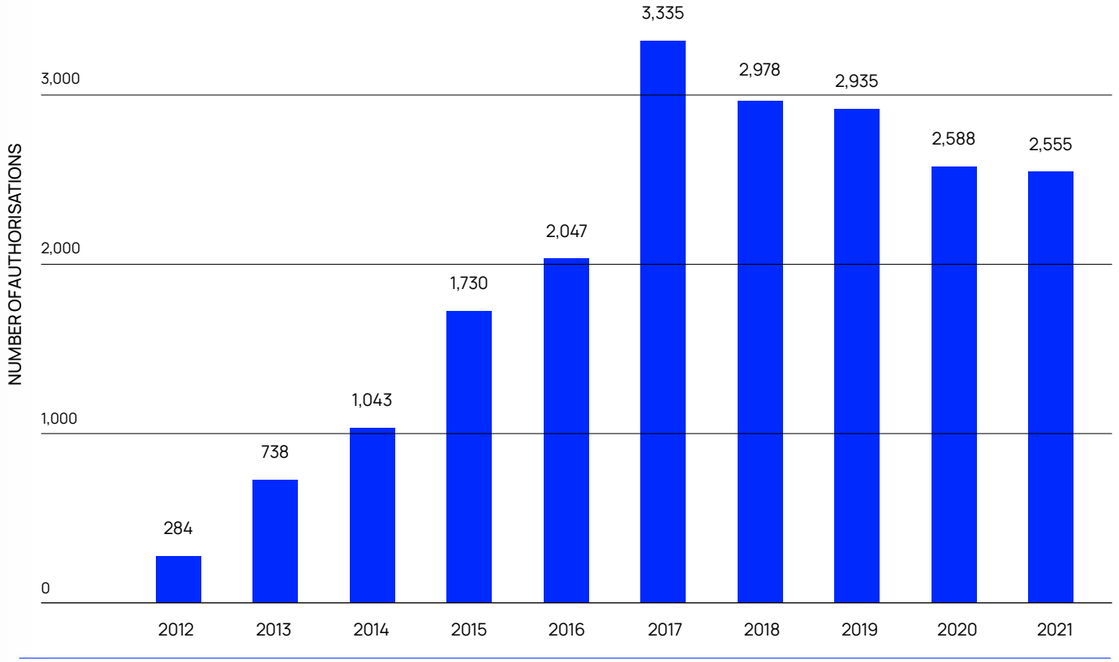
Source: NHSBSA, FOI from Prohibition Partners. ePACT2, NHSBSA Copyright 2022

Switzerland

Medical cannabis access in Switzerland struggles to maintain the growth rates seen at the outset of the access scheme in 2011. While Switzerland has one of the oldest legal protections for unlicensed cannabinoid medicines on the continent, several factors have meant that the number of patients accessing legal cannabis has not been growing very much from around 2017. Figures for medical cannabis usage have been released only in the form of authorisations, which lasted for six months up until 2017, for a year from 2017 and for up to two years from 2021. **As such, the decline in authorisations does not necessarily mean a decline in patient numbers.**

Any doctor may prescribe medical cannabis, however, up until 2022, special permission has been necessary from the Federal Office of Public Health (FOPH), which presents a bureaucratic deterrent for doctors and patients. Only extracts have been available to patients since the start of the access scheme, meaning a limited diversity of products have been available and at higher prices than flower, which also may dissuade patients. Finally, insurance for medical cannabis is not mandatory and for the most part, patients must pick up the cost themselves. In 2022, new laws allowing for prescription, without special approval, may see thousands more patients join the legal medical market. In addition, new rules allowing the cultivation and export of medical cannabis in Switzerland should come into effect this year, opening up the possibilities for domestic operators.

