

MEDICAL CANNABIS IN EUROPE:

The Markets & Opportunities

SECOND EDITION

In-depth look at key European markets and the regulations companies need to understand to tap these revenue opportunities



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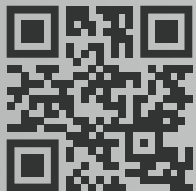



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MEDICAL CANNABIS IN EUROPE: THE MARKETS AND OPPORTUNITY



Alfredo Pascual
MJBizDaily
International Analyst

One year after the first edition of this report, Europe continues being a key region for international cannabis companies trying to scale globally and a place that has provided numerous opportunities to local entrepreneurs.

With a population of more than 500 million, generally high per-capita gross domestic product (GDP) and health-insurance coverage for cannabis in several countries, Europe is seen by many in the industry as having the potential to one day be a larger market long term than the U.S. and Canada combined.

How things evolved in Europe in the past year adds to that optimistic outlook, with sales in Germany and Italy—the two largest markets on the continent—posting double-digit, year-over-year growth in 2019.

While the long-term expectation of Europe being a massive medical—and, eventually, recreational—cannabis industry continues to show promise, this report highlights the reality of the market today, including the actual sales and the regulatory frameworks that exist in the main European markets.

For 2019, Marijuana Business Daily estimates total sales of medical cannabis in Europe ranged from 230 million and 250 million euros (\$251 million-\$273 million), with roughly half those figures represented by the markup pharmacies in countries such as Germany and Italy added before dispensing the products.

For context, total medical cannabis sales in Europe in 2019 were less than half the sales that took place in the U.S. state of Arizona (population 7.3 million) last year.

The European market also continues to present a unique set of challenges for companies and investors looking to make inroads there. The continent cannot be viewed as a single jurisdiction, because a diversity of languages and cultures exist across national boundaries. Meaningful European-wide regulations are scarce, and individual cannabis frameworks vary drastically.

This report provides industry leaders and investors interested in the European markets with a realistic estimate of current market sizes and a detailed analysis of the countries where the most opportunities exist. What it will not provide is long-term, uncertain projections that have no basis in data.

In 2019, sales of medical cannabis in Europe continued to be centered on Germany. Other countries showed positive signs, advancing with legislation that either allowed national production or prescription, but those markets are far from developed.

For producers of medical cannabis that are able to comply with stringent quality requirements, exporting to Germany continues to be the most obvious option, as the country will depend exclusively on imports until at least the end of 2020 to meet its domestic demand.

However, one year after the first edition of this report, we no longer have a solid sense of the ever-growing number of countries and companies trying to export to Germany—there are just too many of them. At the same time, the number of actual companies whose products reach German patients remains just a few and largely unchanged from last year edition.

It's important to note that whenever we mention medical cannabis in Europe, we are referring to products prescribed by physicians and typically dispensed in pharmacies.

Industrial hemp and low-THC CBD consumer products are not part of this report, which also doesn't cover noncommercial access to cannabis, for instance, through home growing or marijuana social clubs.

Because of the ever-changing nature of cannabis regulations and the fact most available official sales data is only through the end of 2019 for most jurisdictions at the time of publication, information in this report should be assumed to be updated through 2019 unless otherwise specified.

I'd like to give a special thank you to the government agencies and officials that provided official data or clarifications, and to all the local experts and industry insiders who helped to make this comprehensive report possible, including Andrew de Roy for his insights on Poland.

If you have any questions or comments, feel free to reach out to me at alfredop@mjbizdaily.com.



Alfredo Pascual
International Analyst

cansativa®

Leading German manufacturer, importer,
and distributor of medical cannabis

THE COMPANY

Founded in 2017, Cansativa is a GMP-certified pharmaceutical company and holds a GDP pharmaceutical wholesale license to trade in controlled substances. From its headquarters in Mörfelden-Walldorf, Germany, Cansativa and its subsidiaries work to professionalize the medical cannabis market, eliminate stigmatization and to permanently serve patients needs. As an owner-managed company, our growth target is linked to a long-term vision – continuously setting industry-wide benchmarks.

Since the very beginning, Cansativa has operated its own distribution and fulfillment center, and as one of its industry's "first movers", it has become a leading manufacturer, importer and distributor of medical cannabis in Germany. From its locations in Mörfelden-Walldorf and Frankfurt am Main, the company supplies pharmacies and pharmaceutical wholesalers nationwide.

CONTACT US!

www.cansativa.de or send an email to
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OUR BUSINESS MODEL



Global footprint – We source medical cannabis globally and collaborate with several **high-class** and **well-known** medical cannabis suppliers



One-stop shop – We positioned Cansativa as the leading medical cannabis focused **wholesaler** with an extensive customer base and a broad product portfolio to serve patients needs



Know-how – Due to our professional integrated **inhouse solutions** we became **experts** within the European medical cannabis industry



Patients first – Our top priority is **process** and **product quality** without compromises to ensure a safe product

Founding of Cansativa GmbH in Frankfurt am Main and receipt of EU GDP wholesale license.

Receipt of EU GMP manufacturing and import license for both Cansativa GmbH facilities

2017

2018

2019

2020

Processing of first import and start of operations

Became leading medical cannabis one-stop shop with an extensive product portfolio



Johann Benedikt Sons
Chief Executive Officer and Founder



Jakob Christian Sons
General Counsel and Founder



beyond pioneering

Health, especially in these strange and uncertain times, has become everyone's primary concern. We are therefore grateful that the production and distribution of Bedrocan's medicinal cannabis to patients around the world will continue as usual. In fact, in some countries, new distribution channels have emerged to meet the needs of vulnerable patients.

Also during a crisis like the COVID-19 pandemic, we are committed to deliver standardised cannabis of pharmaceutical quality. Each product has a distinct chemical profile, with a consistent, defined active ingredient composition of delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD) and terpenes, the aromatic compounds. Bedrocan's cannabis is guaranteed free of microbial contaminants (moulds, fungi, and bacteria), pesticides, and heavy metals.



Bedrocan is the oldest company in the world to provide several chemically different cannabis varieties, which are used by patients on doctor's prescription and as a raw material for the pharmaceutical industry (API). Bedrocan has developed and standardised unique methods of producing cannabis to pharmaceutical standards at a level achieved by no other company until today, which makes Bedrocan the industry leader in cannabis cultivar standardisation.



“You cannot keep patients waiting for medication, which is why Bedrocan takes all the necessary measures to ensure that production – which serves many patients in Europe – goes on according to plan”, says **founder and CEO Tjalling Erkelens**. “These uncertain times will hopefully teach us that money is way less important than people's health. We have to lean on science as our guide on staying healthy.”





EU MARKETS AT A GLANCE: KEY TAKEAWAYS

IN 2019, THE EUROPEAN CANNABIS MARKET WAS VALUED AT 230 MILLION-250 MILLION-EUROS WITH GERMANY “UNCHALLENGED”

Germany continues to be the largest European medical cannabis market, with *Marijuana Business Daily* estimating annual sales in 2019 of at least 170 million euros (\$185.4 million).

Italy was a distant second with an estimated retail value of 20 million euros.

Several other markets also reported medical cannabis sales.

Austria, the Netherlands and Switzerland had sales of just above 10 million euros apiece. In the cases of Austria and Switzerland, most of that was attributable to dronabinol.

Germany not only remains the largest market, but it's also growing faster than the other major European markets.

Sales of insurance-covered cannabis in Germany grew 67% in 2019 over 2018, with the growth of the total market even larger when considering private prescriptions.

Over the same period, total sales in Italy grew 49%. In the Netherlands, kilograms sold grew just 5%, and in Switzerland the patient count actually decreased 1%.

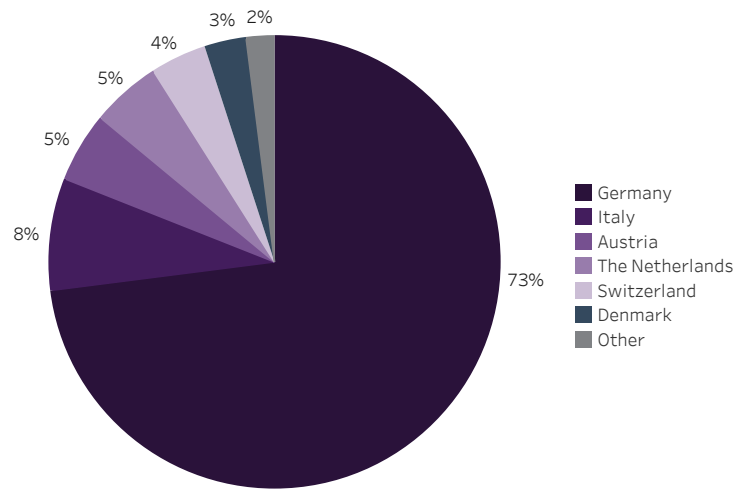
The only other European country where we could find sales of several million euros in 2019 was Denmark, with total sales of 7 million euros.

MJBizDaily estimates that the total retail value of the European markets in 2019 was 230 million-250 million euros. That figure includes sales of isolated cannabinoids and finished pharmaceutical products in addition to flower and full-spectrum products.

Roughly half that value was represented by markups at mom-and-pop pharmacies.

Chart 1: Share of Retail Cannabis Sales in Europe in 2019

**Share of Retail Cannabis Sales in Europe in 2019
(includes all product categories)**



Source: Marijuana Business Daily estimates based on governmental data and information provided by industry stakeholders
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IT WAS A GOOD YEAR FOR EUROPE

We’ve always been cautious when reporting sales in Europe. Instead of accepting wild predictions, we believe companies and investors should pay attention to the actual sales and the regulations that need to be understood in different jurisdictions for businesses to be successful.

Keeping that approach, we’re optimistic to see that sales in Europe enjoyed an impressive growth rate in Europe in 2019, led by Germany and Italy.

The not-so-good news is that the other markets remained largely unchanged, or despite some growth, continued to be too small.

There are even some countries where medical cannabis was legalized years ago where the domestic patient count remains at zero, even as companies are producing for export in them or are in the process of doing so.

UNSTOPPABLE EXPONENTIAL GROWTH IS JUST WISHFUL THINKING

Year-over-year growth was impressive, but irregular across the continent.

Predicting exponential growth of all European markets without hurdles along the way is irresponsible. Reality is different.

For example, the Netherlands in 2017 grew 12% over the previous year. In 2018, amount sold decreased 13%, and in 2019, it remained below 2017 levels, growing just 5%. That's far from exponential growth.

In the last edition of this report, *Medical Cannabis in Europe: The Markets and Opportunities*, a pilot experiment in Denmark caught our attention, with its rapid quarter-after-quarter growth that ended with record sales in the second quarter of 2019.

But in the last quarter of 2019, Denmark's pilot project sales were flat compared to the third quarter 2018. Part of the explanation is that the only oils that had been available had to be removed from the market. But that doesn't explain why sales of flower decreased from the third quarter to the fourth.

In other words: The European markets are more complicated than many would have you believe.

MORE OR LESS THE SAME OLD SUPPLIERS

Several countries and dozens of companies want to supply Germany and other major European markets. But one of the things that didn't change much from last year was the number of growers whose products ended up being sold to German, Italian or Dutch patients.

In 2018, flower grown by Bedrocan in the Netherlands and by Aurora Cannabis, Canopy Growth and Cronos Group in Canada reached German patients. In 2019, only two new Canadian producers exported flower to Germany: Tilray and Wayland Group. And Tilray had already been selling full-spectrum extracts in Germany.

