



**BRYAN, GARNIER & CO**

Investment Banking for a Better Future

# EUROPEAN **CANNABIS**

**The making of an industry**





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**An exciting EUR65bn+ opportunity.** Europe is set to become one of the world's largest legal cannabis markets. With a population of 557 million people, Europe (ex. Russia and Ukraine) could present greater market potential than the US (330m) and Canada (38m) combined, where legal cannabis sales are expected to hit EUR32bn and EUR4bn respectively this year. Today, there is barely a legal European cannabis market to speak of, but the total market (99% illegal), is already at EUR65bn.

**Medical cannabis patient numbers on the rise.** All of today's legal European cannabis markets exist firmly within a medical context, but even here, restrictions on indications and accessibility hurdles limit its use by patients and prescribing physicians. The main reason for regulatory bodies' hesitance is the limited hard evidence from clinical research concerning therapeutic benefits given that research has been hindered/prohibited by different international treaties. In order to discover the benefits and adverse effects of medical cannabis use, nearly every European country follow its own path. The results seem to converge towards abolishing restrictive policies. Cannabis appears to be a safe and effective medication for many patients. It shows promise in the treatment of numerous medical problems including pain, insomnia and anxiety. Imminent reviews by regulators are likely to increase the number of indications for which medicinal cannabis is allowed/reimbursed and also to improve access. Specifically this is the case in Germany, Switzerland, Spain and France, while Israel is already on the forefront of medical cannabis research and access. Simultaneously, discussions concerning legalisation of adult-use cannabis seem to remove some of the stigma among physicians and patients. In 2022, the number of medical cannabis patients is estimated at around 280,000 in Europe led by Germany and Israel, which each count for about 40% of the total. By 2027, we expect this to be 1.6m (CAGR of 40%)

**Legalisation of adult-use cannabis becoming a reality.** The increased use of medical cannabis across Europe along with the production and marketing of CBD products, and the domino effect of adult-use legalisation in the United States and Canada has prompted Europeans to see the legalisation of adult-use cannabis from a new perspective. According

to a report published by First Wednesdays, 55% of Europeans support legalisation of adult-use cannabis, while 29% of respondents are interested in trying it. Malta and especially Switzerland already have an adult-use cannabis market. Israel, Portugal, the Netherlands, and Luxembourg are currently considering adult-use reform. And without any doubt, the most meaningful development is in Germany. Germany's federal government is aiming at full-scale legalisation of the domestic cannabis market, and it seems increasingly likely that adult-use cannabis will be legal late 2024. This could pave the way for legalisation in other European countries. Indeed, the way the German government has approached the international legality question is to send its position paper to the European Commission, whereby the European Commission or a member state can comment on "product-related technical regulations". This procedure takes three to six months, depending on the detail of comments, and it is likely that in this period the European Commission and the German government will also discuss their intended "interpretation declaration". The German government has preferred this "interpretation declaration" to the other contracting parties to the international conventions and the international drug control bodies, according to which they could implement the coalition agreement and declare it to be compatible with the purpose and legal requirements of the convention. If the European Commission follows this German pathway, it would establish a blueprint to legalisation of cannabis in the other European countries.

**The temptation that operators cannot resist.** The potential size of a legal European cannabis market is attracting a whole range of companies from established North American operators to VC backed European start-ups. Indeed, companies that secure significant market share in Europe - once the market opens up - will likely become the largest cannabis companies in the world. With a market that is still in its infancy and could already reach revenues of EUR16.7bn in five years' time, the lure of the European cannabis market opportunity is real.



# THE FUTURE OF THE CANNABIS INDUSTRY IN EUROPE

## SECTION 1



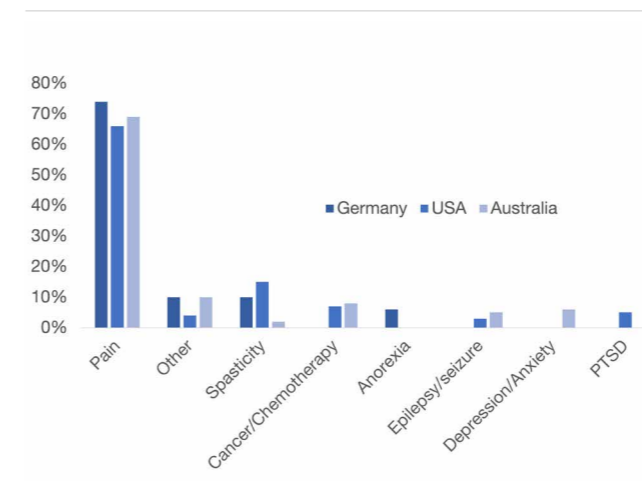
Over the past 20 years, major European countries have started legalising the use of medical cannabis. Israel was the first to make the move. The country has been at the forefront of medical cannabis research since the 1960s and formally legalised medical cannabis in 1999. More than a decade later, in 2013, Italy legalised medicinal cannabis. However, the German legalisation in 2018 is what triggered others to follow, among these the UK in 2018, France in 2021 and Spain in 2022. The trend is growing and imminent reviews by regulatory bodies are likely to increase the number of indications for which medicinal cannabis is allowed/reimbursed, and also improve access (e.g. there

is current discussion about dropping the pre-approval requirement from insurance companies in Germany). Simultaneously, discussions concerning legalisation of adult-use cannabis seem to remove some of the stigma among physicians and patients and with this background we would expect an acceleration in patient numbers. It is also likely that over time there will be some harmonisation of regulations and that the European Medicines Agency will get involved.

Unlike in the US and Canada where adult-use legalisation causes some patients to shift towards this channel, medical cannabis in Europe is likely to be fully covered by health

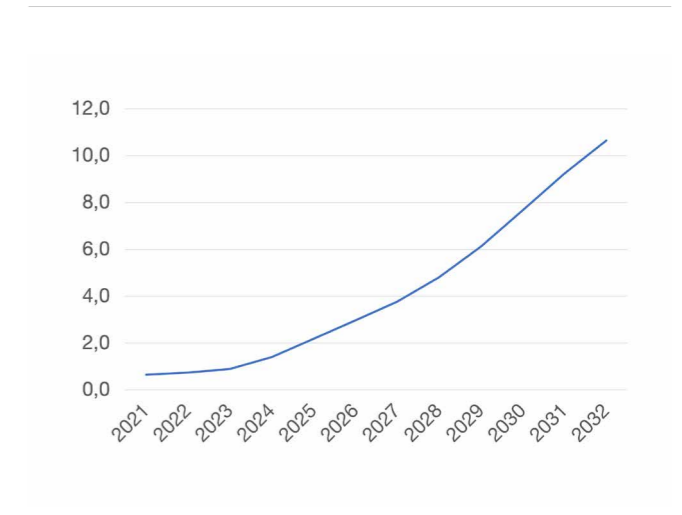
insurance and as such, will remain an important and growing segment. We expect that over time, 1% of the European population (5.6m patients) could be using medical cannabis and that the legal European medical cannabis market could grow to EUR10.7bn in 2032 from EUR0.7bn in 2022. The main conditions that are treated with medical cannabis include pain, anxiety, insomnia and depression, which are all well present in the European population. Chronic pain of moderate to severe intensity occurs in 19% of adult Europeans (106m), anxiety in 5.4% (30m), insomnia in over 10% (55m) and depression in 6.4% (36m).

**FIG 1: CONDITIONS TREATED WITH MEDICAL CANNABIS**



Source: Prohibition Partners

**FIG 2: MEDICAL CANNABIS IN EUROPE (EURBN)**



Source: Bryan, Garnier & Co

Next to the accelerating regulatory changes on medical cannabis use, there are significant regulatory changes on adult-use that are coming about across the continent. Recent progress has notably occurred in Switzerland, the Netherlands and Germany. Since May 2021, Switzerland allows the sale of adult-use cannabis on a trial basis. Local governments, cantons and municipalities, can set up adult-use cannabis pilot projects for up to 5,000 participants (existing cannabis consumers). It is becoming very close to a de facto legalisation. The distribution channel (pharmacies, specialised distribution, social clubs) varies across the different pilot projects, which have already been set up in Basel, Zurich, Geneva combined with Lausanne, and Bern. In the Netherlands, 10 licences have been issued for an adult-use cannabis pilot project to supply 79 “coffee shops” in 10 municipalities.

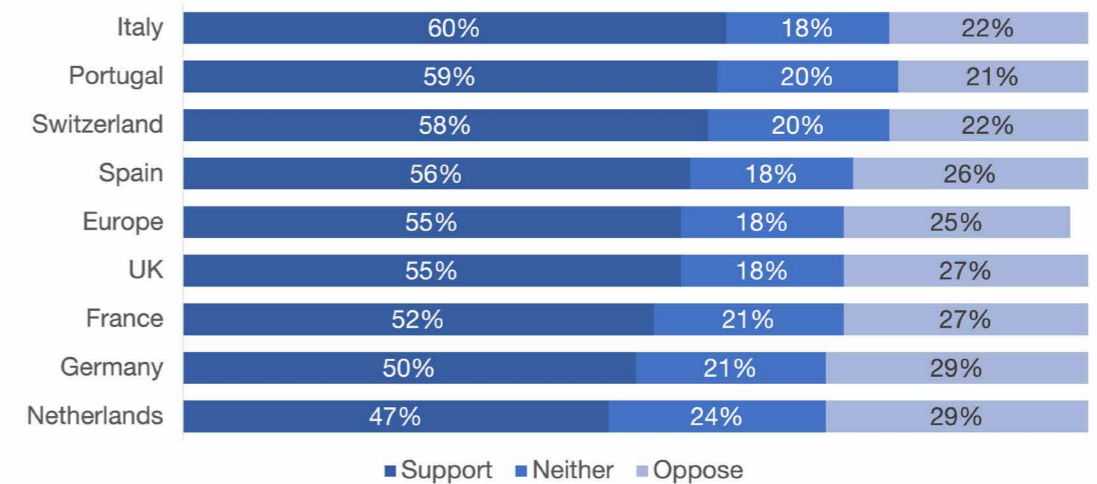
But the most important development is in Germany where the Government coalition of the SPD, Greens and FDP parties are committed to legalising the sale of cannabis for adult-use in specialised, licensed

shops. Technical discussions with national and international experts from the medical and legal fields took place over the summer and a position paper was released at the end of October with a draft bill likely by the first quarter of 2023. Ministers from all parties are continuing to confirm through social media that legalisation is coming and there are indications that the final law could be approved by mid-2023, which could see a legal adult-use market starting in 2024. Nevertheless, there are important legal and production hurdles that need to be solved. The UN Single Convention, the European Council 2004 Framework Decision and the Schengen agreement all require countries to criminalise the production, distribution and sale of cannabis - leaving no leeway to legalise recreational cannabis. The modest recreational cannabis reforms of Luxembourg and Malta (only allowing home growing of cannabis, which is excluded from the European treaties) reflects this. The German proposal is to resolve these international legality questions through and a “notification procedure” for product-related technical regulations to the European Commission and an

“interpretation declaration” for the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, but where it will also require the support of the European Commission. The other key question is how the government who has control of the Bundestag, the first legislative chamber will actually manage to get the law to legalise adult-use cannabis through the Bundesrat, the second legislative chamber, that represents the sixteen federal states. The government has a majority in the Bundestag but the opposition could block or water down legalisation in the Bundesrat. With anticipated legalisation of adult-use cannabis in Germany in 2025, the impact across the European landscape could be significant. Luxembourg, Malta but also Portugal and Switzerland are likely to follow the same time schedule and legal framework as Germany. We assume that a couple of years later (in 2027), in a second wave, countries like the UK, France, and Spain will follow.



**FIG 3: SUPPORT FOR LEGAL, GOVERNMENT-REGULATED SALES OF RECREATIONAL CANNABIS PRODUCTS TO OVER-18S**



Source: First Wednesdays

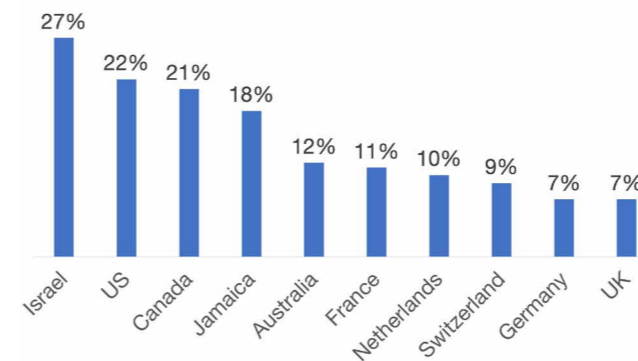
According to a recent First Wednesdays poll, there is majority (55%) support across Europe for legal, government-regulated sales of cannabis products to over-18s. Of the markets that have yet to introduce major cannabis reform, Italy and Portugal stand out as the most supportive of legalisation. Perhaps

unexpectedly, Dutch polling on legalisation is the most pessimistic of the countries surveyed.

The one market that might develop earlier towards adult-use cannabis is Israel, which has already nearly legalised a number of times. The last time this happened was in June

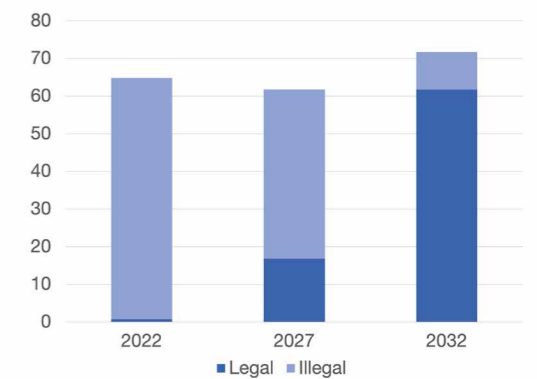
2022, when a proposal was approved by the government’s Ministerial Committee but the dissolution of the Knesset and new elections in October caused another delay. Based on national statistics, 27.0% of adult Israeli’s use cannabis, which is a higher rate than in any other country.

**FIG 4: ANNUAL PREVALENCE OF CANNABIS USE IN POPULATION AGED 15-64**



Source: UNODC

**FIG 5: EUROPEAN CANNABIS MARKET (EURBN)**



Source: Bryan, Garnier & Co

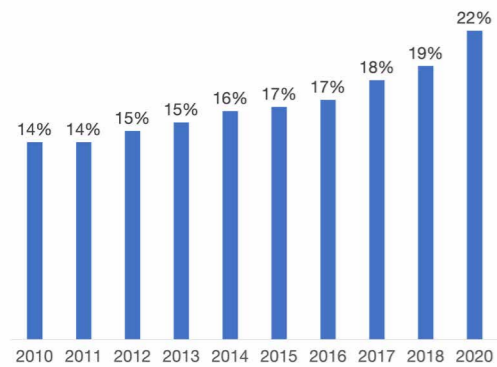


Building on momentum within the European medicinal cannabis market, we expect significant regulatory changes across Europe for adult-use (recreational) cannabis over the coming years with an expectation that the total European cannabis market will be worth EUR13.1bn in five years' time. With a population of 557 million people, Europe

(ex. Russia and Ukraine) presents a greater market potential than that of the US (330m) and Canada (38m) combined. The significant potential of adult-use cannabis in Europe is based on the assumption that nearly one in 10 Europeans use cannabis every year (43.2m). Taking into account growth in the number of cannabis consumers due to legalisation

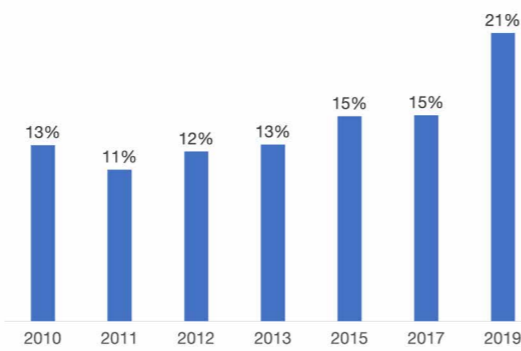
of adult-use, decreasing stigma, ease of access and quality products, the number of consumers is expected to increase to 49.3m by 2027. This trend of increased prevalence in the run-up to and following legalisation has also been seen in the US and Canada.

**FIG 6: US - ANNUAL PREVALENCE OF CANNABIS USE IN POPULATION AGED 15-64**



Source: UNODC

**FIG 7: CANADA - ANNUAL PREVALENCE OF CANNABIS USE IN POPULATION AGED 15-64**



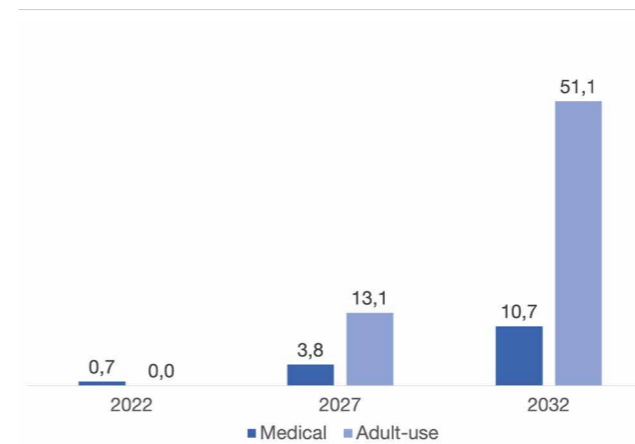
Source: UNODC, CTADS

We estimate annual sales in the European cannabis market in 2022 at nearly EUR65bn, of which 1% (EUR0.7bn) is legal and the remaining 99% illegal. With legalisation developing across the continent, demand is likely to increase, whereas prices are set to decline by about 20% given increased competition for consumers. As a result, the total size of the European cannabis market is likely to decline slightly over the next five years to EUR62bn, but we expect the share of legal cannabis to increase to 27% (EUR17bn). As legalisation gains momentum,

in 10 years' time the overall market could reach EUR72bn, of which 86% (EUR62bn) could be legal. The result is within a flattish overall cannabis market, a booming legal cannabis market to EUR62bn in 2032 from only EUR0.7bn in 2022. Although both medicinal and adult-use are set to drive this legal market size, the share of the adult-use products will quickly overtake the medical market. By 2027, the adult-use market size is expected to reach EUR13.1bn compared to EUR3.8bn for the medical cannabis market.

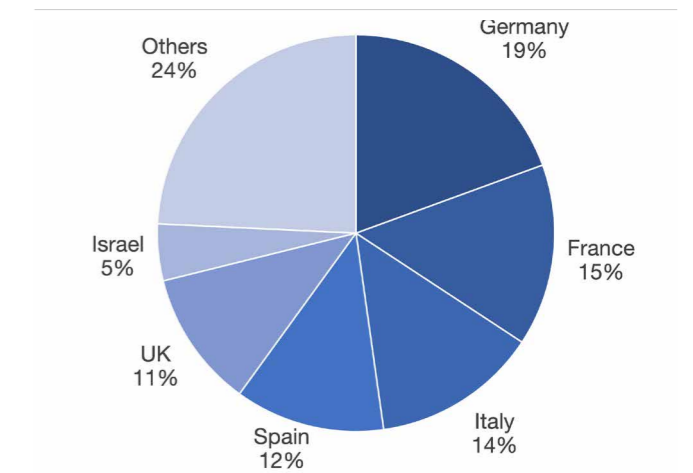
In terms of the main consuming countries, the Top 5 European markets are Germany, France, Italy, Spain and the UK, which together would make up 70% of the overall legal market. The main European producing countries – as it stands today – are Denmark and Portugal with the Netherlands, Germany and Spain having limited own production.

**FIG 8: EUROPEAN LEGAL MEDICAL AND ADULT-USE CANNABIS MARKETS (EURBN)**



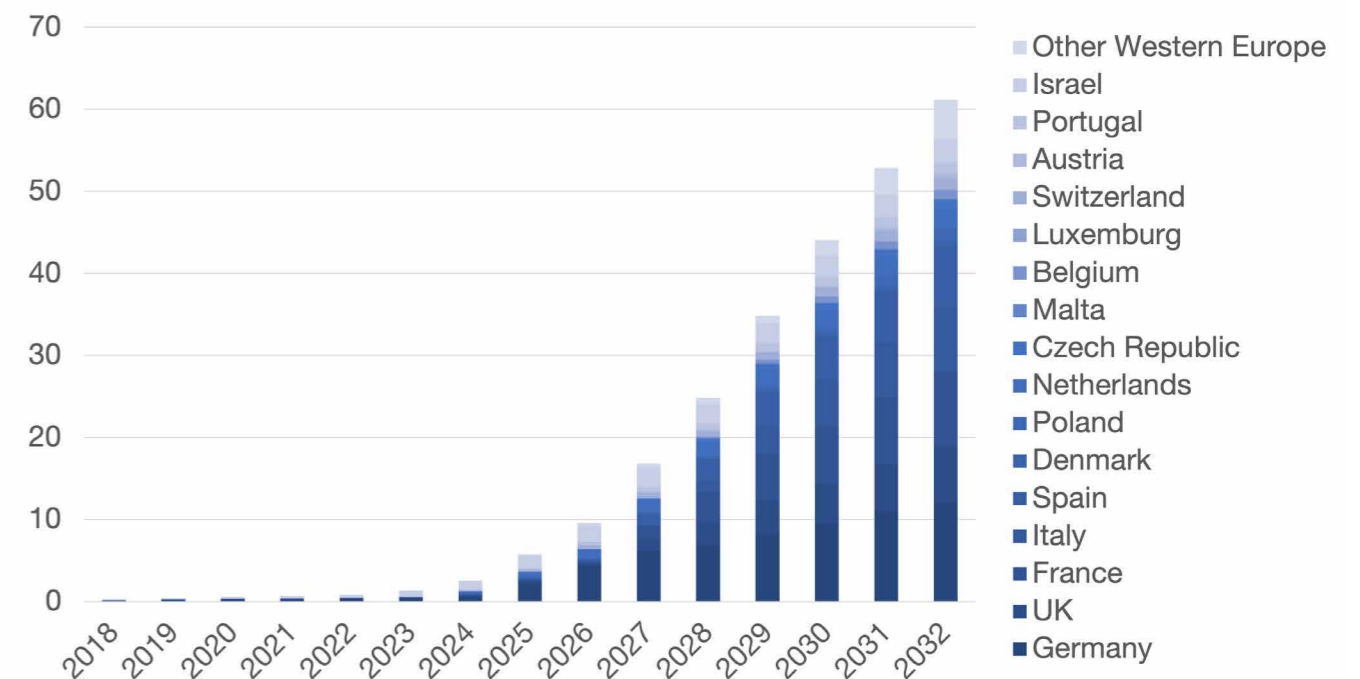
Source: Bryan, Garnier & Co

**FIG 9: MAIN EUROPEAN LEGAL MARKETS 2032 – EUR61.7BN**



Source: Bryan, Garnier & Co

**FIG 10: CHANGE IN THE LEGAL EUROPEAN CANNABIS MARKETS BY COUNTRY (EURBN)**



Source: Bryan, Garnier & Co

## The European CBD market

Although the CBD industry in Europe is still relatively nascent compared to the US, the market is already significant. While there is no industry data on the size of the CBD market, we estimate that in 2021, the CBD industry generated USD770m in sales in Europe, compared with USD4.7bn in the US. The biggest

hurdle for the market to develop is the Novel Food Regulation, which has prevented companies from building a cross-border European business. But as authorisation for CBD novel foods is expected to pass in coming years, the European CBD market could witness exponential growth. Assuming that authorisa-

tions are obtained by 2025, the market size could reach USD2.9bn in 2027. Without these authorisations, the market is expected to grow far more slowly to about USD1.6bn in five years' time.



## Defining hemp CBD

Depending on the taxonomical treatment adopted, the genus “cannabis” (family Cannabaceae) includes up to three species: cannabis sativa, cannabis indica, and cannabis ruderalis. The cannabis plant contains more than 540 phytochemicals, of which 104 cannabinoids have been identified at present. The two most abundant and well-known cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) and these are mostly used to define the

type of cannabis plant or product. Hemp is than generally defined as Cannabis sativa L. plants which contain 0.3% THC or less. Marijuana specifically refers to cannabis products with a substantial amount of THC, the principal psychoactive constituent of cannabis, and that is made from the dried flowers, leaves, stems and seeds of the cannabis plant. Often “cannabis” and “marijuana” are used interchangeably, but they are not exactly the same thing.

CBD is a non-intoxicating cannabinoid derived from the cannabis plant. Most CBD products are made from hemp plants as they contain more CBD and minimal THC. The main difference between hemp CBD and cannabis CBD products is their legal standing.

## Developments in the US market for CBD products

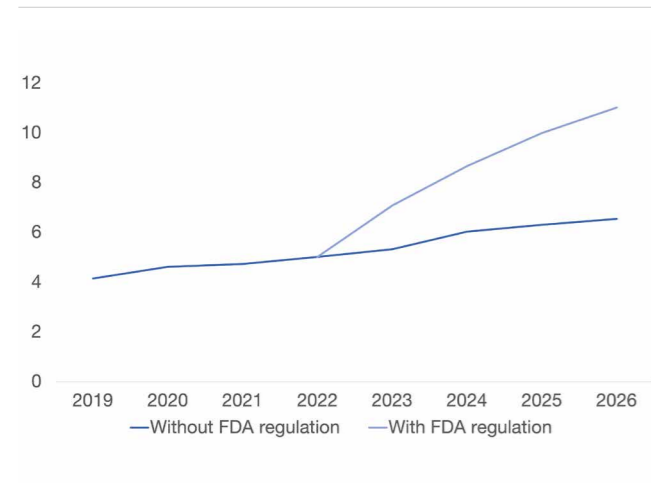
In the US, hemp and hemp-derived products were legalised with the 2018 Farm Bill, removing hemp-derived products from its Schedule I status under the Controlled Substances Act, but the legislation does not legalise CBD generally only CBD derived from hemp. And since then, the US CBD market has grown to USD4.7bn in 2021 (from USD0.6bn in 2018) and is expected to reach USD5.0bn in 2022. The longer-term outlook depends on whether the FDA regulates CBD products. Without regulation, the US CBD market is expected to reach USD6.5bn by 2027 (CAGR 5%) but with regulation the market could reach USD11.0bn within the same time-frame (CAGR 17%).

The issue is that although hemp CBD was legalised in 2018, the Food and Drug Administration (FDA)

and the Federal Trade Commission (FTC) have overlapping enforcement authority over CBD marketing, with the FDA having primary authority over labelling. The FDA has previously issued guidance stating that CBD can be used as an ingredient in cosmetics, but has little else to regulate CBD products. And FDA regulation is necessary because products cannot be considered as a dietary supplement when they contain a substance (such as THC or CBD) that is an active ingredient in an approved drug (in casu Epidiolex), or has been authorised for investigation as a new drug. Therefore, both CBD and THC are excluded from the dietary supplement definition and cannot be sold or marketed as such. Additionally, the FDA argues that it has not enough data yet to determine whether CBD products are safe, while at the same time it has

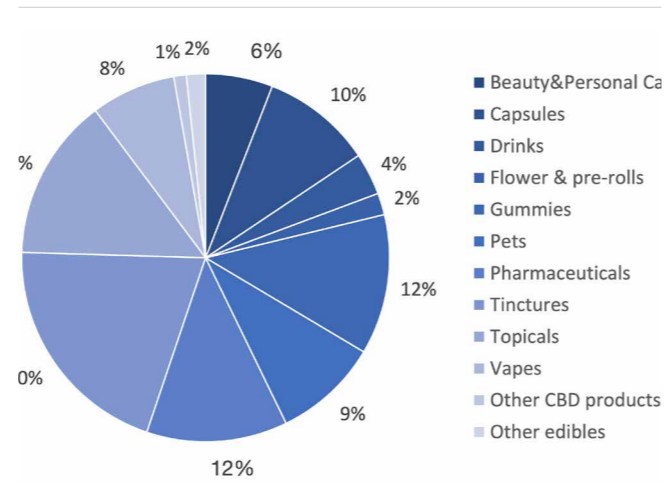
repeatedly discounted industry-funded research on the safety of CBD products as insufficient. Instead, the FDA issues warning letters to CBD companies that fail to heed the agency's labelling requirements and guidance.

**FIG 11: US CBD MARKET SIZE (USD BN)**



Source: Brightfield Group

**FIG 12: US CBD PRODUCTS BY TYPE – 2021 (USD4.7BN)**



Source: Brightfield Group

## A different approach by European regulators

The rapid development of the US hemp and CBD sectors is causing a ripple effect in Europe, where legal hemp cultivation has been taking place for decades, but has traditionally focused more on industrial uses. However, just as the regulation of hemp and CBD in the US varies from state-to-state, differing perceptions of the hemp plant and its derivatives have resulted in divergent market landscapes in the European Union. In the US, hemp is politically and socially associated with marijuana, despite containing negligible amounts of THC and regulation of hemp came after states began legalising medical cannabis. In Europe, CBD is regulated as a derivative of medical cannabis and in most cases the two are not legally distinct or have separate regulations. By contrast hemp is mostly regulated in an industrial context. The hemp CBD market in Europe tends

to act as a gateway or ramp-up into the medical cannabis markets and predates it. The increased interest for hemp CBD is also re-kindling interest in the industrial uses of hemp.

The cultivation, exploitation, marketing and use of CBD are not yet subject to harmonised regulations within the European Union. However, in November 2020, the European Court of Justice ruled that cannabidiol extracted from the cannabis plant should not be considered a drug under the 1961 United Nations Single Convention on Narcotic Drugs. As a consequence, EU Member States cannot, oppose its free movement and marketing, regardless of its form if it has been legally produced by another member state within the EU zone. The raw hemp plant put into circulation must respect a THC concentration of lower than 0.3%. The European Commission

has confirmed this view, but when it is used as a food supplement it falls under the EU Food Safety Regulation that requires EU pre-registration and authorisation for Novel Foods, which are products that have not been consumed in a significant way before May 1997. However, the European directive concerning food supplements, is a framework that offers a margin of appreciation to each member state and hence differences within the EU continue to exist for CBD as a food supplement as well.

In June 2022, the European Food Safety Authority's (EFSA) expert panel on Nutrition, Novel Foods and Food Allergens (NDA) announced that it had already received 19 applications for CBD as a novel food. However, they concluded that there is currently insufficient data on the effect of CBD on the liver, gastrointestinal tract, endocrine system,

nervous system and on people's psychological well-being. The result is that, while waiting for more safety data, it has put on hold CBD novel food evaluations.

Following the novel food change, European companies approached the issue by relabelling their products as "aromatic products". The European Commission has clarified

that the use of hemp-derived CBD is legal in the European Union from February 2021 (when it added cannabidiol to its cosmetic ingredient database CosIng).

## European CBD market size – breaking the USD3bn barrier

Although the CBD industry in Europe is still relatively nascent compared to the US, the market is already significant. There is no industry data about the size of the CBD market and estimates vary widely from USD600m to USD1.3bn, but we estimate that in 2021, the European CBD industry generated USD770m in sales.

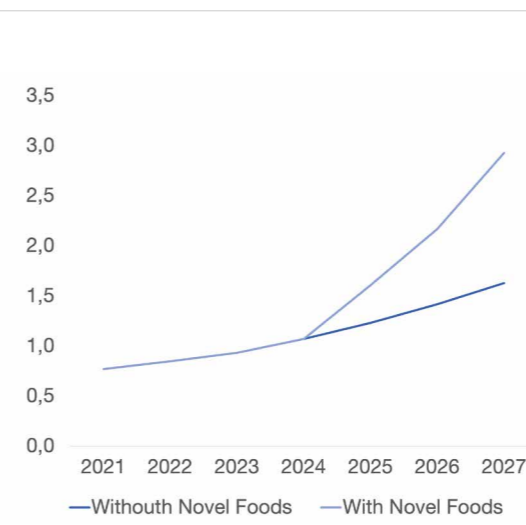
With USD180m in retail sales (for 85% CBD flower) through an extensive network of around 1,700 specialised CBD shops, France is the second largest CBD market in the world, behind the United States, and is the largest in Europe. But in the

UK, with around USD150m of sales - only from tinctures, not flower - the offering is more widespread. In the UK, larger retailers like Holland & Barrett, Boots and also supermarket chains like Tesco and Sainsbury's already store a range of CBD products (including beverages). Even Amazon UK is listing CBD products. But in other countries like Italy, Greece or the Nordic countries, the CBD market is relatively small or non-existent as CBD is part of a medicinal cannabis regulation.

The biggest hurdle for the market to develop is the Novel Food Regula-

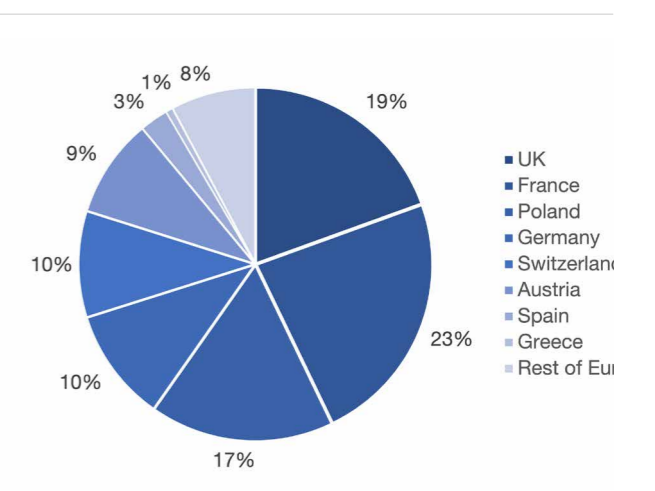
tion, which has prevented companies from building a cross-border European business. But as authorisation for CBD novel foods is expected to pass in the next years, the European CBD market could grow exponentially. Assuming that authorisations are obtained by 2025, the market size could reach USD2.9bn in 2027. Without these authorisations, the market is expected to grow far more slowly to about USD1.6bn in five years' time.

**FIG 13: EUROPE CBD MARKET SIZE (USD BN)**



Source: Bryan, Garnier & Co estimates

**FIG 14: EUROPE CBD MARKET BY COUNTRY – 2021 (USD1.1BN)**



Source: Bryan, Garnier & Co estimates



# THE GERMAN CANNABIS CHALLENGE

## SECTION 2



## Germany's medical cannabis market

Following legalisation in 2017 that allowed and regulated cannabis use for medical treatment, the German medical cannabis market has become the largest in Europe (50% of 2021 sales, ahead of Israel that accounted for 40% of sales). We estimate that in 2021, the number of medical cannabis patients reached 91,000 and the market size EUR325m. However, this is

only 0.14% of the population compared with 0.7% in Canada (where there is already legal adult-use and medical cannabis is not reimbursed except for veterans). With legalisation of adult-use cannabis being discussed and likely to be passed in 2023, medicinal cannabis acceptance amongst patients and physicians as a treatment option should increase while reimbursement by

public health insurance is likely to become a decision for physicians rather than insurance companies. Assuming that medical cannabis is more easily reimbursed (i.e. no pre-approval from health insurers), we expect that by 2027, the medicinal cannabis market could grow to 0.5% of the population or EUR1.4bn (100 tonnes).