Medical cannabis authorisations in Switzerland

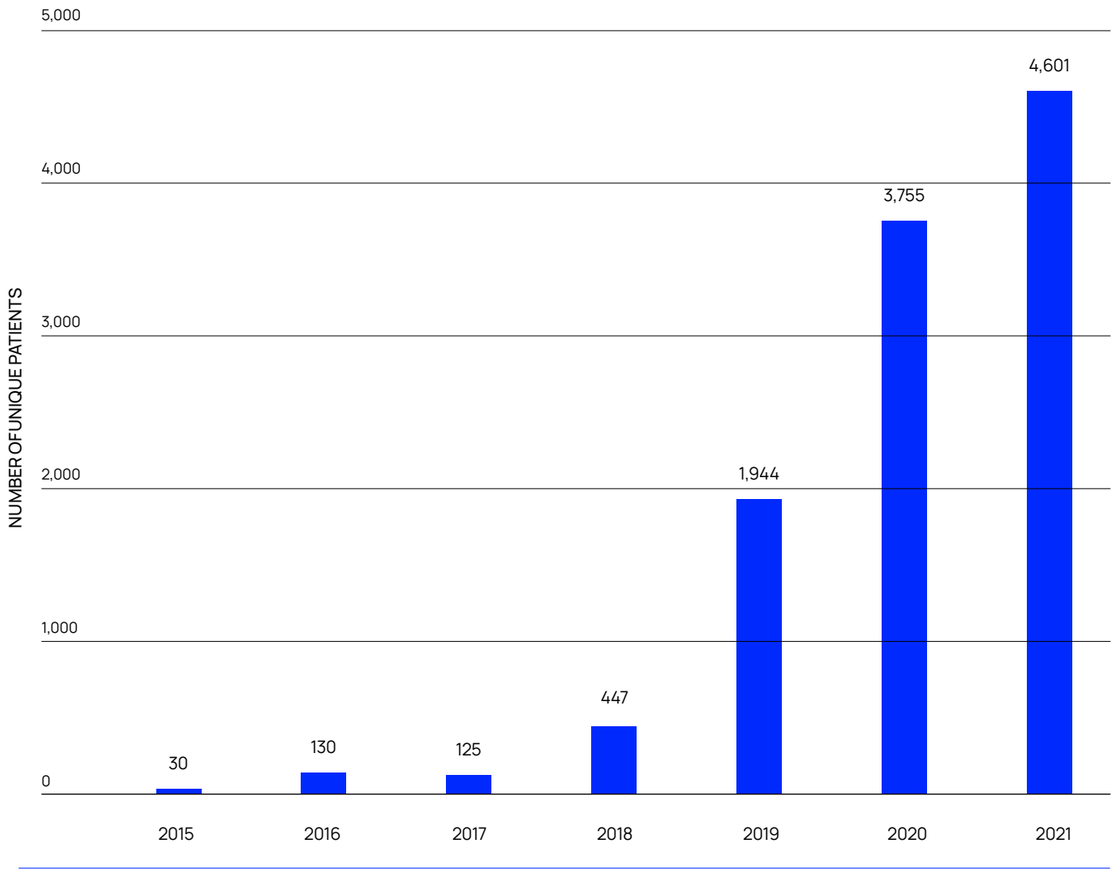


Source: Swiss Ministry of Health, Prohibition Partners; Note:until 2021, the Federal Office of Public Health was required to authorise the use of medical cannabis for every patient before starting treatment. This is no longer the case.

Czechia

Czechia is one of the more progressive countries for medical cannabis usage in Europe, and it has seen a steady growth in patients over the past five years. For example, as of 2020, national health insurance must cover 90% of the cost of medications for patients. Still, several barriers remain to improving patient access in the country. Hana Vágnerová, CEO of the Czech patients association, KOPAC, has told Prohibition Partners that the most significant hurdle is that only specialised doctors who register for providing medical cannabis can treat patients and this number stands at 150 as of February 2022, or about one such specialist per 100,000 people. A limited set of products have been available to patients in Czechia, including: capsules, flower and herbal tea. In Czechia, restrictive tendering processes have meant that a single cultivator (Elkoplast Slušovice, s.r.o,) is licensed, who then supplies a single distributor (Healthcare s.r.o.) with small quantities being imported by private companies. More products are expected on the market soon, as new laws allow for extracts to be placed on the markets as of 1 January 2022. In addition, the law now allows for the introduction of cultivation and export of medical cannabis by private entities, which should increase and diversify supply within the country also.