In Italy, despite a big increase in quantities sold, the suppliers remained unchanged over 2018. Most of the demand was covered by imports from the Netherlands produced by Bedrocan and a smaller proportion supplied by the domestic grow of the Italian army. A fraction of demand was fulfilled by a small contract with Canada's Aurora Cannabis, just like the year before.

ISOLATED CANNABINOIDS ARE HERE TO STAY

While last year's edition of this report didn't dive into the role dronabinol played in the European market, this year's report takes a much closer look. Isolated cannabinoids—THC and CBD—sold exclusively under medical prescription represent a significant portion of the market in several countries.

In Germany, almost 30% of the health-insurance coverage for cannabis products goes to this category, and the category is slowly but steadily growing.

In Austria, dronabinol accounts for almost the entire market, as sales of flower or full-spectrum extracts aren't allowed.

Dronabinol also plays a central role in Switzerland.

Denmark's the pilot project—which allows sales of flower and full-spectrum extracts—gets most of the attention around medical cannabis. But sales of isolated cannabinoids were four times larger than sales of the pilot project during the second half of 2019.

In 2019, Canada's Canopy Growth acquired Germany-based C3 Cannabinoid Compound Co. from Bionorica in an all-cash deal for 226 million euros. It was possibly the largest acquisition in the European cannabis market to date.

C3 is the leading European producer of isolated cannabinoids of pharmaceutical quality.

Until mid-April 2020 when a new supplier became available with dronabinol imported from Israel, only isolated THC from C3 was available to German pharmacies.

SUPPLY ISSUES AREN'T SUCH A BIG ISSUE ANYMORE, BUT THEY REMAIN

One of the challenges often raised with regard to the European medical cannabis markets is an issue with supply, whether undersupply or a lack of accessibility to desired products.

We do acknowledge that consistency of supply has been an issue, for instance, with some strains becoming intermittently or permanently unavailable and new becoming available.

But it's hard to generalize the situation for every European country, so let's consider Germany. When this report was published, there were about 30 different chemovars of flower for which patients could get a prescription and expect to find it in the pharmacy or expect the pharmacy to be able to get it from a wholesaler in a day or two.

It would be great to have more variety, but we can't call a market with dozens of flower varieties available "undersupplied."

When it comes to other types of products in Germany, there's not much from which to choose, but the situation is improving. In 2018, only one supplier of full-spectrum extracts was available, and that total increased to two in 2019. Also in 2019, there was only one supplier of dronabinol, but now there are two.

In subsequent chapters of this report, we describe some serious supply issues in 2019, such as the case when the only full-spectrum oil that was available in Denmark had to be removed from the country.

On a positive note, the COVID-19 crisis of 2020 didn't seem to have much of an effect on the supply of medical cannabis. At least in the largest European markets, the availability of medical cannabis as of April 2020 was as good as any time before, if not better.

PRICES ARE COMING DOWN

Only a year ago, Canadian executives boasted about exceptionally high margins of their products in Europe.

MJBizDaily doesn't just accept those claims, instead seeking out the exact prices that companies were willing to offer to win supply application processes in Europe. And those prices could hardly be perceived as exceptional.

In 2019, the average price at which the German government said it would buy future harvests from the domestic producers is 2.3 euros per gram of flower.

Imported flower in Germany continues enjoying a much higher price, but in early 2020, pharmacists and insurers in the country have entered into a new agreement that is expected to compress margins across the supply chain.

The price at which Aurora offered its flower in Italy was 1.73 euros per gram.

In the Netherlands, the government fixed the price of its ongoing tender at 2.35 euros per gram.

NO PERFECT ESTIMATION

There isn't any straightforward way to know how much medical cannabis was sold in Europe in 2019. No central agency keeps track of sales, and even within individual countries, finding accurate information is challenging.

In the largest market, Germany, the federal government recently admitted to the Parliament that it doesn't know the amount of medical cannabis sales in 2019 and can't estimate demand for 2020.

Some countries, such as the Czech Republic and Denmark, provide extensive detailed information, while official data in other countries, such as Austria, is almost nonexistent.

The problem is exacerbated by the lack of harmonized definitions of medical cannabis.

Efforts by the European Union to achieve harmonization via a resolution passed in 2019 have resulted in nothing meaningful. One year later, it seems it was no more than a declaration of commendable intentions.

Whenever possible, the report is based on official data, but often it has to be complemented with information obtained from industry stakeholders and, as a last resort, educated estimates.

ADULT-USE CANNABIS FAILS TO GAIN TRACTION

While recreational cannabis is not the focus of this report, 2019 was a largely uneventful year for that sector in Europe.

Luxembourg continues to be a leading candidate to become the first European country to legalize commercial production of nonmedical marijuana, a promise made by the new government coalition at the end of 2018. But no big steps were taken since then.

Switzerland has a pilot program for recreational cannabis in the works, but it is still far from being operational.

The Netherlands made some progress with its own experiment, advancing the plan to allow coffee shops in 10 Dutch municipalities to have access to a legal supply of marijuana for the first time. However, none of the largest municipalities—including Amsterdam and Rotterdam—joined.

In Germany, one of the parties in the ruling government coalition changed its position to support recreational marijuana in early 2020. With that, the majority of the members of the German now in Parliament represent a political party in favor of some type of recreational reform.

However, no change is expected in the near term, and Germany's federal government continues rejecting applications for pilot project.

GERMANY: THE EUROPEAN MEDICAL CANNABIS POWERHOUSE

Just as it did in 2018, Germany exceeded the combined sales of medical cannabis of other European nations in 2019.

Sales in Germany grew more than in Italy and the Netherlands, the second- and third-largest markets, respectively, in Europe for flower and full-spectrum products.

Key facts about the German medical cannabis market in 2019 include:

- Roughly 6,500 kilograms (14,330 pounds) of flower were imported to be dispensed to patients in pharmacies, more than double the 3,000 kilograms imported in 2018.
- Statutory health insurers covered 123 million euros (\$134.4 million) worth of different cannabis products in 2019. A little more than half that amount was for flower products.
- German pharmacies processed 267,348 prescriptions under the statutory program in 2019, up 44% from the 185,370 prescriptions they processed the previous year.
- Adding private prescriptions that were paid out of pocket by patients, *Marijuana Business Daily* estimates the total retail value of the market—including all cannabis products—was at least 170 million euros in 2019.
- Germany's market will be 100% dependent on imports at least until the end of 2020, when the first domestic harvests are expected. Even then, imports are expected to continue.

Germany is the economic powerhouse of Europe, with an aging population of more than 80 million, of which 90% are covered by statutory health insurance that is expected to cover the cost of medical cannabis if certain conditions are met.

Until March 2017, the country had a limited framework that allowed the import of medical cannabis only under exceptional circumstances. This changed when a legislative reform expanded access.

The first harvest of Germany's domestic cultivation is expected in the final quarter of 2020, meaning the market is still fully dependent on imports for now.

Even when domestic production starts functioning, it isn't expected to provide enough medical cannabis to meet demand, so imports likely will continue to cover the gap.

ESTIMATING THE MARKET SIZE

The German government has acknowledged it doesn't know the total number of patients being treated with cannabis or exactly how much medical cannabis is sold in the country.

Without a registry of patients or a centralized data base that tracks the total number of medical marijuana prescriptions or sales in Germany, industry watchers can only infer the current total market size and must rely on multiple incomplete sources.

Lack of accurate official information can make it difficult for cannabis businesses when they attempt to plan their strategies in Europe's most important medical marijuana market.

The lack of data also can lead to inaccurate market estimates and forecasts that create confusion among investors and industry players.

Partial sales data based solely on reimbursements made by statutory health insurers is regularly disclosed in Germany. But that does not include information about so-called private prescriptions, which represent a significant portion of the market.

Private prescriptions include sales to patients with private health insurance—which includes about 10% of the German population—or those with a statutory health insurance plan but who were denied coverage by their insurer and still buy medical cannabis with private prescriptions. The latter pay out of pocket.

In Germany, reimbursements for most medical cannabis products work differently than those for finished pharmaceutical products that have marketing authorization and proven efficacy and safety.

In order for medical cannabis to be covered by statutory health insurers, patients must apply for reimbursement. This is the case for all cannabis products except for finished pharmaceutical products Sativex and Canemes when prescribed for their approved, or on-label, use.

In early 2020, the German federal government acknowledged it does not know how many applications for reimbursement were approved or rejected in 2019. Previous disclosures of specific insurers suggest that about one-third of the applications for reimbursement of cannabis products are rejected.

When this happens, patients can still get access to medical cannabis if a doctor issues a private prescription, for which the patients must pay out of pocket.

Exactly how many patients do this and how much they buy is unknown.

Also unknown is the number of patients who, despite having statutory health insurance, do not apply for coverage—for example, the condition isn't serious enough to qualify—and buy cannabis directly with a private prescription.

Another way of estimating the total German medical cannabis market—because of the country's dependence on product from other countries—is using the Federal Institute for Drugs and Medical Devices (BfArM) total imports data because of the country's dependence on product from other countries.

In early 2020, the federal government disclosed that 6,500 kilograms of flower were imported to Germany in the previous year to be sold to patients in pharmacies.

However, this data is far from perfect because not all of what was imported was sold to patients in the same period. Some companies had remaining inventories at the end of 2019.

Cannabis companies looking to use this data to estimate the market size should consider that it includes irregular shipments and occasional abnormally high inventories. With this available information plus specific data collected from local cannabis industry players, we estimate that in 2019:

- 3,275 kilograms of flower were effectively sold to patients whose statutory health insurance covered it.
- Another 2,225 kilograms were sold to patients who paid for it out of pocket.
- 1,000 kilograms remained in stock at the end of the year.

In other words, of the 6,500 kilograms of flower imported into Germany in 2019, we estimate 5,500 kilograms were effectively sold in the calendar year.

Using a somewhat conservative retail price estimate of 20 euros per gram, 5,700 kilograms would equate to a German flower market of almost 110 million euros in 2019.

If we add the almost 60 million euros reimbursed for other medical cannabis products—which include full-spectrum extracts, single-cannabinoid preparations and finished pharmaceutical products such as Sativex—it means the total German market was north of 170 million euros in 2019.

