

THE EUROPEAN CBD REPORT

HEALTH & WELLNESS

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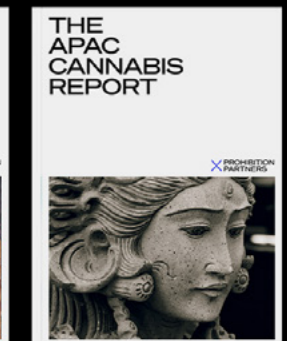
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Introduction



CBD is now one of the most popular wellness products in Europe, with about 11% of respondents to Prohibition Partners' new European survey indicating some usage over the past 12 months. CBD-specific 'bricks and mortar' stores are popping up in virtually every country on the continent and the industry is generating hundreds of millions of euro in revenue each year. However, the legislative and regulatory environment that guides this market is extremely changeable and heterogenous across Europe. Operators need to be acutely aware of these changes as they are driving the business opportunities on the continent

In November 2020, the European Court of Justice (ECJ) declared that CBD cannot be considered a narcotic substance under the European Union (EU) interpretation of the United Nations Single Convention on Narcotic Drugs (UNODC). The ECJ court case against defendants Kanavape represented the most significant hurdle that the CBD industry has had to overcome in order to become legitimised and normalised consumer packaged goods (CPG). It demonstrated the formal separation of CBD, in law, from cannabis. The fallout from this court case is being played out across the continent, with the ruling being referenced in court cases in France, Germany, Italy and others where CBD and hemp traders are establishing their right to continue their businesses which have been running, in some cases, for decades.

The next major step for CBD in the EU and the United Kingdom (UK) is the acceptance of CBD products into the Novel Food Catalogue, under each jurisdiction. In 2019, CBD was declared a novel food in the EU and hundreds of operators have since been working hard to register their CBD products through costly and onerous application processes in the EU. There is now a similar system in the UK. In the EU, products are officially unmarketable while this process is ongoing whereas the UK Food Standards Agency (FSA) allows for product sales during this assessment stage. As of mid-2022, the novel foods assessment process has stalled in the EU, as the European Food Standards Agency (EFSA) has asked the industry to plug gaps in the publicly available data on the safety of CBD for humans. This process will probably take another year or two before the first fully legitimate products are registered.

While regulators consider how to control concentrated CBD products, the supply chain that delivers products to millions of consumers on the continent, continues to develop. The supply of CBD into Europe is currently able to meet the market demands, and there is very likely an oversupply in terms of the raw material. The cultivation of hemp for CBD across Europe is still popular, especially in hubs such as the Baltic nations, Italy, Switzerland and the Netherlands. However, producers have been competing with imports from the United States (US) which massively expanded in 2019. This has driven down raw material and wholesale prices across Europe. Many companies are now opting to move further down the supply chain where there is less competition and potentially higher margins in terms of manufacturing, direct-to-consumer (D2C) sales and tertiary services like legal and delivery services.

CBD products have now been on European shelves for decades, but the influx of concentrated CBD products like flower and the range of oil products is a relatively recent phenomenon. As such, CBD consumer practices in Europe are changing quite rapidly, and as CBD has no international trading codes, and most companies are operating in a legally 'grey' space, there is a dearth of data on consumption patterns. To fill this gap in knowledge, Prohibition Partners surveyed 5,234 people across Germany, the UK, Spain, Italy, Poland, France and the Netherlands on their knowledge and usage patterns of CBD. The survey represents the most up-to-date survey of this population to be found in any publication in the world, as of mid-2022, and offers unprecedented insights into the key metrics of CBD consumption patterns in Europe. **Prohibition Partners examines the financial implications of the current trends in consumption in the CBD market sizing available alongside this report.**

Specific laws and regulations for CBD are lagging far behind the evolution of the market, meaning CBD is now potentially the largest CPG product in Europe which is, in the majority, sold under legally 'grey' conditions. This situation is evolving fast, with new laws, regulations and enforcement practices changing at the European and national level on a quarterly basis. This report is designed to bring readers up to speed on: the CBD industry in Europe in terms of legislation, regulations and enforcement; how to operate a compliant CBD business and the current supply chain and consumer behaviour.



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European Legislation on CBD



Legislation for CBD in Europe is currently fragmented and insubstantial in terms of the legal system in most individual countries. While some rules have been adapted from those pertaining to hemp cultivation, in many cases, specific regulations for CBD products have not yet been established. This has meant that many groups have held off developing their CBD business while others have accepted a high level of risk by operating in an extremely uncertain legal environment.

In general, the tide of international opinion on CBD has turned over the past five years, with the World Health Organisation (WHO) calling for the descheduling of CBD as far back as 2017. Late in 2020, the United Nations Commission on Narcotic Drugs voted to remove cannabis and its derivatives from Schedule IV of the Single Convention. However, the council also voted against the removal of CBD from control under the Convention. The EU voted as a bloc against the descheduling of CBD on the basis that: the proposed definition of CBD products as having less than 0.2% THC 'is not supported by scientific evidence', according to a joint statement from the bloc.

Recently, the UK and the European Court of Justice acted similarly to the US in interpreting that CBD is not to be considered a narcotic substance under the International Convention. The key court case (Kanavape) occurred in France, where distributors were being charged for importing CBD made from hemp flowers which was compliant with Czech laws, but not French. The case was eventually passed to the European Court of Justice who ruled in November 2020 that CBD should not be considered a narcotic under the 1961 UN Convention, as CBD does not, 'have any psychotropic effect or any harmful effect on human health'.

The Court ruled that while CBD could technically have been included in the legislation set out in the UN Convention, banning CBD would be, 'contrary to the general spirit' of that convention and to its objective of protecting 'the health and welfare of mankind'. Furthermore, the Court ruled that the EU states cannot ban the marketing of CBD legally produced in another member state unless a risk to public health 'appears sufficiently established'. As such, CBD is no longer considered a narcotic substance under French, EU or subsequently, UK law. Below, we review the current legal status of CBD under different guises.



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CBD as food

The long road to CBD food regulation in EU



Source: Prohibition Partners

Ingestible products are potentially the most important category for CBD, given the popularity of oils, gummies, edibles, other supplements, drinks etc.. However, producers in this product category are currently wrestling with EU and UK legislation en route to becoming fully compliant consumer packaged goods (CPG). In January 2019, the European Food Safety Authority (EFSA) released a disputed guidance on handling cannabinoid-infused food products, labelling CBD as a novel food, a decision that has also been carried by the FSA in the UK since Brexit.

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

There has been a mixed reception to the Novel Foods ruling as it benefits large operators more than smaller ones. Specifically, the high cost of the applications may lock-out smaller players who cannot afford the time and money to apply for registration. The cost of individual Novel Food applications has been estimated at between €300,000- 400,000 and it can take three to four years. It is for this reason that the European Industrial Hemp Association (EIHA) are combining the funds of members to launch a joint application which all companies can use to develop their CBD products (see interview with EIHA for more). On the other hand, many in the industry also welcome the Novel Foods ruling with the opinion that having some kind of barrier to entry and a set of regulations ensures that only quality CBD products reach the market.

The importance of the latter point is underlined by the frequent findings by inspectors of non-compliant CBD products, with supra-threshold tetrahydrocannabinol (THC) levels, or nominal CBD concentrations. Approval of one CBD product as a novel food will not necessarily benefit other producers, as the approval is specific to the given product and applicant, which is another reason why the EIHA launched a joint application.

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

During the Kanavape court case in France, the question of whether CBD should be considered a narcotic was still alive in the minds of regulators and as such, the applications for plant-derived CBD as a novel food were frozen, with no applications being deemed valid. This situation has progressed. As of December 2022, the European Commission has now listed at least 19 valid applications, and there are over 150 submissions which are not yet validated. The EFSA must now perform a risk assessment for each product before each application is finally approved for marketing by the Standing Committee on Plants, Animals, Food and Feed. However, applications which have been submitted to date, have left out key information on the safety of CBD according to the EFSA. All applications have been paused while this assessment occurs. Different companies and groups are now setting up experiments to plug this gap in data (see interview with EIHA for more).

Since leaving the EU, the UK has had a parallel system of appraisal for novel food products containing CBD. The process of testing the products for potential health risks is similar to the EU but the UK implemented slightly more industry-friendly policies in allowing for CBD products submitted before 4 July 2022 to remain on the market while the assessments were being carried out. As of December 2022, 12,118 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 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.

Cold-pressed CBD and hemp flowers

An exception to the above is the category of CBD product produced with 'cold-pressing' techniques which are considered traditional, rather than for example, using carbon dioxide which can increase the relative concentration of CBD in the final product.

The presence of CBD in the Novel Foods catalogue in Europe is explained differently for cannabinoids and cannabis sativa. The notice for cannabinoids reads as follows:

'Without prejudice to the information provided in the novel food catalogue for the entry relating to *Cannabis sativa* L., extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated.'

And the notice for cannabis sativa reads:

'Some products derived from the *Cannabis sativa* plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel.'

There is some ambiguity regarding the inclusion in the Novel Foods Catalogue of products which contain CBD and which have also been produced, without extraction methods, which increases the relative concentration of CBD. The most common interpretation seems to be that these products are exempt from being considered novel, in the same way that other hemp food products are. On the website of the German Federal Office of Consumer Protection and Food Safety (BVL), they refer to hemp products as follows:

'In the case of plant extracts, it is generally always necessary to check whether the extraction method used results in a targeted accumulation (or depletion) of certain substances, in particular cannabinoids.'

The statement from the German BVL suggests that all cold-pressed hemp products, which do not specifically increase the concentration of CBD, may be permissible. However, this is tempered by statements made by the BVL that, 'it is always necessary to check whether a product with the respective composition was used as a food to a significant extent in the EU before 15 May 1997'. (Printed matter 19/11922). The statement means that each product needs assessment on a case-by-case basis.

It must also be recognised that it is impossible for regulators to ascertain whether a particular product was made using cold-pressing extraction, as opposed to other methods, without formally auditing production facilities. This has led to accusations within the CBD community that some products marketed as cold-pressed have suspiciously high levels of CBD and are in fact the product of more CBD-specific extraction.

Prohibition Partners has asked the EFSA whether CBD products cold-pressed from hemp flowers can be marketed without novel foods approval, and they responded indicating that each country must decide for themselves whether such a product should be considered a novel food. A product must only be checked in one country as to whether the novel foods authorisation is necessary at the EU level, and this ruling is considered valid for all countries, notwithstanding national rules around the marketability of CBD products. Prohibition Partners reached out to several states about this. German regulators passed the issue to provincial regulators, for example, in Berlin, regulators said that nearly all CBD-containing products need to be registered as medicines or novel foods, but made an exception for, 'products made with hemp leaves or flowers (as long as abuse is avoided, e.g. in bread or salami)'. They could not clarify if this was possible for oils. Regulators in Ireland were more positive about these products.



Example of cold-pressed CBD produced in Germany by Herbliz from hemp grown in the US.

EXPERT INTERVIEWS



Dr. Patrick O'Mahony
 Chief Specialist
 Food Science & Technology,
 The Food Safety Authority of Ireland

What position does Ireland take on the novelty of CBD products?

CBD is an issue discussed in the novel foods area only since about 2016 when these unauthorised novel foods, which can be synthetic or derived from the hemp plant began to appear on the EU market. The EU understanding of these products is still evolving at Member State and EU level and their novel food status is set out in the current version of the novel food catalogue which is publicly available on the Commission website. The novel food catalogue is an informal record of discussions by the EU Novel Food Working Group of the novel food status of various foods and ingredients.

What is the novel food status of products derived from cold-pressed hemp flowers?

The novel food status of hemp and hemp-derived products is set out in the current version of the Novel Food Catalogue. A previous iteration (2009) of the Novel Food Catalogue Entry I referred to 'hemp' and parts of the hemp plant only but not CBD products as such since the latter were not even contemplated in 2009 and therefore not on the EU food market at that time:

Without prejudice to other legal requirements concerning the consumption of hemp (*Cannabis sativa*) and hemp products, Regulation (EC) No 258/97 is not applicable to most foods and food ingredients from this plant.

The Food Safety Authority of Ireland's (FSAI) interpretation of the 2009 novel food catalogue entry is that oil simply separated from the hemp plant (e.g. cold-pressing) without further refinement or processing is not a novel food. This is in reality 'hemp oil' rather than 'CBD oil' because there are approximately 120+ cannabinoids present in the hemp plant and methods such as cold-pressing are not a selective extraction procedure. The European Court of Justice concluded in the Kanavape case (Case C-663/18) that CBD derived from the entire plant (including the flowering and

fruiting tops) should not be considered a narcotic drug under the 1961 UN Single Convention on Narcotic Drugs which feeds into the definition of 'food' in EU food law.

Has the 'Kanavape' decision by the European Court of Justice been relevant for any cases which you have seen?

The European Court of Justice case related to a vaping product and does not affect the implementation of EU food law. However, it did clarify that CBD derived from the entire hemp plant is not considered a narcotic drug within the EU. We have not encountered hemp oil derived from 'hemp' flowers alone and the question that might arise there is whether such oil is considered a food or a narcotic drug since the Kanavape conclusion related to CBD from the entire plant rather than just the flower.



In the UK, there is a similar legal division between cold-pressed and other extract products. The UK FSA recently clarified their interpretation of this issue saying; 'A food product made from cold-pressing hemp flower is not novel if the business can provide proof that the production process is cold-compressed'. As such, companies marketing these products are protected by the law.

However, it is yet to be seen how many European countries will adopt this interpretation of the Novel Foods notice on CBD. Cold-pressing of hemp flowers is a much less efficient method of extracting CBD, and usually means the whole spectrum of the compounds in the flower is extracted, which is positive for some patients but has implications for the ability of manufacturers to control the product and its taste.

In Poland in April 2022, the national High Court ruled that hemp flowers in capsules for the purposes of food supplements were not to be considered Novel, as a history of hemp flower consumption has been proven. The prosecution of defendant, Kombinat Konopny, was thrown out. This may set a precedent in Europe, where the marketability of hemp flowers as a food product, regardless of their CBD content, is permitted.

CBD flowers

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

In France, following the Kanavape case, the courts maintained a ban on hemp flowers. A French interministerial decree had declared that hemp flowers 'may only be harvested, imported or used for the industrial production of hemp extracts'. However, in light of the ruling by the ECJ and a subsequent ruling in French law against the narcotic status of CBD, the French Administrative Supreme Court ruled in late January 2022 that 'it does not follow from the investigation [...] that hemp flowers and leaves with a THC content

of no more than 0.3% would be harmful to health to such an extent as to justify a general and absolute prohibition on their sale'. In December 2022 this ban was overturned by the French Council of State - a body which acts as the supreme court for administrative justice in France - rendering all products made with hemp flower and leaves under 0.3% fully legal for sale in France.

In December 2022 this ban was overturned by the French Council of State - a body which acts as the supreme court for administrative justice in France - rendering all products made with hemp flower and leaves under 0.3% fully legal for sale in France.

Similarly, in Spain, at least two court cases have referred to the Kanavape case as justifying the overturning of a prosecution against CBD stores selling hemp flowers, allowing for the flourishing of CBD shops in the country.

Conversely, in Germany the Federal Court of Justice upheld the conviction of two defendants who were originally convicted in a lower court in Berlin for selling large amounts of CBD flower in October 2022. This decision had major implications for the country's growing CBD market. However, the recent decision to legalise adult-use cannabis in Germany also means the complete legalisation of CBD products and would likely cause the expungement of such convictions in the country.

CBD flowers as a tobacco substitute

One of the most popular forms of CBD usage is in the form of flower. Flower is often used for smoking as a tobacco substitute, combined in joints for adult-use cannabis, or is used for making into tea. CBD flowers are marketed in most major cities across Europe, openly by high-street vendors and in online markets. To avoid tobacco and nicotine-related regulations, these products are often marketed as non-consumables like incense and pot pourri. However, there is an increasing trend among regulators to want to classify these officially as tobacco-related products and regulations may develop in this direction. Here we review the legality of these products across the EU.

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 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. Some products, like CBD vapes are circumventing normal regulations such as toxicology studies, while others like e-cigarettes, are subject to national, rather than EU-level, taxations.

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.

Some countries in Europe are already regulating CBD products as tobacco substitutes in their national laws, namely Belgium and Switzerland.



Example of CBD flower being sold as a 'decorative product' openly in Polish shops and websites. Similarly products are available in Belgium and Switzerland expressly for consumption by smoking.

In Belgium, on 11 April, 2019 Belgian Federal Public Service Finances introduced a law declaring 'products intended to be smoked and in which the THC content is below 0.2% are considered tobacco products and will therefore be taxed as such'. The result of the introduction of this law was the closure of many CBD-focused outlets, as margins were heavily compressed. This also came with a range of measures to control CBD flower in the same way as tobacco, including, having a fiscal stamp on packaging, multilingual health warnings and a strict ban on health claims.

In Switzerland, CBD flowers have been available in shops for several years, most often sold as tobacco substitutes. The Swiss Federal Supreme Court established in 2020 that CBD cannabis products are not tobacco substitutes within the meaning of the Tobacco Taxation Act and so are exempt from these levels of taxation. However, the regulations around CBD packaging and marketing, as they pertain to tobacco substitute products, still apply, for example, products must be registered with the Federal Office of Public Health before being marketed, their packaging must contain health warnings and have no health claims.

Prohibition Partners finds it likely that other countries will move to regulate CBD flower products as tobacco substitutes in the same way as these countries.

As with many issues surrounding cannabinoids in Europe, regulation of CBD flowers is now being dealt with at the national level by legislators and the courts. In Italy, in January 2022 the State Regions Conference accepted an inter-ministerial decree which declared that, regardless of the THC content, all cannabis plants, not intended for industrial use, are considered medicinal and should be regulated as such. The implications for CBD law at the national level have not been firmly established and some operators hope hemp plants will still escape the definition of a medicinal plant. The trial of Luca Marola, the so-called initiator of the 'cannabis light' market in Italy, began in November 2022. He is on trial for distribution of the flowers. In Germany, the Higher Administrative Court of Lower Saxony is currently examining a case involving expert cannabinoid lawyer, Kai Niermann, and his clients who distribute cannabis flowers. In Germany, material from the cannabis plant can only be marketed under certain conditions including that the product cannot be used for intoxicating purposes. In the past, in the case of flowers, the position of the Federal Institute for Drugs and Medical Devices (BfArM) is that intoxication cannot be ruled out for hemp flowers being sold for inhalation.

CBD as a cosmetic

The use of CBD in cosmetics is now fully regulated and protected by law in the European Union. The 'de facto' descheduling of CBD by the European Court of Justice (ECJ) has opened the gate for regulators of cosmetic products to recognise and control the substance. In February 2021, CBD was included in the Cosmetic Ingredients (CosIng) database. The CosIng is the European Commission database for information on cosmetic substances and ingredients. Inclusion in the database does not have legal value, but it is a clear indication that EU regulators recognise the legitimate nature of CBD products. Any cosmetic product on the market in Europe needs to be listed on the EU cosmetic products notification portal (CPNP). The lists on this portal are not open to the public, but many companies advertise CBD products as being listed on the portal, so it can be reasonably assumed that regulators have approved them. CBD cosmetic products are now available in major online marketplaces, retail outlets and speciality stores across Europe. As cosmetic products are easier to market than novel foods, which need more onerous approval, many products like CBD oils are being marketed as cosmetics while actually being sold for ingestion.

CBD as a medicine

CBD has the unusual characteristics of being both an over-the-counter (OTC) product, but also one available on prescription in Europe. Many countries have some access to CBD in pharmaceutical products e.g. Sativex and especially Epidiolex (CBD being the only active ingredient in this medicine). Thousands of patients use CBD in the form of Epidiolex in Europe, and GW Pharma saw sales of €20 million in Germany alone in the 12 months ending March 2021.

See section below on CBD sub-markets.



CBD sub-markets



Introduction

CBD is treated differently by regulators depending on the intended use of the product. This is one of the reasons why products in each category differ hugely in terms of; their availability to consumers, the way they are made and the price that they are eventually sold for. Below, we outline some of the major distinctions between the different types of CBD products in Europe.

OTC vs prescription

The most common method for obtaining CBD in Europe is via over-the-counter products, both online and in stores, as in the food, tobacco substitute and cosmetics sections above. However, CBD products are also commonly prescribed on the continent. In countries like Denmark and the Czech Republic, CBD-dominant and balanced CBD-THC products make up the majority of the medical cannabis products prescribed there. There are obvious pros and cons to this method of using CBD for health and wellness purposes. One obvious consideration for consumers is the price.

Prescription CBD

Pros ↑

- Medical supervision
- Public insurance of costs
- More quality assurance

Cons ↓

- Products can be far more expensive
- Insurance does not always cover costs
- Lower range of product choice

EXPERT INTERVIEWS



Susanne Caspar

CEO
Linnea

CBD in Medical Markets Worldwide

There are many different markets for CBD in the world, for extracts specifically Food or dietary supplements and Pharmaceuticals are two, what do you think distinguishes these two markets for consumers and where is Linnea's focus?

Food and dietary supplements markets have products where it is not mandatory for them to be standardized and approved for medical use. They are for daily supplemental use and not meant for treating or curing any specific conditions. The food category of CBD products also offers product formats like smokable flowers that cannot be precisely dosed and are not a type of product health-conscious patients or elderly patients typically want to choose. Medical patients need standardized CBD extracts with active pharmaceutical ingredients and accurate dosing in a product format that is healthy and offers consistent amounts of active ingredient so they have reliable medicine to help treat their conditions. CBD medical products are also quality controlled with validation of methods used ensuring reliability, robustness of process and reproducibility, therefore offering patients the same standard as other pharmaceutical drugs. Many countries do not have clear uniform regulations for CBD in food and dietary supplements or their regulations are complex and do not so far allow for a clear path for approval and market authorization. This leaves unregulated products being sold in gray markets where the products offered do not conform to any consistent or set standards and there is no check on claims, quality, and actual amounts of CBD present. There are however clear regulations in place in many countries for CBD in pharmaceuticals allowing for patients to have access to medical CBD products that offer reliability, quality, standard dosing, and consistency.

Where in the world are your CBD API extracts being used and where do you anticipate expansion this year?

Our API extracts are being used in products all over the globe. In Latin America, our CBD API is in products in Brazil and Argentina with indications for children's epilepsy. Our Latin American part-

ners also have official registration for their CBD products in their countries of business, and these registrations are linked specifically with our CBD ingredients.

Another big market for Linnea is Australia where our CBD APIs are part of popular CBD medical products and some of these products are being used in clinical trials on CBD. We see CBD laws changing in Asia and expect bigger markets to develop there, especially in Thailand where we are creating new business partnerships. We also hope to expand our extracts in the UK and EU through Novel food applications we have in these regions. Novel food regulations in the UK and EU are in process and hopefully there will be advancements in these applications this year. We currently have pending Novel Food applications in both the EU and UK for our CBD Extract and Isolate and we expect in 2023 for the UK to start approving applications such as ours that are in the final examination phase.

Are your CBD API's part of any clinical or preclinical studies you can share?

Yes, in recent years our CBD has been involved in a number of trials, Linnea and our partners are leading several investigations to delineate both the biochemical and efficacy profile of CBD. Our CBD extract was involved in a clinical phase one study with the University of Sydney to look at safety, tolerability and pharmacokinetics. The results showed high tolerability and good safety data. Our CBD was also involved in two in vitro studies, one at the University of Milan that looked at activity in a model of skin inflammation and found a decrease in inflammatory markers overall, and the second at Insubria University which looked at activity in an immune system model and found also a decrease in chronic inflammation markers. Then our CBD isolate was part of an In-vivo controlled study with Mondino Foundation that looked at activity in a murine model of Parkinson's disease and found a reduction of neuron loss and tremors. We think an API company investing in trials is of the utmost importance to show reliable data for efficacy and usage for specific conditions so patients and doctors have CBD medicine products they can rely on and trust.



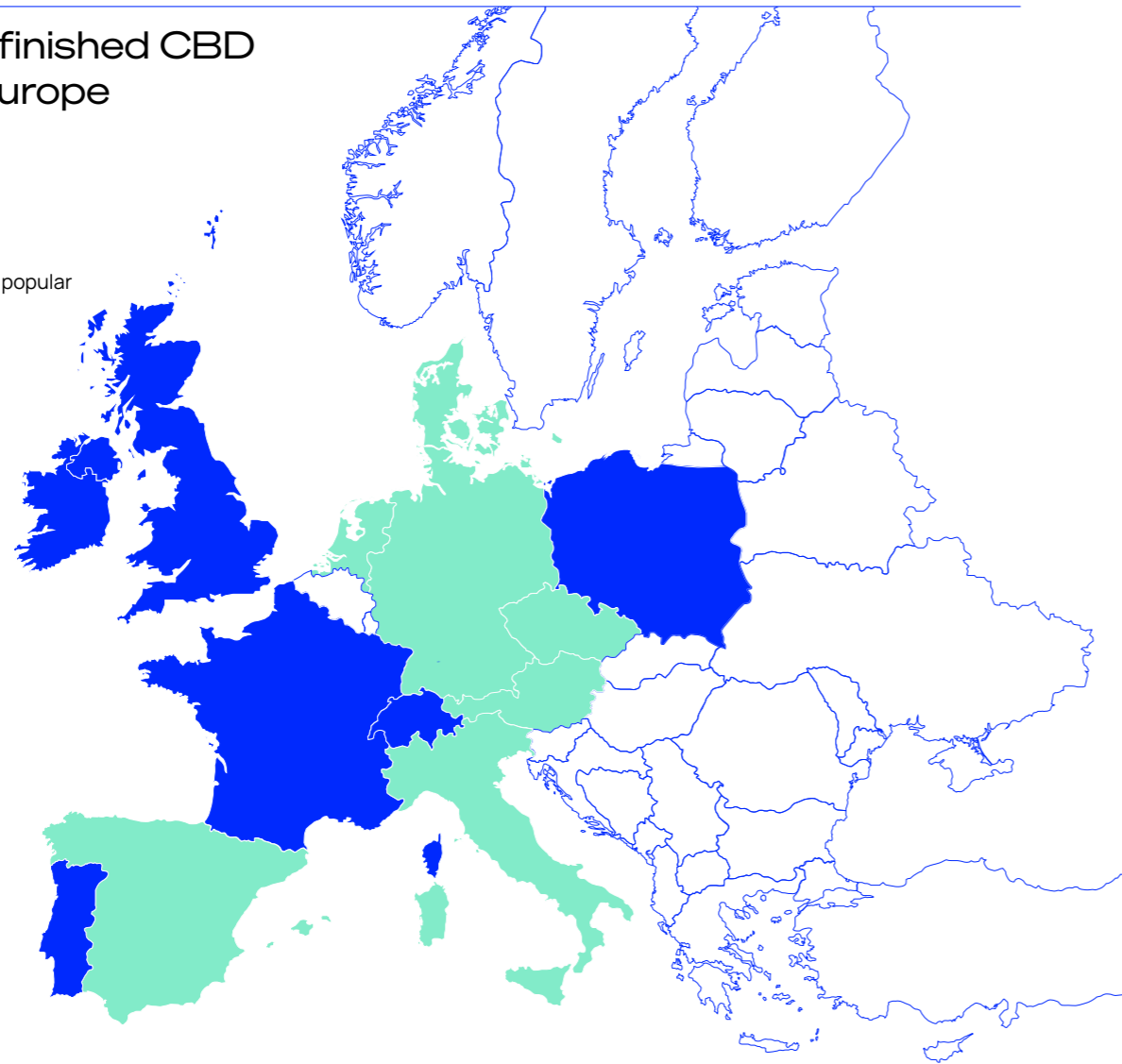
Magistral vs finished products

Within extracts of medical CBD in Europe, there are two major ways in which the product can be delivered to the patients: as a magistral product or as a finished product. In many countries, pharmacists are legally obliged to prepare extracts for patients before dispensing, such as in Italy and as of late 2022, in Spain. In others, like Germany, patients can obtain a pre-made or pharmacy-made extract. From start to finish: the magistral preparation process involves a doctor prescribing a magistral product with specified cannabinoid concentrations, usually from a list of products on a national formulary. The pharmacy then uses any flower or oil product available to make the preparation or extraction to

the specifications of the doctor. In the case of oils: companies sometimes provide extraction kits for pharmacists but in most cases, the pharmacist must run the extraction with their own equipment. This has proven a popular way for doctors, pharmacists and patients to tailor their treatment courses, though it is a time-intensive method of preparation. For all extracts (including high-THC extracts) magistral extracts account for 23% of total medical cannabis sales in Germany, and pre-made extracts account for 11% as of Q1 2022. Prescription CBD products are very popular in Denmark and Czechia, and these are entirely supplied by magistral preparations.

