THE EUROPEAN CANNABIS REPORT

8TH EDITION

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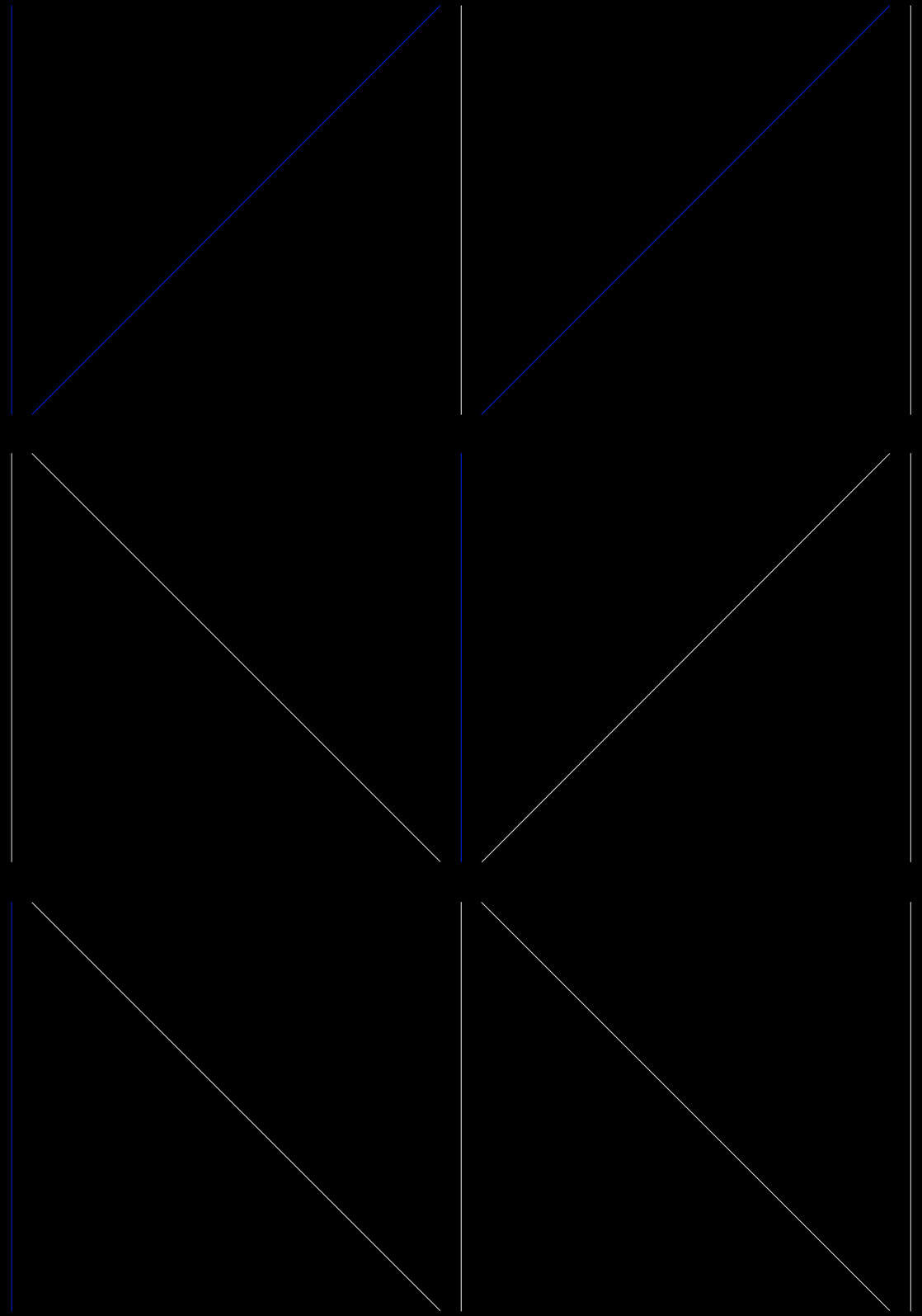

Our reports are the leading source of data and insights for the global cannabis industry.

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

The European Cannabis Report | ABOUT US

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Will Sloane
Head of Growth

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Sponsorship with Prohibition Partners is a unique opportunity to promote your business and brand to the most influential figures in the international cannabis market. Our research, data and content 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

PHCANN INTERNATIONAL

This year, the European medical cannabis industry will continue to not only grow, but diversify. As supply chains continue to expand across the continent, the opening up and development of markets is presenting new opportunities for businesses and investors alike.

At Phcann International, an EU-GMP certified multinational pharmaceutical company headquartered in Warsaw, Poland, our goal is to expand with this increasingly diversified market to provide patients with both high-quality cannabinoids and knowledge about their therapeutic potential.

We work closely with partners, doctors and patients to fully understand patient needs. PHcann's mission is to make available a wide range of medical cannabis preparations for patients, who can benefit clinically at the right time and at an affordable cost.

The company's European pharmaceutical cannabis facility incorporates the latest growing, extraction and packaging technology as well as well-established scientific methodologies to develop targeted medical cannabis products.

The facility has fully vertically integrated indoor operations, its own extraction facility using the latest cold ethanol extraction technology for the production of pharmaceutical liquid forms and formulations, alongside its own laboratory for testing, research and development of cannabinoids.

The facility, which meets the highest standards of the EU-GMP criteria from seed to packaging and storage, has an annual capacity of 15 tons of dry flower and 500kg per day of extraction.

We guarantee the safety of our products with our EU-GMP quality control state-of-the-art laboratory.

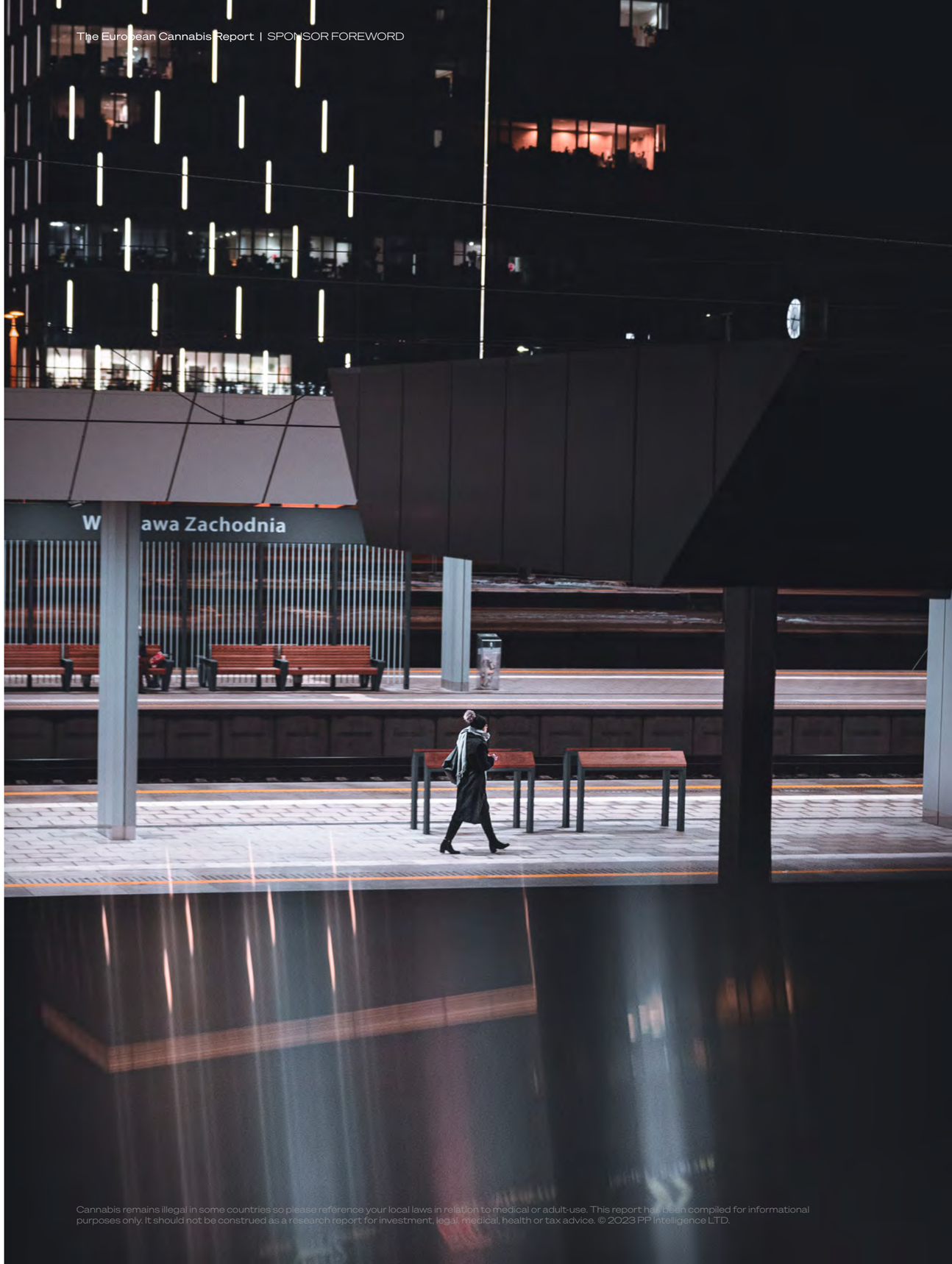
Phcann operates at the highest levels working with government officials in various countries, making sure that all compliance standards and requirements are followed and all certifications and licenses are current and up to date.

Understanding the global market, Phcann has created worldwide infrastructure with its own independent distribution channels on three continents, and has the ability for constant stable supply in a timely manner.

The ability to distribute via our own channels has given us a market advantage, faster market penetration, and the capacity for faster delivery of our products.

With exciting opportunities on the horizon in the European cannabis industry this year, we're excited to be able to play an active role in pushing it forward.

The European Cannabis Report | SPONSOR FOREWORD



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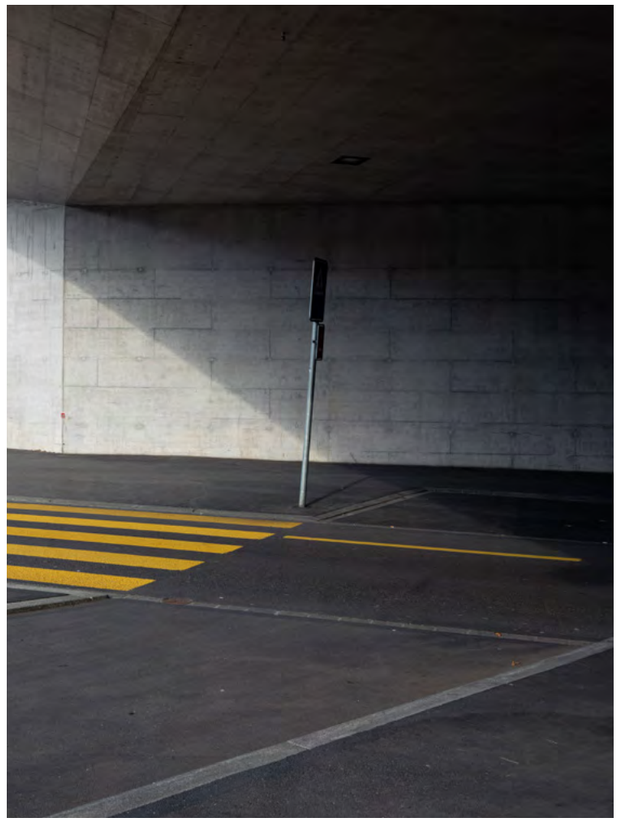
Definitions



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 Cannabis 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 benefits will provide a host of new ways for modulating the endocannabinoid system.

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.

Cannabidiol (CBD)
Major cannabinoid extracted from cannabis sativa (mostly low-THC hemp). It is 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 a treatment for conditions such as epilepsy, as well as pain and insomnia.

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EXPERT INTERVIEW

Zlatko Keskovski
CEO
PHCANN INT Group

Yuval Soiref
Business Development Director
PHCANN INT Group

Vancho Tolomanosi
Business Development Director
PHCANN INT Group

How have the last few years been for you?

Zlatko: Our company was established in 2016 and obtained its license for cultivation and extraction of cannabis for medicinal purposes in 2017.

During that period in Europe, medical cannabis was only legal in a few countries - Germany, for example, only had 2000 patients at that time. I want to point out that we've been involved in the cannabis industry since its beginnings and we closely monitor its development and any potential market changes.

Within the period of the last six years we have gained vast experience in cultivation, the post-harvest process, the needs of the market, as well as the demands of patients within the field of herbal pharmaceutical-form dry cannabis flower production. We have also developed an extraction process,as well as formulation of products in liquid form.

Our company dedicates an enormous amount of attention to the quality of our products and the method of production. We have not only invested in technology but also in human resources who have acquired knowledge and experience tailored to the cannabis industry. Our focus is primarily to establish systems, processes and quality that can be verified to the highest standards.

Our production is EU GMP-licensed to Polish GIF and CUMCS standards. We have an in-house laboratory which is one of the most equipped laboratories for testing of all necessary requirements in accordance to the European Pharmacopoeia and CUMCS standards (from cannabinoids, terpene profiles, pesticides, heavy metals, aflatoxins, microbiology, to product stability within EU GMP and ISO 170025 standards). Although the EU GMP standard is recognised worldwide, we insist on thorough collaboration with regulatory agencies outside of the European continent.

We have presently established ourselves in markets worldwide (depending on their needs), from Brazil to Australia. We are present within three continents and 14 countries at various stages and sizes of operation.

What's changed for you and the cannabis industry from your perspective?

Zlatko: The cannabis industry has changed a lot in the past six/seven years. Every year a new market is legalised while demands also change for doctors and patients who are the last link in this chain.

Today, the quality of production must be at its highest level and must ensure that we pay a great deal of attention to the post-harvest process within the production of dried flowers.

For example, we have discarded all automated and machine processes and replaced these with traditional drying hand trimming and curing. This is with the aim to maintain the quality of the product, the terpene profile and its excellent microbiology. We produce premium flower products without the need for irradiation. Patients are looking for a product that will meet their standards and needs at an affordable price and offer them value for money.

At the moment, the market is a bit crowded but according to regulators' requirements, the needs of patients and the developed knowledge of doctors and their continuing education, this crowded market will filter itself and will stabilise on the basis of quality, fast delivery, easier prescribing and a wider range of disease treatment. To sum it up, all the links in the chain have evolved in the past years fromproducers, retailers, distributors, regulators, doctors, and patients. All of these have individually raised standards to a higher level.

What are the key markets you'll be looking at?

Zlatko: Our strategy is to be present in all markets where medical cannabis is legalised. We have capabilities and registration dossiers for all our products according to EU standards, allowing us to register our products in all markets regardless of their size. Of course, key markets are Germany, Australia and Israel at the moment, while the UK is a market that we expect to develop at the level of these latter three in the next two years. We also have high expectations for markets in Brazil, Poland, Spain, and France. The whole industry certainly believes in the legalisation of cannabis for recreational purposes in Germany, and we are ready to welcome this huge progress in the industry on European soil.

What are the key advantages of your company?

Vancho: Currently the cannabis market is in an exciting place. More and more countries are adopting cannabis both as a pharmaceutical product and for adult-use. We have been continuously growing and developing for the past seven years. The company holds EU GMP certificates along with a host of other government recognised certifications, as well as multi-country registrations. We are also equipped to scale up quickly while providing highly desirable strains at the most competitive prices. In short,we are ready for the next phase of industry growth. This really sets us apart from the competition. I really look forward to seeing where the industry will take us.

What's on your roadmap for 2023?

Zlatko: As I mentioned, we are present in many markets at various stages. We are currently present in Poland, Germany, the UK, Australia, Uruguay, Brazil, the Czech Republic, Macedonia. We are in the process of registration in Israel, Brazil, Italy, Ireland, Switzerland, New Zealand, Portugal and Spain with our own operation or partner companies. This year we also plan to submit a registration in France.

Where do you see the industry heading?

Yuval: I feel like the industry is going toward digitalisation: if we are speaking about cultivation, doctors (prescriptions) or even pharmacies, we believe that the German market will stay stable medically and will keep growing.

We believe that in the near future, patients will be able to sit at home without going to see a doctor to receive their medication . Technology is the future of cannabis. We at Phcann are striving to always work and be up to date with the latest technology providers. This digitisation-era will have a positive impact on cannabis users, recreationally also.

Ultimately, the most important thing is that patients will have a stable supply and a stable product. This is our goal at Phcann International .

SETTING THE STANDARD FOR QUALITY AND INNOVATION IN MEDICAL CANNABIS

- EU GMP indoor vertically integrated licensed facility
- EU GMP/CUMCS Medical flower production with an annual capacity of 15 tons
- EU GMP Cold ethanol extraction with a capacity of 500 kg/day (biomass)
- EU GMP Chemical/physical and microbiological testing laboratory (ISO 17025 accredited laboratory)
- EU GMP Production of pharmaceutical liquid forms/ formulations

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PHCANN INTERNATIONAL

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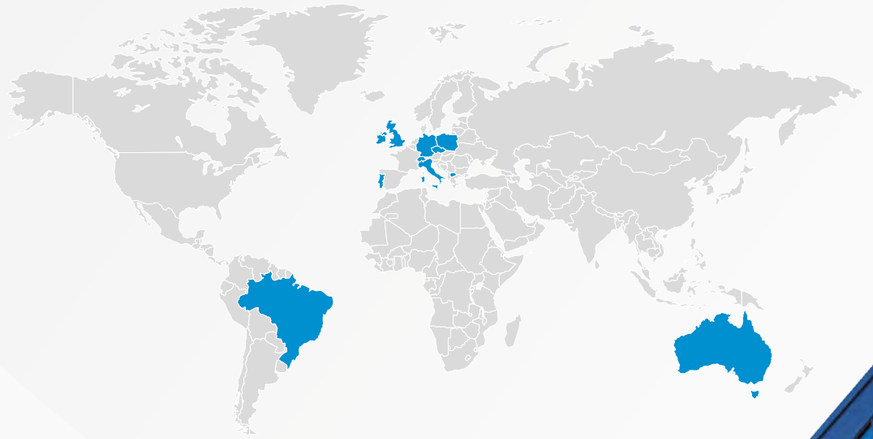

CONTROL UNION IMC G.A.P EQUIVALENT

TÜV AUSTRIA CERTIFIED TÜV AUSTRIA CERT GMBH

EN ISO 9001 20100173003021 EN ISO 14001 20104173003022

EU GMP LICENSED

ISO 17025 ACCREDITED LABORATORY

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Medical Cannabis

The European Cannabis Report | MEDICAL CANNABIS

Executive Summary

The European medical cannabis industry has seen steady growth over the past year and it is projected to reach over €550 million in sales by the end of this year. The UK is set to become the second largest European market over this time, as has been long-predicted by analysts. A large and increasing diversity of suppliers, from a variety of countries, have presence in the market, with Germany and the UK receiving the overwhelming majority of the new supply. Some progress is being made towards regional regulatory harmonisation, with a monograph on CBD flower products being created at the European level by the European Medicines Agency (EMA). Despite it being a tough year for European medical cannabis companies financially, market activity at the end of 2022 gave cause for some optimism.

The European CBD market remains complex, and in some aspects opaque, but increasingly the picture is becoming clearer. The normalisation of various channels of the industry is slowly moving forward, though the wait for novel food authorisations continues. The combined market size of all CBD categories in 2023 is over €2 billion. (to access the Market Sizing chapter, please follow this link). The most significant trend seen in the market is the rise of CBD flower products across multiple countries, which is posing many legal questions and challenges, not least in courtrooms throughout Europe. Another notable phenomenon is the appearance of hexahydrocannabinol (HHC), a semi-synthetic cannabinoid which is similar, in effect, to THC. Regulators are unsure of how to react for now, however a response is expected at some stage. Testing and analysis is becoming more important, ubiquitous and affordable, as the industry adopts a greater focus on transparency and quality in products.

Four European countries are in the process of developing regulatory models for an adult-use cannabis market; Germany, The Czech Republic, Switzerland and the Netherlands. Each country is taking its own approach, though the group can be split into those implementing geographically limited pilot programmes (Switzerland and the Netherlands), and those creating regulations to begin a nationwide market (Germany and the Czech Republic). Delays to the Dutch

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programme have meant that trials in Switzerland, which began in early 2023, are the first adult-use pilot programmes to commence in Europe. Germany and the Czech Republic are reported to be in consultation with one another while each develops its own framework. Each country has published an initial list of proposed features that a regulatory model for adult-use cannabis production and sales would include. Of the two, the Czech Republic's is the more specific, giving a clear and detailed picture of what a legal framework could look like. In all countries, the timeline for when a fully-fledged market will appear remains somewhat uncertain and in all cases hurdles in the form of domestic politics and international laws must be overcome. However, there is strong evidence from some areas that there is the will to overcome these barriers. These early adopters are likely to set a precedent for other countries to follow, and so one or more of the models currently taking shape, may well form the blueprints for a European adult-use cannabis market.

Introduction

The past year has been one of stability for European medical cannabis. There have been no great upheavals or unexpected large-scale shifts in the industry, however it has not been static. There has been a steady development of existing trends. The UK market is growing at a strong pace, which is encouraging for the regional industry, and for global suppliers. A wide and growing diversity of products and players in Germany is resulting in high competition, but steady growth and sizeable margins in the middle and downstream segments of the supply chain mean that the market can continue to support a high number of operators. Denmark and Portugal are increasingly becoming the main hubs of European cultivation, while the Netherlands and Canada are seeing their proportion of the market share declining. Supply chains are becoming increasingly decentralised, with the past year seeing a notable increase in non-European supply coming into Europe, often as intermediate products which need further processing in Germany, Portugal, or the UK, before reaching patients. A promising move towards regional harmonisation in product standardisation is underway, with a draft monograph for medical cannabis flower published for comment recently by the European Medicines Agency. Publication of the finished monograph will represent the first time that there is a true European standard for a medical cannabis product. In financial terms though, 2022 was a difficult year for all industries, and the medical cannabis industry was no different. There have been promising signs in recent months that are giving cause for optimism. Steady growth and development, both at the regulatory level and in terms of market size and industrial activity, are welcome themes for European medical cannabis.

EXPERT INSIGHT

Yves Antoniazzi

Managing Director
Astrasana Holding AG

The Swiss cannabis market opened up dramatically in August 2022 when a revision of the country's narcotics legislation significantly streamlined access to medical cannabis for patients. By also enabling the importation of medical cannabis for the first time, this move has already invigorated patient growth, which had previously been in decline for half a decade, and sales of medical cannabis are now expected to reach €54 million by the end of 2027, up from €3m in 2023

Switzerland-based vertically integrated cannabis company Astrasana Holding AG, founded by Yves Antoniazzi and his long-term European business partners, became one of the first Swiss companies to initiate medical cannabis imports to the country in November 2022.

We spoke to Mr Antoniazzi about the current situation in Switzerland, and how Astrasana is positioning itself to take full advantage of the developments.

In Switzerland, we closed a joint venture with Solumedics which had all the required licences for importation. This enabled us to import the first batch of medical cannabis and sell the APIs to pharmacies.

It also gave us a kickstart into the medical cannabis industry in Switzerland, and we were able to secure clients and sales in the country quickly.

How has the market changed over the last two years?

The long-awaited consolidation in the Swiss CBD market came to a head in the final quarter of 2022, so we are now seeing the prices come up again.

The moment couldn't have been better to launch the Astrasana Group's operations, which focuses on both the medical and recreational CBD side of things.

Do you think the expanding recreational cannabis trials will encourage further growth for cannabis operators in Switzerland?

Overall, I think the pilot recreational trials are a good thing to prepare the population for the full legalisation in our country.

However, there is one big negative aspect, which people are only now starting to realise. The pilot projects in Switzerland are the perfect excuse for the government to defer full legalisation.

It enables them to claim that the study results are not satisfying or the data is not thorough enough, so they can extend the trials for another three years and continually delay the release of the cannabis regulation law, which was actually expected by the end of this year.

What operations does Astrasana currently have in Switzerland?

We have a manufacturing site for cannabis-based medical products in Zurich. The site focuses only about 25% on flower production, and is mostly about the post-harvest process.

Our main target is to establish an EU-GMP facility which is allowed to import, handle, manufacture and repackage cannabis-based APIs and then sell them to other pharmaceutical companies.

The price of medical cannabis raw material has massively dropped worldwide, in a similar way to what we've seen in the CBD sector.

I think, as a European company, our focus should be mainly on having the perfect sales infrastructure and on building a solid portfolio of international clients. Currently in cannabis, having the clients is key – raw materials can easily be found elsewhere.

The European Cannabis Report | EXPERT INSIGHT

We have also just agreed a deal with a large pharmacy in Zurich to extend their facility and open a pure medical cannabis pharmacy where Astrasana's board member Dr Sorg will prescribe medical cannabis directly on site.

This will allow the patient to purchase their products in the same building that they receive their prescription.

I'm pretty excited about this project. We don't only want to sell bulk API's to pharmacies, but we also aim to serve the full value chain and get a better understanding of patients, which is essential in the medical cannabis industry.

Why is this ease of access so important, and do you intend to expand this to other markets?

As mentioned before, we want to be a part of the whole value chain of medical cannabis. In the Czech Republic, our partner Pilulka has a big hospital pharmacy and we were able to take a second facility together just next to it.

From there we will import and manufacture a range of cannabis-based medicines and then transfer them over to the pharmacy, and sell there directly to the patients.

We also plan to sell these products to other pharmacies in the country. Having direct patient experiences helps us to understand their needs in the future.

What other operations do you have in the Czech Republic?

Our regional subsidiary Astrasana Czech SRO was able to quickly create a further pharmaceutical subsidiary called Astrasana Pharma SRO, where we entered the joint venture with Pilulka.

In the Czech Republic, extracts for medical cannabis therapies have been legal since 2022.

Since my team and I have always been really strong on the extract side of the market, we will focus on importing and establishing more extracts for pharmacies and doctors in the country.

The medical cannabis flower market is already well established in the Czech Republic, but there are many older people who don't like to smoke but still want to benefit from the medical benefits of cannabis. We see this as a potentially big market for us.

Elsewhere, we are involved in the first Czech medical cannabis research project. This newly launched study at the Business University of Prague VSE is examining the economic aspects of the plant and its products.

The international university network CEMS is also participating in the study, with world-leading business universities, multinational companies and NGOs. Under the leadership of Prof. Tomas Ryska, the team is comparing hemp-based active ingredients with conventional drugs.