MARKET SIZE: IMPORTS

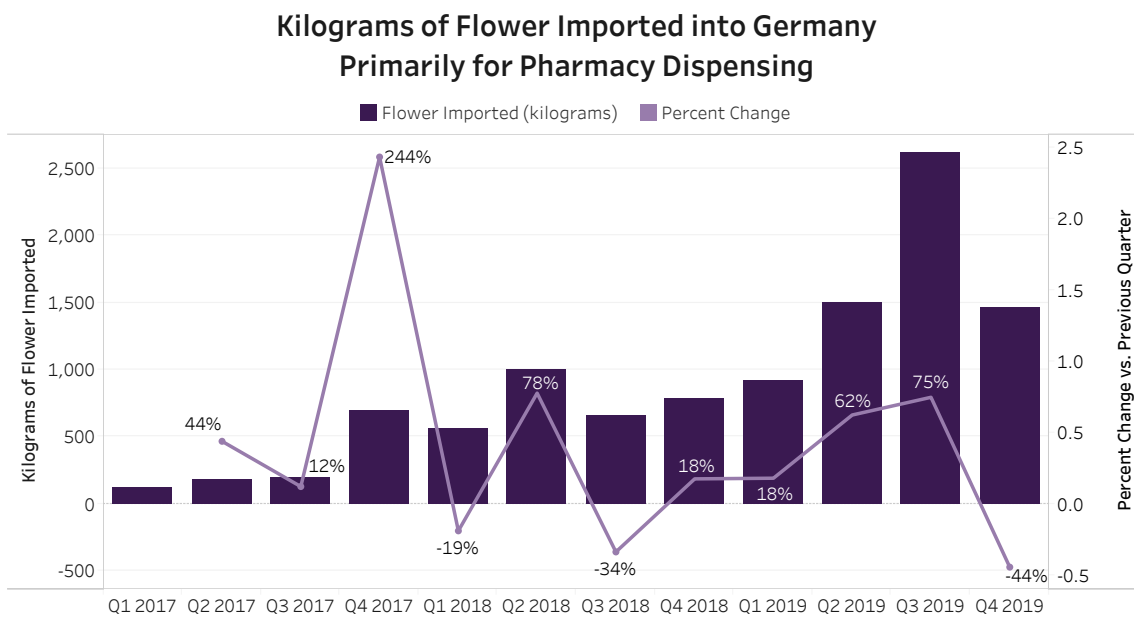
According to the federal government, Germany imported 6,728 kilograms of medical cannabis flower in 2019, primarily for pharmacy dispensing.

But because a little more than 200 kilograms imported were then exported to other countries such as Italy, the final number of kilograms that were imported to Germany in 2019 to dispense to patients there was 6,500.

That's more than double the total for 2018, when about 3 metric tons were imported.

Since the beginning of Germany's current medical cannabis framework in early 2017, imports of flower into that country have doubled annually.

Chart 1: Kilograms of Flower Imported into Germany



Source: German Federal Institute for Drugs and Medical Devices & Marijuana Business Daily estimates ©2020 Marijuana Business Daily, a division of Anne Holland Ventures Inc. All rights reserved.

Import data from the BfArM confirms the strong growth of the German market, which has driven investments in medical cannabis production facilities in Europe and abroad.

However, inconsistent supply—as reflected in the chart above—indicates that quarter-over-quarter growth is anything but stable. For instance, in the final two quarters of 2019, values changed from +75% to -44%.

Relying solely on import data to estimate the size of the German cannabis market likely would lead to an inaccurate representation.

In the third quarter of 2019, a record 2,674 kilograms of medical cannabis were imported into Germany, but trouble started brewing in the final quarter of the year when a sharp decline in imports occurred.

The temporary unavailability of products from Canadian producer Aurora Cannabis partially explains the decline. The unavailability of product started at the end of November 2019, and the company resumed sales at the beginning of February 2020.

Aurora’s problem stemmed from a missing permit for ionizing irradiation of cannabis products.

In addition to the 6,500 kilograms imported into Germany, another 1,053 kilograms of flower were imported to manufacture dronabinol in 2019.

MARKET SIZE: REIMBURSEMENTS

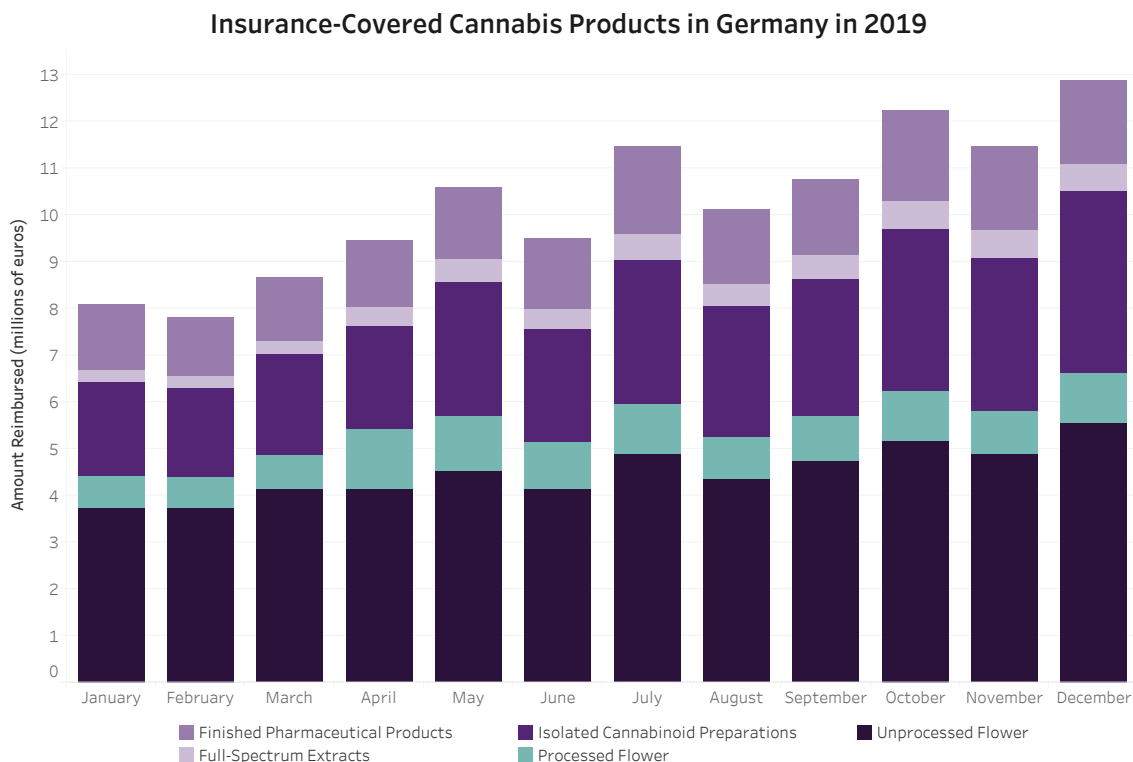
German statutory health insurers reimbursed 123 million euros worth of medical cannabis products in 2019.

That total represents a 67% jump over the 74 million euros reimbursed in the country in 2018.

German pharmacies processed 267,348 prescriptions under the statutory program in 2019, up 44% from the previous year.

The larger increase in euros than in number of prescriptions indicates that doctors issued prescriptions for larger quantities on average.

Chart 2: Insurance-Covered Cannabis Products in Germany in 2019



Source: GKV-Spitzenverband & Marijuana Business Daily estimates
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Despite some supply issues toward the end of 2019, reimbursements for medical marijuana reached 36.6 million euros in the fourth quarter.

That's a 13% increase over the previous quarter, when 32.3 million euros worth of medical cannabis was reimbursed.

December 2019 marked the biggest reimbursement month since the current regulatory framework was implemented in early 2017, with total reimbursements reaching almost 13 million euros.

Of that December total, 6.6 million euros worth of flower were reimbursed, up 14% from the 5.8 million euros covered by insurers in November.

Products from Aurora Cannabis became temporarily unavailable at the end of November. The December increase in flower reimbursement suggests German patients who had been using Aurora's flower found replacement varieties from competitors.

All reimbursement data is based on retail prices at pharmacies, which are the only authorized points of sale to patients in Germany.

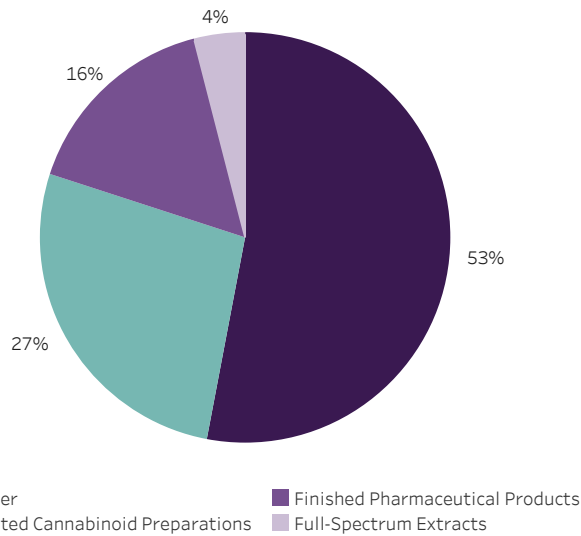
For cannabis not included in the finished pharmaceutical products category, pharmacies mark up prices as much as 100%.

Reimbursement data does not include private prescription sales, which are paid by patients directly.

- Flower—which includes unprocessed flower and flower used in preparations, typically sold as ground flower—represented 51% of total cannabis reimbursements during the fourth quarter, almost exactly the same as in the previous quarter.
- Reimbursement of full-spectrum extracts grew slightly but remained at only 5% of the reimbursed market.
- Coverage of cannabinoid preparations increased slightly from the previous quarter and now stands at 29% of the insurance-covered market. In 2019, this category was represented mostly by dronabinol manufactured in Germany by C3, a subsidiary of Canada's Canopy Growth, but also includes pharmaceutical CBD supplied to pharmacies to be sold exclusively under prescription.
- Finished pharmaceutical products, a category represented mostly by Sativex, slightly decreased from the previous quarter, reaching 15% of the reimbursed market in the quarter.

Chart 3: Product Mix by Sales in 2019

Product Mix by Sales in 2019



Note: Data excludes private prescriptions.

Source: GKV-Spitzenverband & Marijuana Business Daily estimates
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2017 LAW AMENDMENT

The current cannabis framework in Germany became effective in March 2017.

Previously, only the finished pharmaceutical products Sativex and Canemes could be prescribed like any other medicine, and about 1,000 German patients had a special permit from the BfArM to buy imported cannabis flower under a strict regime of case-by-case exceptional authorizations.

BfArM granted roughly half those special authorizations in 2016. The rapid growth in the number of applications for exceptional authorizations was one of the factors that pressured the government to implement a more comprehensive framework.

Another factor was that, after long judicial processes, at least one patient obtained authorization from a federal court to grow cannabis for their own medicinal purposes at home. The argument, in a nutshell, was that the patient couldn't afford the imported products so their constitutional right to health wasn't being guaranteed.

To avoid continued growth in the number of case-by-case exceptional authorizations for imports and the precedence of home-growing permits, the German government passed new legislation and implemented it in 2017. With the amendment, all previous special authorizations were terminated.

The legislative changes that went into effect in March 2017 modified:

- The Narcotic Drugs Act (“Betäubungsmittelgesetz” BtMG) allowing domestic cultivation of medical cannabis in Germany.
- The fifth book of the Social Code (“Sozialgesetzbuch Fünftes Buch-Gesetzliche Krankenversicherung”) mandating statutory health insurers to cover treatment with cannabis products under certain conditions.

The 2017 amendment created an agency, Cannabisagentur, to regulate the domestic supply of medical cannabis.

The Cannabisagentur, which is under the BfArM, doesn't directly cultivate, manufacture, import, store, deliver or sell medical cannabis but has control over such activities that service providers of the agency execute.

Under the new framework, statutory health insurers are expected to cover the cost of prescribed cannabis if certain conditions are fulfilled.

Private prescriptions are available where patients cover the cost of medical cannabis independently instead of working through statutory health insurers. Private prescriptions are also used by patients who have private insurers, which is about 10% of the German population.

Any physician except dentists and veterinarians can prescribe medical cannabis for any condition and statutory health insurers will likely cover the cost, provided:

- The patient is seriously ill.
- Cannabis is used as a last resort.
- It is highly likely prospect that cannabis will provide a positive effect to treat the disease or its symptoms.