Patients accessing medical cannabis in Czechia



Source: SAKL, Prohibition Partners

The European Cannabis Report | COUNTRY FOCUS

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EXPERT INTERVIEWS

Dr. Anne Schlag

Head of Research
Project Twenty21

How is the progress with Project Twenty21 overall?
T21 continues to go from strength to strength, with over 2,200 registered patients now. We are grateful that we are able to continue the project beyond its previously estimated completion date (i.e. the end of 2021) and so continue to serve patients and develop the scientific evidence base on medical cannabis.

How is patient access progressing in the UK?
Considering that medical cannabis has now been a legal medicine in the UK for over three years, patient access still leaves a lot to be desired. Access to medical cannabis on the NHS is severely limited, restricted to only four conditions and a limited range of products. That means that the majority of patients are having to go via the private route, which- although costs have come down notably over the past few years- it is still prohibitively expensive for most patients, many of whom are treating chronic conditions, that means they need their medications over very long periods of time. Just this week, Drug Science, together with the charities End our Pain and Medcan, hosted an event at the House of Lords entitled '3 prescriptions in 3 years' referring to the fact that since the rescheduling on 1 November 2018, only three whole plant prescriptions have been written on the NHS, leaving patients with severe treatment resistant epilepsies to suffer- even though in these cases, medical cannabis has been clearly shown to be effective. UK patient access needs to be improved!

What are some major barriers to patient access which remain in the UK?
There are a range of issues that present barriers to patient access. The costs of private prescriptions are still very high, and there is limited- if at all- reimbursement through health insurances as in other countries, such as Germany.

Also, understandably, prescribers tend to adhere to the NICE guidelines, which at present, are still very restrictive. For example, in these guidelines, medical cannabis is not recommended for chronic pain- even though this is the condition patients most often look for medical cannabis for, in the UK, as well as globally. Likewise, the BPNA guidelines are very restrictive, and in light of this many doctors do not feel comfortable in prescribing. Most doctors have not been trained in prescribing cannabis, and add to this that cannabis is still a rather stigmatised substance, and it is easy to see why there is such caution, which unfortunately contributes to the limited patient access.

Also, prescriptions cannot be written by GPs initially- which is a shame, as many of the conditions are actually conditions patients come to see a GP for, rather than a specialist.

Only doctors on the specialist register can initiate a prescription, but under a shared care agreement, any doctor or prescribing pharmacist can actually continue such a prescription, under the supervision of the specialist- a fact that is often not known!

If a consultant continues the prescription then the trust can fund it in principle but they won't, with it being an unlicensed medicine and NICE not approving it so this opens up their clinicians to taking responsibility for the prescription and therefore possible litigation. It should be straight forward but it isn't; sadly.

How important is the lack of guidance from NICE on medical cannabis in the UK, do you see this changing in the near future?
The guidance from NICE (as well as other bodies, such as the BPNA) is important, as understandably, physicians do not like to go against the guidance issued. The sole focus of NICE on randomised controlled trial (RCTs) evidence is misplaced in relation to medical cannabis but in our era, RCTs are perceived as the gold standard in medicine. I'm not sure how quickly this will change but if you look at the history of medicine, the nature of accepted and acceptable evidence has been changing drastically in the past centuries- I can well imagine that this will be the case here, too, especially if we continue to build up the Real World Evidence (RWE) in a highly systematic manner, and with the assistance of new healthcare technologies.

Related to the reimbursement issue above, is pricing still an issue for patients in the UK? How might this evolve going forward?
Costs are still an issue and we very much hope that this will be resolved in the not too distant future. NHS prescriptions for a wider range of conditions, and a broader variety of CBMPs would be the best way forward.

A high percentage of patients on Project Twenty21 are using medical cannabis flowers, do you have any thoughts on the product formats being used and if this will change in the future?
As CBMPs become more widely used in medicine, there is likely to be a move away from flower (not entirely but its 'market share' will reduce). Currently the majority of medical cannabis users in the UK are not 'naive' but often already have a history of treating illness/es with cannabis - and they have used cannabis sourced from the illicit market (from necessity). When seeking legal cannabis they are perhaps more familiar with/ comfortable with flower (which dominates the illicit market to a greater extent than its current domination in the medical market) and therefore seek flower prescriptions. When CBMPS come more mainstream - and the patient population includes an increasing number of cannabis naive patients, we might expect that these patients are more likely to be prescribed other products such as oil.

In the future, other changes may include the introduction of alternative routes of administration - such as 'patches' that different companies are developing, which may be helpful for certain conditions.