## Europe's largest medical cannabis market

In 2017, Germany legalised the use of medical cannabis allowing doctors to prescribe cannabis even if other treatment options are available. Before, medical cannabis was only available to seriously ill patients with a special permit from the Federal Institute for Drugs and Medical Devices that was rarely granted.

There is no data available on the number of cannabis patients, cannabis prescriptions or sales, but we estimate the total number of patients that used medical cannabis in 2021 at around 91,000. These estimates are based on the 9,007kg in sales volumes of cannabis flower recorded by pharmacies, an average consumption of 220g of flower (in Canada consumption per registered patient is 220g p.a.) with this flower representing just over half of total cannabis reimbursements by public health insurance companies.

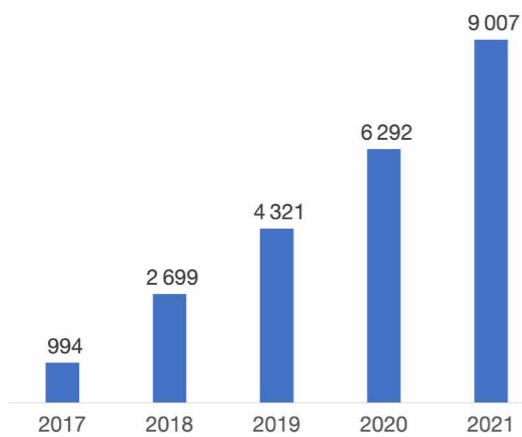
In 2021, public health insurance companies, which cover 90% of

the German population, reimbursed EUR185m in total (+12%) for unlicensed and licensed medical cannabis products, EUR76m (41%) for cannabis flower, EUR63m for oils (34%) and EUR46m (25%) for cannabis-based pharmaceuticals (Canemes, Epidyolex, Sativex). These reimbursement statistics do not include private prescription sales, which are paid out of pocket by patients. Industry participants indicate that these private prescriptions account for about half of the volumes, enabling us to estimate the total medical cannabis market at around EUR325m in 2021. This represents about 50% of the total European medical cannabis market, which is still small compared with overall 2021 US spending on medical cannabis of USD10.8bn according to Grand View Research. In Canada, the medical cannabis market stands at USD350m (but includes about 260,000 patients who pay an average of USD6.16 per gram).

In view of current trends, we expect the German medical cannabis market to grow towards EUR0.4bn in 2022 (EUR40m per quarter from the public health insurance market and EUR60m from the self-care market). Indeed, import data suggests that wholesalers are expecting good growth with 20,566kg of cannabis imported in 2021 (+71% vs 2020), including 5,678kg in Q4, the highest quarter on record. Less than half of these imports made it as flower products on pharmacy shelves, the remainder was used for extracts and dronabinol production, part was lost in the trimming (20-30% loss), but what remained was indeed stocked for growing sales in 2022 (some flower is also sent back as it does not fulfil quality requirements).

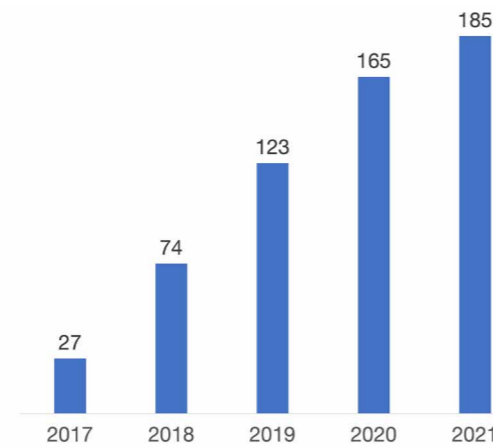


FIG 15: SALES OF MEDICAL CANNABIS TO PHARMACIES IN GERMANY (KG)



Source: Federal Institute for Drugs and Medical Devices

FIG 16: REIMBURSEMENTS TO GERMAN MEDICINAL CANNABIS PATIENTS (EURM)



Source: GKV

## How is the current medical cannabis market organised ?

The supply and demand chain for medical cannabis in Germany starts with the Federal Opium Agency, that regulates the import of medical cannabis, and the Cannabis Agency, that controls its domestic production. Both sit within the Federal Institute for Drugs and Medical Devices

(BfArM). Complementing this federal regulatory regime specific to medicinal cannabis, authorities at the state level quality-test and verify for compliance all drugs, including medical cannabis, imported from outside the EU. Once on the market, medical cannabis is distributed by importers

and wholesalers. The product is delivered through pharmacies to the patient (only on prescription), or as required to processors. Health insurers are expected to cover the cost but have to formally give permission in each case.



## Prescribing medical cannabis and obtaining health insurance approval remains challenging

German medical cannabis rules allow any general practitioner to prescribe cannabis flowers and extracts for any indication where the doctor and patient anticipate potential benefit. However, in order to be reimbursed by health insurance providers, prescribing physicians are obliged to follow a lengthy bureaucratic process that can often discourage them from prescribing medical cannabis, and even when they do this, health insurers still decline 30-40% of cases:

- A permit from the health insurance provider has to be obtained before the first prescription is issued.
- Insurance providers need to make their decisions within three weeks of receiving the application, and can only turn it down if they have strong

justification. If the insurer decides to obtain expert advice, the decision period is extended to five weeks. In the case of a planned prescription in the context of specialised outpatient palliative care, the decision must be made within three days after receipt of the application.

- The maximum amount for prescription for a 30-day period was set at 100 grams of cannabis flower with no restriction on any particular variety.

In September 2022 however, the German Society for Pain Medicine and health insurer AOK began a trial in Rheinland/Hamburg whereby the approval process is simplified, allowing doctors, not insurers, to decide whether a patient can obtain medical cannabis.

Next to reimbursed cannabis prescriptions, patients can opt at any time for a private prescription, where they bear the cost of the drug itself. This self-care market is gaining strength and could be regarded as a precursor to the adult-use market. Nevertheless, still only 1-2% of German physicians are currently prescribing cannabis although there is anecdotal evidence that influenced by the process to legalise adult-use cannabis, the number of prescribing physicians is increasing. In a recent development, one of the major health insurers, Balmer, also stepped into the discussion with a series of educational web pages about cannabis.



## Domestic developments: price reform and domestic production

### Price reforms

Until a year ago, pharmacies were allowed to add a 100% surcharge to the sale of unaltered forms of cannabis flowers because they are defined as an extemporaneous mixture, which means that the pharmacy has to prepare the product according to a prescription. If, for example, the pharmacy bought the medicinal cannabis flowers for EUR10 per gram, the pharmacy was allowed to charge the patient EUR20, and the patient would be reimbursed for EUR20 by their statutory health insurance company. Consequently, pharmacies had little interest in reducing the price of medical cannabis, because the higher the price, the higher their surcharge. This has changed.

### Domestic cultivation

In 2019, in a highly competitive bidding process, BfArM commissioned three companies (Demecan, Tilray, Aurora) to establish domestic production of cannabis flower with high, medium or balanced THC content. The initial total volume that the three could produce was 10.4 tonnes over four years (with provisions for possible increases): one tonne per year each from Aphria (Tilray) and Auro-

ra, and 600kg per year from Demecan. All three are adding domestic production to their wholesaling business, sourcing medical cannabis from Canada, Europe and Australia. However, their domestic harvest will be collected and distributed by Cansativa on behalf of the Cannabis Agency, which will reportedly pay the three producers an average farm gate price of EUR2.20/g (low prices

per additional gram. This reduced somewhat the amount patients are reimbursed, although pharmacies could still charge more and created downward pressure on prices in the supply chain, which was exacerbated by some larger pharmacies that do not charge the full 100% surcharge but limit it to EUR1 per gram for example. This latter system is notably what has allowed a self-care market to develop where “patients” obtain a prescription but cover the cost themselves and as a result are able to buy quality assured cannabis at illegal market prices (EUR7 to EUR12).

were a key criterion in the bidding process). The Agency will sell to pharmacies at a price of EUR4.30/g, taking into account administration costs, but without adding a profit margin for itself. Tilray was the first to deliver domestic cannabis in July 2021.

## Imports: still growing with sources diversifying

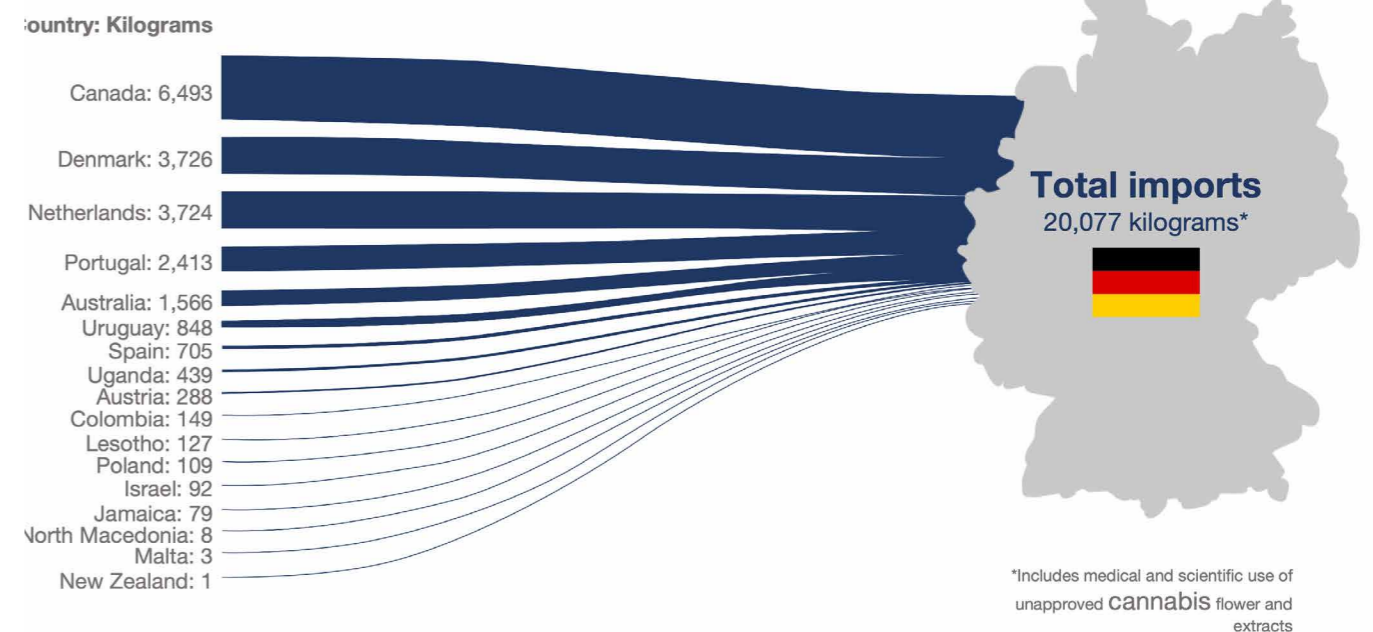
Although there is some domestic production, most demand is met by imports. Initially Germany relied on the Netherlands and Canada to import with well-established medical cannabis companies, such as Dutch group Bedrocan and Canadians Tilray, Canopy Growth, Aurora and Cronos, benefiting from the lack of internal production. However, the number of Canadian providers has since expanded and imports

have diversified to Denmark, Portugal, Australia, Uruguay, Spain and others.

Medical cannabis flower imports increased from 1.2 tonnes in 2017 to 9.4 tonnes in 2020 and to 20.6 tonnes in 2021. There is no overall quota for imported quantities, but importers have to apply for permission to import specific quantities and qualities. Medical cannabis can be

imported from any country that has established a cannabis agency or similar public authority supervising its cultivation. Proof of this has to be provided by the importer by way of a licence or similar document held by the relevant grower. To ensure compliance with the quality requirements for any drug marketed in Germany, exporters also need to work with their importer and seek permission from the relevant state authority.

FIG 17: GERMAN MEDICAL CANNABIS IMPORTS – 2021\*



Source: Germany's Federal Institute for Drugs and Medical Devices, MJBiz



# Recreational cannabis consumption might soon be legal in Germany

## The positives: political commitment and clear timeline

The new coalition government, SPD, FDP and the Greens, that took office in December 2021, wants to go further in the legalisation of cannabis and prior to forming the government, the different parties agreed to legalise the sale of cannabis for recreational use for adults in specialised, licensed shops. Because there was no firm commitment on timing and given the other issues that the coalition needs to deal with (Covid-19, climate change, surging inflation, energy reliability, invasion

of Ukraine, etc), it was assumed that legalisation would be more likely at the end of their four-year term, i.e. 2025.

However, the political consensus proved to be much stronger. Before the summer 2022, politicians from all parties were pressuring the Federal Health Minister Karl Lauterbach (SPD), who promised to prepare the new law over the summer months. Indeed, technical discussions with national and international experts

from the medical and legal fields took place over the summer and a position paper was presented on 26 October by the German health minister Karl Lauterbach with a draft bill likely in the first quarter of 2023. Ministers from all parties continue to confirm through social media that legalisation is in sight and there are indications that the final law could be approved by mid-2023, which could see a legal adult-use market starting in the 2024.

FIG 18: WHAT FEDERAL MINISTERS ARE TWEETING

Justice Minister Marco Buschmann (FDP)	The legalisation of cannabis is coming.
Health Minister Karl Lauterbach (SPD)	We are now accelerating the legalisation process.
Agriculture Minister Cem Özdemir (Greens)	We legalise!
Finance Minister Christian Lindner (FDP)	When would Bubatz be legal? I would say: soon.

Source: Twitter

## Hurdles to overcome: international treaties and the Bundesrat

Important legal and production hurdles and considerations nevertheless need to be tackled:

**Legal framework.** Although there is some German cannabis production (10.4 tonnes over four years) the medical market relies mostly on imports and so will, in all likelihood, the recreational market. While importing cannabis for medical purposes is legal, under current international drug policy agreements, the legality of importing cannabis for recreational use could be challenged - even legalising domestic production and sale of non-medical cannabis would breach a number of international treaties. UN international drug treaties require countries to criminalise the production, distribution and sale of cannabis - leaving no leeway to legalise recreational cannabis. While UN treaty requirements can be breached without direct sanctions, the enforcement and commitment mechanisms are stronger at the EU level and include heightened diplo-

matic pressure and the risk of significant fines. Of particular relevance is a European Council 2004 Framework Decision (2004/757/JHA) requiring that member states make the cultivation, production, distribution, sale, import & export of drugs - including cannabis - a punishable and criminal offence. Personal cultivation, production and possession are explicitly exempted from the scope of the framework, leaving some latitude for European reform in these areas. The Schengen agreement also obliges signees to curtail the illegal export, sale and supply of "narcotic drugs and psychotropic substances, including cannabis".

The modest recreational cannabis reforms of Luxemburg, Malta and Italy reflect this. It is speculated that efforts by Luxembourg to fully legalise recreational cannabis were scaled down after pressure from the French government. However, it is unlikely that Germany would yield to this type of

pressure and would even, on the contrary, spark a full legalisation of cannabis across the EU.

The German proposal is to resolve these international legality questions through a "notification procedure" for product-related technical regulations to the European Commission and an "interpretation declaration" for the UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, but where it will also require the support of the European Commission.

Bundesrat discussions. The other key question is how the government would actually manage to get the law to legalise adult-use cannabis through the Bundesrat. The government has a majority in the Bundestag but the opposition could block or water down legalisation in the Bundesrat.



## The key issues from the position paper by the German Federal Government

On 26 October, the German health minister Karl Lauterbach presented the position paper – approved by the federal cabinet – for legalising production, distribution and sale of limited amounts of cannabis for recreational use. However, before drafting the law, the position paper is sent to the European Commission whereby the European Commission or a member state can comment on “product-related technical regulations”. This procedure takes three to six months, depending on the detail of comments, but it is likely that in this period the European Commission and the German government will also discuss their intended interpretation declaration. The German government has preferred this interpretation declaration to the other contracting parties to the international conventions and the international drug control bodies, according to which they could implement the coalition agreement and declare it to be compatible with the purpose and legal requirements of the convention. And on that, Karl Lauterbach said while the package could be seen as “the most liberal cannabis legalisation project in Europe”, its purpose was to increase, not decrease, public oversight. The proposals would create “the most strictly regulated [cannabis] market in Europe, with the clear objective of decriminalisation and improving protections for young people and public health”. But if the EU Commission does not agree with that, it can initiate infringement proceedings. However, in his presentation

Karl Lauterbach made it clear that if the commission believed that the German model was not compatible with EU law, the government would not try to proceed to legalise cannabis on that basis.

Once the consultation with the European Commission and other member states has been finalised, a draft law will be put in front of German lawmakers in the Bundestag. Hence a draft law would be filed at earliest in the first quarter of 2023, but that approval could take some time with legalisation to take effect some time in 2024. Key provisions in the plan are:

- The plan, would allow adults (18 years and older) to purchase and possess up to 30 grams of cannabis for their own recreational consumption.
- Cultivation would be allowed in indoor and greenhouse facilities “to ensure appropriate quality control.”. According to the health minister, at the moment, the plan is for complete cultivation in Germany, but that is not as such expressed in the position paper.
- Cultivation would be limited to three plants per person and sales will be limited to federally licensed specialised stores and possibly pharmacies and on-line sales. Sales could not take place a store where tobacco or alcohol is also sold.
- Advertising and marketing cannabis products will also be banned, according to the plans.
- There will be no general limit on THC, but the government could

consider a THC limit for products sold to people aged 18-20.

- Under the framework, all ongoing criminal proceedings related to offenses made legal under the reform would be suspended and closed upon implementation.
- Cannabis would be subject to the country’s sales tax, and the plan calls for an additional “cannabis tax.” However, the plan does not specify that number, instead arguing that it should be set at a rate that makes the legal selling price competitive with that of the illegal market.
- Legalisation of cannabis would also include declassifying cannabis for both medical and adult-use purposes. It would no longer be considered a narcotic substance under the nation’s drug laws, which would also facilitate access for Germany’s medical cannabis patients.

## Estimating the potential of a fully legal German cannabis market

In 2022, we estimate the legal medical cannabis market at 21 tonnes (EUR370m) and the illegal adult-use cannabis market in the region of 900 tonnes, which could be valued at EUR9.5bn (assuming an illegal market price between EUR7 and EUR12 per gram). With legalisation of adult-use we expect three main drivers of the legal adult-use market: an increase in cannabis consumers, a gradual overtaking of the illegal

market and a decline in prices. We estimate that the total market potential of the German legal medical and adult-use market is likely to be around 1,500 tonnes (200 tonnes medical and 1,300 tonnes adult-use) and EUR12bn, of which EUR3.0bn medical and EUR9.0bn adult-use.

This is more noteworthy than the often-quoted potential size of 400 tonnes or EUR4bn in revenues cited

in a late 2021 study by Justus Haucap of the Düsseldorf Institute for Competition Economics. According to the same study, legalisation could create 27,000 new jobs and generate EUR4.7bn in tax revenue (EUR1.8bn from a cannabis tax alone), social contributions and saved costs (including policing, courts, and prisons).





## Significant upside to the current medical cannabis market

As the largest medical cannabis market in Europe, we estimate that in 2021, Germany had about 91,000 patients in its programme. This only represents 0.1% of the population compared to 0.7% for Canada. Using Canadian medical patient numbers this would indicate an underserved gap of 500,000 patients. However, we believe that as adult-use cannabis legalises, medical cannabis will also become less stigmatised among physicians and patients and easier to access (there is current discussion about dropping the pre-approval requirement). Assuming that it remains a reimbursed medical product, the number of medical cannabis patients could grow to 1% of the population. In Canada, 1% of the population was registered as a medical cannabis patient in Q3 2019. However, since the majority of the medical cannabis was not reimbursed and prices declined in the legal adult-use market, medical patients were driven to the latter market. Indeed, in total, 6% of the

Canadian population declares that it uses cannabis for medical purposes.

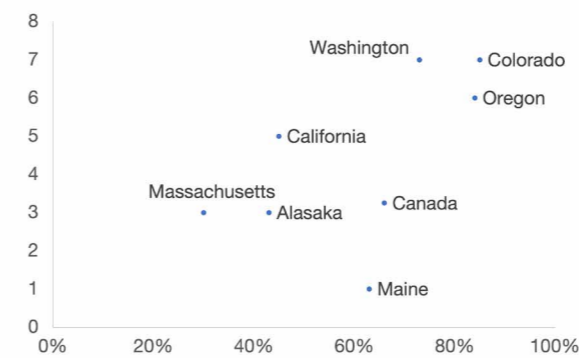
In Germany, at the prevalence rate of 7.1% and assuming the same consumption patterns as in Canada (i.e. an average of 160 gram of equivalent dried cannabis flower per annum per cannabis consumer), we estimate that the current illegal German cannabis market is 950 tonnes or EUR9.5bn at the average EUR10/gram illegal market price. However with legalisation of adult-use, the past 12-month use prevalence of 7.1% is expected to rise. In Canada, the past 12-month use increased to 21% of the population from 12% before legalisation. In California, it increased from 17% just before legalisation to 21% just after. In Germany, an increase of prevalence to 10.7% (+50%!) would result in total demand of 1,500 tonnes of which about 200 tonnes of medical cannabis and 1,300 tonnes of adult-use cannabis. At that prevalence of 10.7% and assuming a 15% decline in the market

price (which was the case in Canada post legalisation) to EUR8.5 per gram, the cannabis market would potential be valued at EUR12.0bn, of which EUR3.0bn medicinal cannabis and EUR9.0bn adult-use.

In Canada it took seven quarters for the legal market to surpass the illegal market and that trend is still continuing, albeit at a somewhat quieter pace (9% gain annually). Three and a half years since the legalisation of adult-use, the legal market now represents 69% of the total market. That is very similar to the trend seen in the US where in most states, it takes over five years for half of the illegal market to be displaced by legal sales. We assume that in Germany, legal cannabis would account for 55% of the total market and that over 10 years the illegal market would disappear. As such we look for a total legal cannabis market by 2027 of EUR6.1bn (EUR1.4 medical cannabis and EUR4.7bn adult-use).

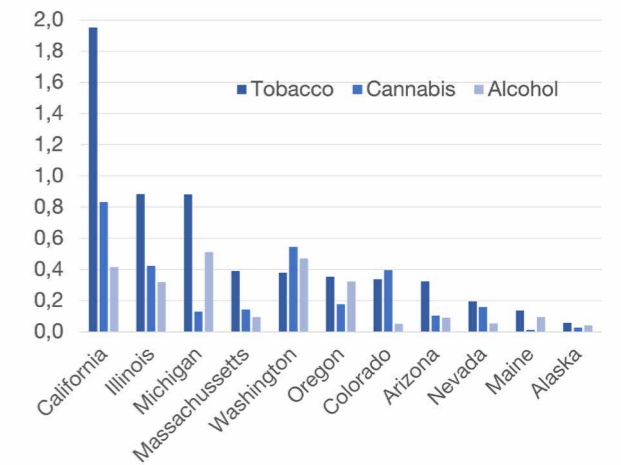


FIG 19: REGULATED CANNABIS SALES AND TIME SINCE ADULT USE LEGALISATION



Source: Office of Cannabis Policy Maine, Statistics Canada

FIG 20: STATE LEVEL "SIN TAX" REVENUE 2021



Source: ITEP

## Factors that can influence the size of the market

The potential of the legal adult-use cannabis market will depend on how consumers access and how pricing is set, more specifically:

**Distribution model.** The coalition agreement of the current German government did mention that a licensed retail system for recreational cannabis would be implemented. Nevertheless, given that today with the self-care medicinal cannabis system (i.e. the non-reimbursed medicinal cannabis), pharmacies do play in this quasi-recreational market, it is likely that pharmacies will also be able to apply for a recreational cannabis retail licence. Other issues concerning distribution are whether there would be a cap on the number of stores and if mail order should be allowed. Different pharmacy associations are vocal on avoiding the prospect of cannabis becoming considered as a luxury

food and emphasise the fact that only pharmacies can guarantee the safety of the product.

**Production and quality insurances.** Another question is whether cannabis for recreational use will have to follow the same quality criteria as medicinal cannabis? For manufacturing medicinal cannabis products, EU-GMP certification is needed. And for cultivation of cannabis to be used for manufacturing, whether domestic or foreign, a GACP (Good Agriculture and Collection Practices) certificate is required.

**Taxes.** In Germany, there is no maximum price for medicinal cannabis, which is sold through pharmacies where prices (including the mark-up for magistral preparations and the 19% VAT) range from EUR7 to EUR20 per gram. In pharmacies that add a modest EUR1 mark-up,

prices tend to be EUR10 to EUR14 per gram but in pharmacies that add the full 100% mark-up the final price to consumer ranges from EUR15 to EUR20 per gram. Producers are selling to pharmacies somewhere between EUR4.50 and EUR10 per gram. Given that current illegal market prices are between EUR7 and EUR10 per gram, retail prices will need to come down to at least that level if the legal market wants to compete with the illegal one. The price can then be divided among producers, wholesalers, retailers and the government. But levying taxes at about EUR4.5 per gram as suggested by Prof. Dr. Haucap of the DICE (or even EUR6.0 per gram as others are suggesting) would leave at best only EUR5.5 per gram for producers and retailers, leaving only a small margin for both or a too high price for the legal cannabis market to compete with the illegal one.

## Insights from Canadian cannabis legalisation

Our estimates for German cannabis market potential are based on the insights learned from the legalisation, consumption patterns and organisation of the Canadian cannabis market. More details are provided further on in this report, but the main points are:

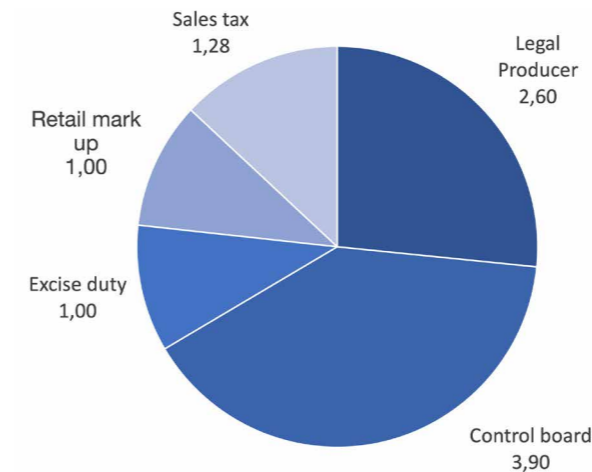
- About half of cannabis consumers use cannabis at least once per week and their consumption accounts for 95% of total cannabis consumption.
- 19% use cannabis daily, accounting for nearly 40% of total cannabis consumption.
- The average amount of cannabis used on a typical use-day is 1.1 grams for those that use dried flower/leaf.
- On average, the 5.5m Canadian cannabis consumers use 926 tonnes of cannabis, representing average consumption of 164 gram p.a. This is very similar to the 1,500 tonnes that the 9.5m Californians use (160 gram p.a.)
- In the run-up to and just after legalisation of recreational cannabis, past-year cannabis use increased to 21% in 2021 (6.4m) from 12% in 2015 (3.6m).
- Legal producers take home only 27% of the price that consumers pay (EUR9.78). Revenue for the government is estimated at 63% of the retail price: taxes (23%) and intermediation of the control boards (40%).
- Cannabis prices have been decreasing both in the run-up to and the years following legalisation due to the high number of licensed producers (776) and inventory (since end 2020 there is 1,000 tonnes of legal

cannabis in inventory while 12-month trailing legal sales are about half of that). With price declines accelerating, current prices are on average CAD9.78 per gram.

- Medical cannabis users with prescriptions declined to 0.7% of the population (from 1.0%) although 6% of the population uses cannabis for medical purposes.
- It took less than two years (seven quarters) before the legal recreational market surpassed the illegal market.
- As of 30 June 2022, the Canada-wide adult-use cannabis store count reached a new high of 3,231, which is around one store for every 2,000 cannabis consumers. With a potential of 6.9m consumers (10% prevalence), there is probably room for 3,500 dispensaries in Germany.
- From an economic perspective, the cannabis industry has been a great success where it has been legalised, and with more to come as the industry grows. In 2021, Canada collected CAD1.1bn (23.3% of sales to consumers) in excise and sales taxes on sales of CAD4.8bn. Similarly in 2021, California collected USD1.3bn in excise, sales and cultivation tax (24.9% of sales to consumers) on taxable sales of USD5.3bn and employed 83,607 in the industry. Furthermore, according to a study by Deloitte, the average direct employment contribution of the cannabis sector over the four years from 2018 to 2021, exceeded 14,000 FTE with the direct and indirect total amounting to 31,000 FTE. Our own estimates are that the

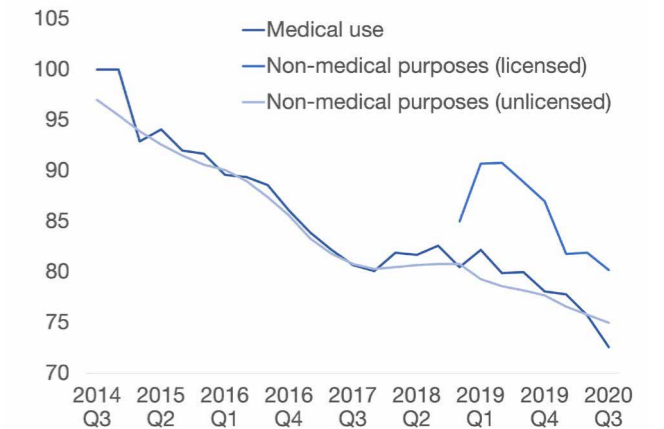
cannabis industry currently employs 18,000 FTE directly, of which 7,800 at LPs, 9,700 at retailers and 500 in logistics. Numbers on the impact of the cannabis industry in the US are similar. In 2021, the 11 US states that allowed legal sales within their borders raised USD3bn in cannabis excise tax revenue, an increase of 33 percent compared to a year earlier and 20% more than alcohol excise taxes and profits (in the case of state-run liquor stores). Cannabis sales tax revenue across the states increased 34% from 2020, totalling more than USD3.7bn according to a recent Marijuana Policy Project (MPP) report. According to Leafly's jobs report, in 2021, the US cannabis industry supported a total of 321,000 jobs, which was expected to increase to 430,000 jobs in 2022 (the overall market size in the US is expected to grow to USD32bn in 2022 from USD25bn in 2021).

FIG 21: RETAIL PRICE BREAKDOWN (CAD9.78)



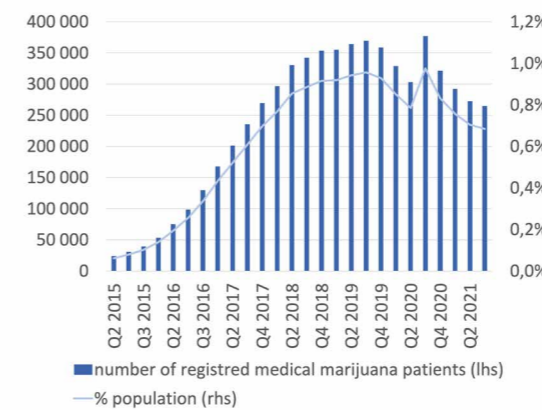
Source: Bryan, Garnier & Co estimates

FIG 22: CANNABIS PRICE INDEX, CANADA



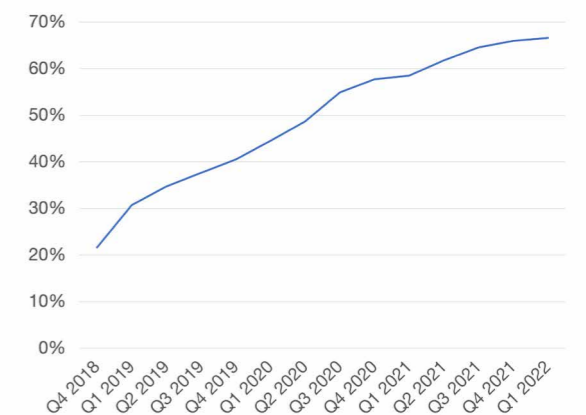
Source: Statistics Canada

FIG 23: QUARTERLY NUMBER OF CANADIAN MEDICAL MARIJUANA PATIENTS AND SHARE OF POPULATION



Source: Health Canada

FIG 24: SHARE OF THE LEGAL CANADIAN CANNABIS MARKET

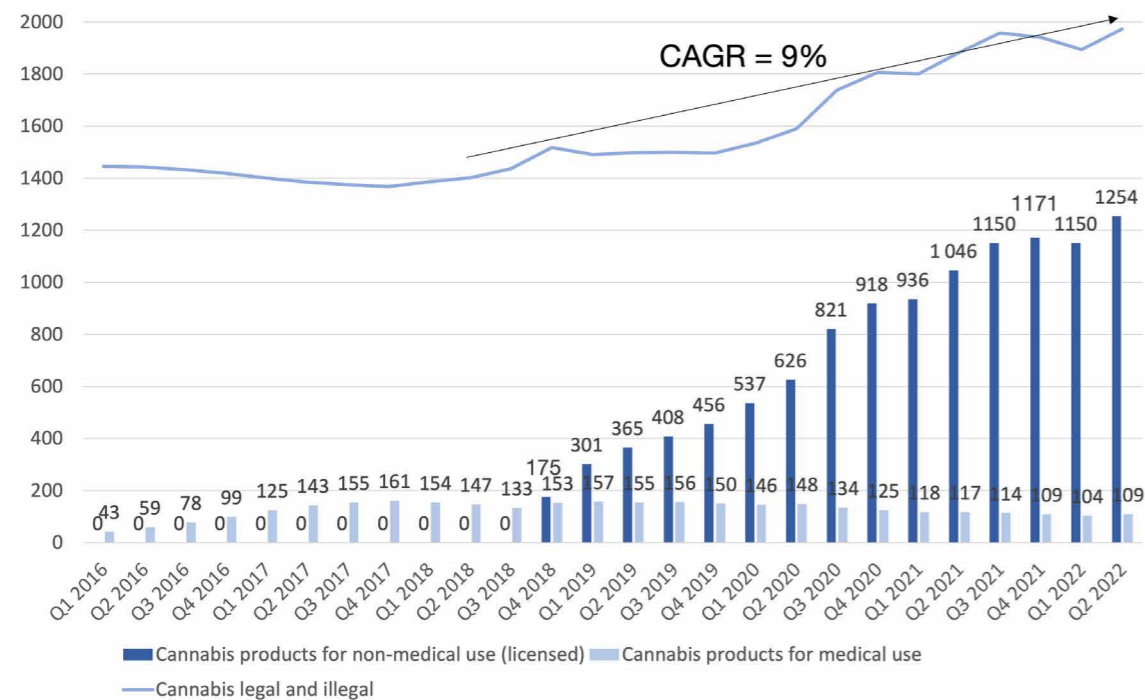


Source: Health Canada





FIG 25: QUARTERLY SPENDING MEDICAL AND ADULT USE (CADM)



Source: Health Canada

## Detailed Canadian survey results

We have used two Canadian studies to guide us in estimating the current and potential size of the German and European cannabis markets. The first study is the Canadian Alcohol and Drugs Survey (CADS) which is published every two years. Some of the key findings about cannabis in the 2019 CADS were the following:

- In 2019, the prevalence of past-year cannabis use (for medical or non-medical purposes) was 21% (6.4 million), an increase compared to 2017 (15% or 4.4 million) and compared to 2015 (12% or 3.6 million). Cannabis was legalised and regulated in 2018.
- 36% (2.3 million) reported cannabis use for medicinal purposes, unchanged from 2017 (37% or 1.6 mil-

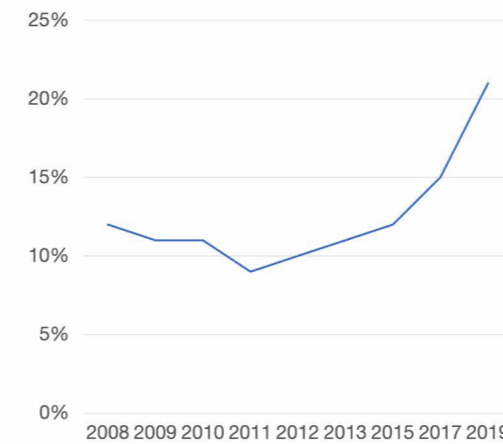
lion). The main medical conditions for which Canadians used cannabis for medical purposes were anxiety (33% or 641,000), arthritis (21% or 416,000), depression (8% or 156,000), and other medical conditions (32% or 623,000).