Patients and their doctors also need to agree to participate in an anonymous study about the treatment, with the BfArM collecting the data. Preliminary results of this survey have shown that the most common condition for which cannabis is prescribed is chronic pain.

PRODUCTS AVAILABLE

Doctors in Germany have several options to choose from if they want to consider prescribing medical cannabis treatment. This ranges from finished pharmaceutical products with marketing authorization, such as Sativex, to unprocessed flower.

FINISHED PHARMACEUTICAL PRODUCTS

There are two cannabis products with marketing authorization. Unlike flower and preparations, these pharmaceutical products, if used in-label, don't require special authorization from the statutory health insurance for reimbursement. They include:

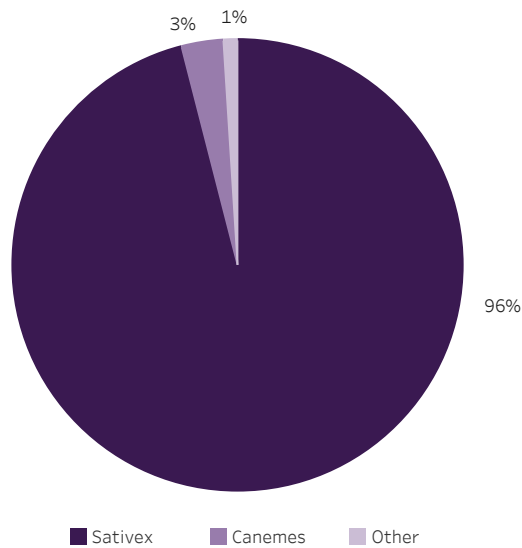
- Sativex, which has a close to 1:1 ratio of THC-to-CBD. The marketing authorization in Germany is for treating multiple sclerosis.
- Canemes, which contains the active ingredient nabilone, a synthetic cannabinoid that mimics THC. If other medicines don't work, the marketing authorization in Germany for Canemes is to treat nausea and vomiting experienced by patients with cancer who are undergoing chemotherapy

Other finished pharmaceutical products that don't have marketing authorization in Germany—such as Marinol—can also be imported. But this is rarely done because locally produced generic dronabinol is less expensive than Marinol imported from the United States.

Of these products, Sativex represents almost all the finished pharmaceutical products category.

Chart 4: Reimbursement of Finished Pharmaceutical Products in 2019

Reimbursement of Finished Pharmaceutical Products in 2019



Source: GKV-Spitzenverband & Marijuana Business Daily estimates
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SINGLE-CANNABINOID PREPARATIONS

The single-cannabinoid preparations category includes products without a marketing authorization that use THC, CBD or a combination of the two isolated cannabinoids.

Prescriptions of these preparations are quite common in Germany, representing at least a quarter of the total statutory health insurance-covered market.

Pharmacists use the single cannabinoids as ingredients to prepare magistral preparations for patients according to a doctor’s prescription, usually in the form of capsules or drops.

Part of the popularity of single cannabinoids in Germany could involve the fact that a German company, Bionorica, sold isolated cannabinoids to pharmacies there long before the 2017 reform.

The company also sells to other countries, mainly Austria, Denmark and Switzerland.

The cannabinoid division of Bionorica was acquired by Canopy Growth in an all-cash deal for 226 million euros in 2019. Canopy renamed its acquisition Cannabinoid Compound Co., or C3. The deal was one of the largest cannabis acquisitions in the European market to date.

Most of the single-cannabinoid preparations category in 2019 was represented by dronabinol, which until early 2020 was available only to German pharmacies from C3 in its pure form together with a kit to prepare the prescription.

Dronabinol’s makers have failed in bids to make the drug registered pharmaceutical in the past. Without marketing authorization, statutory reimbursement for donabinol in Germany is not automatic.

The single cannabinoid category, as of April 2020, includes dronabinol manufactured by C3 in Germany and a new supplier that just entered the market.

German firm Cantourage imports dronabinol from Israel, which German pharmacists can buy as an alternative to C3's dronabinol.

During 2019, the price at which pharmacies could buy dronabinol from C3 depended on the quantities ordered. For example, the price for 100 milligrams was 53 euros while the price for 1,000 milligrams was 340 euros.

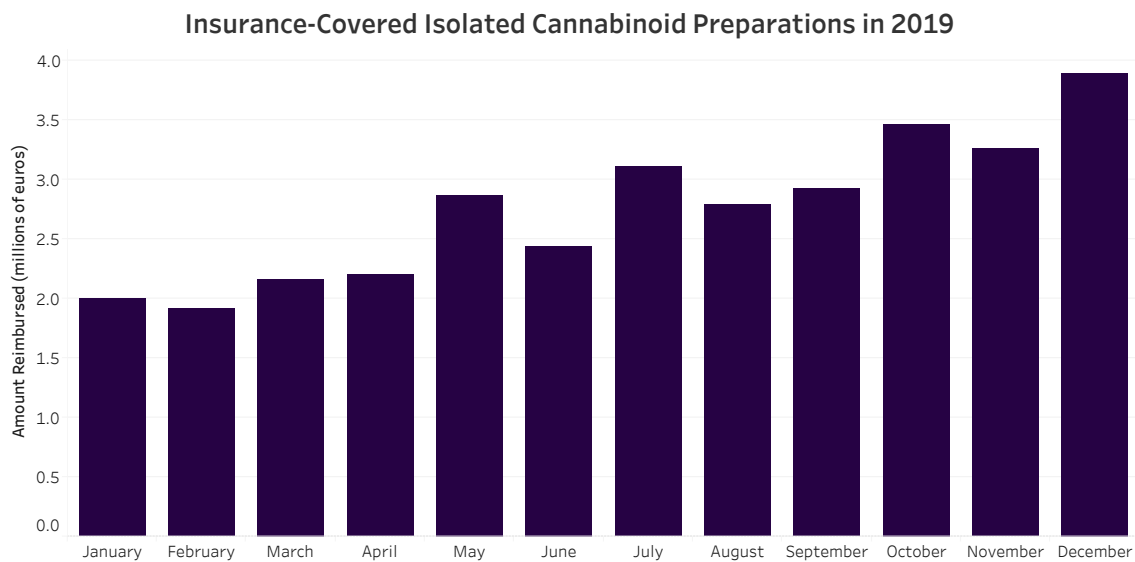
In addition to pure THC, C3 and other companies also sell pure CBD to pharmacies.

In early 2020, one new CBD option that pharmacists can dispense to patients became available.

Cologne-based distributor of medical cannabis Cannamedical started offering pure CBD in kits with which pharmacists can compound preparations according to a doctor's prescription.

The price at which the pharmacies buy the CBD varies depending on the size of the order and the supplier, but in 2019, it was typically 60 euros-70 euros per gram.

Chart 5: Insurance-Covered Isolated Cannabinoid Preparations in 2019



Source: GKV-Spitzenverband, German import data & Marijuana Business Daily estimates
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FULL-SPECTRUM EXTRACTS

Aurora and fellow Canadian producer Tilray were the only companies with full-spectrum extracts in the market in 2019.

Since 2017, Tilray has offered two products: THC25 and THC10:CBD10. Both are sold in 25-milliliter bottles.

- THC25 has 25 milligrams/milliliters of THC and less than 0.5 milligrams/milliliters of CBD. Tilray imported 1,924 units of those products in 2019.
- THC10:CBD10 has 10 milligrams/milliliters of THC and 10 milligrams/milliliters of CBD. Tilray imported 27,719 units of those products in 2019.

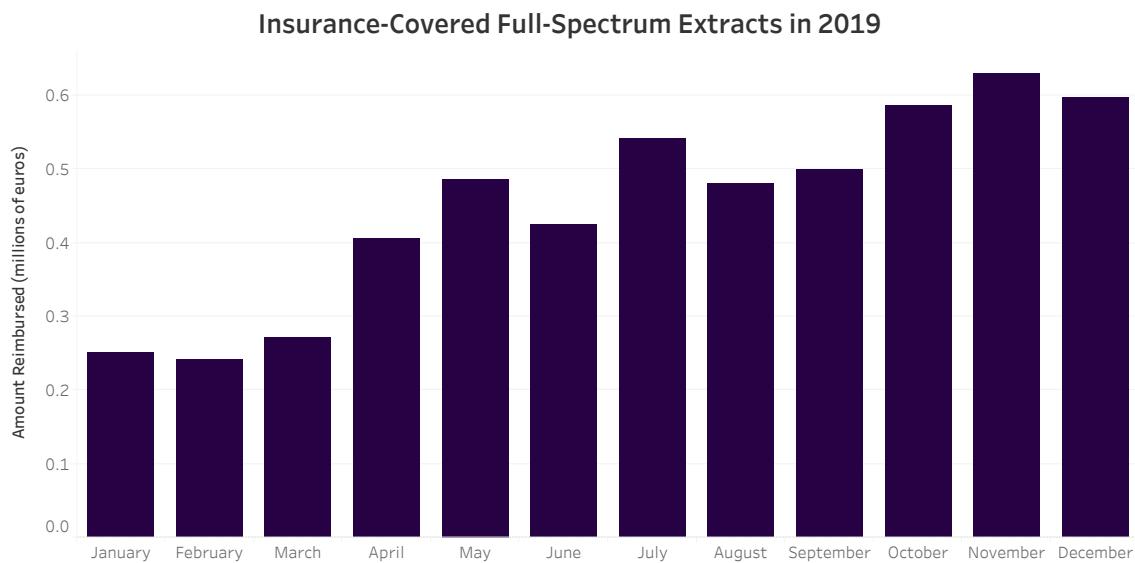
Aurora started selling oils in Germany in 2019. Government data shows Aurora imported 61.98 kilograms of those products.

Aurora’s full-spectrum extract in Germany is called Pedanios 5/1 and is sold to pharmacies in 10-gram bottles that contain 5% THC.

Pharmacists mix the Pedanios 5/1 extract as needed according to the individual prescriptions.

The price at which pharmacies bought the full-spectrum extracts from wholesalers during 2019 depended on the specific product but was in the range of 100-200 euros per unit. Retail price was much higher because of the roughly 100% markup applied by pharmacists until early 2020.

Chart 6: Insurance-Covered Full-Spectrum Extracts in 2019



Source: GKV-Spitzenverband, German import data & Marijuana Business Daily estimates
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FLOWER

Dozens of flower varieties were available in German pharmacies in 2019, but a big number of those suffered supply disruptions throughout the year.

An *MJBizDaily* survey of pharmacies showed at least 30 different strains were available as of April 2020.

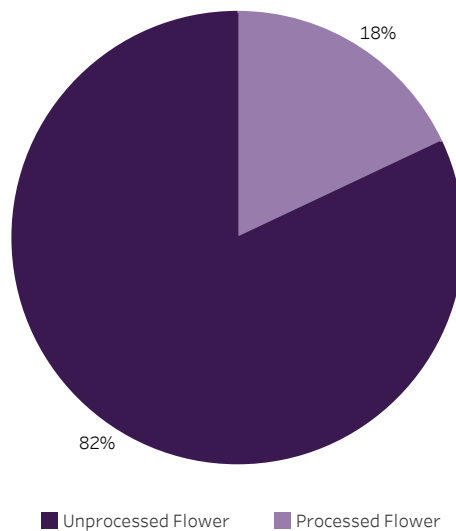
More strains have import authorizations in place but haven't become available for pharmacies to order.