What do you see next for Project Twenty21? (If not covered above)
We are hoping to be able to continue to help patients access the products they need, whilst at the same time, continuing to collect data and widen the scientific evidence base on medical cannabis. We are keen to further widen the range of conditions and clinics and reach even more patients. Ultimately, we hope that the scientific evidence collected will influence policy and decision-making, so that patient access can be improved!

On this note, Drug Science has just started a new study to investigate the potential benefits of (CBD dominant) medical cannabis on patients suffering from Long Covid. The rationale behind this is that many of the symptoms of long Covid such as fatigue, muscle pain and insomnia are already being treated with medical cannabis. This study will run for five months from February until June 2022. 30 participants who have experienced long-COVID symptoms will be enrolled after approval from their GPs, then administered daily doses of medical cannabis (in oil form).

Throughout the study these patients' wellbeing will be monitored. Data will then be anonymised and analysed by our researchers, in an effort to establish whether medical cannabis is an effective treatment for their condition.

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EXPERT INTERVIEWS

Bek Muslimov
Co-Founding Partner
Leafy Tunnel

Nikolay Tretiyakov
Co-Founding Partner
Leafy Tunnel

Can you summarise what Leafy Tunnel does?

Leafy Tunnel is an early-stage venture capital firm investing in alternative medicine to address mental health and pain disorders. The team at Leafy Tunnel has embarked on a mission of dedicating themselves to humanity's quest for longer, healthier and happier lives by advancing a new class of medicine with extraordinary therapeutic potential. Our team has worked together for a long time and invested in exciting and fast-growing technology and life science companies.

Leafy Tunnel Fund 1, which is domiciled in Guernsey and advised by Leafy Tunnel Ltd, has an investment strategy that focuses on investing in European medical cannabis companies and global medical psychedelics companies at Seed and Series A stages. The team also feels extremely privileged to say that this is the first fund with such an investment strategy to be regulated both in Guernsey and in Europe.

How easy or difficult is it for European cannabis companies to raise funds now?

This depends on the type of companies being considered, the company's stage and which markets it is targeting or operating in. Generally, we are seeing a growing interest from many investors in European cannabis who are coming from a range of different backgrounds, such as tech and crypto. Even on an institutional level more and more investors from the US are becoming increasingly interested in considering investments in European cannabis companies and therefore, the pool of investors for companies is growing quite quickly, giving them more opportunities than before to source investments.

Your group is focused on medical cannabis, will you ever venture into the CBD or adult-use cannabis markets?

We are solely focused on the medical market for the first fund, whereas for future funds, the adult-use space could be a sector that we begin to consider in more detail. This would also heavily depend on the regulatory framework around the recreational adult-use market and its maturity as well.

When your fund invests in a company, do you or your own investors become involved in the running or mentoring of companies or is there more of a hands-off approach?

As a team we are focused on being a value-add investor for all our portfolio companies. This is an important aspect of our investment philosophy, particularly considering the fact that we are early-stage and long-term investors. We tend to work very closely with the founders to assist them in structuring and scaling the company, whilst also giving them access to our network to help them in any way that we can.

What would you say to a company or an early-stage startup looking to secure capital in European cannabis at the moment?

At Leafy Tunnel, we have developed a range of investment criteria, refined throughout many years of our prior early-stage investing experience. Firstly, we look at the start-up's ability to reach a multi-billion addressable market in at least five years. Secondly, we place significant emphasis on the team and their execution capabilities where we also look for a combination of commercial and medical expertise within the team. With this in mind, we would highly recommend that founders of startups assemble a well-balanced team that can complement each other's skill sets. In addition, we look for founders and management teams who have 'skin in the game' and are well-incentivised through equity ownership. Thirdly, another important consideration for companies is the defensibility of their business model which can be attained through the credibility of their product, distribution channels, or intellectual property. Finally, we look for founders who are transparent in their communication with investors and offer a high standard of governance within the company's operations.

EXPERT INTERVIEWS

Denise Faltischek

Chief Strategy Officer
and Head of International
at Tilray

Why has Tilray focused on the European market instead of just the domestic Canadian market?