Magistral vs finished CBD extracts in Europe

- Finished extracts only
- Magistral extracts more popular than finished products

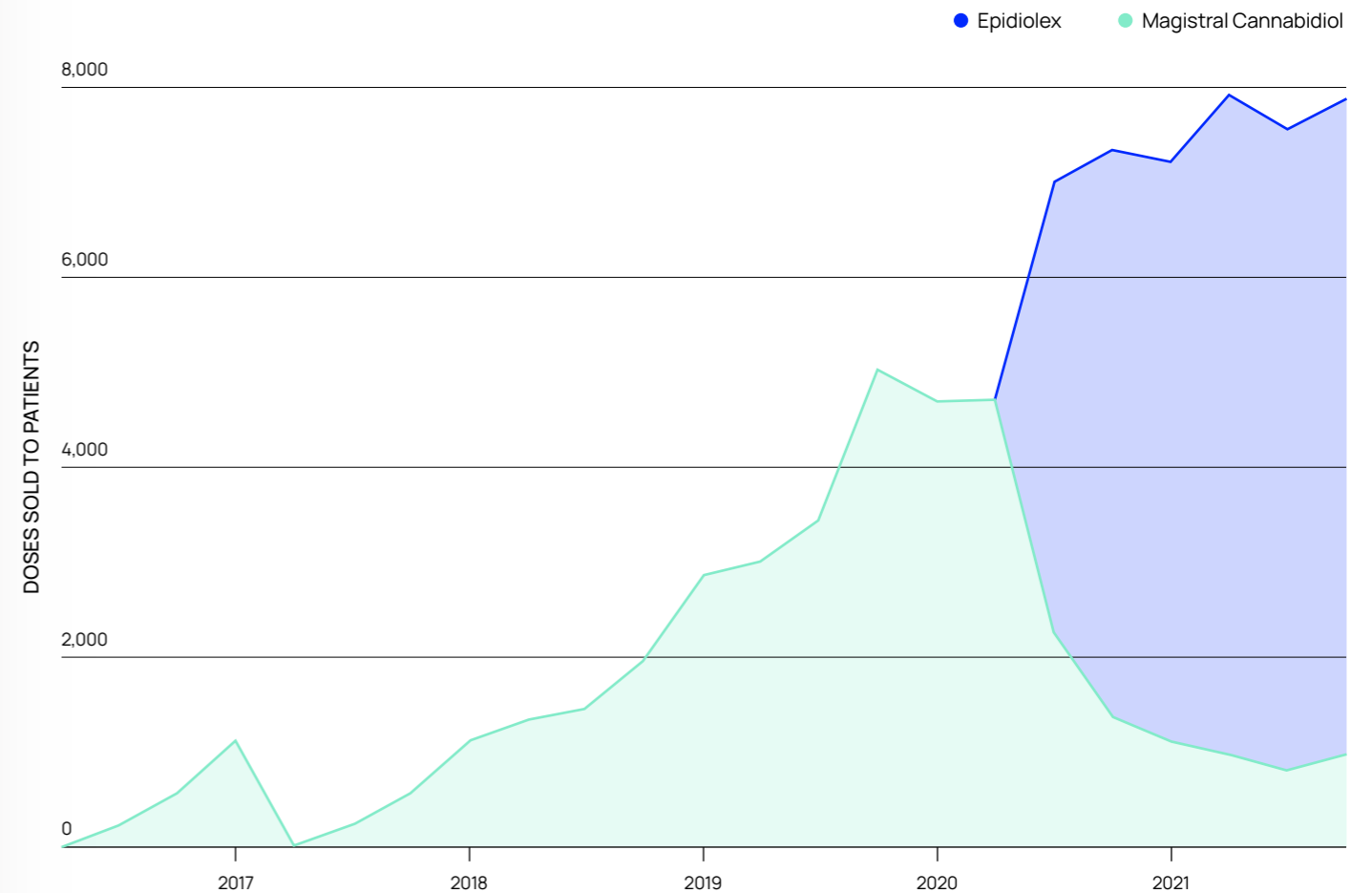


Source: Prohibition Partners, August 2022

Unlicensed prescription vs Licensed prescription

Medical CBD can come in unlicensed and licensed forms. Licensed medicines here refer to products which have passed clinical trials and are prescribed, as any other medicine, whereas unlicensed products are prescribed on the basis of an exceptional access scheme, as in most of Europe and North America. Epidiolex is the main form of licensed CBD medicine in the world, developed by GW Pharmaceuticals (now part of Jazz Pharmaceuticals) in the UK and used against certain rare forms of epilepsy. These products need to undergo authorisation at the EU level under central marketing authorisation with the European Medicines Agency or at the national level.

Impact of Epidiolex on prescription magistral cannabidiol



Source: Danish Medicines Agency, Prohibition Partners

Epidiolex costs in the range of €170.9 per gram of pure CBD as per the current price to patients in Denmark. There are a wide range of prices for prescription CBD flower in Europe, but an average calculated by Prohibition Partners shows a gram equivalent of pure CBD costs €97.13. Over-the-counter products in Denmark can be found for €50 per gram of CBD, often with further discounts of 50% and upwards due to price compression. However, products become more or less expensive to patients based on pricing reimbursements. In Germany, Italy, the UK and Spain, public insurance offers a full reimbursement for patients for Epidiolex prescriptions. Reimbursement for unlicensed prescription CBD medicines are more variable, for example, in Germany, around half of all patients are reimbursed whereas in the UK, none are.

Different countries in Europe treat prescription CBD in different ways. Many countries have some access to CBD in pharmaceutical products e.g. Sativex and especially Epidiolex (CBD being the only active ingredient in this medicine). Thousands of patients use CBD in the form of Epidiolex in Europe, and GW Pharma saw sales of €20 million in Germany alone in the 12 months ending March 2021. In addition to pharmaceutical CBD, unlicensed prescription CBD products are available in many European countries. For example, in Germany, at least nine CBD-dominant flowers are available on the market and several extract oils. Even in restric-

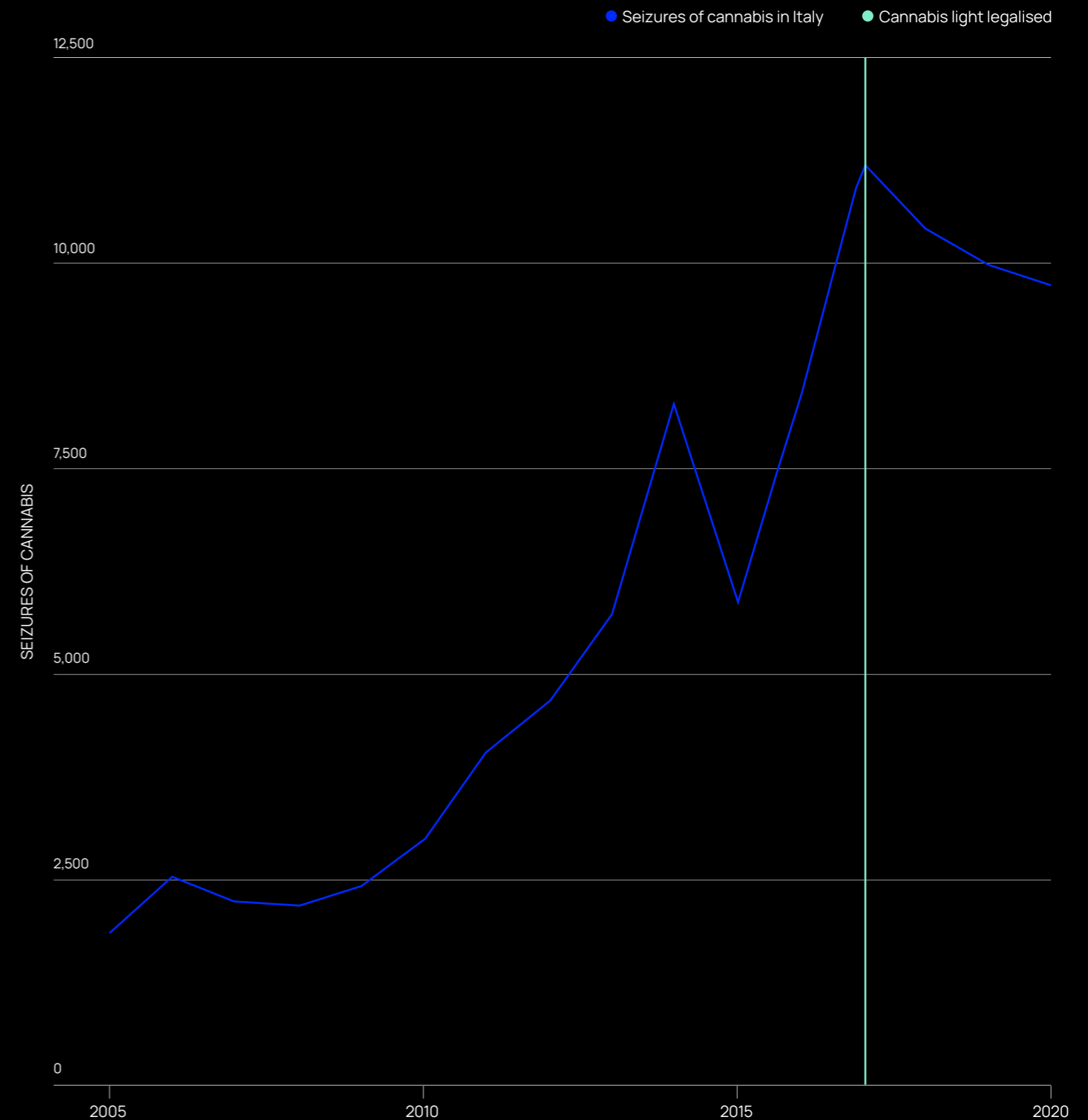
tive countries such as Ireland, Bedrocan flowers with a low-THC and a high-CBD content are available, on prescription, via special access pathways.

OTC CBD vs adult-use cannabis

In Europe, cannabis and CBD are treated as very distinct products by regulators. However, there is considerable crossover in their usage. This is counter-intuitive to many in the cannabis or CBD industry, where there are assumptions like: most people use cannabis because of its psychoactive, THC based effects and that CBD products are not used for this purpose nor can they be. However, previous surveys by Prohibition Partners have shown a large overlap between CBD and cannabis users. The clearest data on the competition between over-the-counter CBD products and cannabis comes from the legalisation of CBD flower (THC <0.6%) in Italy at the end of 2016. By the beginning of 2017, 'cannabis light' shops were in most regions of the country, and this caused a drastic reduction in the amount of recreational cannabis on the streets. Similar reductions in the amounts of prescription drugs have been observed.



Impact of CBD sales on the black market in Italy



Source: Prohibition Partners, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

Prohibition Partners expects that for anywhere that CBD flower is legalised, many consumers will shift from using unregulated high-THC products over to regulated CBD products. However, once this is followed by the commercialisation of adult-use cannabis, it is likely that many 'cannabis light' users will then switch over to buying adult-use cannabis. We predict a market for CBD flower will certainly endure for those consumers who; prefer the effects of CBD, who do not enjoy the high of THC heavy adult-use cannabis; or for those who wish to include CBD flower in their high-THC products to balance their THC intake or to replace tobacco in their joints.

Minor Cannabinoids

Aside from the well known cannabinoids of THC and CBD, there are a range of over 100 cannabinoid compounds which are variously referred to as 'minor cannabinoids', with biological activity, which have been established, but poorly investigated by researchers. For the most part, these cannabinoids remain unregulated at the EU level. One sign that minor cannabinoids could become a focus of European regulation came in the fallout of the ECJ and Kanavape case where CBD was definitively classed as a non-narcotic substance. A document published by the European Commission in June 2021 titled 'Overview of the EU acquis applicable to cannabis in its different forms and components', stated that; 'The Commission services are assessing the implications of this judgment for other non-psychoactive cannabinoids'. Psychoactive is not a well defined term scientifically speaking, but another document dating back as far as 2002 from the EMCDDA titled 'Medicinal cannabis

and derivatives' includes CBD, cannabinol (CBN), cannabichromene (CBC), and cannabigerol (CBG), amongst these.

Minor cannabinoids are not a strictly defined category. In common usage, minor cannabinoids refer to any cannabinoid or cannabinoid acid apart from THC and CBD. Minor cannabinoids such as cannabigerol (CBG) normally exist in the cannabis plant in trace amounts but can be present in much higher concentrations depending on the strain of the plant. In general, it is expected that non-psychoactive minor cannabinoids will be treated by European regulators in a similar way to CBD. The entry in the novel foods catalogue of the EU mentions minor cannabinoids by name including: 'delta-9-tetrahydrocannabinol, its precursor in hemp, delta-9-tetrahydrocannabinolic acid A, delta-9-tetrahydrocannabinolic acid B, delta-8-tetrahydrocannabinol, cannabidiol, its precursor in hemp cannabidiolic acid, cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin'.

Therefore, any product containing the above cannabinoids would need approval as a Novel Food before being marketed as a food or supplement in the EU. These laws have been enforced at the EU level in the past. For example, in July 2021, a CBG supplement originating in Austria was removed from the market in Germany, Spain and Switzerland and notified to the European Commission.

Below, is a table of the three most common minor cannabinoids and their potential medical and wellness uses. It should be noted that no firm evidence from clinical trials proving the efficacy of these substances, beyond doubt, has been produced.

Potential uses for minor cannabinoids

	Psychoactivity	Potential bioactivity	Potential treatable conditions
CBN	Mild	anti bacterial, anti-inflammatory, pain relief, skin repair, anti-insomnia, anti-convulsive	arthritis, seizures, skin conditions, Crohn's disease, pain conditions
CBG	Negligible	anti-acne, anti-inflammatory, neuroprotective	cancer, Crohn's disease, irritable bowel syndrome, multiple sclerosis, Parkinson's disease, glioblastoma
CBC	Negligible	slow down of the proliferation of cancer cells, anti-acne, anti-inflammatory, neuroprotective, pain relief	depression, acne, neurological disease, pain conditions

Sources: See Appendix for research articles.

Beyond these three, there are several other minor cannabinoids which are gaining niche usage in Europe. One which may cause legal issues in the near future is the naturally occurring delta-8-THC, a nearly identical compound to the more well known delta-9-THC (referred to here as THC). Delta-8-THC is psychoactive to a similar extent to that of THC but was made legal in the US accidentally under the 2018 Farm Bill. Delta-8-THC products are available online and in stores across Europe, but regulators are yet to catch up with this particular trend.

For a more thorough treatment of minor cannabinoids, see Prohibition Partners' Pharmaceutical Cannabis Report 2nd Edition.

Aside from potential medical uses, there is an established market for some minor cannabinoid products, especially CBG and CBN. In particular, CBG is becoming a more normalised product on the European market. In May 2021, CBG was added to the European list of Cosmetic Ingredients (CosIng), which represents, at least, a formal acknowledgement of the use of CBG in products on the market, albeit not a legal acceptance. Several products are already registered on the EU Cosmetic Products Notification Portal and are widely available. For example, the CBG oil pictured here is offered by Royal Queen Seeds and is claimed to be Cosmetic Products Notification Portal (CPNP) listed.

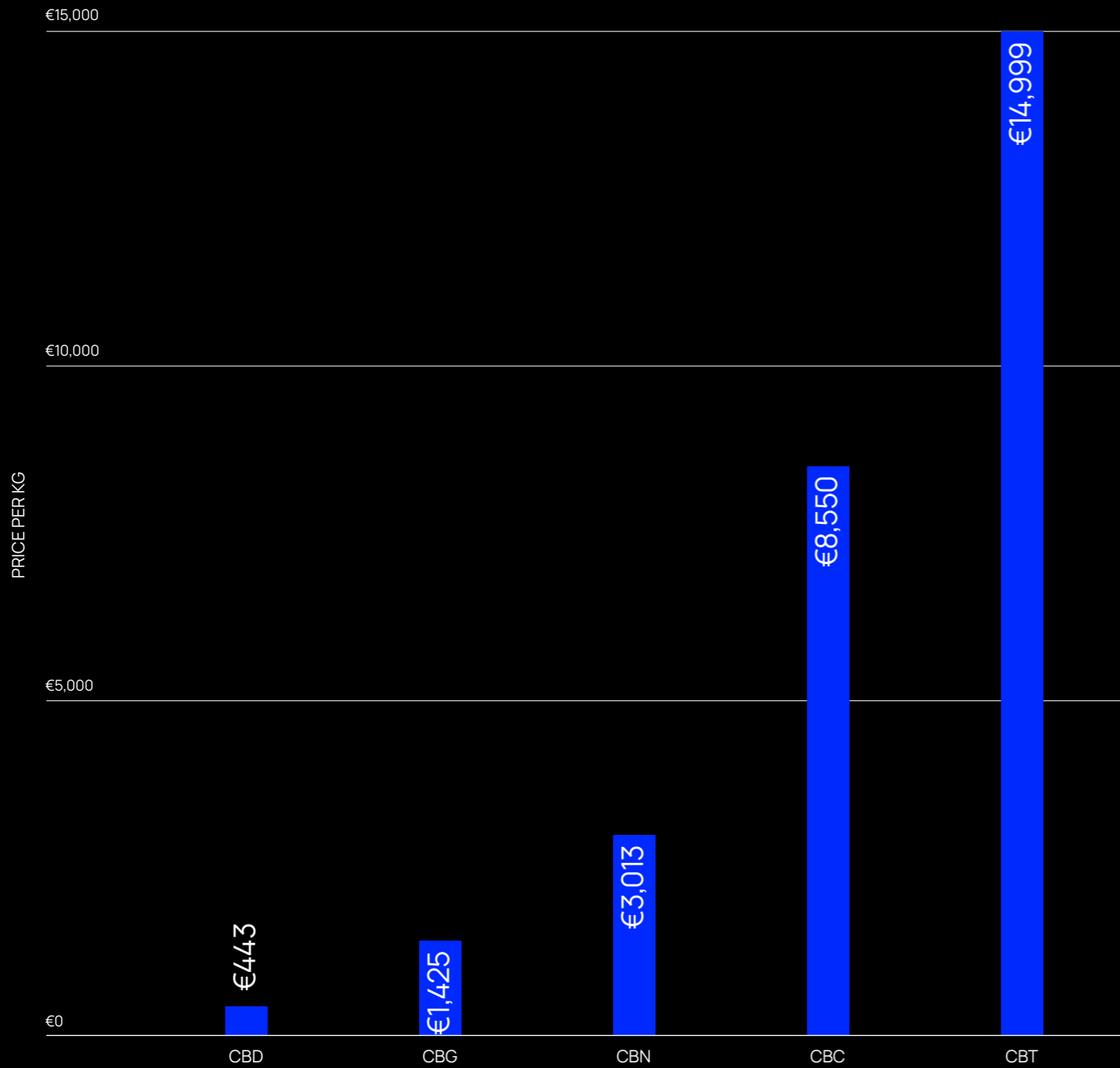
CBG specific strains of hemp are now available in Europe as well. In May 2022, the first high CBG strain of hemp, Enectarol was registered in the EU Plant Variety Database, allowing farmers to cultivate the strain which offers an unusually high yield of CBG, as compared to normal hemp strains.

The wholesale price of minor cannabinoids has generally come down over recent years due to an influx of growers and imports from the US and other regions. However, the price remains considerably higher than that of CBD. Part of the reason for this is the lower number of producers. There is also the fact that minor cannabinoids are less concentrated in most hemp varieties than CBD, thus making extraction of an equivalent quantity more cost-intensive. The variety of minor cannabinoid products available with pricing on wholesale exchanges was considerably lower than that of CBD, but Prohibition Partners has obtained the following data which is, at least, indicative of prices of isolate on the continent.



Example of a minor cannabinoid product marketed in Europe, CBG Oil by Royal Queen Seeds

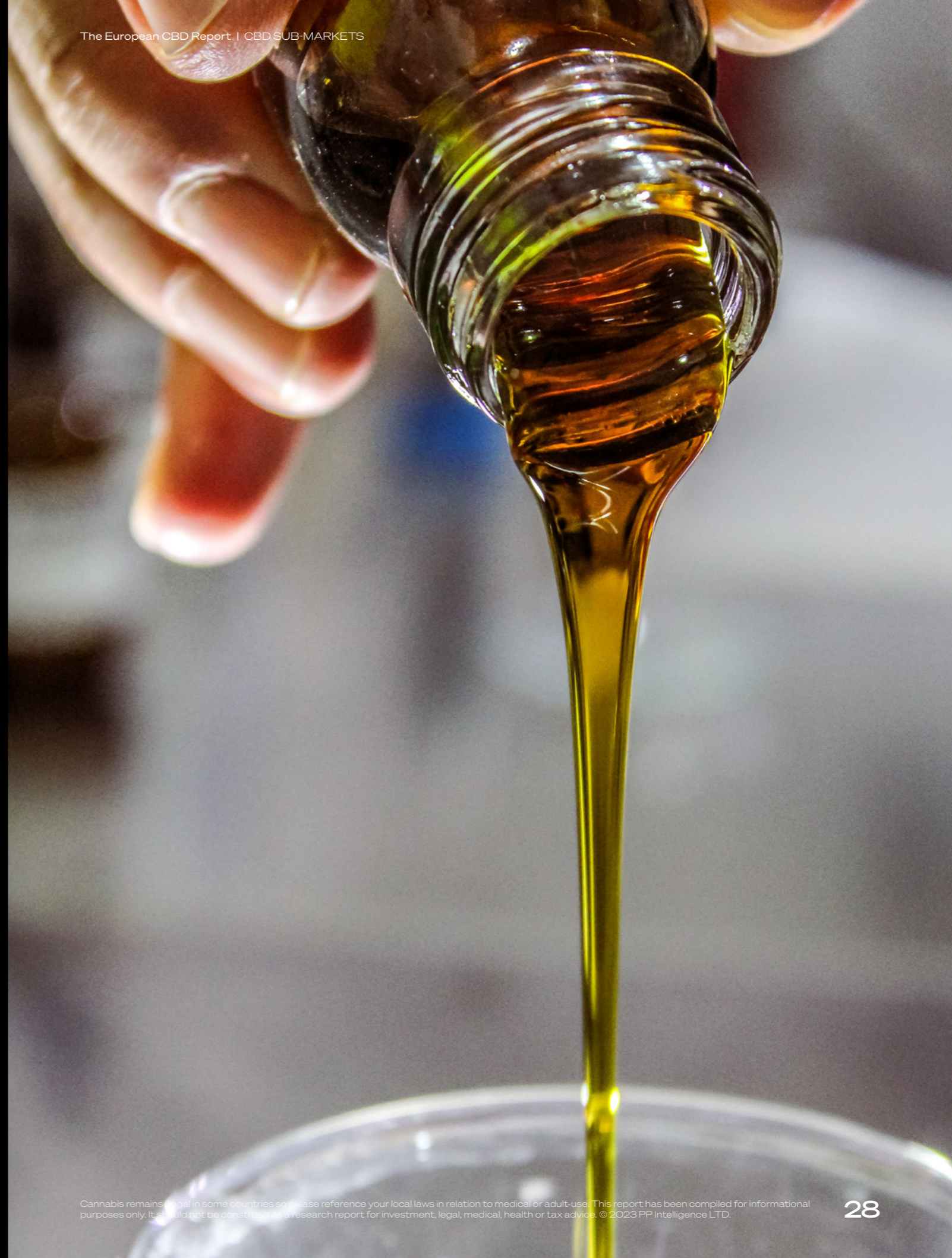
Average wholesale price of minor cannabinoid isolates in Europe



Source: Various wholesalers, Prohibition Partners

As can be seen from the chart, the isolates of various cannabinoids vary widely in price. A kilogram of CBC can be more than 20x times the price of CBD. Only one supplier displaying the price of a rarer minor cannabinoid, cannabicitran, was found and shows how high the price can be to extract cannabinoids with a lower density in plant

material. Similar factors affect price amongst minor cannabinoid suppliers, such as the presence or lack of a GMP certification. European Union - Good Manufacturing Practice (EU-GMP) CBG, intended for use in medical products, costs as much as €8,800 as compared to the average €1,425 for CBG intended for OTC and wellness products.



Compliance



Compliance for CBD in Europe can be a maze of international, EU, national and sub-national legislation as well as a heterogeneous mix of enforcement policies. For example, in Germany, the authority for the recognition of a CBD product as Novel or not, relies, not with the EU nor German regulators, but at the level of individual provinces. At the EU level, the most common category of CBD products are virtually all being sold under legally dubious conditions, as the vast majority of operators who have been doing business for years, ignore the Novel Foods status of CBD in favour of continuing their previous business practice while the assessments are carried out.

As the regulations around CBD vary with their intended use, many operators circumvent laws simply by marketing products for uses other than the ones for which they are obviously bought, for example, CBD-rich hemp flower being sold as incense. As seen with the case of novel drugs being sold as bath salts or novel cannabinoids being sold as incense in health shops across Europe in the 2010s, this legal situation is inherently unstable and will need to be resolved before too long.

Some violations of compliance are more egregious than others. For example, Prohibition Partners has learned, through speaking with industry groups, that it is likely that a lot of hemp in Europe is being grown with seeds which are not on the registered catalogue of hemp varieties in order to cultivate hemp with a higher CBD yield. Similarly, companies in Switzerland are now reported to be artificially lowering the THC concentration of hemp flowers through 'washing' with pentane before spraying them with mixtures of terpenes and cannabinoids. Both of these issues could be tackled with a mix of increased inspections and potentially, the establishment of higher EU-wide limits on the THC allowable in hemp and CBD products.

In the gaps between regulations, many operators are now adopting their own standard practices to ensure that when regulation and enforcement do catch up with the industry, they are left on the right side of the law. Below, we outline some of the most important

practices to help operators understand what the legal and suggested industry practices currently are.

THC levels

Regulations on CBD are not unified across Europe, and many regulators are struggling to keep up with market practices, which develop in the absence of specific legislation. One aspect of this uncertainty manifests itself in the limits placed on THC concentrations in CBD products. Many countries operate with a limit of 0.2% or 0.3% THC for CBD products on the market. This, in turn, stems from the legislation surrounding allocation of the Common Agricultural Payments which, until the end of 2022, will only be given to hemp farmers if their plant leaves and flowers contain less than 0.2% THC w/w and their seeds are from the approved catalogue of seeds in the EU.