Patients can purchase unprocessed flower or a doctor may prescribe it ground or packaged for use as tea, which is considered "processed" flower or "flower used in preparations."

We estimate at least 80% of the flower covered by insurance in Germany is sold "unprocessed."

Chart 7: Reimbursements for Flower in 2019: Processed vs. Unprocessed

**Reimbursements for Flower in 2019:
Processed vs. Unprocessed**

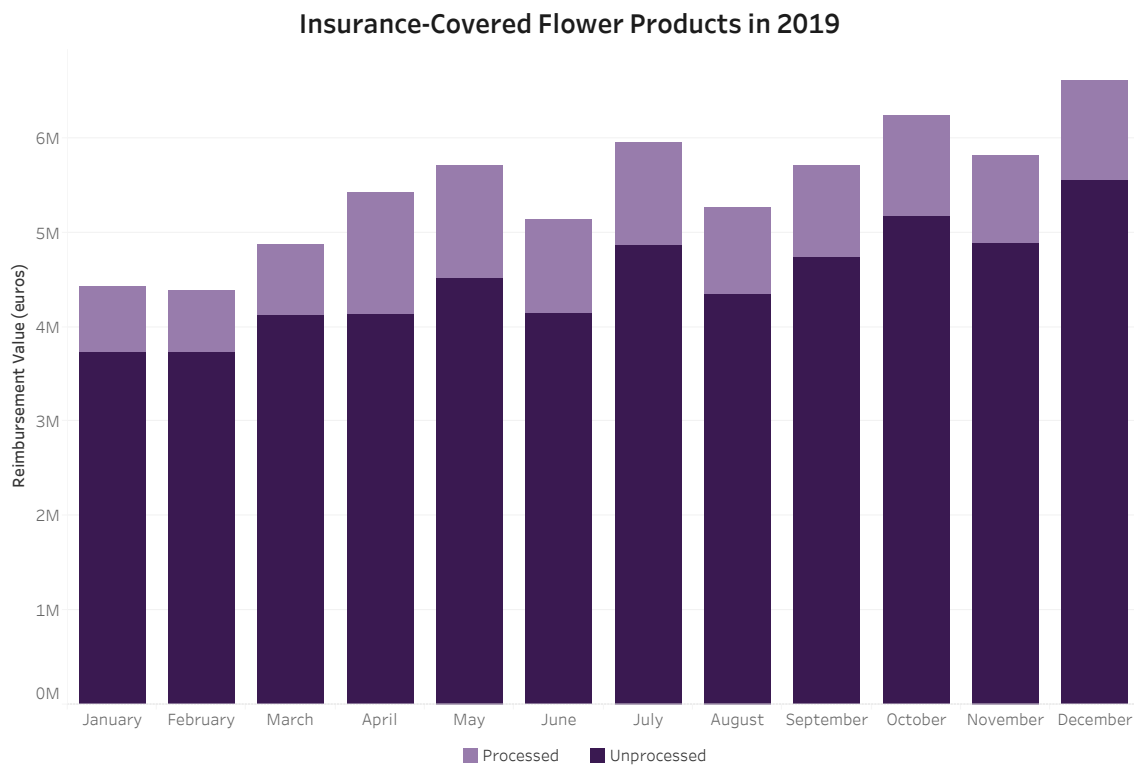


Source: GKV-Spitzenverband & Marijuana Business Daily estimates
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When prescribing flower, doctors need to specify in the prescription the exact product, and pharmacists are not allowed to change it for an equivalent one unless a new prescription is provided.

Flower for sale must specify THC and CBD content, with a variation of 10% permitted. A doctor may prescribe a maximum 30-day supply of up to 100 grams of flower per patient.

Chart 8: Insurance-Covered Flower Products in 2019



Source: GKV-Spitzenverband & Marijuana Business Daily estimates
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DISTRIBUTION

Producers that want to distribute to German pharmacies need to either own or have an agreement with a German importer. Only pharmacies can sell to patients.

German importers must:

- Be a registered business with commercial register entry through the Handelsregister.
- Have a pharmaceutical wholesaler license issued at the regional government level.
- Obtain a license for dealing with narcotics at the federal level.

To acquire the necessary licenses, importers must employ at least one pharmaceutical expert responsible for narcotics and have extensive security measures in place. A plan including the type of product to be imported and annual amounts must be provided to German authorities.

Other permits—which a company must apply for at a regional level and federally—could be required depending on the specific products for import and the country of origin.

The federal government confirmed at the end of February that, so far, flower for patients in Germany came from only Canada, the Netherlands and Portugal.

As of April 2020, we are not aware of a change in this situation, but the BfArM already granted the first import permits for flower from Denmark and Spain. There might be a significant delay between obtaining the import permit and getting product in the market, because other requirements must be fulfilled.

Three of the major Canadian companies serving the German market have acquired importers in the country: Aphria, Aurora Cannabis and Canopy Growth.

Three additional Canadian producers have supply agreements with German companies and provided product in 2019: Cronos Group, Tilray and Wayland Group.

The wholesalers that had product imported from countries other than the Netherlands as of early 2020 were:

- Aurora Cannabis, which distributes its own products produced in Canada.
- Cannamedical, which distributes products imported from Canadian producer Wayland, and products from Portugal produced by Tilray. According to Cannamedical, the company imported 1,158 kilograms in 2019, which represent 18% of total imports.
- Canopy Growth, which distributes its own products produced in Canada.
- Pohl Boskamp, which distributes products imported from Canadian producer Cronos.
- Tilray, which distributes its own products produced in Canada.

Some of the suppliers listed above also import Dutch flower.

As of early 2020, there were dozens of wholesalers importing only Bedrocan products from the Netherlands to distribute to pharmacies.

Monthly exports from the Netherlands normally are divided equally among German importers, but deals between wholesalers are also common.

When it comes to non-flower products, only two companies imported in 2019 cannabis extracts from Canada.

Tilray started selling these products in 2017 and Aurora in 2019.

Dronabinol is produced in Germany by C3, the former cannabinoid division of Bionorica now owned by Canopy Growth. For some of C3's production, flower from Austria and the Netherlands is imported. In April 2020, German firm Cantourage became a new supplier of dronabinol, which it imports from Israel.

Sativex—a finished pharmaceutical product with marketing authorization—is produced in the United Kingdom.

As long as regulatory requirements are fulfilled, there is no cap on how much a company can request to import.

The BfArM claims that it allows the import of medical cannabis only from cultivation that takes place under state control, compliant with the 1961 Single Convention on Narcotic Drugs.

In early 2019, the first cannabis shipments from Australia and Latin America—specifically from Colombia and Uruguay—were approved. However, these shipments were for testing purposes only and not for distribution to pharmacies and, ultimately, patients.

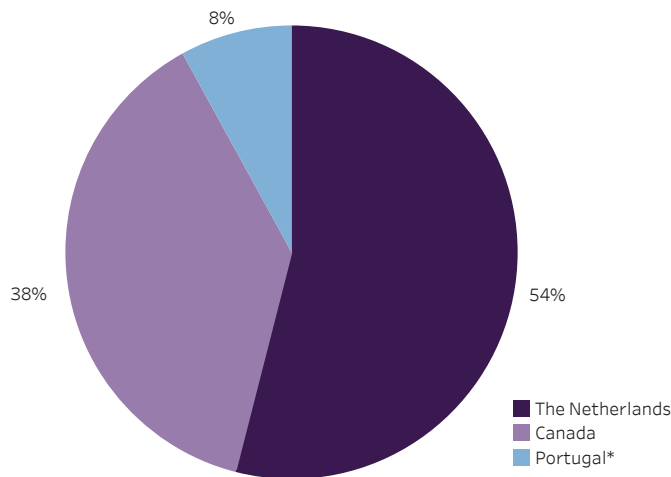
The import from Uruguay, even if symbolic, was significant. It suggests that having a recreational cannabis program that is out of compliance with international treaties is irrelevant to German authorities as long as medicinal production is regulated in compliance with the 1961 Single Convention on Narcotics Drugs.

Previous replies from the German government to Parliament said that Uruguay wasn't complying with international drug control conventions because of its recreational program, casting doubt Germany could ever import from the South American country.

But the 2019 shipment from Uruguay suggests German authorities now see Uruguay as having separate and independent regulatory systems for production for medical and recreational use.

Chart 9: Flower Imports by Country of Origin

Flower Imports by Country of Origin



*Imports from Portugal began at the end of 2019, and it's likely that most of the product remained in stock to be sold to patients in 2020.

Source: German Federal Institute for Drugs and Medical Devices, Dutch Office of Medical Cannabis, company information & Marijuana Business Daily estimates

DUTCH SUPPLY

Dozens of German companies—as of April 2020, there were 30—import product from a single source in the Netherlands for distribution in German pharmacies.

The Netherlands has an agreement to supply 2,500 kilograms per year to Germany in 2019 and 2020.

That means that Dutch imports represented almost 40% of the total German imports of flower in 2019.

As of early 2020, the Netherlands' Office of Medical Cannabis (OMC) is shipping 200 kilograms per month to Germany, which is divided more or less equally among the German wholesalers that want to import the products.

Until July 2019, the agreement between the Dutch and Germany was for 1,500 kilograms per year, but the minister of medical care of the Netherlands informed the Parliament that exports of medical cannabis flower to Germany were going to increase immediately, with the goal of shipping 2,500 kilograms in 2019 and another 2,500 in 2020.

To increase the quantities shipped to 2,500 kilograms in 2019, the plan was to ship 1,500 kilograms by August 2019 and the remaining 1,000 before the end of December.

In the letter to the Dutch Parliament, the minister explained the request for an increase came from his German counterpart because of an increase in the number of medical cannabis consumers in Germany and the fact that the nation's domestic production won't be available before the end of 2020.

The Dutch minister mentioned in the letter to the Parliament that the Netherlands' current production capacity can fulfill the German request.

As of early 2020, only Bedrocan was growing medical cannabis flower for commercial purposes in the Netherlands, whose exports are carried out by the government Office of Medical Cannabis.

This is not the first time the agreed-upon supply quantities between the two countries have increased. In August 2018, they were boosted from 700 to 1,500 kilograms.

FLOWER PRICE

Prices across the supply chain in Germany changed significantly in April 2020, since an agreement between pharmacists and insurers—retroactive to March 2020—modified the payment that pharmacies receive from statutory health insurers, with the purpose of bringing down prices overall.

IMPORT PRICES

The Office of Medical Cannabis of the Netherlands typically sells all flower for 5.40-5.80 euros per gram plus 6% value-added tax (VAT) and shipping.

Import prices of Canadian products are hard to establish because there are only a couple of exporters and importers that have little incentive to disclose the prices at which they sell or buy. However, we expect the price range paid to import medical cannabis flower to be between 4 euros and 7 euros per gram, depending on a variety of factors.

The price paid by pharmacies to wholesalers also isn't fixed or publicly available because it's determined on a case-by-case basis. Conversations we've had with wholesalers and pharmacies place the price range between 8 euros and 14 euros per gram.

We expect average wholesale prices to decrease to less than 10 euros per gram in the coming months because of the agreement signed between pharmacists and insurers in April 2020.

PRICES UP TO MARCH 2020

The markup by pharmacies to determine the retail price was regulated by law.

For flower sold as “unprocessed,” the pharmacy used to mark up the price by 100% and add the price of the container, a narcotic prescription fee and VAT.