We firmly believe that Europe is well positioned to assert itself as a new hub for cannabis with regulatory reforms across the continent progressing. Not only are countries easing medical cannabis regulations, but several are also supporting recreational use. In December 2021, Malta became the first European country to legalise the cultivation and possession of cannabis for personal use. This is likely to be the start of a wave of change in Europe as Germany's new government, as well as The Netherlands, Switzerland, and Luxembourg revealed intentions to legalise cannabis for recreational use.

We at Tilray see ourselves as a frontrunner in the further development of this profitable and professional market given our proven track-record. In addition to leading the medical and adult-use cannabis markets in Canada, Tilray has a unique strategic position in Europe with its global footprint. We were among the first licensed producers to cultivate and manufacture medical cannabis in three countries and currently operate EU GMP-certified cultivation and manufacturing facilities in Canada, Portugal and Germany. In addition to our 'state of the art' facilities, Tilray also operates a subsidiary in CC Pharma, which is a medical distribution business to 13,000+ German pharmacies.

Now is the moment to further grasp the opportunities and project the European cannabis industry forward - the potential is enormous. For example, the eventual adult-use market opportunity in Germany is the largest opportunity in Europe. Germany alone has two and a half times the number of people than Canada, which at a very straightforward level shows how much more potential there is in Europe than Canada alone. We consider ourselves both a Canadian and a European company overall.

Why have many companies shifted their supply from Canada to Europe?

Almost all of the products we supply in Europe are now Europe-grown. This allows us to work more closely with regulators and auditors to ensure our products are of the highest quality, and that there are no compliance issues. In addition, countries in Europe can be more business-friendly in some sense, for example in Portugal, licensing is much more streamlined than in Canada. Growing in Europe also shortens our supply chain which has cost benefits, environmental benefits obviously, and benefits for the quality and shelf-life of products as they are consumed closer to the harvest site and date.

Can you outline your investments in Europe to date

There are a couple of highlights regarding our European operations. Part of our infrastructure includes two EU-GMP cultivation facilities including our production sites in Portugal and in Germany, where we are the only company currently supplying the government with domestic products.

We have invested in European infrastructure more than any other cannabis company in the world. The purpose of this is currently to serve the medical cannabis patient population. However, we are closely watching the developments towards the legalisation of adult-use cannabis in Europe with the knowledge that we can adapt our facilities to cater for this attractive market also.

How can patient accessibility be improved in Europe?

Education of patients and doctors, and the gathering of strong data to convince regulators are two issues Tilray is working on constantly in this context. For education, Tilray offers conferences and webinars for patients and doctors as one example. In the realm of clinical evidence, we have several projects for both clinical and observational data gathering which we hope will further convince regulators to open up accessibility to these vital medicines.

But there is also a need to improve the regulatory frameworks.

One example of this is in Germany. Despite its proven therapeutic benefits, medical cannabis remains difficult to access for many patients because the prescription is currently regulated as an exception and requires corresponding justification. Other countries should learn from these weaknesses to set the course for broad, safe, and high-quality patient care across Europe.

What do you think about the stability of supply in Europe, considering there are intermittent shortages on the continent?

Consistency of product is a key tenant of Tilray's operations. This is true, both of quality and supply. This is part of the reason why we have European facilities, to make sure our product is on the doorstep of patients and can be delivered consistently along a short supply chain. Before we even enter a new market, we need to know that regulations and regulators are supportive of businesses in maintaining such consistency; we will not move into a country if we aren't assured of this. Some countries are more challenging than others, for example the import regulations in Poland make it difficult for any company to maintain supply, so we make sure we have a team on the ground there to optimise our supply with regulator input.

How easily can medical cannabis companies adapt to an adult-use market in Europe?

In our case, we believe a key aspect is that we can adapt the skill set of our staff and intellectual property to give us a big head start. This means using knowledge developed in Canada e.g. on cultivation methods, using our genetic strains and applying 'know-how' in tapping emerging markets. We have seen the transition from medical to medical and adult-use in Canada and we know where the challenges and opportunities lie. This is, of course, on top of the fact that the majority of our supply chain and equipment can be easily switched to adult-use production, as we are dealing with essentially the same plant; just under different regulations.

How do you feel the European adult-use market will develop in Germany compared to North America?