The THC limits on hemp under the Common Agricultural Policy (CAP) were designed, not with CBD in mind, but for the industrial hemp being grown in fields and used for seeds and fibre. Taking the same plant, processing it into a concentrated extract and selling that extract in food and cosmetic products was not considered when these regulations were drawn up, and they are not always sufficiently detailed for the limits they impose to be suitable for this separate line of industry. The regulations regarding hemp and hemp products are often thought to apply to CBD products only because they are the closest thing countries have to CBD-specific laws.

Across the region, authorities have not dealt with the fact that, at some stage in the production process for extract-based CBD products, the content of THC in intermediate products being handled by the producer will exceed any national limits of what is permitted without a licence. This is simply due to the nature of producing concentrated extract. Due to decentralised supply chains these concentrated products are often, not only handled by companies without the legally required licensing, but also traded between these companies, even across borders.

As of March 2022, the EU has implemented a law regarding the permissible THC concentrations permitted in hemp seed products, at THC levels of 3.0 milligram/kilogram for dry products such as flour, proteins, seeds, snacks and 7.5 milligram/kilogram for hemp seed oil. This clarification goes some way to unifying laws on hemp around Europe, but the CBD industry in general is yet to benefit from this.

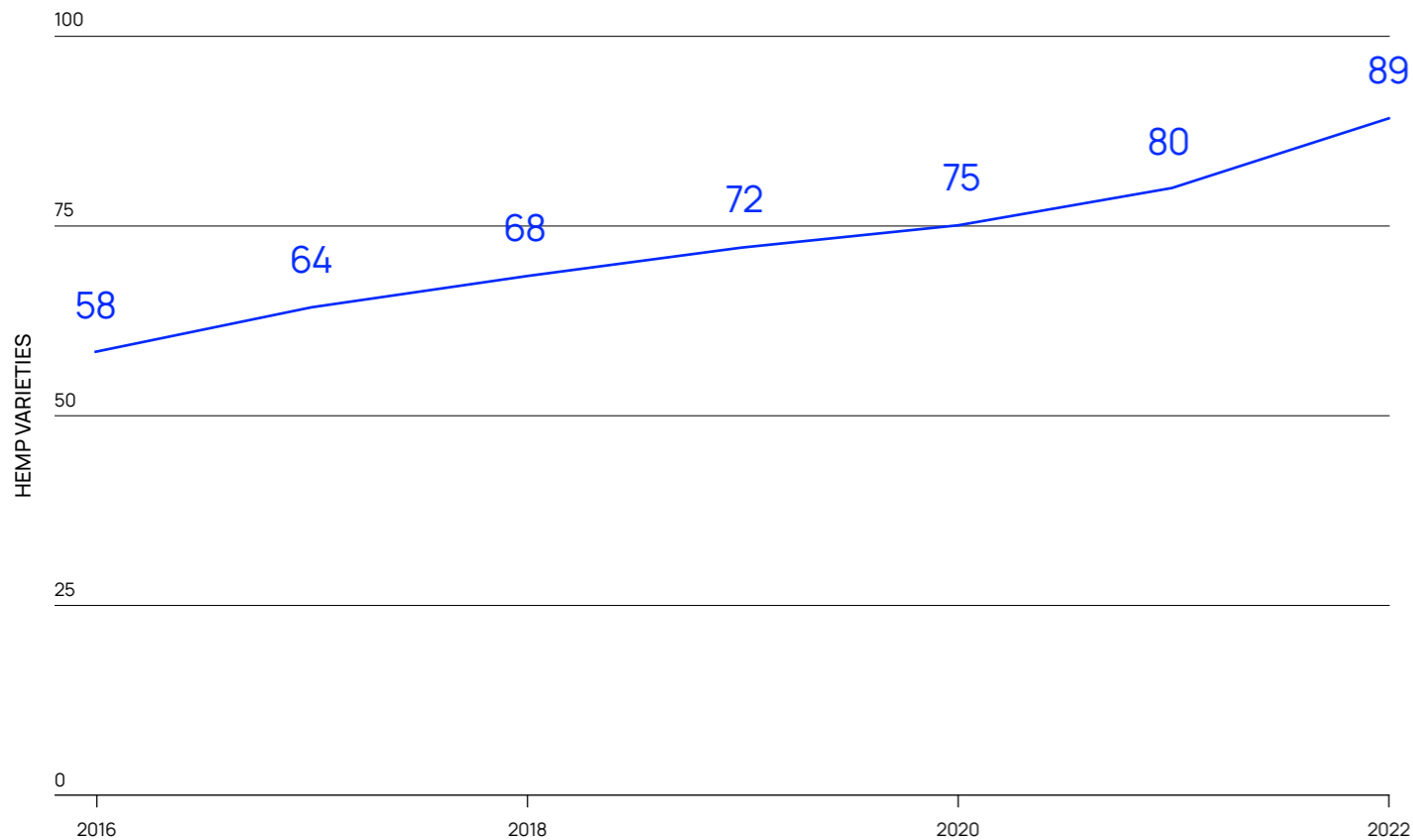
Seeds, genetics

Hemp cultivation has seen a renaissance in Europe since the introduction of specific rules on cultivation were introduced in 2013. EU regulation 1307/2013 allows for grants to hemp farmers only on the basis of the cultivation of cannabis sativa L. plants for industrial purposes with a level of THC which does not exceed 0.2% of the dry weight of the flowering material and leaves. The EU also maintains control over the varieties of cannabis seeds which can be used by limiting CAP payments to farmers who are using approved varieties. These approved varieties are screened for THC concen-

trations and the stability and reproducibility of these levels across seasons. Many varieties are specifically cultivated for traits other than CBD production, such as seed and fibre production.

In February 2022, the EIHA announced an upcoming regulatory change in Europe that would allow the marketing of hemp seed varieties that exceed the allowable THC levels for two consecutive years. However, countries will be obliged to report this to the EU, and CAP payments will be cut off for the producers in countries where over-the-limit THC is reported. The EIHA has stated that this may open the door to the registration of varieties of hemp known to produce above 0.3% THC.

Approved varieties of hemp in the EU



Source: EU plant variety catalogue, Prohibition Partners, August 2022

Europe is only now witnessing a sharp increase in new entries of hemp varieties as the registration on the EU database is a very rigorous and long process. Firstly, strains need to be trialled outdoors, tested for THC levels and stabilised which can take one to two years. Following testing, companies need to apply the strain for registration in an EU country, such as in the Netherlands for Enecta. This national registration can take up to two to three years. Once the variety is registered nationally, the European Commission is notified and the variety can be included in the EU catalogue and marketed in Europe. This whole process can take up to five years, thus we are only witnessing the introduction of new varieties with high CBD and other cannabinoids now, following the rise of CBD popularity in the mid-to-late 2010s. As of December 2022, 15 new entries have been added during the year, which is around twice as many as the 12 months previously. While CBD is of most interest, there have been recent additions which are bred for the production of other minor cannabinoids such as a strain for CBG 'Enectarol' which was added in April 2022.

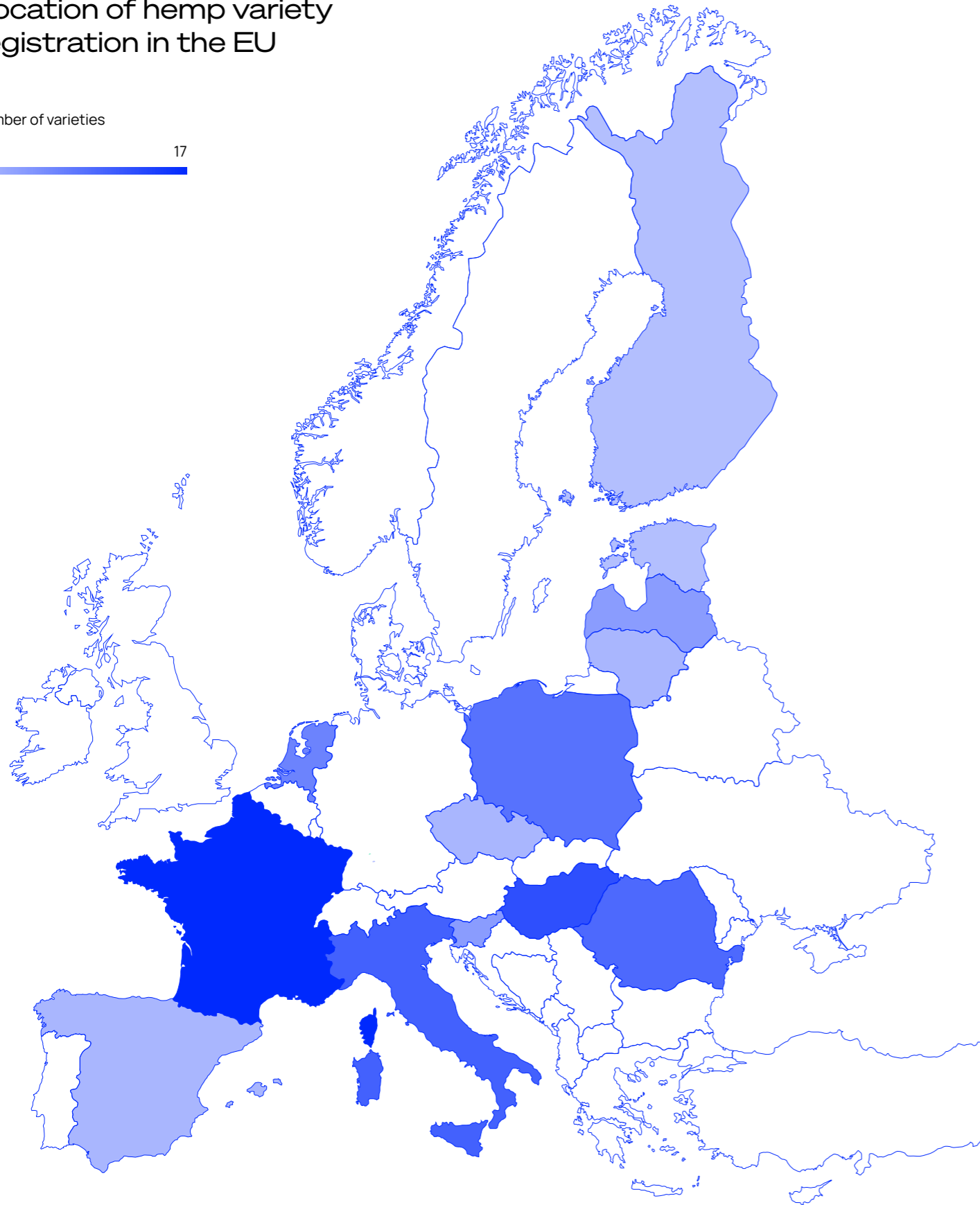
To be listed, varieties must meet specific standards on:

-  **Distinctness**
-  **Uniformity**
-  **Stability**
-  **Value for cultivation and use**
- This value is based on:
-  **Yield**
-  **Resistance to harmful organisms**
-  **Response to the environment**
-  **Quality characteristics**

Location of hemp variety registration in the EU

Number of varieties

1 17



Source: Plant variety database, Prohibition Partners, August 2022

Cultivation of hemp is spread across the entire EU, but there is a concentration of registered varieties in countries like France (17), Hungary (14), Italy (12), Romania (11) and Poland (10). These countries are also generally known to be hotspots for cultivation in terms of acreage and product output.

Prohibition Partners has learned through interviews with industry operators that it is highly likely that international companies (predominantly in the US), are extracting CBD from non-EU approved hemp strains, which have a higher cannabinoid content, under the guise that it was sourced from approved EU varieties. Thus, these companies can yield and supply far more CBD at a far cheaper rate, compared to their European counterparts. This has put strain on the supply chain for European players, as extractors and manufacturers cannot compete against the prices caused by international dumping practices. Due to the lack of traceability and governance, it is close to impossible for authorities in Europe to determine whether the CBD product/ingredient produced internationally and sold in the EU, actually stems from EU approved strains, thereby allowing these practices to continue to flourish.

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Testing & Analysis

Regulations

The analysis of cannabinoids in Europe is based on the methods and regulations given by EU reference regulations (EU Delegated Regulation 2017/1155 of the commission), various national regulations and specifications (such as Law 242/2016 in the particular Italian case) and specialised governmental and non-governmental methodological texts such as the recommended methods for the identification and analysis of cannabis and cannabis products, by United Nations Office on Drugs and Crime; AOAC International (Association of Official Analytical Chemists); ASTM (American Society for Testing and Materials). This is with regard to the concentration of cannabinoids and specifically tetrahydrocannabinol, which is the key metric for considering a product psychotropic or not.

More complex is the issue related to microbiological, multiresidual or heavy metal analysis, for which operators still refer to; the specifications for cultivation for medical purposes (medical cannabis), the limits that have emerged from the U.S./Canadian market and the European Pharmacopoeia, specifically Ph.Eur. 2.2.29 (cannabinoid analysis) 2.4.24 (residual solvents) 2.6.12, 2.6.13 (microbiology). Also for microbial/fungal derivation we have measures of particular mycotoxins which are a required parameter for cannabis food products which are also recently required by the UK FSA for Novel Food products. Such substances, if taken orally, can lead to poisoning, much as they cause lung cancer if smoked.

For cannabis foods, the THC limit is between 3 and 7.5 milligram/kilogram. This means that these measurements are in the range of about parts per million, and so this is necessarily tested with mass spectrometers coupled with gas chromatography or liquid chromatography. These instruments, which are particularly expensive and complex, require a long time to perform analysis and higher costs, therefore increasing the economic challenges to food operators.

With regard to hemp and its derivatives, the methodology of analysis specified in European law is gas chromatography. Unlike mass spectrometry where separate fragments are compared in a database, it is calibrated with quantitative solutions of certified standards that allow fast and accurate analysis at a considerably reduced cost.

Gas chromatography has pros and cons. On the one hand, it is the selected method because, by heating the sample under analysis, it converts all THCA to THC and always returns the total THC value contained in the sample, without the need for mathematical derivations. On the other hand, when it is necessary, for research and development purposes for example, to evaluate the concentration of other cannabinoids or simply their acid forms (CBDA, THCA, etc.), it may be much more convenient to rely on High Performance Liquid Chromatography (HPLC) analysis.

Choosing a test

In this maze of indications, regulations and intended uses, one of the most common problems is precisely that of selecting the correct self-testing analysis service by operators. In fact, the risk is that of performing analyses, which are far too precise and expensive (since they are performed by mass spectrometry); or that of having HPLC analyses performed, with the purpose of validating the THC content of an entire batch, when in case of controls, the authority will instead make use of Gas Chromatography - Flame Ionisation Detection (GC-FID). For these and other reasons, it is important to rely on a trusted laboratory that routinely handles cannabis and can best advise on what to do.

Certification

Another important point to consider is comparability between results of laboratories. To ensure that the results of analyses performed in different laboratories in different countries are still comparable, tests undergo accreditation.

Laboratories holding operational quality certifications (e.g., ISO 17025), must calibrate the analytical instruments with CRM (Certified Reference Material) standards, calibrate the scales and dispensing tools at ISO17025 accredited bodies and participate in Proficiency tests. These procedures are implemented to ensure the metrological traceability of the instruments and therefore make the results comparable.

National accreditation bodies (such as Accredia in Italy or UKAS in UK or ANAS in the USA) are part of an international network through mutual recognition agreements and worldwide associations, such as ILAC - International Laboratory Accreditation Cooperation which establish standards for testing and calibration of tests internationally.

Recognition by global and European accreditation networks ensures that the laboratory's operations conform to international standards and that its procedures are uniform with those applied by other laboratories. This assurance of uniformity forms the basis of analytical comparability and should allow for results with minimal variation (e.g. for cannabinoids potency up to 10%: tolerance limit) on identical samples.

In essence, the quality control landscape, like the cannabis market itself, is undergoing adjustment, and international standardization. Standards of testing are currently often applied as guidelines at national levels, rather than as legal necessity. While the process of standardization of testing methodologies is carried out specifically for hemp and cannabinoid-related products, the best course for industry operators is to use labs which adhere strictly to established international best practice.

Certification of products

The majority of CBD products being sold to customers in Europe are currently circumventing the sparse regulations relevant to CBD products. This situation is temporary, while regulations and law enforcement gradually adapt to this relatively new class of product. Below, Prohibition Partners provides an overview of certifications required for various CBD products in Europe depending on their intended purpose.

Certifications and notifications for CBD products in the EU

Consumer products

	Key certification
Foods/Supplements	→ Novel Foods Catalogue
Cosmetics	→ Notification on the cosmetic products notification portal
Smokeable flower, vapes etc.	→ Not allowed (in future Notification on EU Common Entry Gate)

Medical products

	Key certification
Licensed	→ EU Medicinal Product Marketing Authorisation, EU-GMPi/ii
Unlicensed Finished products	→ EU-GMPi
API	→ EU-GMPii

Source: Prohibition Partners



The certifications and notifications listed above are the main ones which companies must deal with at the EU level before placing products on the market. It should be noted that for smokeable products, CBD flower has not been approved, and virtually all marketing of CBD flower is done under false pretences e.g. as potpourri or incense, though future updates to policy will probably place CBD with other tobacco and related products. In addition, national laws apply to most products.

Generally speaking, in the case of consumer products, notification or certification at the EU level allows for marketing at the national level. This applies also to licensed medicines like Epidiolex. This does not apply however, to unlicensed CBD medicines, for which national authorities are the only source of approval, often on a compassionate use basis, or a cannabis-specific pathway. While GMP is listed as a certification above, the real certification is based on the infrastructure used to produce the product rather than on the product itself.

In many cases, the industry operates without adequate oversight from regulators, meaning there are no specific requirements for instance, for monitoring of accuracy of CBD content or other cannabinoids and terpene levels, nor are there specific laws for product packaging and labelling. Many companies take it upon themselves to self-regulate, and provide certificates of analysis, of good agricultural and collection practice (GACP) and GMP compliance, of ISO standards and display this on business-to-business (B2B) and business-to-consumer (B2C) websites. It is expected that, in the near future, regulators will catch up and formulate specific standards for these purposes and that these laws will replace the self-regulation occurring at the moment.

'Grey' market vs legal market

Under EU law, no products containing CBD are legal to market in Europe as a food or smokeable product. The story is a little different in the UK, where the FSA has allowed products to remain on shelves while Novel Foods assessments are being carried out. However, CBD products are nearly ubiquitous on the continent and are available via specialist stores, in high-street retailers and online. In an interview for this report, Lorenza Romanese, Managing Director of the European Industrial Hemp Association said, 'CBD products have been traded for 15-20 years in Europe, they are an integral part of many people's lives and that is why operators, including EIHA members continue to trade their products while Novel Foods assessments occur'. Ms. Romanese also points to the difficulties of removing products from the market considering there is such a large online presence.

Prohibition Partners surveyed every country in Europe to determine whether CBD-specific shops were operating in Europe and

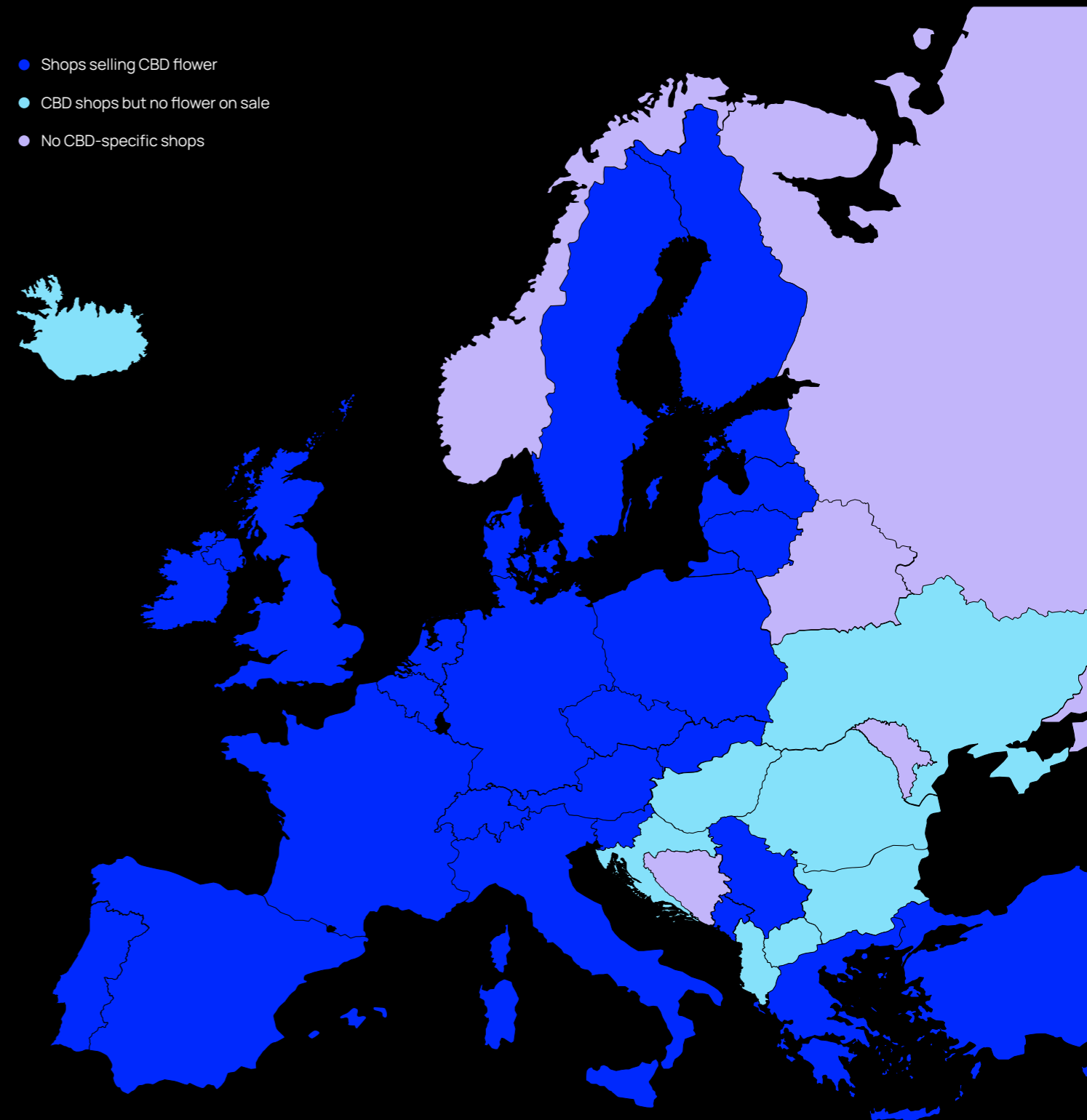
whether they were offering CBD-rich hemp flowers. In the majority of European countries, CBD-specific stores are operating with 'bricks and mortar' locations, in addition to the online stores sending CBD products to customers across Europe. Some exceptions exist, especially in North Eastern Europe; countries such as Norway and Russia maintain a total ban on CBD-specific shops, in line with a general anti-cannabinoid stance maintained in these countries. In the vast majority of European countries, consumers are able to go to a shop in the main street and purchase CBD flower, often marketed as incense and scent-related products, though the clear intention is for inhalation.

For the purposes of this report, Prohibition Partners surveyed 5,112 people across Europe in July 2022 and found, for example, that around 8% of respondents had used CBD flower products over the past 12 months. A similar 8% said that they had used CBD-specific stores in the past 12 months. This represents a massive proportion of the population who are obtaining products which are available on a legally 'grey' basis. It would be difficult to find a correlation in any other CPG industry in Europe in terms of the number of users, and this highlights the urgent need for clarification and unification of regulation in Europe on the use of CBD products.

It is clear that this situation will not remain as such for long. Regulators are gradually catching up with the industry, for example, by implementing changes to the laws surrounding food and nicotine products. For now, law enforcement is lagging behind the implementation of laws by a distance, mostly due to uncertainty on the part of legislators and enforcement on which rules apply for which products. For example, in France, the Kanavape case stemmed from the prosecution of CBD vape sellers Kanavape, which passed all the way to the ECJ before the prosecutors lost the case. This inevitably reduces the confidence with which law enforcement are willing to prosecute further cases. As these laws are cleared up, and the novel foods process reaches its conclusion, it is expected that enforcement of current EU law will resume, the 'grey' market will be cleared up, and operators who are currently self-regulating to high standards or are participating in the novel foods applications will be the ones who will still be operating in five years. Until then, a massive 'grey' market will continue to thrive.

Countries with active CBD grey markets

- Shops selling CBD flower
- CBD shops but no flower on sale
- No CBD-specific shops



Source: Prohibition Partners, August 2022

Supply chain

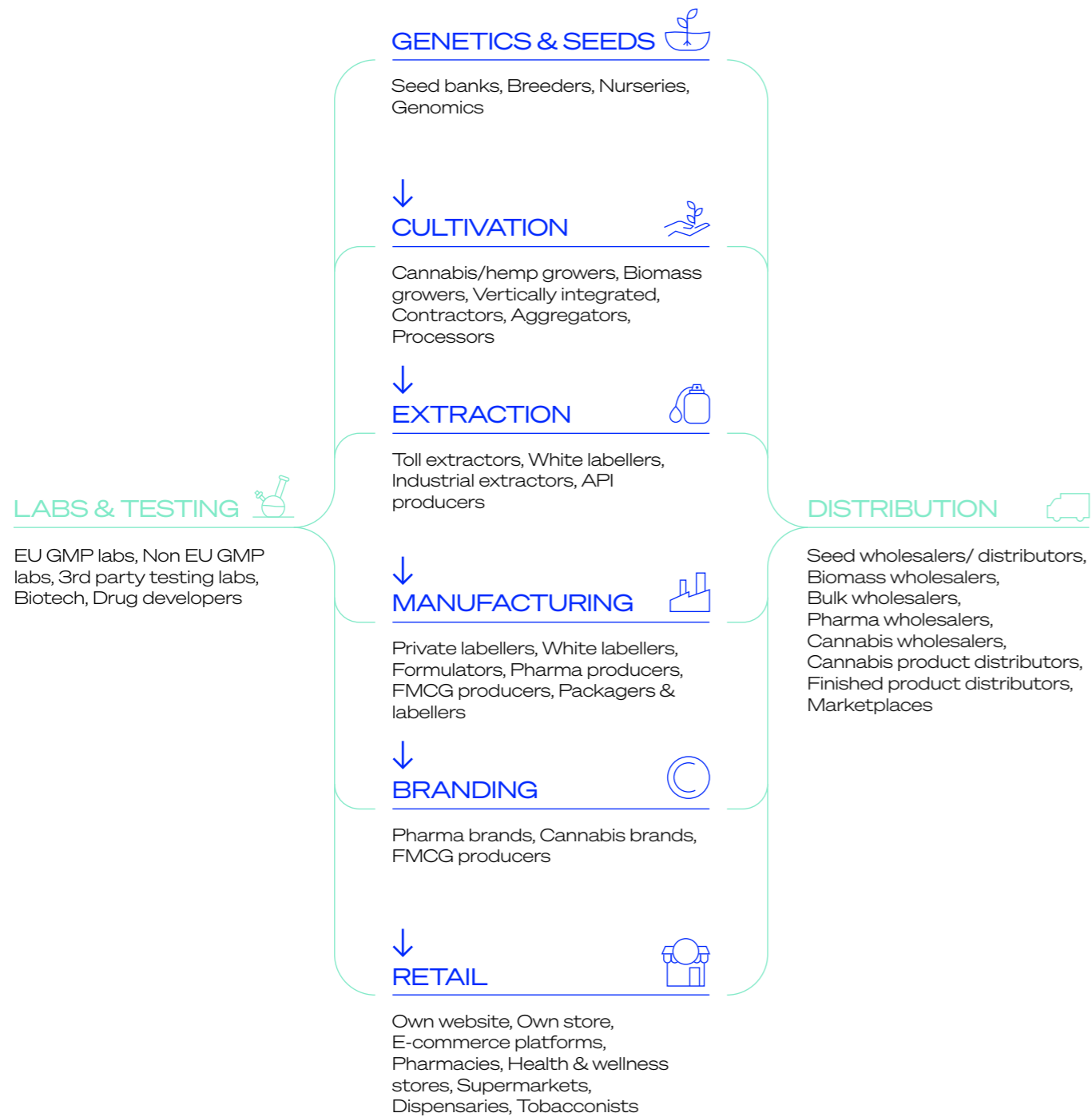


Vertical integration vs niche operations

The supply chain of CBD is similar to many agricultural products in that it has distinct processes for cultivation, processing, branding and retailing. In Europe, companies can choose to operate in some, or all, of many segments of the supply chain. In Europe, CBD is competitive enough such that most niches of the industry have some operators competing for market share. Prohibition Partners has developed a schematic of the CBD supply chain, illustrating the niches within which companies can operate. The strategies employed by early players in the cannabis market often aimed for full vertical integration, owing in part to the novel and strict regulations being implemented, which meant that a high degree of 'control of product' offered certain advantages.