If a pharmacist purchased 10 grams of flower for 100 euros, the retail price could have included:

- 100 euros (example of price the pharmacy pays for the flower).
- 100 euros (100% markup).
- 2.60 euros (container price).
- 38.49 euros (19% VAT).
- 4.26 euros (narcotic prescription fee).
- 245.35 euros (total price for 10 grams).

For prescriptions, the pharmacy must provide a discount of 5% over the final price.

If the flower was “processed,” for instance, ground by instruction of a doctor, the pharmacy added to its purchase price: the cost of the container, a 90% markup and several other items with fixed values.

If a pharmacist purchased 10 grams of flower for 100 euros, the retail price could have included:

- 100 euros (example of price the pharmacy pays for the flowers).
- 90 euros (90% markup).
- 2.60 euros (container price).
- 3.50 euros (Rezeptzuschlag, a fixed formula fee that could be as high as 6 euros).
- 8.35 euros (Festzuschlag, a fixed fee).
- 38.85 euros (19% VAT).
- 4.26 euros (narcotic prescription fee).
- 247.56 euros (total price for 10 grams).

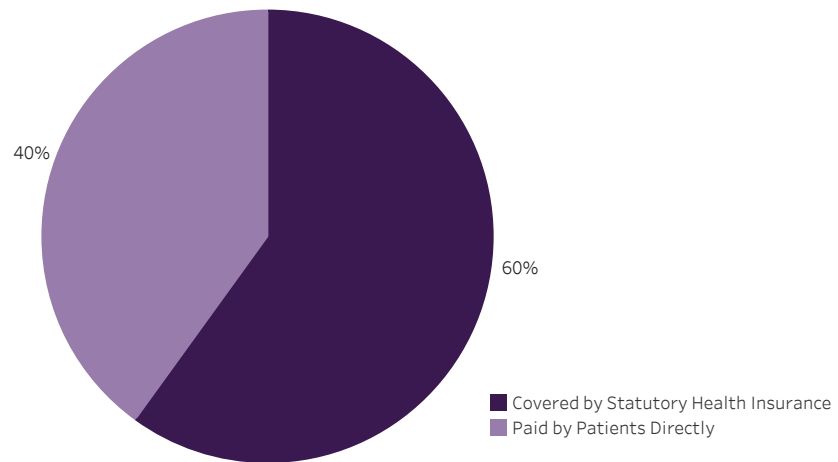
If the product is covered by statutory health insurance, the pharmacy must provide a fixed discount of 1.77 euros.

We’re aware of some pharmacies that in 2019 voluntarily chose to not apply the roughly 100% markup and instead offered a somewhat lower price.

We estimate that statutory health insurers reimbursed 60% of the total flower sales in 2019 while 40% was paid out of pocket by patients.

Chart 10: Cannabis Flower Coverage in Germany in 2019

Cannabis Flower Coverage in Germany in 2019



Source: GKV-Spitzenverband, company information & Marijuana Business Daily estimates
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PRICES FROM MARCH 2020 FORWARD

In April 2020, the German Pharmacists Association (Deutscher Apothekerverband, DAV) reached a new price agreement with the National Association of Statutory Health Insurance Funds that is likely to impact wholesaling business margins.

German pharmacies will now start calculating differently the price at which they sell medical cannabis to patients with a statutory health insurance prescription. This applies to flower, full-spectrum extracts and dronabinol preparations.

The new price agreement establishes a fixed amount that insurers will pay pharmacies, regardless of the price at which pharmacists sourced the products.

The new price agreement is the result of lengthy negotiations between pharmacies and insurers. A law from August 2019 mandated the two parties to agree—before the end of February 2020—to a price reduction to save about 25 million euros from the GKV coffers, which would ultimately benefit German taxpayers.

In 2019, statutory health insurers spent 123 million euros reimbursing medical cannabis; the new pricing aims to save up to 20%.

The agreement was recently reached, but it applies retroactively to March 1, 2020.

Until now, pharmacies had little incentive to negotiate cheaper prices from their suppliers because the pharmacy markup was a percentage over the price at which they bought from the wholesalers. A higher purchase price meant a higher margin for the pharmacy.

But with the new rules, pharmacists have a strong incentive to buy cheaper if they want to keep their current margins. What insurers will pay pharmacies will be significantly less, especially for larger prescriptions.

The new price agreement is complex. For small prescriptions up to 15 grams, only a small difference with the previous system exists. But for larger prescriptions, the price per gram that pharmacies will receive from statutory health insurers will be significantly lower than 20 euros or more per gram of flower.

Following are examples *MJBizDaily* calculated based on the new price agreement for “unprocessed flower”:

- For a 10-gram prescription, pharmacies will receive 19.04 euros per gram.
- For a 30-gram prescription, 16.13 euros per gram will go to the pharmacies.
- For a 100-gram prescription, pharmacies will receive 13.32 euros per gram.

Nothing changed for patients who have a statutory health insurance prescription since they are still responsible for only the usual 5- to 10-euro copayment.

The new price agreement also doesn't directly affect patients who access medical cannabis through private prescriptions or pay out of pocket. They will continue to pay to pharmacies using the previous calculation system.

However, if pharmacies start buying at a lower price, this could benefit patients paying out of pocket since the 100% markup will be lower than before.

EU-GMP AND OTHER QUALITY REQUIREMENTS

Cannabis sold in Germany must abide by the Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practice (GMP) quality standards.

Obtaining European Union-GMP certification is one of the key requirements for any business looking to sell its medical marijuana products in Germany.

But there's a widespread misconception that after obtaining this certification, little else is needed to start supplying cannabis to German pharmacies.

Other quality requirements for flower products include compliance with:

- The German Pharmacopoeia (DAB) Monograph, which, among other things, mandates for flower products a deviation of no more than 10% from the declared THC and CBD value.
- European Pharmacopoeia requirements. This includes testing results below certain levels of microbiological quality and heavy metals.

Other quality requirements, such as stability data, also apply to flower and other products that are offered for sale to patients.

A German monograph for cannabis extracts is in the works as of April 2020.

In the case of irradiated medicinal products, a specific permit is needed.

In Germany's comparatively decentralized health system (compared to other European countries), midlevel regional government authorities or municipal governments are the ones responsible for performing GMP audits and issuing certifications.

After a period of more than one year transpired without any new Canadian facility receiving EU-GMP certification, TerrAscend received the certification for its facility in Mississauga, Ontario, in May 2019. The operation was certified by the Düsseldorf government.

Iuvo, the German importer of TerrAscend products, obtained the necessary import authorization from the BfArM, but the products were still not available in the German market as of early 2020.

In early 2020, two new Canadian facilities obtained EU-GMP:

- Brampton, Ontario-based producer Northern Green Canada.
- Strathroy, Ontario-based Natural MedCo, a subsidiary of Eve & Co.

Both were certified by the regional government of Upper Bavaria in March 2020.

Aphria obtained the certification for its facilities in Brampton and Leamington, Ontario, from the Maltese Medicines Authority in January 2020.

Products from the newly certified facilities in 2020 weren't available for German patients as of the end of April 2020. This indicates that EU-GMP certification is just one of the hurdles companies need to address before they can supply the German market.

Previous certified facilities in Canada from which products already made their way to patients in Germany include:

- Aurora Cannabis facilities in Cremona, Alberta, and Bradford, Ontario, which were certified by Berlin's Office of Health and Social Affairs, as well as the facility in Markham, Ontario, which was certified by the governmental district of Cologne.
- Canopy Growth facilities in Smiths Falls, Ontario, and Niagara-on-the-Lake, Ontario, which were both certified by the Tübingen administrative government.
- Cronos' facility in Stayner, Ontario, which was certified by the Schleswig-Holstein government.
- Tilray's facility in Nanaimo, British Columbia, which was certified by the Düsseldorf government and the Czech State Institute for Drug Control.
- Wayland's facility in Langton, Ontario, which was certified by the Landesdirektion Sachsen.

Other companies in non-European countries, for instance in Australia, have received GMP certification issued by their domestic health authorities.

A producer that has been GMP-certified by a non-European Union country that has a GMP mutual recognition agreement (MRA) with the EU could qualify to distribute in Germany if authorities consider medical cannabis to be covered by the MRA.

New certification audits involving cannabis facilities in Canada and elsewhere screeched to a halt as of April 2020 given the travel restrictions in place in most of the world amid the coronavirus pandemic.

As a result, the companies whose facilities weren't audited before the pandemic faced a challenging situation when this report was published, with the chances of getting EU inspectors to travel overseas slim.

This means, for now, that the handful of EU-GMP-certified companies supplying Germany with medical cannabis from Canada and from inside the EU are likely to continue enjoying an effective oligopoly.

That might not last long, however, as more domestic producers in EU countries such as Denmark, Malta, Portugal and Spain become certified by their respective domestic health agencies.

That would allow medical cannabis producers in those countries to ship throughout the European Union.

IONIZING RADIATION

Achieving EU-GMP is a key certification to enter the German market, but it's far from the only quality requirement.

One notable example is compliance with the acceptable levels of microbiological quality of medical cannabis flower.

Acceptable microbial levels are defined in the European Pharmacopoeia, and producers may comply with those levels either by growing in an extremely clean environment or by irradiating the flower to decontaminate it.

Irradiated cannabis—a common practice in Canada—requires an extra permit to be imported into Germany.

Irradiation must occur in a laboratory that's compliant with stringent German requirements, and easy access to such facilities might not exist in every country.

In addition, the German importer of an irradiated medicine must apply for a special permit to distribute it. This permit is known in Germany as AMRadV.

Germany's medicines law prohibits the sale of medical products that underwent ionizing irradiation unless the AMRadV permit is obtained.

Irradiation of the products could have a big impact on businesses because of the operational, financial and bureaucratic challenges it could represent for unprepared companies.

Companies that grow a product that is not compliant within the acceptable microbial levels have no other option than to irradiate their cannabis flower if they want to have their products available in German pharmacies.

However, even companies that grow "clean" product might want to consider irradiation for safety considerations. The companies might want the microbial count as close to zero as possible in consideration of patients with a depressed immune system.

It is generally accepted that irradiation does not change the levels of THC or CBD, but it could reduce the presence of some terpenes. Some argue that less terpene content diminishes the therapeutic value of the flower.

Companies that grow "clean" product and are in a position to choose whether to irradiate need to balance these two factors.

If irradiation is needed—or wanted—finding a qualified laboratory to do it could prove a challenge in many of the countries now aiming to export to Germany.

Testing is necessary to determine whether flower is compliant with acceptable microbial levels, though it is possible the results could vary depending on how the testing is done.

That is why it is important that testing is done in accordance with the German Pharmacopoeia Monograph, which establishes a detailed testing methodology, as well as procedures the European Pharmacopoeia describes for testing different contaminants.

German importers of irradiated medical cannabis flower must submit an application to obtain the AMRadV permit from the BfArM for each variety of flower they intend to distribute.

This is the case even if another importer already submitted an application for the same product, which usually happens for flower imported from the Netherlands by several distributors.

The BfArM charges a fee of about 4,500 euros per application. So, if an importer wants to distribute only three types of flower—high-THC, high-CBD and balanced, respectively, what many would consider “the minimum” offer of products—the importer must plan to pay 13,500 euros in fees to the BfArM just for authorization to distribute those irradiated products.

With dozens of wholesalers importing Bedrocan flower varieties from the Netherlands, it means that the BfArM possibly processed hundreds of permits that were largely identical because they were all asking approval for the same five products.