The focus lays on gaining detailed understanding of the experience of medical cannabis patients, as well as those of doctors and pharmacists prescribing and preparing medicinal cannabis products.

We hope the findings from this study can be incorporated into the marketing of cannabis-based drugs in the future. This will also, hopefully, help to improve cooperation with authorities and physicians as well as improve the sensitisation of patients.

Hurdles and uncertainties on all sides will be reduced, and a profitable application of optimally tolerated active substances will be achieved.

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Do you currently have any operations outside of Europe?

We also have operations in Japan, where we mainly focus on the sale of raw materials. Chikako Yoshida, who was one of the first people to successfully import CBD into the country back in 2018, is our Astrasana Japan's regional director.

We are now looking to establish a physical store in the centre of Tokyo. Cannabis is still quite a sensitive topic in the country, and we want to help provide more education around the benefits that cannabis can offer.

On the other side, I think that there is still enough potential to establish a foothold in the Japanese B2C market, and establish a consumer brand in the region.

You're active in three of the most important markets in European cannabis (Switzerland, Germany and Czechia); how do you see the European cannabis market developing over the next 5 years?

Over the next few years, I think we will see more countries legalising CBD flower in the same way as tobacco products. France, for example, has recently implemented a framework where larger tobacco companies already list CBD products following a change in law earlier this year.

At the same time, I think either Germany or the Czech Republic will launch the decriminalisation of high-THC cannabis, before Switzerland is in line. My bet is on the Czech Republic, as they are already really liberal and have a 1% THC limit.

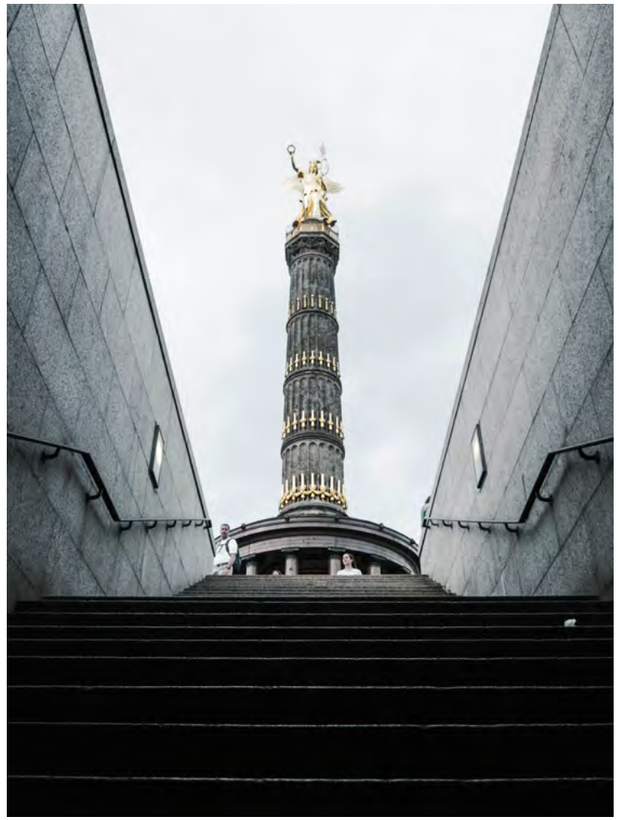
Do you think developments in the medical cannabis or recreational markets will be more important for the development of the European industry moving forward?

For the whole of the cannabis industry, it is very important that both markets keep growing, although it needs to be said that the medical market in Germany and the free oral CBD market across Europe are already quite saturated.

We also need to realise that once prices crash, it doesn't necessarily mean that the prices will increase later on when there are fewer companies producing the raw material.

That's why continuing to be innovative in the cannabis industry is essential. Astrasana has decided to keep focussing on the sales side and always stay as close as possible to the end consumer in the value chain.

Legal & Regulatory Overview



The European Cannabis Report | LEGAL & REGULATORY OVERVIEW

The modern era of medical cannabis treatment in Europe can be most accurately conceptualised as having begun in 2017. This was when medical cannabis access was legalised, or at least widened, in several European countries, including some of the region's largest economies - namely Germany, Italy and Poland. Though some medical cannabis legislation and programmes were active in the region long before this (most notably in the Netherlands, where medical cannabis treatment has been a feature of healthcare since 2003), they are insignificant in comparison to what has taken place in the past six years. This period has seen a remarkable shift in the scale and speed of development of the medical cannabis industry across Europe. Many countries have introduced their own programmes to allow, not only medical cannabis treatment, but increasingly, also its production. Key European markets have attracted significant investment as European and international firms have competed for a share of the growing regional industry. Progress has not always been straightforward however - rosy-eyed predictions about the European cannabis market following a similar trajectory to that seen in Canada, or in certain states in the US, has proved to be wildly optimistic. The current state of the sector poses serious challenges for those operating within it, as well as for those who are looking to participate in it. Understanding the complex, shifting regulatory landscape, which underpins growth in the sector and shapes its development, is fundamental to achieving success in European medical cannabis.

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EXPERT INTERVIEWS

Susanne Caspar
CEO
Linnea

"The state of the European Medical Cannabis Market Now and into the Future"

What is the current state of the medical cannabis market for Linnea in Europe, and specifically for extracts, which are a big part of your business?

Cannabinoids is a booming market with high double-digit growth where Linnea is one of the first movers in pharma grade cannabinoid ingredients with high brand recognition, reliable high quality products & regulatory backbone. Linnea is among the largest CBD API and pharma GMP extract manufacturers. Recent independent market research showed Linnea is positioned in third place in CBD-medical cannabinoid markets in Europe, Latin America and Australia for extract/oil sales. We have been producing CBD cannabinoids since 2017, CBG cannabinoids since 2021 and at the end of 2022 Linnea received a narcotics license from Swiss Medic, the regulatory agency in Switzerland. We are now one of the first companies in Switzerland to be able to produce and export high THC APIs. We have already started producing high THC extracts in our laboratories at the start of this year, becoming one of the first Swiss companies to do so. We see in Europe there is a high demand for GMP certified cannabinoid extracts, as GMP certification is a legal requirement by many countries for sales of cannabinoids. We also see a demand for high THC extracts and different strength options of THC extracts as well as blended cannabinoid extracts, such as THC and CBD together at equal or varying strength ratios. With these important distinctions in mind we are now developing multiple extract options for THC ingredients and cannabinoid blends that also utilize our popular CBD and CBG APIs.

What requirements do you think are crucial for ingredient manufacturers selling to the medical cannabis market in Europe?

GMP certification of the local Health authority is a must. Also important is good knowledge of country-specific cannabis legal frameworks and having a solid market entry strategy for these rapidly changing regulatory environments. A company having their own laboratories to ensure quality of products through each step of production is crucial as well as having an R&D department to work with business partners to develop products for their specific markets. Also vital is having a scientific department to develop clinical and preclinical studies in collaboration with universities and scientists to support applications of cannabinoid ingredients. Having Drug Master Files (DMF) available for business partners for registrations in their countries also has big value. And manufacturers should ensure that all quantities of product from a few grams to kilos, as well as quantities in tons, always have the same pharmaceutical quality.

How do you think the cannabis markets will evolve over the coming years to finish out this current decade?

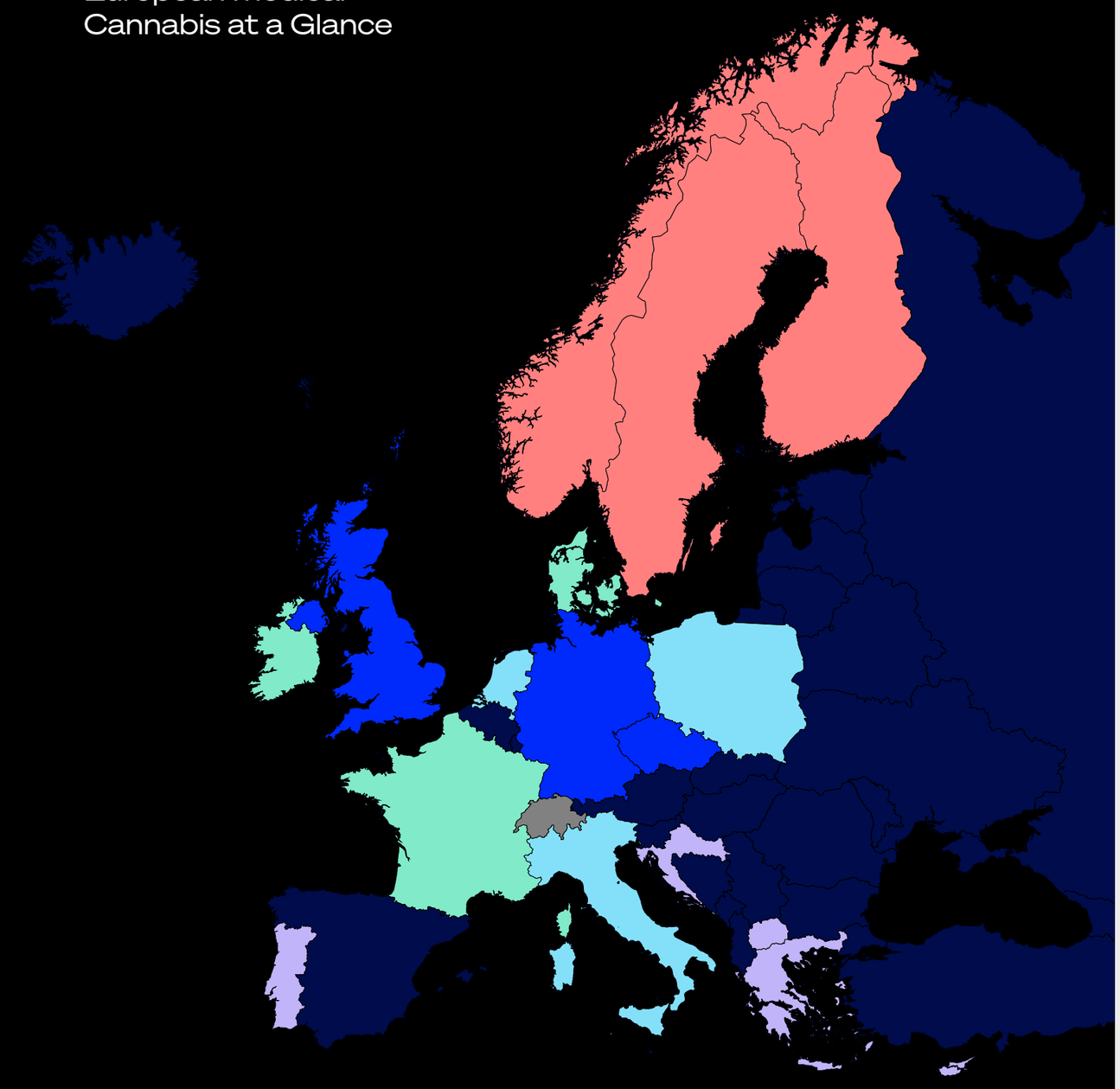
The pharma cannabinoid extracts & isolates market is experiencing strong double digit growth year after year driven by regulatory opening, market education, offer development, product naturality & versatility. There is increased legalization & ramp-up of medical cannabis in key markets (e.g. Germany, Australia), with on-going medical trials in new geographies (e.g. France with ANSM program). We also see both patients and doctors, turning to medical cannabis solutions as efficiency and safety is proven and products are available. There is also further development of different product forms beyond flowers, with extracts and isolates, and increased indications for treatment, like epilepsy and pain relief.

Overall the market will grow double digits in flowers and extracts. In some countries in Europe today, the share of flower is greater than that of extracts. However, we believe that this will change. Countries that have had a functioning medical market for a long time show that the share is shifting towards extracts. As well, pharmaceuticals will dominate more than 50% of the market in Europe and in much of the world. We expect the same trajectory in the market as smoked flower is not a typical format for medicinal delivery of cannabinoids. Flower is not standardized, it has low and highly variable bioavailability and the potency and format is inconsistent and unreliable. Additionally smoking is not a healthy format for consumption for many patient groups and frequently not preferable by

many patients as well. Extracts are standardized and reliable batch after batch so they can easily be dosed exactly to the mg for patients. As well extracts are taken sublingually offering high absorption and bioavailability and are a healthy option for any age group and health condition of patients. As recreational markets develop in Europe we expect flower consumption will move more to recreational markets as it fits more with this type of consumer, and medical markets will be dominant in extracts/dilutions for patients needing cannabinoids for specific medical conditions at specific dosages. We expect registration for more finished products forms will be approved as companies start clinical trials and the share of licensed products will grow.

We expect to capture a higher % of the medical market as this shift to extracts/oil occurs and companies are looking for innovative GMP certified cannabinoid API extracts and isolates for their formulations for medical products and magistral product kits. We have a big R&D pipeline to support this market growth with a focus on THC, CBD and CBG new product development and combinations, as well as new delivery systems for CBD.

European Medical Cannabis at a Glance



FREE MARKETS

These are medical cannabis markets open to free market competition.

Germany – High public reimbursement. Large number of suppliers currently, intense competition. Relationship with distributors essential.

The UK – Very little public reimbursement, access is almost exclusively through private clinics. Large number of suppliers, intense competition. Relationship with distributor and private clinic networks essential.

The Czech Republic - High public reimbursement. Patient access is limited by a reasonably small pool of prescribing doctors that have to apply to become authorised medical cannabis prescribers. High competition, approximately five current suppliers with recent reports of further suppliers entering the market. Domestic production regulations are currently in transition, which could see a new domestic supply being set up in the coming years.

PILOT PROGRAMMES

These are countries which have national medical cannabis pilot programmes which run until a specified end date, beyond which, it is likely medical cannabis access will be widened (if the trial programme is not extended). Products used in these programmes require approval from health authorities, which makes market entry difficult.

Ireland - Programme runs until July 2026. Less than 100 patients are currently receiving treatment, with growth being slow. Six products have been approved from four producers.

France - Programme runs until 26 March 2024, approximately 2,200 patients have been treated under the programme over the past two years. Nine products approved from six producers, provided to the programme free of charge by producers. A tender process is currently underway to secure additional supply for the final year of the programme, with producers being paid for products supplied.

Denmark - Programme runs until 31 December 2025, currently 400-500 patients treated each quarter, with seven products approved from three producers.

Luxembourg - Original programme ended in 2021, after which came a long review period of its success. A second pilot programme is expected to come into operation in the near future. Patient numbers approximately 1,000 annually. Low number of products, from three suppliers.

TIGHTLY CONTROLLED MARKETS

These are medical cannabis markets which are under tight governmental control. This can take the form of product approval requirements, tenders for supply, government-controlled distribution etc..

The Netherlands - Market supplied entirely by one domestic producer, under a tightly controlled supply agreement. Government-controlled distribution. No market entry possible unless negotiated directly with the government. Approximately 13,000 patients annually.

Italy - Market supplied by tenders, limited domestic production, and supply agreements negotiated by the government. Four producers supply approximately ten products. Market inefficiencies exist, product shortages are common. Approximately 50,000 patients annually.

Poland - All products must go through an application process which can take two to three years. Currently eleven products are on the market, from six producers. No public reimbursement, treatment is prohibitively expensive for patients. Market inefficiencies exist, product shortages are common. Approximately 20,000 patients annually.

MARKETS IN TRANSITION

These are markets where the regulations around medical cannabis treatment have recently changed significantly, so the market is undergoing a transition.

Switzerland - A change in regulation in August 2022 has opened the Swiss market to new suppliers, via both imports and the establishment of Swiss-based production. Previously a tightly controlled market, where medical cannabis access was granted based on special authorisation from the health authority. Any doctor can now prescribe medical cannabis at their own discretion. Still no public reimbursement, approximately 4,000 patients treated in 2022.

EARLY/SLOW MARKETS

These are markets where medical cannabis treatment is legal, but patient numbers are extremely low due to the lack of a developed infrastructure for treatment - e.g. lack of prescribing doctors, restrictive conditions for prescribing, incomplete regulatory framework for medical cannabis treatment, lack of available products, lack of awareness of structures and processes for medical cannabis treatment etc..

Croatia
Malta
Portugal
Cyprus
Greece
North Macedonia

EXCEPTIONAL ACCESS MARKETS

These are markets where medical cannabis is only accessed under exceptional circumstances. Patients are given authorisation on an individual basis, and products are imported in extremely low quantities on their behalf.

Finland
Norway
Sweden

SPONSORED CONTENT

Ready, set, grow: How to jump start and future-proof your cultivation company

Horticulture lighting expert Jörg Meyer-Brenken, Fluence EMEA's Lead Account Manager for Cannabis, is candid about European market progress. "Everything is moving much slower than we expected when we started," he says. Yet, this lighting engineer "by education and by heart" advises cultivators not to be complacent.

With over 80 EMEA cannabis customers spanning over a dozen of countries, he expects swift market transformation. Now is the time for growers to find knowledgeable partners with proven success so they can hit the ground running and win.

Meyer-Brenken's teammate Franz-Josef Sima, who joined Fluence last year, draws on more than a decade of cannabis cultivation and consulting experience as Fluence EMEA's Horticulture Service Specialist (HSS) for Cannabis. He agrees that diverse, successful project experience establishes a competitive edge.

"You will be able to learn from pioneers and get the best extraction of knowledge from experienced people," Sima explains. "Growers must adapt quickly and understand the challenges of compliance and consistent production cycles, not to mention large-scale related issues that come along."

Cultivators positioned for growth will reap rewards in faster times to market and improved quality, consistency, and yields — which translate to faster return on investment (ROI) and reduced entrepreneurial risk. Now is the time to ask: Why take the chance on something less?

Reassess your market approach

Slow-moving markets provided operators with time to fail and regroup. As legalization breakthroughs happen, that luxury will disappear. Pressure to shorten learning curves and get to market faster and better will force new approaches from established growers and newcomers.

"Many operators thought they could copy-paste growing experience from mastering cucumbers, peppers, herbs and tomatoes, but cannabis is another plant, so that's a mistake," Meyer-Brenken says. "Also, trying to scale underground growing practices won't do the trick."

"We've seen that first-movers can come away for a limited time with less quality and less predictability, but in the end, I'm 100% sure that uniform year-round production and stable supply fulfilling very narrow specifications on the product will be key," he says. "This will be especially true for medical cannabis facilities but we will see it resonate across the whole market."

Tight operating expense (OpEx) control from the start and a Total Cost of Ownership investment perspective are critical, as proven in California, where HPS (high-pressure sodium) growers struggled with their business case when sales prices fell and energy costs rose.

Sima adds that transitioning gray or black market growers often stumble with criteria and compliance: "Usually they rely on people from the cannabis space, where only a few know how to bring all the parts together: pharmaceutical, cultivation, facility designs, and — most importantly — repeatedly produce consistent, quality cannabis that stays within requirements."

Cultivators can avoid mistakes and profit from lessons already learned. "How can people get faster return on investment? Get knowledgeable persons on deck," Sima says.

Profit from experience and research

With foreign companies already in the European market, teams with multiple-market experience deliver major benefits. Fluence is the market leader for LED lighting solutions in the U.S., as well as key EMEA markets, including Israel, Switzerland, South Africa and Portugal. Half of Portugal's licensed producers trust in Fluence solutions and services. In Israel, Fluence market share approaches 85%.

The European Cannabis Report | SPONSORED CONTENT

While the Fluence EMEA team speaks 17 languages, they also partner with regional companies that share their vision and mission to be their feet on the ground in areas like the Middle East and Africa. Customers enjoy quick response times, local warehousing, and easily connect with people in their time zone who speak the local language and understand local rules, regulations and culture.

Sima says Fluence is also part of several consortiums, collaborating with leading brands and researchers, with internal Fluence scientists pioneering global cannabis research. From specialists like Sima to account managers and technical teams, indoor and greenhouse cultivators get comprehensive support from seed, clone or tissue culture to flower and post-harvest.

Fluence research is driving improved financials and changing how cultivators grow. With high light intensity and various light spectrum regimes, Meyer-Brenken says operators can increase production without expanding canopy space: "So if you're in Switzerland, where property is crazy expensive, you just grow more per cubic meter instead of having to add another square meter."

Capitalize on comprehensive expertise

Meyer-Brenken explains success takes more than buying LEDs: "We're selling light solutions and services. You have to know how to design the whole thing, then how to use it. Not only the lights but also everything around the grow."

While good growers will eventually find their way, he says it may take them a year or more. "We have seen that, with our help, they can make a jump start. They hit the ground running in half the time, and this is just pure money if you have a sellable batch."

The Fluence team goes into a grow to understand and help with all the customer's needs. This involves lighting, but also standard operating procedures (SOPs) and expert insights into inter-related growing environment conditions crucial to success. That doesn't stop with the sale.

In the HSS, head growers and COOs find a sounding board and ally to run challenges by Fluence experts and share knowledge and expertise through training, workshops and one-on-one. Being part of Signify, a multinational company with more than a century in business, strengthens confidence in Fluence for investors and C-level executives.

Sima explains that by capitalizing on deep, detailed knowledge and comprehensive experience in facility design, construction, cultivation and all facets of the cannabis industry, including EUGMP compliance, customers can get it right from the start.

Leverage industry innovation

Fluence is passionate about sharing knowledge and advancing the cannabis industry. R&D breakthroughs get absorbed by the team, deployed to customers and drive internal innovation in products and techniques. Then the knowledge is published for everyone's use.

"That goes back to the spirit of Fluence. We're so grateful to be able to work in this industry and help patients and users get good and safe product. This is the whole idea, this spirit that we really want to help the industry," Meyer-Brenken says. "We believe this whole industry is still in its infancy and if we don't share, we will block the development and we will not be as fast as we could be if we work all together. We've tried to lead here by example. So what we know, we share."

Sima adds that cannabis cultivation procedures are crystalizing into a handful of best practices representing the fastest, most efficient, most successful path. "If you don't choose that, you're already below the quality you can reach. Best practices for quality and consistency are always the core areas of focus for Fluence," he says.

Whether it's research, new product development, or next-generation innovations, Fluence is always working on the next thing. "Through our open innovation process, we can ensure collectively to our partners and customers that we're already at work on the next important innovation benefitting premium cannabis cultivation," Meyer-Brenken says.

Whether you're an established cultivator or new to the market, you can jump start and future-proof your operation with proven, science-led expertise. As the European market moves forward, will your company be one that leads?

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. © 2023 PP Intelligence LTD.

The following table shows a number of the key characteristics of the sector.

Key Characteristics of European Medical Cannabis

	In terms of patterns of consumption - it is highly fragmented, and it will remain so. Though there is a relatively high level of integration in healthcare between European states, healthcare policy is still ultimately decided on a country-by-country basis. This is particularly true in the context of medical cannabis which, as both a scheduled narcotic under international law and an unlicensed medicine, usually requires the establishment of dedicated legal frameworks to define the conditions and processes where prescription and patient access is allowed at a national level.
	In comparison to the development of medical cannabis in states in the US, European regulators draw a much clearer distinction between medical and legal adult-use cannabis (which does not yet exist to any significant degree in the region). This results in medical cannabis being part of a much more controlled and bureaucratic system in European countries than in states in the US.
	As an emerging market, the pace of change is rapid. Regulatory and market developments are happening on a continuous basis at European, national and local levels, affecting supply chains and putting pressure on operators to adapt their business models to suit new environments.
	At a global level, Europe is the number one export destination for medical cannabis products because a small number of key markets not only allow imports, but are overwhelmingly supplied via imports. As the global medical cannabis industry is also developing quickly, new players are constantly emerging which is creating intense competition.
	European Union - good manufacturing practice (EU-GMP) (or equivalent) certification is crucial for the final processing steps of medical cannabis products intended for the European market. The current consensus is that cultivation does not need to be covered by EU-GMP certification, but apart from a few exceptional cases relating to domestic (Czech and Italian) production, products must undergo processing in an EU-GMP facility before being used to treat patients. The path to attaining such certification is a long and expensive one, so non-EU cultivators are increasingly finding ways to partner with EU-GMP manufacturers rather than obtaining EU-GMP certification themselves.

Source: Prohibition Partners

The challenges inherent in the European medical cannabis arena are often also associated with opportunity. A dynamic and shifting economic landscape constantly generates new opportunities, and allows businesses which are able to adapt quickly, to succeed. A high barrier to entry in certification and quality requirements endows businesses, which have the capacity to meet them, with high strategic value. In addition, though the nature of the regulatory landscape prevents full harmonisation of consumption patterns, the same is not true for production. Supply chains are increasingly being set up in a decentralised manner across the continent, with cultivation in one country, processing/manufacturing in another, and distribution and retail sale in a third. The licensing frameworks for medical cannabis production will differ between countries, but there are already integrated systems in place between European countries allowing for the import and export of different pharmaceutical raw materials and APIs, which accommodate bulk medical cannabis intermediate products (including bulk flower and extracts).

At the finished product level, there is some movement towards harmonisation across the region in the standardisation of medical cannabis flower products. A new monograph for cannabis flower is being created by the European Medicines Agency (EMA) for publication in the European Pharmacopoeia. This monograph will serve as the reference guide for the parameters which all medical cannabis flower products must adhere to. Though the monograph is still being finalised, a draft version was released in October 2022, and the final version is not likely to differ significantly from this. The following is a quick overview of the key takeaways from this draft monograph.

Proposed new European monograph for Cannabis Flower

DEFINITION

Dried, whole or fragmented, fully developed shoot apices of female cultivars of *Cannabis sativa L.*

PRODUCTION

If the herbal drug is to be prescribed to patients, the shoot apices are cut directly at the base, with minimal stalk remaining.

CANNABINOID CONCENTRATIONS

Note: *'Total THC' and 'Total CBD' calculations include 88.7% of the volumes of THCA or CBDA content in a sample, which convert into THC and CBD respectively via decarboxylation (to a maximum efficiency of 88.7%).*

Three proposed chemotypes:

High THC type
(10.0 % - 30.0 % total THC / max. 1.0 % total CBD)

THC/CBD type
(3.0 % - 15.0 % total THC / CBD)

High CBD type
(5.0 % - 20.0 % total CBD / max. 1.0 % total THC)

Content Limits:

Total Cannabinol (CBN): max. 1.0%.

+/- 10% allowance for error of the labelled total amount of Tetrahydrocannabinol (THC) and total Cannabidiol (CBD)

No terpene requirements

TESTING

The proposed limits for heavy metals are significantly lower compared to those provided in the general Ph. Eur. monograph *Herbal Drugs* (presumably due to the potential inhalation use).