However, the lesson learned there and from other similar industries is that it is often more efficient to compartmentalise the supply chain, and for operators to specialise and compete in one segment rather than along the chain. This is especially true for CBD as the regulations surrounding these products are lighter than for medical and adult-use cannabis. The cultivation and manufacturing processes can largely be handled by existing methods and protocols, so long-standing companies, for example, that deal with cultivation and extraction are equipped to operate in the market and in some cases this makes it an easy choice to integrate them into a product's path to market.

CBD supply chain has the same segmentation as medical cannabis, with very little overlap in actors between supply chains



OTHER ANCILLARY SERVICES

Banks, Insurers, Lawyers, Auditors, Real Estate, Technical Consultants, Equipment providers, Compliance experts, Logistics, Certification providers, Technology providers

Source: Prohibition Partners

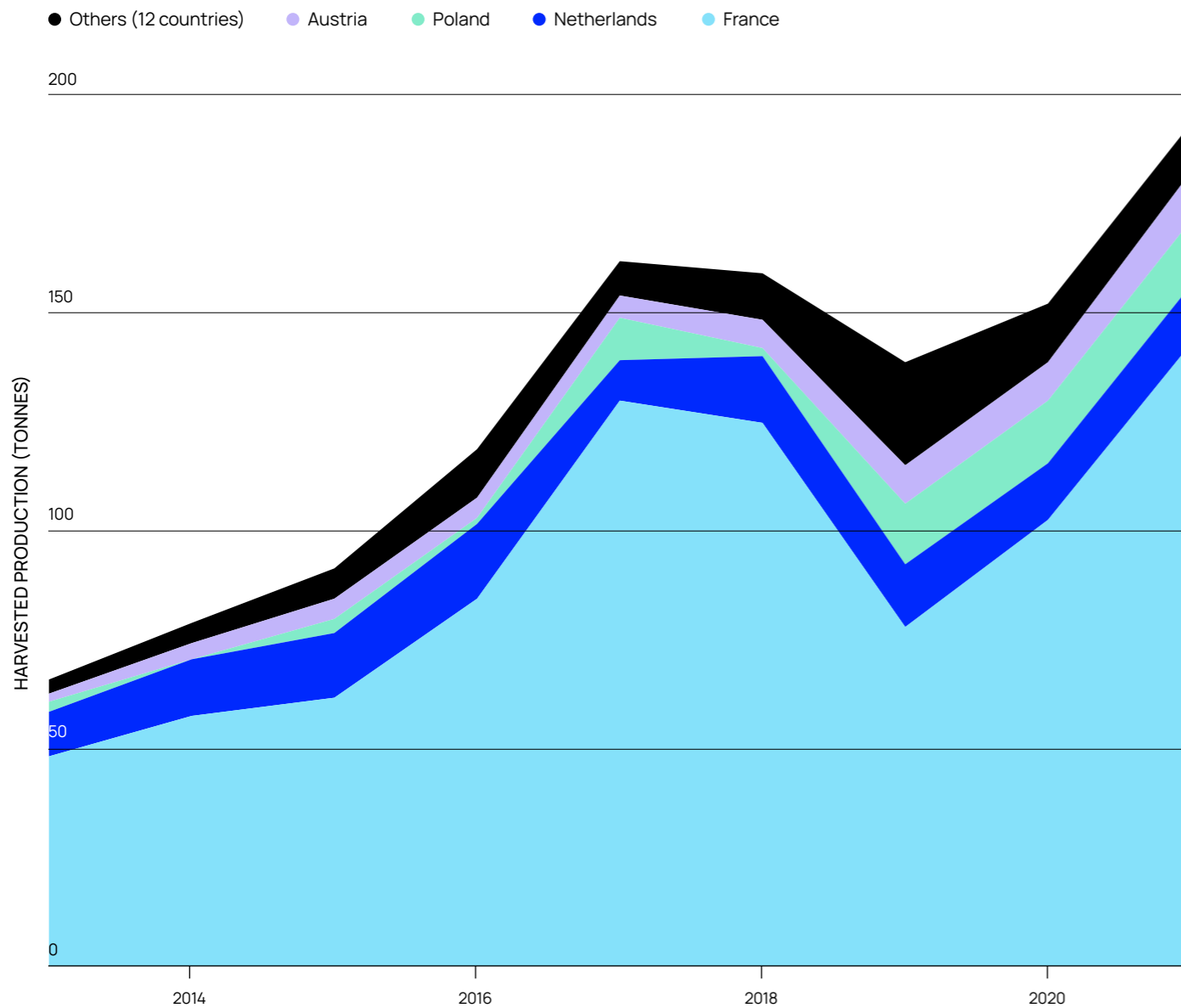
Below we provide deeper analysis into some of the most important sectors attracting the most attention in the industry.

Cultivation

Cultivation of hemp in Europe has been increasing steadily over the past decade. EU level data shows that from 2013 to 2021, the amount of hemp produced increased by almost 200%. Part of this growth can be attributed to the increasing number of countries who report-

ed their statistics to the EU. However, according to the data we have from the EU and from speaking with operators, it remains obvious that the amount of hemp being produced in Europe is increasing steadily as the demand for CBD but also fibre and seeds increases.

Hemp production in the EU



Source: EU statistics office (Eurostat), Prohibition Partners.

The production of hemp in Europe is currently mostly directed towards seed and fibre production, so it is not straightforward to ascertain CBD production from these figures. Our sources confirm that production in Germany and France is for more traditional fibre, seed and grain than for CBD. In a more qualitative manner, from conversing with operators and analysing the market, Prohibition Partners believes that the majority of production is occurring in countries such as Italy, the Netherlands, Switzerland, Poland, the Czech Republic, Lithuania, Romania and Slovenia. Central and Eastern Europe is a stronghold for the production of hemp and CBD in Europe. This is due to a strong cultural affinity for the production of hemp along with forward thinking policies, suitable climatic conditions and affordable land and labour. Countries like Italy, the Czech Republic and Switzerland benefit from allowing hemp with THC of more than 0.2%, providing more flexibility for farmers to grow high CBD strains.

Business models

Hemp cultivation is currently a very competitive field in Europe, with competition coming from within and outside the continent. Companies are employing several strategies in order to stay ahead and most employ a mix of white labelling, private labelling and contract growing.

EXAMPLE 1: Granjacia

Granjacia in Spain is an example of a company offering contract grows for hemp in Europe and also white and private labelling of products. This means that Granjacia facilitates the contracting of hemp cultivation between a company and hemp farmers in Spain. In addition, the company cultivates its own hemp which it then processes in GMP facilities and offers it as private label formulations (where the buyer specifies the product to be formulated) and white label preparations (where Granjacia formulate products to be sold 'as is' to clients for branding and marketing). The company offers products for OTC purposes rather than a company like CBDepot who have an emphasis on active pharmaceutical ingredient (API).



EXAMPLE 2: Vitality CBD

Vitality CBD is an example of a vertically integrated CBD company involved in cultivation. Unusually in the European market, its hemp comes mainly from farms in the UK. The company processes the product itself and offers its own branded formulations, such as oils and cosmetics. The company was originally part of the vertically integrated medical cannabis producer EMMAC, before being purchased by global vertically integrated wellness platform Yooma Wellness for ~€12 million in early 2021, which hints at the viability of vertical integration in the sector.



Supply and demand

From the many operators spoken to for the purposes of this report, the consensus is that there is currently an adequate supply of hemp for CBD in Europe. On record, CBDepot told Prohibition Partners specifically; '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 agreed with the above with the caveat that the amounts currently being grown for the purposes of fibre and hemp production are less than half of what current demand would support.

However, when assessing the commercial opportunities for the production of hemp, it is important to remember that the value of hemp cultivation flowers for CBD production is far greater on a per kilogram or per hectare basis than the production of hemp for seeds and fibre. In the US in 2021, on a per hectare basis, crop production for hemp flowers was almost forty times more valuable than that of seeds. Some of this value would be lost as cultivation of cannabinoid-rich flower is more cost intensive than production of seeds. Such statistics cannot be generated for Europe, as the system of tracking is not designed to account for the production of hemp for flowers. However, it can be assumed that a somewhat similar ratio exists for the value of producing hemp for different purposes.

Profitability of hemp production in the US

Production for	Pounds produced	Hectares Harvested	Value derived (US\$ millions)	Value per area (US\$ thousand per hectare)
Flower	19.7	15,980	623	39
Grain	1.86	3,515	42	12
Fibre	33.2	12,690	41	3
Seeds	4.37	8,255	6	1

Source: National Agricultural Statistics Service 2021, Prohibition Partners

Manufacturing

Manufacturing of CBD products in Europe is carried out by vertically integrated players as well as contract manufacturers. The EIHA has, in the past, suggested that European processing plants handle hemp that is 90% grown in Europe, and 10% from imports. There are no international trade codes for CBD and national reporting is almost completely lacking, so it is not possible to determine quantitatively where most manufacturing is occurring. However, from Prohibition Partners' study of the market, we estimate that the majority is being carried out in countries such as; Germany, Switzerland, Italy, the Czech Republic, Poland and Croatia.

Certification

As mentioned above in the 'certification' section, for the most part, CBD in Europe is not subject to many certification requirements. Therefore, the CBD products in Europe have been processed using a plethora of methods across a wide range of countries. The only exception is for CBD used as an API; as prescription medicines in Europe need to be produced under EU-GMP conditions, (see below). A large number of companies are currently manufacturing CBD products in Europe or are otherwise involved at some stage of the manufacturing process. A full spectrum of strategies are being employed by companies from total specialisation to more generalised offerings. Below, we explore some of the ways in which these companies vary their strategy.

Extraction methods

Aside from flowers, most products advertised as CBD products have undergone extraction to excise CBD from the hemp plant it is derived from. One exception is for products which have undergone a more general form of extraction, for example where the hemp flower is cold-pressed to extract the full-spectrum of cannabinoids and terpenes etc., from the hemp plant. CBD can be extracted from the hemp plant in a wide variety of ways. Manufacturers operating in Europe in general prefer CO2 (more expensive but scalable and flexible in terms of cannabinoid output) and ethanol-based (cheaper but less flexible) extraction methods primarily for cost-effectiveness but also for reasonable reliability and reproducibility. For a fuller treatment of extraction methods, see Prohibition Partners' Extraction Report 2021. We examine three of the most relevant extraction methods in Europe below.

Alcohol extraction (ethanol)

Ethanol extraction is one of the most popular methods used in the industry for its universal capacity as a solvent to extract cannabinoids and terpenes at a relatively low cost. One example of a company employing this method in Europe is CanX who produce CBD in Romania mainly for the European and Japanese markets, with headquarters in Canada. The company emphasises that ethanol extraction is FDA-approved and designated as Generally Recognised as Safe (GRAS) by them also.



Supercritical CO₂ extraction

Carbon dioxide (CO₂), is another popular method already relied upon in other extraction industries, such as with coffee, for its decaffeination. One of the main drawbacks of CO₂ is its elevated price, with machines of around a five litre capacity being at a starting price of US\$100 thousand up to figures close to US\$0.5 million for capacities above 20/25 litres. This represents a major challenge for operators who are short of capital and for any escalation of its use. In Slovenia, PharmaHemp, who are a major wholesale and whitelabeller of CBD in Europe, employ this method. They emphasise that while CO₂ extraction is the most expensive method of extraction to operate it is also 'widely considered the most effective and safest plant extraction method'.



Cold-pressing

Cold-pressing of hemp products to produce CBD is a much less efficient and cost effective method than modern extraction methods in terms of the amount of CBD retained and the cost of processing. The main benefit is that in Europe and the UK, cold-pressing of CBD products is considered a traditional method of hemp processing and, as such, it is not subject to the novel foods ruling, and can be marketed without such an approval. Cold-pressing is a non-selective method of extraction, meaning that generally, the concentration of cannabinoids and terpenes in hemp material is not altered in any particular way other than in natural variations in the process of pressurising the plant material to 'squeeze' out oils. One example of an operator using this method at scale is German-based Florapower who offer contract extraction and extraction infrastructure and emphasise that, 'the CBD / THC content can be chosen freely' though it is not obvious how this is achieved. A major obstacle for cold-pressing is the challenge in scaling the methods, but Florapower advertises from 30 kilograms to several tonnes processing capacity per hour. One question is whether the extraction efficiency (% of CBD retained in final product vs raw material) is high enough with this process to be commercially viable for CBD products.



Business models

CBD specialised vs generalised companies

CBD manufacturing is not subject to the same strict regulations as medical or adult-use cannabis. This means that the infrastructure used to produce CBD does not need to be as bespoke as it is in the other cannabinoid industries and there are a lot more operators using various methods in CBD than in medical cannabis in Europe. For one thing, extraction methods do not need to be EU-GMP certified for health and wellness products, whereas they do for medicines, meaning health and wellness operators have more room to experiment with new methods. Also, the licensing for cannabis manufacturers means the barrier to market entry for CBD is lower than it is for cannabis and this in turn is due to the fact that CBD is not classified as a narcotic substance in the EU and the UK. This means that large, generalised companies can operate in the space. There is a balance to be struck for any operator using such services between specialists who may have more dedicated and flexible services and generalists who are proven and who can probably process with competitive rates at large scale.

EXAMPLE 1: NateCO₂

NateCO₂ based in Germany, is probably the largest manufacturer of hops using CO₂ methods in the world. NateCO₂ has offered hemp-specific services on its website since 2017. The company emphasises that its scale and experience means that it offers competitive technical equipment and legal 'know-how'. This contrasts with contract manufacturers, such as CanX, who specialise entirely in the manufacturing of CBD and hemp-derived products.



White/Private labelling

Many manufacturers in Europe offer white and private labelling services. Private labelling services allow the client to dictate the characteristics of the product while white labelling agreements allow for the purchase of a finished product for subsequent branding. These strategies offer many benefits such as: a reduced initial investment in the set up of cultivation/manufacturing capacities; less risk in terms of changing regulations, market prices and issues such as harvest yields as well as a more focused business that can concentrate on areas such as marketing and distribution which in themselves are very complex and competitive fields. The disadvantage is that the company gets less control over the supply chain they are reliant on and of course the company also pays a premium to the provider for the service. Leading white-labelling firm Ilesol Pharmaceuticals claims that currently around 90% of brands in Europe are white-label though this is difficult to verify. Many companies listed above offer white labelling services.

EXAMPLE 2: Labrocan

Labrocan, based in the Netherlands, is a large supplier of raw materials but also white labelling services. It is unique in providing both hemp-derived CBD and synthetic CBD. Its synthetic CBD is also unique in that the source is not purely chemical but rather, reprocessed lichen and citrus skin that is discarded from other industrial processes. The company offers a range of products including oils, cosmetics and pet food products.

Example of white label capsules available from Labrocan



Distribution

At the moment, CBD is not a commoditised product, in the sense that while all CBD is chemically identical, the raw materials being traded are not seen as equivalent. The source of the product and the methodologies used to obtain it remain crucial parts of the valuation, and the variation in the composition of more whole-plant extracts, which contain wide cannabinoid and terpene profiles, defies standardisation. The potential end point of the development of the extracted cannabinoid isolate market is commoditisation, in line with similar industries like coffee beans. However, the market is not currently suited to commoditisation due to a lack of consensus on nomenclature and the classification system for various CBD raw materials like isolates, distillates, full-spectrum, broad-spectrum etc. The EIHA has published some definitions but they are by no means adhered to across the market, as of yet. This means that buyers, often only have, cannabinoid concentrations and a price to work from in terms of 'deciding criteria'. Buyers lack the means to assess the quality in other terms, for example the option of standardised testing methods applied for heavy metal contamination, cannabinoid variation between batches etc.

EXAMPLE 1: NaturAlpes

NaturAlpes is an example of a brand which offers wholesale services of its finished products only. It uses Swiss-grown hemp to produce its CBD which it then sells D2C on their website but it also provides the option for retailers to stock its products in-store.



One result of this lack of uniform regulation of the market is that third party marketplaces have not really taken over from traditional, one-to-one deals between suppliers and clients in the way that it has for many other bulk material markets. Buyers often stick with one, or a short list of suppliers, as it is quite difficult to understand the quality being offered by competitors. In the UK, this is even more apparent as the novel food applications include the source of the raw material, meaning a brand cannot switch supplier after approval, which limits the flexibility of operators and also contributes to operators submitting dozens of applications to cover their bases in case of future changes to supply lines.

Business models

Many of the companies listed above could be considered wholesalers, as any white labelling company is in essence providing bulk product to clients. However, we draw some distinctions here between the types of products being offered by wholesalers.

EXAMPLE 2: Hempati

Hempati, based in Italy, is an example of a raw material wholesaler who acts as 'point of sale' for cultivators in Europe, especially Switzerland and Italy. In terms of 'value added', it only offers products which have been laboratory tested for their CBD and THC contents. Hempati also offers white labelling services.



EXAMPLE 3: CannMed

Based in the UK, CannMed specialises in bulk imports of hemp and derivative raw materials for wholesale in Europe. CannMed focuses on the UK market but it supplies raw materials and white labelling services across Europe.



EXAMPLE 4: Brains Bioceutical

Brains Bioceutical is an example of a company that spans the categories of wholesale API and OTC products. Brains produces branded OTC products but also offers wholesale API. It can do this as the company produces its CBD in EU-GMP facilities. For API in Europe and elsewhere, this is a necessary certification. With its OTC products, the high standard of production means Brains' products can be marketed at the higher end segment, and at a higher price than non-GMP products (see pricing, below).



Wholesale prices

The early days of wholesale CBD were reasonably lucrative for the small number of farmers and processors who tapped into the demand for these products early on. However, the price of CBD raw materials and wholesale products has dipped dramatically in Europe in recent years. This is partly due to the increasing number of farms producing hemp in Europe, but also, the massive increase in the scale of production in the US. Large operators in countries such as the US and China can now import CBD products like isolates and flower at very competitive prices, which has squeezed out almost all of the profit margins from the production of hemp for CBD flower.

The recent consensus is that the trend of reducing prices of CBD derivatives may have bottomed out in Europe, as the number of US hemp farms has radically declined since a 2019 high. Below, we consider some of the prices Prohibition Partners has found in a survey of the market for two of the most common products, CBD flower and CBD extracts.

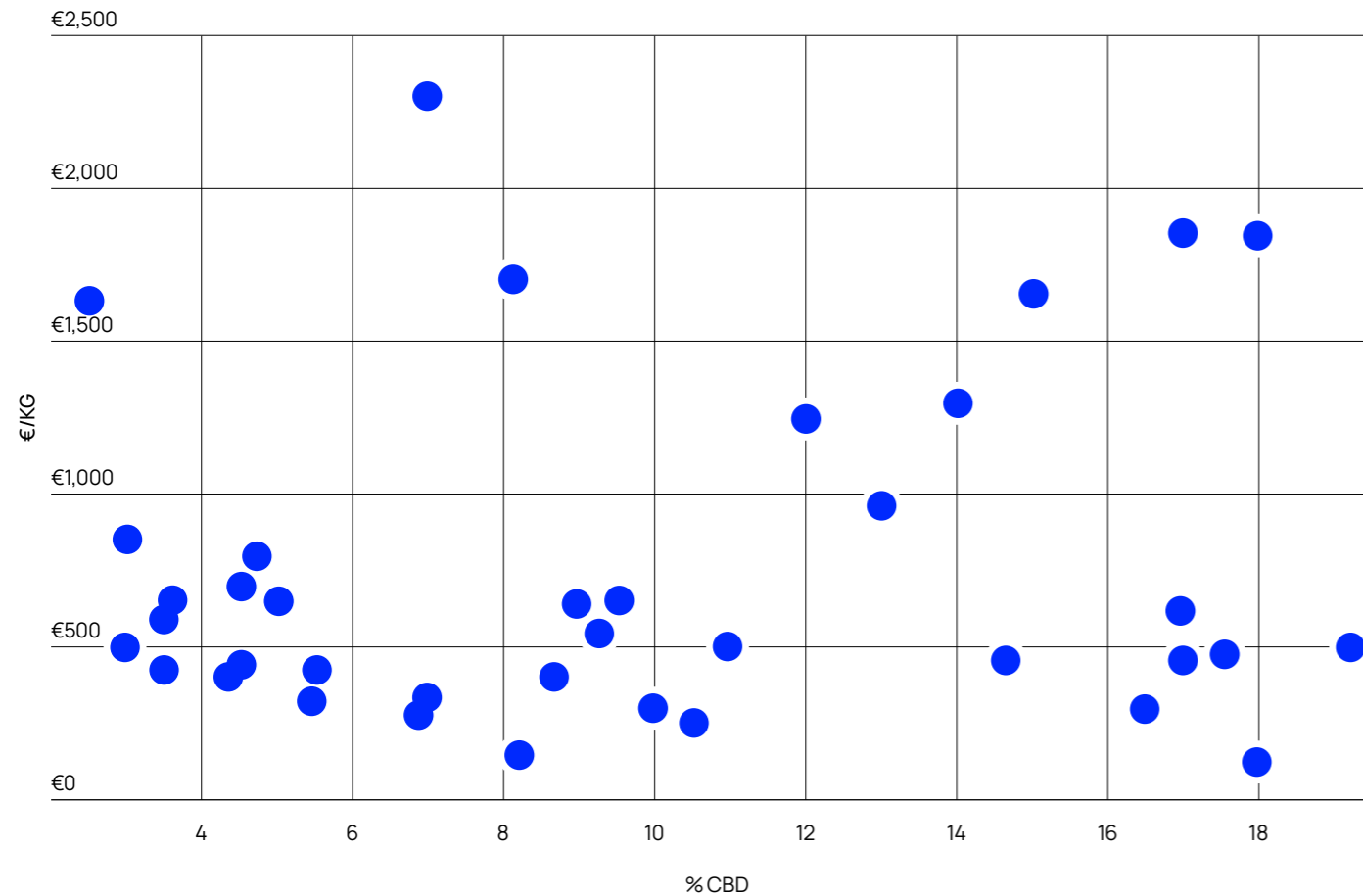
As can be seen from the data below, the CBD market in Europe is yet to settle and consolidate. Prices vary widely between suppliers for similar products. Even amongst wholesalers, very similar products will see one product costing much more than the other. Prohibition Partners expects that prices will cohere around a centre point in the not-too-distant future as; more suppliers are priced out of the market, more marketplaces centralise the market and spot pricing becomes less common.

While a number of factors variably affect the pricing of each wholesale product, a universal factor is scale of order. For each category such as, flower, isolate and distillate, the price of a kilogram of pure CBD, or its equivalent, can vary tenfold. For isolates, buyers could expect around a 20% discount on average when purchasing large quantities of product e.g. 10 kilograms vs 1 kilogram. For flowers, discounts can be considerably higher, for instance an average of ~50% discounts were offered for flowers if orders were above 20 kilograms vs 1 kilogram.

CBD Flower

As of July 2022, the price of CBD flower in Europe varies widely. The definition of CBD flower here is that the wholesale product is marketed as a CBD flower. The actual content of CBD in the products varies from ~2% up to 20%. The chart below shows the very loose relationship between the CBD content and the price of flowers per kilogram.

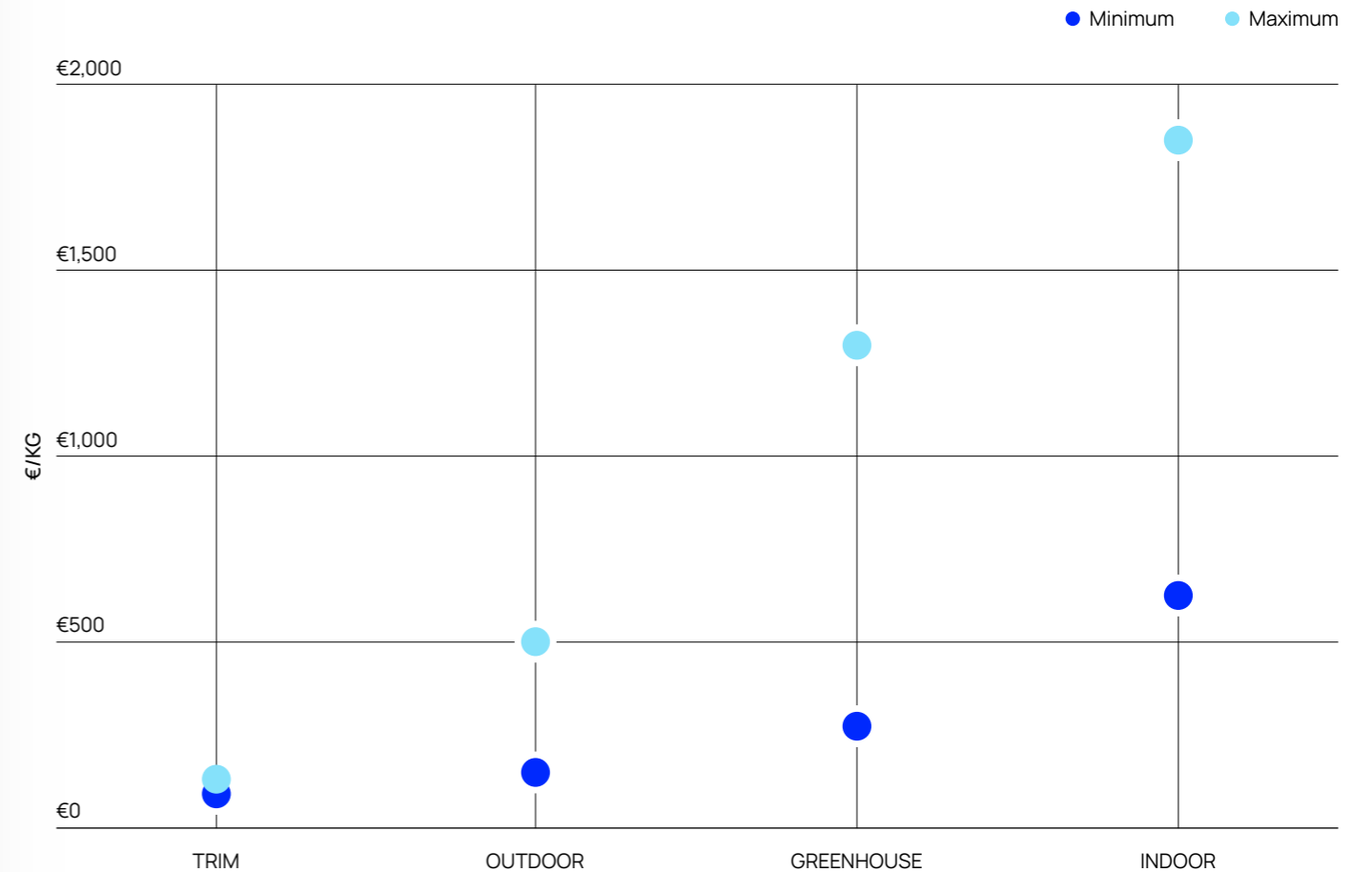
Wholesale price of CBD flower in Europe



Source: Various CBD wholesalers from EU and external sources, Prohibition Partners, August 2022

As is the case with adult-use and medical cannabis in the states, CBD flower prices in Europe vary widely depending on the conditions in which they are grown, specifically whether they are grown indoors, in greenhouses or outdoors. These three methods represent a spectrum of cost-intensiveness and control over product quality, with indoors representing the highest, outdoors the lowest and greenhouses in the middle. This is intuitive based on the costs; electricity to power lights indoors vs using the sun in a greenhouse. Indoors, factors such as light, wind, soil nutrient content, pests and water can be more precisely controlled to produce flowers which are both larger in volume and more dense in cannabinoid content. Trim, which is often the leaves closest to the flowers as well as some flower-cutoffs, fetches the lowest price by far.