Not only is the direct financial burden significant because of the fees, but the paperwork and time involved, which could take several months, can delay the product’s time to market.

The BfArM requires a long list of documents in which the irradiation process needs to be explained in detail.

The flower produced in the Netherlands by Bedrocan is irradiated by a third-party laboratory in the country of origin.

In November 2019, *Marijuana Business Daily* reached out for comment to all the Canadian companies that were exporting to Germany.

Cronos and Wayland said they don’t irradiate their flower products that currently are sold in the German market.

A spokesperson for Canopy Growth told *MJBizDaily* that “the process isn’t always applied, but if it ever were, it would be carried out in Canada. It could be performed in-house by Canopy or by a third party.”

As for Tilray, a spokesperson said:

“All shipments of medical cannabis as finished goods from Tilray’s Canadian facility and (future) shipments from Tilray’s EU campus in Portugal, to be sold in pharmacies as Tilray products, are irradiated by a qualified GMP-certified third party.”

A past Tilray bulk shipment from Portugal to Germany was not irradiated in Portugal. The importer, Cologne’s Cannamedical, confirmed it will not irradiate the product before it is distributed.

In the case of Canadian producer Aurora Cannabis, a spokesperson said it does not “gamma-irradiate” its products, but as *MJBizDaily* subsequently reported, the Canadian company had to temporarily stop sales of its product in Germany because of noncompliance with AMRadV.

The company had been applying an irradiation process that it calls “e-beam” without having the necessary permit, so it had to temporarily stop sales of its products from the end of November 2019 until early February 2020 when it was finally able to resolve that situation.

DOMESTIC CULTIVATION TENDER

The German subsidiaries of Canadian producers Aphria and Aurora Cannabis, along with Germany-based Demecan, are the only domestic growers of medical cannabis. The first domestic harvest is expected before the end of 2020.

The three companies were selected as winners of the second application process attempt by the German government for domestic cultivation.

The original application process suffered delays and was finally canceled because of lawsuits around the process.

The second and final application process, which started in mid-2018, drew 79 applicants for 13 available lots. The winners were determined by a points system, with 40% of the points determined by price and 60% by technical documents.

Combined, the three companies are expected to produce 2,600 kilograms of pharmaceutical-quality cannabis flower per year in Germany over a four-year period. They can sell their product to the cannabis agency only at the price offered during the application process.

Pursuant to the German reform of medical cannabis in March 2017, a government cannabis agency was created under the BfArM as mandated by the 1961 Single Convention on Narcotic Drugs.

The cannabis agency is tasked with managing and controlling domestic cultivation and its distribution in Germany.

The price at which the agency will buy from the growers is specific to each of the 13 tendered lots, of which Aurora and Aphria have five each and Demecan has three.

The companies have not disclosed the prices they offered during the application process, and the government did not reveal how much it will pay each company, only the total.

In the disclosure, the government said it will buy at least 650 kilograms of medical cannabis flower from domestic producers for approximately 1.5 million euros per quarter, which sets the average wholesale price at 2.3 euros per gram.

Each quarter, the 650 kilograms will be distributed as follows:

- Aurora: 250 kilograms
- Aphria: 250 kilograms
- Demecan: 150 kilograms

German growers are incurring significant capital expenditures to build the bunker-style, indoor cultivation facilities required by German regulations.

In the company's third-quarter 2019 earnings conference call, Aphria's management said capital expenditures required for the company's German facility were 25 million euros, of which 8 million euros had already been spent.

Demecan announced in October 2019 that it raised 7 million euros, but the company didn't reply to *MJBizDaily* requests for comment asking if it would need more capital raises to become fully funded to build the facilities as agreed to with German authorities.

Even assuming an optimistic scenario in which the government buys more than the planned quantities over a four-year period contracted with the domestic suppliers, achieving a profitable result from the German grow operations will be challenging.

The price that pharmacies will pay for the products will be higher than the average 2.3 euros per gram at which the companies will sell it. This is because the markup by a distribution company will have to be included in the supply chain, plus a markup by the cannabis agency to cover its costs.

But even after those markups are included, the price that pharmacies will pay will most likely be well below the 10 euros per gram or more that they have been paying until early 2020.

Only three types of medical marijuana will be grown in Germany:

- Type 1 has between 18% and 22% THC and less than 1% CBD. Aurora will produce 1,000 kilograms of Type 1 cannabis per year, Demecan 400 kilograms and Aphria 200 kilograms.
- Type 2 has between 12% and 16% THC and less than 1% CBD. Aphria will produce 400 kilograms of Type 2 per year and Demecan will produce 200 kilograms.
- Type 3 has between 5% and 9% THC and between 5% and 9% CBD. Aphria will produce 400 kilograms of Type 3 cannabis per year.

Growers must deliver at least 80% of the agreed-upon quantities. Certain scenarios in which the cannabis agency buys more than 100% of the agreed quantities are possible.

The companies will not extract or manufacture any products with their harvests.

Cannabis produced in Germany, like imported marijuana, must abide by the GACP and GMP quality standards. Other quality requirements include the German Pharmacopoeia Monograph and stringent microbiological purity levels.

The agency believes packaging will primarily consist of 50-gram containers. The locations from which the distributor will have to pick up the products will be:

- Aurora's facility in Leuna, Saxony-Anhalt (eastern Germany).
- Aphria's facility in Neumünster, Schleswig-Holstein (northern Germany).
- Demecan's facility in Ebersbach, Saxony (eastern Germany).

Harvested product will not be transported to the BfArM, nor will it be stored there. The agency remains the owner of the flower throughout the distribution process, with the distributor remaining a service provider.

The federal government has said in the past that the country will most likely continue to rely on imports, and federal authorities are not currently considering an increase to the quantities of domestically produced cannabis, nor initiating a new application process.

The government also does not plan to export medical cannabis produced in Germany.

DOMESTIC DISTRIBUTION TENDER

In March 2020, the BfArM launched an application process looking for a distributor to service the government's agency.

The winning company will ship all domestically produced medical cannabis flower to pharmacies.

The process is ongoing as of April 2020.

The requirements and awarding criteria indicate that companies with experience distributing narcotic drugs—and those able to offer a low price for their services—will have the highest chances of winning. No cannabis-specific experience is required.

The deadline to submit the applications, which must be filed electronically, originally April 28, was extended to May 26.

While the announcement did not provide a reason for the shift, the coronavirus pandemic was a likely cause. The BfArM received requests to postpone the application deadline amid the current crisis.

In its reply, the BfArM agreed but maintained the contract initiation date.

The plan is to begin the contract in September to start with the first delivery in October.

The winner will provide the services from September 2020 until the end of 2025, at the latest.

This does not directly affect imported medical marijuana distribution, which is expected to continue as usual. The application process pertains only to distribution of domestically grown cannabis.

With domestically produced flower cheaper than imports at this time, once German-grown flower reaches pharmacies, it could bring down average wholesale prices.

However, given current growth in demand, domestic grows are unlikely to provide enough cannabis, and imports will remain necessary.

Applicants to become Germany's distribution service provider for medical cannabis must offer a price per gram, and if all the requirements are fulfilled, the lowest price will represent the determining factor to win the contract.

Offers will be considered using up to two decimal places.

The contractor will provide the following services to the cannabis agency:

- Set up a distribution and logistics system for the supply of the products to pharmacies.
- Process commercial orders, including invoicing.
- Pick up the products from the producers' locations, inspect them and deliver them to buyers.
- Store products for later distribution.
- Organizational processing in case of batch recalls and return of cannabis to the producer for destruction.
- Documentation obligations related to the Medicinal Products Act ("Arzneimittelgesetz," AMG) and the Narcotic Drugs Act ("Betäubungsmittelgesetz," BtMG).
- Communication with the cannabis agency and other miscellaneous tasks.

Applicants must have a registered company compliant with relevant AMG and BtMG legislation. They must prove they have experience distributing narcotics medicines – subject to AMG and BtMG requirements – from Jan. 1, 2017, until the end of the application process. (A minimum delivery of 10,000 packages of narcotic drugs in a 12-month period could be required.)

Previous distribution experience must include storage, transport and delivery to pharmacies and other customers. The sale did not need to be made in the bidder's name, and qualifying documents may be from another country.

Other requirements of the application process include:

- Specification of the technical specialists to be employed, including their qualifications in order to meet the requirements of the AMG and BtMG.
- A declaration that the bidder already has the required storage and other necessary business premises—compliant with the AMG and the BtMG—at disposal or will have them if their application is selected.
- A statement showing the average annual number of employees of the company, along with the number of managers in the past three years.
- A business liability insurance policy with certain minimum conditions or a declaration that such insurance would be contracted in case the distribution contract is won.
- An indication of which parts of the contract the applicant may intend to subcontract.
- Good distribution practices audit with no significant deficiencies found.

EFFICACY OVER UNFETTERED ACCESS?

To avoid the proliferation of court-approved home grows, German legislators approved the 2017 reform that provided general access and mandated statutory health insurers to provide compensation as long as certain requirements are fulfilled, including that cannabis be prescribed as a last resort.

Although it was the Legislature that enacted a reform providing more generalized access, it can't be ignored that the move was done only under the pressure of the courts.

In an interview with Handelsblatt in April 2019, BfArM President Karl Broich called medical cannabis a “system rupture” because marijuana prescriptions are permitted without the same level of efficacy requirements needed for other prescription medications.

The BfArM president sees the current arrangement allowing prescriptions without trials as transitional and said it's a system he wants to “get away from as soon as possible.”

Broich said the BfArM's objective is to get more cannabis products with proven efficacy on the market. So far, that short list consists of Sativex and Canemes.

That means efficacy and intellectual property might play greater roles in separating the winners from the rest of the pack.

Medical cannabis businesses prioritizing science might see certain advantages in Germany because policymakers and physicians generally feel more comfortable with products with proven efficacy over products such as flower that are prescribed only as a last resort.

That doesn't mean that flower is going away. In fact, the BfArM in 2019 granted the first domestic licenses for growing and, in 2020, will grant the distribution license for that flower production, demonstrating a commitment to the use of flower for the time being.

But products with finished clinical trials and proven efficacy will continue to enjoy a higher status.

This was also reflected in mid-2019 in a letter signed by about a dozen associations representing German doctors that appealed to the medical community, journalists, insurers and politicians to adopt a "more responsible" approach toward medical cannabis.

The signatory associations included the German Association of Palliative Medicine, German Association for Psychiatry and Psychotherapy, German Neurological Society and German Pain Society.

The associations focused criticism on:

- The media, for often presenting medical cannabis in an overly positive way and without making the distinction between two distinct categories—finished pharmaceutical products with marketing authorization as well as products used to dispense magistral preparations in pharmacies.
- A lack of information regarding medical cannabis flower. Doctors generally don't know which varieties should be prescribed for which conditions and in what dosages. Doctors are also worried about the lack of information regarding side effects.
- Biased sources of information. The associations say publicly listed companies spend large amounts of money on marketing.
- Cannabis producers for inviting doctors to visit their facilities and meet "experts." The associations called out producers for finding ways to make German doctors aware of their products in questionable ways.