- The majority (84% or 5.2 million) of those who reported using cannabis in the past year reported using cannabis in the past three months, an increase from 2017 (75% or 3.3 million). Of those who had used cannabis in the past three months, many reported they consumed cannabis on a daily or almost daily basis (27% or 1.4 million, unchanged from 32% or 1 million in 2017). Just over two-thirds (69% or 4.1 million) of those who used cannabis in the past year

reported using cannabis in the past 30 days.

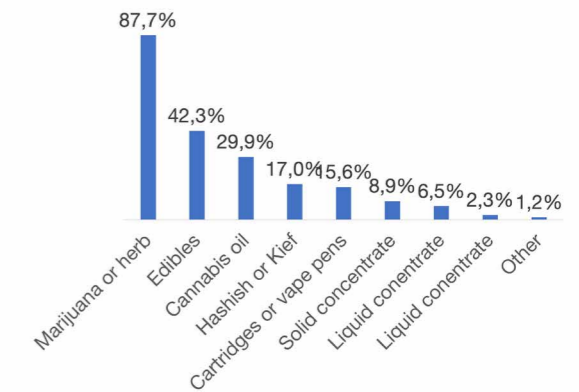
- Canadians reported using a variety of different cannabis products in the past year. Marijuana or herb was the most commonly reported product used (88% or 5.4 million), followed by edibles (42% or 2.6 million), cannabis oil (30% or 1.9 million), hashish or kief (17% or 1.1 million), and cannabis cartridges or disposable vape pens (16% or 965,000). Other cannabis products include solid concentrate, liquid concentrate, liquid (in drinks, such as tea), and other products (all under 10%).

FIG 26: PAST-YEAR CANNABIS USE



Source: CADS 2019

FIG 27: CANNABIS PRODUCTS CONSUMED, 2019



Source: CADS 2019

A second study that we use, specifically to provide a view on consumption frequency and amount, is the Canadian Cannabis Survey developed and implemented by Health Canada:

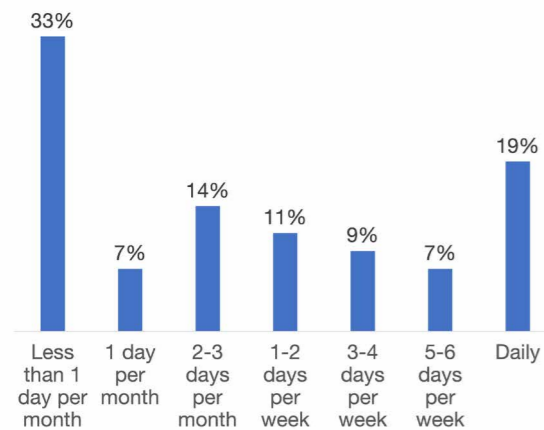
- The latest 2021 survey found that 25% of Canadians reported they had used cannabis (14% for medical and 86% for recreational purposes, with 22% of those using cannabis for medical purposes having a document from a healthcare professional). When recruited, respondents were informed that the survey was about cannabis, which may have created a participation bias with cannabis users possibly more likely to complete the survey. Due to the data collection methodology, the CCS expects that its general population prevalence estimates for cannabis use are higher. Indeed in the 2019 survey, it also recorded a 25% prevalence rate while the CADS survey recorded 21% prevalence.
- Over half (53%) reported using cannabis three days per month or

less, and 19% reported daily cannabis use. Overall, 17% of Canadians aged 16 years and older reported using cannabis in the past 30 days, the average number of days was 14.3. The average amount of cannabis used on a typical use day was 1.1 grams for those that had used dried flower/leaf; 1.3 servings for those that used edible products and 0.8 millilitres for cannabis oil.

- The average price per unit for the more frequently used product types was CAD9.78 per gram of dried flower/leaf and CAD8.32 per serving for edibles, both unchanged from 2020.
- People were also asked to rank which factors most influenced who they usually obtain cannabis from. The three factors with the highest percentage of first priority ranking were price (28%), safe supply (26%) and quality (14%).
- Zooming in on medical use only, the average amount of cannabis used on a typical use-day was 1.7 grams for medical cannabis users

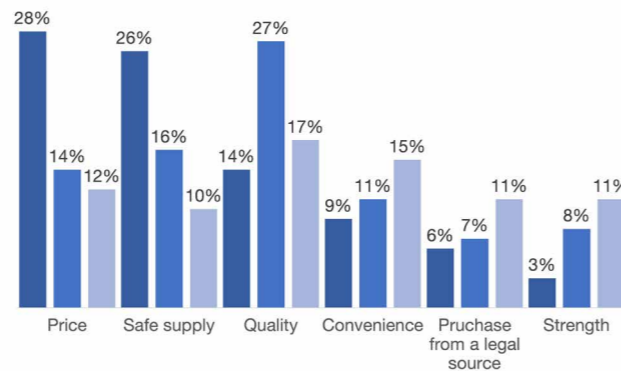
for those that used dried flower/leaf, 1.3 servings for those that used edible products and 1.1 millilitres for cannabis oil. For the more commonly purchased products, the average price per unit was CAD10.32 per gram for dried flower, CAD5.87 per serving for edibles, and CAD13.62 per millilitre for cannabis oil for oral use, all unchanged from 2020.

**FIG 28: FREQUENCY OF CANNABIS USE IN THE PAST 12 MONTHS, 2021**



Source: CCS 2021

**FIG 29: FACTORS THAT MOST INFLUENCED FROM WHOM CANNABIS WAS OBTAINED, AMONG PEOPLE WHO USED CANNABIS IN THE PAST 12 MONTHS, 2021**



Source: CCS 2021

## Cannabis taxes: excise duty and sales tax

Cannabis is subject to the following taxes in Canada:

- **Federal excise duty tax:** The federal government's excise duty on dried cannabis flower is either CAD1 per gram or 10% of the value of the gram, whichever is higher. Excise cannabis tax revenues are split 25/75 between the federal and provincial, local and territorial governments. The excise tax is based on a wholesale price. Indeed, licensees who package cannabis products for sale are required to affix a cannabis excise stamp prior to delivery to a purchaser. Cannabis products

exempt from duty tax include: low-THC cannabis products (less than 0.3% THC), cannabis grown for personal use, and medical cannabis (only available with a prescription).

- **Sales tax:** Canadians pay a sales tax when they purchase most goods and services. Also known as a Value Added Tax (VAT) in some countries, sales taxes in Canada come in various formats. There is the federal sales tax referred to as the Goods and Services Tax (GST). Individual provinces may levy a provincial sales tax (PST) or retail sales tax, and some provinces combine their PST

with the federal GST for a Harmonised Sales Tax (HST). In Quebec, the provincial sales tax is called the Quebec Sales Tax (QST). The sales tax is added to the cost of goods and services and is generally due at the point of sale. The total sales tax varies from 5% to 15%. In the most populous provinces, it is 15% in Quebec, 13% in Ontario, 12% in Alberta and 5% in British Columbia.

## The power of the control boards

Next to the taxes, the organisation of the cannabis retail market through the provincial controls boards further diminishes the amount that legal producers obtain from cannabis sales. Indeed, in 2001, medicinal use of cannabis was legalised in Canada and in October 2018, recreational use became legal. The provinces and territories then became responsible for regulating the sale of adult recreational cannabis in retail and online environments. Most jurisdictions require licensed producers to sell all cannabis products to provincial and territorial control boards, which then sell to consumers online and through their own government-run retail model, a privately run model, or a hybrid of the two. At end-February 2022, there were 3,029 stores in Canada, almost an 85% increase on February 2021, when there were 1,645 stores (with the number rising to 3,162 stores at end-April 2022). While some provinces and territories have experienced no growth, with the number of stores in Prince Edward Is-

land, New Brunswick, Nunavut, and the Northwest Territories remaining constant throughout 2021, and Yukon only recently gaining two new stores in February 2022, other provinces have seen significant growth. Ontario more than tripled its number of cannabis stores, growing from 406 in January 2021 to 1,295 by the end of the year. Saskatchewan and Manitoba doubled their store numbers, respectively from 57 in January to 120 in December 2021, and from 60 in January to 130 in December 2021. Nova Scotia's stores increased by 63% from 22 in January to 36 in December 2021. British Columbia, Quebec, Newfoundland, and Nova Scotia have also all experienced smaller, but notable increases. While some provinces that allow private retail, such as Saskatchewan and Manitoba, seem to be growing at a healthy pace along with the population, the number of stores in Ontario and Alberta has led to questions of saturation. Furthermore, since 8th March 2022, private retailers in Al-

berta can now sell online and these private online sales could prompt an even more competitive cannabis marketplace in the province. Alberta has consistently had a strong store count relative to other provinces, and this has resulted in strong per capita sales figures. Furthermore, in Ontario, farmgate and retail expansion is underway. At least 20 Licensed Producers have already applied for a Retail Operator Licence and two farmgate retail stores are already open for business.

But even in the private retail model, control boards from the provinces have significant market power. Indeed, the control boards of Ontario and Quebec are probably the largest buyers of cannabis in the world and demand much from their suppliers in terms of quantities and price discounts. From the retail price, the control boards take 50-85%.





FIG 30: CANNABIS RETAIL MODELS AND DISTRIBUTION MODES IN THE PROVINCES AND TERRITORIES

	Store count February 2022	Retail model	Physical retail	Online retail
Newfoundland and Labrador	38	Public		x
		Private	x	
Prince Edward Island	4	Public	x	x
		Private		
Nova Scotia	36	Public	x	x
		Private		
New Brunswick	20	Public	x	x
		Private		
Quebec	84	Public	x	x
		Private		
Ontario	1398	Public		x
		Private	x	
Manitoba	149	Public		
		Private	x	x
Saskatchewan	129	Public		
		Private	x	x
Alberta	752	Public		x
		Private	x	
British Columbia	405	Public	x	x
		Private	x	
Yukon	7	Public	x	x
		Private	x	
Northwest Territories	6	Public	x	x
		Private		
Nunavut	1	Public		
		Private		

Source: Statistics Canada

# DETAILED DISCUSSION OF OTHER **EUROPEAN** **MARKETS**

## SECTION 3





Among one of the most developed markets in the region is Israel, which has a long-standing tradition in cannabis research and one of the highest use-rates across the globe. The medicinal market is already well developed in the country and continues to gain strength while at the same time,

## Israel

Israel has a strong tradition in medical cannabis research and its medical cannabis market is larger than the rest of Europe combined. As of August 2022, there were 118,000 patients (1.2% of population) consu-

ing 47 tonnes of cannabis this year. There have been several attempts to legalise adult-use but for various reasons the move continues to be postponed (lately because of the dissolution of the Knesset and

there is a majority in favour of legalising adult-use cannabis. From a consumption perspective, the other important markets are France, Italy, Spain and the UK. Together with Germany, they would make up 70% of the overall legal cannabis market. The main European producing

countries are Denmark and Portugal where government medicinal cannabis is legal but development of their own internal markets is slow and the focus has been on establishing cultivation opportunities. There is also limited cultivation in the Netherlands, Germany and Spain.

the expected election in October 2022). With a prevalence rate of 27%, an adult-use is likely to reach 265 tonnes in the foreseeable future.



## Medical cannabis

Israel has been at the forefront of medical cannabis research since the 1960s, when Hebrew University chemist Raphael Mechoulam first isolated THC, as well the cannabinoid 2-AG and anandamide. Israeli scientists and entrepreneurs continue to develop new strains of cannabis, cultivation methods, such as generating THC-laden cells inside a sterile bioreactor, and medical applications for cannabinoids. The Israeli government formally legalised medical cannabis in 1999.

Medical cannabis permits in Israel are issued by the Medical Cannabis Unit of the Ministry of Health following an application by physicians specialised in the ailment that the patient is looking to treat with cannabis. The medical cannabis programme in Israel requires that patients attempt other medical treatments before cannabis is approved. The following conditions are approved for medical cannabis in Israel:

- Patients undergoing chemotherapy treatment, immuno-therapy or radiology.

- Crohn's disease.
- Ulcerative colitis.
- AIDS (HIV).
- Multiple sclerosis.
- Parkinson's disease.
- Epilepsy.
- Tourette's syndrome.
- Patients being treated in a pain clinic (such as fibromyalgia) and people suffering from post-traumatic stress disorder (PTSD) may be eligible to receive a licence to use cannabis.

The preliminary monthly prescription is for up to 20 grams of flower per month, in which "the concentration of active ingredients is the lowest", but physicians can request to increase the prescription to 30 grams per month and in certain circumstances to 100 grams per month. We estimate that on average in 2021, Israeli patients received 37 grams per month (445 grams per annum). Medical cannabis for licensed patients in Israel is subsidised and cheaper than on the illegal market. The cannabis is sold out of pharmacies and dispensaries or by delivery. The prices can range from about 9

shekels (EUR2.80) per gram to about 40 shekels per gram (EUR12.50). Meanwhile, on the street, cannabis costs anywhere from around EUR10 to more than EUR30 per gram depending on the quality and the quantity ordered.

Medical cannabis consumption in Israel grew to 43 tonnes last year, from 28.5 tonnes in 2020, according to the Health Ministry. Israel's medicinal cannabis market was valued at around EUR264m in 2021, which was the second largest market after Germany (EUR325m) although in terms of patients it was slightly larger. On average in 2021, there were around 96,000 patients (91,000 in Germany) and according to the latest figures, this climbed to 118,000 in August 2022. Despite the numerous Israeli companies producing medical cannabis, Israel imports more than half of its supply (22 tonnes in 2021).





## Adult-use

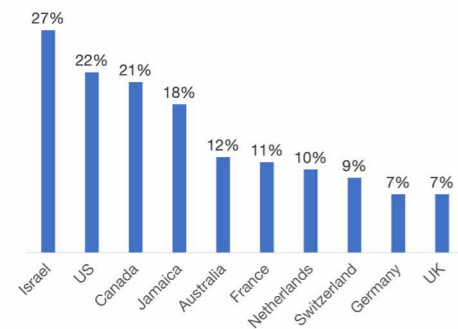
Full scale recreational legalisation has been anticipated for several years, with further decriminalisation in the interim. Cannabis has been semi-decriminalised since 2019, with fines remaining for small-scale possession. In July, 2021, Israeli lawmakers rejected a bill that would have decriminalised recreational cannabis use. The bill had already been approved by the government's Ministerial Committee for Legalisation, and a year earlier, two other bills

to regulate use and sales passed preliminary readings in the Knesset, Israel's parliament. A new proposal containing mostly the same criteria was approved by the government's Ministerial Committee in June 2022 but the dissolution of the Knesset and the expected election for October 2022, is likely to delay legalisation. The proposals would have legalised the sale and purchase of cannabis for personal use for people over the age of 21 in authorised re-

tail stores. In addition, it would have decriminalised possession of up to 50 grams of cannabis and legalised possession of up to 15 grams.

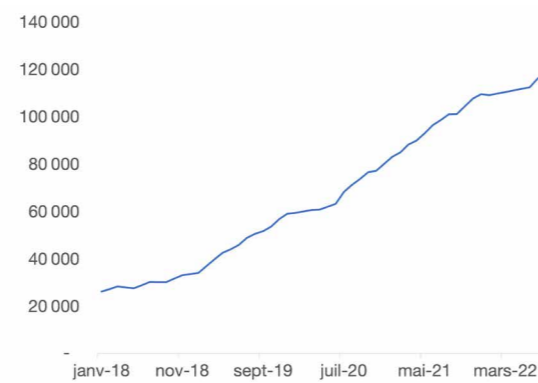
Based on national statistics, 27.0% last year and 19.1% last month, cannabis use (i.e., marijuana and hashish) has been reported among 15–64 year olds. This is a higher rate than levels reported in other countries.

**FIG 31: ANNUAL PREVALENCE OF CANNABIS USE IN POPULATION AGED 15-64**



Source: UNODC

**FIG 32: ISRAEL - NUMBER OF MEDICAL CANNABIS PATIENTS**



Source: Ministry of Health



## CBD

Israel has considered removing CBD from its list of dangerous drugs on several occasions, but the move had never been implemented. Last December, Health Minister Nitzan Horowitz and Health Ministry Director-General Nachman Ash said they were establishing a committee to look into the implications of removing substances or products containing CBD from the list.

On 28th February 2022, the Ministry of Health decided to adopt the recommendations of the special

committee headed by Prof. Shoki Shemer that was appointed for the purpose of examining how to make cannabidiol (CBD) a legal substance in Israel. According to the committee's recommendations, CBD will indeed be excluded from the Dangerous Drugs Ordinance so that the marketing of CBD oil will be possible (similar to how hemp seed oil is marketed). However, the production and marketing of food supplements, food products and cosmetics containing CBD will not be possible for at least another two years, like the marke-

ting of CBD flowers. Only CBD oil, as long as it contains less than 0.3% THC, can be freely marketed. Food products with CBD will be defined as a novel food and will need to undergo a safety assessment by the National Food Service, prior to its approval for marketing in Israel. Although the sale of hemp seeds are illegal in Israel, hemp seed oil is legal because it was explicitly excluded in the Prohibited Drugs Ordinance.

## Switzerland

Switzerland is one of Europe's most well-developed cannabis markets with an expanding medical cannabis segment and a CBD category fuelled by its relatively liberal regulatory framework and a wellness-orientated population with high disposable income. The adult-use cannabis pilot schemes will be influential at both the national and regional levels and create space for a full market to emerge with several long-standing local cannabis players waiting to launch products. The Swiss CBD market is estimated at around EUR75m, but is likely to stabilise in the short term as the legal medical and adult-use cannabis market picks-up.

Whereas until recently, the medical cannabis market was strictly regu-

lated and limited to about 3,000 patients, since 1st August 2022, treating physicians can decide whether to prescribe cannabis without being limited to a list of indications. Medical cannabis can be imported or grown domestically. We expect the Swiss medical cannabis market to represent 20 tonnes over time. Along with opening access to medical cannabis, local governments can set up pilot projects for adult-use cannabis, which comes very close to a de facto legalisation of adult use cannabis. All cantons and municipalities can set up a project that can include up to 5,000 participants (existing cannabis consumers) for each project. These pilot projects are not only set up to use pharmacies as their distribution channel, but other formats are emerging and

include specialised retail outlets or social clubs. Important is that those pilot projects also help the Swiss regulators to develop additional adult-use legalisation. For pilot projects, the cannabis products that are used need to be of Swiss organic origin. For next year, we expect the Swiss adult-use market to already include 20,000 users for demand of four tonnes.

Discussions are already underway as to how to fully legalise the adult-use market, so we would expect that to happen in the same time-frame as German adult-use legalisation. We believe that over time, the legal adult-use market could be close to 180 tonnes.

## Medical cannabis

Before the recent change in medical cannabis laws, the use of cannabis for medical purposes required an exceptional licence from the Federal Office of Public Health (FOPH), for which treating physicians had to apply. In total about 3,000 of these exceptional licences were granted and all medical cannabis was supplied by one pharmacy in Bern. However, the FOPH has been urging for a change in regulations as it estimated that over 100,000 Swiss people use cannabis for medical reasons (but are supplied by the illegal market).

In March 2021, the Swiss parliament amended the Swiss Narcotics Act to lift the ban on medical cannabis, which was then formalised by the

Swiss government on 22nd June 2022. Since 1st August 2022, patients will no longer be required to obtain permission from the FOPH. Instead, the treating physician is to decide whether to prescribe cannabis (there is no limiting list of indications). Physicians must collect pseudonymised data from the treatment with cannabis and the FOPH is to keep a register with the data for scientific evaluation and statistical purposes. With a prescription, patients can obtain their medical cannabis (and there is a wide range of product formats available) from any pharmacy. Currently, medical cannabis is not reimbursed by the national health insurance. We expect prices for medical cannabis to fall to

the illegal market price of between EUR8 and EUR12 per gram, which is also the price-range the adult-use pilot projects need to use. Medical cannabis can be brought to the market by a licensed production company that a) imports GACP cannabis, or b) gives a specific order (volume and specifications) to a Swiss cultivation company. Legalisation also allows for the export of medical cannabis for commercial purposes through the authorisation companies need to request from Swissmedic, the Swiss surveillance authority for medicines and medical devices.



## Adult-use cannabis

As well as opening access to medical cannabis, local governments can set up pilot projects for recreational cannabis which comes very close to a de facto legalisation of adult-use cannabis. All cantons and municipalities can set up a project that can include up to 5,000 participants (existing cannabis consumers) for each project.

Already in September 2020, the Swiss parliament adopted an amendment to the Narcotics Act that allows pilot projects for the distribution of non-medical cannabis. Subsequently, in March 2021, the Swiss government set the criteria for these pilot projects. Both the amendment and the ordinance entered into force on 15th May 2021, and will remain in force for 10 years. The aim of the pilot projects is to explore the advantages and disadvantages of the controlled distribution of cannabis within a scientific framework. In particular, these projects are intended to test and document consequences on the physical and mental health of users and their ability to perform tasks, document their consumption habits and socio-economic characteristics, and measure the effects on the local illegal drug market, youth protection, and public safety and order.

Pilot projects are authorised by the FOPH after consultation with the affected cantons (states) and municipalities. They must:

- be limited in time, locality, and scope,
- provide insights as to how the new rules affect the way cannabis is used

for non-medical purposes and how it affects users' health,

- not affect public health, the safety of youth, public safety, or public order, and
- use cannabis products of Swiss origin that comply with Swiss rules on organic farming and contain less than 20% THC.

The ordinance specifies that pilot projects must be limited in duration to five years and may be extended once for a period of two years. No more than 5,000 participants are allowed per study. Participants must:

- prove they have previously consumed cannabis,
- reside in the canton where the pilot project is taking place, and
- provide written consent to participate.

Other important elements concerning the pilot projects are that:

- minors, people incapable of judgment, pregnant or nursing women, and people who suffer from a disease for which the consumption of cannabis is contra-indicated are prohibited from participating.
- advertising cannabis products is prohibited,
- cannabis products for the pilot projects may be sold only by qualified personnel and must be secured against theft. Participants are to receive an amount equivalent to their usual monthly consumption, up to a maximum of 10 grams (pure) THC per month. They may not receive the products for free. The price must take into account the active substance content and the local black market price.
- consumption is limited to personal

use and may not take place in public. Violations may result in sanctions or in an exclusion from the study in cases of repeated violations.

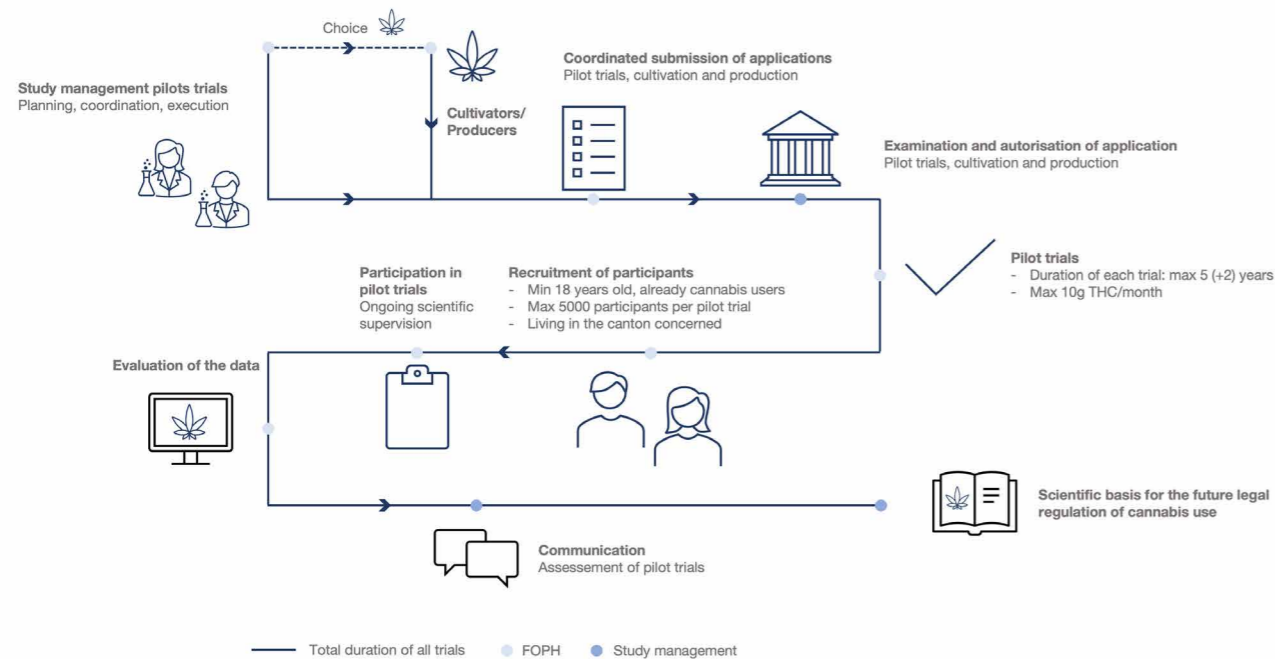
- study participants are to receive a participant card.
- the participants' health must be monitored.

The company performing the pilot project must update the FOPH yearly on the progress of the pilot project. Results must be documented in a research report that must be sent to the FOPH. The Federal Office of Public Health is to inform the public periodically on the progress. It must also evaluate the research reports and write a report on the need for amending the narcotics Act for the Federal Council, which will in turn inform the Swiss parliament.

The pilot project of the city of Basel was the first to be approved (April 2022) and was due to start in September but quality issues regarding the soil (not fully organic) is causing a delay. About 400 consumers in the city are allowed to buy cannabis from selected pharmacies. Other regions that have applied to set up trials include Zurich, Geneva combined with Lausanne; and Bern. These pilot projects are set up not only to use pharmacies as their distribution channel, but other formats emerge and include specialised retail outlets or social clubs (e.g. the Zurich trail). Important is that those different pilot projects also help the Swiss regulators to develop additional adult-use legalisation.



FIG 33: PROCEDURE FOR CANNABIS PILOT TRIALS



Source: FOPH 2021

In June 2022, a study conducted by the University of Geneva and EBP, a consulting firm, explored the benefits of full cannabis legalisation. According to the researchers' findings, approximately 56 tonnes of cannabis is consumed every year in Switzerland. Based on this data, annual revenue for adult-use cannabis

sales could collect up to EUR600m. The industry could generate 0.06% of the country's economy. Legal cannabis could also provide up to 4,400 full time jobs, in comparison to the country's Swiss accident insurance, which has about 4,200 employees.

Our estimates are significantly ahead of these and believe that already today the illegal Swiss market is about 120 tonnes and the potential of a legal market could be close to 180 tonnes.



## CBD products

Within the current regulatory framework in Switzerland, CBD products can be produced, processed, sold and purchased as long as the level of THC remains below 1%. In contrast to these CBD products, it is not permissible in Switzerland to commercially produce, own, sell or purchase cannabis products that have a THC level exceeding 1% (except for the medical cannabis and adult-use pilot projects described above).

CBD products with less than 1% THC are not subject to the Federal Act on Narcotics and Psychotropic Substances. However, there are still other product specific regulations that apply. CBD is used in a wide range of processed products such as medical products, foodstuffs (e.g. hemp tea or hemp seed oil), utility products (incl. cosmetics and e-cigarette liquids), tobacco products and tobacco substitutes or other products containing CBD.

These CBD products must comply with the rules and regulations applicable to the category of products with which the particular CBD product is associated. The association of a CBD product to a specific category of products is usually linked to the intended purpose of use. If the relevant product is not covered by any specific laws, the product is subject to the Federal Chemicals Act and Federal Act on Product Security (a catch-all regulation).

For example, according to the Swiss Federal Customs Authority, in principle, all cannabis products that can be used for smoking or can be vaporised are subject to tobacco tax (association based on the intended use or Verwendungszweck). In contrast, CBD products such as oils and cosmetic products, which are thus clearly not intended for smoking are not subject to Swiss tobacco taxation. Furthermore, under current tobacco regula-

tions, e-cigarettes are not subject to Swiss tobacco tax. In the past it has often been unclear whether dried hemp flowers are subject to tobacco taxes, i.e. whether dried hemp flowers should automatically be considered as a replacement for a tobacco product. In a recent judgement, the Swiss Federal Supreme Court concluded that there is no sufficient legal basis for applying the tobacco tax to hemp flowers. As a result, the Swiss Federal Customs Authority was required to adjust its practice. According to its new publication, the Swiss Federal Customs Authority states that CBD products that do not contain tobacco are not subject to tobacco tax and thus no entry in the reverse register is necessary.

The Swiss CBD market is estimated to total around EUR75m, but is likely to stabilise in the short term as the legal medical and adult-use cannabis market picks up.

## France

French legislators seem to anticipate a positive outcome for the current medical cannabis trial as they have already issued a decree to legalise medical cannabis production and distribution as soon as the Health Ministry decides that medical cannabis should be avail-

able for patients. If that happens, it could open another significant market for medical cannabis for potentially 650,000 patients (140 tonnes). Adult-use cannabis is currently not yet being discussed despite cannabis being popular with an estimated 7.0m illegal cannabis users.

Given an increase in prevalence after a potential legalisation, a French adult-use market could well reach 1,200m tonnes by 2032, matching demand from German consumers by that time.

## Medical cannabis

In March 2021, the French government launched a trial to collect data on the efficacy and safety of cannabis for therapeutic purposes, as well as to lay the foundations for its long-term availability. Around 2,000 patients are participating in this study. The trial is being carried out under the control of the Agency for the Safety of Medicines and Health Products (ANSM). France's programme is providing free cannabis medicines to eligible patients including cancer patients, people with nerve pain that is not treatable by other methods, people with certain forms of epilepsy and people in palliative care. Cannabis treatment can also be prescribed for children in cases of refractory epilepsy or cancer. The products that are administered are oil-based formulations or dried flower for vaping and some 215 hospitals are participating. The experiment also enables a test of the logistics of prescribing and distributing cannabis, while a mandatory education programme for doctors and pharmacists is in place.

The medical cannabis for the pilot programme is imported from Australia, Canada and Israel and is provided for free by a number of international companies that have been selected by the ANSM inclu-

ding Australia-based Althea, Canada-based Aurora Cannabis and Tilray, Israel-based Panaxia and UK-based Emmac Life Sciences (part of US-based Curaleaf). Australian Little Green Pharma is the main supplier, providing about 60% of the prescribed volumes.

The results of France's programme are only expected in September 2023, but there are indications that the outcome will be positive. Indeed, in February 2022, the government already issued a decree authorising medical cannabis cultivation, production, and distribution from 1st March 2022, providing that the concerned product:

- has received an authorisation (i.e. market authorisation, early access authorisation, compassionate access authorisation or import authorisation), or
- has been registered as a homeopathic drug, and
- meets the requirements set by an upcoming decree due to be published by the Health Ministry on a proposal from the Director of the ANSM, and is manufactured as required by Article L. 5121-5 PHC or any equivalent internationally recognised standards to guarantee its quality, security and medical purpose.

For the moment, no medical authorisation has been issued, but the ANSM has started work on defining the specifications of cannabis-based medicines.

It remains unclear whether the French authorities will continue to accept cannabis flower as medicine. Given the language of the resolution, however, specifically "only growers who have contracted to supply their production (to a licensed and authorised manufacturer) may cultivate cannabis plants for the purpose of manufacturing medicines," it appears that flower may not be the preferred route. France has already tried to ban CBD flower but France's highest court, the Council of State, lifted the ban (at least temporarily).

## Adult-use cannabis

Although there is some progress on medical and wellness cannabis policies, a recreational reform is not for the near term. Not only was a bill to legalise cannabis proposed by the left-wing LFI rejected at 53-80

in January 2022, but there are also reports that Luxembourg's legalisation plans resulting in its framework being rowed back from commercial access to home grow, was on the back of interference from France.

Nevertheless, prevalence rates in France (11% last year prevalence and 6.4% last month prevalence) are the second highest in Europe (behind 11.4% in Spain), according to the UNODC.

## CBD products

Currently all CBD products including CBD flower are allowed for sale in France. Although data regarding the CBD market size is not very reliable, the French Professional Hemp Trade Union (SPC) estimates that CBD market in France totalled around EUR180m in 2021, with the Association of French Cannabinoid Producers (AFPC) estimating that flower represents 80-85% of sales. This indicates substantial growth in the size of the market which was estimated at EUR131m in 2020 (New Frontier estimates), with the number of CBD shops rising to 1,700 by the end of 2021 from 400 at the start of the year, following the 2020 ruling on CBD.