Arsenic: max. 0.2 ppm

Cadmium: max. 0.3 ppm

Lead: max. 0.5 ppm

Mercury: max. 0.1 ppm

Foreign matter (e.g, mould, soil etc.): Max. 2 % if the herbal drug is to be prescribed to patients (i.e. if the herbal drug is not only to be used as a starting material for the preparation of extracts etc.), it does not contain any seeds and the whole herbal drug does not contain any leaves more than 1.0 centimetre in length.

Loss on drying: Max. 10.0 %.

However, regarding mycotoxins, pesticides and microbiological quality it is still required to refer to the general Ph. Eur. monograph *Herbal Drugs*.

STORAGE AND LABELLING

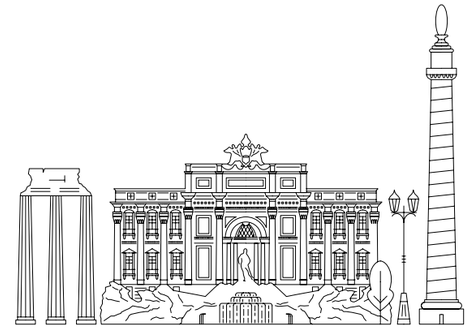
Storage: in an airtight container. The label states the contents of total THC and total CBD (%). In addition, the label states if the herbal drug is to be prescribed to patients (*Dispensing Drug*).

Source: Prohibition Partners

In order to establish a European Union (EU) herbal monograph for cannabis flower, the EMA's Committee on Herbal Medicinal Products has requested the submission of scientific evidence on cannabis flowers to be used as part of the assessment. The submission period is from 15 February to 14 May 2023. More information is available at EMA's procedures for monograph and list entry establishment website.

European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
ITALY	Two tiers of prescription (pay prescription for private healthcare and reimbursed prescription for public healthcare).	**Pay prescription:** all doctors, for all pathologies supported by scientific evidence, when traditional treatments failed or require increases in dosage that could comprise the patient. **Reimbursed prescription:** each region has unique limitations on pathologies treatable, prescribers and products. A therapeutic plan by a specialist is always required. General practitioners provide renewals of prescription according to the therapeutic plan.	**Pay prescription:** all pathologies supported by scientific evidence **Reimbursed prescription:** each region has limitations on pathologies. Generally there's covering for chronic pain, spasticity, chemotherapy, muscles spasm, anorexia, glaucoma.	**Flowers:** **Bedrocan:** Bedrocan, Bedica, Bediol, Bedrobinol, Bedrolite **Italian army:** FM1, FM2 **Little Green Pharma:** BillyButtons **THC oils:** Farmalabor oil 15% **CBD** (API)	**Flower:** Fixed price for patients at €9/gram

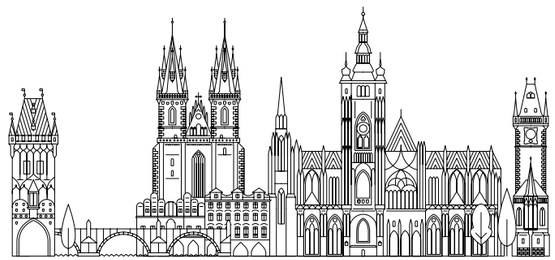


Source: Prohibition Partners

European Overview Tables

CZECH REPUBLIC

REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
Public health insurance will cover 90% of the costs with the maximum volume being 30 grams per month, or up to 180 grams if the insurance company doctor approves.	Only doctors with a specific specialisation may prescribe medicinal cannabis, and only for specific health indications according to the doctor's specialisation. **Specialisations include:** Oncology, Neurology, palliative medicine, treatment of pain, rheumatology, orthopaedics, infectious medicine, internal medicine, dermatovenerology, geriatrics, psychiatry, opthamology. In order to prescribe medicinal cannabis the specialist doctor must apply to the State Institute for Drug Control for authorisation to prescribe. Electronic prescription only to patients 18 years and older. Amount is limited to 180 grams of dried cannabis per person per month.	Treatment resistant chronic pain and conditions associated with multiple sclerosis, cancer and AIDS.	All flowers which can be used for medical cannabis are those whose levels of THC (tetrahydrocannabinol) fall within 0.3 percent to 25.0 percent and whose levels of CBD (cannabidiol) do not exceed 23.0 percent. Obtained by patients as an individually prepared medicinal product (IPMP), prepared by a pharmacist, upon a doctor's prescription. Domestically grown flower can be used as long as grower has a permit from the State Institute for Drug Control. Motagon recently introduced Gorilla Glue (26%THC, 0%CBD), Motagon/PHCANN int. extract (25/25 and 25/1.7), French cookies (24% THC), La Sage (22% THC) and Hellfire (20%THC). In the past, products from Tilray, Aurora, Canopy Growth and Bedrocan have been imported though it is unclear what stocks are kept currently. Private Individuals may also cultivate medical cannabis provided it adheres to the regulation.	**Flower:** Price cap of €6.41 /gram

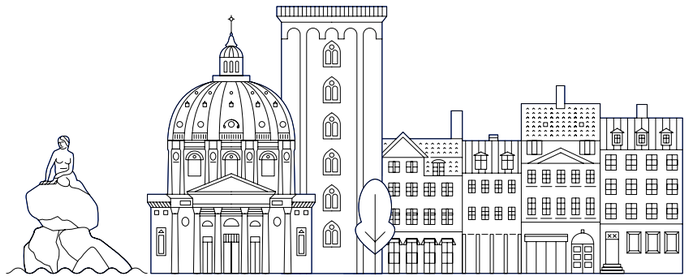


Source: Prohibition Partners

European Overview Tables

DENMARK

REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
Applications are individually assessed based on the criteria of the Danish executive order on reimbursement. The Danish Medicines Agency grants single reimbursement to patients suffering from disease if assessing that the medicine will work or considering it highly likely that the cannabis-based medicine will work. Single reimbursement is not granted before all other treatments with authorised medicines have been tried for the disease in question. On the pilot programme: citizens who are terminally ill are reimbursed 100% and other citizens are reimbursed 50%.	All doctors can prescribe medical cannabis products, for all conditions. Danish Medicines Agency (DMA) indicates prescription only when traditional treatments fail. DMA recommends not to treat people 18 and under.	Products on the pilot programme can be prescribed for any patient for any disease.	Bedica 'CannGros' Bediol 'CannGros' Bediol 'Scanleaf' Bedrocan 'CannGros' Billinol 'LGP' THC Olie 'Stenocare'	**Flower**: €20/gram **Oil:** €200-300/30 millilitre **Capsules:** 2.5-5 milligrams THC, €250-300/60 capsules



Source: Prohibition Partners

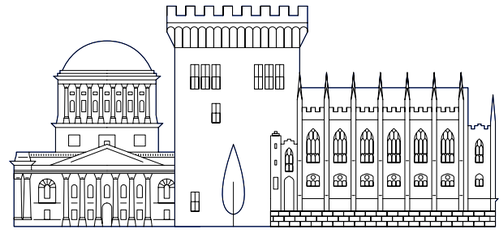
European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
GERMANY	Patients with serious illness can, under certain circumstances, be reimbursed by their public health insurer. Reimbursal base price is set at €4.30/gram. If you are privately insured, pay whole cost upfront and apply for reimbursal through insurance provider.	All doctors can prescribe medical cannabis. Patients can receive a medical cannabis prescription from a physician if any of the following criteria apply: i) A general standard therapy does not exist for their disease ii) The standard therapy does not apply according to the justified assessment of the treating physician, considering side effects and disease status of patient iii) There is a reasonable possibility that medical cannabis will have a positive effect on the disease process or on serious symptoms If the above requirements are fulfilled, health insurers must reimburse the costs for cannabis therapies apart from in exceptional circumstances.	Technically any if they meet the requirements Most treated conditions are: pain, spasticity, anorexia, epilepsy, ADHD, Tourette Syndrome.	Over 300 products (flower + extracts) on the market as of February 2023.	For private patients, the prices on average in August 2022 were: **Flower:** €12.1/gram **Oil:** €10.5/millilitre

Source: Prohibition Partners

European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
IRELAND	Medical cannabis is reimbursed automatically under ministerial approval. When accessed under the new Medical Cannabis Access Scheme, reimbursment is granted on a case-by-case basis and only for patients obtaining via: a Medical Card, the Long Term Illness Scheme or Drugs Payment Scheme. If patient is not eligible for reimbursal, cost will be paid out of pocket.	Under the medical cannabis access programme, specialist doctors can prescribe after they have applied to register their patients for prescription. When applying via ministerial approval, specialist doctors can prescribe or they can provide a recommendation which is used by the patient's personal general doctor.	Severe, refractory (treatment-resistant) epilepsy. Treatment resistant MS-related spasticity. Nausea from chemotherapy when anti-sickness treatments aren't working. Any condition theoretically, given ministerial approval.	Aurora high CBD oil drops CannEpil Tilray Oral Solution THC10:CBD10 25 millilitres Aurora Sedamen Softgels Oleo Bedrobinol Oleo Bedrocan	



Source: Prohibition Partners

EXPERT INTERVIEWS

Philipp Hagenbach
COO
Cannavigia

Pia Meyer
Product Manager
Cannavigia

Why are the Swiss Pilot Projects such an important milestone for the industry?

Philipp: Until recently, recreational cannabis has been illegal in Switzerland and classified as a narcotic drug. It wasn't until May 2021, when an amendment to the narcotics law was passed by parliament, that pilot projects were made feasible. The start of the first trial end of January this year marked the very first time that recreational cannabis could be legally purchased in Switzerland and was also the first nationwide legalization attempt in Europe. While Germany, Portugal, and the Czech Republic are closely watched for their approaches to cannabis legalisation, Switzerland's pilot projects offer valuable insights into how to create a scientific basis for future legislation. I believe that many countries can learn from Switzerland's innovative approach and eagerly await the outcome of these projects.

Can you tell us how you are involved in the projects – as a company and personally?

Philipp: For the pilot trials, we have extended our existing software with the Cannabis Dispensary System (CDS). With Cannavigia, the companies cultivating cannabis for the projects, can monitor and document their supply chain and cultivation from seed to delivery, ensuring the quality of the products. The CDS is then used by the project leaders to register trial participants pseudonymously as well as include selected dispensaries where participants can purchase cannabis. The CDS allows dispensaries to keep track of their narcotics inventory, sales, as well as the specific quantities dispensed to participants, guaranteeing that only those who are authorised to do so can buy the cannabis goods.

Pia: Internally, Philipp and I led the development – of course with a great team behind us. We participate in meetings with external parties like the Federal Office of Public Health, the project leaders of the different cantons or the police. In these meetings as well as through frequent exchange with the different stakeholders, we gather the various requirements and ultimately start developing and implementing the needed functionalities in the CDS.

Why is this involvement so important for your company?

Philipp: We have the chance to contribute our ideas to this brand-new way of thinking! Thanks to our involvement in the pilot projects, we have the chance to be part of regulation changes and law making in a political sphere of a new and emerging industry. Further, the trust of the Swiss government granted our company and the software high credibility and enormous recognition. This makes us more trustworthy with other regulators and potential clients. We have already seen evidence to support this as we had the privilege to discuss related strategies with legislators from other countries.

Pia: The pilot projects are the perfect example of why we have developed our software: complete supply chain transparency and traceability. This is why we are so proud to talk about it and why this is a big milestone for our company.

What have been the challenges in making this work?

Philipp: There are numerous stakeholders whose needs we had to capture and serve. You believe you've thought of everything when you start planning, developing and reviewing, but there is always more to consider. And since we were creating something completely from scratch rather than simply improving upon something, there was ongoing planning and issue solving. The project was, still is and will always be exciting. Yes, there have been challenges, but I am safe to say that we celebrated more successes. It is amazing to see how everything came together in the end.

The first pilot trial, Weed Care, began at the end of January, and both project leaders and pharmacies have begun using the CDS. What has the feedback been so far?

Pia: We received very positive feedback overall! The project leaders were able to successfully register participants using the Cannabis Dispensary System, while the pharmacies use the CDS every day to

track the dispensing of cannabis to consumers. Questions about the application of the software may arise occasionally, but we maintain regular communication with all stakeholders, which has made the overall handling very satisfactory. Additionally, the feedback has provided us with valuable insights on what we can improve and what might be helpful for our work with upcoming projects.

Does this mean that you already work together with other pilot projects?

Pia: The second pilot trial Züri Can, led by the Psychiatric University Hospital Zurich and the city of Zurich, has recently been approved by the Federal Office of Public Health and the cultivation for this study will start soon. Two of our clients, Swiss Extract and Pure Holding, will be delivering the cannabis for Züri Can and will use the Cannavigia software to track their plants and processes. Further, we are also providing the Cannabis Dispensary System to the Züri Can project leaders and to the pharmacies, social clubs and the drug information centre of Zurich that will serve as dispensaries. We are currently discussing with the project leaders whether any additional functionalities need to be developed for this exact study and we are preparing the training for all stakeholders involved.

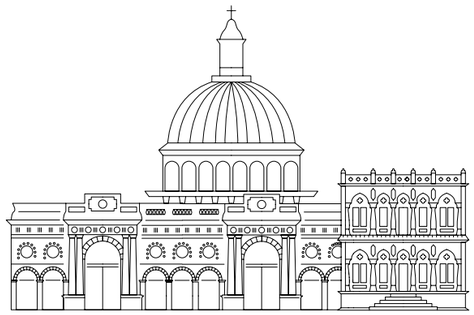
Philipp: Besides the two already approved projects, many more will follow that we can assist with our system. We are looking forward to finding out which ones will be approved next and with whom we will be collaborating with.

Do you see the pilot projects also fit for other countries?

Philipp: I firmly believe that pilot projects are a good approach for a structured and well-thought-out legalisation process. However, every country must take its unique nation-specific factors into account and find a way to legalise cannabis that fits its market, economy and population. Regardless of the path chosen, the safety of consumers is vital. Ensuring transparency and traceability in the supply chain is crucial, and consumers must know the products they are purchasing and consuming.

European Overview Tables

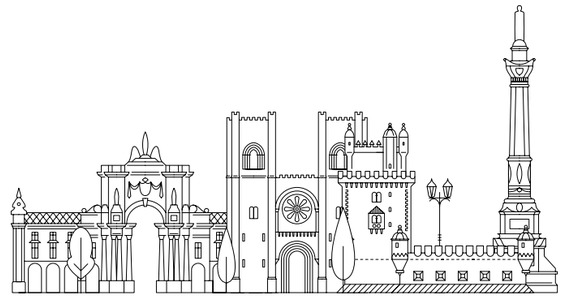
	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
MALTA	Prescription medicines prescribed by a doctor are non-reimbursable. The only exception is when one is an inpatient in a hospital, and for three days after patient is discharged. Low income and/or chronic illness may entitle you to free prescriptions. Otherwise the patient pays out of pocket.	Can be prescribed by any doctor if it is considered that there is no viable alternative after all other treatment options have been tried. Doctor must first get approval from the superintendent of public health.	MS Chronic pain Chemotherapy side effects 'Debilitating conditions'	**Dried Flower:** Aphria 20/1 Aphria 22/1 Aurora 20/1 Aurora 22/1 Bediol Bedrocan Cannabis 1A 18/1 Carbasi Verde Pedanios 20/1 Pedanios 22/1 Salus Biopharma Medical Cannabis Flower, Strain: EMT-2, THC 20%, CBD <1% ZeraMed ZeraUltra s22:0 **Cannabis extract standardised in MCT oil:** Adven 10/10 Full Spectrum Extract Adven 20/0 Full Spectrum Extract Aphria 0:25 Aphria 10:13 Aphria 20:6	**Flower:** €10-16.50/gram



Source: Prohibition Partners

European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
PORTUGAL	Cannabis-based medications are priced like other medications in Portugal. Maximum price mechanism determines prices based on comparison with approved wholesaler prices in reference countries for the same medicine, or a identical active substance and dosage profile. Four bands of copayment depending on use and need (15%, 37%, 69%, 90%). Around 20% of the population opts for private healthcare, in order to cover more of the costs for treatment and medication, unclear if private insurance covers medical cannabis more than public health.	Any condition, but is most likely to be prescribed for conditions involving severe chronic pain and spasticity that has proven to be unaffected by treatment.	Spasticity associated with MS or spinal cord injuries. Nausea from chemotherapy, radiotherapy, HIV treatment, and hepatits C treatment. Appetite stimulation for palliative care patients undergoing cancer or AIDS treatment. Chronic pain Tourettes Epilepsy disorders Therapy-resistant glaucoma	Tilray Medical Cannabis Products (First company to receive Portugese government's approval). "Medicines, preparations and substances based on the cannabis plant' means the leaves and flowering or fruiting tops of the plant, the oil and other standardized extracts or preparations extracted or obtained from the cannabis plant".	**Flower:** €10/gram



Source: Prohibition Partners

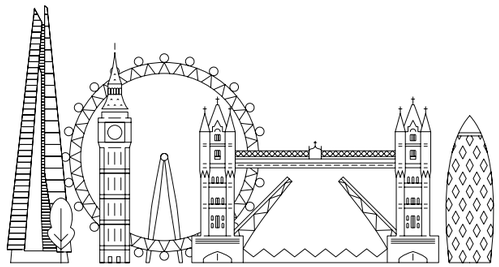
European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
SWITZERLAND	Treatment with medical cannabis products is not covered by the compulsory health insurance (OKP). Can sometimes be covered in exceptional cases. Possible in cases of hardship (the use of the product is expected to provide a major therapeutic benefit against a disease that may be fatal for the insured person or result in severe and chronic health impairments, and no other effective and approved treatment method is available due to a lack of therapeutic alternatives) and upon request of cost approval by the treating physician.	Every doctor can prescribe medical cannabis, and no longer requires a special permit. Responsibility of treatment lies exclusively with the physician. During first few years, doctors will have to regularly report to the FOPH (health authority) a whole range of data regarding the therapies.	Any condition, but is most likely to be prescribed for conditions involving severe chronic pain and spasticity that has proven to be unaffected by treatment.	Branded products are approved by Swissmedic, and all subsequent ones must be as well. Magistral preparations (if approved preparations are unsuitable): NRF 22.10: Cannabidiol oil 50 milligrams/millilitres; 100 milligrams/millilitres NRF 22.11: Cannabis resin oil 25 milligrams/millilitres Dronabinol NRF 22.12: Cannabis flowers for inhalation after vaporisation NRF 22.13: Single dose cannabis flowers for inhalation after vaporisation NRF 22.14: Cannabis flo-wers for tea preparation NRF 22.15: Cannabis flowers in single doses for tea preparation.	**Flower:** €8.32-12.5 /gram

Source: Prohibition Partners

European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
UK	NHS medical cannabis prescriptions (free) exist but are extremely difficult to get. Market is almost entirely private medical cannabis prescription. Private insurers may cover the cost if it falls in line with insurance firm's requirements, medical insurers will usually not cover it, however.	Cannabis-based medicinal products can be prescribed if conventional treatments have been tried and have failed to work. Clinicians (public or private) may prescribe unlicensed medications if they are on the GMC specialist register. Must take in to account GMC guidance and NHS trust governance procedures. Specialists on the GMC should only prescribe within their area of expertise.	As with prescribing any other unlicensed medicine, it is a clinical decision to determine the most appropriate medication or course of treatment to prescribe for a patient, having taken into account the patient, the clinical condition, the clinical evidence of efficacy and safety and the suitability of licensed medicines.	Approximately 90 products (flower + extracts) on the market as of February 2023.	Average price as of August 2022 were: **Flower:** €11.4/gram **Oil:** €7.1/millilitre



Source: Prohibition Partners

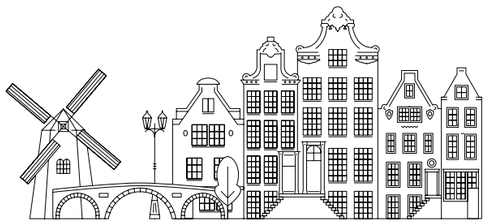
European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
POLAND	There is no reimbursement for medical cannabis.	Any doctor can prescribe medical cannabis via a narcotic prescription. Many doctors do not prescribe cannabis due to a lack of knowledge and training for cannabis treatment, or of available cannabis products.	No list of indications published by regulator; the decision to prescribe is left to the physicians. No official information on conditions for which there are prescriptions, but in one of the leading cannabis clinics the most reported conditions are: cancer (related symptoms) (35%), pain (24%), autoimmune diseases (11%), mental health disorders (8%), epilepsy (7%) and neurological disorders (6%).	Cannabis floris extractum normatum THC 10% CBD<1% (PharmaCann/ PHCANN int.) Cannabis floris extractum normatum THC 5% CBD <1% (PharmaCann/ PHCANN int.) Cannabis Flos THC 22% CBD 1% (Aurora) Cannabis Flos THC 20% CBD 1% (Aurora) Cannabis Flos THC 8% CBD 8% (Aurora) Cannabis Flos THC 20%, CBD ≤ 0.5% (Canopy Growth) Cannabis Flos THC 8%, CBD 7% (Canopy Growth) Cannabis extractum normatum THC 10% CBD<1% (Vetos Farma) Cannabis Flos THC 18% CBD ≤ 1% (S-Lab) Cannabis Flos THC 18% CBD 1% (Tilray)	**Flower:** €8-17/gram

Source: Prohibition Partners

European Overview Tables

	REIMBURSEMENT & HEALTH INSURANCE COVERAGE	AUTHORISED PRESCRIBERS & PRESCRIPTION CONDITIONS	TREATABLE PATHOLOGIES	AVAILABLE PRODUCTS	MEDICAL CANNABIS TREATMENT PRICES (AVERAGE)
NETHERLANDS	There is no public reimbursement for medical cannabis. Some private health insurers reimburse medical cannabis treatment.	Any doctor can prescribe medical cannabis.	All conditions, but in particular: Pain and muscle spasms/ cramps associated with (MS) or spinal cord damage Nausea, reduced appetite, weight loss and debilitation associated with cancer and AIDS Nausea and vomiting caused by medication or radiotherapy for cancer and HIV/AIDS Chronic pain (nerve pain, phantom pain, facial pain or pain that persists after a cured shingles infection) Tics associated with Tourette Syndrome Glaucoma (if standard treatment is not effective) Various forms of epilepsy.	Bedrocan flos 22% Bedrobinol flos 13.5% Bediol flos (granulated) 6.3% Bedica flos (granulated) 14% Bedrolite flos (granulated) <1% Bedrolite CBD 10% oil Cannabidiol Sublingual Drops 0% Bediol 1.3 / 2.0% Bedrocan/Bedrolite 10/5 oil Sativa 2.0/5.0 % oil Sublingual Drops 2.0% Indica 5.0/5.0% oil Sublingual Drops 5.0% Bediol 0.65%/1% Ointment	**Flower:** €5.50/gram **Oil:** €4-20/millilitre



Source: Prohibition Partners

The European Cannabis Report | LEGAL & REGULATORY OVERVIEW

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. © 2023 PP Intelligence LTD.

EXPERT INTERVIEWS

Dr. Chiara Liberati
Italy

This section contains interviews with doctors actively prescribing medical cannabis treatment in the following countries; Italy, Switzerland and Spain. They each outline their personal perspectives on the state of medical cannabis treatment in their countries.

How long have you been prescribing medical cannabis for?
I have been getting into the medical cannabis world for almost five years and I have been prescribing it for at least three years.

How did you start prescribing medical cannabis? Was there a system of support in the process, or was it a case of self-teaching?
A passion for Integrative and Complementary Medicine led me to looking around and getting informed about cannabis. The major incentive came from patients who were already informed about that kind of treatment and who asked me for it in my clinics. I started studying it and reading all the scientific publications and literature I could identify and I found out about the Cannabiscienza Master's Degree, a training course I warmly recommend to my colleagues in order to get a conscious approach to cannabis. As of today, I am still training both independently and autonomously. I had the chance to get in touch with many professionals whom I am still in contact with and who are a source of personal growth.

In what ways have things changed in your experience since then?
Knowledge of phytocomplexes allowed me to approach pain and related diseases from another perspective. It is not just an additional available therapeutic option I have for symptom control, but it is a precious opportunity to help a patient find his or her lost balance, their homeostasis. It is not always possible to achieve this goal, but the patient appreciates improvements in their general condition which allows them to have a more dignified quality of life. With medical cannabis I feel stronger in my work.

How many patients do you currently treat with medical cannabis? What pathologies?
Currently, I am treating about 200 patients with medical cannabis. The pathologies I usually prescribe it for are mainly characterised by chronic pain, both oncological and benign as well as that of fibromyalgia symptoms. In the oncological environment, for example,

cannabis allows me, in addition to pain management, to support patients in active therapy (I am referring to chemotherapy and radiotherapy) by offering them an additional option, as well as an alternative to conventional therapy, when this turns out to be ineffective. Just think about chemotherapy-induced nausea and vomit , as well as inappetence that afflicts many patients in cancer therapy. In these cases, medical cannabis has been proved to be useful and supportive. As far as fibromyalgia symptoms are concerned, since a dysfunction of the endocannabinoid system has been hypothesised, medical cannabis helps fibromyalgic patients in managing, not only the pain symptoms, but also all those symptoms that characterise this syndrome, from insomnia to brain fog, from dysbiosis to depressive syndrome.

Has the number of patients you treat with medical cannabis increased in the past year, or have you seen an increase in a specific demographic, or treatable condition? What factors are behind this growth, or what factors constrain it?
The number of patients asking to be treated with medicinal cannabis has certainly increased and, when I see the necessity, I talk with my patients about it, proposing it as an integrated medical therapy in association with the current conventional one. There are undoubtedly a series of factors that limit the number of patients who can take advantage of the national health service's reimbursement. Unfortunately, up to today, there is still defective training and knowledge about cannabis, starting from General Practitioners who very often oppose the medical prescription, despite the fact that the patient is provided with a therapeutic plan. There is also a lot of misinformation in this environment and all this destabilises the patient. Another factor that constrains the number of patients is the limited availability of the product on the Italian market. The unguaranteed monthly availability of cannabis-based products often makes therapies not feasible on a long-term basis, creating discomfort and concern in the patient who has benefited from this phytocomplex.