Wholesale CBD flower price in Europe



Source: Various CBD wholesalers from EU and external sources, Prohibition Partners, August 2022

The price of CBD flowers in Europe can vary greatly depending on the source and setup of the growth operation. The cheapest outdoor CBD flower that Prohibition Partners found was priced at €150/kilogram and was grown in Italy. The highest price went for hand-trimmed indoor flowers, at €1,850/kilogram; incidentally also from Italy. The variation in price between products differed at the absolute and relative levels. While indoor varied the most, in absolute terms, at a difference of €1225/kilogram, greenhouse-grown flower had the highest coefficient of variation (0.67), owing to a higher relative range of €1025/kilogram on an average price of €625/kilogram.

Another factor which affected the price of CBD flower was the quality of the bud, regardless of the source. For example, one particular wholesaler offers indoor flowers at €1250/kilogram for premium buds from a particular batch, while smaller buds, with

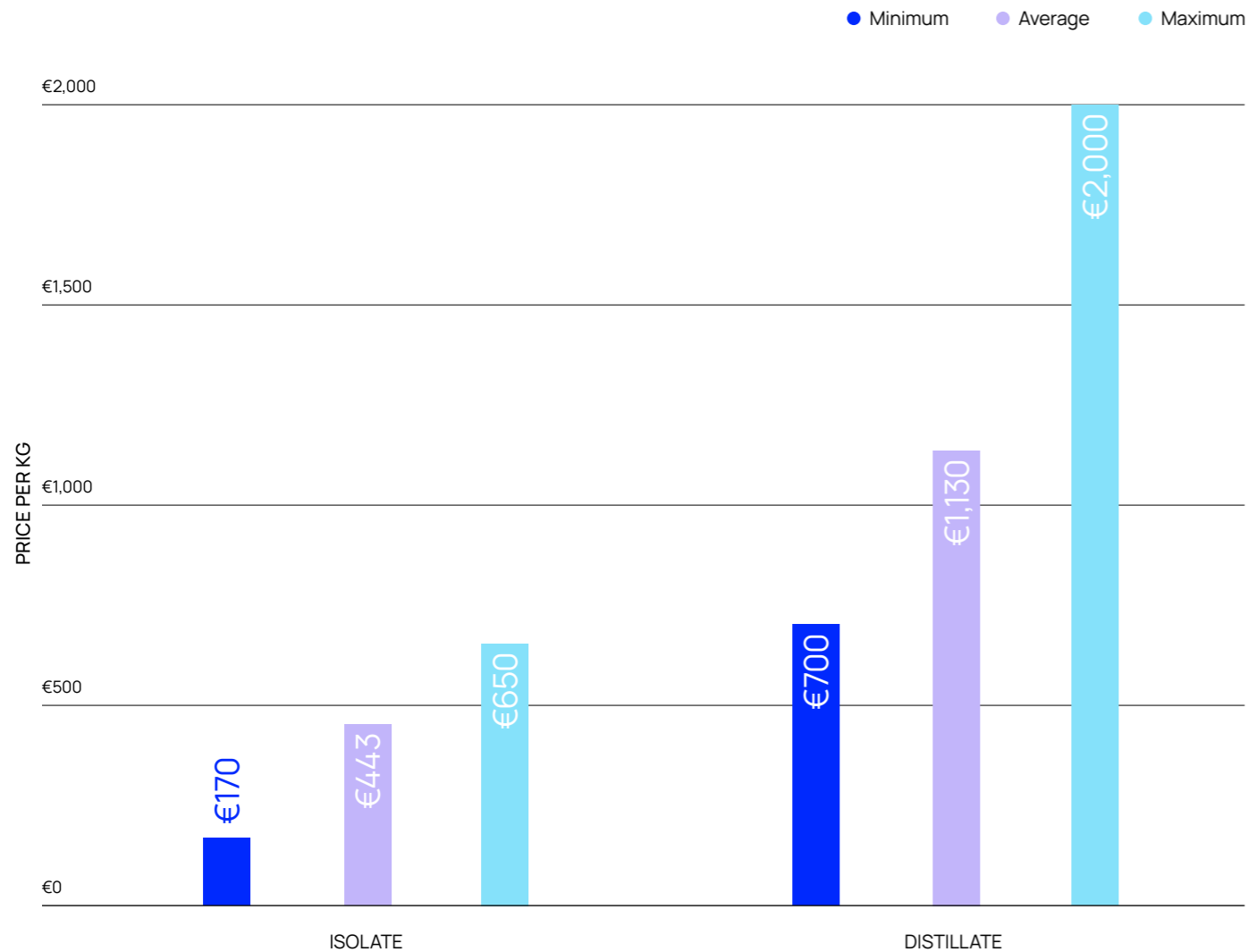
less guarantees of quality are priced five times lower, at €250/kilogram. The quality of the premium buds was due to the presence of less seeds in the flower, and a tighter control of CBD and moisture levels. The hand-trimming of CBD bud generally fetched a higher price than machine trimmed though not many wholesalers made this information available, without a formal enquiry.

CBD Extract

As with flowers, extracted cannabis raw material also varies wildly in price, despite a relative similarity between products. As with flowers, buyers can make large cost-savings by shopping around the various wholesalers to find the best deal on extracts. Below, we examine the wholesale prices for CBD isolate and distillate. CBD distillate is the material extracted from hemp plants which still contains a small amount of other biochemicals such as cannabinoids

and terpenes. Isolate is a purer product, generally in the region of 97-99.9% pure. The average purity of CBD which we found in samples of distillate was 93.5% compared to 99.3% for isolate. The benefit of isolate is that you can be assured of a purer product, allowing for more control of cannabinoid content in the final product. However, many buyers are interested in the terpene and minor cannabinoid profile, as these provide 'test and scent' characteristics of extracts. In addition, many believe the presence of other cannabinoids and terpenes offers an 'entourage effect', increasing the positive effects of CBD, though the evidence for this phenomenon remains shaky in the opinion of the author.

Price of wholesale CBD Extract in Europe



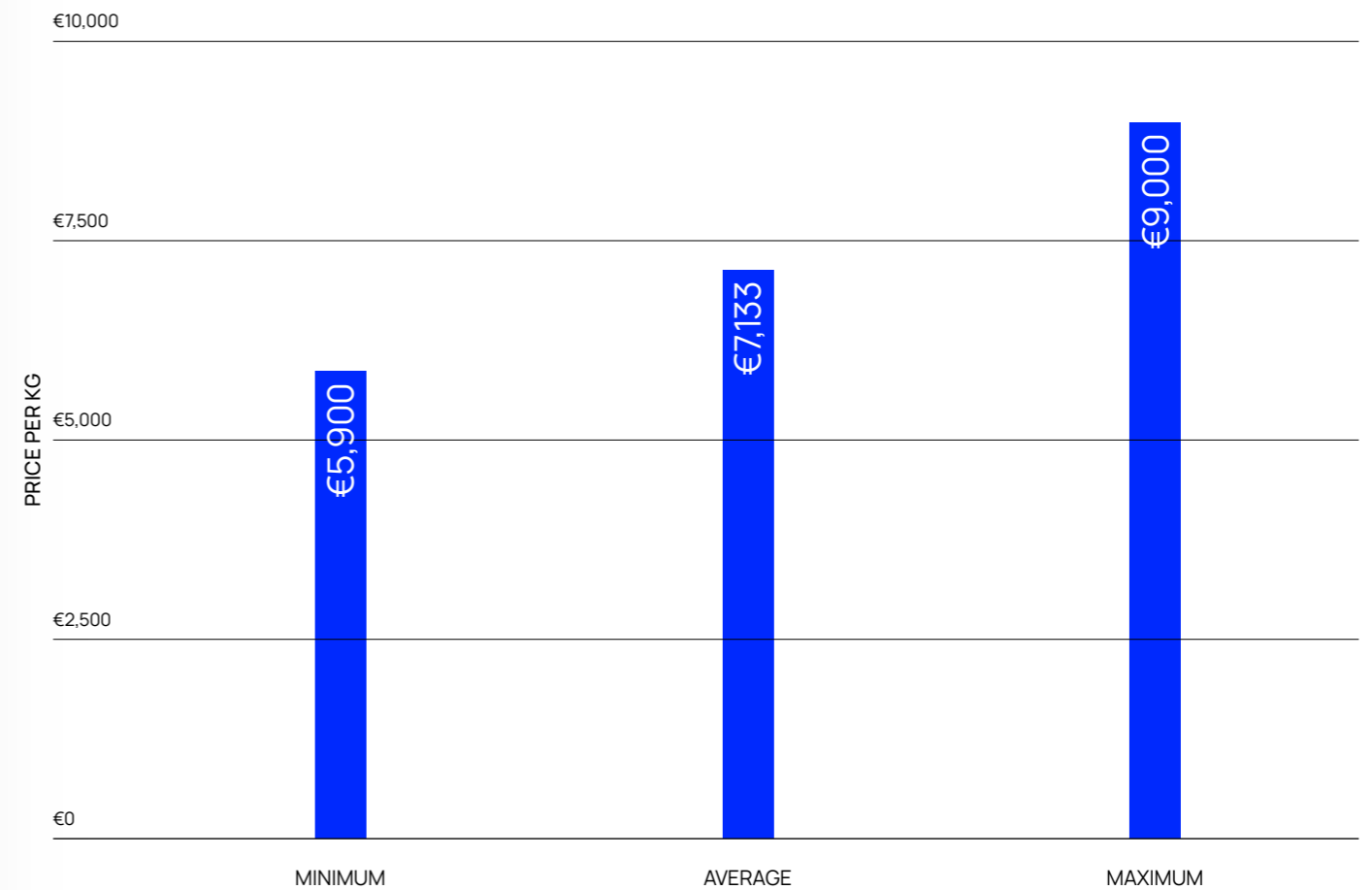
Source: Various CBD wholesalers from EU and external sources, Prohibition Partners, August 2022

The price of distillate in Europe is currently far higher than the price of isolate. This mirrors developments in wholesale pricing in the US. The average price of distillate came to €1130/kilogram while that of isolate came to just €443, though from speaking with buyers in Europe, it is common for the price of transactions to be closer to ~€200. The most expensive distillate was around three times as expensive as the cheapest, at €2000 compared to €700. Two factors are important in this discrepancy. The most expensive distillate product found was produced under GMP conditions, and had a purity of 95% CBD content while the cheapest product found was only 92% and was not produced under GMP certification. While GMP is not necessary for products like foodstuffs and smokeable products, it increases the perceived quality of the product and therefore the value at market. To a degree, the same wholesalers charged more for a similar distillate product with a higher concentration of CBD.

API

CBD API is almost an order of magnitude more expensive than cheaper isolate products in Europe. This is due to the stringent compliance requirements for the production of API in Europe. There are many costs associated with setting up a GMP-compliant supply chain. In particular, setting up a GMP-compliant manufacturing facility is onerous to the degree that many buildings need to be designed for the purpose of API manufacturing rather than being adapted retrospectively e.g. where the main production room needs a certain ventilation system and to be a certain distance from washrooms. In addition, the cost of mock inspections and certification can cost in the range of €100 thousand to several hundred thousand euro.

Price of CBD API in Europe



Source: Various CBD wholesalers, Prohibition Partners, August 2022

CBD API can also be sold for a much higher price than non-prescription CBD. As detailed in the product format section, licensed medicines with CBD (Epidiolex) can cost consumers €170.9 per gram of pure CBD compared to €25 per gram for OTC CBD. API will remain a distinct market with prices which are more resilient against price drops due to the higher barriers to market entry, and the higher minimum requirements for the production of these products for wholesale.

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 set up 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 affect; what can be measured, how it can be measured, to what 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 following parameters:

- Cannabinoid potency
- Heavy metals
- Microbiology
- Solvent residues
- Pesticides
- Terpenes

- Mycotoxins
- Polycyclic aromatic hydrocarbons (PAHs)
- Dioxins and polychlorinated biphenyls (PCBs)
- Phenols and polyphenols

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.

Points of sale

Due to the changing regulatory environment, the CBD industry has a unique retail landscape in Europe. Similar to vaporisers and electronic cigarettes, Europe has seen the rise of shops tailored only to CBD and hemp related products over the past ten years. As with vapes, CBD is now a more mainstream product, and it has been integrated into many retailers' offerings, both 'bricks and mortar', as well as online stores. The acceptance of CBD into major retail channels such as Sainsburys in the UK and Rossmann in Germany further legitimises CBD as a safe and desirable product in the mind of consumers. This has been bolstered by the acceptance of CBD on major e-commerce sites, most notably eBay, which began listing CBD products early in 2022.

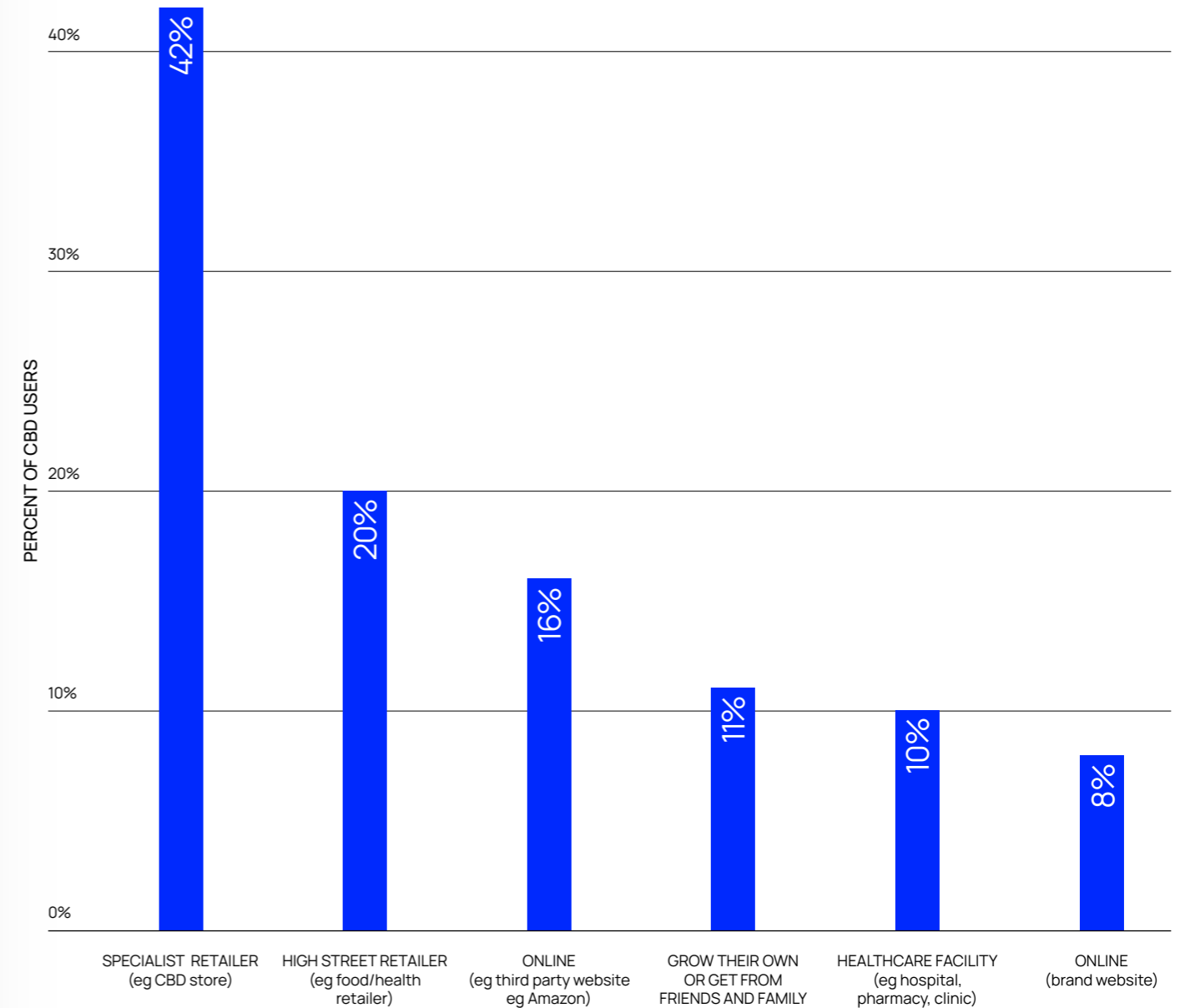
In order to understand where consumers are currently sourcing their CBD products, in July 2022, Prohibition Partners surveyed over 1,050 CBD users across key markets in Europe to discover how people on the continent are buying their CBD products (see the section on Consumers for more detail).

The results show that the most popular route for consumers using CBD products is via specialist CBD and hemp stores, which, as mentioned in the 'Grey Market' section, are ubiquitous in Europe. In terms of consumers, 65% of them choose one route and stick to it, while 27% use a combination of two and just 8% use three or more routes to source their product. Surprisingly, no such significant differences were found between age groups nor between sexes.

Users above the age of 30 were as likely as those below 30 to use online stores instead of 'bricks and mortar' stores, potentially an effect of increased online shopping in the wake of the pandemic.

Retail routes for CBD products in Europe

50%

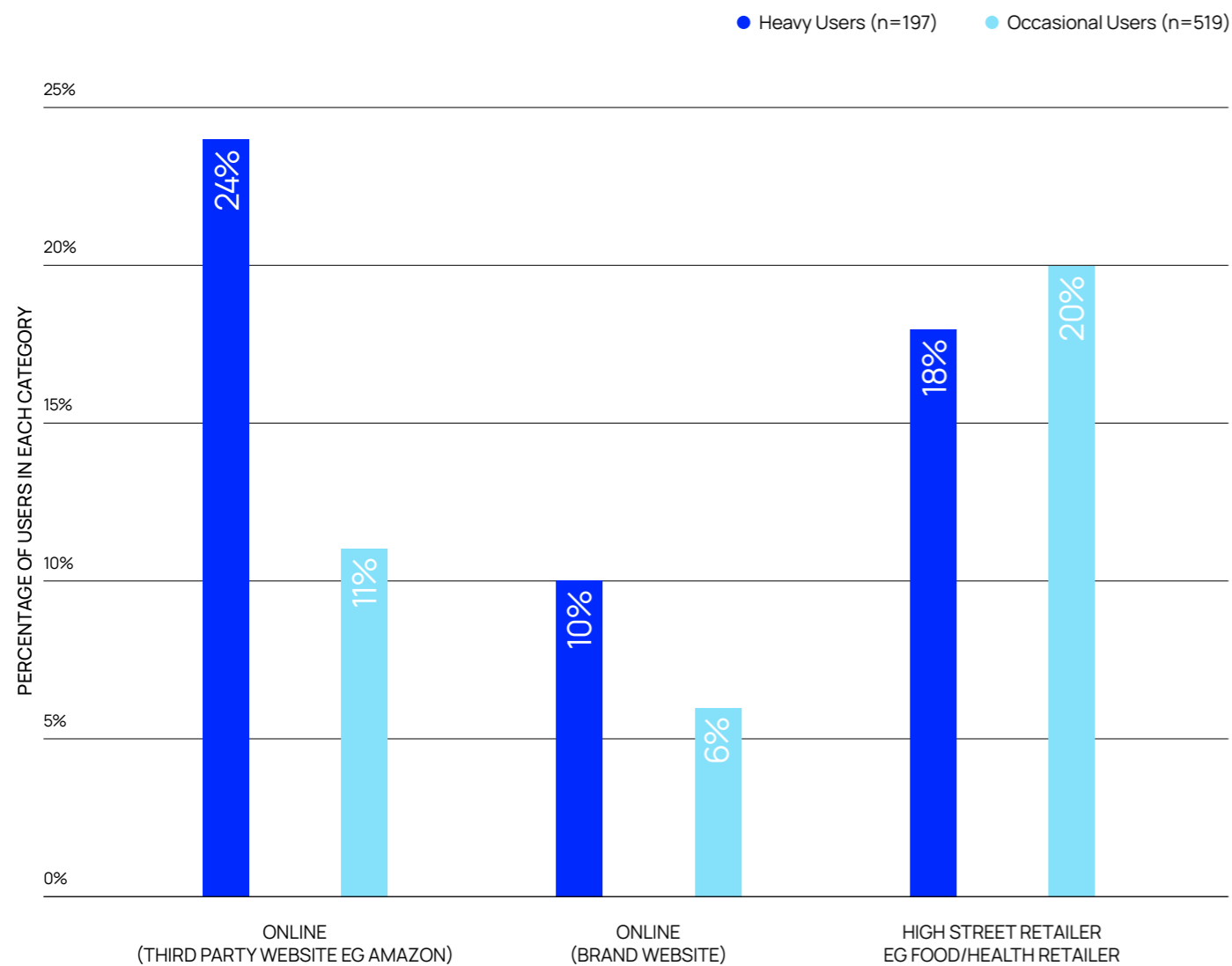


Source: Prohibition Partners, Respondents were asked, 'Where do you buy your CBD products (select as many as apply)', July 2022, n=928 users from the UK, Germany, Poland, France, the Netherlands, Spain and Italy.

Retail routes varied for some categories based on whether the CBD user was a heavy user (twice per week or more, n=197) vs an occasional user (less than once per month, n=519). In particular, heavy users are more likely to source their products from online retailers than 'in person' in stores. Occasional users were more likely to use high street retailers. There are various explanations for this. For one thing, online prices are expected to be lower due to lower overheads and a larger scale of operations, which is especially important for heavy users seeking to offset costs. Secondly, it is expected that occasional users may not have

chosen specifically to shop for CBD products but found them as part of their routine shopping. The familiar setting of a health food or grocery store may also convince new buyers to try an unfamiliar product, where they would be less likely to try from a less trusted online source.

Retail route of CBD users



Source: Prohibition Partners, July 2022, n=716 CBD users from the UK, Germany, Poland, France, the Netherlands, Spain and Italy.

Price

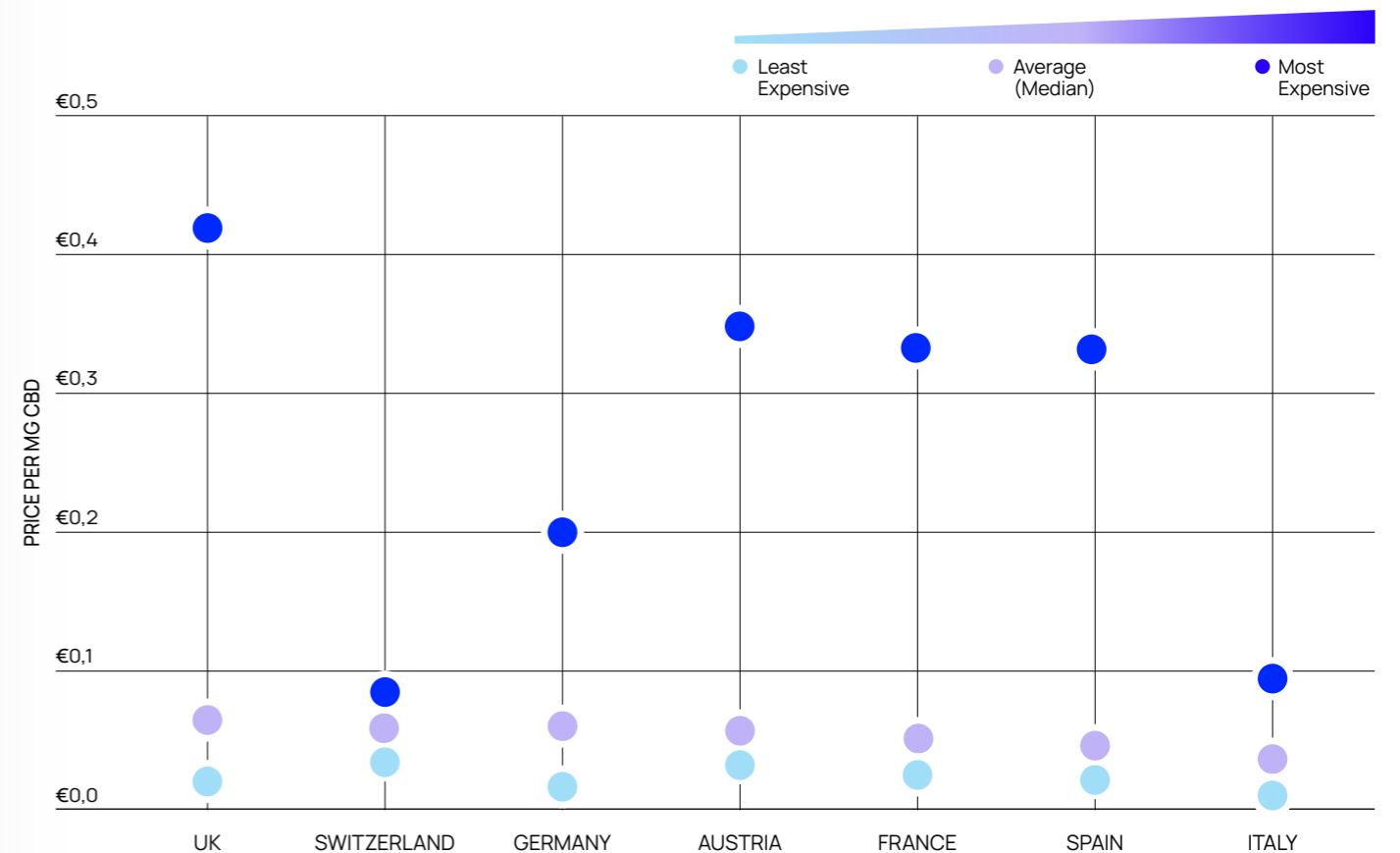
Pricing at 'point of sale'

For the purposes of this report, Prohibition Partners queried Prohibition Partner's CBD pricing database of CBD consumer products currently on the market in Europe. In order to obtain the key data on prices in Europe, as of Q3 2022, we focused on 968 products from 163 brands available online on national websites across the following countries: the UK, Switzerland, Germany, Austria, France, Spain and Italy. Overall, we found that the price of CBD products varies significantly based on their intended application. As retailers struggle to establish market position, discounts are very common, with virtually all retailers maintaining a permanent 'sales' page, with products from each category being offered with up to 75% off the original price. Our data shows that prices have not changed significantly since 2019, though there was evidence of a price compression in 2020, from which the market has now recovered.