Already in 2020, the European Court of Justice ruled that CBD is not a narcotic drug because "it does not appear to have any psychotropic effect or any harmful effect on human health". The ruling was made in relation to the prosecution in France of KanaVape, a company that exports CBD oil made from whole hemp plants. Under French law, only the fibre and seeds of hemp (a variety of the cannabis plant containing

less than 0.2% of the psychoactive cannabinoid THC) may be put to commercial use, not the flower. The court ruled that the French ban on the marketing of hemp-derived CBD products contradicted EU law on the free movement of goods. This ruling allowed for CBD products to be put on the market across the EU.

In June 2021, the final appeals court ruled that CBD could be sold in France if it was produced in a European country. But the court did not rule on whether selling CBD in France was legal or not. Trying to impose a ban on CBD flower, on 30th December 2021, the French government issued a decree allowing certain varieties of cannabis, without narcotic properties, to be used for industrial and commercial purposes under two cumulative conditions: the plant is one of the authorised varieties of cannabis (*Cannabis sativa* L.), and the plant as well as the end-product, must have a THC content of less than 0.3%. However, the harvest, import and use of flowers and leaves could only be limited to the industrial manufacture of extracts and explicitly

prohibits the sale to, the holding by or the use of raw flowers and leaves (which could be smoked) by consumers in all their forms, alone or mixed with other ingredients. Many French associations officially and publicly opposed these restrictions and requested that the highest French administrative court, the Council of State (Conseil d'Etat), cancel the further prohibition applicable to raw flowers and leaves. On 24th January 2022, the Conseil d'Etat decided to suspend this prohibition pending its final decision on the legality of the specific restrictions applied to raw flowers and leaves. The final decision has not yet been issued and could take up to three years.



## Italy

### Medical cannabis

The Italian government legalised medical cannabis in January 2013. Patients can obtain a cannabis prescription from a doctor (in some regions only a specialist, but in most regions also GPs), who has the freedom to prescribe cannabis for any pathology as long as there is a scientific study that supports the use of cannabis for that condition. In most regions, cannabis prescriptions are reimbursed for indications like glaucoma, Gilles de la Tourette syndrome (GTS), vomiting and nausea as a result of chemotherapy, radiotherapy and HIV therapies; spinal cord injury; multiple sclerosis; appetite stimulants in patients with anorexia, cachexia and AIDS. But in some regions (e.g. Lombardy), reimbursement also includes chronic pain. The government guideline for patients is that they must first try conventional treatments before resorting to cannabis. Any pharmacy is able to dispense cannabis.

Supply of cannabis flowers takes place through three channels:

- Imports of Bedrocan products (Office of Medical Cannabis) that through 6 licensed API importers/distributors are available in most pharmacies. The OMC also sells directly to hospital pharmacies.
- National production at the military pharmaceutical plant in Florence. Although the MOD's capacity is 500 kg, it only produces 250-300 kg. Alongside the MOD, the private sector can also grow cannabis for CBD, if it is able to grow according to GACP and have an agreement in place with a pharmaceuti-

cal GMP processing facility to produce CBD isolates of pharmaceutical grade. The only company currently allowed to grow hemp for CBD extraction is Bio Hemp Farming. Furthermore, in April 2022, the Ministry of Defence published a notice with the aim of selecting companies able to cultivate cannabis for THC and CBD flower, to be supplied to the Military Chemical and Pharmaceutical Plant in Florence for the manufacture of medicines and pharmaceutical raw materials. Bidding was closed on 29th July, but the commission to evaluate them is supposed to meet by the end of November.

- Calls for tender. To cover their shortfall, the MOD issues public tenders which they sell to the pharmacies (at the same price as the national produced products). (The first two tenders were won by Aurora and the third one by Little Green Pharma.)

In addition to cannabis flowers, recently the Ministry of Health approved industrial standardized extracts (so far 4 such industrial extracts have been allowed – two from Curaleaf, one from Tilray and one from Avextra Pharma).

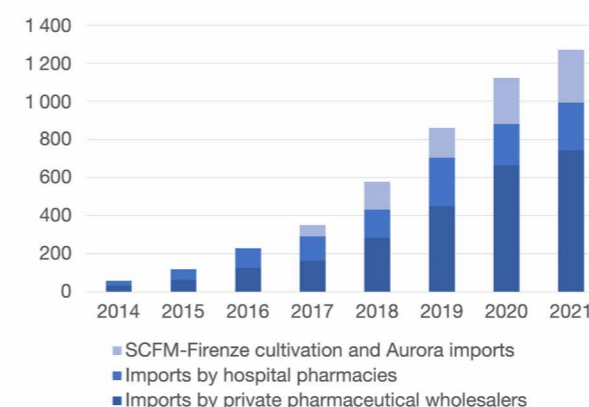
According to the Ministry of Health, a total of 1.3 tonnes of medical cannabis was sold in 2021 (of which nearly 1,000 kg from Bedrocan and the remainder from MOD production and imports for the MOD). For 2022, the Ministry of Defence is set to produce 280 kg and 1,000 kg can be imported – 900 kg from the Netherlands. However, according to industry participants, this is only enough

to meet about 35% of current total medical cannabis demand. We estimate there are currently 40-50,000 patients (50ml extraction with five grams of cannabis per month), for whom supply is inconsistent (about half of their requirements). In order to serve existing patients, around 3 tonnes should be made available. However, patient demand in Canada of over 200 grams indicates that market demand could be over 10 tonnes for existing patients.

With 40-50,000 patients, Italy is potentially the third-largest medical cannabis market in Europe, after Germany (91,000 patients) and Israel (96,000), ahead of the Netherlands where there were 10,000 active patients during 2021. But because requests to import/produce are not keeping up with demand, supply is falling short of demand and is very volatile, resulting in unfilled cannabis prescriptions and uncertainty among patients.

Shortages across the whole country are a regular feature and the reality for Italian cannabis patients is that they cannot rely on a single product being available throughout the year with the risk of having to interrupt their therapy. The Ministry of Health has been preparing solutions for these issues, which could lead to more import licences and/or higher import quantities from current medical cannabis suppliers. We understand that a new 1,000kg tender from the MOD will be awarded by the end of the year.

FIG 34: ITALY – MEDICAL CANNABIS SALES THROUGH PHARMACIES (KG)



Source: Ministero della Salute

FIG 35: ITALY - STATE CANNABIS PRODUCED BY THE ARMY



Source: nextquotidiano

### Adult-use cannabis

Adult-use cannabis is illegal in Italy. However, on 19th December 2019, the Italian Supreme Court (Corte di Cassazione) ruled that small-scale cultivation at home should be ruled out of the scope (excluded from the application) of criminal law, in as far as it appears to be intended exclusively for personal use, due to the rudimentary techniques used, the small number of plants, the modest quantity of product obtainable, and the lack of any further indicator of any collusion with the illegal drug market." The Supreme Court therefore confirmed a common judgement widely used in Italian lower courts: defendants were acquitted when it was obvious or proven by their defence that the cultivation was intended exclusively for personal use.

This paved the way for adult-use legalisation in Italy, at least to some

extent. Since the 2019 ruling, lawmakers in Italy have tried to pass a comprehensive adult-use legalisation measure. In September 2021, Italy's Lower House justice committee approved a reform that would allow small-scale cultivation of four cannabis plants at home. However, no law was passed. Instead the Italian government supported a proposed referendum that gathered 630,000 signatories, to decriminalise cannabis cultivation for personal use. But this was deemed inadmissible by the Supreme Court on the basis that it would violate multiple international obligations. As a result, at the end of June, Italy's Parliament resumed the debate again after the Justice Commission of the Chamber of Deputies approved the initiative to legalise self-cultivation of up to four cannabis plants at home for personal consumption. The next step is for the proposal to be debated

in the plenary session of the Lower House. However, the government has also developed its own proposal, which was included in its Annual Report on Drug Addiction, and sent to parliament. This proposes not only a change in the law on drugs allowing home cultivation of up to four plants, but goes even further than the parliament proposal by also arguing in favour of the decriminalisation of sales of small quantities when they are made on a non-profit basis. However, with although the new government has not positioned itself on adult-use cannabis, we believe it is likely to take a while (five years +) before any further debate on the adult-use cannabis market re-emerges.

## CBD

In Italy, CBD is an API that can be sold through pharmacies – any other CBD product that can be ingested is illegal (although Italians do order on-line from abroad). As far as the use of CBD in food and food supplements is concerned,

these are considered novel foods and therefore require a specific authorisation by the European Commission according to EU Regulation 2015/2283. To date, no authorisations have been granted and as a consequence CBD cannot

be an ingredient that can be used in food and food supplements. Italian regulations do not prevent CBD from being used as an ingredient in cosmetics.

## Spain

Given that CBD products are limited to cosmetics and topicals, the current legal cannabis market is concentrated in the 500 cannabis social clubs, 400 of which already in the Barcelona area. We understand that there are about 200,000 members in total at these clubs (the smaller ones have 10-20 members the largest ones have over 1,000 members). Furthermore, although

in essence these associations are private members' clubs, they have become the main point of sale to tourists, with a membership fee generally of around EUR10 that often goes towards the first purchase. As a consequence, we estimate that these social clubs could well have revenues of around EUR200m. Legalising adult-use cannabis is not being discussed for the moment.

However, there is a significant opportunity developing with a medical cannabis market set to be put in place probably by the middle of next year. Assuming that medical cannabis is fully covered by public health insurance, we expect that this market alone could potentially reach 100 tonnes (EUR800m).



## Medical cannabis

Spain currently allows only two drugs containing cannabis derivatives to be administered in hospitals, one to treat muscle stiffness linked to multiple sclerosis and the other for epilepsy seizures (respectively Epidyolex and Sativex).

For other cases, i.e. sclerosis, cancer or other chronic pain diseases, patients need to go through home-grown or a Social Club of Cannabis (CSC). Although cannabis cultivation is a criminal offence when it promotes, favours or facilitates the illegal consumption of drugs, case law provides that cultivation and possession of narcotic substances that are not intended for trafficking but for one's own consumption and certain hypotheses of shared use (the Social Clubs) in which there is no purpose or risk of diffu-

sion, is unpunished. Nevertheless, consumption or possession of cannabis even if this is not intended for trafficking "in places, roads, establishments public or public transport" is considered as a serious offence.

However, Spain is in the process of changing its medical cannabis laws. Last June, the Spanish Congress of Deputies passed the medical cannabis reform and the AEMPS now has six months to produce guidelines for actual dispensation. No specifics are yet available, but it is likely that by the end of 2022, medical cannabis will be available upon prescription from any doctor, distributed by pharmacies and reimbursed by the Spanish Health System. We understand that as a first step there will be a limited number of indications but alongside

pain (which tends to be 70% of all prescriptions), these could include cancer, endometriosis, fibromyalgia, and epilepsy. Most patients will also not be able to access flower which is still limited for "research purposes."

As this medical cannabis system is very similar to the German medical cannabis set-up, except that there is greater acceptance (and prevalence) of cannabis to start with, patient numbers should develop in a similar way to the German market. In Israel and Canada, respectively 1.2% and 0.7% of inhabitants use medical cannabis, which, if applied to Spain, would indicate that about 300,000 or more patients could benefit from this change in the law.

## Adult-use

It is prohibited to produce, import or sell recreational cannabis. Notwithstanding this, case law determines that the cultivation of cannabis for self-consumption is not a crime in Spain. Cannabis is decriminalised for personal home cultivation and private use. A thriving scene of over 1,000 cannabis social clubs operate as non-profit organisations across the country. Registered

club members can purchase and consume one of the widest sets of product formats available in Europe's recreational markets. Multiple bills have been submitted to formally legalise the market to varying degrees but these have faced political resistance from the Socialist Party. In October 2021, the left-wing government coalition party Unidas Podemos (UP) proposed a bill that

would legalise home cultivation, non-profit CSCs, and commercial production. The social club model is advanced compared to most of Europe, with edibles, concentrates and vape products available and opportunities for retail branding and experiences. Cultivation for lucrative purposes and cultivation in visible places is illegal.



## CBD

At present, the only CBD products that are legally permitted for commercial purposes are topicals and cosmetics derived from industrial hemp containing less than 0.2% of CBD. However, tinctures, capsules, supplements, oils, gummies, edibles, chocolates, vapes, dried hemp flower or tea are off limits. For CBD foods, producers need to ap-

ply to the European Commission for permission to sell as a novel food.

However, the extraction of CBD from industrial hemp is subject to a licence from the AEMPS. Therefore, even though this variant of cannabis may be cultivated without the authorisation of the AEMPS, no cosmetic products may be manu-

factured with CBD extracted from those plants without an authorisation or registry. In addition to the above, in the case CBD products were authorised or registered and then sold as cosmetic products, these products must meet all the standard requirements for placing any type of cosmetic product on the market.

## Cultivation

In Spain, cultivation of cannabis that is not aimed at producing fibres, grains or seeds and with a high content of THC (above 0.3%) may only have two different purposes:

- A licence can be obtained for cultivation of cannabis plants for research purposes, such as the creation of cannabis varieties or seeds for therapeutic use or research into the physical and pharmacological properties of cannabis and its products. These licences are granted for a year and are renewable (for subsequent one-year periods) upon request until the end of the research project.

- There are also licences for cultivation of cannabis plants for medicinal and scientific purposes: a general licence that authorises concrete activities, and a specific authorisation regarding each concrete plot of land or cultivation site.

The grant of licences and authorisations is subject to the applicant fulfilling certain requirements. Licences and authorisations from the Spanish health agency Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) are specific to the persons or entities, plots of land, timing and products for which they have been issued and, conse-

quently, do not confer any rights to otherwise dispose of the products or plants out of the scope of the licence granted. To date, the AEMPS has granted nine authorisations to cultivate cannabis to nine entities for research purposes. Additionally, five other companies have been granted authorisations for the production and/or manufacture of cannabis and its products for medical and scientific purposes, five for crops for research purposes, one of which is for content lower than 0.2% THC, one licence for cultivation for educational purposes only and two for cultivation for medicinal purposes.



## United Kingdom

Although cannabis legalisation for medical purposes was supported overwhelmingly by the British government, the sector got off to a difficult start. At the moment, GPs are not able to prescribe cannabis to patients, only a specialist doctor can do this. Furthermore, the NHS will only advocate the use of medical cannabis in three circumstances: in cases of rare, severe epilepsy; to deal with chemotherapy

effects such as nausea, or to help with multiple sclerosis. However a boom in private initiatives in the form of trials is providing access for patients and recording data to convince the NHS to include medical cannabis for a broader range of conditions. Still, to date, only 15,000 patients have access to medical cannabis as a treatment. Probably because of that, the UK has one of the strongest CBD markets

in Europe, although CBD flower is not legal, valued at EUR150m. CBD is not a legally controlled cannabinoid in the UK and also for the Novel Food Regulation, the Food Standards Agency has taken a more liberal stance, allowing 12,000 food products with CBD to remain on sale until a final decision on authorisation has been taken.

## Medicinal cannabis

Cannabis-based medicinal products were legalised in 2018, and consumer cannabinoids are subject to novel food approval by the Food Standards Authority (FSA). Although medical cannabis was legalised in the UK in 2018, the legal market has been slow to take off despite an estimated 1.4m people across the UK (2% of population) currently using cannabis for medicinal purposes. Estimates for the current number of legal medicinal cannabis patients is

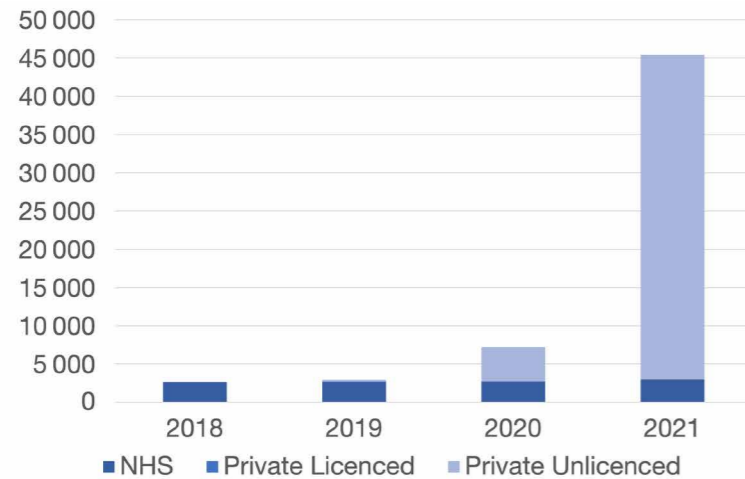
around 15,000 of which only 50 for the NHS and the rest through private health care (Project Twenty21 has around 5,000 patients). Other medical cannabis users turn to the illegal market for supplies but there are also some patients that purchase CBD oils from commercial retailers.

Since 2018, the NHS has approved just three prescriptions for unlicensed cannabis medicines for

children with treatment-resistant epilepsy. However, the number of prescriptions for licensed cannabis medicines (including Nabilone, Sativex and Epidyolex) have been rising slowly over the past four years to nearly 3,000 in 2021. The number of privately prescribed unlicensed cannabis medicines reached 42,393 in 2021.



FIG 36: UK – CANNABIS PRESCRIPTIONS



Source: Department of Health and Social Care

## Prescription of medical cannabis products

Although medical use of cannabis was legalised in 2018, the National Health Service (NHS) has not been promoting its use but wants to see more evidence of its therapeutic benefits before recommending it more widely. In fact, only a few hundred NHS prescriptions have been written since 2018. There are a number of barriers in place that make it difficult to receive an NHS prescription for cannabis-based products:

- Firstly, cannabis can only be prescribed by a specialist hospital doctor (not by a GP).
- Secondly, the prescription can only be written after off-label medications and all other ‘licensed options’ have been explored, and exhausted. Among these “licensed options” are also the three cannabis-based pharmaceuticals that are licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. These

are Epidyolex, Sativex, and Nabilone. Sativex is licensed to treat spasticity in adults with Multiple Sclerosis who have been unresponsive to standard anti-spasticity medication. Nabilone is licensed for treatment-resistant nausea and vomiting caused by chemotherapy. Epidyolex is licensed for the treatment of seizures associated with two forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome.

- Thirdly, the National Institute for Health and Care Excellence (NICE) makes recommendations about what medicines doctors should prescribe. According to these guidelines, medical cannabis can only be prescribed and is paid for by the NHS for: 1) adults with vomiting or nausea caused by chemotherapy, 2) people with muscle stiffness and spasms caused by multiple sclerosis, and 3) children and adults with rare, severe forms of epilepsy. The

recommendation is also not to offer cannabis products for chronic pain except for CBD only as part of a clinical trial.

However, where the NHS guidelines restrict the number of conditions that NHS specialists can treat with medical cannabis, specialists working with private clinics in the UK can use their professional judgement to prescribe unlicensed cannabis-based products. But patients then need to turn to the private and far more expensive health-care system. Currently the five biggest private medicinal cannabis clinics in the UK are:

- The Medical Cannabis Clinics
- Cannabis Access Clinics
- Sapphire Clinics
- My Access Clinics
- Integro Clinics

## Clinical studies – Project Twenty21

To make medical cannabis treatment more affordable, gather clinical evidence on its therapeutic benefits (in order to convince the NHS) and remove liability for specialists who prescribe a medicine that is not licensed, a number of clinical studies for cannabis-based products for medicinal use without marketing authorisation, have been set up. But here again, prescribing cannabis-based products for medicinal use is restricted to specialists (GPs can make a referral to a specialist doctor). Nevertheless, there is a broad range of cannabis products that can be prescribed to ensure that where there is a clinical need, a patient will be able to ac-

cess appropriate cannabis-based medicines. From the different research programmes, Project Twenty21 is the largest observational medical cannabis study (currently around 5,000 patients) in Europe, gathering data on the efficacy of cannabis-based medicines for a wide range of conditions, while increasing patient access across the UK.

Prices of the Project Twenty21 products remain capped at GBP5 per gram of flower and GBP5 per ml of oil. Typically, patients prescribed flower will require up to 1g per day, equating to GBP150 each month. For epilepsy patients, a month’s

treatment is capped at GBP550. The Project Twenty21 formulary includes a range of indica & sativa flower products with varying CBD & THC ratios as well as an increased number of different oils. These are produced/distributed by the project partners:

- Khiro Life Sciences
- Cellen Therapeutics
- Lyphe Group
- Jamaican Medical Cannabis Corporation

Furthermore, if a Twenty21 product is deemed unsuitable, specialists are free to prescribe a product outside of the formulary.

## Adult-use

Recreational use of cannabis is not legal in the UK. However, cannabis control varies by region, from prohibition to de facto depenalisation. Although there is no immediate lever for reform or centralised campaign in the UK, there are signs of an ap-

petite for reform among public authorities and healthcare institutions. Decriminalisation is backed by organisations including the Royal College of Physicians, the Faculty of Public Health, the Royal Society for Public Health and the British

Medical Journal. In 2022, the Mayor of London, Sadiq Khan, announced his intention to introduce a pilot across three London boroughs to study the effect of diversion schemes on crime and reoffending rates.





## Cultivation

In the UK, cannabis, cannabis resin, cannabidiol and cannabidiol derivatives are classified as Class B drugs under the 1971 Misuse of Drugs Act. The 2001 Misuse of Drugs Regulation provides the legal framework for access to controlled drugs for legitimate purposes. In the UK, a Schedule 1 controlled drugs licence is required to grow cannabis, irrespective of the THC content of the plant. To lawfully use the controlled parts of the plant (flower and leaves) licensing permissions to enable possession, production and potentially supply of 'Schedule 1' material would be required as the possession of harvested material from controlled parts of the plant would be unlawful without a licence.

All cultivation (irrespective of THC content and/or medicinal purpose), production, supply and possession of cannabis is only permitted under a Home Office licence. The Home

Office only issues licences for cultivation of hemp plants from approved seed types with a THC content not exceeding 0.2% and only harvesting of stems and seeds from hemp plants is allowed. The legally controlled parts of the plant (i.e. the leaves and flowers) cannot be used under an Industrial Hemp licence and must be destroyed. However, the Home Office also issues licences to grow medical cannabis.

Only about 20 farmers in the UK now grow cannabis/hemp on a total of 800 hectares, according to the British Hemp Alliance that compares with about 50,000 hectares in the entire EU and 13,000 hectares in the US. To our knowledge, only three licences to grow commercial medical cannabis have been issued by the Home Office. A first one (1998) was for GW Pharma, which currently produces close to 400 tonnes of cannabis p.a.. Since then,

new medical cannabis production facilities have been approved in the UK, including a 2.5-hectare greenhouse for Glass Pharms in southern England. Both Celadon and Ananda Developments have been approved to produce test batches of cannabis, allowing for the development of stable genetic strains. In January 2021, Northern Leaf secured the first cultivation licence on Jersey for a 75,000 sq. ft facility. The first licence for cultivation was issued to 4C Labs on Guernsey in September 2021. No unlicensed medical cannabis produced in the British Isles has reached the market.

Furthermore, although the production, sale and use of CBD products is fully legal, the process of extracting CBD oil from a hemp plant is not. As such, CBD has to be imported from abroad.



## CBD

CBD is not a legally controlled cannabinoid in the UK so the possession and supply of CBD oil does not require a Home Office licence in the UK (though it may need to comply with other product regulation where supplied for particular purposes, e.g. novel food, food supplement or cosmetic products legislation). However, as mentioned before, growing cannabis including hemp is subject to a licence from the Home Office. There are a number of strict regulations that govern CBD:

- CBD products cannot contain more than 0.2% THC
- CBD producers must receive a licence from the UK Home Office
- To sell CBD you need to be a licensed medical distributor or sell the product as a nutritional supplement.
- CBD products must be properly labelled in accordance with 2003 Food Supplement Regulations
- CBD Cosmetics require Cosmetic Product Safety Report
- CBD Vape Products should be in line with non-nicotine e-liquid regulations
- The sale of CBD flowers and buds is illegal even if the THC content is below 0.2%

In the UK, CBD is mostly available as a food supplement in the form of cannabis oil. Pre-Brexit, in 2019, the European Commission listed CBD as a 'novel food' in the EU novel foods catalogue and post-

Brexit, EU law was signed into UK law and still applies. Novel foods are defined as foods that do not have a history of consumption in the EU before May 1997. Before a novel food can be legally sold in the EU, it is required to have a pre-market safety assessment and authorisation under the Novel Foods Regulation (EU No 2015/2283).

As of February 2020, food and drink products containing CBD are considered novel foods and require a Novel Food Application at the FSA. Example of CBD Novel Foods:

- CBD oils, capsules and sprays
- CBD gummies, mints and sweets
- CBD infused drinks - teas, coffee, beer, soft drinks etc
- CBD snacks

However, in order not to disturb the market, the FSA published a list of CBD products for sale on 12th February 2020, that can remain on the market until a final decision on authorisation is made. (Currently, no CBD products have been authorised for sale in the UK.) A first draft in March 2022 included 3,500 companies, but that number has since jumped to 12,000 in June. Further requests to have products put on the public list or evidence sent are no longer being accepted. Businesses can continue to apply for authorisation of CBD food products however, new applications will not be eligible for the public

list and should not be put on sale until they have been authorised. As such, the list of products that can continue to be sold makes the UK the first country in the world where there is a regulated market for orally consumed, non-psychoactive legal cannabis extracts.

Estimates about the size of the UK's consumer CBD market vary from GBP300m (CBD-Intel) to GBP690m (The Association for the Cannabinoid Industry (ACI) and Centre for Medicinal Cannabis (CMC)). However, market participants are not witnessing these sales levels, given that CBD flower is not legal. Hence we prefer a more cautious estimate of around USD150m.

High street chains such as Holland & Barrett, Boots and Lloyds Pharmacy are all stocking CBD products as they provide the most accessible products for both producers and consumers. All CBD oils incorporated into high street products are imported into the UK, predominantly from the US and Eastern Europe.

## Denmark

Only 6.3% of the population uses cannabis in Denmark, one of the lowest levels in Europe, meaning the Danish cannabis market is unlikely to be sizeable. The medical cannabis programme in Denmark is not very successful, given rigid regulations and relatively high prices, while the medicinal can-

nabis market is relatively small (300 kg) but could expand if there is more political support. There is some discussion about setting up a trial programme for adult-use cannabis, but nothing concrete has developed. In Freetown Christiania, the utopian commune in the heart of Copenhagen, open cannabis sel-

ling and usage were for decades an accepted city tradition. In more recent years, however, the trade has been taken over by gangs and international drug traffickers with police reporting estimates of over DK-K1bn (EUR130m) worth of cannabis traded annually in the city's streets.

## Medical cannabis

Medical cannabis is legal in Denmark. Danish patients are able to access medicinal cannabis in different ways: through authorised medicines, compassionate use permits for not authorised medicines, magistral preparations, prescriptions in another EU country or through the medicinal cannabis pilot programme.

There are currently two authorised cannabinoid-/cannabidiol-containing medicines in Denmark, Sativex and Epidyolex. Sativex can be prescribed by neurologists to patients with multiple sclerosis. Epidyolex is an oral solution which can be prescribed by medical specialists in neurology and/or paediatrics for the treatment of rare forms of epilepsy known as Dravet syndrome and Lennox-Gastaut syndrome. Doctors can also apply to the Danish Medicines Agency for a compassionate use permit for medicines that are not authorised or marketed in Denmark. This is relevant for the medicines Marinol and Nabilone, which contain synthetically-produced can-

nabinoids and for who the manufacturers have not applied for authorisation in Denmark.

Since 2011, Danish physicians have already been able to prescribe cannabis through what is known as the magistral order. Indeed, under their own responsibility, doctors are free to prescribe anything, including magistral cannabis preparations, that in their opinion will medically benefit the patient. When doctors prescribe through the magistral order, they must provide a "recipe" for what the drug should contain and how it should be dosed. The pharmacy then produces the drug and hands it to the patient. There are only two pharmacies in Denmark that manufacture drugs for the magistral order, and only Glostrup Pharmacy handles cannabis.

In view of Denmark's membership of the EU, it is possible for patients to receive prescriptions e.g. in Germany or the Netherlands and obtain dispensing of cannabis in another

EU country. Some used this method before the trial programme(see below) came into effect, and some use it if they are unable to find a doctor in Denmark who will prescribe cannabis. In order to be allowed to carry the medicinal cannabis across the border a medical pass/pill pass is required. The drug may be used for 30 days.

On 1st January 2018, a four-year medicinal cannabis pilot programme was launched (since extended by another four years to 31st December 2025) whereby any doctor can prescribe herbal cannabis for all patients and all diseases. The products available in the pilot programme depend on the manufacturers of cannabis products. They apply for admission of cannabis products to the programme with the aim of making these products available for prescribers. The cannabis products included in the pilot programme are not authorised medicines, neither in Denmark or any other country. One of the implications of this is that doctors must accept full res-

ponsibility for prescribing a product, e.g. by determining the dose for the individual patient. The Danish Medicines Agency has issued a guideline for doctors who consider prescribing medicinal cannabis to their patients. It advises that medicinal cannabis should only be considered for the following indications for which there is some supporting evidence of a beneficial effect: painful spasms caused by multiple sclerosis or spinal cord damage, nausea after chemotherapy and neuropathic pain, i.e. pain due to a disease of the brain, spinal cord or nerves. However, neither the law nor the pilot programme's guideline prevents doctors from prescribing medicinal cannabis to patients with other illnesses than those mentioned. Pro-

ducts under the pilot programme can be reimbursed under a special scheme: terminally ill patients receive full reimbursement for cannabis products in the pilot programme. Other patients receive a 50% subsidy amounting to up to DKK10,000 a year. Currently only eight products are registered for use on the pilot programme, including Sedemen Aurora Nordic Cannabis, Bedrocan CannGros, Billiono Little Green Pharma and Stenocare THC Oil.

The programme is not very successful and the vast majority of patients still seem to use the illegal market. Considering all regulated medical cannabis products, including those accessed via the trial programme and magistral

preparations, there were nearly 2,000 patients per quarter in 2019, falling to a little more than 1,400 on a quarterly basis at the end of 2021 (about 3,000 prescriptions). The lack of success can be attributed to the expensive prices of the medical cannabis and doctors who are not prescribing. And with little demand for medical cannabis in the trial programme, the amount of available products has dropped. We could find that currently only Stenocare offers a THC product and its 30ml bottle of THC oil from Stenocare costs EUR331,27 or EUR11.04 per ml. The cheapest flower product is Bedrocan CannGros which sells for a package of 5 gram at EUR93.21 or EUR18.64 per gram. Illegal market prices for flower are EUR5-12 per gram.

## Cultivation

Cultivation of industrial hemp in Denmark has been legal since 1998. Under EU and Danish law, cultivation of industrial hemp is legal only if the plant's THC content does not exceed 0.2%. The Danish Agricultural Agency regulates and reviews the applications for commercial cultivation of industrial hemp, which takes approximately six weeks for approval. The permit for hemp cultivation is valid for one year. Licensed growers can cultivate, process, and sell industrial hemp for commercial purposes, including hemp seeds for food and cosmetics, hemp seed oil, hemp flour, grains, and hemp

protein powder. Growing hemp for medicinal cannabis is not permitted under this licence. Only the Danish Medicines Agency can issue medicinal cannabis permits. On 1st January 2018, when the Danish Parliament introduced its medical cannabis pilot programme, it also allowed domestic cultivation, manufacturing and distribution of medicinal cannabis as well as its import into Denmark. Furthermore, legislation introduced in January 2019 permits export of cannabis bulk and cannabis products. The Danish Medicines Agency (Lægemiddelstyrelsen) grants

the necessary authorisations. In 2021, the Danish government passed new legislation making the cultivation and production of cannabis products permanently legal in Denmark. Danish companies can therefore cultivate cannabis plants and produce medical cannabis products in Denmark without any legal constraint on production capacity. Cannabis operators that have growing facilities in Denmark include Little Green Pharma, Aurora and Stenocare.



## Adult-use

Cannabis in Denmark is illegal for recreational use although it has been unofficially tolerated in the Copenhagen district of Freetown Christiania for many years. Both the Danish government and the city of Copenhagen are working on proposals to legalise adult-use cannabis.

In March 2022, five political parties within the Danish government proposed the development of a five-year recreational cannabis pilot programme, using a model similar to that proposed by the Municipality of Copenhagen, whereby sales from state-controlled outlets are legal, and citizens can buy, store, grow and consume cannabis for personal consumption.

The proposed model, involves legalising the use of cannabis and establishing public outlets in municipa-

lities that wish to join the scheme. The elements of the scheme are as follows:

- The wholesale segment: production must be legal and take place in Denmark.
- The retail sector: controlled outlets located centrally in the city districts, staffed by trained employees and providing information on products, harmful effects and treatment options.
- Product and price: the products must meet the expectations of those who use cannabis products, and prices must correspond to the price on the illegal market.
- Buyers: buyers must be over 18 years of age and resident in Denmark.
- Prevention and treatment: a prevention strategy must be developed with efforts that take into account the possibilities and challenges of

the trial scheme. The proceeds from the sale of cannabis products must be used for prevention and treatment of abuse.

In Freetown Christiania, the famous utopian commune in the heart of Copenhagen, open cannabis selling and usage were for decades an accepted city tradition. In more recent years, however, the trade was taken over by gangs and international drug traffickers with police reporting estimates of over DK-K1bn (EUR130m) worth of cannabis traded annually in the city's streets.

sold legally from a pharmacy and only to patients with a prescription from a doctor.

If the product is a food supplement or a cosmetic product, either the rules on food supplements (novel food application) or cosmetics must be followed.

## Adult-use

Denmark follows most countries in Europe in distinguishing between cannabis and industrial hemp. The most important threshold for the distinction of the plants is its THC content. If the plant has less than 0.2% THC content, it is considered to be industrial hemp under Danish law. If the THC content is above 0.2%, it is considered to be cannabis.

In July 2018, Denmark decided that

cannabis with less than 0.2% THC content would no longer be on its list of euphoriant substances. With this change, CBD became legal to some extent. Products derived from hemp, such as hemp seed oil is legal in Denmark. On the other hand, CBD oil derived from cannabis is illegal. Furthermore, oils are sold as food, medicines and cosmetics, three areas governed by separate legislation. In the case of cannabis, oil for medicinal use can only be

## Portugal

Although there is a medicinal cannabis market, only Tilray has a product that is approved by Infarmed. In Portugal, all drugs are decriminalised and there is strong political momentum

## Medical cannabis

Portugal legalised medicinal cannabis in 2018. Medical cannabis needs to be prescribed by a doctor and dispensed by a pharmacy. The prescription of medical cannabis can only take place when conventional treatments are not efficient or cause relevant adverse effects and the therapeutic indication of the cannabis-based medicinal products, preparations and substances have been approved by Infarmed. The recently approved Tilray flower can be used for the treatment of:

- Multiple sclerosis.
- Spinal cord injuries.
- Nausea, vomiting (resulting from chemotherapy, radiation therapy, and combined HIV medication for hepatitis C).

to fully legalise adult-use cannabis, but the country seems to be waiting to see how German legalisation takes shape. We expect adult-use in Portugal to launch at the same time as the

- Appetite stimulation in palliative care.
- Tourette's syndrome.
- Epilepsy.
- Other severe seizure disorders in children.
- Therapeutic-resistant glaucoma.
- Chronic pain.