What are the main barriers to your patients in getting medical cannabis treatment? Is access becoming easier or more difficult for them?
The Galenic prescription of medical cannabis allows the trained doctorto prescribe it to all patients but they often have to face expensive costs. The prescription, with reimbursement from the national health service, allows the patient to take advantage of the therapy but it has limitations. First of all, not all regions of Italy have the same statute regarding the provision of medicinal cannabis. For instance, the list of pathologies for which the phytocomplex can be prescribed can vary, as can the types of cannabis. In the case of oil we have an extraction limit of 10%. This obviously determines a reduced prescription in terms of daily dosage. Last but not least, there are still a small number of prescribers working under the national health service. This makes the possibility to prescribe cannabis difficult, prompting the patient to turn to the private service and purchase it on their own.

Do you find the variety of products you have to choose from adequate, or too limited?
I think that the variety of products available is still limited and this causes difficulties in guaranteeing treatment continuity for patients who benefit from medical cannabis.

Are there aspects of the medical cannabis system in Italy that you wish patients or doctors were more aware of?
As history teaches us, everything new is always greeted with mistrust and suspicion. Over time and with experience, what is new becomes familiar and often welcomed, and it is what is happening with medicinal cannabis. Its past, which made cannabis famous in terms of recreational use is still a heavy burden before it can be accepted as therapy by society. Both doctors and patients are still skeptical about the therapeutic potential and the concrete benefits this phytocomplex can give. Surely more widespread training would help to overcome these difficulties.

What are the most difficult parts of treating patients with medical cannabis for you, in a practical sense, and what developments would make your work easier?

The difficulties I face in starting therapy with medicinal cannabis are many. First of all, the cultural heritage of cannabis, known only for its recreational use still scares many patients away from accepting it as a therapeutic prescription. Communicating effectively with patients is essential to help them understand that it is a phytocomplex with therapeutic purposes. Furthermore, in Italy the regional rules about cannabis prescription create bureaucratic barriers for the prescription of cannabis with the Servizio Sanitario Nazionale (SSN) reimbursement system (national health service). For example, a patient living in a region other than Lombardy will be prescribed cannabis with a Galenic prescription according to the formalisms of the Di Bella Law. Each region, moreover, has its own list of pathologies for which the reimbursement of the prescription is foreseen and this makes it even more difficult to start a therapy with continuity. Equality throughout the nation for the prescription of cannabis would certainly make access to treatment easier and simpler for the patient. Another aspect that I consider important is the lack of subject knowledge and the distrust that I observe in many colleagues; the same distrust and detachment that the medical profession still has towards Integrated and Complementary Medicine. In fact, it very often happens that the patient does not receive a red prescription, despite having the therapeutic plan in hand, because the doctor does not know cannabis or, worse still, 'does not believe in this therapy'.

Do you see significant developments happening currently, or in the near future, and are you optimistic about the progress of the medical cannabis system in Italy?

Yes, I am and I want to be optimistic about the future progress of the medicinal cannabis system in Italy. Cannabis is a precious resource for the patient that must be known and shared. The real therapeutic possibilities require scientific studies and constant research in order to transform it into objective data that clinical practice confirms on a daily basis. The feedback I receive from patients is positive, many of them are grateful for the chance to be treated and for having experienced its benefits. Unfortunately, the cultural heritage of recreational cannabis is still a heavy burden that limits access to treatment.

EXPERT INTERVIEWS

Dr. Iris Pleyer
Switzerland

How long have you been prescribing medical cannabis for?
I have been prescribing CBD since 2012 and THC and other cannabinoids since 2020. I prescribe cannabis medicines for acute and chronic pain (dysmenorrhoea, endometriosis), chronic neuropathic pain, epilepsy, muscle spasticity, social anxiety and depression, anti-inflammation, sleep disorders, attention deficit/hyperactivity disorder (ADHD) and neurodegenerative conditions. I prescribe CBD for withdrawal from alcohol and other substances.

How did you start prescribing medical cannabis? Was there a system of support in the process, or was it a case of self-teaching?
I lived in Austria (Vienna) until 2021. I started by learning about the subject and then a colleague who had been working with cannabis medicine in Vienna for 30 years trained me.

In what ways have things changed in your experience since then?
Here in Switzerland, the Narcotics Act has changed things with effect from 1 August 2022. The prescription of cannabis medicines in the form of magisterial prescriptions, but also of finished cannabis medicines, has been simplified.

How many patients do you currently treat with medical cannabis? What pathologies?
I have fifteen patients here in Switzerland, eight patients in Austria and two patients in Hungary. Mainly cancer patients. But also patients with substance withdrawal, social anxiety, sleep problems and chronic pain (polyneuropathies, gynaecological patients).

Has the number of patients you treat with medical cannabis increased in the past year, or have you seen an increase in a specific demographic, or treatable condition? What factors are behind this growth, or what factors constrain it?
I had a lot of patients in Vienna. Here I am slowly building up new patients. I have experienced an increase in demand since 1 August 2022. I think the growth in new patients is being constrained by a combination of issues around; regulation, product availability and doctor training.

What are the main barriers to your patients in getting medical cannabis treatment? Is access becoming easier or more difficult for them?
There are not enough doctors writing up cannabis medicines. The prejudice of doctors is very strong. There is a lack of training for doctors, pharmacists and medical staff. Licensing by the Federal Office of Public Health (FOPH) in Switzerland is still very cumbersome. There are still no guidelines for the prescription of cannabis flowers. Access for patients is somewhat easier, but still too cumbersome.

Do you find the variety of products you have to choose from adequate, or too limited?
I think the selection is already much better. The flexibility and willingness of pharmacists in Switzerland is not as good as in Austria. But it is getting better.

Are there aspects of the medical cannabis system in Switzerland that you wish patients or doctors were more aware of?
There is no access to cannabis doctors that patients can see. In Germany it is much more transparent. The network of these doctors should also be quickly accessible to doctors, pharmacists and medical staff. The authorisation by the Federal Office of Public Health should be simplified.

Do you see the developments happening currently as significant, if so why? If not, why not? Are you optimistic about the progress of the medical cannabis system in Switzerland?
I think the development towards cannabis medicine is extremely important. The focus is on the patient! Providing the patient with a herbal medicine with few side effects was and is the goal of cannabis medicine. 'Green gold!' To enable death with dignity is possible with cannabis medicine. I am also an anaesthetist and have seen and experienced a lot.

EXPERT INTERVIEWS

Dr Mery Penya
Spain

How long have you been prescribing medical cannabis for?
I started prescribing in 2019, so about four years.

How did you start prescribing medical cannabis?
I was trained as a physician in Colombia. There, in 2007, I took a class which covered the endocannabinoid system, and it blew my mind. A few years later I came to Spain to study Chinese medicine. I knew about the Observatorio[1] in Madrid, so I signed up to their emails, and in 2018 I attended their medical cannabis congress in Barcelona. During this event, I had the chance to network for the first time with many industry professionals, and soon after that I was offered a position at the Kalapa clinic in Barcelona, where I still work at the moment.

Was there a system of support in the process, or was it a case of self-teaching?
The real teachers were the patients. Medicine is a complex art, so no matter how much you read and study, it is only when you start treating patients that you really start working it out. I think about it like being a pilot and needing hours of flying experience. Kalapa provided me with the necessary theoretical background for my practice, mostly through their 2019 manual for health industry professionals, whose content is still largely relevant today.

In what ways have things changed in your experience since then?
Since other countries have started their own programmes (e.g. France and the UK), I don't treat many patients from countries other than Spain. In terms of the style of my practice, and my clinical experience, nothing has really changed. I have more expertise now, so I've learned to listen to patients more.

How many patients do you currently treat with medical cannabis? What pathologies?
About 250-300 in the last six months. A large percentage of the patients I treat have epilepsy conditions which are difficult to treat. We have a large number of paediatric patients - especially those suffering the consequences of perinatal hypoxia. Chronic pain and fibromyalgia are also frequent, as well as cancer and autism-related conditions.

Has the number of patients you treat with medical cannabis increased in the past year? Or have you seen an increase in a specific demographic, or treatable condition?
We've seen an increase in the last couple of years in patients with autism and difficult-to-treat epilepsy, as well as women with endometriosis. In general, I think that there is an increasing number of people seeking alternative models of medicine.

What are the main barriers to your patients in getting medical cannabis treatment? Is access becoming easier or more difficult for them?
I think in Spain things are becoming harder and harder over time. We've had a committee studying the possibility of regulating medical cannabis, and we are eagerly waiting for the Spanish Agency of Medicines and Health Products for guidelines, but sadly these haven't been provided yet. I think that there is still a lack of political commitment from the relevant governmental agencies and bodies that should be working on it. In Spain there are so many actors involved in this debate, and so many different industries and investigations going on, but I think that we are still years away from a situation where patients will be able to access medical cannabis legally and easily .

At the moment, most of the patients in Spain are sourcing high THC products from cannabis associations, which remains a 'grey' legal area. There is a lot of self-cultivation also, but most patients can't afford to grow their own plants.

1 Observatorio espanol https://www.oedcm.com/

Do you find the variety of products you have to choose from adequate, or too limited?
Yes, I'm really happy with the choice of products we have available at the moment, there is a huge availability of different flowers and oils. In the past few years I have been working with many different types of emulsions and liposomal products, which are really interesting. Unfortunately, I believe that once a proper legal framework is established, many of these products are unlikely to be approved due to all the limitations around EU-GMP etc..

On the bright side, product testing (generally by chromatography) is getting increasingly cheaper and more accessible, so it is now far easier to learn the exact composition of each product, which is important in the medical context.

At the moment, we partner with a cannabis association which allows us to track the entire process of the development of the product. We know where the seed comes from, and where the botanical product is produced, and we have data on the quality of the botanical product. The association is responsible for the extraction, providing us with testing analysis on the extracts. Once the extracts are approved, the association creates the final oil product, which is tested again, providing us with detailed information on the exact content of the medicine I'm prescribing.

What are the most difficult parts of treating patients with medical cannabis for you, in a practical sense, and what developments would make your work easier?
The high cost of testing for medical cannabis products is certainly a barrier to patient treatment. Affordable analysis in reputable and trustworthy labs. is crucial as it allows us to know exactly what is in the products we prescribe.

Beyond this, high product prices remain the main barrier for patients. In Spain, patients have to cover the cost of the products themselves, and, for those in need of high dosages, the treatment can be really expensive. If we consider the case of a family with a child that needs 24/7 supervision, paying the cost of products on top of treatment can be extremely challenging.

Do you see significant developments happening currently, or in the near future, and are you optimistic about the progress of the medical cannabis system in your country?
Spain is a complex country. We have so many experts in so many different fields related to the cannabis plant, but there is still a huge gap between the research and the practical reality of patients and treatment. Nevertheless, one thing that I am really optimistic about is the potential for treating endometriosis in Spain. It was remarkable and surprising to me that endometriosis was included in the list of conditions for which the Spanish Agency of Medicines and Health Products should establish guidelines. We have lots of preclinical and anecdotal evidence for the use of medical cannabis to treat endometriosis, but we don't have much clinical evidence. It's a pathology that I feel very strongly about, because there is not enough awareness of the symptoms.

It is surprising to me that Spain would be the first country to really investigate medical cannabis for treating endometriosis. This is really promising because endometriosis is a condition that has many different mechanisms of pain involved and medical cannabis can be a very safe and effective option to deal with it. This condition involves the central and peripheral nervous systems, there are hormonal issues behind it, there is inflammation, there is migration and cellular proliferation, and medical cannabis is useful in all these contexts. It is also a great opportunity to explore new product formats, topical deliveries and suppositories; so there is great potential for a specialised industry to develop around this condition.

Supply Chain

European perspective: increasing diversification of supply, steady but limited growth in demand

European supply diversified throughout 2022, continuing a trend previously seen in 2021. The overall share of the two largest suppliers of the market historically - Canada and the Netherlands - remains in decline, while new or increased imports from Australia, Africa, South America, Israel, the Caribbean, as well as from some European countries, are meeting a rising demand in the region.

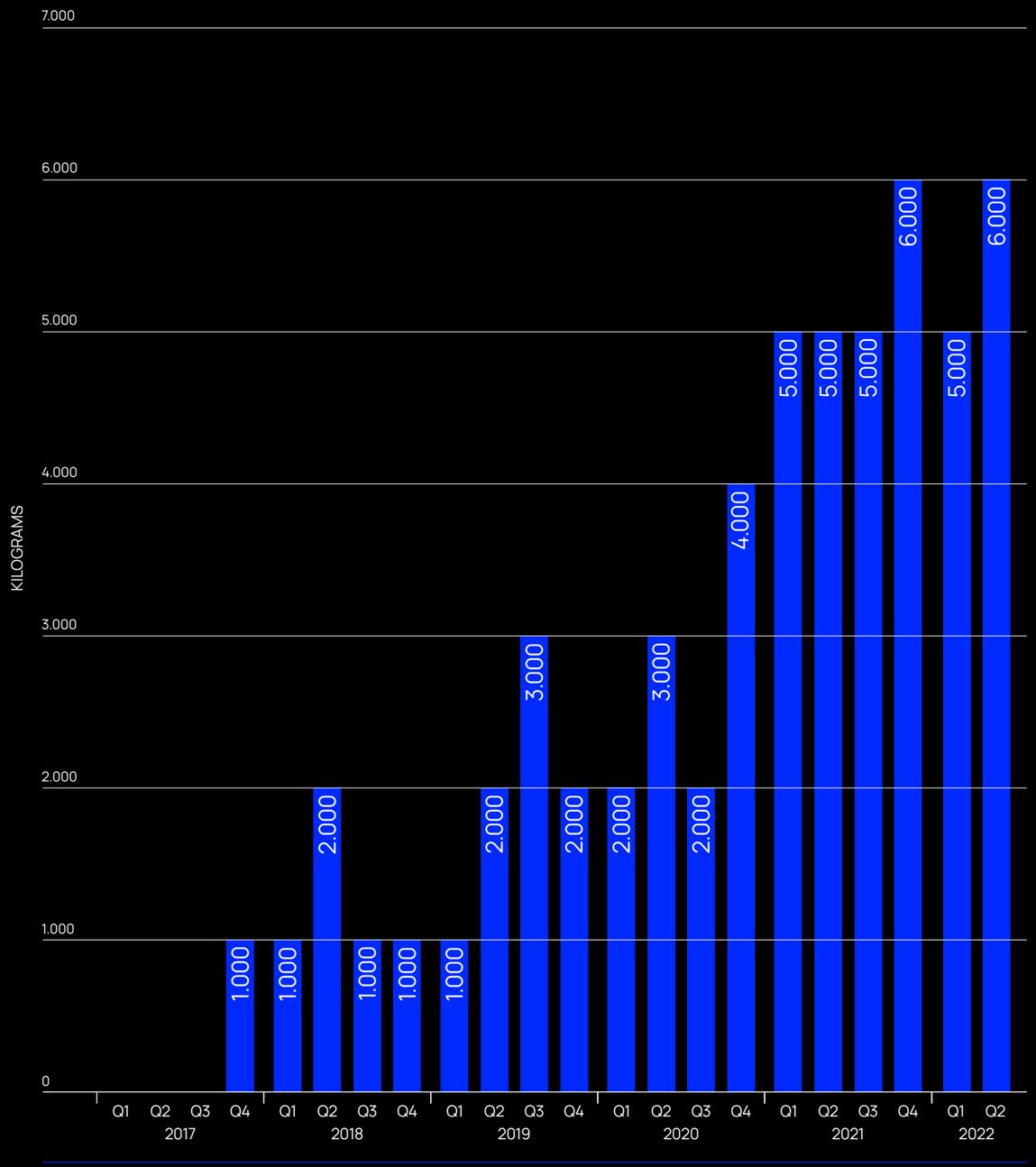
A characteristic shared by a growing proportion of the new product being imported to Europe is that it is cultivated under good agricultural and collection practice (GACP) conditions, and it undergoes final processing in the EU under EU-GMP conditions, resulting in an EU-GMP certified end product. This GMP 'conversion' import process was first seen in 2020, when several tonnes of flower grown in Uruguay by Fotmer Life Sciences under GACP certification were imported to Tilray's Portugal facility, and were processed into products used for treating patients in Germany. The method has since been repeated elsewhere, for example by Cantourage, a German-based distributor, that imports flower from a range of non-EU cultivators, processes the flower through partners in Germany and Portugal, and distributes the end products in Germany and the UK.

With regard to the supply coming from within Europe, European production is growing, but there are still a limited number of key players involved, with suppliers based mainly in Portugal, Denmark, the Netherlands, Spain and Germany. Demand for medical cannabis in Europe is still rising, but remains concentrated in key countries - with the UK and Germany representing the overwhelming majority of new demand.

Germany: intense competition, upstream margins squeezed

The German Federal Institute for Drugs and Medical Devices (BfArM) has released data showing that German imports of medical cannabis grew by 647 kilograms in H1 2022 as compared to H1 2021 - representing a moderate 6.5% increase. Given that Germany is by far the largest European medical cannabis market, that it relies overwhelmingly on imports to supply its market, as well as the fact that a significant proportion of these imports are re-exported to other European countries, German medical cannabis imports are a reliable bellwether for the European market as a whole.

German medical cannabis imports - quarterly breakdown

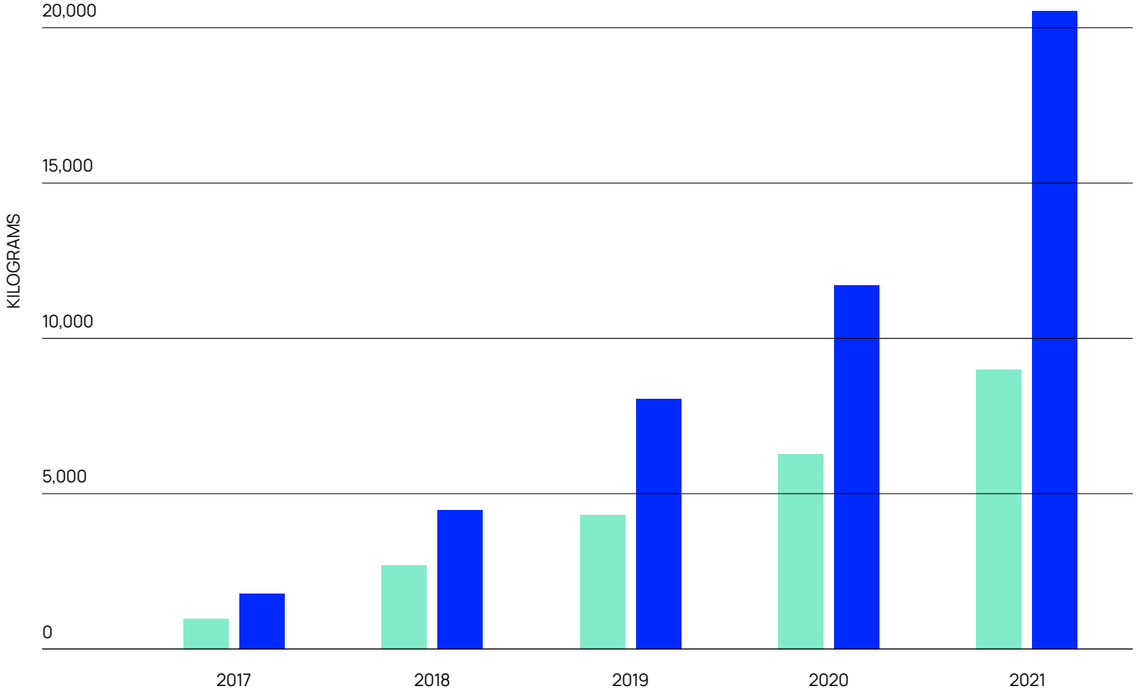


Source: BfArM 2023

Though data on the breakdown of exporting countries was not released by BfArM, indications are that Canadian exports have once again seen their share of the total market (by volume) fall in 2022, as they did in 2021. This comes primarily as the result of two independent factors: firstly, the increase in competition from both non EU-GMP and EU- GMP certified (or certifications held as equivalent under Mutual Recognition Agreements) producers in established exporting countries such as Australia, Portugal, Uruguay, Spain and Denmark (exports from the Netherlands to Germany actually declined in 2022), as well as in newer exporting countries like Jamaica, South Africa, Lesotho, Uganda, Israel, Colombia, North Macedonia, New Zealand, Saint Vincent and the Grenadines; and secondly, the relocation of production for the European market from Canada to Europe - Tilray in Portugal and Germany, and Aurora in Denmark and Germany.

The conclusion which can be drawn from the fact that there is a clear 'step-up' in competition of supply for the European market, while growth in demand remains mild, is that the market as a whole is heading towards oversupply, if it is not there already. The following comparison of German imports vs sales to pharmacies illustrates this.

Sales vs imports of medical cannabis in Germany



Source: German Bundestag, BfArM. Prohibition Partners

Though specific volumes of German re-exports of imported medical cannabis are not released, demand for imports in the rest of Europe is not sufficient to account for the gap between imports and sales to pharmacies in Germany. Likewise, though some imports in 2021 would not show up in 'sales to pharmacies' data until 2022, the shelf lives of these products is not long enough for stock carried over from 2021 to account for a large proportion of the discrepancy.

Reports from Germany in 2022 have indicated that many products do not make it to patients before their expiration date. Doctors and patients have a diverse range of products to choose from, which is positive in that it allows for experimentation to determine the optimal product for specific cases. However, there are also reports of an inconsistency in labelling and accompanying data with products, as well as an overall confusion on the part of doctors regarding the proper processes and relevant factors when prescribing medical cannabis to patients, exacerbated by an overwhelming array of different products.

In this market scenario, profit margins at upstream stages in the supply chain are squeezed for medical cannabis sales in Germany. It is possible that some companies are willing to forgo margins in the short to medium term in the expectation that the medical or recreational market will boom in the coming years, and that having an established foothold in Germany will afford them a valuable advantage when this time comes.

The United Kingdom: high growth continues, import regulations shape market

Analysts have long predicted that the UK would grow to become Europe's second-largest medical cannabis market, and 2023 is set to mark the first year that this will be the case, with annual patient count and retail sales both expected to grow significantly.

Though there are still very few cases of patients accessing medical cannabis through the National Health Service (NHS), there is a proliferation of clinics that are offering private consultations and prescriptions for medical cannabis treatment. These clinics include some pre-existing medical clinics which have decided to offer medical cannabis treatment, but they are mostly dedicated clinics which have been newly set up for the purpose of offering medical cannabis treatment. The nature of these clinics varies - some are independent businesses operating from one location, some are networks operating facilities in various locations, all offer online services, and some are exclusively online.

Doctors play an even more significant role in the UK medical cannabis market than in most other major European markets due to their role in imports. In order for products to be imported, a letter of 'anticipated demand', written by a prescribing doctor, must first be obtained, which is reported to cost approximately £1,000 (doctor's time and administration costs). In the letter, the doctor states a requirement for specific quantities of named products for their prescription purposes over the course of the following months (there are loose limits on how many months supply can be procured at once, usually three months at a time). It is only with such a letter that an importer can import medical cannabis products in bulk into the UK. Each letter can be used only once, and it only permits the importation of the exact quantity of each named product as stated in the letter.

This results in relationships with specific clinics - and the doctors within them - being more important to importers and distributors operating in the UK medical cannabis market than is the case in other European markets. Since only specialist doctors can initiate medical cannabis treatment (general practitioners can handle repeat prescriptions), these letters are being written by specialists. Since the number of these doctors prescribing medical cannabis is still relatively small - reported to be slightly over 100 - the pool of doctors to choose from to write such letters is likewise limited.

The unique dynamic of the UK medical cannabis market has created a system where commanding large market share is currently largely dependent on being part of (or controlling) an interwoven network consisting of; clinics, doctors, pharmacies and importers/distributors. Though there are slightly over 20 clinics active in the market, three clinics which are part of such networks currently cover over 60% of the market share between them. These networks are:

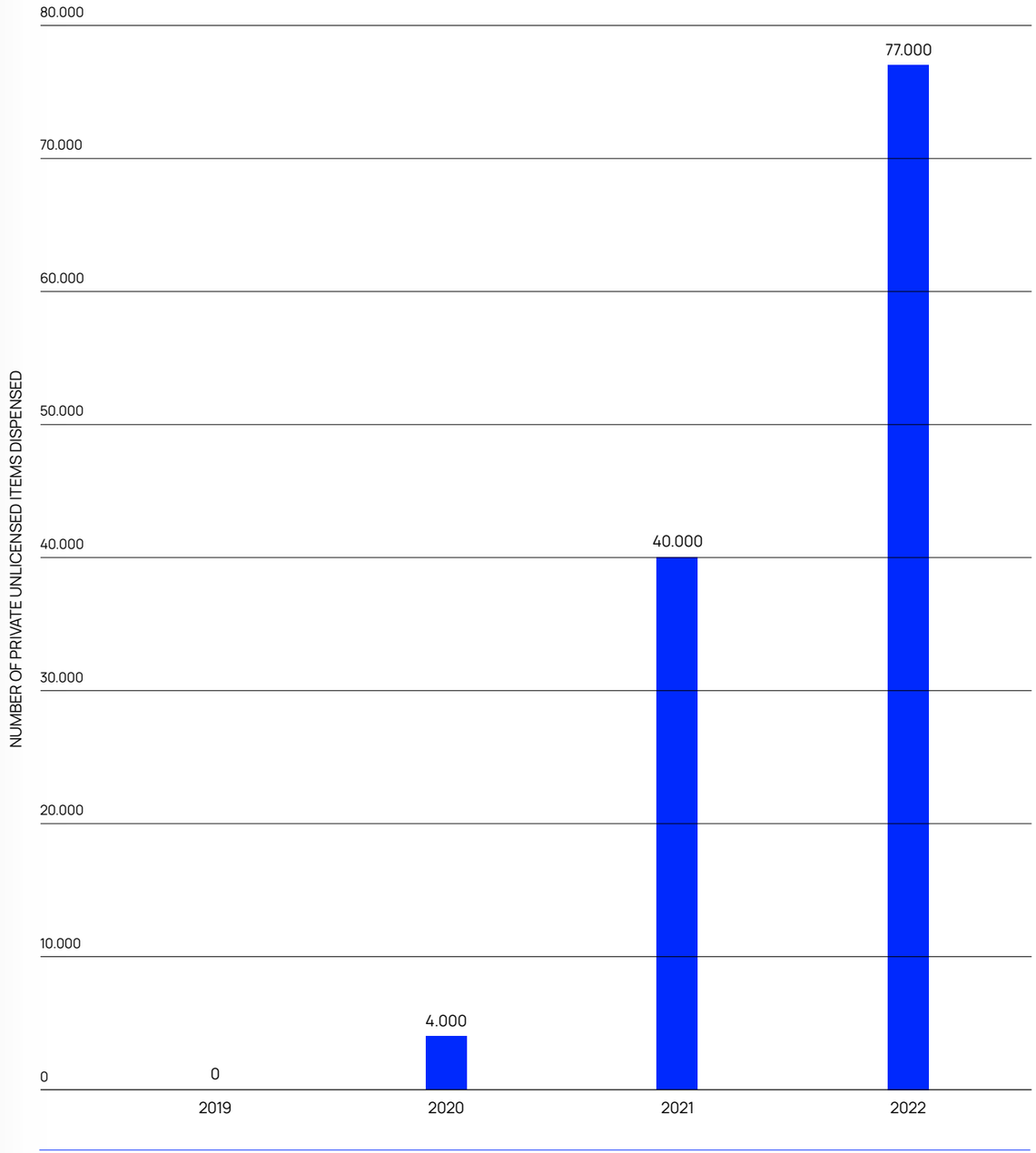
1. Lyphe Group network - Lyphe owns the largest cannabis pharmacy and the largest cannabis clinic as well as having the best selling range of cannabis products under its Noidec's brand. Lyphe has two key strategic partners to help serve the UK market - a contract manufacturer based on mainland Europe and a controlled drug importer based in the UK. Lyphe focuses its investment and resources on its direct-to-patient model and technology.