Price per country in 2022

Overall, the average online price of CBD products does not vary significantly between countries. This explains why most suppliers are offering the delivery of products across the whole continent rather than in individual states. This compresses prices; many consumers are happy to buy from online marketplaces like Alphagreen, that deliver across Europe rather than from a more expensive local store. The average price per milligram of CBD in oils varied from €0.04 in Italy to €0.07 in the UK. In every country, the majority of products were priced according to CBD content and thus exhibited a similar cost per milligram. However, in all countries but Italy and Switzerland, outliers were common, where some retailers or brands offered premium products at a much higher price, which meant the most expensive CBD oil products were almost ten times as expensive as the least expensive ones, on a €/milligram basis. Italy and Switzerland did not display this large range in price. This could be due to the fact that the CBD market is more established in these countries than others (e.g. in that they have established cannabis light markets), and that prices have coalesced around a central point.

Price of CBD Oil in Europe



Source: Prohibition Partners, August 2022

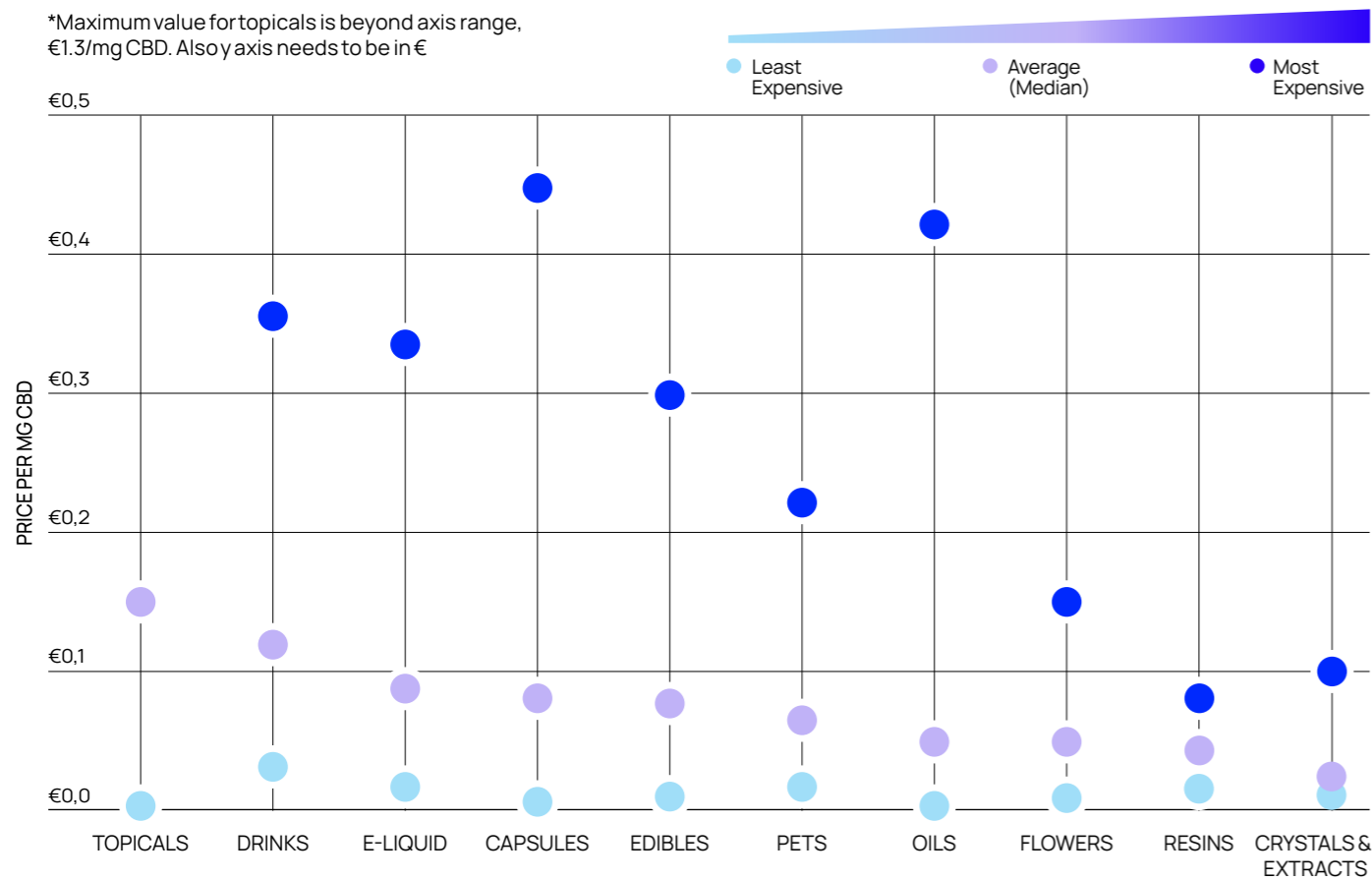
Price of CBD per product category in 2022

The mean price of a milligram of CBD in a consumer product is €0.08 but this varies widely across categories. There are several factors at work here; the cost of compliance e.g. stricter rules on consumable products than cosmetics, the variable adherence to compliance rules in different categories e.g. higher compliance levels with existing rules in cosmetics than in edibles, the value added of other ingredients, and finally the cost to produce e.g. flower is less processed than oils and can be manufactured for a lower cost. Supply and demand levels also play a role, as the ample supply of isolates from the US has pushed the price of isolate and crystals considerably lower than other categories. In addition, many more consumers are currently buying oils and flowers than isolates, which is a less familiar and less easily consumed product.

The average price of products on a €/CBD basis varies widely with product format, from €0.15 for topicals to €0.02 for crystals and extracts. This can be interpreted similarly to the reasons explained above, but also in general, it can be said that cosmetic CBD products are the most likely category to contain ingredients other than CBD which is expensive and this decouples the pricing of the products from CBD alone. The price of cosmetic products is based, the least, on the content of CBD, and so these products had the greatest range of prices. However, the price of capsules and oils also exhibits a particularly large range between the most and least expensive products, though this can be interpreted by the marketing around these products, with premium wellness products offered at higher prices, which cannot be said of drinks and flowers. Oil and flower products were some of the least expensive products on a €/milligram CBD basis. This is intuitive for flowers, which is a lightly processed product. For oils, this also reflects the fact that there is significant competition in this category, and it has many more operators.

Price of CBD Products in Europe

*Maximum value for topicals is beyond axis range, €1.3/mg CBD. Also axis needs to be in €

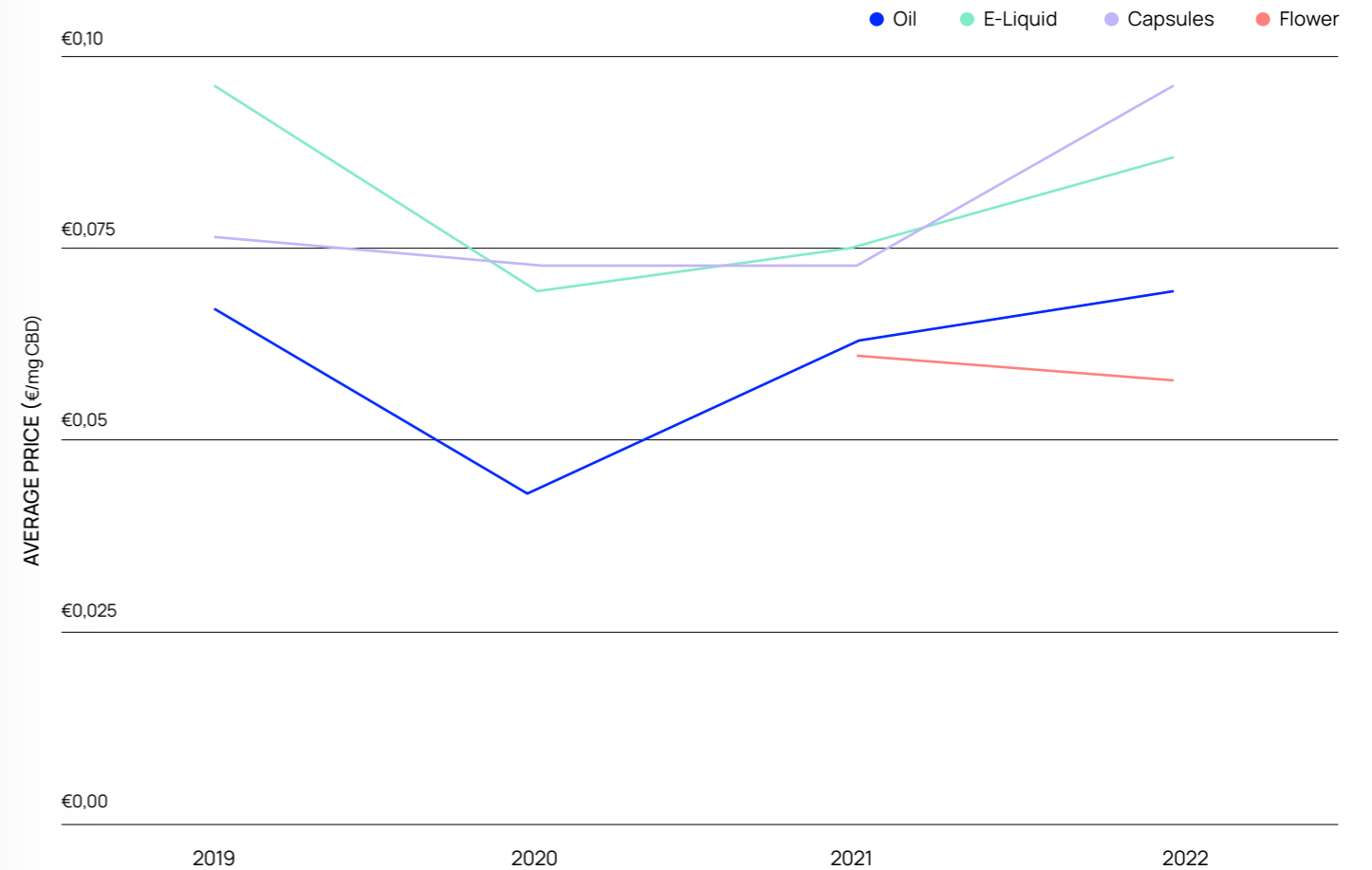


Source: Prohibition Partners, August 2022

Price trends

The price of CBD products at 'point of sale' in Europe has not undergone as dramatic a change as has the wholesale price on the continent. Below, we compare the price of products across four categories, gathered from Germany, the UK, France and Italy over the past four years.

Price of CBD Products in Europe



Source: Prohibition Partners

A general trend can be observed of a price compression during 2020, possibly in the wake of the increasing supply of product and raw materials from the US which began to decline after 2019. As such, there has been a recovery in the pricing of products, based on CBD content, over the past two years. Prohibition Partners began tracking flower prices, at scale, in 2021, and there has been a moderate decline, potentially owing to the fact that more countries in Europe are embracing these products, and there are more operators in the market. While

some price compression might be expected from the increase in supply since 2019, the prices in 2022 look very much like they did three years ago. Companies seeking to meet the upcoming standards in Europe and the UK may be paying more to meet compliance requirements and passing these additional costs onto consumers. It is interesting to note that the price of more highly processed products; such as e-liquids and capsules, have tracked close to each other, while the price of oil and flower are more closely aligned to one another.

Challenges to the growth of the CBD market

Regulation

The establishment of a clear and detailed regulatory framework for the CBD industry to operate within is an ongoing process at the European level, as well as at the national level in every European country (with the possible exception of Switzerland, which has a well-defined system for the licensing and commercialisation of CBD).

The three ongoing Novel Food authorisation processes in the EU, the UK and Switzerland run parallel to the industry in Europe. The requirement for, and current lack of, Novel Food authorisations for ingestible CBD products represents one of the primary barriers to full legitimisation of the industry. The Swiss process currently has no applications under review, while the UK and EU processes have both been widely criticised for their inconsistency, and for placing an unnecessary strain on CBD operators which is significantly hindering the sector. In the UK, this has taken the form of the publishing and republishing of the list of ongoing applications (which determines which products can continue to be marketed legally), the moving around of deadlines for application submission, and the effective freezing of supply chains which the Novel Food application process entails.

There are a variety of other regulatory issues which present challenges to the CBD industry in Europe, including: that proposed THC limits in foodstuff products do not reflect current or expected market practice; that there is no alignment in terms of trade codes to use for CBD products; and that many national industries still adhere to regulations created for industrial hemp (focused on fibre or seeds) rather than for the CBD industry (focused on flower and cannabinoids). The momentous ruling in November 2020 by the European Court of Justice (ECJ) on CBD (stating that CBD is not a narcotic and can be traded within the EU) effectively ensured the continuity of the market, and in the absence of comprehensive regulation, the industry continues to grow and develop, but further regulatory changes are required to unlock its full potential.

Transparency

The lack of transparency in terms of European CBD arises from a number of issues, but the most significant are regulatory uncertainty and lack of standardisation. Because there are no clear guidelines or any oversight from regulators, and because there is a lack of awareness and knowledge in the industry due to its recent emergence, there are no agreed terms of definition and it is often difficult to distinguish quality in the case of product and production.

What this means in practice is that buyers cannot always be certain of what they are buying because terms like 'full-spectrum' or 'distillate' can mean different things to different operators. This leads to a breakdown in trust between companies as it is all too easy for a buyer to be misled, intentionally or unintentionally, and ultimately disappointed.

Though the pace of progress is slow at the regulatory level, there are encouraging signs of development from within the industry. The EIHA recently released proposed definitions of terms for concentrated extract products which, if adopted by the industry, would go some way towards solving the issue of standardisation. The growth of testing within the sector also increases transparency around product quality, and raises standards as the practice is adopted across the sector.

Shipping

Shipping CBD products across European borders has significantly risen over the years however it can still be considered a significant 'pain point' in the industry. Due to the lack of education for custom authorities and the scarcity of import guidelines for CBD/hemp products, the industry still faces importation problems with products being seized at borders, especially those from international markets.

The majority of CBD shipments in Europe tend to be small scale shipments (< 10 kilograms) of CBD bulk products. They are primarily handled through standard shipping services such as DHL and UPS etc. These shipments tend to be discreet and are usually not stopped by custom officials, however, there still lies a significant risk that customs may hold the product for several months for inspection before it is released. This has a disruptive impact on the time and costs for European CBD players and the overall supply chain, as the longer products and materials/ingredients are halted the shorter their shelf-life becomes. To mitigate this risk for larger transactions, where a blockage by customs can be financially detrimental, many CBD businesses prefer specialised distribution companies with CBD experience. According to the players interviewed by Prohibition Partners, these experienced CBD distributors and logistic providers hold strong knowledge of the relevant regulations, practice by jurisdiction and CBD friendly entry ports.

Brexit is another factor that has made the trade of CBD across Europe significantly more complicated as importers and exporters need to obtain an Economic Operator Registration and Identification (EORI) Number by the HMRC which has to begin with 'GB'. In addition a complete custom declaration is required and an application submitted for customs freight simplified procedures. It is also advised by Mackrell Solicitors, a UK based law firm that specialises in cannabis laws, that companies should consider appointing a customs agent as well. Thus, post Brexit import/export procedures create additional barriers for the CBD trade between the EU and the UK as they are costly and time consuming.

Genetic Restrictions

As mentioned briefly in the 'Compliance' section of the report, the hemp varieties currently cultivated in the EU for CBD production may only stem from the EU listed varieties and are subject to a THC limit of 0.2%. In late 2021, the European Council announced it would raise the THC limit for industrial hemp to 0.3% in 2023 through the adoption of the new Common Agricultural Policy (CAP). Although this announced increase is positive for the development of the European CBD industry, the slight increase was not received with a lot of positive response as European players felt that it did not create much of an advantage on an international level as federally in the US and Canada the THC limit is already set at 0.3%. The reason many CBD players in Europe and the globe are urging regulators to increase the THC threshold to 1%, is that a higher THC limit broadly translates to higher cannabinoid concentrations in the hemp plant allowing companies to increase the amount of CBD they can yield.

Alongside the minute increase in the THC limit, companies and cultivators are still restricted to the variety of hemp they can grow based on the EU catalogue. This provides little space for CBD producers to use new and innovative varieties of hemp which are more cost and time effective for CBD production. It can take up to five years and be very costly to register a hemp variety in the EU catalogue. Enecta is one of the few European hemp seeds and genetics companies who secured their high CBD and CBG strains, Enectaliana and Enectarol, in the European Plant Variety Database recently. However, for most CBD producers this procedure is not financially feasible and is therefore limited to the official list, resulting in lost potential cost benefits.

European CBD Survey



European CBD Survey

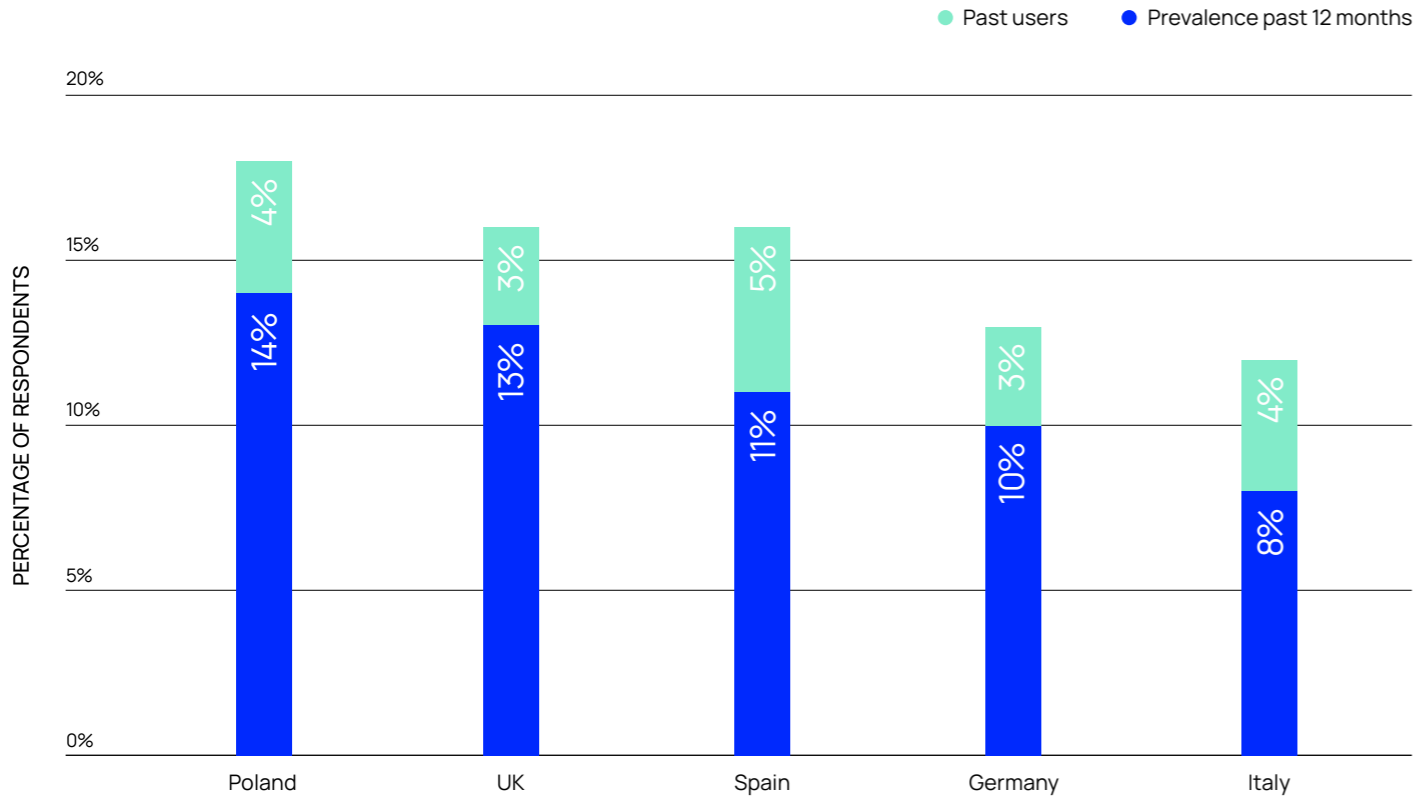
Scope and limits of the European CBD Survey

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 Appendix for the 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 a CBD product in the last 12 months.** An additional 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 people surveyed having at least heard of CBD products. This is being fuelled by better knowledge about the safety and effectiveness of CBD products e.g. for wellness purposes in terms of anxiety, sleep issues and pain conditions. CBD products are also being included in fast-moving consumer goods (FMCG) product portfolios and their availability at mainstream retailers is increasing.

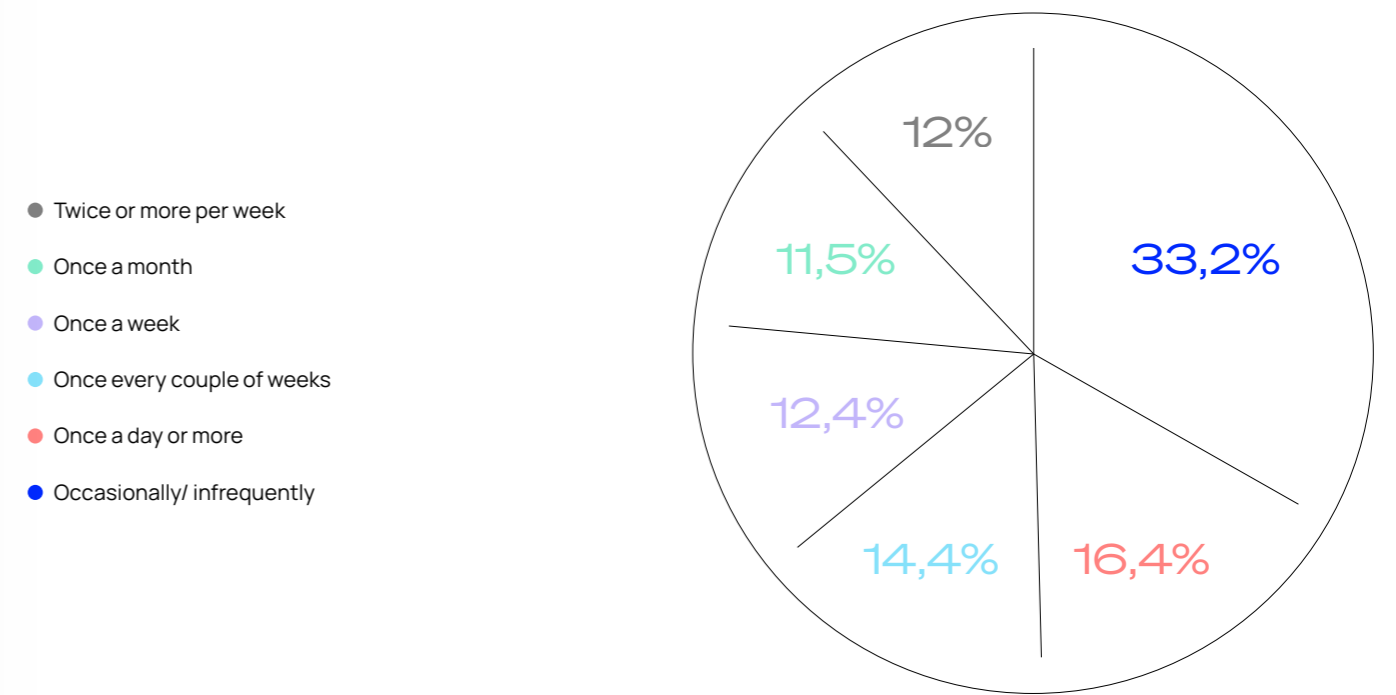
Prevalence of CBD use in Europe



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 because 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 CPG product across most European countries, despite the lack of regulation and any enforcement of laws.

Frequency of CBD use in Europe (n=1056)



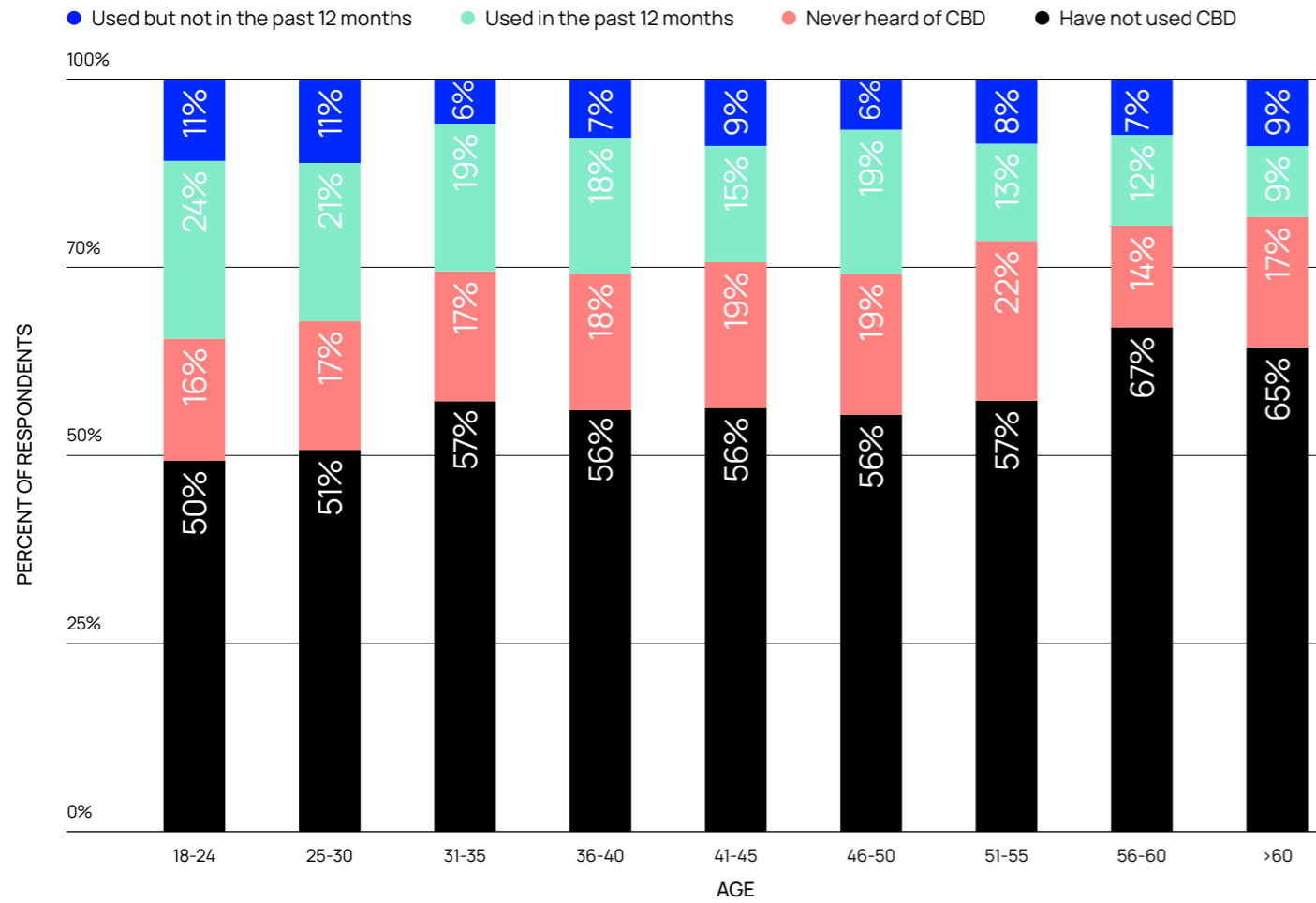
Source: Prohibition Partners, July 2022

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 figure speaks to the volume of people on the continent who are, at least, curious about CBD products and who 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 a portion of the population 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 increasingly open to incorporating these products into their daily lives.