All drugs require a licence from Infarmed (Autoridade Nacional do Medicamento e Produtos de Sa de I.P.). Infarmed is a division of the Portuguese Health Ministry, responsible for the regulation, control and evaluation of medicines, medical devices and cosmetics, and is also in charge of medical cannabis. So far, Infarmed has only authorised Tilray to sell medical cannabis

German adult-use market and expect a potential of 140 tonnes in legal cannabis (of which 20 medicinal and 120 adult-use)

flowers with 18% THC. Furthermore, there are currently only two applications for ACM (Authorisation to Place on the Market) for cannabis-based substances, one relating to dried flower for inhalation by spray and the other relating to an oral solution.

After proposals from the producer, Infarmed has set the price for 15 gram bags of medical cannabis at the point of sale in pharmacies at EUR150 per bag of 18% THC flower, which is similar to the pricing on the illegal market.



## Adult-use

Producing, importing, and selling recreational cannabis is prohibited in Portugal. However, because it is decriminalised, it is not a crime to possess plants, substances, or preparations in quantities that do not exceed the average individual consumption level over a 10-day period.

Portugal decriminalised consumption and possession of all drugs (and cannabis) for personal use as early as 2001. Since then, it has been treating drug addiction as a public health issue rather than a criminal matter. Thanks to this, Portugal has experienced a remarkable 50% drop in drug addiction, and legalisation could be the next step.

## CBD and Industrial use

Use of cannabis plants other than for medicinal purposes is prohibited, with the exception of the use of fibres (stems) and seeds of low-THC varieties of cannabis for industrial purposes (hemp). Concerning hemp products, CBD was not explicitly banned and was legal over the counter as a food supplement. However, in 2018, Portugal banned all CBD food products due to the European Union's Novel Food Regulation. In 2018, Portugal also established its medical cannabis laws and made CBD a prescription-only product insofar as CBD, as a substance extracted from the flowers and leaves of the cannabis plant

There is strong political momentum to fully legalise adult-use cannabis, but the country seems to be waiting to see how German legalisation takes shape.

In June 2022, the Bloco de Esquerda (the Left Bloc), Portugal's left-wing democratic socialist party, delivered a new draft law to the Assembly of the Republic proposing the legalisation of cannabis for personal use including the creation of specialised cannabis stores, the sale of cannabis online and the domestic cultivation of up to five plants per person. Although the proposal allows edibles and drinks containing cannabis, it bans the sale of cannabis enriched with aromas, fla-

(and not from the stalks and seeds), must be treated as a controlled substance. Consequently, the plant may only be cultivated and marketed in accordance with the rules for the cultivation and marketing of controlled substances (i.e. essentially for medicinal purposes). Furthermore the use of cannabinoids (such as CBD, THC, CBG, CBN), in food are considered unauthorised novel foods, similar to plant parts and their extracts. Thus, the commercialisation of foods containing these substances is not authorised.

The cultivation of hemp for industrial purposes is legal, provided that

vours or additives. The state would also be able to limit THC levels, as well as the consumer price, in order to combat trafficking and the illegal market. The previous draft from the Left Bloc was presented about a year ago, and supported by the Liberal Initiative, but expired with the fall of the government and the end of the legislature. However, the Left Bloc is no longer part of the government as the centre-left socialist party (PS) won an outright parliamentary majority in the January general election. There is some division in the PS on the subject but a freedom to vote within the PS could gather enough support for the proposal.

it is cultivated outdoors. Cultivation can only take place in an area at least five hectares in size while transplanting plants is not allowed and the density of sowing cannot be less than 30 kg per hectare. It is also forbidden to transport flowering plant juices off the farm (even if they can no longer be used for industrial hemp cultivation) and rules have also been established on the reuse of opened seed packages.

## Austria

Austria has many different rules related to cannabis. The current medical cannabis market is small and touches only 1,200 patients who mainly consume Dronabinol. It is unlikely that reforms will increase access to medical cannabis for Austrian patients in the near future. The government has stated its opposition to introducing more progres-

## Medical cannabis

Cannabis is not legal in Austria, other than by prescription that can be obtained by patients suffering from MS, AIDS, cancer and nervous system disorders. However, only three products are currently on offer: Sativex, Nabilone and Dronabinol. Cannabis flower buds are not allowed.

Of the three, Dronabinol is most often prescribed as it is the cheapest, although in fact all three products are expensive. Patients can claim the cost back from their medical insurance company.

Medical cannabis and cannabis for scientific purposes cannot be cultivated in Austria by any party other than the Austrian Agency for Food and Health (AGES) that grows on

sive regulations, or those allowing for extracts and flower products to be prescribed in the country.

However, there are voices that advocate for the legalisation and decriminalisation of cannabis. So far, however, there been no parliamentary majority for this, since apart from the Greens and the NEOS,

behalf of the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection (BMSGK),

In recent years, the agency cultivates about 360 kg of medical cannabis each year, all of which is exported to private companies to manufacture into finished products like Dronabinol before being partially reimported. Despite the 2008 law enabling cultivation of cannabis for medicinal and scientific purposes, Austria has yet to make government-grown and sanctioned cannabis available to its medical cannabis patients.

According to the Austrian Federal Ministry for Social Affairs, Health, Care and Consumer Protection (BMSGPK), 6,460 grams of Drona-

binol (pure THC) were imported into Austria in 2021, a 28% increase on 2020, but just 20% more than the previous peak in 2019. To produce these 6,460 grams, producers would need about 50 kg, making Austria a net exporter of medical cannabis. At a cost of EUR0.8/mg of Dronabinol, the Austrian legal medical cannabis market could be estimated at just over EUR5.0m. At a daily consumption of 15mg, the 6,460 grams of Dronabinol could supply only 1,200 patients.



## Adult-use cannabis

Personal use of cannabis is decriminalised in Austria. The sale of cannabis seeds, seedlings, and plants is also allowed. However, the commercial sale of cannabis is illegal and punishable as a criminal offence. It is technically legal to grow an unlimited amount of cannabis plants as long as they are kept out of the flowering phase and the cultivator can prove they are not planning to produce psychoactive cannabis. Cannabis consumption cannot be punished by law. However, possession, cultivation, the sale and passing on of cannabis from one person to another (without a formal transaction, like passing a joint for example) is all illegal. As

mentioned above, the cultivation of THC-rich cannabis is only legal for medical use when grown by the state-owned entity AGES.

Cases of possession rarely result in any criminal proceedings and people found in possession of cannabis can opt to attend a rehabilitation programme which automatically waives any further court proceedings.

In 2021, an individual application was filed with the Constitutional Court to declare several provisions of the Act on Addictive Drugs as unconstitutional and certain pro-

visions of the Regulation on Addictive Drugs as illegal. Through a decision issued on 1st July 2022, the Constitutional Court refused to deal with the application. The Court ruled that it is within the creative leeway of the legislature to apply stricter rules on the consumption of addictive drugs, covered by legislation under international or community law (in particular, Article 36 of the Single Convention on Addictive Drugs, the United Nations Convention on Psychotropic Substances and the Convention implementing the Schengen-Agreement).

sued licence. Home-grown is also legal as long as the plants contain no more than 0.3% THC.

There are an estimated 250 CBD shops in Austria, which would imply a market size of around EUR70m.

## CBD products

CBD was completely legal in Austria until the government banned it in the form of supplements, food products, and cosmetics in 2018 after the enactment of the EU's Novel Food Regulation. The new law prohibits the sale of CBD products marketed for "promoting health", such as food (including dietary supplements) and cosmetics. However,

the ban does not include essential oils, raw plant extracts, cannabis flowers, CBD teas, and hashish with less than 0.3% THC and retailers continue to sell CBD labelled as aroma products.

Cultivation of hemp with less than 0.3% for fibre, seeds, and leaves is entirely legal with a government-is-

## Belgium

Medicinal and adult-use cannabis is not legal except for licensed pharmaceutical medicines based on cannabis (Sativex and Epidyolex). Political parties are divided over the issue. On the French-speaking side, the largest party SP (socialist party) finds like-

minded people at Ecolo, DéFi and the PTB/PVDA. On the Flemish side, there is less enthusiasm for the legalisation of cannabis with N-VA and CD&V opposing, but also Voorruit, Groen, Vlaams Belang and Open VLD do not support the idea. However, the

Mayor of Brussels (SP) is suggesting that a larger debate needs to take place in the run-up to the elections in 2024. However, with neighbouring Germany, France and the Netherlands all developing their cannabis laws, it is likely that Belgium will also follow.

## Cannabis

In principle, the cultivation, import, sale and possession of (medicinal or adult-use) cannabis is not allowed under Belgian law. Only licensed pharmaceutical medicines based on cannabis are available (Sativex and Epidyolex). These medicines are only reimbursed if they are prescribed by a neurologist and obtained from a hospital pharmacy.

Doctors in Belgium have 'therapy freedom'. This means that all physicians in Belgium can prescribe medicinal cannabis for any condition, on their own responsibility and with the patient's consent, and cannot be subject to regulatory limitations. However, patients will not be able to obtain their medicinal cannabis from a Belgian pharmacy but could use their prescription to buy medical cannabis from a Dutch pharmacy, although they would break Belgian law by importing and using their medicinal cannabis.

By the Law of 7 April 2019, Belgium created a government agency for cannabis that will have the exclusive right to distribute medicinal cannabis. This "cannabis agency" is to be

established within the FAMHP and will be solely responsible for designating the areas where cultivation will be permitted, granting licences to cultivators, purchasing and taking possession of the cannabis, and importing, exporting, wholesale trading and maintaining stocks of medicinal cannabis. Hence, medicinal cannabis will only be available from growers licensed by the agency and through a regulated distribution chain. However, the cannabis agency is not yet active. The bill follows research promoting the benefits of cannabis for medicinal use. In 2014, a working group set up within the FAMHP issued an advisory report that concluded medicinal cannabis can be useful for certain pathologies where traditional drugs are less effective. The legal framework resembles the Dutch model. In 2000, the Netherlands established the Medicinal Cannabis Agency (Bureau Medicinale Cannabis), which also has the exclusive right to distribute cannabis for medicinal use.

Although cannabis is technically illegal in Belgium, personal possession has been decriminalised since 2005 fol-

lowing a ministerial guideline that attributes the lowest priority to the prosecution of cannabis possession of one cannabis plant or three grams of cannabis – in the absence of aggravating circumstances (such as committed in the presence of a minor, committed in the activity of a criminal organisation, causing harm to another individual) or disturbance of public order (i.e. possession of cannabis in prison or youth protection institutes, possession of cannabis in an educational institute or in its immediate vicinity; possession of cannabis in a public place or place that is accessible for the public).

Following these guidelines, Cannabis Social Clubs, formalised as non-profit organisations, have emerged with the "one plant per member" principle. Some of these CSCs are also specifically looking to provide medicinal cannabis. However, these CSCs are in a fairly vulnerable position and many have been subject to police interventions, with their crops confiscated and left facing criminal proceedings.

## CBD

Belgium has no specific regulations on CBD and follows European regulations that allow the production and sale of all CBD/hemp products (cosmetics, aroma therapy, massage, decoration, etc.), except for food supplements and other foodstuffs for which a novel food application needs to be submitted to the European Commission. Although for certain types of food, derogations may be granted (e.g. beverages with hemp seed extracts), for herbal teas made from hemp leaves and flowers, no derogation is granted, even in the case of very low THC levels.

Pharmacists can dispense magistral preparations on pharmaceutical raw materials such as cannabidiol (CBD) if they meet the following criteria:

- using raw materials such as CBD with trace amounts of THC for pharmaceutical compounding is only acceptable if the patient is exposed

to up to 1 microgram  $\Delta$ 9-THC per kilogram of body weight per day. To our knowledge, only one company in Belgium has been authorised by the Federal Agency for Medicines and Health Products (FAHMP) to supply CBD powder to pharmacists for use in magistral preparations at this time.

- cannabidiol-based preparations can only be supplied on a doctor's prescription.
- since February 2020, CBD oil for external use can be sold in pharmacies.

Cannabis/hemp can be cultivated if its THC level is less than or equal to 0.2% and for which a cultivation authorisation has been granted by the regional competent authority. Commercial production of hemp fibre for industrial purposes is allowed

In Belgium, plant-based smoking products containing CBD and some THC content are legal and belong

to the category of "other smoking tobaccos", which defines the products such as dried hemp flowers that are tobacco-free that can be consumed through combustion and do not contain more than 0.2% THC. These products are taxed with an additional 30% duty and 21% VAT.

We estimate the total CBD market in Belgium at about EUR12m, with sales through roughly 200 CBD stores (estimate of the Tobacco and Alcohol Control Service) on top of tobacconists, bookstores, night shops, pharmacies and online sales.



## Czech Republic

Cannabis in the Czech Republic is illegal for recreational use, but personal possession has been decriminalised since 1st January 2010 and medical cannabis has been legal since 1st April 2013. There is some debate on allowing adult-use cannabis, and given its long-standing tradition in cannabis usage and the changing nature of the industry in neighbouring Germany, as well as

in Austria and Switzerland, we expect the Czech Republic to quickly in the footsteps of Germany.

Despite partial coverage by the health insurance system and a relatively high acceptance of cannabis, the medicinal cannabis market is still relatively small – official figures reveal that in 2021 only 109.4 kg of medical cannabis was released

to 4,601 Czech patients. At a fixed price of EUR6.41 per gram, the overall market was only EUR0.7m in 2021. In contrast, the CBD market is better developed as Czech regulations allow all products (incl. food) from hemp with a THC content of up to 1%. We estimate the current Czech Republic CBD market at EUR15m.





## Medical cannabis

Since 2013, medicinal cannabis has been legalised in the Czech Republic. Patients of 18 years and older, have access to cannabis for medical use for certain symptoms, such as chronic intractable pain or nausea in connection with treatment of HIV disease. They can get medical cannabis with an electronic prescription from registered health-care professionals. The amount is limited to up to 180 g in total of dry cannabis per person per month. In relation to the use of cannabis within ambulant care, public health insurance covers 90% of the price of cannabis for the end-consumer up to a limit of 30 g per month. The Czech government has also set a price cap of EUR6.41 per gram.

Growing cannabis for medical use is allowed upon obtaining a licence to grow cannabis plants and permission to sell medical cannabis. The licence is issued by the State Institute for Drug Control (performing this for the State Agency for Medical Cannabis - SAKL) for a

maximum period of five years and can be prolonged (the request for prolongation must be submitted by the licence holder six months before expiration at the latest). Permission to sell medical cannabis is issued by the Ministry of Health for a maximum period of five years and this can be prolonged similarly to the licence (the request for prolongation must be submitted six weeks before the permission expires). Cannabis for medical use cultivated in the Czech Republic may only be sold to another holder of the permission issued by the Ministry of Health. The same applies to the transfer of other rights related to addictive substances. To import cannabis for medical use, an import permit from the Ministry of Health is required. The permit is issued for a maximum of three months. An individual permit is required for each individual import.

According to an amendment to the Act on addictive substances (which regulates the use of cannabis) that

came into effect on 1 January 2022, multi-supplier cultivation licences could be granted, and exports abroad would be possible. An important change is that upon meeting statutory requirements, anyone can obtain a licence for growing medical cannabis (effective as of 27th August 2022). Prior to this change, the licence was subject to a public tender which led to a situation where only one entity held the licence, preventing others from growing medical cannabis.

Medical cannabis sales in the Czech Republic increased by 63% in 2021. Official figures reveal that a total of 109.4 kg of medical cannabis was released to 4,601 Czech patients last year compared to 67.0 kg to 3,755 patients in 2020. The State Agency for Medical Cannabis (SAKL) statistics also reveals that in the first six months of 2022, 4,176 patients were prescribed 73 kg by 191 doctors.



## Recreational use

The recreational use of cannabis is not allowed in the Czech Republic, but personal possession has been decriminalised since 1st January 2010. Possession of up to 10 grams of dry cannabis for personal use, or cultivation of up to five plants, is classed as a civil offence under laws enacted in 2010. On conviction, fines of up to CZK15,000 can be imposed, but are typically much lower. However possession of larger amounts can lead to a jail sentence of one year. Trafficking is a criminal offence, with the minimum

penalty set at two-year imprisonment and a maximum penalty set at 18 years imprisonment, though sentences of 10–18 years are only imposed in extreme cases. A suspended sentence or other alternative punishment is usually imposed in the case of minor trafficking that does not generate a significant income.

At the moment, there is a political consensus to legalise adult-use cannabis, and the country's anti-drug coordinator Jindřich Vo-

bořil's is expected to propose a plan to the government by the end of 2022. Given the changing nature of the industry in neighbouring Germany as well as in Austria and Switzerland, we expect the Czech Republic will follow quickly in the footsteps of Germany if it does not legalise adult-use cannabis earlier.

## CBD and industrial use

All industrial cannabis substances, extracts, and tinctures with a THC content of up to 1 percent that do not have narcotic effects are exempt from the substance abuse regime. Hence cannabis that contains a maximum of 1% of THC is permitted for industrial, technical, and garden purposes.

However, this only applies if the products meet the safety condition of the General Product Safety Act and, in particular, are not hallucinogenic. Industrial cannabis containing up to 1 percent THC can be grown without a permit. At the same time, growers do not have to prove the THC content of their industrial cannabis plants if they use

certified seeds listed in the EU catalogue of varieties of agricultural plant species.

Legal rules regulating the use of CBD within different products are not unified but the new law that came into effect on 1st January 2022, explicitly recognises the possibility of processing industrial cannabis (THC of up to 1%) for food or cosmetic purposes. "A handling licence is not required for the handling of industrial cannabis plants or industrial cannabis, in particular for industrial, food, cosmetic, technical or horticultural purposes."

As regards food and food supplements, pursuant to Regulation (EU)

2015/2283 of the European Parliament and of the Council of 25th November 2015, CBD is considered a "novel food" and therefore will need authorisation to be sold on the market. However, the Czech State Agriculture and Food Inspection Authority is of the opinion that products from hemp leaves or seeds that naturally contain CBD are not considered to be "novel foods". On the other hand, synthetic cannabinoids are considered "novel foods" and would require authorisation under the above regulation before they could be placed on the market.

As regards CBD cosmetics, Czech law only requires that cosmetics cannot contain any THC. There-

fore, THC-free CBD cosmetics are legally permitted. CBD cigarettes need to be distinguished from e-cigarettes (and liquid fills/cartridges) and herbal cigarettes. Under cur-

## Luxembourg

Cannabis in Luxembourg is legalised for medical use and decriminalised for recreational use. In 2018, as part of the coalition agreement, the Luxembourg government

## Medical cannabis

Medical cannabis was legalised in 2018 (28th September 2018) and authorises any doctor who has followed a specialised course of a minimum of six hours, to prescribe medicinal cannabis to patients for:

- serious diseases, in the advanced or terminal phases, resulting in chronic pain,
- cancerous diseases treated with chemotherapy inducing nausea or vomiting,
- multiple sclerosis with symptomatic muscle spasticity.

rent law, use of CBD in e-cigarettes is not permitted at all. On the other hand, the use of CBD in herbal cigarettes is permitted. In any case, it is forbidden to manufacture any

committed to drafting legislation on recreational cannabis. Owing to political pressure from France/Europe, the project was put on hold for some time and a less ambitious

The prescription of medical cannabis can be for cannabis flower but also for all the other components and compounds, such as extracts, tinctures and oils of standardised and certified quality. The dispensing of medicinal cannabis is reserved for hospital pharmacies.

The maximum coverage period for a prescription is 30 days and the maximum quantity of dried flowering tops is set at 100 grams and for cannabis extracts at 1,000mg THC per 30 days. Out of the 2,200 doc-

CBD products for oral use that are made of either the flowering or fruiting tops of the cannabis plant, regardless of the THC content in the original cannabis plant.

draft bill has now been presented to allow home-cultivation of a maximum of four plants per household.

tors that practice in Luxembourg, about 240 have completed training that allows them to prescribe medicinal cannabis.

In 2020, doctors prescribed 140 kg of cannabis for medicinal use, almost three times more than in 2019. This growth continued in 2021 with doctors prescribing 70 kg already in the first four months, or half the total of 2020. Currently there are about 700 or so patients that are treated with medicinal cannabis, averaging 200 g of cannabis per person.

## Adult-use

In 2018, as part of the coalition agreement between political parties (Accord de coalition 2018-2023), the Luxembourg government committed to drafting legislation on recreational cannabis. Owing to the Covid-19 situation and also political pressure from France, the project was put on hold for some time, but returned to parliamentary discussions in October 2021, resulting in a draft bill that was presented on 15th June 2022:

- Cultivation of cannabis at home will be allowed for adults: it is proposed that adults (i.e. 18+ years) will be able to legally grow up to four cannabis plants per household (and not per adult) from seeds, for personal consumption. There are no plans to limit the amount of cannabis seeds that a person of legal age may acquire and possess, nor are there any plans to provide for thresholds for THC levels within the seeds. It should be possible to buy the seeds in stores anywhere (in

Luxembourg, abroad and/or online).

- Eventually, the plan is to allow domestic production of seeds for commercial purposes. The legal framework applicable to professional producers will require some adaptations in this regard. The ban on cannabis consumption in public places should be maintained, as well as any sales of cannabis or derived products (even for free).

- All consumption limited to 3 grams is decriminalised and the criminal procedure is lightened: A decriminalisation for the offences of consumption, possession, public transportation, and acquisition of cannabis is foreseen, when the quantity in question is inferior or equal to 3 grams, in the absence of indications of sale or traffic and/or other aggravating circumstances. It is thus planned to replace the basic criminal fine of EUR251 to EUR2,500 currently in force with a fine of EUR25 to EUR500 and the possibility of issuing a simple war-

ning taxed at EUR145, if and only if the threshold of 3 grams is not exceeded. Payment of the simple warning and handing over the cannabis to the police authorities issuing the simple warning for destruction would automatically put an end to criminal proceedings. Above the 3 grams threshold, the offender is considered a drug trafficker. In this case, the police authorities will not be able to issue a simple warning, and regular criminal proceedings will enter into play.

- The legislative timeline is still unclear at this point: On Wednesday 15th June 2022, Luxembourg's Minister of Justice, Sam Tanson, presented the planned amendments to the law concerning the sale of medicinal substances and the fight against drug addiction. The timetable for adoption of the draft bill has slowed due to the health crisis and as a result, no official date has been set.





## CBD

CBD is legal in Luxembourg, provided that it comes from hemp/cannabis with less than 0.3% THC content. Furthermore, CBD products are only legal for adults, this means that you have to be at least 18 years old to buy CBD. The use of hemp/cannabis in herbal smoking products is only allowed if the product does not contain any tobacco and if the THC share is below 0.3%. According to the amended Tobacco Control Act of 11th August 2006, it is forbidden

to sell «herbal smoking products containing CBD» to persons under the age of 18.

The seeds of industrial hemp and products made from them, such as hemp oil, can be used as food products. The flowers are well known as tea.

Extracts from the cannabis sativa plant with concentrated CBD follow European regulations, which means

that CBD foods or CBD oils for consumption account as food products «without history of consumption» and will need to follow the Novel Food Regulation.

According to estimates, there are currently about 40 CBD shops in Luxembourg, which would imply a market size of around EUR1m.

## Malta

In 2015, the Drug Dependence Act laid out a set of legal guidelines regulating the possession and use of medical cannabis with a prescription from a local doctor. Patients suffering from certain conditions must visit a doctor who decides whether medical cannabis is appropriate for them. The prescription is then filled by a pharmacy. There is no reimbursement through insurance.

In 2018, Malta went on to officially legalise medical cannabis, allowing companies to produce, cultivate, import, and process cannabis as long as it is purely for medical purposes and in line with the scope

of the Production of Cannabis for Medicinal and Research Purposes Act. All of these activities must be carried out in a supervised and controlled environment and activities can only start once all regulatory requirements have been met.

Malta legalised recreational cannabis in December 2021 through a non-profit model of social clubs and home cultivation. Adult possession of up to 7 grams of cannabis and home grow of up to four plants is legal for those over 18 years of age, with up to 50 g storage of dried product permitted. The reform followed after a policy change in 2015 that shifted from a strict model of

enforcement to limited depenalisation. Sale and public consumption remain prohibited, but by the end of this year not for profit social clubs will be allowed. These clubs will be able to cultivate the plant on behalf of members (up to 500) and provide them with up to 7 grams per day and 50 grams per month. However as of September 2022, eight months after the new rules on cannabis use came into effect, the government has not issued a single licence allowing such clubs to begin operating.

## Netherlands

Cannabis in the Netherlands is illegal, but is decriminalised for personal use. Recreational consumption of the drug is tolerated, and it is available in coffee shops (although their source is obviously the illegal market). Recently a pilot programme was set up whereby 10 cities in the Netherlands are participating in tests for the legalisation of cannabis production. The pilot programme involves 10 cultivators supplying almost 80 coffee shops. However, the pilot scheme has

been delayed a number of times as the selection of growers (incl. Aurora, Village Farms International,...) has taken longer than expected and also these growers need some time to start the cultivation. The current expectation is that in Q2 2023, the sale of fully legal adult-use cannabis will start for a four-year period (that could be prolonged). Halfway into the process, the Dutch government is expected to undertake a first evaluation.

Since 2003, a legal cannabis prescription drug has been available in Dutch pharmacies but its success is limited as it is not covered by health insurance and the National Health Institute concluded that there are no conditions for which medical cannabis can be considered a suitable treatment, due to a lack of clinical data.

## Medical cannabis

The medical cannabis programme of the Netherlands is run by the country's Office of Medicinal Cannabis (OMC), which is also responsible for the production of cannabis for medical and scientific purposes. The OMC provides medical cannabis exclusively to pharmacies, hospitals, pharmacy-holding GP's, and veterinarians. There are currently five types of cannabis that are produced by Bedrocan for the OMC, with THC levels ranging from 1% to around 22%, and CBD levels that range from less than 1% to over 9%. Two of these are available as "dried flower heads," three are sold as "finely-ground flower heads".

Patients can obtain a prescription from any doctor able to prescribe for all possible conditions. The OMC lists the following conditions

as ones that can be treated with cannabis:

- Pain.
- Muscle cramps and muscle spasms caused by MS or spinal cord injury.
- Nausea, decreased appetite, weight loss and weakness related to cancer and AIDS.
- Nausea and vomiting caused by medication or radiation therapy for cancer, hepatitis C or HIV infection and AIDS.
- Chronic pain (particularly nerve pain, for example caused by nerve damage, phantom pain, facial pain, or pain that persists after a cured shingles infection).
- Tourette's syndrome.
- Glaucoma, if standard treatment is not effective enough.
- Various forms of epilepsy (also in children).

However, the OMC indicated that "we are also learning from the experiences of doctors and patients who use cannabis for the treatment of other conditions," including Crohn's disease and ulcerative colitis, migraine and cluster headaches, dystonia (abnormal muscle contractions), rheumatic diseases such as rheumatoid arthritis and fibromyalgia, ADHD, post-traumatic stress disorder, restlessness caused by Alzheimer's disease, itching and brain trauma.

Medical patients in the Netherlands pay an average of EUR5.5 per gram (for a 5 gram order) for cannabis, excluding the prescription fee. The price is the same regardless of the variety of cannabis selected by the patient.

The number of medical cannabis dispensations in the Netherlands peaked in 2017. In that same year, the National Health Institute (Zorginstituut Nederland), the body that officially advises insurers on the impact and financial feasibility of different medications, published a review on medical cannabis. It concluded that there are no conditions for which medical cannabis can be considered a suitable treatment, due to a lack of clinical data. As a result, a number of health insurance companies withdrew cannabis from their policies, subsequently leaving patients without affordable access (reimbursement differs among the healthcare insurers). This had the dual effect of halting insurance reimbursements for medical cannabis, as well as deterring doctors from prescribing treatment

with medical cannabis. The number of dispensations dropped to 42,000 in 2021 from 53,300 in 2017. In 2021, the amount of medical cannabis sold was 685 kg (EUR5.1m).

In line with a reduction in dispensations, the total number of patients obtaining medical cannabis declined from 13,000 in 2017 to 10,000 in 2021. These patient numbers reflect a fraction of the total patient population in the Netherlands. In 2018, the Dutch government's Lifestyle Monitor survey showed that just one in 10 medical cannabis patients obtained cannabis by prescription, while the rest sourced from coffee shops, street dealers, and home cultivation (out of cannabis users aged 18 and older, 83.5% used cannabis recreationally, 5.8% used cannabis only

for medical reasons, and 10.7% used cannabis both as a medicine and recreationally).

Another potential reason for the drop in patient numbers and dispensations could be the presence of the 564 coffee shops in the Netherlands, which provide non-medical cannabis at affordable prices but under a legally grey governmental 'policy of toleration'. Coffee shops also have the advantage of offering a wider range of cannabis strains and product formats than pharmacies, which are limited to just five strains produced by the sole domestic commercial cultivator Bedrocan, on behalf of the Dutch Office of Medical Cannabis (OMC) which also has a monopoly on exports.

## Adult-use

According to the 2021 National Drug Monitor, approximately 1.26 million Dutch people aged 18 and older had used cannabis in the past year (8.0% of this age group). Last-year use is highest among people aged 18-19 and 20-24, (23.5% and 26.1%). The figure for last-month use among people aged 18 and older is 5.1%. More than a third (33.7%) of the last-month users smoked cannabis (almost) every day. Of cannabis users aged 18 and older, 83.5% used cannabis recreationally, 5.8% used cannabis only for medical reasons, and 10.7% used cannabis both as a medicine and recreationally. Of those who (also) used cannabis as a medicine, 90.6% did so without a doctor's prescription.

In the Netherlands, it is against the law to possess, sell or produce drugs. However, the Netherlands has a policy of toleration regarding cannabis. This means that the sale of small quantities of cannabis in coffee shops is a criminal offence but the Public Prosecution Service does not prosecute coffee shops for this offence. Neither does the Public Prosecution Service prosecute for possession of small quantities of cannabis. These quantities are defined as follows:

- no more than 5 grams of cannabis (marijuana or hash);
- no more than five cannabis plants.

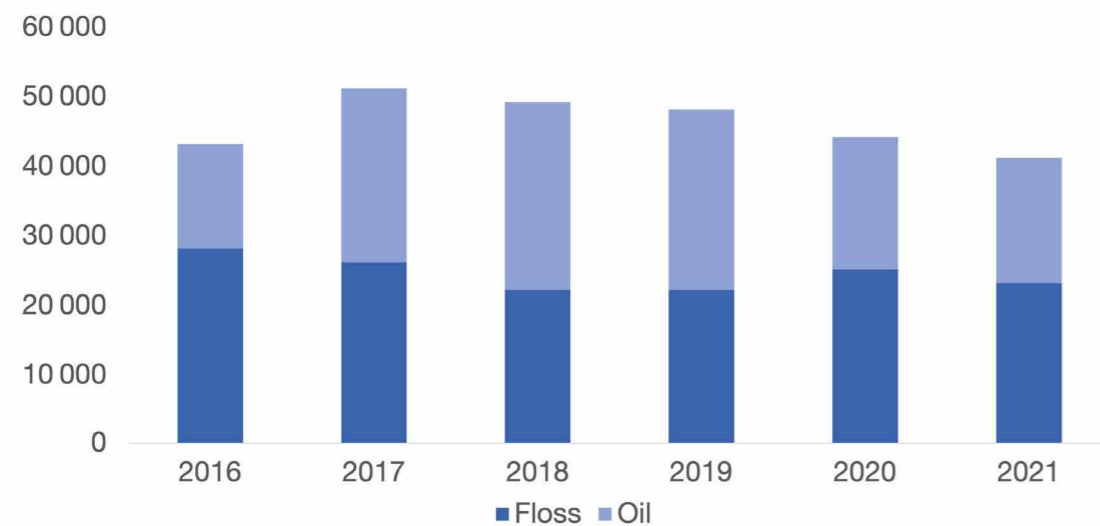
Additionally the sale of cannabis in coffee shops is tolerated as long as the coffee shop keeps to the pres-

cribed rules of not causing any nuisance, not selling hard drugs, not selling to minors, no advertising and not selling more than 5 grams of cannabis in a single transaction. Furthermore, it is up to municipalities to determine whether to allow coffee shops to operate within their boundaries, and if so, how many. They can also impose additional rules. Cannabis has been available for recreational use in coffee shops since 1976.

Though retail sales are tolerated, production, transportation, and bulk possession of cannabis outside of retail stores is illegal, preventing testing for contaminants and dosing. After legalisation and regulation of the entire supply chain in other countries, 10 cities in the Netherlands are participating in a pilot project to test the legalisation of cannabis production. The pilot programme involves 10 cultivators supplying almost 80 coffee shops, which currently operate in a system where sales are legally tolerated but cultivation is prohibited. The experiment is meant to prove whether it is possible to legalise cannabis cultivation. The independent research will also take into account the effects that this could have on safety and public order and health. The 10 municipalities involved are Almere, Arnhem, Breda, Groningen, Heerlen, Hellevoetsluis, Maastricht, Nijmegen, Tilburg, and Zaanstad. The four largest Dutch cities of Amsterdam, Rotterdam, The Hague and Utrecht decided not to partici-

pate because they did not approve of the way the trial was designed. However, the pilot scheme has been delayed a number of times as the selection of growers (incl. Aurora, Village Farms International,...) has taken longer than expected and also these growers need some time to start the cultivation. The current expectation is that in Q2 2023, the sale of fully legal adult-use cannabis will start for four-year period (but could be prolonged). Halfway into the process, the Dutch government is expected to undertake a first evaluation.

FIG 37: NUMBER OF MEDICINAL CANNABIS PRESCRIPTIONS



Source: SFK



## CBD

Production of CBD is illegal in the Netherlands, except for personal use. Its legal status comes from old legislation, which was more about hashish oil production than CBD. The Dutch Opium Act was amended in 1999 to legalise hemp for industrial production. As a result, the cultivation of hemp plants with a THC content lower than 0.2% was legal, but the production of CBD was not, because it is an extract of the plant. However, there is a loophole. If the hemp is grown in the Netherlands and then processed into CBD abroad, it can be legal-

ly sold in the Netherlands again. However it should have a THC level of less than 0.05%, not 0.2%.