2. Curaleaf network - Curaleaf owns an importer (Rokshaw), clinic and pharmacy. The company manufactures its own products, with cultivation in Portugal (Terra Verde), and manufacturing/processing in Spain (Medalchemy) and the UK (Rokshaw), though it also uses a manufacturing/processing partner in Germany for its own products, as well as supplying UK patients with various other brands. Sapphire Clinic operates in this network.

3. IPS Pharma/Grow Pharma network - IPS Pharma owns an importer, pharmacy and a UK manufacturing/processing facility. The clinics operating in this network are; Cannabis Access Clinics, My Access Clinic, and Integro Clinic. Also has a joint cobranding agreement for the GROW/PHCANN flower brand with North Macedonian producer NYSK Holdings/PHCANN.

The NHS Business Services Authority released data in response to a request from Prohibition Partners detailing the number of unlicensed medical cannabis items being prescribed each year in the UK. The data shows a massive increase each year since 2019, albeit from a low base. **Based on our calculations**, which conservatively assume all quarters are equal, the annual number of products for 2022 amounts to about 76,600, a 90% increase from 2021. One item here refers to a single product on a prescription e.g. if a patient is prescribed three packages of Tilray 25:1 oil and one of Noidecs 20:1, these would register as just two items.

Privately prescribed items of medical cannabis in England



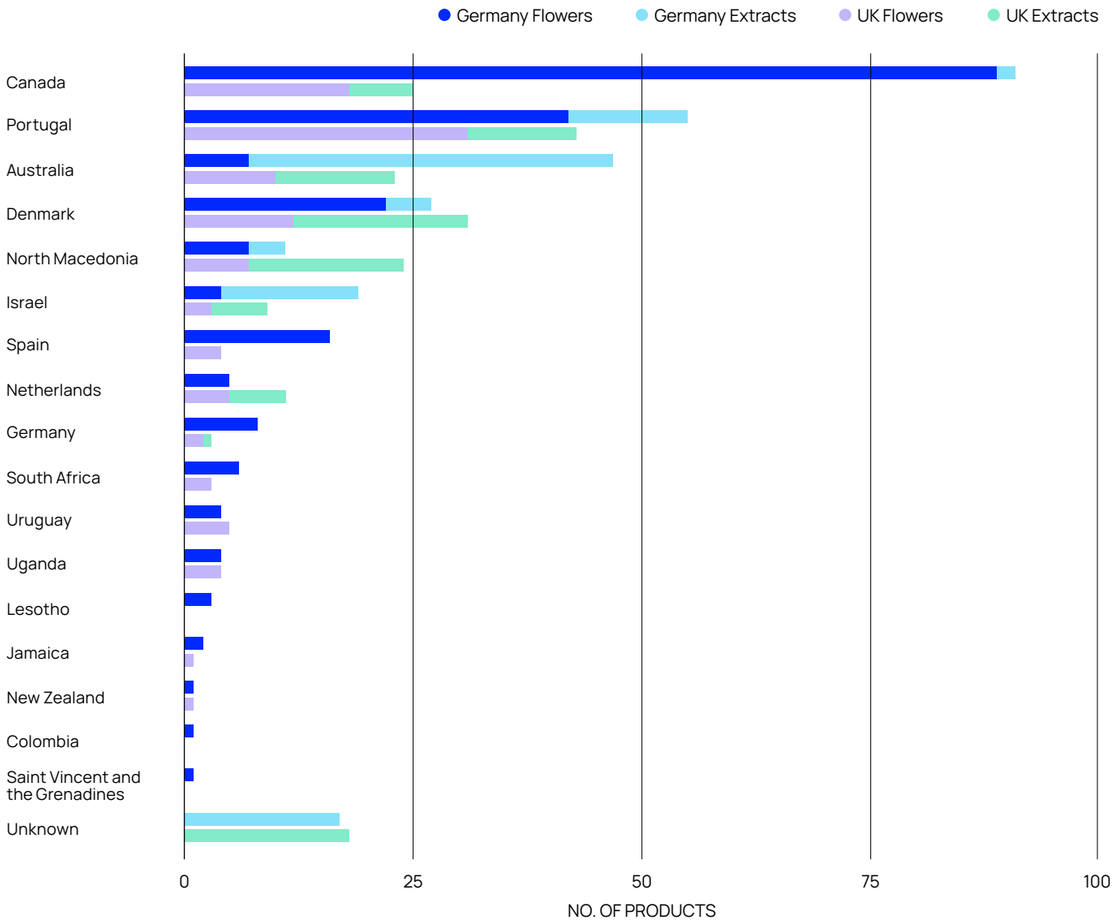
Source: National Health Service Business Services Authority (NHSBSA), freedom of information (FOI) from Prohibition Partners. [ePACT2, NHSBSA Copyright 2022]

Products and supply chain data - Germany and the UK

The following data is created using public product databases in Germany and the UK. The data does not show sales volumes, so it is not a precise representation of market share in terms of volume in the UK and Germany. It does however present a picture of the breakdown of products available on these markets, with information on the supply chain of these products, including; origin country, manufacturer and distributor. Some products are sold white label to multiple distributors, and branded as different products by each distributor. In these cases we have considered each branded product as a separate product on the market.

The following graph shows the breakdown of flower and extract products on the German and UK markets by the country in which the flower used for production was cultivated.

Cultivation country of products in Germany and the UK



Sources: Bund Deutscher Cannabis-Patienten e.V., 2023; Cannabis Ärzte, 2023; Medbud, 2023

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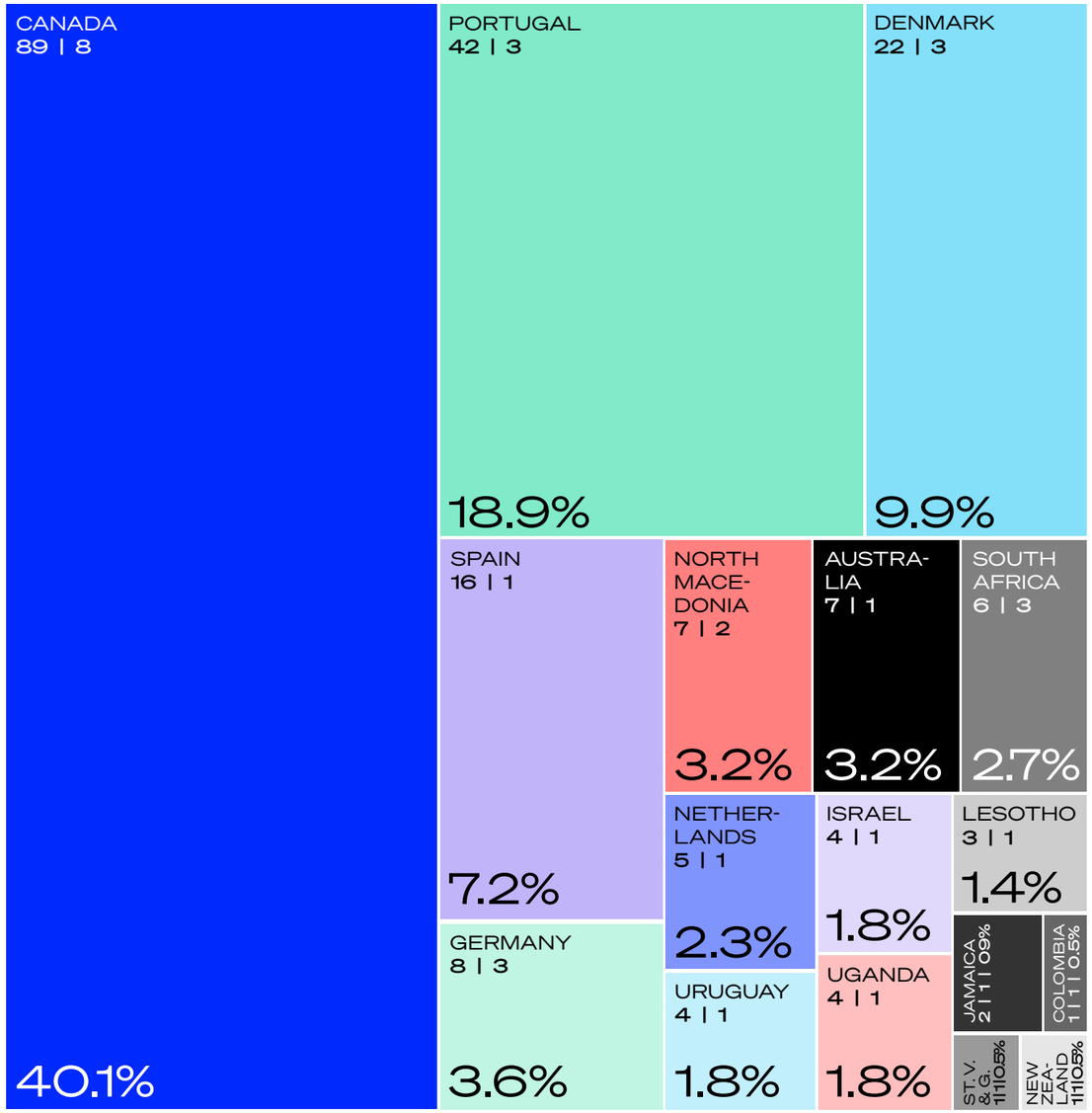
The data available from these databases makes it possible to see the wide variation in countries which are now supplying the German market.

Cultivation country of flower products in Germany (222 total products)

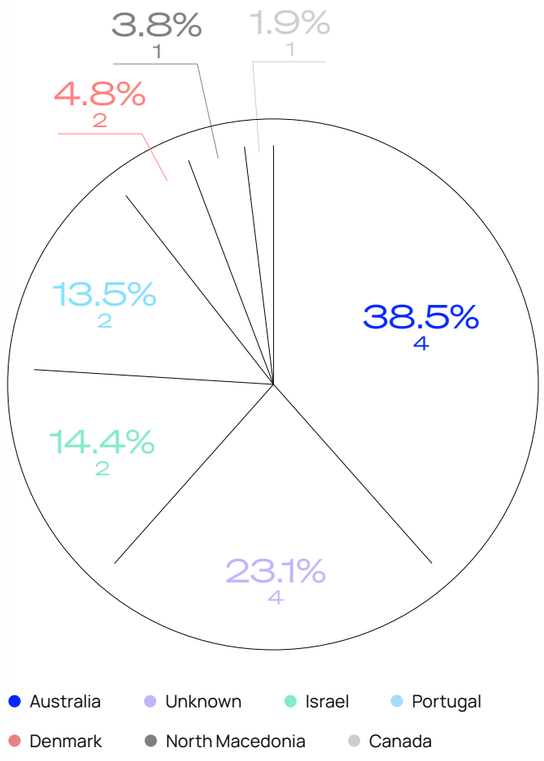
COUNTRY | NO. OF PRODUCTS | NO. OF MANUFACTURERS IN COUNTRY



Sources: Bund Deutscher Cannabis-Patienten e.V., 2023; Cannabis Ärzte, 2023

Likewise, the following pie-chart shows the breakdown of extract products by the country in which the flower used to produce them was cultivated. Here there is a reasonably large 'unknown' category, because the origin country is not always listed in the databases. In some cases it was possible to track products back to the cultivator, but given that supply chains are sometimes more extended for extracts than for flower products, this was not always possible.

Cultivation country of extract products in Germany (104 total products)



% of Products and No. of Manufacturers

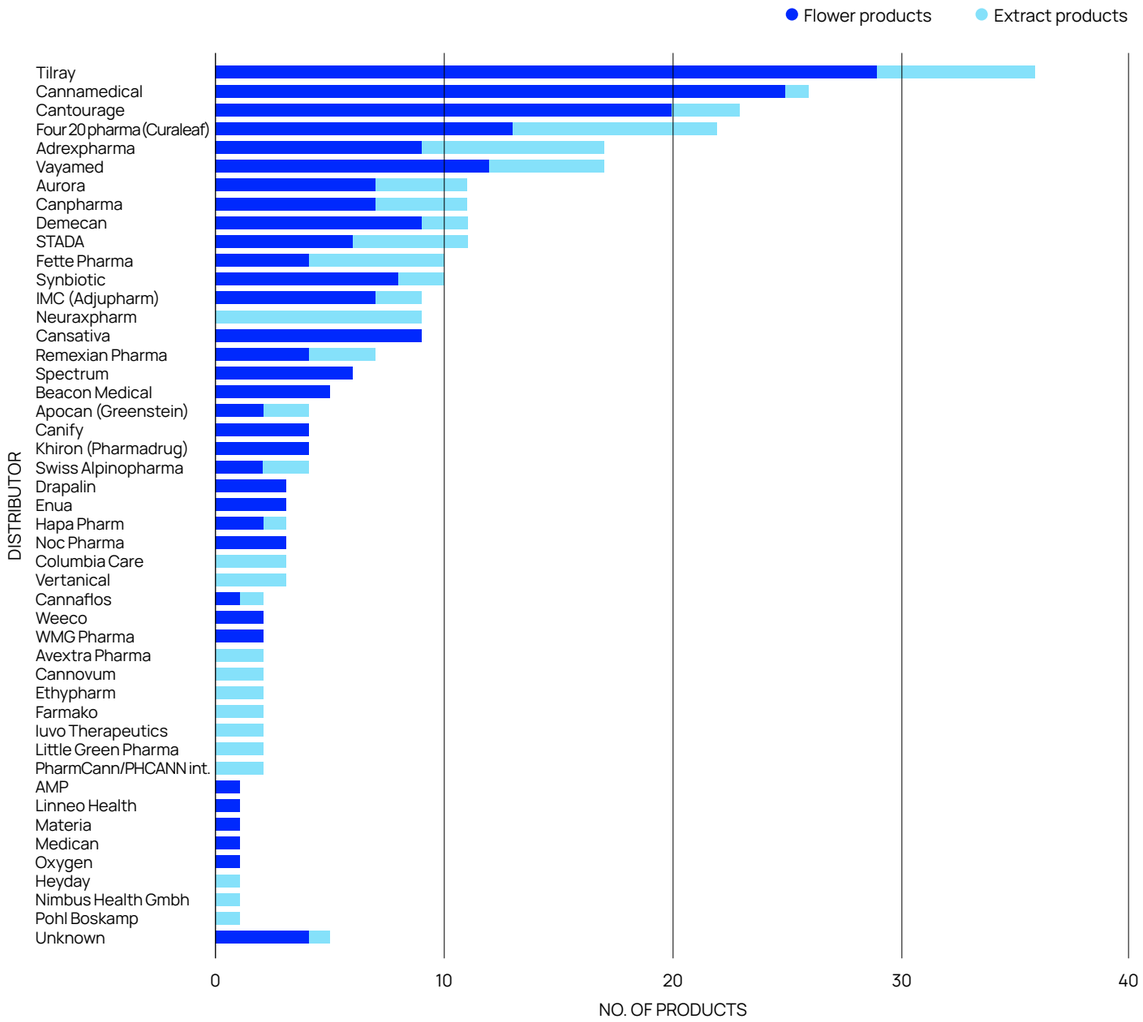
Sources: Bund Deutscher Cannabis-Patienten e.V., 2023; Cannabis Ärzte, 2023

It should be noted that the vast majority of extract products are formulated in the same country where cultivation takes place, however there are some cases where cultivation and extraction take place in different countries - e.g. Curaleaf's supply chain with cultivation in Portugal and extraction in Spain.

From the two diagrams above, it can be seen that the lead suppliers of flower for extract products, Australia and Israel, supply a much smaller proportion of flower products on the market. Furthermore, the proliferation of supplying countries for the flower market has not yet taken place to the same extent for the market of extract products.

The wide diversity of producers and products in the German market is reflected at the wholesale level, with a large number of players competing for market share. While large vertically integrated players like; Tilray, Aurora and Curaleaf, still command large market shares, increasingly the main players in distribution are more dedicated distributors like; Cannamedical, Vayamed and ADREXpharma. These companies source white label from producers abroad and sell it in Germany under their own brand.

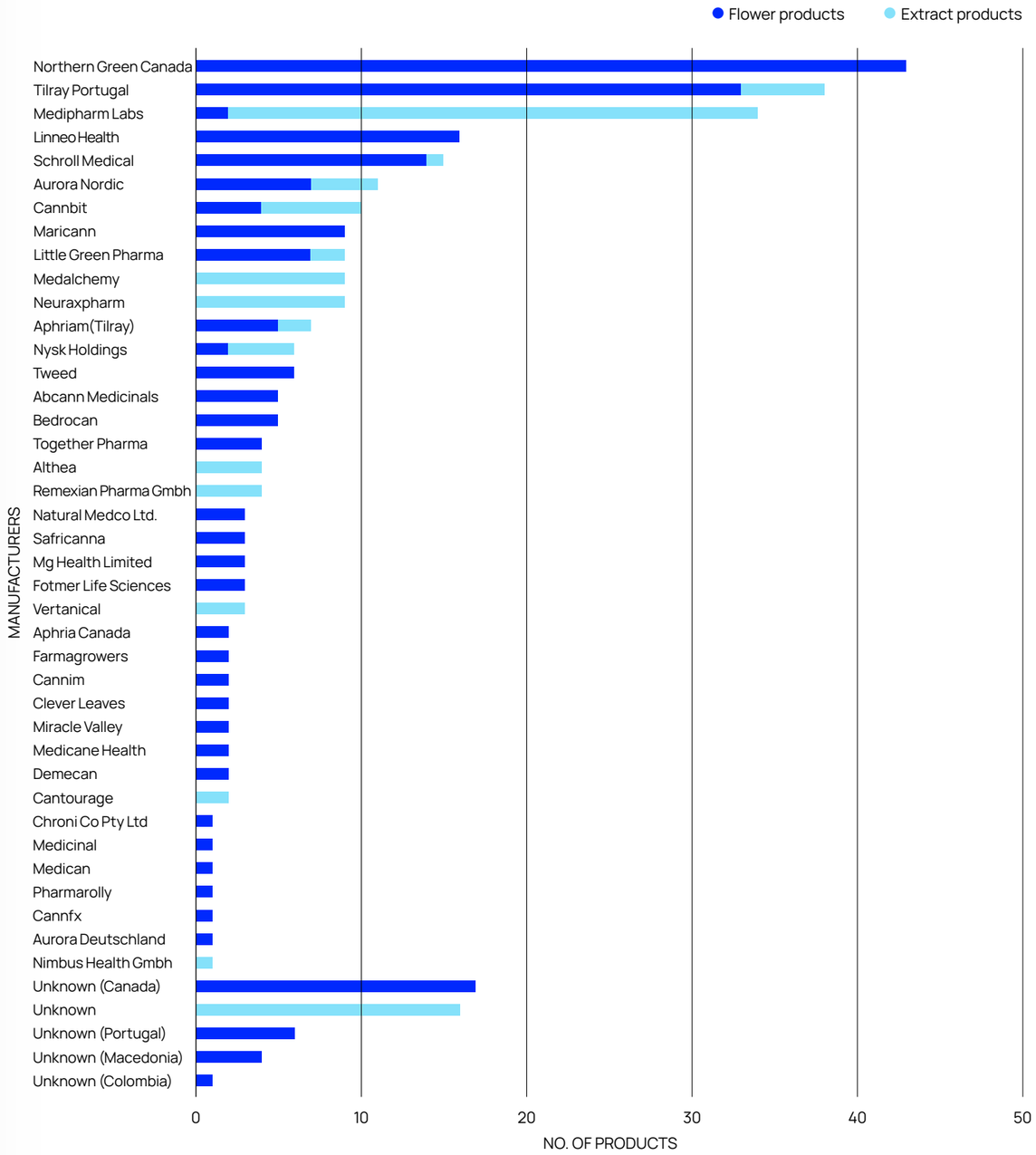
Products in Germany by distributor (326 total products)



Sources: Bund Deutscher Cannabis-Patienten e.V., 2023; Cannabis Ärzte, 2023

Looking at the list of manufacturers behind all products in the German medical cannabis market, an expected trend can be seen whereby those companies selling white label to various distributors dominate the market in terms of product count. All of the top five manufacturers supplying the market are selling their products white label to distributors, with Tilray being the only one which also sells under its own branding and distribution network. Technically, Tilray has the largest presence of any manufacturer by product count in Germany, supplying products from its facility in Portugal, from Aphria's facilities in Canada and in Germany (under a domestic production tender contract). The next four largest suppliers by product count do not have distribution networks in Germany and sell to various players, with Australia's Medipharm Labs particularly dominant in extracts.

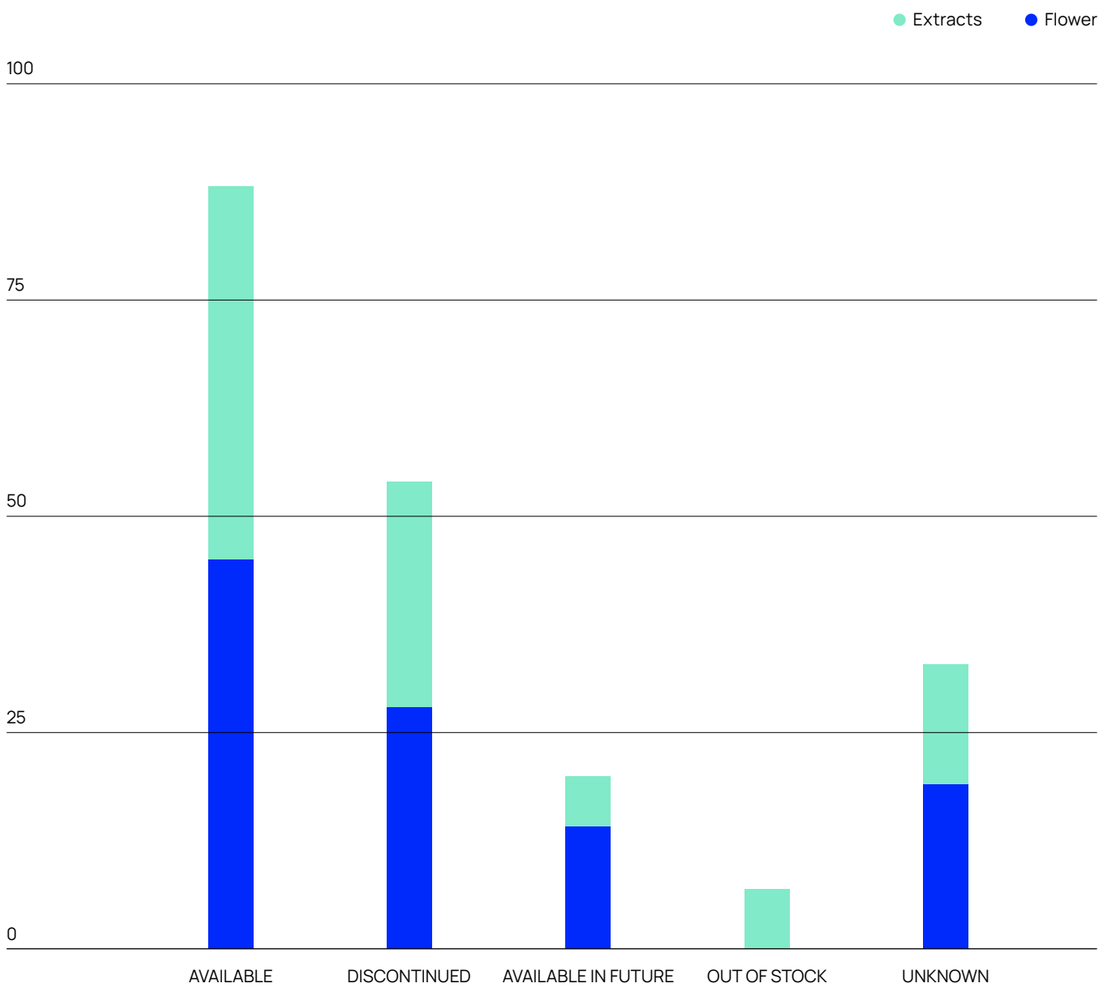
Products in Germany by manufacturer (326 total products)



Sources: Bund Deutscher Cannabis-Patienten e.V., 2023; Cannabis Ärzte, 2023

The availability of medical cannabis products in the UK is inconsistent, in part due to the previously discussed difficult and bureaucratic system of importation. For this reason, in the product database which tracks medical cannabis in the UK, there is an indication of what the status of availability is for each product. Out of 202 total products, only 88 were listed as available at the time data was collected for this report.