There are definitely a lot of lessons to be learned from legalisation in North America. Pitfalls in regulation, taxation and licensing can all be hindrances to market development and therefore the absorption of trade from the black market into the regulated legal markets. The German government will definitely be looking across the ocean to seek advice from regulators there, but also to industry players like ourselves to understand how best to move forward. We are happy to be in a position to offer our help to German authorities in this regard.

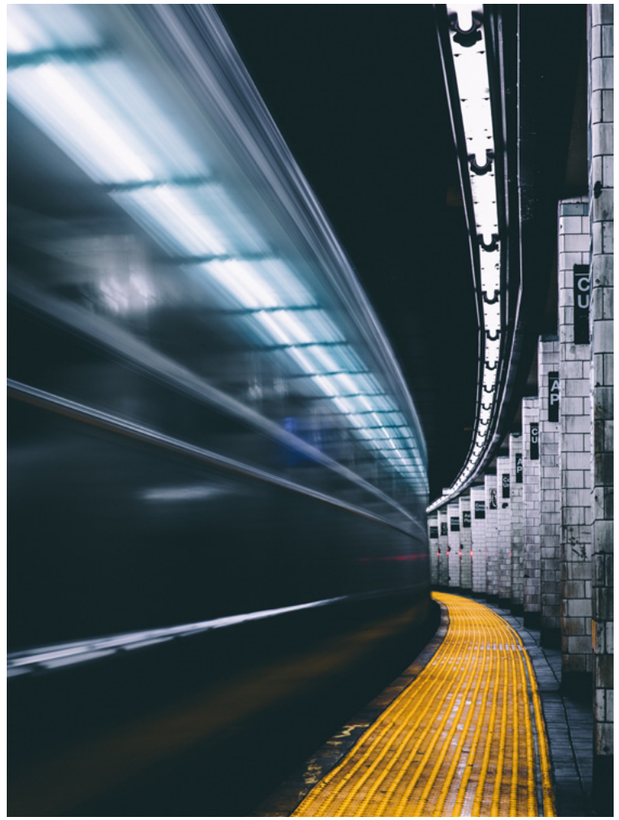
Do you see environmental impacts becoming a more important factor for cannabis patients, and other stakeholders?

At the moment, the focus is on opening up accessibility. This is true from the patient's side, but we expect very much that the environmental, social and governance (ESG) guidelines will become something that is demanded in the near future. People will hold us accountable for our societal and environmental impacts in the long term. Our executive leadership thinks about ESG quite often. The former business of our CEO had a lot of ESG tenets built into the DNA.

Besides shortening your supply chain, is there anything else Tilray does to improve environmental impacts?

Yes there are several key points we are focussing on. It is important to note that the environmental benchmarks set in other industries are not present in cannabis cultivation. Companies like ourselves are basically building out their own framework on this front. There is scope for the industry to collaborate more on this in the future. On a facility basis, we are doing a lot of reusing of water as this is key in cannabis cultivation, and a lot of recycling. Since our most recent mergers, a new environmental impact strategy is a priority for the company.

Acronyms



API	Active Pharmaceutical Ingredient
BfArM	Federal Institute for Drugs and Medical Devices
CBD	Cannabidiol
CBG	Cannabigerol
CBMPs	cannabis based medicinal products
CBN	Cannabinol
CosIng	Cosmetic Ingredients
CPG	Consumer Packaged Goods
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EMEA	Europe, Middle East and Africa
EU	European Union
FOPH	Federal Office of Public Health
GMP	Good Manufacturing Practices
MS	multiple sclerosis
MSOs	Multi-State Operators
NHS	National Health Service
NICE	National Institute for Care Excellence
OMC	Office of Medical Cannabis
OTC	Over-the-counter
PCBs	Polychlorinated Biphenyls
PTSD	Post-Traumatic Stress Disorder
RCTs	randomised controlled trials
RWE	real world evidence
SAKL	State Institute for Drug Control
SCFM	Office of Stabilimento Chimico Farmaceutico Militare
SFK	pharmaceutical key figures foundation
SKUs	stock keeping units
THC	Tetrahydrocannabinol
TGA	Therapeutic Goods Association
UNODC	United Nations Office on Drugs and Crime
URPL	Office for Registration of Medicinal Products
WHO	World Health Organisation

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