Generational gaps

In general, CBD is more commonly used by the younger generation rather than those aged 50 upwards. This is normal for new industries, where young consumers are more open to trying new products while the older generations can take longer to adopt them. A respondent aged 18-24 in Europe is around twice as likely to report past-year usage of CBD when compared to a respondent in the 50-60 category. In addition, the percentage of people who have heard of CBD is much higher for younger generations, where new trends spread faster, especially those related to wellness. The prevalence of people who have never heard of CBD peaked in the 51-55 age category, while those in the 18-24 category were most 'in the know' about the products.

Prevalence of CBD users in Europe by age



Source: Prohibition Partners, n=955, July 2022

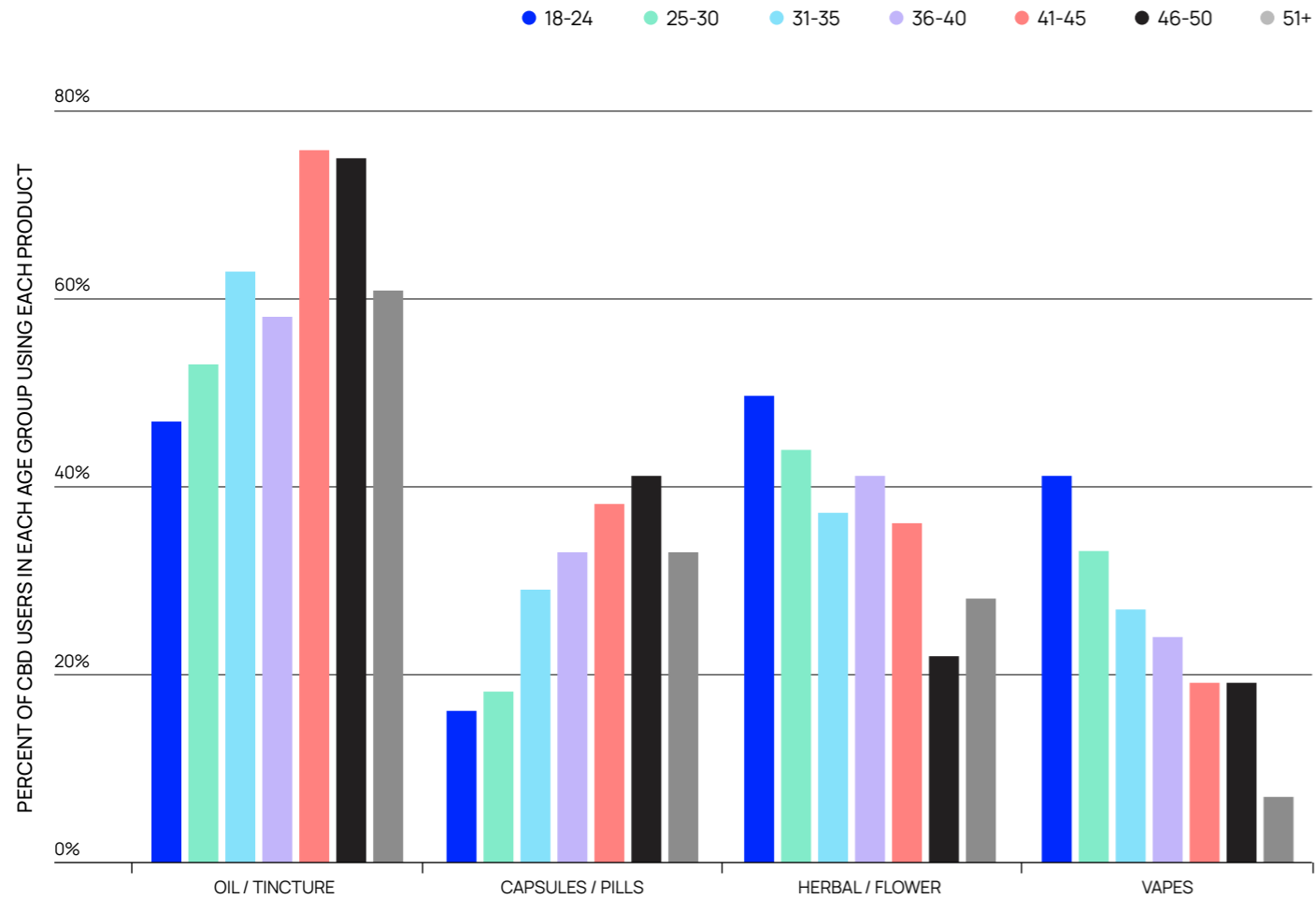
Formats

Prohibition Partners surveyed 955 CBD users on their purchasing habits to understand the current state of the market. Overall, it is clear that oils and tinctures remain the most popular product format, with over 56% of past year CBD consumers reporting some usage of both. This makes sense as oils are a familiar product format in the wellness category. Oils are also easily dosed and are commonly available throughout Europe, partly as legally 'grey' food supplements, but also as cosmetics, which can be used topically but also in some cases ingested like regular CBD oil. Hemp flowers are currently the second most common method of CBD product consumption on the continent, surpassing food and drink formats respectively. As discussed above, CBD flowers are regulated very differently in different countries. In some, like the United Kingdom, CBD flowers are, in theory, not marketable and especially not as a tobacco substitute, whereas in Italy and Spain, more liberal regulations have allowed the 'cannabis light' market to flourish.

The usage of different CBD products varies widely across age groups. The split can generally be traced along the lines of familiar product formats such as oils, capsules and pills more often used by older age groups and the more novel product formats on European shelves such as herbal material, flower, e-cigarettes and vapes used by younger age groups. This can be expected to level out in the coming years. As CBD flowers become a more accepted product format for consumers, and regulators are more easily able to distinguish between legal and illicit products, more shops will begin offering them. The novel and inhalable product formats of flowers and vapes are also expected to be regulated properly in the upcoming updates to tobacco regulations in Europe (see section on the regulation of CBD as a tobacco substitute).



Format of CBD product usage by age group



Source: Prohibition Partners, n=955, July 2022

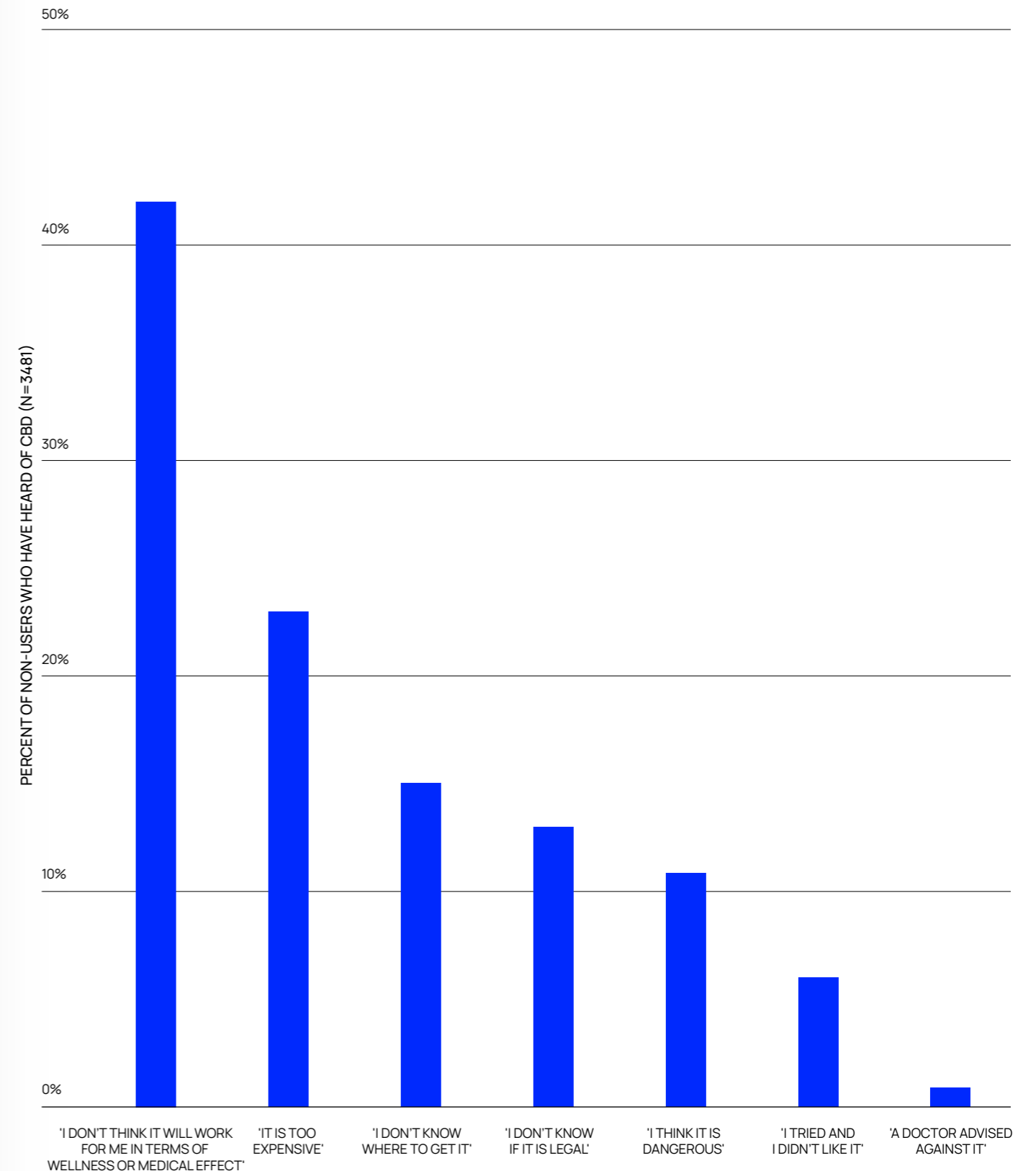
Reasons for non-use

Respondents who indicated that they had heard of CBD, but 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 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 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 in terms of the latest studies on CBD safety and efficacy. These initiatives 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



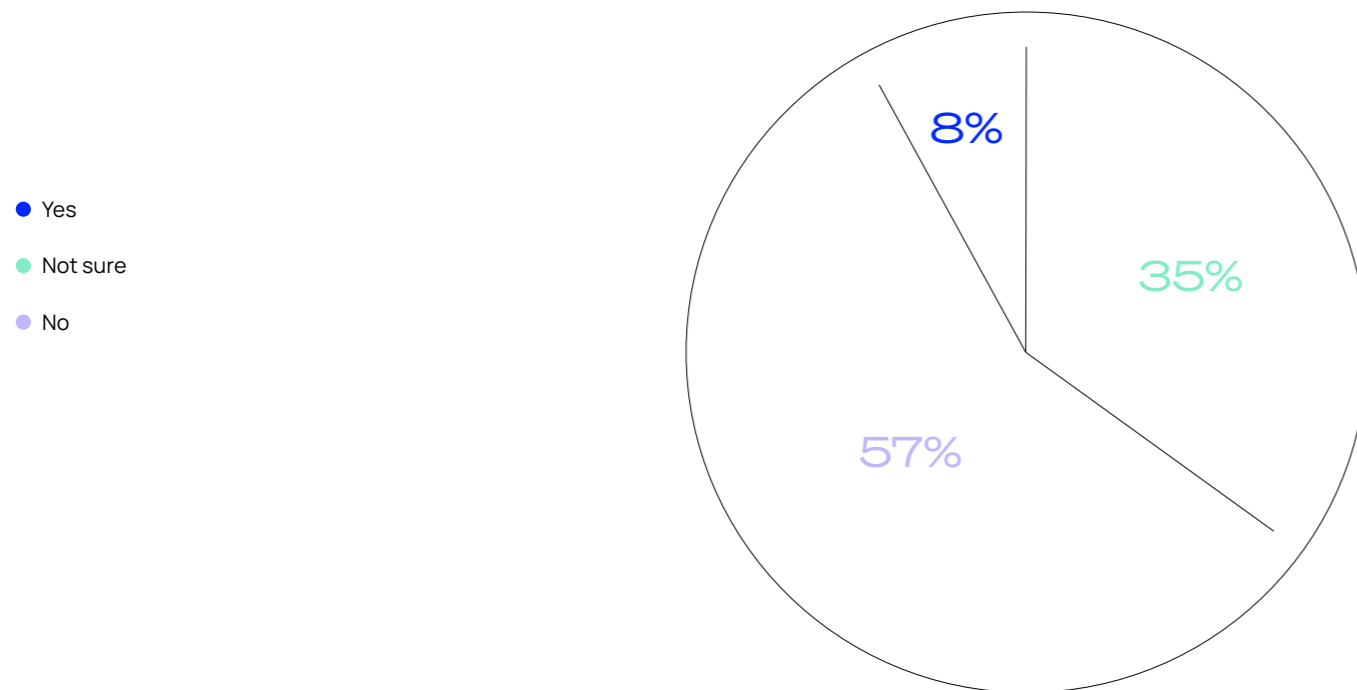
Source: Prohibition Partners, N=3481, July 2022

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 did not consume CBD products in the past 12 months have indicated that

they intend 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.

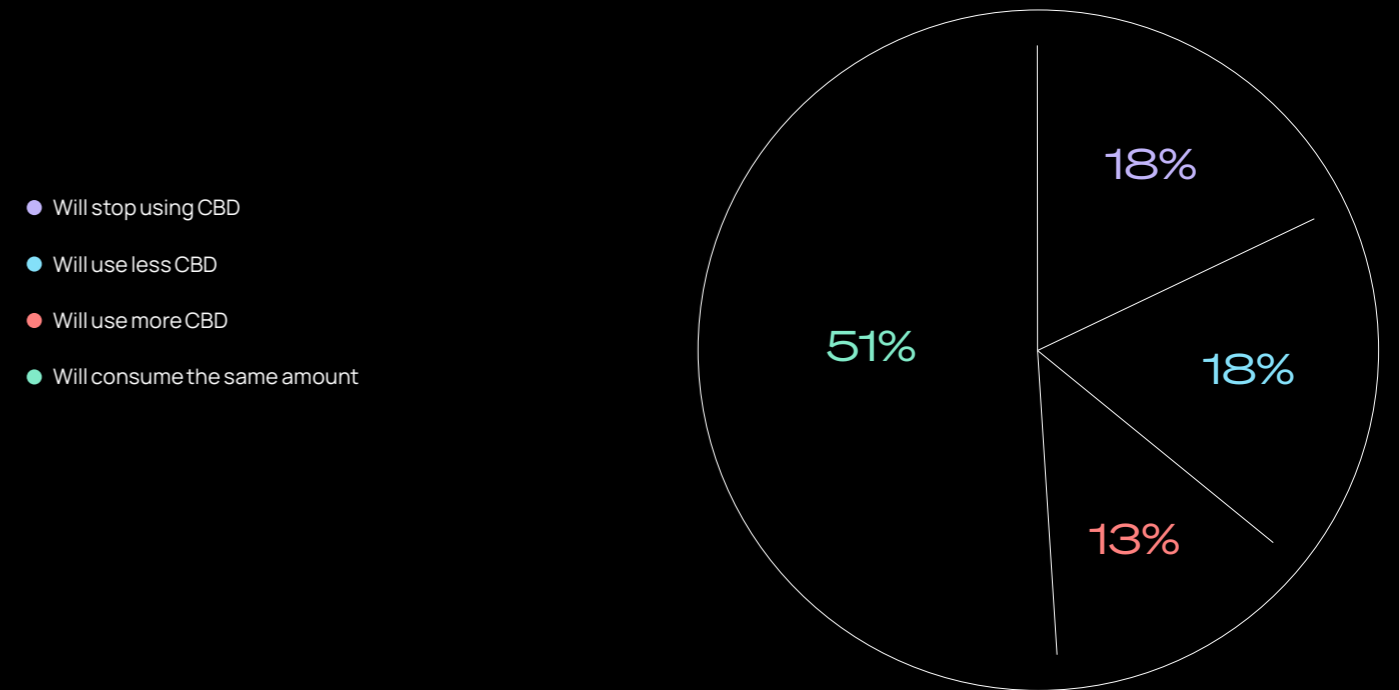
Will non-CBD consumers begin using CBD in the next 12 months?



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

Prohibition Partners also asked current consumers how they felt their consumption would change in the next 12 months. A large number (36%) of consumers indicated that they would reduce or discontinue their use of CBD products over the next 12 months. This high turnover rate is manageable now for the young industry but deserves close attention by operators, as eventually the reliability of revenue generation and a stable consumer base will be necessary to support the industry.

Will CBD consumers continue using in the next 12 months



Source: Prohibition Partners, n=943, July 2022

Overall, while around 36% of the current users consider decreasing or stopping their usage of CBD products, about 64% are willing to use the same amount or more. On top of that there is an 8% of the non-users that are likely to begin using CBD products and 35% that may be potential users for the future. On balance, this means there will be a net inflow of consumers to the European CBD market in the next 12 months. See Prohibition Partners' CBD Market Sizing available alongside this report for more information on how this will look from a financial modelling perspective.

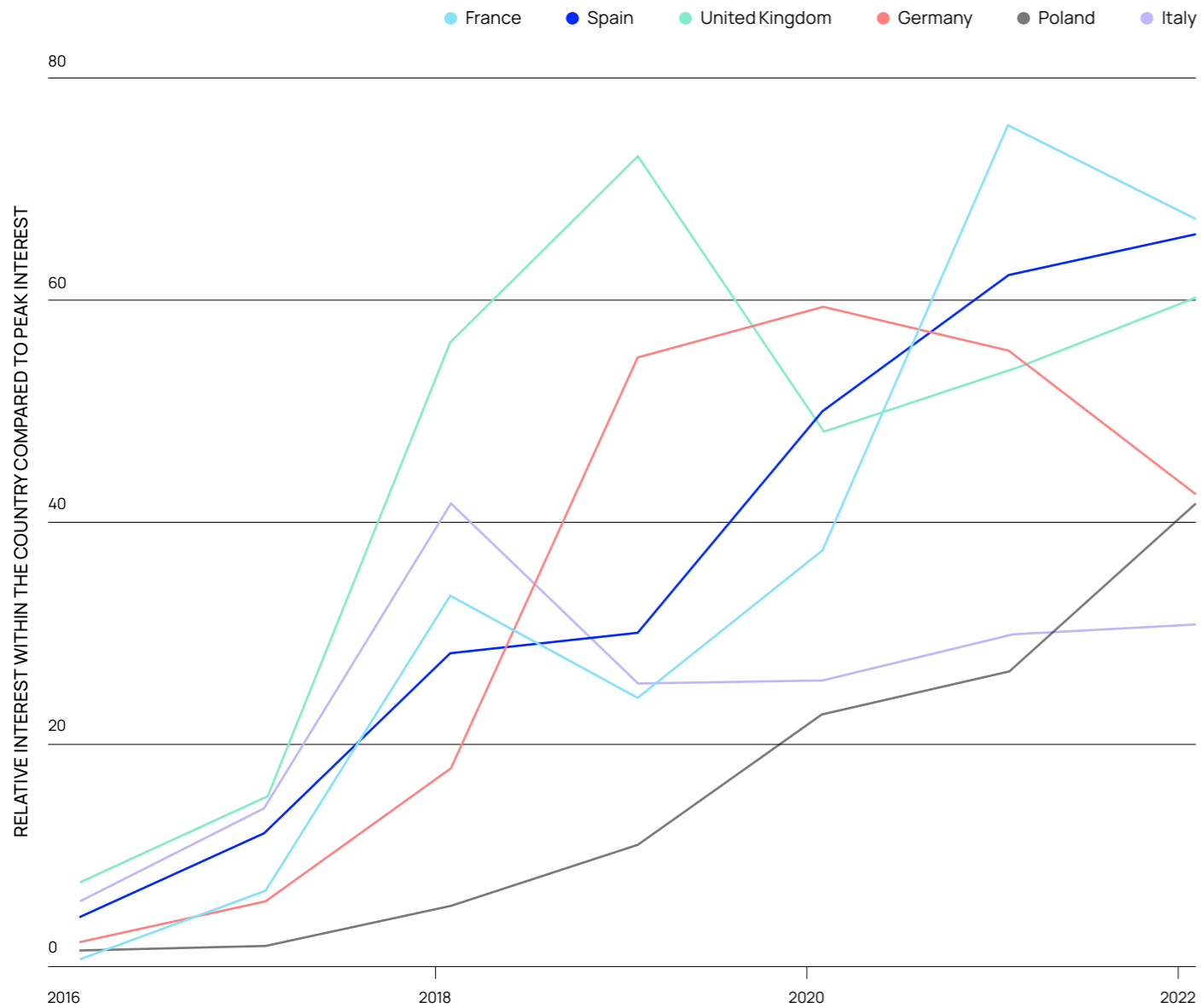
Market development



The CBD market in Europe is still at an early stage, and it is not yet clear in which way it will develop. As it is in large part a 'grey' market, the revenue being generated in CBD in Europe largely goes unreported. In addition, very little data is available on the amount of CBD being bought or traded (owing to a lack of internationally recognised trading codes). Here, we briefly summarise two sources of data which provide a proxy for market development in addition to Prohibition Partners' CBD market sizing data, and the above surveys. As can be seen in the Google Shopping search interest and in the results of the Prohibition Partners' CBD survey, there is clearly a growing interest amongst European consumers in CBD products. However, as shown by the results of public companies, most of the revenue being generated is not supporting large public companies but rather smaller private enterprises. Even then, it seems likely that the majority of companies operating in CBD in Europe are not making profits currently.

Google Shopping trends make search data available from the company's search engine for marketplace products. The results, for any product, ranges from 0-100; representing the periods with the highest and lowest relative search frequency. This is supported by similar results being found when searching for 'CBD oil' or similar products, when using search trends rather than shopping search trends. We have averaged out monthly values over the year to smooth out stochastic values and to make the information clearer.

Search interest in CBD on Google Shopping



Source: Google Shopping, Prohibition Partners, July 2022

As can be seen, there is a general increasing trend in the interest in CBD purchases on Google Shopping across most European countries. Some countries have peaked in recent years, such as Italy and Germany which had their respective peaks in 2018 and 2020 though interest remains strong. Germany is the country showing the largest decrease in average interest in the past three years. This data compares favourably with the same trends seen in the US, where a strong decline in interest in CBD has been registered since 2019.

Public Companies Financials

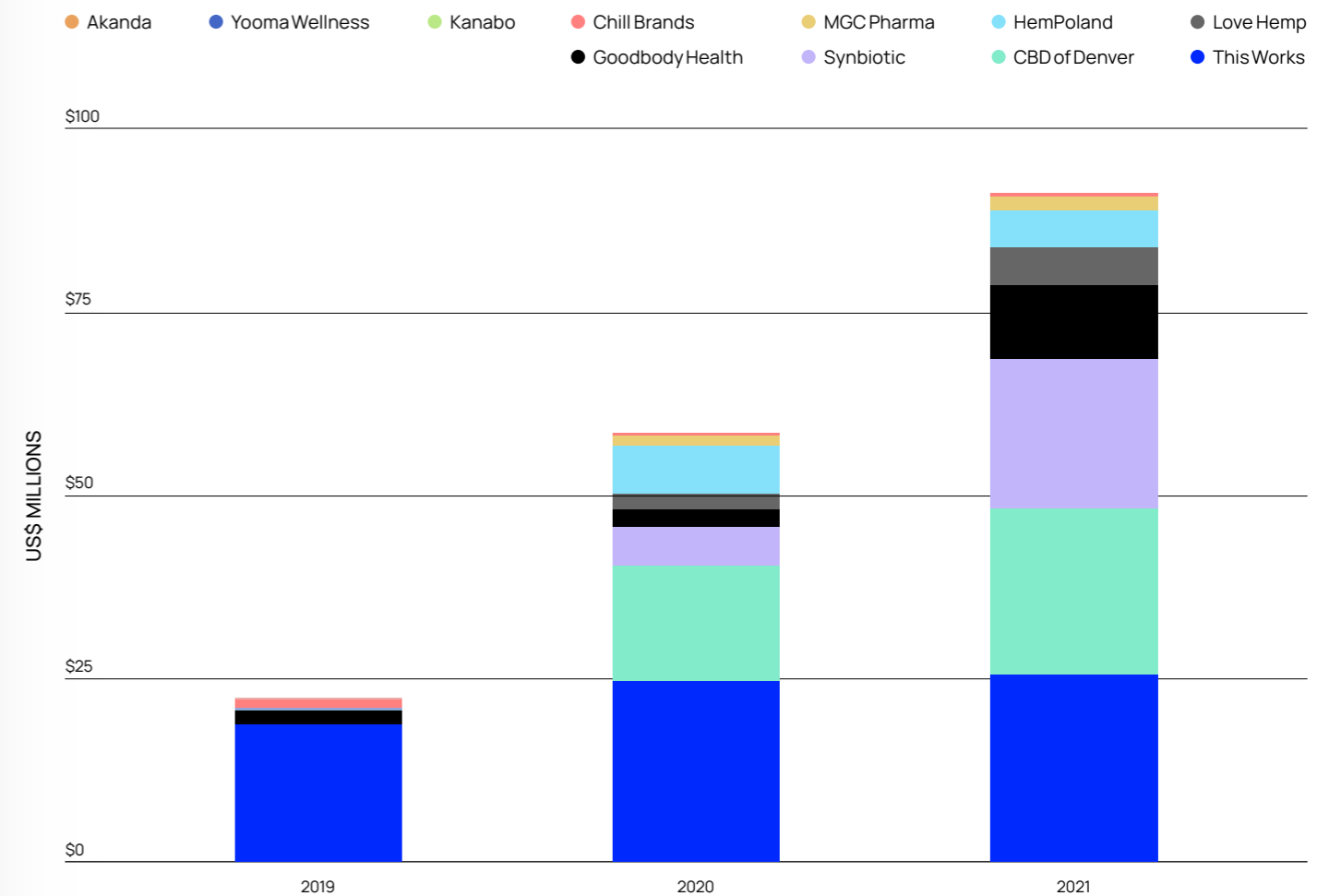
Prohibition Partners carried out a review of the annual financial statements of companies operating in the CBD space in Europe and have found the results to be troubling for those involved in the sector. It should be noted that the companies here operate in a variety of verticals (e.g. medical CBD vs OTC CBD, and for some Europe is not their sole market). As is described above, it is likely that the majority of CBD in Europe is being sold under legally 'grey' circumstances, and the vast majority of revenue is being captured by private companies without any obligation to report to anyone. Even still, the imbalance between the revenue and the cost of sales, as well as other expenses shows that many companies are overstretching in the European CBD space. While it is tempting to think that early arrivals to the market who catch a large part of the share will be the ones to survive consolidation after regulations and enforcement catch up with the industry, the lessons from

the Canadian cannabis sector should be borne in mind. Over investment, across multiple segments of a supply chain, has seen the loss of billions of euro from large Canadian companies. While the scale is much smaller for European CBD companies, the lesson remains the same; if profitability is not emphasised early on, it is likely that the company will not reach profitability as the market matures.