Availability of listed products in the UK (202 total products)



Source: Medbud, 2023

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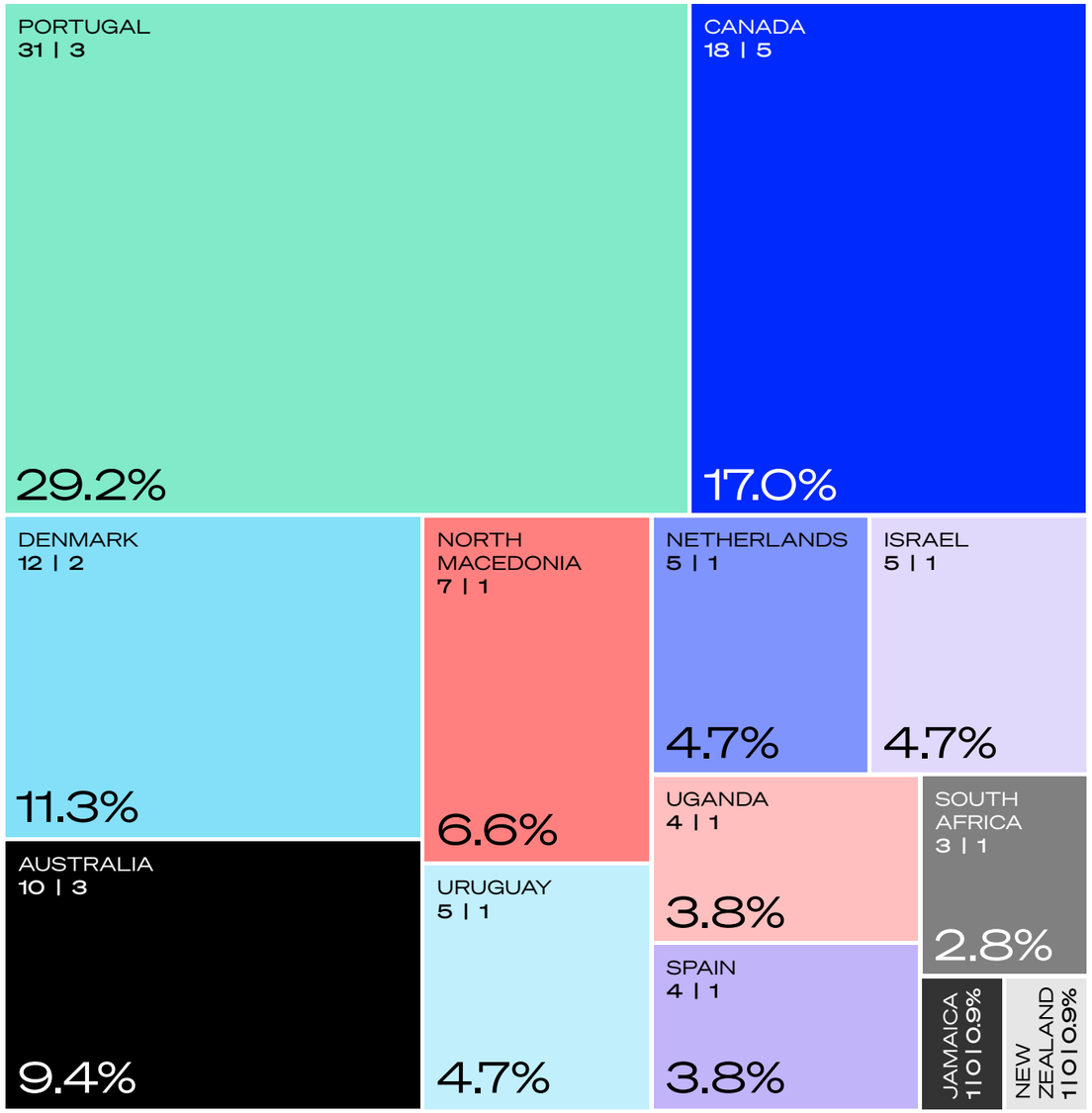
The geographical breakdown of cultivators for products in the UK medical cannabis market is largely the same as for Germany, though it is less dominated by the biggest country - with Portugal accounting for approximately 30% of products in the UK as compared to Canada representing 40% of the total in Germany.

Cultivation country of flower products in the UK (106 total products)

COUNTRY | NO. OF PRODUCTS | NO. OF MANUFACTURERS IN COUNTRY



Source: Medbud, 2023

The breakdown of cultivating countries for extract products in the UK market is similar to that seen in Germany, though with a slightly more even distribution of products by country.

Cultivation country of extract products in the UK
(97 total products)

Source: Medbud, 2023

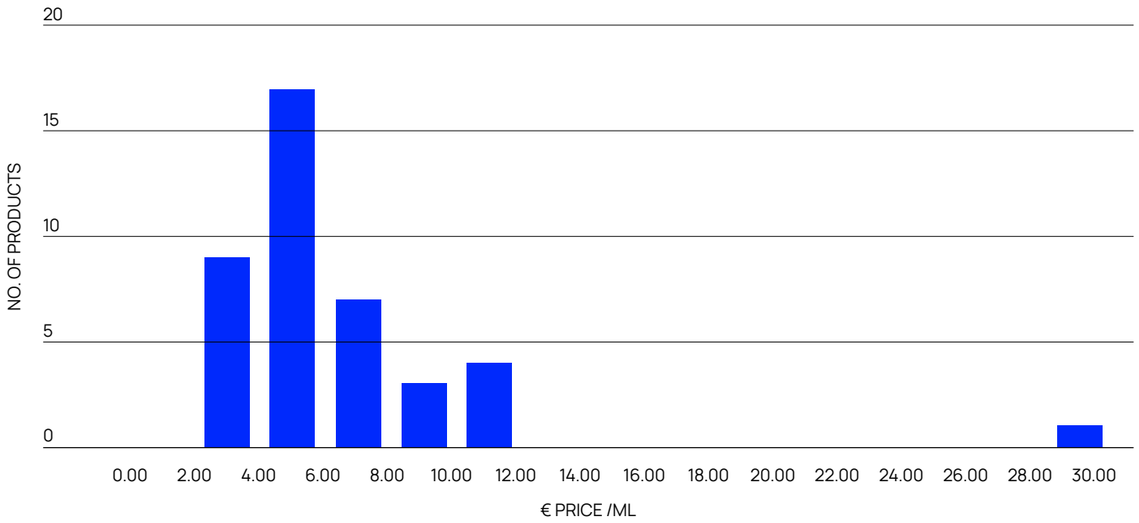
In the UK database it was possible to determine the location where products underwent their final steps of processing. For flower products this happened primarily in the country of cultivation (apart from the supply chains of Cantourage and Curaleaf, which are spread over multiple countries). However, for extracts, a large proportion of the final processing was done in the UK and Germany. Curaleaf is responsible for the vast majority of these products through Rokshaw, a UK subsidiary, and a partner in Germany.

Country of formulation by extract product in the UK
(97 total products)

Source: Medbud, 2023

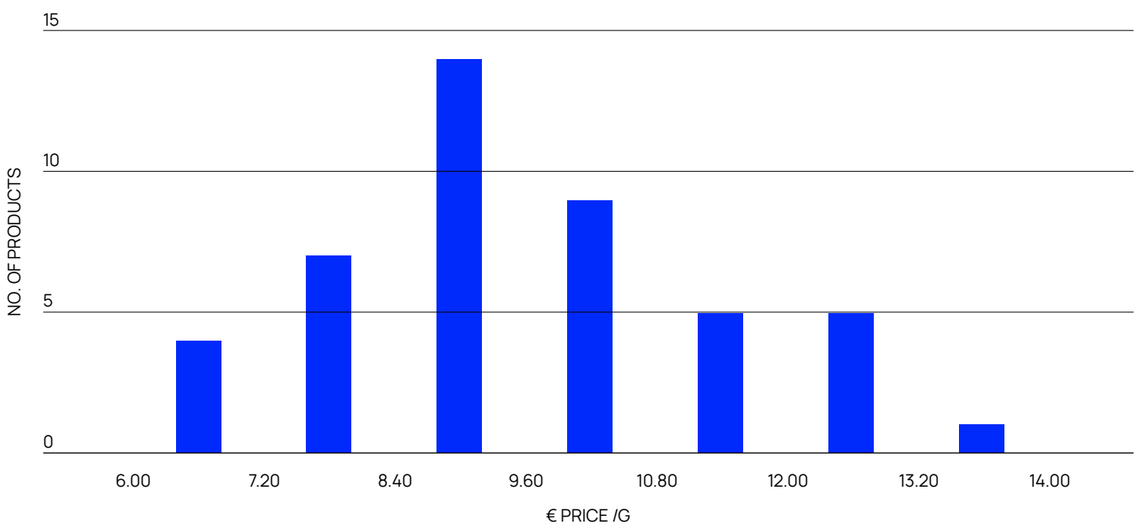
The price of products was also given in the UK database, which is even more crucial for UK patients than it is in most medical cannabis markets, as there is no medical insurance coverage for medical cannabis products. Price per millilitre of currently available extract fell between €2 and €12 per millilitre (with the exception of one Bedrocan high CBD oil product), with most being between €4 and €6 per millilitre. Prices for flower products meanwhile were all in the range of €6 to €14 per gram, with most products costing between €8.40 and €9.60 per gram.

Price per millilitre of extract products in the UK - available only (40 products)



Source: Medbud, 2023

Price per gram of flower products in the UK - available only (44 products)



Source: Medbud, 2023

The Netherlands and Denmark: Bedrocan move is symbolic of long-term trend

Measured by export volume, the Netherlands no longer occupies the position it did some five years ago as one of the leading global exporters of medical cannabis. According to exclusive data received by Prohibition Partners from the Dutch Office of Medicinal Cannabis (OMC), total exports in 2022 reached just 3,277 kilograms, their lowest level since 2018. While not an insignificant amount, this barely ranks them in the top five export countries - with Canada, Portugal, Australia and Denmark now estimated to ship greater quantities internationally - and there is a strong likelihood that exports from some South American and African countries, as well as from Israel, will also soon grow to eclipse annual Dutch export volumes (if some do not already). This is the result of policy - all the named countries above have multiple licensed cannabis producers exporting, while the Netherlands only currently permits one company, Bedrocan, to produce medical cannabis for both the domestic and international markets (though in 2020 there was a tender process intended to establish a second producer, which was ultimately unsuccessful). Every gram of product which Bedrocan produces in the Netherlands is sold at a fixed price to the OMC, which is in control of distribution and export agreements, and is cautious about large-scale exports. Dutch policy documents explicitly set a maximum quantity of 100 kilograms per year for a maximum period of three years to be exported to any country, unless the Minister for Health gives express permission otherwise.

Where the Netherlands does remain a global leader in medical cannabis export however, is in its geographical reach. There are 15 countries to which the Netherlands has exported medical cannabis to over the last two years. With the exception of Canada, no country exports medical cannabis to as diverse a range of countries as the Netherlands, and international demand for Dutch medical cannabis exceeds supply every year, according to documents published by the OMC.

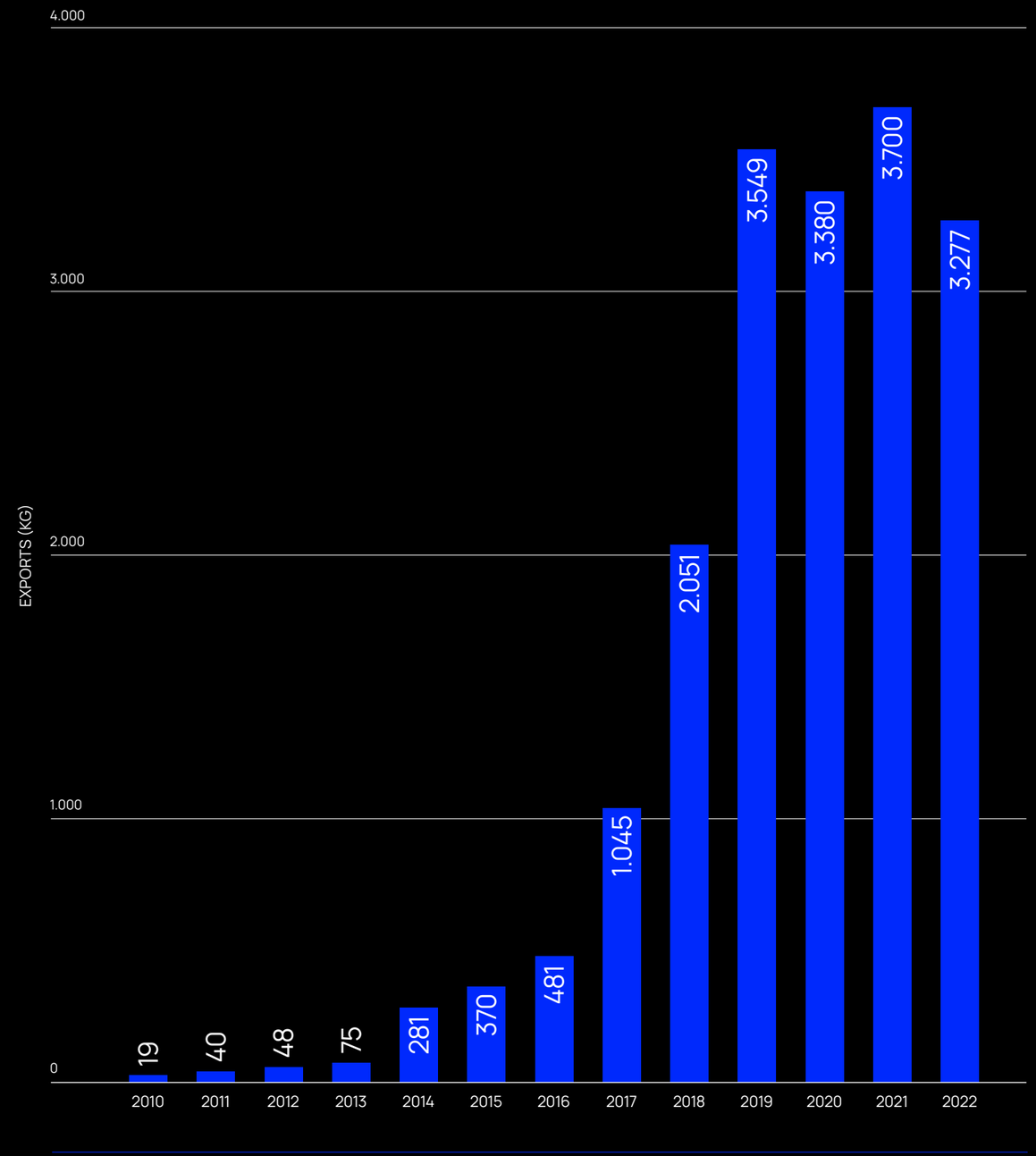
Current Dutch policy around the export of medical cannabis is based on countries becoming self-sufficient in their medical cannabis needs - the export guidelines prevent the Netherlands from assuming the role of structural medical cannabis supplier. However, were this policy stance to change, the Netherlands would be in a strong position to capitalise on the growing demand for high-quality medical cannabis internationally. Having produced medical cannabis in the country since 2003 and exported it since 2006, with everything consistently overseen by the OMC during this time, the Netherlands has had a long time to standardise its processes and increase product quality and consistency, as well as the reputation of its exported product abroad.

Bedrocan has been the company at the centre of the Dutch medical cannabis regime since 2003, and it has greatly benefitted from being its sole provider, however it has also been limited by it. Without the means to negotiate supply agreements or pricing, the company has been restricted in the degree to which it is able to expand. This makes the January 2023 announcement that Bedrocan is establishing a production facility in Denmark significant, in that it marks a new era for the most recognised and long-established medical cannabis producer in the world. For the first time, Bedrocan will be able to negotiate commercial agreements directly, which opens up new possibilities for expansion and growth of the company. Initial reports are that existing product lines will be replicated in the facility, with the addition of at least one new high-CBD flower strain, so the reputation and name-recognition of both the company and of its products, cultivated over 20 years in the Netherlands, can be fully appreciated.

In stark contrast to the Netherlands, Danish policy for the past several years has been explicitly directed towards establishing large-scale cannabis production for the purpose of becoming a leading medical cannabis exporting country - it has welcomed various international medical cannabis producers, and helped to guide them in setting up in the country through its 'Invest in Denmark' programme. If this division in policy on medical cannabis persists between the two countries in the coming years, the current trend will also continue - seeing Denmark becoming increasingly integral in the global medical cannabis supply chain, while the Netherlands becomes increasingly peripheral. Bedrocan will not become the cornerstone of Danish medical cannabis exports in the same way that it has been for the Dutch, however it brings with it decades of experience in manufacturing and standardising medical cannabis products in an EU-GMP environment - something few companies can claim - and it will probably become a valuable addition to the budding Danish medical cannabis sector. The decision of the company to spread its wings beyond the Netherlands is just one part of a wider redrawing of the map of European (and global) medical cannabis supply which is currently taking place. However, in the context of these two countries, it is a particularly symbolic one.

The European Cannabis Report | SUPPLY CHAIN

Dutch Medical Cannabis Exports by Year



Source: OMC, Prohibition Partners

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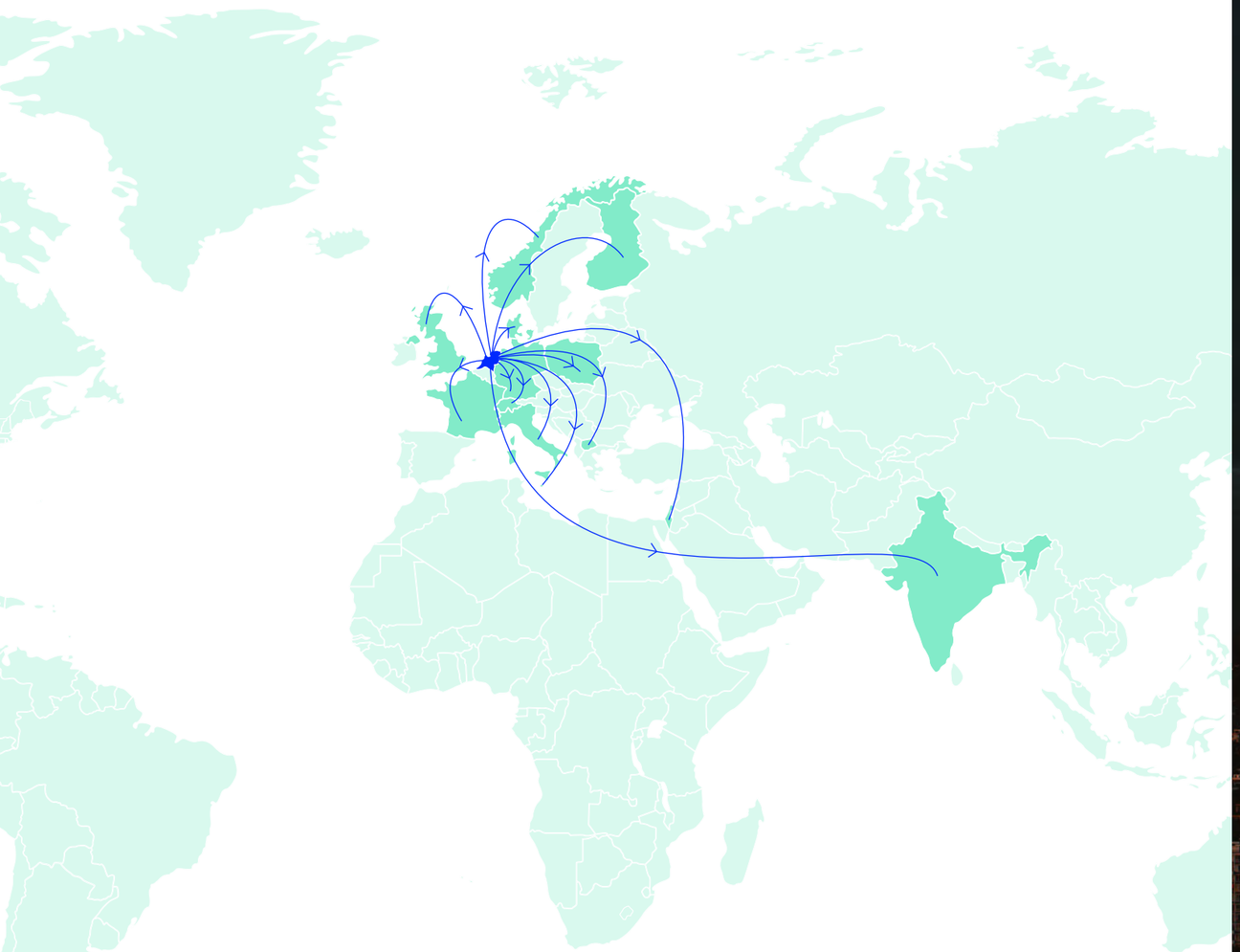
Where the Netherlands Exported to in 2022



Germany	2000 KG	Italy	850 KG	Norway	≤100 KG	Denmark	≤100 KG
Switzerland	≤100 KG	Israel	≤100 KG	Macedonia	≤100 KG	Malta	≤100 KG
India	≤100 KG	UK	≤100 KG	Finland	≤100 KG	Poland	≤100 KG
France	≤100 KG						

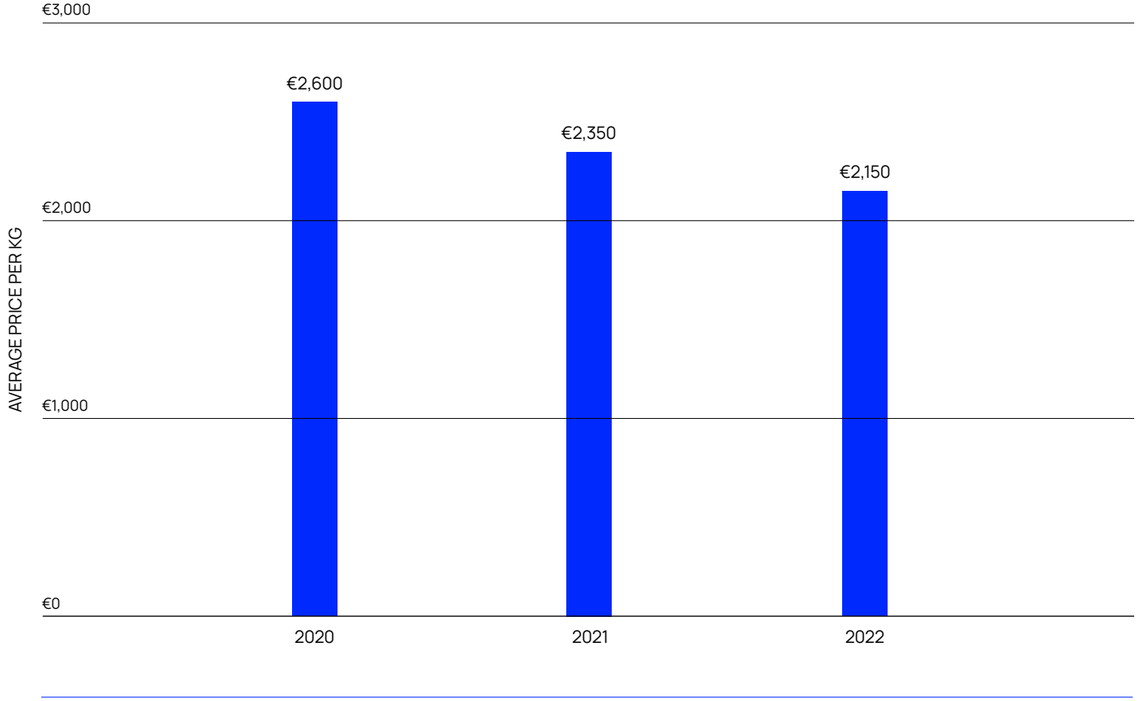
Source: Contact with CIBG (Dutch Ministry of Health, Wellbeing and Sports)

Wholesale market: price of medical cannabis flower declining

Medical cannabis prices in Europe are a little less elastic than those in North America primarily because the markets are more tightly regulated. Some governments - e.g. Italy, Netherlands and Germany - set the domestic wholesale price of cannabis which producers must abide by, and stringent quality requirements, like EU-GMP, ensure that the price floor is more firmly set than in less regulated markets.

Prohibition Partners has secured exclusive data from Canadian customs' authorities on the quantity and value of exports from Canada by region which is instructive about the price trends across Europe. Our data shows that from January 2020 to October 2022, the average wholesale price of medical cannabis flower being sent from Canada to Germany fell 20% from approximately €2,600 per kilogram to €2,150 per kilogram.

Declining price of Canadian medical cannabis flower exports to Germany



Source: Exclusive Canadian Customs data made available to Prohibition Partners

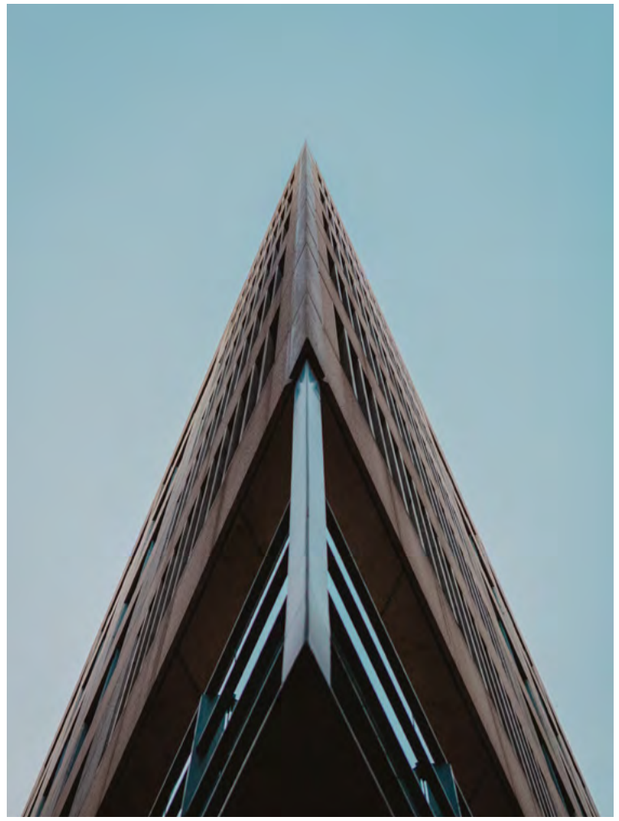
Several countries centrally control the price of cannabis in Europe. The German domestically cultivated medical cannabis has a market price of €2.30 per gram, or €2,300 per kilogram. This price is set by the German Federal Institute for Drugs and Medical Devices, and is a low price for high quality medical grade cannabis. The price at which the Dutch OMC buys medical cannabis from Bedrocan under their tender agreement is fixed at €2,350 per kilogram, and it is subsequently exported for approximately €5,300 per kilogram.