In the Netherlands, selling CBD is not only restricted to coffee shops and as long as the THC level is kept below 0.05%, CBD can be sold legally in all shops.

Furthermore, the use of CBD is increasingly being extended to other foods, such as sweets and drinks. The main rule remains that CBD is not yet an approved novel food and producers are not allowed to

trade CBD in the Netherlands. The Dutch Food and Consumer Product Safety Authority (NVWA) can take enforcement action, but the NVWA has indicated that the Food Catalogue is used as a guideline and is not legally binding. Looking at the intervention policy of the NVWA, it can be concluded that in practice the NVWA will take less enforcement action, since the use of CBD in foods is not seen as dangerous for health.

## Poland

There is no adult-use cannabis market in Poland, nor are there discussions about moving that way. Prevalence rates are very low at 3.8%. There is a medicinal cannabis market which is heavily regulated in which it takes 12-18 months to obtain a registration and which shields the market from heavier competi-

tion. We estimate there are currently about 6,000 patients, but with an expected import of just 700 kg this year, consumption per patient is still low (110 gram) and probably as a result of not being insured. And with no discussions about health insurance coverage, we expect this market to develop only slowly.

The current market size is around EUR8m. In contrast, the Polish CBD market is estimated at EUR130m and is positioned as having the potential to address particular lifestyle issues such as pain relief and sleep improvement.

## Medical cannabis

Poland legalised medical cannabis in 2017. Any doctor with a licence to practice can prescribe cannabis that patients are able to obtain from any pharmacy. Initially doctors were reluctant to prescribe cannabis because of the stigma around it. However, that has changed over the years and it has become part of potential treatments.

Because there is no domestic production in Poland, medicinal cannabis is imported mainly from Canada and Denmark. Importers need to register their products at the Office for Registration of Medicinal Products which so far has approved just eight strains of medical cannabis (three from Canopy Growth, four from Aurora and one from Tilray). And only at the end of 2021, the first pharmaceutical raw material for the preparation of prescription medicines in pharmacies in the form of cannabis 10% THC extract received marketing authorisation (+ Panaxia 2.5% THC and Pharmacann two products/extracts 10% THC and 5% THC). Imports of

medical cannabis also need specific approval by the Chief Pharmaceutical Inspectorate before being distributed to Polish patients and this can be a lengthy process, with long delays experienced by importers. Currently no reimbursement for medical cannabis is offered in Poland and the average price of PLN550-620 (EUR115-130) for 10-gram packages of cannabis is reported to be prohibitively high for many patients.

Nevertheless, Poland is among the fastest growing markets for medical cannabis in Europe and has the potential to grow into one of the largest in Europe. In 2020, around 200 kg was imported and that increased to 450 kg in 2021 and 500 kg after just nine months in 2022. Currently about 10,000 patients use medicinal cannabis and none is, by law, reimbursed by the national health insurance.

Changes are being made to make cannabis more available. Since May 2022, up to 12 state research insti-

tutes can grow cannabis for medical purposes, under the Ministry of Agriculture. However, only one specific institute, The Polish Institute of Natural Fibres and Medicinal Plants in Poznań, has been preparing for domestic production and with a capacity of 1 tonne of dried flower, should be able to produce enough medical cannabis to cover current demand. The main argument for starting production in Poland is to lower (halve) prices of medical cannabis which currently sells at a price per gram of PLN 60 (EUR12). Indeed, out of this EUR12 per gram, importers receive EUR7.4, wholesalers have a 20% mark-up, pharmacies another 25% and VAT is 8%. For the moment, the government does not intend to involve private Polish companies in growing cannabis for medical purposes as it argues that it cannot do that under the UN Single Convention on Narcotic Drugs.

## Adult-use cannabis

There is no discussion about adult-use legalisation of cannabis.



## CBD products

Despite the fact that only CBD flowers are legal (not extracts) as long as they contain no more than 0.3% THC, there is a thriving market in CBD products (oil, cosmetics, food, cosmetics only being legal if they are made from hemp seeds only) with most companies selling CBD extracts as a dietary supplement (8% VAT). In Poland, CBD products are positioned as having the potential to address particular lifestyle issues such as pain relief and sleep improvement, which tends to attract health-conscious customers. It is worth noting that by law, CBD products cannot make any concrete claims of therapeutic

effects, thereby limiting marketing opportunities. Other drivers include growing consumer awareness of CBD and an expanding offer of products, players and, hence increasing availability. Euromonitor estimates that in 2021, the Polish CBD market was worth about EUR0.2bn and could double to EUR0.4bn in 2026, but we are slightly more conservative with an estimate at EUR130m.

Poland also has a large cannabis production. Around 1960, hemp occupied as much as 30,000 ha. Later, this popularity weakened somewhat. Polish cannabis

growers cultivated 3,600 ha in 2020 (but that fell to 2,300 ha in 2021). For the cultivation of hemp in Poland to be legal, the farmer used to need to obtain the appropriate permit. However, since March 2022, the procedure to cultivate hemp has been simplified and has moved to the National Agricultural Support Centres (KOWR) that only record where a crop is located (no permits are needed anymore), which is similar to tobacco growing.

# CONVERSATIONS WITH **KEY OPINION LEADERS**

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## SECTION 4







**Tilray has the stated target to reach USD1bn of revenues in Europe. That is pretty ambitious. How do you see the European market than developing?**

**Denise:** When we talked about our one billion target, part of that is obviously attributable to adult use legalisation. We've also talked about our business in terms of four buckets: medicinal cannabis; adult-use cannabis; adult-use beverages; and wellness with better for you food products, personal care products and CBD products. Currently, our business in Europe only is comprised of the medicinal cannabis. We have a small CBD business under Pollen in the UK, but that was launched just recently. And as we look at our longer-term European strategy, we will look to build out medicinal cannabis and adult-use cannabis. And also we'll look toward our wellness space and potentially the adult use beverage to mimicking the four pillars throughout our global footprint.

If I zoom in on the European medicinal cannabis, we will look to continue to grow this business as it will always continue to be a major pillar for us. And then we see adult use as literally sitting in a different pillar. And for the other

**Denise Faltischek**, Chief Strategy Officer and Head of International  
**Carl Merton**, CFO  
**Sascha Mielcarek**, Managing Director Europe

pillars we look at cannabinoids more as an ingredient rather than just a product in itself. I think in terms of adult use, we do view the European market as a potentially larger market than the US given the population size. We also believe that there will be adult-use adoption in Europe before the US.

**Sascha:** So maybe elaborating a bit on where we are in the medical cannabis market. We have a leading position in that market, which is still mainly Germany. There are some additional marketplaces which are far below the level of Germany. We do see France coming online at the beginning of next year, Spain in the middle of next year, we expect some growth in the UK and we have just launched in Poland. So by the sheer expansion of our footprint, applying the German model, we see us multiplying our medicinal cannabis revenues. And then from a more theoretical point of view, I'm a big believer that legalisation of adult-use will actually fuel the dynamic of medical. We are still at only 0.1% of medical cannabis prevalence. If cannabis becomes a consumer good, then it also becomes a major medical product that even GPs will no longer shy away from. We see also strong signs that Germany will become

an adult-use market late 2023 or early 2024. We feel that we are very well prepared for it, plus it might be the beginning of a domino effect over Europe as a whole. So we expect other markets to become legal adult-use following on the German example. So both of these markets again we see very dynamically growing in the short term. It also looks like the German government is thinking of lifting some of the remaining hurdles in the medical cannabis market, because it would be a little contradictory if you still have no reimbursement for some cases.

**Carl:** And then just to supplement that, I think it's a little too simplistic to assume that what happened with medicinal cannabis in the US and Canada post adult-use legalisation, will get duplicated in Germany. The key difference is that the German market is predominantly reimbursement based. And if you just extrapolate the Canadian and the US experience on medical without extrapolating based on the reimbursed side of Canada and the US. The Canadian medicinal cannabis market is diminishing when it concerns people who pay out of pocket, because it's just easier to go to the adult-use store than it is to go through all the hurdles for medical

because there's no price difference. But in Germany there will still be a price difference, because it will still be reimbursed. And so that would still motivate people to get cannabis either free or, at a substantially reduced price through whatever benefit coverage they have. Also in Canada the proportion of the medicinal market that is reimbursed (e.g. veterans) has very little churn.

**Can you walk me through the supply chain and indicate what are the assets that you have in the European market.**

**Denise:** We are uniquely positioned because we've got two EU GMP facilities in Europe and the location of those two facilities is important. As you know, we have our facility in Cantanhede which is equipped to for about 27 tons of product. It's a greenhouse project that we can expand and we have also outdoor capabilities that we don't utilise yet. There's room for two more greenhouses if we should so desire to build them. And in that facility, we also have capabilities to extract. So basically, we're doing all of our whole flower products as well as our extracted products through Cantanhede, both for the European market as well as for the Australian/New Zealand market. And then as you know, we also have our facility in Germany in Neumünster, which is the facility that is cur-

rently servicing the tender to the German government. That facility is important.

**Sascha:** Our facility in Neumünster allows us to choose depending on the final regulations in the German adult-use market, to supply from within or to supply from outside. We have an approved site, and a relationship with the regulator and are already adapted to the German specifications and regulations. That site can then be expanded as we need, or as we choose, or as we have the investment appetite.

**Could you talk about the European business model or strategy?**

**Denise:** Our overall vision at Tilray is to help people to have their very best life one person at a time. When we talked about being a wellbeing company, building connections is also helping with wellbeing. I think we all saw this in the last couple of years during covid. We were separated from each other and now yearn for the connections with one another, with family, with friends, etc. We see that cannabis-related products can bring people together in many different ways.

So our vision is of being a wellbeing company includes building connections through our products and our mission is to be the wor-

ld's most trusted and responsible supplier of those products. And, you know, we love to do that through education, etc. And so if you think about the entire model, what we're doing is we're building a branded business in all the various categories where there's a sort of a commonality in ingredients. All of our geographical locations including Europe will mimic that vision and mission. If you look at Europe, we're already fulfilling the mission quite extensively in terms of being that most responsible and trusted leader and part of that is through education, communication around responsible usage, keeping it out of the hands of youths.

**So how does all that reflect in revenues and profits?**

**Denise:** Distribution revenue is around USD200m and then basically our cannabis business is on top of that. Our International Cannabis has generated USD50-60m in the last couple of quarters on an annualised basis. That international cannabis business doesn't just comprise European cannabis, but includes Australian and New Zealand. And then from there we are looking to build both organically as well as through M&A towards a USD1bn business by the end of Q4 2024.

**Carl:** In terms of profitability, the distribution business is always

low margin. It has gross margins 12-15% and EBITDA margins 3-5%. And for the international cannabis business it has margins which are very close, if not slightly higher than, the margins in our Canadian business.

**What is the most interesting project that you're working on in Europe?**

**Sascha:** Without a doubt the adult-use legalisation in Germany is a game changer for the whole marketplace. So it's the combination working on market access in the medical market and on the

start of adult-use. And in the European landscape, the top five markets (Germany, UK, France, Italy and Spain) are all moving towards legalisation of cannabis. It's a fun time to be in the European market.

**The last question I have for you is what is the most important decision that you will need to take this year?**

**Sascha:** It's the investment decision on how far to expand our supply towards those markets that are building. There's always a bit of uncertainty about the speed

and exact timing at which those markets are developing. So we have to take an investment/capex decision for a potential revenue in one and a half years. That's probably the critical decision to take right now.

**Carl:** I think the advantage that we have over some other players is the size of our existing structure. And so you know, the things that we do versus what they may have to do will end up being different because we've already made a portion of our investment.



**How do you see European medical cannabis markets developing?**

With the developments in Germany, UK and Spain, you can say that the train has left the station when it comes to medical cannabis. Even traditionally conservative markets have changed their mindset in support of medical cannabis. It will just continue to grow. One country that did a huge favour to the whole industry is Germany. Germany took a big step, developing a medical cannabis market with every doctor being able to prescribe, establishing distribution via pharmacies, reimbursement through health insurance, and allowing imports in addition to domestic supplies. On top of that, Germany also started running an observational trial from day one, so since 2017, data has been mandatorily collected with every patient that is reimbursed, having to anonymously take part in the data collection. Now, with five years of data collection, the available dataset is becoming more robust and shows very good results that can be used universally.

**And where do you see Khiron in this market?**

In 2019, I started building the Khiron European business from

**Franziska Katterbach**  
President Khiron Europe

scratch and we focus on our four key stakeholders: patients, prescribers, pharmacies and insurances. If these players don't work together, there is no business for medical cannabis. So, we focus on their interests and then we have to present great options because it is these players that are going to decide if you're going to have a successful business or not.

Therefore, we start with educating doctors and the doctors' societies. You can only have a good fruitful conversation with doctors about medical cannabis if you can show them evidence. At Khiron, we have evidence from across the globe as we have data from both Latin America and Europe. This puts Khiron in a unique position to compare results from our clinics globally and enables the international cannabis company to incorporate these insights into targeted product and therapy development. We understand our products as well as dosage and this is what doctors appreciate. We also understand the pain points of the patients. Patients obviously want their indication to be treated and their symptoms to be lifted, but they also need affordable prices, and they need to be connected to the doctor. You need to bring them into an ecosystem where they can feel safe that they are getting the

right product at the right price. Through our medical outreach programme in Germany and our clinic in the UK, we've built a trusting relationship with the doctors where we can speak openly on what worked and what did not.

We need to listen to the patients on what is really needed and what is really working – supply is no longer an issue in Germany and the UK, but the products need to match the patient's needs. So, it's not sufficient just to bring random cannabis products – you need to bring the right products, individualised products that are demanded by patients and prescribers!

At Khiron, we understand patients as we have our own clinics in several countries and we connect with patients daily. We have a great medical outreach team based in Germany that are visiting with doctors and are listening to what the doctors are experiencing and what they need.

In addition to doctors, you need to have a good relationship with the pharmacists who are the ones actually dispensing the product. So if the pharmacist doesn't care for your product, patients will have a hard time to have their prescriptions fulfilled and ultimately, there's no business to be made as



a company. With more than 18,000 independent pharmacies in Germany, that's a lot of pharmacists you need to maintain a relationship with. This is why Pharmadrug and their direct access to all of those pharmacies was such a key acquisition for Khiron and our existing medical outreach programme.

Ultimately, we must not forget the importance of insurance coverage provided by different insurances. In Germany, coverage for medical cannabis is mandated by law, whereas in the UK it is out of pocket for all patients. As an industry, we need to build the body of evidence to get medical cannabis on the recommended drugs list by the NHS.

What makes Khiron unique is that we know exactly what is missing on the global markets and we have our toolkit for repairing the market gaps.

**Are the products that you sell in Europe from your cultivation in Colombia?**

We have our grow in Colombia but there are excellent growers in southern Europe so we partnered with a few of them. We have an excellent network of growers and partners in Europe, so we do not need to invest in our own cultivation in Europe. One of the first things we did was bring our registered cannabis varieties over from

Colombia for local cultivation within our European network.

**That brings me to the question of where you can actually make money in Europe?**

I don't think that the cannabis industry is different from any other industry: with the right strategy and business model you can also make money throughout the whole value chain, from seed to patient. However, I don't think that vertical integration is a feasible model in Europe as there is already an existing infrastructure. Here, it's always been treated as "just another pharmaceutical", so anyone manufacturing or processing cannabis has to operate within the same guidelines and regulations that any manufacturer of medicinal products needs to comply with. And within the pharmaceutical world, you see a lot of horizontal integration and partnerships with companies that are well-established to perform specific stages of manufacturing. I think it's hard to be good at talking to and educating a doctor and speaking that language and at the same time be excellent in growing because to have EU GMP dried flower you have to be excellent – every flower from each harvest needs to be within tight specifications. So, to grow the product to the required level is an art. I think you can make money with just a focus on that. We focus on specialisation, prioritisation and

division of work instead of doing everything and we decided that we wanted to be at the back-end where the margin is very attractive. Once doctors, patients and pharmacies trust your product you have a medical cannabis brand and broaden your product suite with the right products.

**What is Khiron Europe doing in terms of revenues and where will you be in a few years' time?**

2021 was our ramping up year in Europe. We just started in the second quarter of 2021 in Germany and for the first year we did around CAD1.5m in Europe. For the first two quarters of this year, we have already done CAD2m just in the UK. We just got regulatory approval for our Pharmadrug acquisition and with this new set-up, we are well positioned to sell more products at higher margins.

**So you can see the business at a certain stage doing EUR10-15m just in Europe?**

Yes, but then you have to grow the market. We need to start somewhere, so we launched the first couple of products, we're now expanding our portfolio, so we can offer a broad selection of different cannabis flower varieties, but we also need to have different oral dosage formats like oils for patients that do not want to inhale cannabis. And while we bring more pro-

ducts, we expand our education for all stakeholders and build the dataset to convince health care professionals about the positive effects that medical cannabis can have. Once we achieve that, the sky is the limit. Just the German insured market alone was at EUR185m last year. That's a big number!

**What is the most interesting market for you today? Is it Germany or is it maybe the UK or Spain?**

Germany is the largest market but there are a lot of players on the market. Currently, the UK is smaller but there are also fewer players. With our own clinic that operates in London, we are very well positioned there. So, for us, the UK and Germany are equally interesting but as an international company of Colombian origin, we are of course also eager to expand our activities in Spain. Last month, Spain regulated the medical use

of cannabis, a measure that took the Spanish government 25 years. So far, Spain has been an important exporter of medical cannabis in Europe, but Spain itself had not adopted a national medical cannabis legislation. Our subsidiary Khiron Life Sciences Spain has been active there since 2019. For the past three years, we worked to encourage the regulatory shift in Spain by promoting educational initiatives together with a network of national collaborators such as the Spanish Society for Research on Cannabinoids (SEIC), the Iberoamerican Cannabinoid Research Network (CANNALATAN), Canabmed (ICEERS), the Cannabis Hub (Polytechnic University of Barcelona), the Sociedad Clínica de Endocannabinología (SCE) and the Technological Agroalimentary Center in Extremadura (CTAEX). Our European scientific and medical team was educated at Spanish universities, and we are ready to swiftly leverage our experience in Latin America, with a variety of

proven medical education programmes and a portfolio of registered cannabis plant varieties used to treat over 25,000 patients and already successfully imported into Spain.

In general, we do not have priority countries. If we believe a country is interesting for us, we will go in with full conviction. As I said, we have our toolbox, our understanding of products, our portfolio, our network, our dataset as well as the knowledge of how to speak to doctors and how to educate them. We are only at the beginning of Khiron's growth in Europe.



**Fleta Solomon**  
CEO Little Green Pharma

**What is the background of Little Green Pharma and why the interest in the European market?**

I started Little Green Pharma (LGP) at the beginning of 2017. I had finished my MBA, medicinal cannabis had just been legalised in Australia. Serendipitously, I was made aware of a child suffering 70 seizures a day, who just would not respond to traditional medical treatment. Although the parents were worried about prosecution, they did try medicinal cannabis and the child's life changed significantly, reducing the number of seizures from approximately 70 to 0-4 per day, which was incredible for both the child and its family. Around the same time I was introduced to an older man who was well connected and had a hemp licence so knew how to grow cannabis sativa plants. This is when it all came together. I remember sitting with him on a park bench in southern Australia, and I wondered if we could help people around the world with cannabis medicines that we grew right here in Australia. That is when Little Green Pharma was born. Since then, LGP became the first company in Australia to grow, produce and sell cannabis-based medicines to patients. We had about a two-year head start before any other Australian companies started

to produce cannabis medicines for patients, so we had a great first mover advantage, which has helped to position the company optimally. As we led the Australian industry, we were the first to export cannabis medicines overseas. Due to Australia having a Mutual Recognition Agreement with the European Union, we found ourselves in a unique position to be able to export to the emerging European market and be one of the first movers.

We recognised early that Australia is only a small country with 26 million people, so we quickly made plans to expand and go overseas to Europe where we believe as a business, the real commercial opportunity lies. This is where we believe the profits will come from. It's such a large market with over 500 million people there and LGP is strategically positioned in a number of these countries, ready to deliver its premium medicines.

**So you bought the Danish facility of Canopy Growth?**

We were fortunate to acquire this extraordinary facility in June 2021. At that moment, our Australian facility was nearing its capacity so we needed to expand or purchase another operation. We were

lucky to come across the Canopy Growth facility in Denmark. At the time, Canopy was shutting down many of its facilities across the globe. The Danish facility was so well suited to us that it fit like a glove given its EU-GMP premium quality capabilities and our proposed markets.

The previous owners spent a huge amount on building and setting-up the facility and we were fortunate enough to buy it for only CAD20m. The facility was EU GMP, already producing and with a future capacity of up to 30 tonnes of biomass. It's either one of, or perhaps it is the largest EU GMP medicinal cannabis facility in Europe. It was only three years old, already operational, already exporting. It took us another year to optimise the operations to suit LGP. And we now have far greater efficiencies at the Danish facility. The game plan is that we will be able to serve the European market from that facility, and focus on the APAC and the Oceanic region from our Australian facility. For the moment, we still send some products from Australia to Europe (extracts and flower) and from Denmark to Australia (flower), but this involves rather large complexities and costs in importing and exporting logistics.

Currently in Australia, the market is moving to a majority flower market where patients demand high quality and various cannabis strains with unique properties. As such, Australia, quite similar to Germany, has taken on a bit of a 'craft beer' model as opposed to a supplier selling generic products. We currently have 30-40 different genetics being grown in Denmark in anticipation of the needs and wants of patients, doctors and distributors.

**What do you see as the most interesting European markets for you?**

Germany is obviously a very exciting market. It's already there. It's a proven market. The LGP model in Germany is mainly through white-labelled medicines that we produce exclusively for our distribution partners and we aim to obtain a 10% market share through our key partnerships. When the country moves to an adult-use market, this will clearly create some exciting opportunities for certain producers but will depend on what the framework looks like. It is possible that LGP will be very well positioned since it is just across the border and able to produce 30 tonnes of EU-GMP grade medicinal cannabis biomass.

However, perhaps for us the most exiting markets are France and Italy. Both have so much potential

when they mature and the barriers to entry in these markets are extremely high with a very limited competitive landscape. In Italy, the sole pathway into the country for flower is through a government tender, for which only LGP and Aurora have been successful. LGP won the recent tender and successfully delivers the cannabis flower and is waiting for the next big tender.

In France, the government-led medicinal cannabis trial was given to four suppliers, for which LGP is the largest contributor to date. After running for two years, the French trial is due to end in March 2023. Within six months after the trial ending, medicinal cannabis legislation is expected to change. We have a great relationship with the ANSM which is leading the trial and are provide the bulk of the medicine. Moving forward, LGP is in a very good position with a good brand reputation to capture market share.

Also worth mentioning is Poland. Poland could become a very interesting market for us. A registered medicine is required to gain presence in Poland and this procedure can take more than 18 months. For the moment only two/three companies have this type of registered product. LGP submitted a dossier about a year ago so we hope to soon have our own LGP medicines registered in the country.

For Little Green Pharma, France, Italy and Poland are particularly promising markets as they are all relatively large and have a limited number of competitors due to very high entry barriers.

**How does this all translate into revenue and profit figures?**

Together with both of our facilities, LGP can produce over 30 tonnes of biomass. Our Australian operation is pretty much at full capacity and the Danish facility just increased annual production to about 3 tonnes, giving us plenty of capacity as demand builds.

Until recently, almost all our sales have been generated by the Australian operations and the Australian market. Over the last 12 months, our revenue was AUD14.6m (roughly double that of the previous 12 months) with over 90% from Australian sales. Moving forward, that is expected to change as the European revenue number increases and surpasses the Australian figures at some stage.

We continue to sell our product in the Danish medical cannabis market, but this is a small market with potential to grow. In Germany alone we have agreements in place for over AUD\$33m over a three-year period. In Italy there is a new tender (worth AUD4m) coming up (we won the previous one), in France we are the main



supplier (60% market share) in the pilot programme (and there is some speculation that suppliers might be reimbursed), in the UK, we will start delivering from this month and have an annual revenue opportunity in place of about AUD1.4m. The future revenue stream from European sales is the sole focus for Little Green Pharma.

#### **And what about profits?**

Before we acquired the Danish facility we were at break-even in Australia. Our aim is to get our Eu-

ropean operations to break-even and this is our focus and priority.

#### **What is the most important decision that you made or will make this year?**

This is one that we took recently already. Our focus has been on gaining efficiencies within the Danish facility and this meant right-sizing our operations. Unfortunately, we halved the number of staff at the facility which is never an easy thing to do. However, LGP has always run a tight ship so we opted for multi-skilled wor-

kers across improved operational processes to get one of Europe's biggest EU-GMP medicinal cannabis facilities to be delivering the highest-quality flower at an optimal cost per gram, right in the market where we want to be.



#### **What is the background of your company? And from where did your interest in the European market originate?**

Clever Leaves was founded in 2016 by three Colombians: Julián Wilches, who previously acted as Director of Drug Policy for the Colombian Ministry of Justice and Law, Gustavo Escobar who was part of the IQ team, Sanford Group in Colombia and myself. I was previously a founding partner of Mojo Ventures, focused on working with start-ups and small companies to achieve unprecedented growth and profitability. Before that I was president/CEO at IQ Outsourcing, a leading Colombian business process outsourcing firm that is part of the Sanford Group. And we started there with a very simple notion, which was to produce cannabis where it makes sense and sell it in markets where it makes sense. We entered the cannabis market with a long-term view that it would take time to reach profitability. In the early years (2016/2017), we started testing different strains, finding out where it would make most sense to grow, understanding extraction (at that time Colombia was an extraction only market). At the same time, we were working to get our cultivation and extraction licences. In January 2018 we joined forces with Northern Swan, an American

#### **Andrés Fajardo**

Co-founder and CEO of Clever Leaves

cannabis-focused fund and expanded the operations in Colombia. In 2019 we started building our brand in Germany and at the same time our capital partner Northern Swan was starting a company in Portugal. But it became very apparent, that we had the operational experience and capabilities while Northern Swan held the corporate finance expertise. So we integrated the two companies in October 2019. At that point, Kyle Detwiler who was the CEO of Northern Swan became the CEO of the company. Then we went public at the end of 2020 and as of March this year I became again the CEO of the company. So that is how we came to be. Again, driven by the simple notion of cultivating cannabis where it makes sense and selling it where it also makes sense.

#### **So your interest in the European market was there from the start?**

Absolutely. I would say the European market really interests us from an end-market perspective. We started in Germany very early on and now have a presence in Germany in different ways: first we invested in Cansativa where we are now a minority investor (9%) and we have a supply agreement for high THC flower from our Por-

tuguese facility contingent upon us receiving EU GMP certification. Second, we started building our own distributor capabilities in 2019, and this year, we received all of the required regulatory licences, permits and certifications to be able to distribute medical cannabis to wholesalers and around the 20,000 pharmacies located in Germany. And thirdly, we have different partnerships like with Ethypharm, a specialty pharmaceutical company for the distribution of cannabis extracts from Colombia or with Cantourage for the distribution of medical cannabis flowers (from Portugal) throughout Germany. So Germany was a key market for us from early on. Right now we're still working on other European markets like the UK, Spain, Italy, Poland and France. Also very early on, we wanted to make sure that we had production within the EU because from a geopolitical risk perspective, it's always good to be within the European Union. And as the adult-use market is opening up, being in the European Union might be an advantage. Additionally, we wanted to serve the market with extracts and flower and originally Colombia was an extract-only market. That is why we decided to invest in cultivation in Europe and we selected Portugal for a variety of reasons including its geographic location within Europe,

the availability of talent for agriculture and the relatively lower factor pricing over there, etc. That's what led us to invest in Europe, in production as well. So now, Europe is not only an end-market for us but is also important from a production standpoint. And even though we now have flowers from Colombia coming, the reality is that the flower that we have in Colombia is different from the flower that we have in Portugal. So it's a very complimentary production asset.

#### **What are the most interesting markets in Europe for you?**

There are a few interesting European markets and I would probably put them into three types of markets. The first type is where the direction of the market has become clear, and that is Germany, where we are going to the market in different ways. In Germany, we have our own licensed wholesaler, distributor and importer or narcotics, which is geared towards bringing our own branded flower IQANNA to the market. We launched earlier this year with the flower from a third party but we now have our own flower coming from Portugal. We are doing some commercial services for others but our business is to position our own brand in the market. This is critical. Next, for our extracts we believe it is better to work with a pharmaceutical partner, Ethypharm. And thirdly, we have dis-

tribution partners such as Cannabisativa and Cantourage. A second type of market is where there are signs that the market could become very interesting. That is for us the UK and Poland. The UK for me is intriguing because I've always thought it should be a much larger market. Poland is different but there we are working through the registration of our product, which can take 18 months to two years. We are also doing this process in Mexico and have done it in Brazil. And then there is the third type of market where something is going to happen but we don't know not yet exactly how it is going to work. Examples here are France, Spain and Italy. For both markets, we have our eyes open and are paying attention.

#### **What does your European footprint look like?**

In Portugal, south of Lisbon, we have 2.4 hectares of greenhouses that are built and operational. We have been producing GACP certified flower in Portugal and selling it to Israel, Australia and Germany. We also have a Portuguese extraction and post-harvest facility which we expect to be EU GMP-certified before the end of this year. So the idea is to be able to produce EU GMP-certified flower from Portugal. We have a team in Portugal of around 80. In Germany, we have a small commercial team of five people and we outsource every-

thing else. For the other markets (Poland and the UK), we are still working with our clients from the outside. In Israel, our going to the market is different. We have a team in Israel, we import flower, we have an agreement with Intercure for importing flower but also for technical collaboration, and help them to expand internationally. We are also trying to become the platform for others to expand in Israel.

In Colombia, we have 18 hectares of active greenhouses a little north of Bogota where we have been growing since 2018 and where we are producing quite significant amounts for extraction. That cultivation is GACP-rectified. Next we have an EU GMP-certified CO2 extraction facility where we produce isolates and final products in the form of oral solution. But we are ramping down our extraction as we are really focusing on developing our flower product in Colombia. Currently about 50% of our production comes from Colombia, but because we have the capacity in Colombia and that we can now export flower from Colombia, the share of Colombia in production is going to increase.

**Following on from that is a question on the size of revenues from Europe. For the company you are looking for 2022 revenues of between USD20m and USD25m. How much of that will stem from Europe?**

We do not disclose those specific numbers. But what I can say is that that we have five key markets: the US, where we do not sell cannabinoids today, Australia, Brazil, Germany and Israel. I think revenue from the markets in which we sell cannabinoids will be very balanced, but definitely Germany and Israel are two of our key markets. Columbia is not an end-market for us.

#### **What are your competitive advantages in the European market?**

Number one is that we have a presence in markets like Germany and Israel, where we compete. You cannot compete properly from abroad. It's also something that we intend to do in the other

markets like the UK and Poland as they start evolving. Number two is that having cultivation in Europe is going to be a competitive advantage, from a geopolitical perspective, from a legal/regulatory perspective and even from a perception perspective, as Portugal has a good perception around the globe. Number three is our ability to produce at a relatively low cost, and this is going to become a longer term advantage as well.

#### **What is the most important decision that you will need to take this year?**

I would say that probably the most important thing that we are doing this year is taking our products to the different markets. It sounds relatively straightforward, but I have

to say that we worked a lot this year on how to get our extracts from Colombia and our flower from Portugal in the different markets and ensure that we can reliably continue to supply the markets. We are 100% focused on execution. On top of that, we're focusing on exporting high THC flower from Colombia, to Germany, Australia and Israel. That's something we expect to happen before the end of this year.





## Tjalling Erkelens

Founder and Chairman of the board at Bedrocan

**What is your appreciation of the growing trend in Europe for legalisation of both medical and recreational cannabis. And where do you think this is going to end up at?**

We see the introduction of medicinal cannabis programmes across Europe as a promising development for patients. The opioid crisis in the US has created a need for alternatives and while a large scale clinical study with medicinal cannabis in therapeutic areas such as chronic neuropathic pain is lacking, there is now a lot of anecdotal evidence, especially with the legalisation of cannabis for medicinal purposes in several European countries in recent years, and data from smaller clinical studies like the one Bedrocan completed in 2018 in collaboration with the Leiden University Medical Center (LUMC) that demonstrate the effectiveness of inhaled medicinal cannabis products in therapeutic areas such as chronic neuropathic pain.

Another secular trend in Europe that favours the medicinal cannabis market is an aging population. Chronic pain has been described as a silent epidemic in older adults and considering that 20% of the European population is now above the age of 65, the already fragile European econo-

mic system could incur significant healthcare costs associated with this disease. In that regard, inhaled medicinal cannabis products offer a cost-effective and relatively safer alternative to opioids.

These two macro themes combined with a growing body of evidence when it comes to safety and efficacy, albeit that it is largely anecdotal, mean that there is a strong commercial case for the development of a medicinal cannabis market. While this view is not very different from what the industry as a whole thinks about the medicinal cannabis market in Europe, our view on the size of the European medicinal cannabis market is a lot more conservative than the industry. Most industry analysts were predicting in 2018 that Europe would already be a multi-billion dollar market by 2022. That has not been the case and in fact, it is unlikely that it will get anywhere close to the expectations of the industry, despite the positive macro themes I just pointed out. And that is mainly because of the fact that medicinal cannabis is still an unregistered product and offered under compassionate programmes in Europe. This means that prescribers are not always open to putting patients on cannabis

treatment given the lack of clinical evidence. Prescriber uptake is also low because of a lack of knowledge about products. Finally, the lack of harmonisation with regards to regulations in the European Union is another reason for a slower-than-expected evolution in the medicinal cannabis market in Europe.

We believe that going forward these three factors, namely harmonisation of EU-wide regulations, more clinical evidence and prescriber education, should be key drivers for growth. Another growth driver is favourable reimbursement policy especially in countries where medicinal cannabis is not covered by insurers but more clinical evidence and awareness among prescribers will also be the basis for a more favourable reimbursement policy.

We generally refrain from making any projections on what the size of the medicinal cannabis market in Europe will reach, mainly because it is still a nascent industry and we have no precedent or comparable products to derive any assumptions from. Therefore, it is hard to quantify the future of the European medicinal cannabis market. For internal business cases, we usually rely on the market size as it is and not

what it will evolve into in the future. Even estimating the true size of the market as it is right now is a challenge given the lack of reliable data sources.