Revenue

The revenue growth for public companies operating in the European CBD sector is relatively healthy. For the period 2020 -2021 (aligned with company fiscal years rather than calendar years), revenue for this group of companies grew by about €32 million, or 56% in total, with an average company Y/Y increase in revenue of 44%. Notably, two of the top three companies for revenue are backed by North American groups.

Total revenue of public companies operating in European CBD



Source: Public companies financial reports, Prohibition Partners.

UK-based 'This Works' is a leading CBD brand in Europe and was acquired by Canopy Growth in 2019 for €50 million. The company saw a slight decline in revenue for the years 2021 and 2022, from €32.6 to €31.6 respectively and accordingly, Canopy Growth has updated its goodwill estimate of the company which took a €13.6 million hit based on updated market predictions. Colorado based CBD of Denver focuses on facilitating market entry into Europe for North American players as well as operating B2B and direct to consumer (D2C) services in Europe. Synbiotic on the other hand, is a German-based company which has subsidiaries in virtually all of the supply chain segments. It should be noted that most companies are making less than €10 million in revenue per year, which speaks to the drastically fragmented market in European CBD, compared to North American cannabis where billions are being made each year. It will be hard for these CBD companies to grow their revenue to this scale before competition for the hundreds, if not thousands of 'grey' market operators are integrated or regulated out of the market.

Separate to these companies who generally operate in OTC and the unlicensed CBD sector, the licensed prescription medicine, Epidiolex, owned by Jazz Pharmaceuticals, earns hundreds of millions of euro of revenue each year, with €30 million earned in Germany in 2021 alone thanks to the full market authorisation the medicine carries, and the insurance reimbursement that comes with this.

Profit

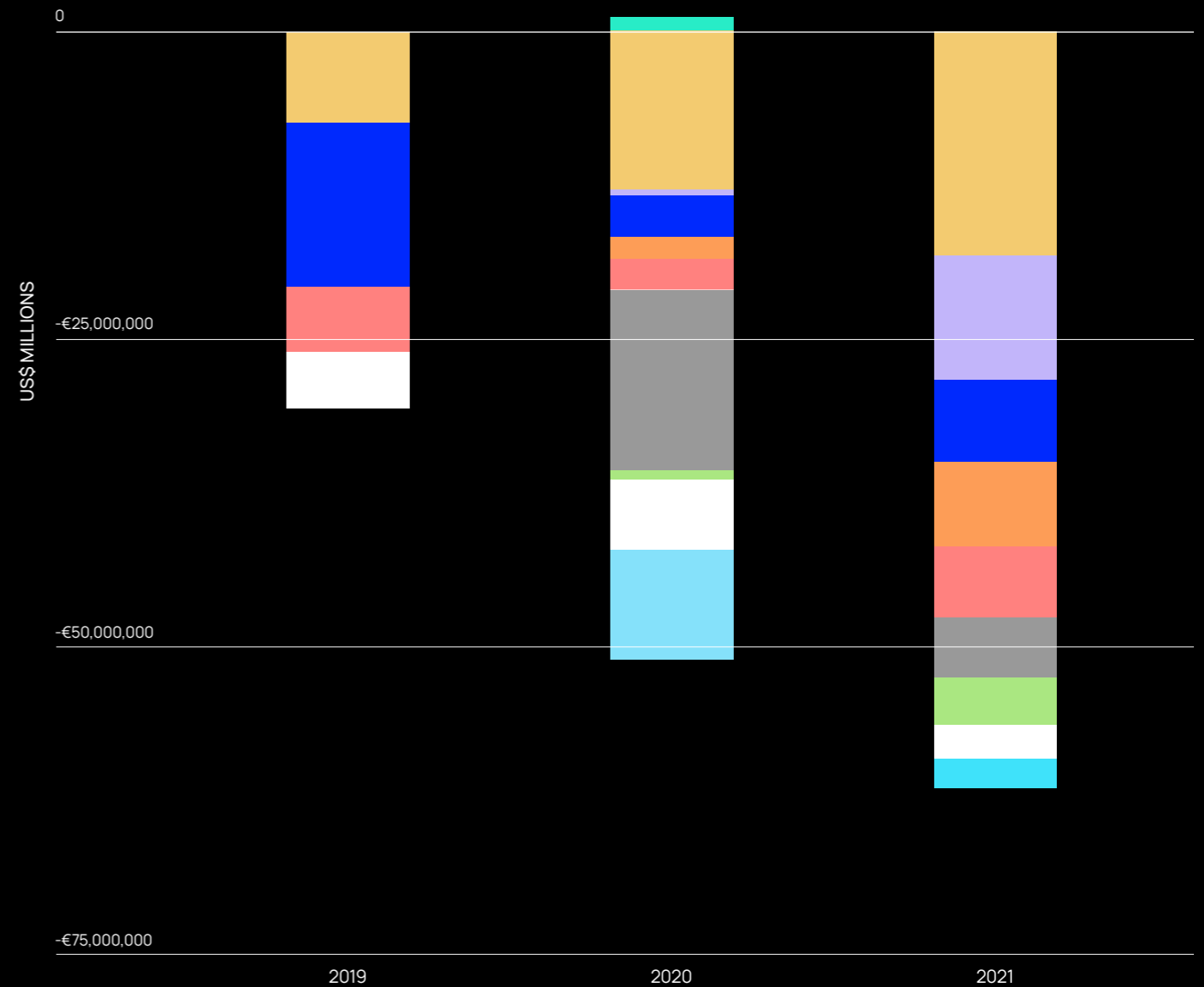
Virtually no public company operating in the European CBD market is making an operating profit as of mid-2022. Indeed, as the number of operators increases and they each increase in size, the losses are mounting. The scale remains small compared to North American markets or even European medical cannabis markets, but still, €10s of millions are being lost before tax by public European CBD companies. This is attributable mostly to the early nature of the market, and the fact that most companies are still fighting for market share before regulations which properly support the industry are in place. In some cases, groups are still setting up in the CBD market. For example, Chill brands finished divesting from a natural resource business in 2021, while Akanda and MGC Pharmaceuticals are focused on developing medical products, with less focus on the CBD OTC market. In particular, MGC Pharmaceuticals are in the process of developing licensed cannabis medicines which by its nature requires companies to post operating losses while research and product development is carried out.

The above group of companies had a combined operating loss of €62 million for 2021 (aligned to the company fiscal year), a 23% increase on 2020. Six companies increased their operating losses, by an average of 400%. Three companies; Love Hemp, HemPoland and Goodbody Health reduced their operating losses, by an average of 65%.

Total operating profit/loss of public companies operating in European OTC CBD

- CBD of Denver
- HemPoland
- Goodbody Health
- Kanabo
- Love Hemp
- Chill Brands
- Akanda
- Futura Medical
- Synbiotic
- MGC Pharma

€25,000,000



Source: Public companies financial reports, Prohibition Partners.

An exception to the above list of companies is CBD of Denver, who have posted small operating profits for the period 2019 to 2021 at €108 thousand, €1.1 million and €220 thousand respectively. CBD of Denver has managed to do this by being an early player in the Swiss market, operating and acquiring businesses that have sold B2B and D2C at high margins. See Interviews section for a discussion with the CEO of CBD of Denver on how they have achieved this and what the company plans to do next.

Insolvency and Divestment

Several large Canadian companies have divested from European CBD in the recent past, though this may have more to do with the downturn for large cannabis companies than the performance of the sector in particular. In 2020, Aurora divested from their hemp cultivation and CBD processing assets in Lithuania for €2.2 million which they acquired in 2018 for \$9.8 million. More recently, The Green Organic Dutchman (TGOD) is selling their subsidiary HemPoland who offer branded products, wholesaling and labelling services and are a leader in the European sector. TGOD acquired HemPoland in 2018 for €7.6 million, with an initial promised investment of €10 million for expansion purposes. The company is now expecting a return of about €7.6 million, a considerable loss on initial investment. While both companies say that this is part of restructuring to focus on core assets, it is obvious that neither subsidiary were making money for their group or the sales would probably not be taking place. Halo Collective Inc., based in Vancouver, sent a letter of intent (LOI) to purchase Swiss CBD producers, Phytocann in early 2022, for up to €100 million based on the company's revenue of €17 million in 2020. The LOI was cancelled in July 2022 based on 'challenging' market conditions in the US where Halo is based.

During 2022, one leader in the European CBD market, Always Pure Organics (APO), after being valued at around €140 million midway through 2021, became insolvent. Not many details have emerged about the cause of insolvency, but APO operated with an aggressive expansion strategy and it is possible that the company failed to reach profitability before investor funds ran out. The fall of such a large leader in the European market should demonstrate very clearly the risks involved in this young and competitive field.

Recent large investments

While some groups are leaving the CBD space in Europe, others are doubling down on this young market. For example, Tilray launched a new CBD brand in the UK called Pollen in early 2022. Pollen will offer its products such as gummies and drink drops on Amazon UK. One of the top selling CBD brands in the world, Charlotte's Web entered the UK market by means of a distribution deal with local group, Savage Cabbage. The company has also made a big statement of intent by placing several applications for Novel Foods in the UK.

Several large transactions took place in 2021. In May 2021, we saw the acquisition of Italy based, Canapar, who are on their way to developing a vertically integrated presence in Europe for €20 million. Canapar have sales contracts for at least €7.7 million per year for several years. In August, Yooma Wellness acquired CBD manufacturers and brand, Vitality CBD, for €11.9 million. Vitality had a H1 2021 revenue of €1.9 million. In October, Canada-based, High Tide, acquired Blessed CBD in the UK who produce and sell CBD both D2C and B2B in the UK, for over €13 million based on revenue of €6 million in 2020.



Summary



In summary, the CBD industry is currently thriving in Europe, serving millions of consumers with a variety of products across the continent, though often under legally 'grey' circumstances. Regulators and law enforcement have a long way to go to catch up with industry practices before fair and uniform rules are established which optimally protect users; thereby offering the highest quality regulated products while supporting the industry that supplies these. Until then, the 'grey' market continues to evolve, with many legitimate operators adopting a policy of self-regulation 'in lieu' of government supervision, though often ignoring the Novel Foods regulations at the EU level. At the same time it should be recognised that the industry suffers from a sub-section of companies operating in bad faith, providing products with mis-reported cannabinoid levels or with the presence of novel synthetic cannabinoids. This threatens the safety of consumers, and less importantly, the reputation of the industry.

Looking forward to the next two to five years, Prohibition Partners expects to see fully legal CBD food products being sold on the shelves of major retailers in every country on the continent. The rules on the marketing of CBD as a tobacco substitute will be updated and CBD flower will be taxed and sold as such, across the whole continent. As these regulations become increasingly enforced, we expect that many smaller operators will be removed from the market, either from an inability to meet the compliance requirements, or by consolidation into larger operators who have the capital to do so. Large online marketplaces like eBay and Amazon will offer a full suite of products for consumers in Europe to order in addition to smaller brand websites. The supply chain is likely to shift somewhat back towards the European producers, as the number of producers in the US gradually declines and the CAP continues to protect farmers from other low-cost areas for cultivation.

This report reviews the state of play in relation to the current laws and regulations, as well as examining the status of the supply chain. This has been done as part of Prohibition Partners' goal of assisting companies to understand where the business opportunities are developing in the CBD industry, which regulations apply and which may apply in the near future. If you would like to understand more about the CBD industry in Europe, see the market sizing information available alongside this report, which examines the financial projections for the market up to 2026. See also Prohibition Partners' other CBD focused reports such as the Impact Series, covering topics such as CBD Foods and Petcare in-depth. The company continues to offer industry-leading insights as part of on-going webinars and events alongside Cannabis Europa. Email Info@ProhibitionPartners if you would like to know more about any of the topics discussed here.

EXPERT INTERVIEWS



Lorenza Romanese

Managing Director
EIHA

The European Industrial Hemp Association (EIHA) is the only pan-European membership organisation in the industrial hemp sector. They are leading the way for the evolution and unification of hemp and CBD regulations in Europe. They are supported by 200+ members, primarily farmers, processors and manufacturers; representing the entire chain from seed to shelf. The EIHA are currently in the process of obtaining approval on a joint application for Novel Foods which their members can then exclusively utilise to bring products to market on the continent.

Tell us about your joint novel foods application.

We have launched the novel foods application for three categories: one for each of isolated CBD, synthetic CBD and full-spectrum CBD. We like full-spectrum the most because we think it holds the most promise for use in wellness settings. Isolated CBD is a special case because we think there is little money left to be made from this substance. The price of isolated CBD has plummeted with the increase in imports from the US over recent years and it is now too competitive a market for healthy margins to be maintained. US operators have much more freedom in their regulatory settings so they can scale their operations easily and for now, outprice EU operators.

The process is going well. The EFSA recently asked the current applicants to fill certain gaps in the data and this will lengthen the time to reach approval for some but we are well prepared.

Were you surprised about the EFSA announcement that they want more data on the safety and efficacy of CBD?

Not at all. When entering the novel foods applications process, there is a standard set of data that you can expect to need before gaining approval. There has been a need for a large scale, standardised study on the safety and toxicity of CBD for some time now. This is part of what the EIHA is doing, investing €3.5 million with our members into a new toxicity screening for CBD and THC. This study will power our novel foods application. When we started our joint novel foods application, we assessed the gaps in the literature around CBD and identified the same ones that the EFSA have now made their announcement about. The FSA in the UK also found similar gaps in the past, no one should be surprised.

Will your toxicity act as a valid source of toxicity data for other companies as well?

No, according to article 26 & 27 of the Novel foods when you create new data by means of new experiments, you have the right to protect it for five years, the so called intellectual property rights. That means we hold a sort of 'patent' on this safety data, no one else can use it. This is important because it is an expensive process to obtain this data, our members have paid a lot and so they deserve to be protected.

What do you think about the gap between the regulation around CBD as a novel food and the industry practice of placing products on the market before gaining approval? Why is CBD already so ubiquitous in Europe?

It should be noted that this is the practice of virtually every CBD company on the continent at the moment, the current patchy regulation and enforcement lends itself to the arising of this 'grey' market which we see in Europe. CBD products have been traded for 15-20 years in Europe, they are an integral part of many people's lives and that is why operators, including EIHA members continue to trade their products while Novel Foods assessments occur. Furthermore, this product really cannot be removed from the market overnight. Law enforcement can shut down in-store sales if they want to. But in the case of online sales, this is impossible for local enforcement to stop.

The FSA in the UK have been better than the EFSA on this issue in that they explicitly allow for the marketing of CBD products while the novel foods process is undertaken. This is much more preferable to the practice of the EFSA.

What will be the impact of the increased levels of THC in hemp in the EU next year according to guidelines in the CAP?

The increase in the limits on hemp production will be significant. It automatically will apply across the entire EU. If individual coun-

tries want to continue getting the subsidies to their farmers and allow them to compete with other EU countries, they will have to allow for the cultivation of hemp varieties with 0.3% THC. If countries want to maintain 0.2%, they will have to prove to the EU why they need to do this, but they will not,, we expect every country to comply with the new limits.

From 1 January 2023, we will have unified maximum limits on the concentration of THC in seed-derived products.

EXPERT INTERVIEWS



Boris Bañas

Co Founder and CSO
CBDepot

Where do you source your hemp? Is there enough supply at the moment?

As most of our production ends up in the pharmaceutical segment, CBDepot is only buying EU-grown, EU-origin hemp certified under principles of GACP (Good Agricultural and Collection Practice). Between suppliers in Europe and importers, there is easily enough supply of extractable biomass.

How much of the CBD in Europe is from hemp cultivated in Europe; can companies here compete with imports from, for example, the USA?

I believe this is a very marginal amount.

2019 brought an unprecedented growth in cultivation in the USA. Massive over-production meant drastic price reduction of imported isolates and distillates. Recently price tags of US-origin CBD hit \$200 per kilo. This has nothing to do with costs of manufacture and means basically no one can make a profit in that vertical.

Most of US production suffers from supposedly illegitimate handling of Intermediate Hemp Products and Waste Hemp Products as seen for example in the highly publicised court case of Hemp Industries Association vs Drug Enforcement Agency (DEA) case which was ruled on in June of this year.

Which products do you see people in Europe using the most?

Oils and distillate remain the most popular choice among consumers in Europe. They are easily dosed and at this point, the most familiar format for CBD products on the continent.

Why do some countries have a more open attitude to hemp than others?

I am not convinced this is an issue of cultural differences between countries.

Rather, it is a function of enforcement of non-compliant products on the national level. These, essentially, are almost all CBD products except cosmetic products having undergone the risk assessment and being listed in the CPNP. We all know foodstuffs and supplements must not contain CBD prior to novel foods authorisation and yet there are many products on the market.

Tobacco Product Directive still recognised only nicotine-containing e-liquids and yet CBD is being sold as incense and tobacco alternatives regularly and some countries enforce the law more than others.

What are the benefits of synthetic vs plant-based CBD and do you see much appetite from operators for synthetic CBD?

There is really no 'technical' advantage of highly purified form over the synthesised option. The legal status of either one is defined by statutory elements in each jurisdiction.

Neither of them are free from harm of the THC element in the first place. While in the isolate we call THC an impurity, in the synthesised product we consider it a synthesis artefact. It then boils down to the level of what 'THC-free' you are selling and to who: while pharma-grade CBD may contain up to 1000 ppm (0.1%) of THC, food or cosmetic regulations for THC are much stricter e.g. at 3 ppm (0.0003%).

Do you consider cold-pressed hemp flower oils as legitimate food items in Europe or do you think regulators will crack down on these?

We consider them legal products but not CBD-specific products. If any hemp derivative is presented as a cannabinoid-specific product and contains CBD beyond contamination levels, then it is a novel food. It does not matter if extraction or other traditional manufacturing methods have been used.

Do you see any threats within the industry at the moment?

Yes, people need to pay more attention to the emergence of novel cannabinoids chemically converted from abundant supply of CBD isolate: such as D10THC, HHC, CBD-O-acetate, H4CBD, etc. These products are being sold and may be harming consumers. In addition, this is not good for the reputation of the industry. Also, some operators are circumventing laws by producing products with <0.3 THC but then spraying them with cocktails of terpenes and cannabinoids before selling to markets. The prevalence of this kind of behaviour is widespread and needs to come under much stricter scrutiny by regulators, in addition to allowing a higher %THC in Europe so operators don't continue these practices.

EXPERT INTERVIEWS



Sanja Bonelli
CEO and Founder
Herbliz

What are the main challenges facing a company like Herbliz at the moment; be it regulatory or from consumer behaviour?

We are still facing many challenges on the regulatory side. CBD is considered a novel food and can only be sold as a cosmetic. The authorities are very strict regarding the declaration, which requires more administration and great attention to detail for us; we cannot use health claims in any way.

For consumers, terms such as cosmetic oral care oil are confusing, as well as not knowing what effect a product may have on their body. Unfortunately, this often results in a poor consumer experience. Legal clarity is needed to ensure standards around product quality and claims so that we can provide the right education and marketing strategy to attract consumers and positively influence any purchase decisions.

From what I understand, you offer both cold-pressed and extract-based (CO2, alcohol, or other) CBD products - is this correct?

At HERBLIZ Berlin we specialise in supercritical CO2 extraction. CO2 extraction, for us, is the more effective variant because all cannabinoids and terpenes can be gently extracted. The obtained extract is a so-called 'Full-Spectrum Extract', which always contains a touch of THC. The THC can be removed either by adding solvents or by the, so-called, 'harmonic' evaporation. This is what we do for our Broad-Spectrum Extract. Having our own manufacturing facility in the heart of Berlin, we also offer white and private label production. Here, of course, customers can choose between cold-pressed and CO2 extraction for their products.

Do you find that cold-pressed products are more accepted by regulators?

First of all I would like to emphasise that we need to distinguish between cold-pressed CBD and cold-pressed hemp seed oils here. The Novel Food Act states that: 'Hemp and related prod-

ucts, such as cold-pressed oils, are not novel because there is evidence that they were consumed before May 1997. This is not the case with CBD extracts.' Cold-pressed CBD is therefore considered a novel food, just like CO2 extracted; the authorities do not distinguish between the two.

That said, I would like to address the two different extraction processes.

Cold-pressing allows oxygen molecules to enter throughout the process. During the process oils diminish in quality when exposed to oxygen, which then shortens their shelf life.

In contrast, CO2 extract is a completely closed system; raw materials are compressed downward by the pressure of CO2 gas and liquid. Unlike the cold-pressed method, the oil is extracted without direct contact with oxygen. Most importantly, supercritical CO2 extraction allows for useful terpenes, flavonoids, etc. to be extracted.

This method also precedes the Novel Food Act and was first used in the 1970s. Nevertheless, the EU determined CBD as a Novel Food, which is why CO2 extracted CBD oils are considered a novel food - even though the final product is a pure concentrated liquid extract that retains all the natural benefits, preserves the best colour, contains low THC levels, and has the longest shelf life possible.

Do you find that customers are more attracted to cold-pressed products over extract-based ones?

Actually, to be honest, I don't think that many customers know the difference.

Still, I would like to point out again that, as described before, the products lose quality during the cold-pressing process, due to the oxygenation.

This is not the case for the CO2 extraction process, which is why this is the best possible process; pure and with the lowest THC content product for the end consumer.

How do you see the evolution of in-store vs online purchases of your products?

In the last two years - due to the COVID-19 pandemic - people have increasingly shopped online, simply because there was no other option. At HERBLIZ, we are seeing this development continue. Our retail sales aren't as close to online sales as they used to be.

Of course, this could also be due to the fact that our online customers are well educated about our products through product pages and information, as well as through our blog. In retail, customers find it more difficult to immediately understand the product and its effect.

Do you find more interest in cosmetics over consumable oils at this point?

Both! In terms of the scale, there is very little willingness by large retailers in Germany to list CBD oils because of the absence of legal clarity. Therefore, there is more interest in cosmetics at the moment. We also have many new customers in the retail sector, which is why the cosmetic products receive a lot of interest. On our website, however, the classic CBD oils and vapes are clearly favourites with our regular customers; but also with our new customers. This is again due to the good information we provide about our products.

How are sales doing in 2022 as compared to other years?

We, at HERBLIZ, fortunately doubled our sales in the first half of this year. Nevertheless, the market is consolidating and we see a general decline in sales. The price of CBD oil is falling and there are many brands and a huge range of products on the market. In this sea of offers, it is difficult for the consumer to know which product is of good quality and which isn't. It is therefore our responsibili-

ty to educate our customers accordingly. Despite the many challenges that the industry is navigating, I do believe that CBD still has significant market and sales potential and that it will recover once we get legal clarity and the consumers can better understand its benefits.

EXPERT INTERVIEWS



Paul Gurney

CEO and Chairman
CBD of Denver

Where is the hemp cultivated for your CBD products and where do you sell most of it?

For us, Switzerland is the only place. The indoor CBD being produced indoors in Switzerland is the best in the world, second to none. We sell the entirety of this product to customers and clients in Switzerland and across Europe.

Your company generally posts operating profits which is in contrast to many public CBD companies in Europe, how do you achieve this?

This sector is not an easy business for anybody. Operators in Switzerland had a great arbitrage opportunity, where companies could make some profits while profits were high and this certainly played to our advantage.

Like all commodities though, eventually growers overproduce and prices come down. This is why it is so important to diversify into areas where you can keep your margin. Since I took over earlier this year, we have been in the process of moving the business into other areas related to CBD. We are now positioning to bring our business closer to the customer, so the digital marketing/retail/distribution end of things.

How is the European CBD market viewed from the States, is the patchwork regulation and implementation of law a big challenge for you?

Regulations are a challenge for everyone in this industry, and compliance must be a key part of everyone's strategy. Even within Europe, the laws can differ between countries and the application of the law can vary from time to time and state to state. It's hard to believe but I don't think the US players really understand that a large market for over-the-counter CBD products actually exists in Europe. Partially this must be because the European CBD market is so different to anything in the US, you really need to be here or have a strong partner here to understand it.

Are you finding more growth in your B2B wholesale or D2C sales?

A combination of both really, the market continues to evolve and clients/consumers are looking to participate with professional firms who can deliver the same quality and standard with every interaction. This is the advantage we bring.



Appendix



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Data collection for survey:

The respondents were recruited via Prolific, a survey platform which consistently returns the highest quality data compared to similar services (Damer et al. 2021). The relatively large sample size and the number of CBD users across Europe who responded to the survey (1056) means the results give a good indication of the behaviour of consumers across the continent as of July 2022. The survey was run in two rounds, one to ascertain prevalence of use and basic behaviours of non/users which 5,234 people completed, with a second round to ascertain more in-depth behaviour of CBD users, which 955 CBD users completed. Samples of less than 400 people were obtained in France and the Netherlands, so while their responses contribute to the European-level inferences, no national-level inferences are drawn. The participants were balanced in each country for gender but not other metrics, meaning the samples are not nationally representative across all demographics.

Acronyms



GC-FID	Gas Chromatography - Flame Ionisation Detection
AOAC	Association of Official Analytical Chemists
ASTM	American Society for Testing and Materials
HPLC	High Performance Liquid Chromatography
ILAC	International Laboratory Accreditation Cooperation
DEA	Drug Enforcement Agency
API	active pharmaceutical ingredient
APO	Always Pure Organics
B2B	business-to-business
CBC	cannabichromene
CBG	cannabigerol
CBN	cannabinol
CBD	cannabidiol
CAP	Common Agricultural Policy
CPG	consumer packaged goods
CosIng	Cosmetic Ingredients
CPNP	cosmetic products notification portal
D2C	direct to consumer
EORI	Economic Operator Registration and Identification
EC	European Commission

ECJ	European Court of Justice
EFSA	European Food Standards Agency
EIHA	European Industrial Hemp Association
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU-GMP	European Union - Good Manufacturing Practice
EU	European Union
FMCG	fast-moving consumer goods
BfArM	Federal Institute for Drugs and Medical Devices
FSAI	Food Safety Authority of Ireland
FSA	Food Standards Agency
GACP	Good Agricultural and Collection Practice
GRAS	Generally Recognised as Safe
BVL	German Federal Office of Consumer Protection and Food Safety
LOI	letter of intent
OTC	over-the-counter
PCBs	polychlorinated biphenyls
PAHs	Polycyclic aromatic hydrocarbons
THC	tetrahydrocannabinol
TGOD	The Green Organic Dutchman
TED	Tobacco Excise Directive
TPD	Tobacco Products Directive
UK	United Kingdom
UNODC	United Nations Single Convention on Narcotic Drugs
US	United States
WHO	World Health Organisation



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