Some deals have been struck with producers in low-cost countries which could undercut suppliers from the northern hemisphere. In 2020, Uruguay sent exports to Germany from Fotmer Life Sciences, via Tilray Portugal, at a price of €2,720 per kilogram, with subsequent shipments at €1,700, though this needed further processing at EU-GMP facilities to make it compliant for sale in Europe. Nevertheless, the price offered by Fotmer represents a significant reason as to why exports from South America and Africa will soon increase, especially if they can meet EU-GMP standards.

Production costs have a large bearing on the price which wholesale cannabis can be offered at. As mentioned, it can be considerably cheaper to cultivate cannabis in warmer climates with cheaper land than in northern countries. For example, PharmaCielo, a Canadian company with cultivation activities in Colombia, has been growing its crops at a reported cost of US$0.03 to US$0.04 (€0.028 to €0.037) per gram. This is orders of magnitude lower than growers such as Tilray, who have reported production costs in the range of US$0.72 (€0.67) per gram in 2022, though differences in reporting methods and levels of compliance (e.g. EU-GMP vs non EU-GMP, adult-use cannabis vs medical) may account for some of this difference. Another case is Clever Leaves, who has been producing more cannabis in Portugal rather than in its Colombian facilities and has seen its production costs increase to $1.13 (€1.05) per gram in Q3 2022 vs US$0.15 (€0.14) in 2021.

Business & financial overview

Signs of recovery after a difficult year



The European Cannabis Report | BUSINESS & FINANCIAL OVERVIEW

Almost every market across Europe found 2022 to be a volatile year. Economies, still scrambling to regain traction after the global COVID-19 recession, have been dealt a string of blows to their recovery. After a European 'green wave' in 2021 saw investment and investors flooding into the burgeoning cannabis industry, the downturn which had begun in the latter months of the year, accelerated throughout the entirety of 2022. As extraneous economic circumstances turned investors' attention sharply away from higher-risk sectors, European cannabis stock values fell just as sharply, seeing access to capital dry up along with the momentum behind the market. However, in a reversal of activity, the final quarter of the year began to show the green shoots of recovery, with the evolving promises of reform across the continent encouraging tentative capital to return. February 2022 marked the one-year anniversary of the first cannabis company to list on the London Stock Exchange (LSE) in its 320-year history, 'opening the door' for a string of others to follow suit. The unbridled optimism which had accompanied this landmark event had largely subsided by the start of 2022. During the summer of 2021, industry insiders suggested between 15 and 20 companies had started the initial public offering (IPO) process, but by early 2022 less than a dozen of these were left in the running.

While cumbersome additional requirements announced by the Financial Conduct Authority (FCA) deterred many from specifically targeting the LSE, a '180 degree shift in sentiment' meant this slowdown was felt across Europe. The same month, Europe witnessed the full scale invasion of Ukraine by Russia, seeing global markets plunge by double digits over the proceeding weeks. Global stock market prices fell around 25% in 2022, while cannabis stocks experienced an overall decline of 60%, with nearly four times the volatility. The war not only hit cannabis stocks significantly harder due to the transfer of capital towards risk-averse investments, but it also posed many longer term threats to the industry, not least pushing cannabis legislative reform down the list of priorities for European governments. As EU-GMP certified medical cannabis is required to be grown indoors, requiring massive amounts of electricity and water, the spikes in the cost of gas and energy have significantly impacted on what were already razor thin margins. The evisceration of market value cannot be solely attributed to extraneous market conditions though, with the performance of companies within the sector, also playing a key role. Public boardroom disputes, poor financial management, high management turnover rates and low returns on investment have plagued a number of publicly listed cannabis companies throughout 2022. The more mature North American cannabis market, to which many investors look for indicators about how the European market may evolve, also had a troubled year with many of the biggest players reporting tens of millions in losses. This meant institutional investors, already scarce due to the regulatory hurdles and limited access to banking and insurance associated with the cannabis industry, remained especially cautious throughout the year. Euroclear, the main investment clearing house for cannabis stocks, also announced plans to pull out of the cannabis market, providing another hurdle for those looking to invest, and more importantly for companies looking to raise capital. Of the 30 European cannabis stocks tracked by BusinessCann throughout 2022, only pharmaceutical giant Jazz Pharma and Futura Medical, both of which receive the bulk of their revenue from markets other than cannabis, saw their values grow last year. The average decline in stock price for publicly listed cannabis companies in 2022 was around 64%, seeing more than £1 billion wiped off their collective market value.

While 2022 has undoubtedly been a tough year for the European cannabis industry, those who have managed to weather the storm may soon be able to reap the benefits. Anticipated consolidation in the coming months will hopefully restore some confidence from investors, seeing those with unworkable business models fall by the wayside and those with agile, profitable frameworks commanding a larger slice of the market. Furthermore, the latter months of 2022 and early months of 2023 have pointed to an increase in investment, available capital, and regulatory progress

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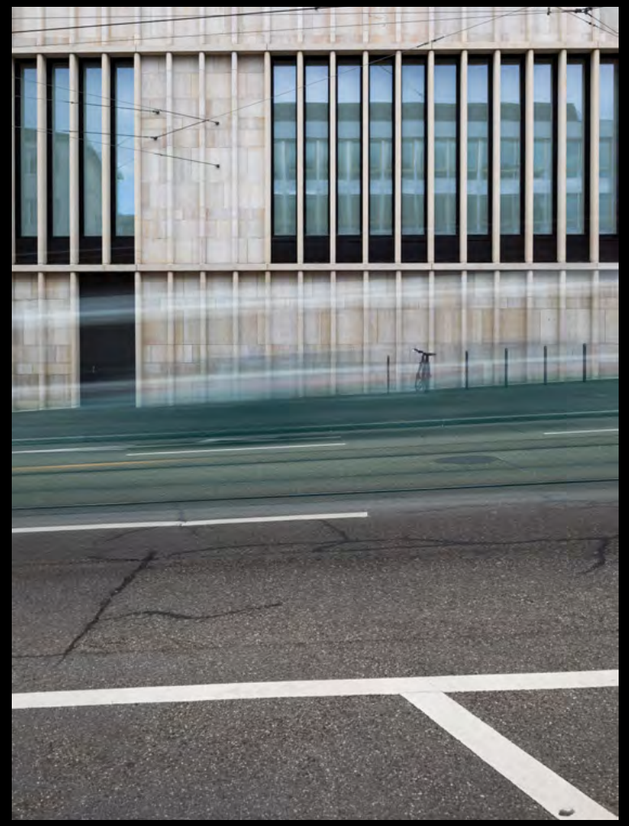
across key markets. In early October 2022, Berlin-based cannabis operator, Sanity Group, closed Europe's largest ever cannabis investment round worth €37.6 million, bringing its total funding to date to over €100 million. A month later, Danish medical cannabis firm, Stenocare, announced that it had secured further funding, providing it with sufficient runway to reach break even for the first time. Weeks later, Cantourage became the third and largest major European medical cannabis operator to publicly list its shares this year, offering 'approximately 15%' of its total bearer shares available in free float on the open market of the Frankfurt Stock Exchange (FSE), valuing the company at just over €80 million. Another German operator, Cannovum, announced plans in early December to move its shares onto the 'Primärmarkt' (Primary Market) of the Düsseldorf Stock Exchange, before launching a secondary listing on the larger FSE and Xetra exchange the same month. This was closely followed by Greek cultivator Hellenic Dynamics, which became the second company after Celadon and the first pureplay cannabis cultivator in history to list on the LSE following protracted negotiations with the UK's financial regulator, valuing the company at £31.2 million. These late financial developments were mirrored by regulatory advancements, seeing the Council of the European Union, the legislative body of the EU, adopt a new human-rights based drug policy which could act as a catalyst for reform into 2023 and beyond.

In a year dominated by economic upheaval, worst-in-a-generation inflation and a tightening of the purse strings of almost every industry and market across the continent, the nascent European cannabis industry has been harder hit than most. The winds of 2022's financial storm, to which companies have had little choice but to hunker down and wait, have helped expose which businesses have been built on resilient foundations and which have not. For many representatives of institutional capital who have remained cautious of cannabis investment this will be no bad thing, helping accelerate the process of consolidation and the suppression of poor business practice necessary to build confidence and trust.

Conclusion

Europe remains the centre of attention when it comes to the development of the medical cannabis industry at a global level. This is not only because it has the potential to become the largest market, but also because it is open to international players. The myriad of different players entering the European medical cannabis market and establishing a presence all have one eye on the future; however, having a clear vision of what that future will look like is essential to success in such a complex and dynamic market environment. Adaptability is also key, and increasingly specialisation is becoming a more successful strategy than supply-chain coverage. The nature of growth and development in the European medical cannabis industry is unpredictable, but the scale of growth in the long term is less so. The size of the European healthcare market and the sustained momentum of medical cannabis within it at a regional level mean that opportunities are guaranteed. However, the past number of years has shown that low-resolution tactics aimed towards dominating future market share at all costs will falter if the speed of market development does not meet expectations. Focused, well-informed market strategies will allow businesses to stand the best chance of taking advantage of these opportunities as they arise.

CBD



Introduction

The CBD industry in Europe is in an interesting phase of its development. The market is huge, and established - products are on shelves in the high streets of capital cities across the continent - and yet there is still widespread confusion on the part of businesses, consumers, and even of regulators themselves regarding what uses of CBD are legitimate in different commercial environments. There is progress on the regulatory front however, and at a European and national level, measures are being taken to normalise and standardise the position of CBD in the main sectors in which it exists as a consumer product. The main regulatory hurdles which the industry now faces concern the legal position of CBD flower (which is most neatly regulated as a tobacco substitute), the issue of permissible THC limits in products (highly variable by country), and the ongoing wait for novel food authorisations. In the absence of comprehensive product standards, and as a response to the lack of transparency which has been a feature of the market so far, product testing through third-party laboratories has become ubiquitous for high-quality producers in Europe - and testing is becoming more rigorous as well as affordable. The market remains somewhat oversupplied at the business to business (B2B) level, however the rise of testing is increasingly allowing businesses to more accurately assess value and quality - products sold cheaply and without accompanying Certificates of Analysis (CoAs), or with heavily dated CoAs, are now easily identified as being of questionable standard. This new focus on quality is seeing more emphasis placed on traceability, transparency, and production methodologies than was previously the case, and is a welcome sign for the development of the sector.

For more in-depth analysis of CBD in Europe, read The European CBD Report™, published in January 2023.

Regulation & Legal Analysis

For CBD products in Europe, the subject of legality is a complex one. This is primarily due to the following four factors:

1. **There are a wide variety of formats and intended uses for the products in which CBD is present** - from cosmetic products for topical use, to flower products for smoking, to CBD-infused food and beverage products or concentrated dietary supplement products for ingesting, the list goes on - different regulations apply to each industry, and to the place of CBD within them.

2. **CBD products often contain trace amounts of THC, which is a heavily regulated and tightly controlled substance, and intoxicating when consumed in sufficient volume.** Many recent developments and disputes in terms of the legal position of CBD products across Europe have centred more on the trace levels of THC in products rather than on the CBD itself.

3. **The modern CBD and hemp industry has developed rapidly, and much of the existing regulatory infrastructure in Europe was created to regulate the traditional hemp industry - which consisted of textiles, agricultural products and traditional hemp foods.** These regulations are neither detailed nor focused enough to provide legal clarity for all the current applications of hemp and CBD across different industries.

4. **There are multiple (often overlapping) legal regimes which are relevant for CBD products in Europe** - vertically - at local, national and international levels - and horizontally -with jurisdiction often shared between medicines/narcotics authorities, food safety authorities, cosmetics authorities etc.. Decisions made at higher authoritative levels go some way to informing and harmonising those made at lower levels, but with such a high degree of complexity in the subject, there are often contradictory decisions and practices being carried out across Europe regarding CBD products, despite harmonisation in regulation, practice and enforcement being the desired state of affairs from all parties involved.

Despite the complicated nature of its regulatory status, a diverse range of CBD products are available to all European consumers through online shopping, and increasingly also through 'bricks-and-mortar' retail (though this varies widely on a country-by-country basis). A constant element of the CBD industry in the region over the past several years is that there has been an obvious gap between regulation and market practice, meaning that supply chains are set up and products are manufactured and sold, while regulations about what is strictly allowed and what is not remain blurred. In this context, clampdowns and restrictions in the industry are the result of individual authorities' interpretations of existing legislation, and the enforcement of these interpretations is somewhat arbitrary and inconsistent both between, and even within, countries in Europe. However, recent years have seen significant progress made in specific areas which have clarified some legal aspects of the CBD industry in Europe. The two most important developments have been:

- **CBD was exempt from consideration as a narcotic** (November 2020) The decision of the Court of Justice of the European Union (CJEU) that CBD, whether plant-derived or synthetic, and extracted from any part of the plant, including flower and leaf, is not considered a narcotic. This was a landmark case, and this decision has meant that the possession and trade of CBD is not considered to be a criminal offence in the EU. Before the 2020 CJEU decision, there was space for a legal interpretation of CBD as an 'extract of cannabis', and anyone possessing or trading it could be charged with drug trafficking.

- **CBD became recognised as a standard ingredient in cosmetics.** In February 2021, CBD, whether plant-derived or synthetic, was included in the EU Cosmetic Ingredients Database (CosIng). While CosIng is not a legally binding document, it serves as a guideline for member states adopting

cosmetics' legislation. This means that the use of CBD in cosmetic products is legal at virtually every level across Europe.

These developments represent the first steps towards true regulatory harmonisation of the CBD industry in Europe, and their impact was significant, however the degree to which they have clarified what activities and uses are legal for CBD in Europe is limited in scope. CBD is unequivocally permitted in cosmetic products and is not a narcotic, but in order to legitimise and regulate the full scope of market activity for which CBD is currently being used, the following developments must take place at a national (though preferably a European) level:

- **Product-specific THC limits must be set**
  The issue of acceptable THC limits in CBD products is the focus of many recent and ongoing cases in the national courts of European countries (see **Legal clarity of THC limits in CBD products**). Every country takes the view that there is a level of THC concentration in a product which renders that product illegal, but there is no consensus on where that line should be drawn - it currently ranges from 0% - 1% depending on the country (or in the case of the UK, 1 milligram per product) - and many have not clarified the matter at all. In the latter scenario, industry operators usually adhere to the level which defines the legality of industrial hemp in their country of operation, usually 0.2% or 0.3% THC, but recent rulings in German and Irish courts demonstrate that adherence to these limits does not indemnify businesses from legal liability (see **Legal clarity of THC limits in CBD products**). This is significant, because when THC limits are exceeded, the offending party can face criminal charges. Without the establishment of a defined limit on THC concentration in CBD products, it is left to the discretion of the judge in each individual case to determine legality.

  International narcotics law serves as the basis for most national legislation on the subject - the relevant texts are the 1961 UN Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances. The relevant part of the 1971 Convention in this case states that psychotropic substances in products (in this case THC in CBD products) must, 'be in such a condition that they will not in practice be abused or recovered'. This leaves significant space for interpretation, and results in an inconsistent application of the law across Europe. The situation would be improved if there was a European standard of:
  - What constitutes the minimum dose of THC which is considered to have a psychoactive effect (called the 'doping dose' in Italy).
  - What is the maximum concentration or overall volume of THC permitted in consumer products, by product category (cosmetics, food and beverage, smoking etc.).
  - What is the maximum concentration or overall volume of THC permitted in B2B products.

- **The place of CBD flower must be decided**
  Another major theme of the recent and ongoing court cases in Europe is that many of them concern CBD flower, rather than extract-based products. Because of its similarity to black-market high-THC cannabis, CBD flower is more prone to being seized by authorities. It is also closer in a legal sense - the 1961 UN Single Convention on Narcotic Drugs defined the term cannabis as pertaining to the 'flowering and fruiting tops' of the plant. What is currently posing legal problems is both the question of the potential for low levels of THC in CBD flower products to be abused, as well as that of whether hemp flower should be legal at all, regardless of the cannabinoid content.

- **Marketing authorisations for CBD products as Novel Foods must be granted**
  Despite the ubiquitous presence of CBD in the European supplements and health food market, it is still not strictly legitimate as a food ingredient from a European perspective. Different countries currently take different approaches to enforcement of this fact, but CBD food or dietary supplement products are on the shelves of retailers across the continent, as well as being easily accessible online. Until authorisations are granted, CBD will not be a recognised part of the food industry, as it is in cosmetics. For more information on the status and progress of the current CBD Novel Food applications, see the Novel Foods chapter.

Legal clarity of THC limits in CBD products (particularly hemp flower) & risk for businesses

UK

The UK has ongoing cases and has seen low-level convictions for CBD flower sales, and still technically has a legal THC limit of 1 milligram per product, though this is not enforced.

NETHERLANDS

In December 2022 a Dutch court ruled that the retail sale of flower under 0.2% was illegal. A technical limit of 0.05% THC on other CBD products is largely unenforced.

BELGIUM

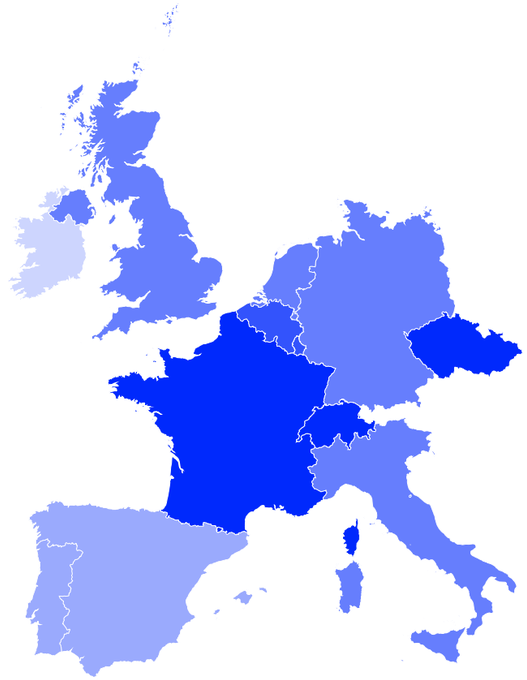
Since April 2019, the sale of CBD flower cigarettes under 0.2% THC is fully regulated in Belgium, but the sale of CBD food supplements remains unregulated.

GERMANY

In June 2022 the highest court in Germany upheld a ruling that the wholesale of two 60 kilogram quantities of CBD flower was a criminal offence, despite THC levels under 0.2%. However, in April 2022, the Berlin Court of Appeal acquitted a CBD flower retailer of the same charges. Product seizures and prosecutions are ongoing.

IRELAND

In October 2022 the highest court in Ireland ruled that the sale of a CBD oil product was illegal due to its THC content, despite containing under 0.2% THC.



CZECH REPUBLIC

Since 2022 the Czech Republic has had a clear 1% limit on all CBD products, and though the sale of flower products is not fully regulated, there have been no recent legal challenges to businesses.

FRANCE

In December 2021, the highest court in France ruled that the sale of CBD products with under 0.3% THC was legal, except for flower and leaf products. However, in December 2022 this ban was overturned, meaning that all CBD products under 0.3% THC are legal for sale in France.

LUXEMBOURG

Since 2019 Luxembourg has regulated the sale of CBD flower cigarettes under 0.3% THC, however the sale of all other CBD products is not regulated.

PORTUGAL

In November 2022, a high profile case was suspended, and 40 kilograms of flower returned to the defendant, because detected THC levels were under 0.2%, however product seizures are still occurring.

SPAIN

Two court cases in Spain in 2021 and 2022 ended with rulings that CBD flower with THC levels under 0.2% was legal for sale, however product seizures and prosecutions are ongoing.

SWITZERLAND

Since 2011 Switzerland has had a clear 1% THC limit for CBD flower products, and this now applies to all CBD products in the country.

ITALY

In Italy there are various ongoing cases, with the authorities of different regions varying in their approach to the industry. Of particular note is an ongoing case in Parma, where the defendant faces a potential six years of imprisonment after 650 kilograms of CBD flower was seized from business premises.

Strong legal clarity,low business risk — Weak legal clarity, high business risk

Source: Prohibition Partners

Flower

The past year has seen a significant rise in the popularity of CBD flower products across Europe, with products being particularly commonplace in; Switzerland, Belgium, Italy, France, Germany, Spain, Luxembourg and the Czech Republic. There is currently no European-level legislation which deals with CBD flower products as herbal/smokable products; however, it is likely that such legislation is not far away.

Of these countries, the only ones which have, in a clear sense, legalised the sale of CBD flower are; Switzerland, Belgium, Luxembourg and France. In the case of Switzerland, Belgium and Luxembourg, CBD flower is regulated and taxed as a tobacco substitute. In the French case, the court decision which overturned the ban on the sale of CBD flower only took place in December 2022, so it is still too early to tell if France will follow the same route of regulation.

In the Czech Republic, though flowers are legally for sale they are not technically legal to be sold for smoking, so they are instead sold as 'collector's items', and there have been no legal challenges to businesses on this basis in recent years. In Italy, Spain and Germany, there are ongoing legal challenges faced by some businesses for selling CBD flower products.

For now, how to regulate these products is left to national authorities, but ultimately it is likely that EU-level legislation will direct national regulation in the coming years, and analysts believe that European authorities will regulate CBD flower as a tobacco substitute product, similar to the approach taken in Switzerland, Belgium and Luxembourg.

The two most important directives relating to tobacco substitute products in the EU are - the Tobacco Products Directive (TPD) and the Tobacco Excise Directive (TED).

TPD

Regulates the manufacture, presentation, and sale of tobacco-containing products, nicotine containing products and herbal smoking products.

TED

Regulates the excise taxes levied on tobacco and tobacco-containing products.

The EU is currently reviewing the regulations concerning tobacco substitutes, with particular attention being paid to e-cigarettes and CBD flower products. The main reason for this update in law is that; while the TPD and related regulations are geared for tobacco substitute products including tobacco-containing products, nicotine-containing e-cigarettes and herbal smoking products; the fiscal policies, like TED, are only established for tobacco-containing products. Thus, a gap has been left for products like nicotine-free e-cigarettes, including CBD vapes, and CBD flowers which are commonly used for smoking.

A new decision on the reform of TPD and TED is expected in 2024 and it is highly likely to impact on the market for CBD-vapes and flowers. CBD flower and vape oils will probably be treated more like tobacco products in that marketing will be severely limited, health warnings will probably be introduced, online sales between countries will probably halt; all while domestic sales continue and specific excise taxes are introduced.

Hexahydrocannabinol (HHC)

HHC is a phytocannabinoid which occurs naturally in the cannabis sativa plant in trace amounts, and has intoxicating effects similar to THC. It does not appear in international narcotics legislation however (and rarely in national legislation, if ever), because it was not sold commercially until several years ago, when it first hit US markets.

HHC is often referred to as a synthetic or semi-synthetic cannabinoid, because to reach any commercially relevant quantity of HHC requires chemical processing - i.e. it is not possible to just extract it and isolate it from the plant in the same way as it is done with CBD and THC. It is possible, however, to take CBD or THC and convert it into HHC via a relatively simple chemical process. Virtually all of the HHC in European markets was created by producers in the USA in this manner, using CBD as the starting material. HHC has been a feature of the cannabis industry in some states in the USA for a number of years.

CBD is preferred over THC as a starting material by US producers because of a legal loophole in the 2018 Farm Bill - that a cannabinoid can be legal if it:

1. Naturally occurs in hemp
2. Is not made from 'non-cannabis materials'
3. Contains under 0.3% THC

Since HHC does naturally occur in hemp, is technically made from 'cannabis materials', and does not contain THC, HHC made in this way seems to be technically legal under this bill. However, it is difficult to prove the origin of HHC, so precisely what starting materials are used for any given HHC product is difficult to know.

In the second quarter of 2022, HHC products appeared in European markets for the first time and since then they have proliferated - appearing in various retailers in a diverse range of product formats. Their legality in Europe - where the legal loophole found in the USA does not apply - is unclear, and will be defined on a country-by-country basis. It is at least a 'grey' area, and in some cases it is probable that existing narcotics legislation may apply to it, even if HHC is not named explicitly in the law. Take the Italian case for example - Art 14(6), Title I of the Consolidated Law on Narcotics states that it considers as narcotics:

'substances obtained by synthesis or semi-synthesis which can be traced back to tetrahydrocannabinol by chemical structure or by pharmaco-toxicological effect.'

So, in this context, even though HHC cannot be traced back to THC by chemical structure, it could be, by effect, potentially rendering it illegal for normal commercial use. It is worth noting here that the US has a similar law (the Federal Analogues Act) which applies to all narcotics - banning any substance which is sufficiently similar to a narcotic substance - so HHC may ultimately become banned in the USA, at the federal level, despite the Farm Bill loophole. This would heavily impact the EU market for HHC because supply would effectively be cut off, and it is uncertain whether conditions would be suitable for production to become established in Europe.

Legality aside, from a health perspective, HHC is largely an unknown quantity. It does not appear in pharmaceutical drugs, and in commercial terms (particularly in Europe) it is a new phenomenon, so there is very little in the way of scientific data on its long-term or even short-term effects. There is also no indication that there is significant interest in conducting such scientific analysis, as HHC is not known to offer any additional health benefits that established cannabinoids do not already provide. This may change if HHC becomes a long term feature of the European market and its investigation is more relevant in the context of public health, but for now, its appearance is a new phenomenon which authorities are only just beginning to take note of. In December 2022, the Lisbon-based European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) held a meeting of technical experts on the subject of HHC and related semi-synthetics cannabinoids, and it is due to publish a report on the matter in Q2 2023.

The European Cannabis Report | REGULATION & LEGAL ANALYSIS

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Novel Foods

Ever since the European Commission (EC) classified CBD as a novel food in 2019; all food, beverage and dietary supplement products which contain CBD, must be sold under marketing authorisation from the European Food Safety Authority (EFSA) in order to be fully legitimate retail products from a European perspective. More precisely - the CBD ingredient itself, which is used in those products, needs marketing authorisation, and that CBD ingredient and authorisation will be tied to specific manufacturing processes and one or more named applicants under which the application was filed. These named applicants will have exclusive rights to allow the use of this authorisation to sell this specific CBD ingredient as a novel food for a period of five years after the authorisation is granted.

Despite this position from the European authorities, the sale of such CBD-containing products continues across the region without a single novel food authorisation for CBD having yet been granted. There are several reasons why this is the case, including that:

- While under EU law novel food legislation applies to all members, in practice some countries take a far less restrictive approach than others, allowing the market to progress and develop in the absence of novel food authorisations.