But as I mentioned, the macro trends are favourable and positive developments with regards to the growth drivers would certainly expand the market. By how much is difficult to predict. The only reliable data point we have comes from the Netherlands, which can be defined as a mature medicinal cannabis market considering that the programme from the BMC has now run for almost two decades. Despite stable supplies, the adoption rate in the Netherlands is only 0.05%. In Germany, where medicinal cannabis is covered by insurance companies, the adoption rate based on our internal estimates for the total number of patients would be close to just 0.1%. Based on this, the total number of patients in the whole of the European Union, if every country allowed access to cannabis for medicinal purposes, would be somewhere between 250,000 and 500,000. Note that this is well below what most industry analysts assume but as I mentioned earlier, we have been far more conservative than the industry in our view, and going by what the actual size of the European medicinal cannabis market was at the end of the first half of 2022, we have been proven right.

The adoption rate would increase significantly if a full-spectrum cannabis product (extracts or flowers) were to obtain a Marketing Authorisation (MA) from the FDA or the EMA or similar regulatory bodies. This is where I would also like to introduce our view on cannabis as a medicinal or pharmaceutical product in the conventional sense i.e. a product that has been evaluated in large scale Phase III studies before obtaining authorisation from regulatory bodies. There is the GW-route that companies can take but then we are not talking about a true herbal product, but a heavily processed pharmaceutical product. On the other hand, taking cannabis in its herbal form all the way to obtaining an MA presents a regulatory challenge given the chemical composition of herbal cannabis. To just meet the safety requirements before a large scale clinical study with the goal of obtaining an MA can be initiated would require data from large-scale toxicology studies and some of these studies alone would cost millions. Developing a true pharmaceutical product with cannabis in herbal form is a costly endeavour and there is no possibility of patent protection given the nature of the product. In other words, the risk reward profile is not favourable for pharmaceutical companies to initiate drug development with herbal cannabis in the conventional sense. This of

course does not mean that there is no interest from pharma at all. The Jazz-GW transaction shows that big pharma has not shut the door entirely on cannabis-based medicinal products with an MA. There are also several pharmaceutical companies in Germany and Italy that distribute cannabis-based products under the existing Special Access Schemes. In our view, the road to an eventual approved full spectrum medicinal cannabis product is a long one and it is an endeavour that would not be undertaken by a single company given the costs and potential rewards. It also requires gathering as much anecdotal evidence as possible to demonstrate safety and efficacy, and participating in smaller clinical studies like Bedrocan has been doing over the years. Harmonisation of EU-wide regulations would also support drug development as it would enable API manufacturers like Bedrocan to develop a certificate of suitability (CEP), which would form a major part of a dossier that can be submitted to regulatory authorities for obtaining an MA.

We have been monitoring developments in the CBD space as well but here again there is more noise and less substance. There might be some value in developing supply chains for cosmetic products that use plant-derived

CBD but for the moment, most of the CBD industry looks like a hype.

There is also a lot of noise about the development of a recreational market in Europe. But again there is not much information on how such a programme will be implemented and how the countries that are contemplating allowing access to cannabis for non-medical purposes will legislate without breaching UN and EU conventions on controlled substances. Moreover, legalisation in Canada has turned out to be disastrous from an economic point of view with massive waste of capital. It is likely that something similar would happen if any country moved forward with legalisation breaching regional and international conventions on cannabis. And legalisation, as we have seen in Canada, has led to negative consequences for patients who are now being supplied sub-standard products. Our hope is that policymakers fully consider the negative consequences of legalising cannabis for recreational purposes, including the social impact given that the long-term hazards of regular cannabis use in young adults has been well-demonstrated. And if policymakers do think that the benefits of legalising cannabis for non-medical purposes outweigh the risks then we hope for a clear bifurcation between medicinal/

pharma and recreational supply chains so that we do not have a repeat of what has happened to Canadian patients.

**Where does Bedrocan sit in that bigger picture? What is your footprint today? Competitive (dis)advantage? Is there a plan to develop something next to BMC? Is the BMC looking for additional suppliers?**

First and foremost, we are strictly a medical/pharma-focused company so Bedrocan would never participate in the recreational cannabis market. Even within the medical/pharma space, we are strong proponents of an evidence-based approach. Our products are never associated with therapeutic claims, something the industry especially in places like Australia is guilty of. Our strategic communication revolves around the strength of our generics and quality management system (QMS), and administering cannabis in the right form so that patients can derive maximum therapeutic benefit.

We have also stayed away from vertical integration and focused our operations on what we do best i.e. cultivation. Our core markets include Germany, Italy and the Netherlands, and we expect to continue to consolidate our position in each of these markets. We are also evaluating

other European markets but as mentioned previously, we are far more conservative in our view on how big the European medicinal cannabis market would be in five years from now.

Our short-term goal is to continue supplying high-quality products to core markets in Europe and collaborate with distributor partners to develop new markets that have come or are expected to come online in the region. We continue to monitor regulatory developments in North America, Latin America and Asia-Pacific and establishing supplies for our products in these markets is a three/five year goal for the company. Our longer-term goal is to obtain a CEP once EU regulations are harmonised and work with potential pharmaceutical partners in developing an approved inhaled medicinal product. To build the case for the latter, we actively seek opportunities to introduce our APIs in clinical studies although given the scale and size of our company, we do not intend to lead clinical studies.

Speaking of competitive advantage, the four pillars that our business stands on are the strength of our genetics, our QMS (we were the first to introduce GMP to the cannabis industry and have developed GMCCP or Good Medicinal Cannabis Cultivation Practice, which would be

a better standard than GACP for indoor cultivation), brand reputation build over two decades of delivering high-quality products to patients through the BMC, and finally our technical know-how or trade secrets when it comes to cultivation practices.

Of course, the way the Dutch supply chain has been created and the fact that Bedrocan has limited control over it given how the medicinal cannabis programme in the Netherlands is legislated has meant that we have not been able to fully capitalise on growth opportunities especially in Germany even though we continue to be the market leader with almost 27% market share in the first half of 2022. However, the medicinal cannabis programme and the role of the BMC has been reviewed by Dutch policymakers and positive developments in that regard are expected in the future. Exactly when those developments happen is difficult to predict given that any change to the policy in the Netherlands would require a legislative change and therefore,

in the summer of 2021, Bedrocan took the decision of expanding its operations outside the Netherlands. We are currently exploring the possibility of setting up a production site in Denmark. More details on this will be available later in the year but with this site, we are looking to capitalise on the type of opportunities that current regulations in the Netherlands do not enable.

**What type of revenue, margins etc are you allowed to achieve given the current pricing agreements with the BMC? Does that need to change?**

We cannot provide details of our framework agreement with the BMC, including agreements on pricing. In terms of revenue, we crossed the EUR15m mark in 2021, which compared to Canadian LPs and MSOs is relatively small, but our focus has always been on building a sustainable business model while delivering quality products rather than use top-line expansion for capital market activities. Indeed, while our revenue is relatively smaller,

we have been immensely profitable with EBITDA margins of more than 40% in 2021. And we have achieved this first and foremost with operational efficiency, which has kept our cost of production low and has given us room to weather the storm in the present environment of higher energy costs. We have also been prudent when it comes to investment decisions, which has enabled us to remain debt-free and maintain a robust balance sheet.

**What is the most difficult decision you had to take this year?**

That's actually the budgets for next year. As you know, electricity prices have been surging and they were just below 50% of our cost of goods before the rise. To compensate for the rise and make sure we stay in the black, we had to cut down our expansion plan for our plant R&D facility. That has been a difficult and sad decision.





## Lino Cereghetti

Chief Operating Officer at Pure Group

### What are the recent key developments in the Swiss CBD and cannabis markets?

The Swiss cannabis market is still young, but has already experienced a lot of change and has had to reinvent itself several times, due to fluctuating regulations and global market dynamics.

In the beginning, we had a regulatory competitive advantage with the CBD regulation in Switzerland (<1%THC), which allowed us to cultivate five times more product than our European competitors. This enabled us to supply the entire European market with cannabis. However, Pure has been aware for some time that this regulatory advantage would be terminated, and that it was only a matter of time before other low production cost countries would follow with the 1% limit. That is why we have built up strong brands over the last few years, placed them directly in the hands of our customers at the POS and focused on better-regulated markets such as recreational and medical THC. In parallel, with Puregene we have built up a world-leading platform for molecular plant breeding from Switzerland and conducted ground-breaking fundamental research for cannabis.

Although the commoditisation was foreseeable, I would be lying if I said I was not surprised by its speed. Many players were caught off guard by the consolidation and are no longer with us. Only those who were able to respond dynamically to the market, or are diversified enough to weather such a situation, are still around today. In the future, Switzerland will no longer compete for the overall market volumes in the low-price segment, but I am firmly convinced that high-quality Swiss cannabis products will always have their *raison d'être* and will create their niche in the European cannabis markets.

With the current regulatory situation, Switzerland is taking the pioneering role in the European cannabis industry that it deserves. We have already taken a pioneering role in a contemporary drug policy with the controlled distribution of heroin, and I am proud that Switzerland is again leading the way in cannabis. Market regulations in Switzerland will have a symbolic character for the whole of Europe.

### Where are you sitting in that market?

In 2016, Pure was a pioneer in the Swiss CBD market. We have grown organically, but extremely

rapidly over the last few years. While in the beginning Stevens focused exclusively on CBD flower production, he has since managed to gather a diversified team of cannabis experts around him, who focus on the different areas of the cannabis value chain in over five subsidiaries, including people from over 10 nations, 15 PhDs and one professor. With the highest number of THC research permits in Europe and the supply of Europe's first legal THC to pilot projects, we are also pioneers in the regulated THC industry of Europe. Established as a powerhouse in our home market, we are now continuously expanding our footprint in Europe. We have strong partners abroad, which implies a large network, but also allows us to scale our capacities according to market demand.

### What is the plan at the company?

Our plan is still the same. We have built and shaped the Swiss cannabis industry over the last few years and are currently expanding our footprint in Germany, Europe, and worldwide. With our international research team and our educational approach, we have been working for years to bring the potential of this versatile plant to society. We are convinced that cannabis and its ingredients are the answer to

many of our most pressing questions. With our differentiated portfolio, we are working to transform the way cannabis is grown, developed, and implemented in our daily lives. Our work is a key driver of cannabis industry regulation and paving the way for global social acceptance of cannabis.

### How is that going to translate into revenue and profits?

Until today, the entire revenue-generating business of the Pure Group was based on cannabis and hemp products with a THC value of less than 1%, respectively on the CBD business. The bulk and wholesale business arm have been exposed to an extreme price collapse and very high fluctuations in demand in recent years, whereas demand and price for end-consumer products and strong brands has stabilised.

However, the Pure Group prepared itself from the very beginning for markets that were far in the future at the time. Especially for market openings in the THC area as well as agricultural markets that the cannabis plant can revolutionise in the near future. Good examples of hemp's potential are its protein productivity, carbon fixation rate, and the development of novel and sustainable building materials and compounds from hemp fibre.

Up to now, despite all the difficulties, CBD has enjoyed an appealing business model with which we have been able to co-finance our plant research and our preparation for future markets. Now the Pure Group is very well positioned for the expected recreational market opening in Germany and probably soon after the nationwide recreational market opening in Switzerland. In our opinion, both markets as well as the medical cannabis market will lead to not just an appealing, but also an extremely successful, business line for the Pure Group in the medium term.

The medium- to long-term prosperity of Pure Group is underscored by our research, which offers tangible benefits (reduced losses in cultivation, quality, and quantity increase) in all current cannabis markets, as well as addressing the future cannabis markets through research-led breeding.

### What is the most interesting project that you are currently running at the company?

The project that is closest to my heart at the moment is the Swiss cannabis pilot project. Switzerland is finally accepting that it has a responsibility to lead an innovative drug policy in Europe, and we are at the heart of it. It makes me proud to be part of these pro-

jects. Never before has legally cultivated cannabis been distributed for recreational purposes in Europe and it is a pleasure for Pure, as a cannabis pioneer, to also pioneer THC regulation in the pilot projects. We are aware of our position as the market leader and the responsibility that comes with it and have supported these projects idealistically and practically since the parliamentary process. Through our commitment, we hope to be able to contribute to functional and constructive new regulation of cannabis and to give back to the Swiss people a plant whose history is closely interwoven with the history of Switzerland.

From a business perspective, the most interesting project that we are currently running at Pure is the preparation for market entry into Germany's upcoming recreational market. The key points recently announced by Karl Lauterbach provide a solid foundation for strategic planning, reinforcing our confidence in entering this market perfectly prepared, financially as well as logistically, with our broad brand portfolio, after years of groundwork with a backpack full of experience.

### What is the most important decision of 2022?

I do not believe that there is a single most important decision.

However, I am convinced that our current positioning is thanks to an accumulation of many good decisions, as well as some wrong decisions and the lessons we have learned from them over the last few years.

But this year we have again succeeded in reaching the milestones we set:

- Expansion through the acquisition of two established Swiss cannabis companies to better foster synergies and integrate additional

branches into the value chain, resulting in overall revenue growth.

- Relocation of Pure Production AG and Pure Pharma AG to the new Pure HQ in Laufenburg.
- Expansion of Puregene AG and takeover of the entire Pure Campus as a sole research location for the rapidly growing Puregene AG team.
- Approval of the first Cannabis Pilot Project in Europe (Weed-Care).
- Passing of the Cannabis Medicinal Products Act.

- Inspection, approval, and start of operations at Pure Pharma AG
- Market entry in Germany (CBD, medical THC) and positioning for recreational THC market opening

## SEED

### Alfredo Pascual

Vice President of Investment Analysis at Seed Innovations

Alfredo, you have been involved in the European cannabis industry since late 2016. Can you share with us some of your observations over these past five years.

When I started, there was barely any talk about a cannabis industry in Europe. And now, just a few years later, this has become quite a dynamic sector. The German market, which has been leading the pack in Europe, developed from almost nothing. Before 2017, there were only about 1,000 German patients who had a special authorisation. Fast forward to 2022: Germany needs to import over 20 tons of medicinal cannabis per year. And now the German government is committed to legalising adult-use. So you could say that's a big change in just a few years.

But also in other European countries there have been some important developments. In the UK there was nothing meaningful going on until a couple of years ago and now there's a rapidly growing market; In France there's an ongoing medicinal cannabis trial with the expectation that it will be extended or turned into a full market in 2023. Similar things can be said about other European countries. In some countries, de-

velopments have centred on production for export. For instance, in Portugal and Denmark which together with the Netherlands have become the production hubs of Europe. In Denmark and Portugal, the number of domestic patients is quite low considering all the companies that are operating there, mostly to export to Germany. That ever more countries export to Germany is also an interesting development that was not so common at the beginning of 2017, when basically all the supply into Germany stemmed from the Netherlands and Canada. Now it also includes countries from Africa, Latin America and Oceania. Growth in the German market has generated a lot of changes in other European and non-European countries.

#### **So let's go forward five years from now Alfredo. What would you see in your crystal ball?**

That's always a difficult question. I think it is reasonable to expect that five years from now there will be a recreational market in Germany and perhaps in other European countries. The actual timeline that German legislators are promising is more optimistic than that, with Federal Health Minister Karl Lauterbach considering legalisation in 2024 "realistic" if

all goes well. However, those of us who have been working in the industry for a while, know that it's not just about legalisation, it's also about implementing the law and the hurdles that come along the way. But it is reasonable to expect that five years from now there will be a recreational market in Germany. One of the effects to be expected from that is that companies will face a decision: whether to try to be both "medical" and "recreational", or to focus on being a truly medical company, or focus solely on the recreational market. Now, there's a large number of companies operating in the medicinal cannabis market because that's where they can operate legally, but many would rather be involved in the recreational cannabis market. Those companies are likely to quickly pivot towards the recreational market once cannabis for adult use is legalised and that may relieve pressure in the medical market, which has become quite competitive. There are now too many companies following similar business models in the European medical cannabis industry. I expect that five years from now, there will be a clearer divide between companies operating in the recreational market and companies operating in the medical market. And the Euro-

pean medical cannabis industry has an advantage over North America, which is public health insurance reimbursement at least in some countries.

**Within that framework, how are you steering the investments of Seed Innovations?**

Seed Innovations is an investing company that is listed on the AIM London Stock Exchange and focuses on the cannabis industry. Cannabis is currently about 40% of our portfolio, the other 60% being for the most part, biotech companies and one gaming company – part of what we call our legacy assets. Our focus is on emerging industries, high growth, fast-moving sectors, and technologies of the future. And cannabis is one of those, but it's not just cannabis. Our latest investment was in Clean Food Group, a company which among other things is trying to manufacture at scale a palm oil substitute in the UK. Within cannabis, our investments include medical cannabis with some CBD as well, but no recreational because of the Proceeds of Crimes Act from 2002. Our two largest investments in the cannabis sector are Avextra and Little Green Pharma. Avextra is a private, vertically integrated German company with cultivation in Portugal and manufacturing capabilities in Germany. Little Green Pharma is publicly

listed on the Australian Stock Exchange, it's a market leader in Australia and has a large cultivation facility in Denmark that it acquired from Canopy Growth over a year ago.

What is your feeling on how the German legislative process is progressing?

Two positives and two question marks. First, the two positives. One can sense a genuine commitment from the German government to legalise adult use and there's an explicit, tentative timeline. This is important because without a timeline, things are just too intangible and it's hard to keep policy makers accountable. In October, a position paper with the key points of how the coalition government sees legalisation was presented. Germany will use this paper to engage in dialogue with the EU to confirm whether legalisation would comply with EU and international law. If that goes well, the first draft law is expected to be introduced to the Bundestag early next year and Federal Health Minister Karl Lauterbach has signalled that it would be realistic to expect legalisation in 2024. In the meantime, there are still plenty of unanswered questions. Some of these questions are about details such as whether there will be online sales or if onsite consumption will be

legal. But in my view the two key issues are:

- whether Germany's argument that its legalisation proposal is aligned with the object and purpose of the international drug control treaties and EU law will be accepted by the EU Commission and other member states. The way Germany is justifying its legalisation proposal is comparable to what Uruguay did almost 10 years ago, but Uruguay obviously didn't have to deal with EU authorities. International treaties should be interpreted not just textually but also in light of their object and purpose (see Art. 31 of the Vienna Convention on the Law of Treaties). And it could be argued that the object and purpose of the 1961 Single Convention was to protect the health and welfare of mankind, as per its preamble first sentence. Germany is arguing that the prohibitionist interpretation of the international drug control treaties failed to achieve the object and purpose of those treaties (health, welfare) so something different must be tried. And Germany is also saying that its legalisation proposal (heavily focused on health) would better fulfil the object and purpose of the drug control treaties (something that the prohibitionist interpretation of the last decades failed to achieve).

This is not a bad argument, but it's a risky one. International treaties don't just state purposes but also prescribe how to reach those purposes. I guess we'll soon see how the European Commission «reads» all this.

- The second question, assuming that after a successful exchange with the EU the legislative process begins in parliament, is how the German government will then manage to get this through the Bundesrat, the upper house that represents the German federated states. The government has a majority in the Bundestag, so the legislative process should be smooth there. But at the Bundesrat level things could be more complicated (the Bundesrat has a total of 69 votes. 35 votes are therefore needed to achieve an absolute majority, Ed.). The opposition currently has the ability to block bills that require Bundesrat consent. That doesn't mean that they will want to block it at

all costs. I guess the government and opposition will probably come to an agreement given the consensus culture in German politics. But we still don't know what that agreement could look like.

In short, the positives are the commitment of the government and the clear timeline that they have. The question marks are still international law obligations and later possibly the Bundesrat.

**Thanks for that very detailed answer. To finish our interview, what kind of projects excite you most?**

Let me start with what I don't find attractive, which are businesses whose plans depend on still uncertain regulatory changes. For example, companies that are already including in their projections recreational sales in Germany from January 2024. That's wishful thinking. I mean, is there a tiny chance that that

could happen? Perhaps. But it's quite unlikely. And I'm seeing this with both companies in Germany but also elsewhere, for example companies that are planning to export for the German recreational market in 2024. It's still very unclear how international trade for recreational cannabis will work, if at all.

What I do like are companies that truly understand the actual situation in Europe, in terms of what the actual regulations in Europe are, what the actual market sizes is, and which don't waste several pages of their decks telling investors how big the European market will be in 10 years after many countries legalise. I've seen these projections too many times and seeing that doesn't tell me why we should invest in a particular company. I prefer to see what types of problems these companies want to solve.





**Oliver Zugel**  
Founder and CEO of FoliuMed

**As a starter, Oliver, what was the most important decision that you have had to take this year?**

In a market with opportunities ranging from recreational to medical uses, with a myriad of product forms and a bunch of regulatory pathways, we needed to ask ourselves constantly ‘Where do our core strengths lie?’ discarding many opportunities along the way. For an entrepreneur, that’s probably the hardest thing to do, particularly when you are self-financed and need to chase revenue every day to keep the plants growing and the production line running. As we have seen the demand for our prescription soft gel product growing exponentially this year, we decided to focus on that product at the expense of others where we don’t have the same type of advantage.

**In which market segment do you finally want to position your company?**

We think that a large part of the medical cannabis market as it exists today will either be taken over by pharmaceutical players or migrate towards adult-use, particularly for flower. If that’s true, the dosage forms which will survive for medical patients are pharmaceutical and contain substantial

intellectual property, which is very different from today’s oral solutions which are commodities.

The soft gels that we are making today are affordable and a much better dosage form than tinctures, which cannot be dosed precisely and often have an unpleasant taste. Until now, the problem was that soft gels cost nearly double the price of a tincture, which made them unviable for the broader patient population in self-payer markets. We have solved that problem by sourcing for our German GMP operation a low-cost API from Colombia where the cost of growing the plant is a fraction of what it is in the northern hemisphere. So, we can give doctors and patients a real choice between a tincture and a soft gel at the same cost per dose, well below USD5 per dose. That was unheard of in the industry, and it explains why we believe that it could revolutionise the way oral cannabis medicines are being taken.

**Are you already selling the soft gel product?**

We have a B2B business model and are commercialising them in three formulations: THC-high, balanced and CBD-high. We initially sold only in Australia through a market-leading cannabis com-

pany and are now expanding our footprint to other jurisdictions including Germany, Switzerland, the UK and some Latam markets. Interestingly, whilst the original interest arose from medical cannabis players, we are now increasingly seeing specialty pharma companies interested in the product, as it better supports their clinical trial programmes and IP development objectives than a tincture.

**Does FoliuMed have a competitive advantage?**

Our advantage is built around three pillars: access to low cost, pharma-grade API, the specific production know-how our team has established around soft gels and falling manufacturing costs as volumes increase. This ultimately creates a virtuous circle whereby adding more customers makes the product more affordable. This is what we think matters the most in today’s market where cannabis remains too expensive to become a mainstream treatment option, and in the future needs to be complemented by additional IP, clinical evidence and data around bioavailability and pharmacokinetics.

**When do you expect your products to be available in European markets?**

We are currently examining the

regulatory pathways available to commercialise prescription soft gels in Europe and Latam. In some markets, we will take the compounding pharmacy and in others special access routes established for medical cannabis. We are confident that, during 2023, our soft gels will be available in at the least two European jurisdictions.

**So, are you going to be a pure medical-cannabis company, or will you also be active in the adult-use market?**

What we will do in adult use really remains a reflection in flux, and it is too early to tell. Apart from Germany and Switzerland, we now are seeing Colombia – the country where we started in 2018 – taking an accelerated path towards legalising cannabis for recreational use. What is quite clear to us is that if and when we ultimately enter that space, it will be done through a separate company with a different management team and organisation, complexities as housing pharma and recreational use under the same roof is likely to be a recipe for failure.

**What are the key assets that you can employ for your business model?**

I think that what our customers value most is our pharmaceutical capability, the ability to serve them around the globe and supply

a unique product at a price point that no one else is currently able to match. This we achieve by being vertically integrated from low-cost cultivation in Colombia to pharmaceutical production in Germany and, as in any other business, what really matters the most is the incredible talent we have been able to attract and retain in our company. Since we founded FoliuMed, we have been privileged to work with the same senior management team and this really has been at the root of our success and a source of joy for me and my colleagues every day.

**The cannabis industry around the globe is looking at the liberalisation of the European market. Which developments are you seeing?**

Obviously, there is no single European cannabis market, as every country is writing its own regulations. For a still-small and agile company like ours which has operated in eight jurisdictions since we started, that’s an advantage and an environment in which we feel comfortable. As I said before, we think the European medical cannabis industry is now coming to an inflection point, and the competitive landscape will look very different in the second half of this decade from what it is today. On the one hand, patients will be able to access prescription products which look much more like tradi-

tional pharmaceuticals, and on the other hand there will be cannabis dispensaries retailing a large variety of consumer products as we are seeing in the US – including vapes, edibles, beverages and the like – to supply recreational users. There also is a good chance that CBD will by then have made it into the mainstream food supplement category for low dose consumer applications.

**What do you think about the latest news in relation to German adult-use legalisation and how will it affect FoliuMed ?**

The German government has progressed at a surprisingly strong pace with its electoral promise of regulating adult use and is taking a sensible, and in our view promising, approach with the EU to navigate rough legal waters.

Let’s not forget that it has a difficult balancing act at hand to try and reconcile the priority objective of protecting public health with a myriad of other conflicting interests like combatting the black market, collecting taxes or protecting the environment. Squaring that circle will not be easy, particularly when done through the consensus politics Germans are well known for.

In Germany, we think that contrary to North America, the medical market should remain attractive and FoliuMed, through our unique

capsule product, will play a major role. We are seeing demand grow exponentially, and are pursuing different regulatory pathways in multiple jurisdictions to get the product into the hands of patients and doctors.

In addition, the German government announced that whilst edibles will not be permitted for

adult use, capsules will be. This opens up an opportunity for us to operate on both sides of the playing field as a B2B white label product provider.

Finally, few people are aware that Colombia is also regulating adult use, and this should be achieved even earlier than Germany where 2024 is now the expected due

date. This puts us as a company in a very unique position of being present in two major deregulating markets at the same time.

**SEMDOR**  
PHARMA GROUP

**David Henn**  
CEO at Semdor Pharma Group

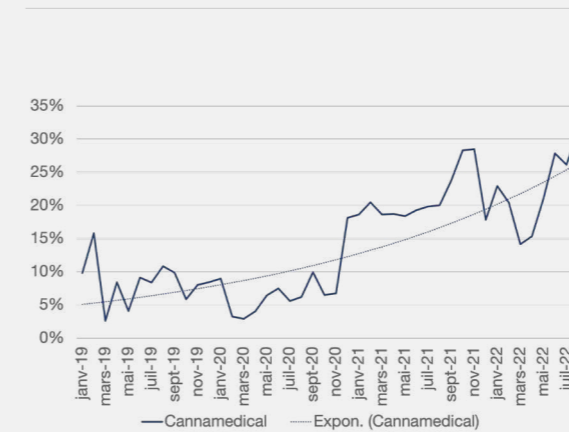
**Cannamedical was one of the first companies in the German medical cannabis market. How have you seen the market evolving?**

The overall cannabis market has experienced strong momentum,

which is reflected in brand diversification, an improvement of the overall supply situation and developments of new dosage forms. The number of actively trading cannabis flower brands has grown from nine to over 30 since mid-2020. Cannabis ex-

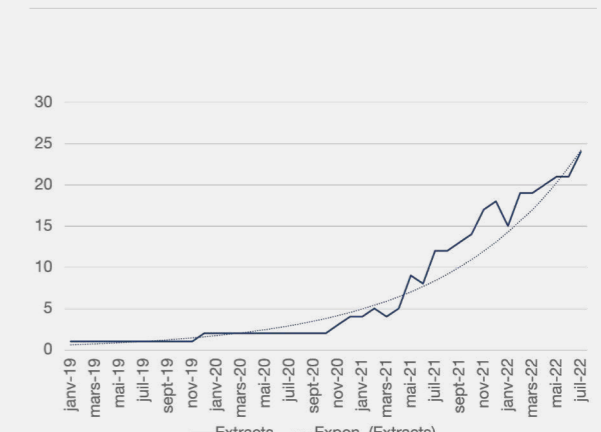
tract brands have grown from three to almost 30 during the same period. As of today, more than 30 suppliers hold an EU-GMP certification status.

**FIG 40: ACTIVE CANNABIS FLOWER BRANDS**



Source: Semdor Pharma Group

**FIG 41: ACTIVE EXTRACT BRANDS**



Source: Semdor Pharma Group

This has also left its mark on the supply of products which physicians are able to prescribe. Germany currently has 1,317 registered cannabis products or "PZNs", of which 1,056 are for flowers, 135 for extracts and 126 for Dronabinol. Germany requires cannabis physicians to prescribe a specific brand and product

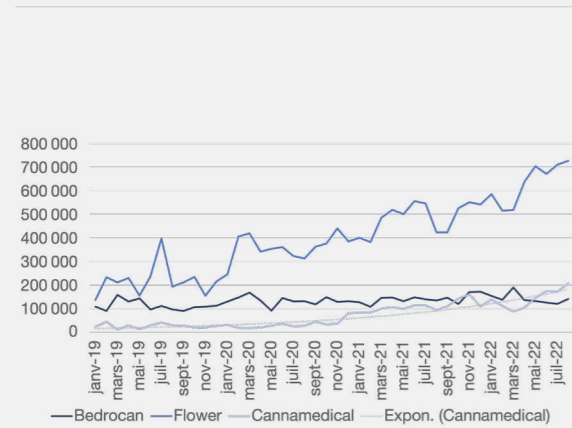
(Flower and Extract) to patients. As a result, physicians and pharmacists rely on brands known for their medical impact, reliability, and consistent availability.

The available data from Insight Health underlines the continued growth of the non-Bedrocan product market. Non-Bedrocan can-

nabis product has grown ~30% year-over-year with total volume of over 700 kgs per month, while the total amount of extract released has remained stable in recent months.

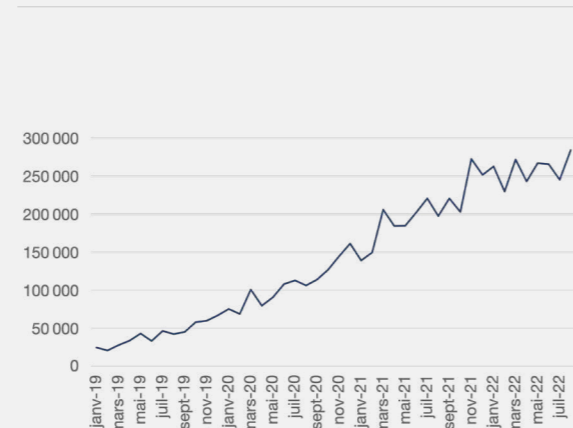
The importance of a strong, established brand in this competitive market environment has increased

**FIG 42: FLOWER (IN GRAM)**



Source: Semdor Pharma Group

**FIG 43: EXTRACT (ML)**



Source: Semdor Pharma Group

significantly in the last twelve months, as product development has become increasingly complex and expensive. Cannamedical has continued to increase its product portfolio awareness despite rising market competition. According to an independent survey by Aposcope in 2022, 33% of all pharmacists recognise Cannamedical as a cannabis brand and associate Cannamedical with good or very good reliability.

Most German brands deploy the same marketing strategy: demonstrate market share growth for investors by discounting products sold to pharmacies, even if the discounts are not economically sustainable. This practice has led to distortion within the market. We expect consolidation within the market as a result.

The market has also been impacted by more selective access to growth capital within the overall cannabis industry in the last twelve months. Investors have become more selective in investment decisions since the peak in 2018/2019, when many companies were able to raise capital on the basis of unrealistic promises of growth that have not been realised to date for various reasons. We expect that German cannabis legislation scheduled to come into effect in 2024 will increase the importance of Germany as a key target for M&A transactions in the space. However, free cash flow and cash planning will continue to increase in importance with only a few select profitable performers present in the market.

**How do you see the medical cannabis market evolving now that there is talk about legalising adult-use?**

Germany, like any other democratic system, follows a clear structure when it comes to new bill introduction. The complexity with respect to a German cannabis law is that several elements in the national legislation must also align with EU institutions and international law. We view as realistic a scenario where legalisation is realised some time in H2 2023.

It is not well known that the German medical cannabis market exists within e-commerce and is supported by a pharmacy-plus concept. We believe that the most efficient path for a successful legalisation remains a pharma-

cy-controlled model, which has a track record for handling and storing narcotic products. The key challenge for German regulators is to decide on the right quality standards now. We believe that the Good Manufacturing Practice “EU-GMP” quality standard is the only reliable option. It minimises the product from microbiological and other substances contamination, regulates the entire manufacturing process, sets standards for documentation and labelling, regulates shelf life, and ensures trackability from seed to sale. As a result of these practices, Germany has a significantly lower batch recall rate compared to other developed markets such as those in the US.

**Would you participate in the adult-use market if it gets legalised, or would you rather stay with the medicinal cannabis market?**

Yes, Cannamedical will participate in the recreational market as it’s a unique greenfield opportunity, but likely under a separate brand to keep our segments independent from one another.

**How are you organising your supply chain?**

CM takes a clear approach of well-structured diversification of its product portfolio supply. The company partners with contract

manufacturers around the world who are capable of meeting our unique quality standards and specifications. The supplier selection and on-boarding process typically takes one year on average from the first contact point to first shipment. We currently source from three continents (Northern America, Australia and Europe) and will introduce Southern Africa grown Cannabis in the near future.

The cannabis market turned from a seller to buyer market in the last years. International investors are focused on collecting volume off-take commitments from German buyers, but will realise soon that their standards will be very hard to meet for importers. Germany imported a total of almost 10,500 kgs of medical cannabis flowers during the first half of 2022, according to new data released by the government.

According to Insight Health, only 5,000 kgs were sold in the same period. This implies a build of inventory, based on any product was neither exported or converted into extract.

**What level of revenue and profit is Cannamedical running at? Revenues?**

We continue our growth journey from 2021 in which we ended the year with revenue growth of

+110% YoY. Cannamedical has a carefully designed cost structure which allows us to generate positive cash flow and profitability at currently sales levels. We are confident in our ability to scale our Semdor Cannabis product and service revenue to EUR40m by 2023.