- Selling CBD novel foods without an authorisation is not a criminal offence in the same way as, for example, selling products which are over THC limits could be, so it is far less legally problematic. Products can still be confiscated or prevented from sale by the authorities, but there are no court cases prosecuting businesses for selling CBD without novel food authorisation.

- CBD does not clearly pose a risk to public health, it is categorically not a narcotic, and is now reasonably well-established in the European market, so there are no strong grounds for enacting

bans on its sale, and to do so would be severely complicated from both a practical and a legal point of view.

- All indications are that novel food marketing authorisations for these types of CBD products will be granted eventually, so while they are not technically fully legitimate for sale right now, they are expected to become so in the future.

By March 2022, the EFSA had received more than 150 novel food applications for CBD, and was conducting safety assessments - the next stage in the process after an application has been 'validated' (meaning it has passed the preliminary phase of assessment and is judged to be a legitimate application) - on at least 19 of these.

In June 2022, the EFSA placed all of these applications 'on hold'. This is the second time that all CBD novel food applications have been put 'on hold', however in contrast to the first such occasion - when the EC was mulling over whether to classify CBD as a narcotic - this time around the development has been widely regarded as a positive one for the industry.

The reason for this optimism is that the EFSA has given clear indications about what is required for applications to move forward. After identifying knowledge gaps in the submitted applications and conducting a systematic review of the existing literature and data, the EFSA highlighted areas where information and scientific assessment were deemed to be lacking.

One key area highlighted was the fact that many of the applications relied on data from medical trials of Epidiolex - the pharmaceutical product containing CBD as the active ingredient, approved to treat seizures associated with a number of conditions - and in some ways the data from assessment of CBD for medical applications is unsuitable for use in the context of a novel food application. In particular, the dosages and associated adverse effects being studied were not sufficient to make conclusive safety assessments for CBD in food products.

The EFSA stated that the applications lacked information in some key areas such as; effects on absorption, distribution, metabolism and excretion (ADME), as well as the liver, gastrointestinal tract, endocrine system, nervous system and psychological function. As well as this, a thorough assessment of the potential for adverse effects in humans and of the potential for adverse drug interactions with prescription medicine was also called for.

While the industry continues progressing and developing even in the absence of novel food authorisations for CBD, it nevertheless remains limited in the extent to which it can grow to its full potential in Europe. Novel food authorisations will represent full legitimacy as a standard food ingredient on a continent-wide basis for the first time, and will probably see the introduction of CBD into more mainstream manufacturing and sales channels. The road map for those involved in the application process is now clearer, and European authorities are engaging in a positive and constructive manner, so once the highlighted gaps in the applications have been addressed there is reason to be optimistic that the first authorisations will soon follow.

It is worth noting that the UK's parallel system of appraisal for novel food products containing CBD has not been put 'on hold', but continues as usual. The process of testing the products for potential health risks is similar to the EU but the UK has implemented slightly more industry-friendly policies in allowing for CBD products submitted before 4 July 2022 to remain on the market while the assessments are being carried out. As of August 2022, 12,047 products have been listed. However, many of these products are close duplicates, differing only, for example, in package size so the number of really unique products is several thousand less than this. For the products listed to date, there are 754 unique manufacturers. One major reason why there are so many more applications for CBD products with the FSA rather than the EFSA is that the method of processing varies. With the EFSA, products can be approved at the bulk ingredient level, while in the UK, specific products need marketing.

Testing & Analysis

The European Cannabis Report | TESTING & ANALYSIS

The significance of the testing and analysis component of the CBD ecosystem is coming into ever greater focus as more emphasis is now being placed on the quality of ingredients and products. Independent laboratory testing on a batch-by-batch basis is currently the most effective means of demonstrating product quality in CBD.

This increase in testing is a positive development for the market. Not only does it generate trust and transparency in the market, but it also drives the growth of a new sub-sector in the supply chain: laboratory testing of hemp and cannabinoids. Established laboratories which test food, chemical and medical products now commonly offer testing services which cater for the CBD industry, and the past few years have also seen the emergence of specialised 'cannabis laboratories' - either as entirely new entities or as offshoots of existing laboratories.

The services offered by the laboratories differ according to a number of factors including; certification, equipment, methodology, expertise and location. These variables effect what can be measured, how it can be measured, the degree of precision and how quickly results can be generated. In general, the quality and safety of hemp and cannabinoid products is measured by analysing the parameters detailed in the following page.

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Analysis Name	Measurement Of	Approximate Price Range* (€)	Relevant Measurement Parameters
Cannabinoid Potency	Legality & product quality	70-100	Cannabinoid profile**
Heavy Metals	Contaminants	75-110	Lead (Pb) Cadmium (Cd) Mercury (Hg) Arsenic (As)
Microbiology	Contaminants	65-115	Total Aerobic Microbial Count (TAMC) Total Yeast and Mould Count (TYMC) Bile-Tolerant Gram-Negative Bacteria (Enterobacteria) Salmonella E. coli S. aureus
Residual Solvents	Contaminants	80-200	Propane Butane Ethyl acetate Ethanol Carbon dioxide Acetone Nitrous oxide Methanol Propan-2-ol
Pesticides	Contaminants	110-200	Pesticide profile**
Terpenes	Product quality	80-200	Terpene profile**
Mycotoxins	Contaminants	100-150	Aflatoxin B1 Aflatoxins B1+B2+G1+G2
Polycyclic Aromatic Hydrocarbons (PAHs)	Contaminants	100-175	Benzo(a)pyrene, benz(a) anthracene, benzo(b) fluoranthene and chrysene
Dioxins and Polychlorinated Biphenyls (PCBs)	Contaminants	100-300	Sum of dioxins Sum of dioxins and dioxin-like PCBS Sum of PCB28, PCB52, PCB101, PCB138, PCB153 and PCB180:

*Prices from across Europe, includes labs with and without ISO-17025 accreditation. Aside from standard price deviations between like-for-like analysis services, prices can also vary considerably based on the number of parameters being measured, and the precision of the analysis.
**There are various methods for measuring these profiles, different methods are used depending on what the possible content of the sample is, where and how it was produced, and what range and granularity of measured parameters are required.

The most significant certification for registered laboratories is ISO 17025, which certifies that a laboratory operates to internationally recognised standards of competence, and generates consistent and reliable results. One of the most important parts of the certification is proficiency testing, where a sample, with precisely measured quantities of ingredients is given to the laboratory for analysis, and the accuracy of the laboratory's measurement of those ingredients is determined to evaluate performance. The ISO certification is not mandatory for every laboratory, but it increases trust among partners.

One of the primary challenges with testing and analysis, in the context of CBD products, is that different types of analysis are relevant for different products depending on the circumstances of their production. For example, hemp grown in one country will potentially be exposed to a specific group of pesticides which are used in that region, while hemp grown thousands of kilometres away in another country will have an entirely different list of pesticides to which it could have been exposed. There are tests which can detect upwards of 500 different types of pesticide at once, but there is no 'catch-all' test to detect and measure all types of pesticide. Similarly, hemp extract can be produced using ethanol extraction or hydrocarbon extraction or CO_2 extraction etc.. In this instance, though it is possible to test for all likely residual solvents, it is far more convenient (and cheaper) if the extraction method used in production is known. Given the international nature of supply chains for hemp and CBD products, and the inconsistent and patchy systems of tracing product origin, testing products fully can be a challenge.

In the optimal CBD ecosystem, testing and analysis should be used to measure product quality and legality, and only as a failsafe against specific potential contaminants which are identified based on production methods (including the quality certifications held by the production facilities involved) and materials. In the current market environment, due to a lack of transparency around product origin and supply chains, testing and analysis is even more important, and it remains the primary means relied upon by industry operators to determine the quality and legality, as well as the safety, of products.

Supply Chain

At the current level of European cultivation, there is an adequate supply of hemp for the CBD market in the region. On record, the Czech extractor CBDepot told Prohibition Partners; 'At the moment, there is enough supply of high quality hemp for the production of CBD in Europe. This is before we even consider the large amounts being imported from abroad including from the US'. Representatives from the European Industrial Hemp Association (EIHA) agreed with the above with the caveat that, the amounts currently being grown for the purposes of industrial use (e.g. fibre and textiles) are less than half of what current demand would support.

There are no companies which could be said to be dominating the European CBD space - different brands and supply chains are leading in different regions, and there are no juggernauts. The vast majority of brands buy their products white label, though there are a small number of vertically integrated players, which cultivate, manufacture and brand their own products.

At the brand level the choice for consumers is still overwhelming, with many small independent companies selling in different markets. Where the supply chain is still relatively consolidated is at the level of extraction, with not many companies extracting CBD in Europe at a large scale. In both cases, the number of operators is partly influenced by the long-term effects of large amounts of cheap, low-quality CBD isolate being imported from North America over the past few years. Cheap CBD isolate has driven down prices for producers, but has provided a cheap source of supply for white label manufacturers, and made setting up a CBD brand quite a low-cost enterprise.

Though it is not possible to determine quantitatively where most manufacturing of CBD products is occurring in Europe, reports indicate that there are a number of hubs in countries including; Germany, Switzerland, Italy, the Czech Republic, Switzerland, Poland and Croatia.

For a more detailed analysis of the current state of the supply chain and corporate landscape for CBD in Europe, read The European CBD Report™, published in January 2023.

European CBD Survey

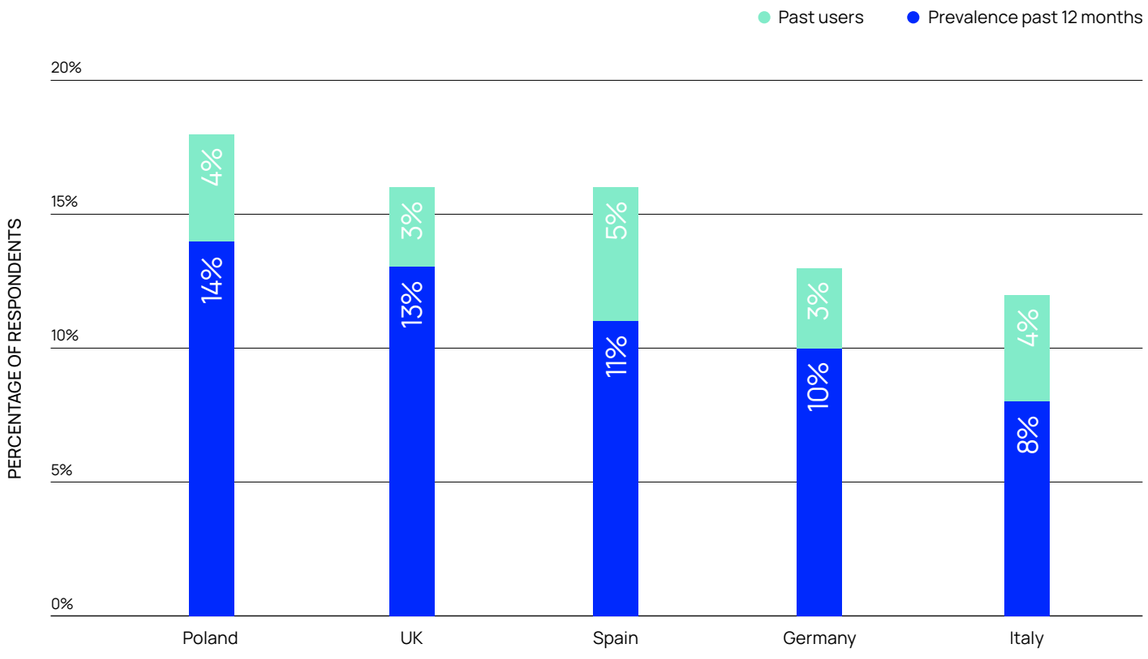
Scope and limits of the European CBD Survey

For the purposes of this report, Prohibition Partners surveyed 5,234 people across Germany, the United Kingdom, Spain, Italy, Poland, France and the Netherlands (see our European CBD Report: Health & Wellness 2023 for description of the data collection process).

CBD Usage is common in Europe

Overall, the prevalence of past-year CBD product usage in surveyed European countries is quite high. **Of the 5,234 people surveyed across Europe, 11% have used some CBD product in the last 12 months.** Another 4% of respondents have used CBD at some point in their lives but not in the past 12 months. CBD products are now very well known across the continent, with just over half of the respondents having at least heard of CBD products. This is being powered by increasing knowledge about the safety and effectiveness of CBD products e.g. for wellness purposes, anxiety, sleep issues and pain conditions. CBD products are also being included by fast-moving consumer goods (FMCG) product portfolios and their availability at mainstream retailers.

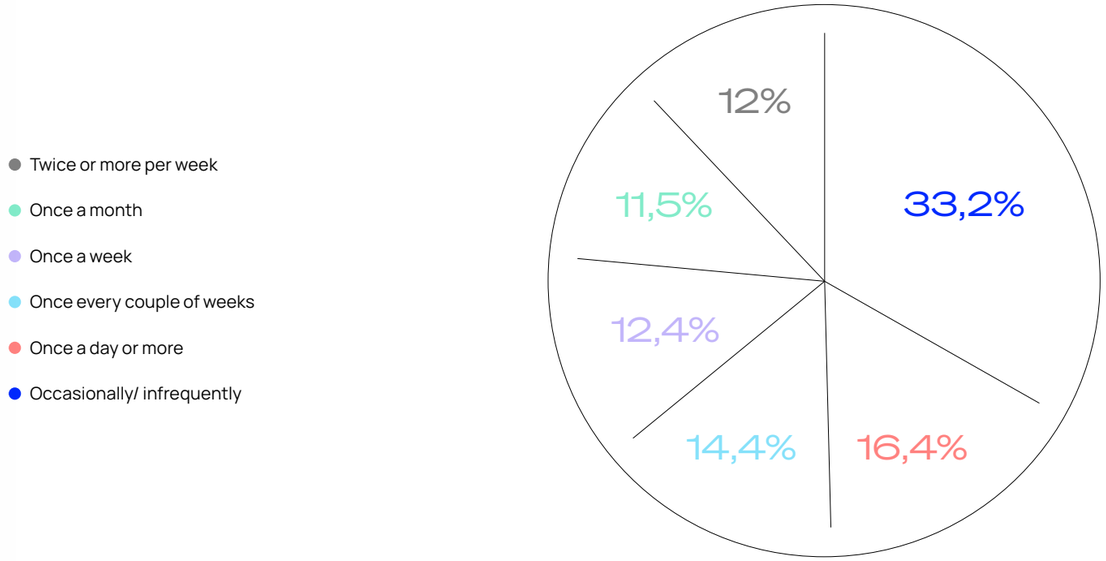
Prevalence of CBD use in Europe



Source: Prohibition Partners, N=4,765, July 2022

The results were generally consistent across countries, with Poland being an exception in both past-year usage and people who have, at some point, used CBD. The highest prevalence of past-year CBD usage was found in Poland, where almost 15% of respondents indicated that they had used a CBD product in the last year. This is in keeping with the development of Poland as a hub for the production and distribution of CBD products. Italy showed the lowest percentage of past year CBD usage at 8%, though this could be to do with the fact that CBD is commonly known in Italy as 'cannabis light' and some consumers may not recognise this as a CBD product. These results confirm that CBD is now a commonly purchased consumer packaged goods (CPGs) product across most European countries, despite the lack of regulation and enforcement of laws.

Frequency of CBD use in Europe (n=1056)



Source: Prohibition Partners, July 2022

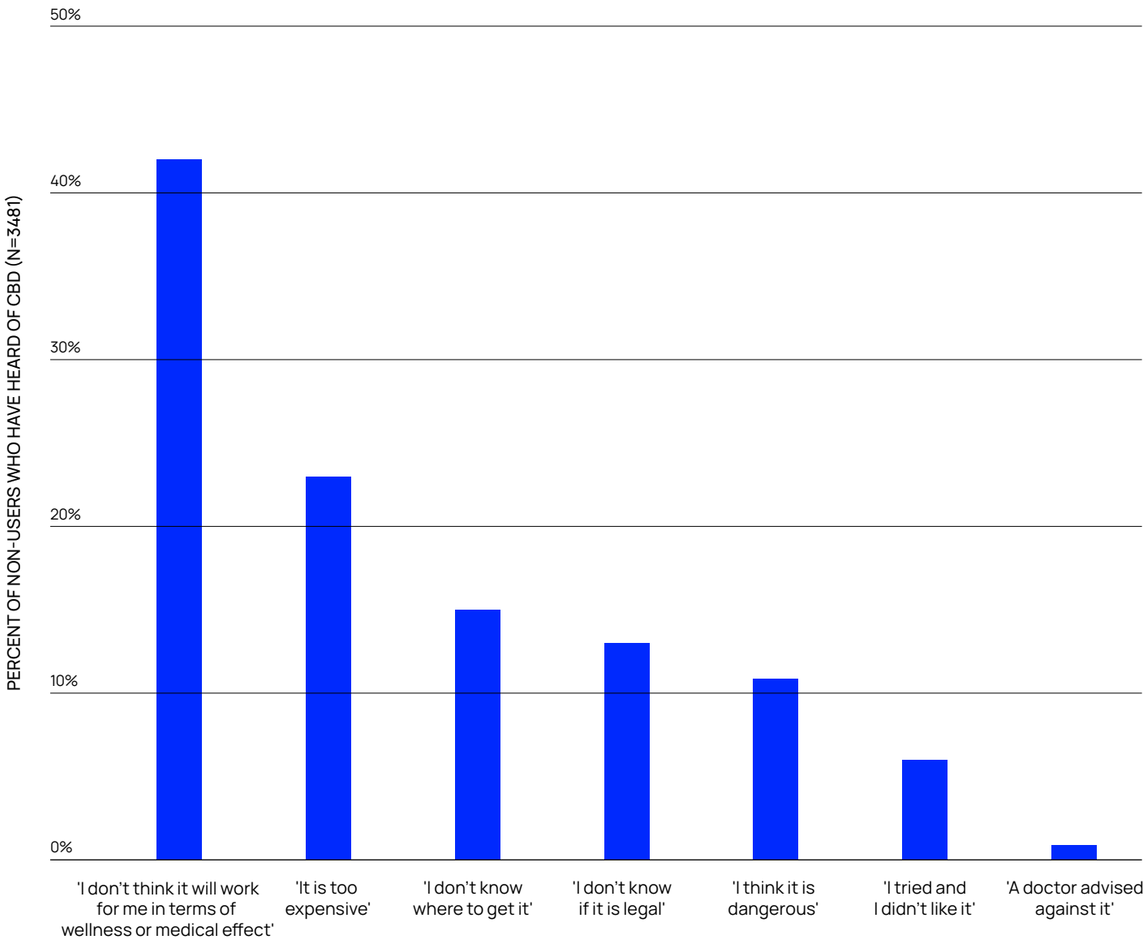
While 11% of respondents indicated that they have used some CBD product in the past year, about 33% of CBD users classified their usage over the past 12 months as infrequent or occasional, meaning less than once per month. This represents the largest single frequency of CBD usage in Europe, and illustrates the volume of people on the continent who are, at least, curious about CBD products and are willing to try them or rely on them for short periods throughout the year. Around 40% of users indicated their usage of CBD as being once or more per week. This represents the smallest population of people who have integrated CBD products into their daily lives, often as part of their wellness routines. Operators in the CBD space should pay close attention to both groups for the reason that frequent purchasers will make up the bulk of the revenue being generated from sales, while the occasional users are those who support companies to a degree, but who may be open to incorporating these products into their daily lives.

Reasons for non-use

Respondents who indicated that they had heard of CBD, but had not used it in the past 12 months were asked about their reasons for not using CBD. Their responses explain why some people are hesitant about entering the market, and what the industry can do in terms of marketing and education to convince people to try these products. The predominant reason stated as to why people are not using CBD products, is a lack of faith that the wellness effects that are much discussed in the media and in CBD marketing, will not be effective for them. This may be true in many cases. However, some factors may be misinforming consumers, such as the lack of awareness around dosing, e.g. where consumers try very small quantities or try for an insufficient length of time before giving up because of a lack of beneficial effects. The industry could potentially do more to educate consumers on appropriate dosing and the management of expectations around which effects can be expected and when. Price is the second most common reason that consumers do not use CBD products. It must be expected that, as more products reach the shelves, especially after the advent of legal novel foods, price compression will drive down the cost of CBD products in Europe, which will further facilitate the entry of consumers to the market.

The next three most common reasons can all be directly addressed by the CBD industry; increased marketing around where to source CBD products, increased education around the legality of CBD and finally increased education about the latest studies on CBD safety and efficacy. These practices would go a long way to solving these barriers to consumers entering the market. Several companies have already integrated these activities into their regular business and content output.

Reasons why Europeans are not using CBD

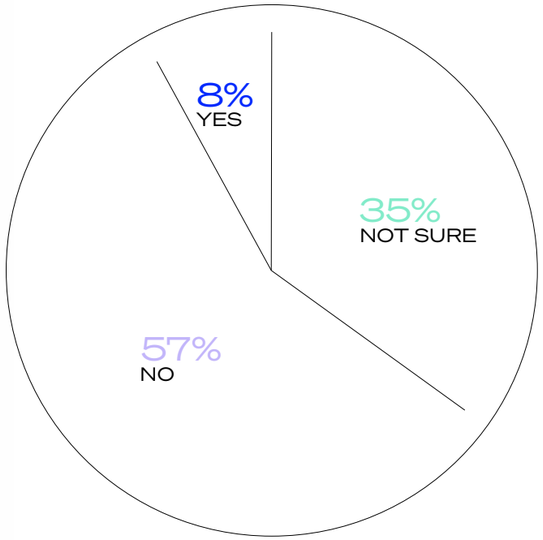


Source:Prohibition Partners, N=3481, July 2022

Growth in consumption across Europe.

Every metric that Prohibition Partners has investigated, after having surveyed thousands of people across Europe, indicates that the number of consumers and the amount of consumption in Europe, is still gradually increasing. Around 8% of people who had not consumed CBD products in the past 12 months indicated that they intended to use them in the next 12 months. This will represent a massive influx of previous and new consumers to the market. This is before considering the 35% of non-users who are 'on the fence' about consuming CBD products in the next 12 months and they may be swayed by strategies outlined in the above section.

Will non-CBD consumers begin using CBD in the next 12 months?



Source: Prohibition Partners, N=3,485, July 2022

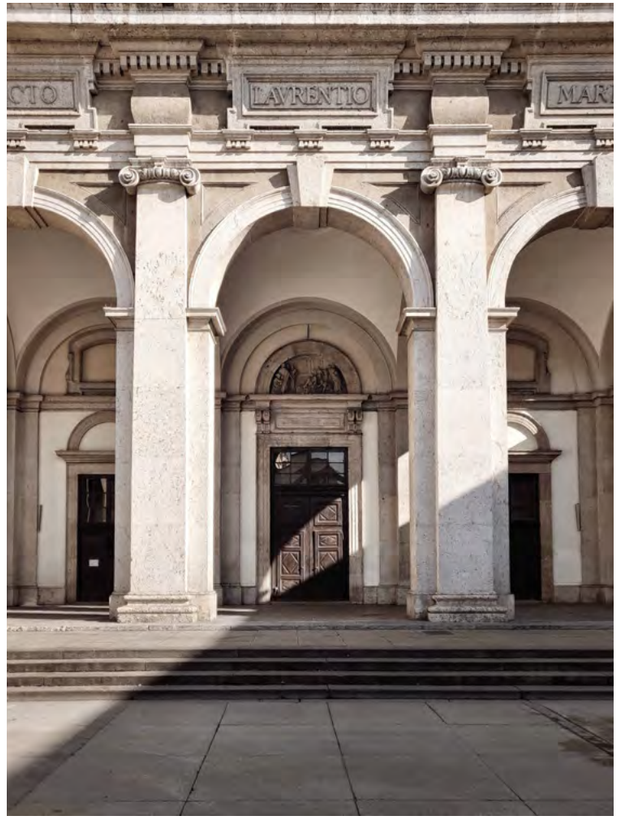
To see the full breakdown of our European CBD survey, please see the recently published European CBD Report.

Conclusion

Though growth in the European CBD market is still strong - our estimates show annual market size in 2023 growing by over 20% from the previous year - the significant developments in the market are now taking place in the form of shifting regulatory structures and trends within the sector, rather than in a spread to new frontiers in Europe. As flower grows as a segment across the region, some regulators are responding proactively by placing it within a legal framework whilst others are choosing inaction and letting the courts interpret the application of existing laws which are often low-resolution and ill-suited to the complexities of CBD. European-level institutions still have their part to play in establishing high level standards and normalising the market, and despite being predictably slow-moving they are largely on the right track. The pitfalls associated with the industry still persist, in particular low-quality cheap extract products and the emergence of new synthetic cannabinoids, but the ability to avoid them is becoming increasingly available and affordable through third-party testing. Trust and transparency is valued more highly in CBD than in most industries in Europe due to the ongoing lack of comprehensive official oversight. Any means to self-regulate is welcomed by consumers and businesses alike.

For a more in-depth analysis of CBD in Europe, read The European CBD Report, published in January 2023.

Acronyms



ADME	Absorption, Distribution, Metabolism and Excretion
API	Active Pharmaceutical Ingredient
B2B	Business to Business
BfArM	German Federal Institute for Drugs and Medical Devices
CBD	Cannabidiol
CBDA	Cannabidiolic acid
CBG	Cannabigerol
CBN	Cannabinol
CJEU	Court of Justice of the European Union
CoA	Certificate of Analysis
CosIng	EU Cosmetic Ingredients Database
CPGs	Consumer Packaged Goods
EC	European Commission
EU	European Union
EFSA	European Food Safety Authority
EIHA	European Industrial Hemp Association
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU-GMP	European Union Good Manufacturing Practice
FCA	Financial Conduct Authority
FMCG	Fast-Moving Consumer Goods
FOI	Freedom of Information
FSE	Frankfurt Stock Exchange
GACP	Good Agricultural and Collection Practice
HHC	Hexahydrocannabinol
IPO	Initial Public Offering
LSE	London Stock Exchange
NHS	National Health Service
NHSBSA	National Health Service Business Services Authority
OMC	Office of Medicinal Cannabis
OTC	Over-the-Counter
TED	Tobacco Excise Directive
THC	Tetrahydrocannabinol
THCA	Tetrahydrocannabinolic Acid
TPD	Tobacco Products Directive

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