**Are you looking at European markets?**

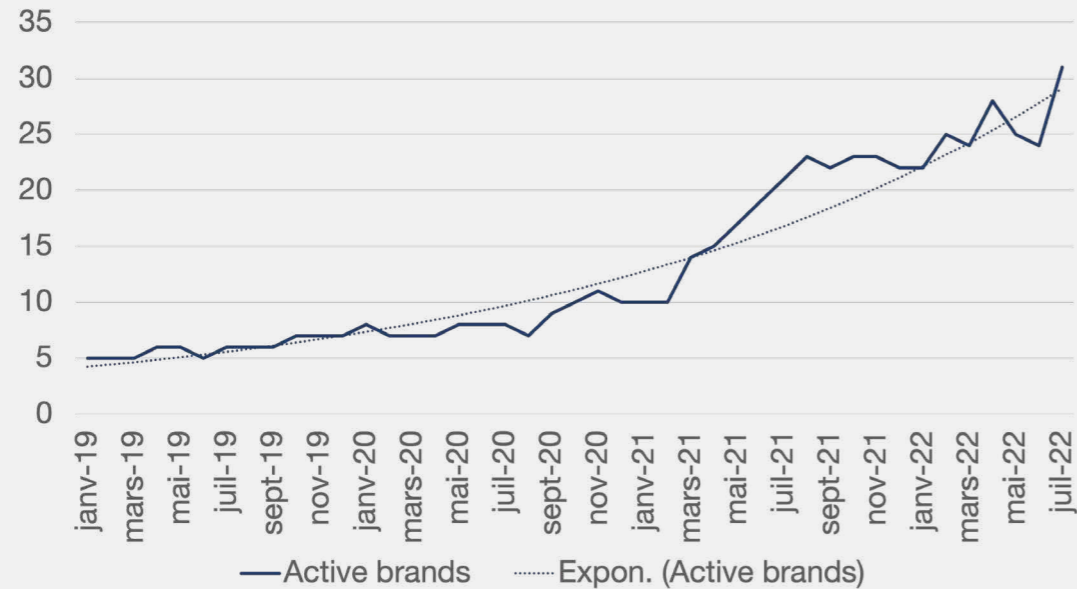
The EU has around 35% more citizens than the US (447M vs. 330M). We believe that it is only a matter of time before there is a united EU medical cannabis market and expect medical law harmonisation within the next 3-5 years. Multiple EU countries including France, Poland, Italy, Czech Republic, and Croatia have established medical cannabis markets showing strong upward development. It will be difficult for Germany standing alone to compete with US market potential, but we maintain a positive outlook on sustaining significant growth in the coming 24 months.

**What’s the most important decision that you took in the past years?**

To trust in our vision and ability, remain confident, reject takeover offers and continue to make investments to expand our business. Cannamedical strongly



FIG 43: CANNAMEDICAL MARKET SHARE



Source: Semdor Pharma Group

benefits from the know-how of our PS Pharma sister company which we continue to access since the merger with Semdor Pharma Group. This partnership allows us to leverage PS Phar-

ma's 20+ years of research and its ability to develop alternative form functions faster than any other market participants in an extremely challenging regulatory environment. Our new 2,500 sqm

facility in Meerbusch will be used to support new dosage forms beginning in Q4 2022, while more broadly supporting overall growth in the medical and recreational cannabis markets



**Florian Holzapfel**  
Founder Cantourage

**How do you see the medical and recreational cannabis market potential in Germany?**

On the medicinal side of the market, business is developing nicely as more prescriptions are written. Business models are evolving, especially with regard to prescription of cannabis. More and more doctors are prescribing – and some specialise in – cannabis, which is helping the overall market. And you see that in the development of all product categories from flowers to extracts and dronabinol (a synthetic form of delta-9-tetrahydrocannabinol, Ed). So growth is extremely satisfactory. Nobody knows exactly how many patients there are, but there must be at least 100,000 and the number is rising constantly. We all know that the potential is much higher, but it will take time to get there. With the prospect of legalisation of recreational cannabis, we are seeing an acceleration in the medicinal cannabis market. This is because there is now a growing understanding also from physicians that this substance is going to become legal and with that, fear and the reticence are easing.

On the legalisation of recreational cannabis, numerous rumours are circulating, but at the end of

the year we will probably have a much clearer view. To my understanding, the government is first going to come out with some kind of positioning paper on how legalisation of the recreational market will look. When we speak with politicians it is already very clear that legalisation will proceed, but it is still unclear what the route is going to be.

**With that view on market dynamics, how are you positioning Cantourage?**

One part of our strategy is to get flower from all over the world to Germany. Here we offer suppliers a quick way (three to six months) into the German market. We have signed up more than 30 partners and already 10 of them are delivering us product for the German market and the remaining ones are coming online in the next six to 12 months. And they're sending us a raw product that we're transforming into a pharmaceutical product here and then we sell it to pharmacies. It's a relatively open system. We are actually the enabler for anybody in the world who wants to get medicinal cannabis to Germany. With those products, we are capturing a good portion of the flower market and we expect to grow our share further when we come online with all

the new suppliers and all the new strains. We have a good range of products. We go from low cost flowers that the pharmacies are selling including VAT for EUR5 – that is a very low price insensitive proposition. On the other side, we are bringing in very high quality flower like MAC 1 from Miracle Valley in Canada, which is seen as one of the best products (25% THC) in the German market and one that sells at higher prices, and we will bring more such products to market. So we actually offer a whole range of products. And also within these we are providing products which address the needs of patients, for example, we don't do any radiation. We have an alternative to reduce the microbiologic load without lowering the amount of cannabinoids and terpenes. So we are offering a whole variety of products in different market segments, but we are also enhancing the quality of the product.

Another part of our strategy is challenging the monopoly of Dermapharm in Dronabinol. We have brought a toner with Dronabinol and that new product eliminates the need for time-consuming processing steps such as liquefaction, weighing and dissolving of the active ingredient in dronabinol. Nobody else has that product in the market right now.

And lastly, we are also looking at extracts and ready-made medicines, but here too we do not want to copy what is already in the market, but are seeking to develop new market-disruptive products.

**So how does your earnings model look?**

We are selling flowers of different producers into Germany and offer them a service including transforming the product from a raw material into a medicine, doing the logistics, handing the narcotics documentation, selling the product to the pharmacists, doing all the billing etc. And for that we are getting a share of the revenue.

**With the wide product range that you have available, would you be able to tell me what the consumer really wants to buy?**

For the moment, demand is strongest for flowers with high THC, also at a relatively high price level. But with new patients entering the market, growth will probably come from both ends of the pricing ladder, especially for those patients that are paying out of their pocket, which is about 50% of the market. Depending on how much those patients buy, it can become an expensive treatment. For a patient who needs 50 grams a month, it makes a considerable difference if the price is EUR5

per gram, equating to EUR250 per month, or EUR15 per gram, costing then EUR750 euros per month. So we see that some patients on a prescription take 20% higher priced products with 25% THC and for the rest take a lower priced product with 18% THC. So it is not black and white, but patients who use cannabis over a longer time horizon tend more towards higher THC products.

Which the most interesting project that you're currently working on besides your stock market listing?

Bringing all these new strains into the market, and changing the understanding how this medicine works, is for me one of the most interesting things. Patients expect cannabis to work like any other medicine that you continue to take once you have a specific dose to which they respond. But in my opinion, that is not the case. I believe that a lot about cannabis is also about changing your treatment from time to time, having different strains and making sure that it helps you in specific situations. It's not that you just have one compound with a certain level of THC and that is that, but it is the variety of different elements that is helping. And a lot of work still needs to be done with regards how the different cannabinoids work together.

**What's the most important decision that you have had to take this year?**

Whether or not the company should be listed on the stock exchange is a tough decision. Advisors tell us that it's a difficult time to go public. But like with other aspects in the development of the company where people have been telling us that it is difficult, we have been successful in implementing our strategy and it's the same with going public. We believe it makes sense for our company to go public, independent of what's happening in the market.



**Tej Virk**  
CEO at Akanda

**Can I, as a starter, ask your view on the development of the European cannabis market.**

I've been involved in the European cannabis space for nearly five years, either as a banker operating in the space or as an executive. I've seen the evolution from the start and my belief going into the European cannabis industry was that we would eventually see a recreational, adult-use industry form. This was a logical derivative, based on what we've seen in Canada and the United States. Canada, federally legalised in 2018, and in the United States, you've seen the state-by-state approach with varying degrees of regulation depending on the state. Legalisation of cannabis in Europe is a natural progression. They are all connected economies that trade with each other, and I'm sure that the Europeans don't want to miss out on the economic stimulus that has come with the rolling out of recreational cannabis in North America. We've seen that the legalisation generated billions of dollars of tax revenue, coupled with significant GDP growth and job creation. In the midst of an economic downturn, high inflation, and increased geopolitical uncertainty in Europe, cannabis looks like a great place to diver-

sify. We've seen the medical cannabis market come together with Germany as a leader, that continues to push for adult-use regulation. It's fascinating that one of the first things that the traffic light coalition put forward publicly was cannabis legalisation. This is highly symbolic and it is creating a lot of market opportunity, as the leader in the European Union, in terms of the size of the economy, you're going to see this echo and reverberate in other countries. The Germans are the de facto bureaucrats within the EU. They will create and pass the law and other EU countries will emulate and copy elements. Because if it passes the German legislative process, I think you have a good chance of passing the French, Spanish, Portuguese, and Italian processes. Akanda Corp is based in Portugal, which provides a great framework to operate as a medical cannabis cultivator and manufacturer. We've now seen some proposed legislation in Portugal to go adult-use as well. So, there is a political will to legalise. But the timing of this is still in question – are they going to legalise before Germany or after? It would be really amazing if Portugal legalised it first to help maintain its leadership position, but we'll see.

Germany recently issued a concept note laying out the key points shaping the regulation of its recreational cannabis market. There is still some way to go and a number of questions to be answered, and the key gating factor is European Commission approval. EC support would have wider ramifications for other countries in Europe that are considering adult-use legalisation. A key question concerning the published guidelines relates to domestic cultivation vs. imports for adult-use cannabis in Germany. For domestic cultivation to be a success, this would require long lead times and huge investment commitments, which may defeat some of the goals of the intended legalisation bill, including consumer safety.

**What are the assets that you have in place to operate in the European cannabis market?**

As it stands, Akanda is a medical cannabis company, but we have declared our intention to enter the European adult-use market once it starts and we see clear rules. But I am not betting on governments. I'm not setting up the business to be dependent on government timelines. Akanda is focused on being profitable in the medical cannabis market in

Europe, which I see as a precursor to recreational use and once we have the recreational rules in place, we will hyper-scale to that opportunity. And I think we have the asset base that will allow us to do that.

There are really two companies within our portfolio that are positioned to benefit from the European opportunity. The first one is our flagship asset, which is Holigen. In Portugal, Holigen has two sites through which we can cultivate and produce medical cannabis products. The first is in Sintra, which is an indoor premium cultivation facility, one of a kind within Portugal, and among a handful of indoor premium cultivation assets located within the European Union. This site has the ability to cultivate approximately two tonnes of indoor premium cannabis per year. It is a GMP-certified operation and what's interesting is that we have the ability to co-manufacture third-party cannabis products so we can import GACP material and manufacture it into EU GMP medical cannabis. We have 10 tonnes of processing capacity of which we use two, so we have an additional eight tonnes to process third-party cannabis into EU GMP medical cannabis. We could import from anywhere in the world where there is a regulated approach to the import and export of cannabis. This includes

Canada, Colombia, Australia, South Africa, etc.

The second site that we have in Portugal is an outdoor greenhouse in Aljustrel, two hours south of Lisbon. The Aljustrel site is 180 acres, enclosed, with polytunnel greenhouses and a post-harvest facility (which can produce potentially 100 tonnes of cannabis). This site is currently on care and maintenance, but is something that we are actively entertaining proposals to commercialise. This is an exciting opportunity for us to achieve real operating leverage, because the site can produce products that are suitable for the European cannabis supply chain for medical uses and it provides us with huge optionality for the adult-use recreational markets, which may have differing standards. So, to hyper-scale to the opportunity we will source material from third-party cultivators around the world and thus unlock the value of Aljustrel. That may continue in an adult use world, depending on the rules yet to be finalised by regulators.

We also own CanMart a fully licensed wholesaler and distribution company within the UK that is able to import and distribute medical cannabis. This is a nice foothold in the UK market that is starting to see more meaningful volumes. Whereas the Ger-

man market is estimated to have between 100,000 to 150,000 patients, there may be 10,000 to 15,000 patients in the UK right now. And they're served largely through the private payer market in the UK, whereas Germany has an element of insurance coverage and reimbursement for medical cannabis products. Having a wholesaler in the UK allows us to participate in another part of the value chain and capture more margin, whereas right now in Portugal, our customers are the wholesalers in other parts of Europe.

**In your company there is a strong bias towards cultivation. Is that the right place to be?**

If you look at Canada, being in the cultivation and production layer is precarious. In North America, we saw massive overbuilding of capacity as a result of capital markets that incentivised companies to build as much as possible. This was way more capacity than what the market could actually absorb. Secondly, there was a limited understanding of what consumers and patients really wanted. We have since learned that demand preferences shift rapidly as consumers adjust to legal, and away from the legacy black market. For me, one of the best analogies is the fast fashion industry. We need to be

drawing more parallels to H&M and Zara, which adapt quickly to changing consumer preferences. Successful players in the United States and Canada are doing this because they're listening to the consumer, who is somewhat fickle in the cannabis space, partly because they're getting used to a new legal market that is different from the black market. Consumers are experimenting with different products. At the same time, it's quite clear that consumers really like innovation, new exclusive strains, and derivative products in vaping. So, this fast fashion element is something we can't ignore. Some of the best players in the United States are the ones that are planning their product cycle forward. Cookies is one of those players, so that's why we partnered with them. We want to be able to tap into that ourselves for the European market.

If we fast forward the flower market in Europe, it's likely that we will have a premium market, that is an indoor grow and a value product market, greenhouse, or outdoor. At the moment, Akanda is focused on indoor premium cultivation, where we can control all the variables. It yields a product that tends to have higher THC, a richer terpene profile, and nicer aesthetic. Also by following European pharmaceutical standards, because you're control-

ling that environment, you likely don't need to irradiate the product which is preferable because irradiation can also change the product for the worse.

What's really interesting about being in production in Europe, is that it is the opposite to what happened in Canada. First of all, there's hardly any indoor cultivation capacity in the European Union. This is limited to players in the Netherlands and Germany. Establishing new indoor cultivation capacity is costly, especially in the current high-inflation environment. So, we like to be in this space where there is scarcity, and we want to extend our lead. At the end of the day, somebody has to make the product. Some European players point to the asset-light advantages of being a marketplace or distributor, but they still need to source the product. We want to be producing premium flowers in Sintra and we're going to be able to produce a value product in Aljustrel. If the rules allow, we could produce vape pen distillates, etc. with 180 acres potentially dedicated to this. Some are arguing that the product can come from other parts of the world, but, as a hedge on the regulations and protectionism, having a foothold in the European Union really matters. We don't know for sure if, in the recreational markets, Germany will import from say Cana-

da which does not import from anywhere else. So what does that mean? Some of it has to do with the UN single convention on narcotics. Some of it has to do with protectionist measures that the government is taking. But at least being in the EU, you have Schengen and you have the single market, which could mitigate against those factors.

**There is a lot happening at Akanda, but what is the most interesting project that you're currently working on?**

That would be the Cookies licensing deal that we did. With Cookies, we're addressing the quality and innovation demands of patients. The agreement provides us with new strains and cultivars, which are leading products in the competitive US market. Cookies is an iconic brand. It's probably the best-known brand in the world and there is a lot of cachets that stems with that. In the European market, where you cannot advertise, brand awareness matters a lot.

What's the most important decision that you have taken this year?

The most important decision was going public on the NASDAQ. Shortly after we announced our IPO, the crisis in Eastern Europe broke out and changed market



conditions dramatically. We even had to postpone our IPO. Nevertheless, we came to the conclusion that we still wanted to do this, because in the background we were working on the M&A of Holigen and other initiatives. And, by being a public company, we would have more flexibility.

I think what we accomplished was pretty special in regard to the entire cannabis space. We have achieved a lot in the short amount of time since Akanda was founded in the summer of 2021: completing a pre-IPO private placement, IPO'ing the company on the NASDAQ, acquiring

Holigen, landing a supply deal in Germany, and importantly the Cookies partnership. I'm very proud of these accomplishments. I'm proud of our team for getting this all together. And now, we have this fantastic opportunity ahead of us, and it's because of the IPO.



**Don Bellamy**  
CEO Linneo Health

**Can you give me some background on how Linneo Health got involved in the cannabis industry?**

Linneo was originally a spin-off from Alcaliber (the leading supplier of opiates to the pharmaceutical industry, Ed.). Today it is an independent company, 100% focused on medicinal cannabis. Linneo grows medicinal cannabis under high-tech greenhouse conditions in Murcia, in south-eastern Spain, and focuses on the cultivation and GMP-certified processing of dry cannabis flowers for pharmaceutical purposes. Our current yearly indoor growing capacity could reach 25 tonnes, and this has the potential to be expanded if needed. Linneo also has access to unlimited, GACP-certified and organic outdoor cultivation to produce biomass for industrial cannabis extracts. Alcaliber remains our exclusive contract manufacturer for extracted products.

**What are your major markets for produce?**

Linneo is the premier B2B supplier for the medicinal cannabis industry in the world. Being 100%-focused on medical products, our accessible markets are those that have appropriate

regulation for medicinal cannabis – for example Germany, UK, Israel and Italy. As more markets introduce cannabis regulations, we continue to expand. We supply a range of high-quality medical-grade cannabis products to various companies around the world who are active in the markets I mentioned earlier, and who have the right licences to be able to access the final customer.

**How do you see the European medicinal cannabis market developing?**

As a general comment, it is clear that every single market, without exception, is under-explored and has potential if you compare it to, for example, some of the usage rates that you see in Canada, or in the United States. In Germany, less than 1% of the general population has had exposure to medical cannabis, significantly below the rate in North America. So even in the most developed European market, we continue to see potential for an expanded market to address patient needs for serious medical conditions like pain, anxiety and insomnia.

In Germany, there is a lot of discussion about recreational use of cannabis. As a company purely focused on medicinal can-

nabis, we don't have an opinion on whether the German people and its government feel this is the right thing to do. My focus is ensuring that, in this debate, patients are not left behind. If Germany chooses to legalise recreational cannabis, I would like to see the rights that German patients have secured over the years and for which they fought so hard, defended. Patients deserve the right to consult a doctor, a right to high-quality product, the right to be able to have a medical discussion with a pharmacist, and ultimately, I believe, the right to reimbursed therapy.

If we then look at the UK, that is a market which is really moving forward. There has been a change of attitude among patients, government and doctors over the use of medicinal cannabis. The UK has become an important market for Linneo and we hope this trend can continue.

Equally important is the Israeli market. Per head of population, Israel is the largest medicinal cannabis market in the world. That is because they have many years of medical science and a society which is very accepting of medicinal cannabis as a treatment. They face intense competition, both domestic and interna-

tional. We are active in Israel and continue to invest in this market to ensure a growing presence.

Competing in Israel obliges you to offer very high quality product, but also do it at a very competitive price. If you can make it in Israel, you can make it anywhere!

The Netherlands is a very developed medicinal cannabis market, but it retains this closed monopoly situation (Bedrocan is the sole cultivator that is allowed, Ed.). It is difficult for external suppliers to enter the Dutch market, and we think that ultimately this limits alternatives to patients.

Many new countries which are beginning to understand how to regulate medicinal cannabis and some big markets that are now taking steps towards creating medicinal cannabis regulation. One of biggest of these is actually in our home market, Spain. The Spanish Parliament has approved the introduction of medicinal cannabis legislation. There is a deadline for presenting a law for parliament to vote on by the end of the year, which is very promising for patients here. And many other markets are considering regulation. Over the next five years, we are excited by the growth potential of Europe. It's going to be a place with different markets opening up, and where many more patients will gain access to

medicinal cannabis. The projections are that by 2026, the medicinal cannabis market in Europe will be the largest in the world.

#### **Is legalisation of adult-use going to change your strategy?**

That's a very complex question and it depends on what governments are going to do. The best analogy I can give you is Canada, where for a few years there was an established medicinal cannabis market, and then ultimately the government decided to allow adult use. In Canada, when the only way to access cannabis was through the medical sector, there was evidence that some were not really patients – pseudo-patients if you will. When recreational sales became legal, many pseudo-patients just found it easier to go to a shop and get their cannabis. This had a small impact in registered patient numbers, but this stabilised very quickly, and growth returned. In Germany, I believe the government will do the right thing for patients and continue doctor prescriptions and reimbursement. I believe that there is a large untapped potential for patients who get real benefit for their untreated conditions.

As I have said, Linneo's focus is purely on medicinal use. We are set up for medicinal quality, standardisation, and meeting re-

gulatory standards. If you are an adult-use company, you're tuned into ever-changing varieties and meeting customer fashion. And you're also focused on competing on price. And these are slightly different drivers to what we have.

There is a great deal of work to be done in developing the medicinal cannabis segment. Inhaling a flower has its therapeutic value, as it is a very short-acting and effective way to get cannabinoids into your system. There are certain conditions like acute pain for which this is ideal. But if you look at a spectrum of different diseases that cannabis in theory can help to treat, there are lots of other presentations that are much more pharmaceutical, that need to be developed to better address patient needs: oils, tablets, sprays, micro dosing. That's where we are heading. Linneo is actively developing products of this type.

#### **How do you see yourselves expanding? Would you contemplate to build your own brand?**

As a primary producer of material, our routes to expansion are clear. You can expand geographically and you can expand in the offering. And we want to do both! So geographically there will be a lot of new opportunities in Europe, and there are clearly new

opportunities beyond Europe that we need to explore. And one day, I can't tell you when, but one day we will be able to enter the big markets in North America. And then there is portfolio diversification. In terms of flowers, that means more varieties, more choice, being precise in the THC specs and the CBD specs, going into rare cannabinoids. And then on the industrial products, with our CMO partners, developing new, more innovative medical products for patients.

#### **What are the biggest challenges that you are facing?**

For Linneo, the biggest challenge is finding the mix between quality and efficiency that establishes our long-term profitability as we

capture our growth opportunities. You need to understand what sort of a business you are, understanding the requirements of your customers and their patients, producing in such a way that you can meet quality and efficiency expectations.

Externally, it's about being better than the competition, but also finding a way through the regulatory inconsistency around the world. I come from the pharma world where, at least in Europe, a lot of progress has been made by the European Medicines Agency towards having a standardised platform. This is far from the reality for medicinal cannabis. We spend a significant amount of time studying regulation country by country, understanding in-

consistency between one rule and another, and then trying to get through all the paperwork to deliver medicinal cannabis to our customers. At some stage, the European Medicines Agency will need to standardise the rules for the benefit of everyone.

Spain is in theory a very suitable place to cultivate. But regulations are very strict here. Coming from the pharma industry, I understand the value of strict regulations, as they ensure quality and serve the patient well. But the same strict interpretation needs to be applied everywhere. Regulatory inconsistencies create competitive advantages or disadvantages, which are not good for our business and, ultimately, not good for patients.



**Constantin von der Groeben**  
Managing Director at Demecan

**How do you assess the political development and potential of the German cannabis markets?**

The key issues paper of the German government for the legalisation of cannabis published last week has great significance for the cannabis industry because it is the first concrete indication of how the federal government envisages the cultivation, distribution, consumption and quality of cannabis and what goals are being pursued with this law.

We clearly see the political will to legalise recreational cannabis soon, and the comprehensive proposals show a deep knowledge of the quite complex matter. We believe this diligent approach will convince many sceptics. Of course, we will have to wait for the EU Commission's decision, expected in the next few weeks, but we are convinced that this proposal will make the legalisation a success. We know that the first consultations by the EU bodies prior to publishing the key issues paper had already been held.

The decisive point is the endeavour to establish fully controlled production only in Germany. There will be no can-

nabis imports into the German recreational market. This provides German business with the required clarity to start investing in German cultivation facilities. It will allow for a tightly controlled production process in the country with no dependency on inspectorates or authorities of other countries. High product quality will become a key driver. And of course, it will be a growth engine for the German economy and the cannabis industry. This is good news!

**Where do you sit in that market (e.g. footprint, assets, capacity, supply chain)?**

DEMECAN is ideally positioned to benefit from the proposed legalisation. This is because we are already cultivating medical cannabis in Germany. Our 100.000 sqm cannabis hub is an ideal place to become the centre of the new recreational cannabis industry. There is enormous expansion potential. We have the know-how, we have the experience, we have the plant material and even the facilities that can easily be expanded. Our current spare capacities will enable us to immediately serve the German market.

For sure, DEMECAN is now in a pole position. Our goal is to

drive growth in the market and be the leader in the new German recreational cannabis industry.

**What is the company's plan? (e.g. strategy, business model, competitive advantage, focus on Germany?)**

We currently estimate the chances of legalising cannabis in Germany to be quite high and are of course preparing ourselves for this. We are working on different angles relative to distribution channels and brand building but most importantly on the expansion of our facilities. Given our deep experience with the medical market, DEMECAN will stand as an expert for high-quality cannabis also in the recreational field. DEMECAN will be there and play a leading role, just because of all our know-how.

**How is that going to translate into revenue and profits? (e.g. last year, this year, 3 years out)**

Please understand that we do not provide concrete sales figures. What I can tell you, however, is that we currently feel very comfortable as a medium-sized company, and we will triple again our sales in 2022 as we already did in 2021 and 2020.

**What is the most interesting project that you are currently running at the company?**

We are working on multiple projects both with regard to the medical as well as the recreational cannabis market. The establishment of our tissue culture lab is probably one of the most important projects as it will be relevant for both markets and gives us leadership in plant propagation in Germany. Our R&D cycles for strain-development of ca. 500 new phenotypes are un-

derway. It is our belief, that only those who know and control the best plant material will win in the market with the highest quality products and brands. No company in Germany has this type of insight into cannabis analyses, today.

**What is the most important decision of 2022 (that you already took or still need to take) ?**

The setting-up our own GMP-certified quality control lab. This allows us to maintain

full control and ownership of the most important aspect of cannabis cultivation: quality. DEMECAN is now able to control the entire value chain. Today, we are the only fully integrated cannabis company in Germany.





## Alex Rabinovitch

Founder and CEO of InterCure

### I have a big question to start with Alex. Can you discuss your company's background, management and strategy?

Israel already decided in the 60s to research cannabis, but in the last four to five years since the pharmaceutical cannabis regulations have been adopted, the Israeli cannabis market has developed strongly from hardly any sales to this year probably around the USD350m (45tonnes). The Israeli regulations are been adopted around the world and eventually, we believe, will also be adopted in the US and Canada. InterCure is an early leader in the global medical-use cannabis market and we were one of the first licensed producers of cannabis for medical use in Israel, where medical use of cannabis has been permitted and regulated since 2008. In pharmaceutical cannabis, InterCure is by far the globally leading company by revenues, by profitability, by growth. We exist already 15 years, so there is a lot of know-how in the company. We have strategic partnership with Teva, Novolog, Charlotte's Web, Tilray, Cookies, Organigram, Clever Leaves, In terms of cultivation, we usually take the infrastructure of others to grow our genetics.

We are a publicly traded company in Tel Aviv, in Toronto and recently also on the NASDAQ. Myself I am the founder of InterCure and serve as the CEO of the company. I have invested about USD25m in this business and I bought recently USD3.5m additionally shares in the open market. We are very fortunate to have Mr. Barak as the Chairman of the Board and believes in our product and strategy. Mr. Barak served as the tenth Prime Minister of Israel from 1999 to 2001 and is the most decorated Israeli soldier.

As I mentioned before we are focused on the international pharmaceutical grade cannabis markets. Although currently 96% of our revenue is from Israel, our aim is to be a global player and the weight of Israel could well come down to around 10% of revenues. However, to win globally, InterCure must dominate first its local market (BG estimates InterCure market share in Israel at about 30%). In the short term our international efforts will be focused on UK, Germany, Austria and Australia (in Q1 2023). We look for developing into highly regulated market, being it pharmaceutical, recreational or CBD markets.

One of the potential growth markets for us is the CBD market. For that we are looking to markets like Israel and Australia. For Europe it remains a question on how regulations will turn out. At least we will require some kind of registration process as a minimum barrier to entry. It looks like the European market for CBD for novel food is a market where we could become active. If there would be no regulations and everybody could enter, it would become a chaotic place and we would not be interested. We are not developing CBD products ourselves but rely on the product portfolio of Charlotte's Web and we will put our effort in registering those products.

Another market that we could enter is the adult-use market. There is a lot of talk on adult-use in Germany and also in Israel, but the process always take longer than anticipated. It will take between 3 and 5 years, but we are getting ready for it.

We are vertically integrated and profitable. We have always been profitable since inception and believe that drives shareholder value. Right now we are paying 23% in taxes but as we will increase our export sales, our tax rate will decrease significantly.

(In Israel when companies export 25% of their revenue, their tax rate drops into the 4 to 7% range, Ed). We have one of the strongest balance sheets in the industry with CAD96m cash at the end of the last quarter (Q2) and are generating free cash.

In Israel, besides serving the market through wholesale, we have also our own pharmacies that are fully dedicated in dispensing medical cannabis. In those pharmacies, you find our own products but also other products as we still cannot cultivate enough of our own high quality product. Through our pharmacies we treat about 70,000 patients each month and offer them a range of products from the very pharmaceutical cannabis to a more lite medical cannabis. We have currently 24 pharmacies of which already 16 are fully licensed for medicinal cannabis. The remainder should be receive their license by the end of the year. We have a total of 400 employees of which 98 are pharmacists. Part of our strategy is that we want to be very close to the patients with our products. We have that in Israel and look for something similar in both the UK and in Germany. In Israel, our pharmacies are located in prime locations in city centers and shopping malls. Also in the UK we will have the first pharmacy with inventory in the heart of London close to Soho. In Israel, about 90% of the sales are in the

pharmacies and the remainder is online. We have been informed by the Ministry of Health that medical cannabis will be turned into a regular pharmaceutical narcotic. So any doctor will be able to prescribe follow on prescriptions. The first one still will need to go through a specialist.

In the second quarter we were on an annual run rate of CAD150m revenues and our second quarter EBITDA margin was 23%.

### Can I ask you about how the recent election results in Israel could influence legalization of adult-use cannabis?

We have a very unique situation in Israel where 85% of the parliamentarians it is in favor of adult-use legalisation. There is no negative stigma around cannabis anymore. In Tel Aviv consumers are smoking cannabis in bars and cafes. Cannabis is decriminalised, but to put proper adult-use legalisation in place you need a stable political environment and that has been lacking in Israel with five elections over the past four years. We believe that if regulation will be put in place it will be highly regulated, just to keep current illegal operators out of the market.

### What do you believe is the biggest opportunity for InterCure?

We believe that in the end the can-

nabis market will be dominated by three or four players. You don't need hundreds or 1000s. There will be consolidation and of course, we want to lead this process and actually put on our platform, all the companies that have a very similar DNA to us. However, it is unlikely that we do something in Canada, where nobody makes any money. The biggest opportunity is without any doubt the US where president Biden has asked the FDA to look into rescheduling cannabis. I believe that the FDA will move towards regulating cannabis. The current regulations on a state level are not of the best standards, but if the FDA would be involved medical cannabis will go through pharmacies and that it will be a prescription product.

In ten years' time we will have many different countries that will have adopted adult-use cannabis, but at this stage it is difficult to say who that will be and in what time frame.

### How do you run your supply chain and distribution?

Everything started with our proprietary genetic selection because the product is a natural product and we cannot add or take things out of it. We register all the strains here in Israel and that comes with some IP protection. Next to the genetics we will also do all the branding ourselves and we are



not reselling any other company's products. Those genetics will be cultivated either in one of our own facilities or in one in our partners' facility. We use all kind of cultivation methods because some genetics are more appropriate for indoor cultivation and others for greenhouse cultivation. Next we have a unique transportation knowledge as we are moving more than ten tonnes of cannabis per year by air. All our products are compatible with Israel GMP or EU GMP. We do convergence between the two and also transform Canadian GPP into GMP. In Israel, we now have the updated Procedure 109 which obliges us to do more than 400 tests, mainly on pesticides. We have already landed two shipments under this new regulation. For packaging we use our partners and don't believe that that is something we need to do ourselves. And then the product goes into our distribution channels. For that we use Teva pharmaceutical logistic hub. But because we are growing so fast, we also started using Novolog, the second largest pharmaceutical distributor, and have our own two logistic hubs. Pharmacies who mostly do not hold any inventory are able to receive orders the same day from our four different warehouses or logistic hubs.

**How price sensitive are Israeli medical cannabis patients?**

Our product portfolio starts with the ultra-medical line for patients with specific indications, especially children with autism and oncology patients. But our portfolio goes up until you know the very light one, which is the cookies genetics. The top prices in Israel for the moment are at 350 shekels (USD100) and the lowest prices are for products from Africa that sell at 100 shekels. We don't have any product at all in this lower priced category. About 75% of the patients prefer to buy the high quality branded products. For the moment there are no edibles on the market because of safety issues with THC edibles that can cause spikes in the stomach or liver. By contrast inhalation or oil under the tongue is very safe. We have edibles under development and will probably need to do clinical trials to register them. The same is likely to be the case for topical products.

**What is your most important decision that you had to take or still have to take?**

I don't think there is one very important decision. With pharmaceutical cannabis being an emerging industry we have to take many

important decisions. For us it is important to stay focus on the most important parts of our strategy which is delivering high quality products and being in territories where we believe in.

**What is the project that excites you most?**

The most exciting project for us is developing in the new markets that we have identified. We are excited to open the first pharmacy in the UK and we are excited to ship products into German market. We want to bring into new markets everything that we have learned in the Israeli market which is the biggest pharmaceutical cannabis market in the world. In terms of potential size of the market, the German market is potentially the most interesting market in Europe because the size of the population and also their appreciation of product quality.

While the Americas have taken the lead in legalising cannabis for both medicinal and adult-use, the point of no return for global legalisation has passed and it is only a matter of time before other regions follow with progressive regulations. This is the case of Europe, where several initiatives have been taken over the last two years to gradually legalise medical cannabis. Specifically, these initiatives concern Germany, Switzerland, Spain, and France, while Israel is already on the forefront of medical cannabis research and access. Simultaneously, discussions concerning legalisation of adult-use cannabis seem to remove some of the stigma among physicians and patients.

Indeed, a number of countries (the Netherlands, Switzerland, Malta, Luxembourg) are going a step further and are trialling adult-use regulations. However, Germany's intent to deliver an adult-use cannabis market could be the trigger for legalisation in other European countries and deliver significant growth in the legal European cannabis industry. The way the German government has approached the international legality question is with an "interpretation declaration" to the other contracting parties. If the European Commission follows this German pathway, it would establish a blueprint for legalisation of cannabis in other European countries. Today, there is barely a legal European cannabis market to speak of, but the total market (99% illegal), is already EUR65bn.





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