The groups appealed to:

- Doctors to prescribe traditional pharmaceutical products with marketing authorization whenever possible and prescribe cannabis flower or preparations only as a last resort, as the law mandates.
- Physicians associations to create guidelines according to the Association of the Scientific Medical Societies in Germany's "Guidance Manual and Rules for Guideline Development."
- Journalists to conduct careful research and verify the quality of their data and always differentiate between finished pharmaceutical products with marketing authorization and medical cannabis.
- Insurers to develop more standardized and binding guidelines around the criteria used to approve or deny cannabis-treatment coverage.
- Politicians to make decisions based on reliable data from independent studies done according to internationally recognized standards of evidence-based medicine.

THE GOVERNMENT SURVEY

Another way in which the focus on efficacy is reflected in the German framework is the ongoing survey (Begleiterhebung) on the medical market.

The federal government disclosed in April 2020 the latest preliminary results, with data as of March 6, 2020.

As in the previous preliminary results of the survey, pain continued to dominate as the most common condition for which cannabis is prescribed.

The preliminary results involved 8,872 patients.

Since early 2017, doctors have had to report anonymized data to the BfArM when they prescribe medical cannabis that's covered by statutory health insurance.

The survey on the medical market will run until March 2022. Once over, the results could provide crucial input for German policymakers to determine the future of medical cannabis coverage.

Doctors are expected to report patient data only after one year of treatment is completed or as soon as treatment is interrupted.

That's why the number of patients included in the survey so far shouldn't be interpreted as the total number of patients in the German market, which is unknown.

Statutory health insurers are supposed to cover medical cannabis only in cases of severe diseases. However, a clear line does not always separate a serious condition from one that isn't, which often leads to disputes between insurers and patients.

Of the 8,872 patients, almost 72% were prescribed medical cannabis to treat pain. This was followed by spasticity with almost 11%.

Anorexia was third with almost 7%.

Other conditions totaled below 5%.

In 36% of the cases reported, the therapy with cannabis was interrupted before one year.

The products included in the study are:

- Cannabis flower.
- Full-spectrum cannabis extracts.
- Single-cannabinoid preparations.
- Nabilone.
- Canemes (only when prescribed off-label).
- Sativex (only when prescribed off-label).

RECREATIONAL REFORM POSSIBILITY

This report focuses on medical cannabis, but considering Germany could represent the largest European recreational market once it's legalized and recent political moves hint at a move in that direction, we've included information on this topic.

In February 2020, one of the German government coalition parties clarified its stance on recreational marijuana in favor of decriminalizing possession and allowing pilot programs involving the legal distribution of adult-use cannabis.

With the Social Democratic Party of Germany (SPD)'s new position, a majority of the members of the German Parliament represents a political party in favor of some type of recreational marijuana reform.

It's also the first time that one of Germany's major parties and part of the government coalition officially favors reform.

The move is seen as a positive because it represents a step forward. But a long and uncertain path remains before any material adult-use cannabis reform takes place in Germany.

German Chancellor Angela Merkel's center-right, Christian-democratic political alliance, or Union, which currently governs with the SPD, still opposes any change.

So does the Alternative for Germany, although those two political groups are unlikely to combine forces for a federal government coalition.

The SPD's position was received with criticism by members of its Union partner.

In a position paper, the SPD parliamentary group announced a move away from prohibition, calling for:

- Decriminalization of possession in unspecified small quantities.
- Experimental pilot programs allowing legal and regulated distribution of marijuana to adults.

"We see the regulated distribution of cannabis to adults in Germany as a good chance for a successful policy, ideally supported by simultaneous strengthening prevention and early intervention as well as counseling and treatment," the SPD paper noted.

The SPD argues that "cannabis use is increasing without break" and that "repressive measures" cause stigmatization and social exclusion.

Prohibition also causes an "enormous financial and personnel" burden on the justice and the police, according to the paper.

Several municipalities have sought permission to experiment with legal recreational marijuana in the past, but they all failed after objections from the BfArM.

"We are convinced that local authorities must be free to decide whether or not they want to enable such model projects," the SPD paper noted.

"We want to give the States the opportunity to transfer the responsibility for licensing to the local authorities, so that nothing more stands in the way of model projects for controlled cannabis distribution at local level."

How distribution would work, and whether it would include private companies, is uncertain.

The SPD paper concluded by acknowledging that the party would have to negotiate any potential reform with its coalition partner, the Union.

Saskia Esken and Norbert Walter-Borjans – leaders of Germany's SPD since December – and other members of the party previously hinted they were in favor of a new marijuana policy, but the official position expressed by the government party in April 2020 marked an important step toward reform.

Three of the four opposition parties with parliamentary representation—the Greens, the Left and the FDP—have supported cannabis reform in one way or another for years.

The next German elections are expected in 2021.

2020

The following observations, derived from the changes we saw in the German market one year after the first edition of our European report, provide insights into what industry watchers can expect during the rest of 2020:

- Flower remains the most popular product, representing half the statutory health insurance-covered market and more than that when considering the total market that includes private prescriptions. This raises some eyebrows among policymakers and the medical profession.
- Now that availability of flower has improved, doctors are confused with dozens of different strains available without clarity around the medical conditions for which these are indicated. Doctors often prescribe flower after requests from patients that empirically tried flower from the illicit market and realized it helps with their condition. That's not how the medical profession works in general, and for a more widespread acceptance of medical cannabis, better evidence is needed.
- Full-spectrum extracts still remain a tiny portion of the market. The situation could change once a German Monograph for cannabis extracts becomes available some time in 2020.
- The implications of the price reform of April 2020 will be seen throughout the rest of the year. We expect to see consolidation in the wholesaling sector of the market. We can't imagine that the number of wholesalers—30 as of April, considering only those importing from the Netherlands—can keep growing much longer.
- 2019 showed that getting new suppliers approved isn't easy. Dozens of companies have spoken publicly about their plans of supplying Germany with medical cannabis for years, yet only a handful of producers have their products available in German pharmacies.
- Slower year-over-year growth shouldn't be surprising. As of press time for this report, the supply situation was quite good in Germany. The strong growth from 2018 to 2019 could be partially explained by an undersupplied market in 2018. Keeping the year-over-year growth rate in 2020 after a better-supplied market in 2019 will be challenging.

ITALY

Italy continues to represent the second-largest medical cannabis market in Europe by volume of flower and other full-spectrum products sold as magistral preparations.

Key facts about the Italian medical cannabis market in 2019 include:

- 861 kilograms (1,898 pounds) of flower were sold, up 50% from sales in 2018.
- More than 80% of the flower sold to patients was imported from the Netherlands. The rest was either produced domestically by the army or supplied to the army by Aurora Cannabis, which produced it in Canada.
- The retail value of the market is hard to accurately assess because of the large number of possible products that could be prescribed, but we estimate it at about 20 million euros (\$22 million). About half that value is represented by the pharmacies' markups.

Patients in Italy bought preparations containing 861 kilograms of medical cannabis flower in 2019, which is a nearly 50% increase over the 578 kilograms they bought in 2018.

An accurate estimate of the total market value in euros is largely impossible—especially the retail value—because the price at which pharmacies sell medical cannabis to patients is based on a fixed tariff but varies widely depending on the specific prescriptions.

Authorities do not disclose sales numbers in euros. Rather, they report the total kilograms of cannabis flower delivered to pharmacies for them to prepare and dispense.

Marijuana Business Daily estimates that pharmacies paid almost 9 million euros for the 861 kilograms of flower used in 2019. Pharmacists used that flower as raw material for the magistral preparations they sold to patients.

At least half the final price of the medical cannabis prescription depends on the specific type of preparation and materials needed, according to the individual prescription. And there is a huge number of possible combinations of types of preparations—oil, capsules, creams, etc.—and dosage determined by a doctor's prescription.

With all those caveats, we still estimate the total retail value of the Italian medical cannabis market in 2019 is in the ballpark of 20 million euros.

Italy attracted significant attention from Canadian companies in 2018 and 2019 because many hoped it could represent the next big European export destination after Germany. So far, however, Canadian companies have supplied only a small fraction of the Italian medical cannabis market.

Bedrocan products exported by the Dutch government Office of Medical Cannabis (OMC) provide the bulk of the medical cannabis for Italy, representing just over 80% of the 861 kilograms of flower supplied to pharmacies in the country in 2019.

Italy is the second-largest export destination for the Dutch OMC.

The rest of the total supply is distributed to pharmacies by the Italian Ministry of Defense, which grows some cannabis domestically and buys the rest from Canadian producer Aurora.

The Italian Ministry of Defense has an effective monopoly on domestic production. Its Stabilimento Chimico Farmaceutico Militare (SCFM) has a grow facility in Florence that produced no more than 100 kilograms per year in 2018 and 2019.

The SCFM also issued two supply application processes in the past to buy cannabis from foreign producers for distribution to pharmacies.

The first application process took place in early 2018 and the second in mid-2019. Both were won by Aurora, allowing the producer to supply the SCFM with a fixed quantity at the price the company offered in the application process.

All medical marijuana flower sold in Italy is produced in facilities with European Union-Good Manufacturing Practice (EU-GMP) certification and irradiated to reduce as much microbial contamination as possible.

AVAILABLE PRODUCTS

Medical cannabis flower and other full-spectrum products are sold as magistral preparations in pharmacies and under prescription.

In principle, any physician can prescribe medical cannabis, regardless of the specialization, but some small differences exist depending on the region.

The prescriptions must include—among other information—the exact product, quantity prescribed, instructions for the pharmacist, instructions for the patient and a reason for prescribing. Prescriptions are valid for 30 days.

For cannabis sold as magistral preparation, patients must sign a consent form acknowledging receipt of an unregistered product. The types of conditions for which doctors can prescribe cannabis isn't limited.

However, this isn't the case for United Kingdom-based GW Pharmaceuticals' Sativex, which has been available as a registered medicine with marketing authorization since 2013 to treat symptoms in patients with multiple sclerosis.

Unlike Germany, where pharmacies often sell “unprocessed flower”—which accounts for about half the medical cannabis market—pharmacists must process the flower in Italy.

This includes, for instance, grinding the flower and selling it for vaporizing or preparing an oil count as magistral preparations. Pharmacists must follow the doctors’ instructions stated in the prescription.

In other words, Italian pharmacists consider cannabis flower a raw material.

Another difference between Germany and Italy when it comes to magistral preparations is that Germany pharmacists typically don’t extract the flower to produce oils, but Italian pharmacists are required to do so if prescribed by a doctor.

Pharmacies are the only point of sale available to patients. While there are almost 20,000 pharmacies in Italy, fewer than a thousand are known to dispense medical cannabis because of the special knowledge and equipment required.

Ten different flower strains were available to pharmacists in Italy in 2019, and most of them still are in 2020, with different availability throughout the year:

- **The five Bedrocan strains, exported from the Netherlands by the OMC are:**
 - Bedrobinol (13.5% THC and <1% CBD).
 - Bedrocan (22% THC and <1 % CBD).
 - Bedica (14% THC and <1% CBD).
 - Bediol (6.3% THC and 8% CBD).
 - Bedrolite (<1% THC and 9% CBD).
- **The two strains produced by the SCFM are:**
 - FM1 (13-20% THC and <1% CBD).
 - FM2 (5-8% THC and 7.5-12% CBD).
- **The strains Aurora Cannabis sells to the SCFM are:**
 - Three (one high in THC, one high in CBD and one balanced) from the lots of the application processes that the company won in early 2018 and` exported throughout 2018 and 2019.
 - Two (one high in THC and one balanced) from the application process that the company won in mid-2019 and which it started exporting that same year.

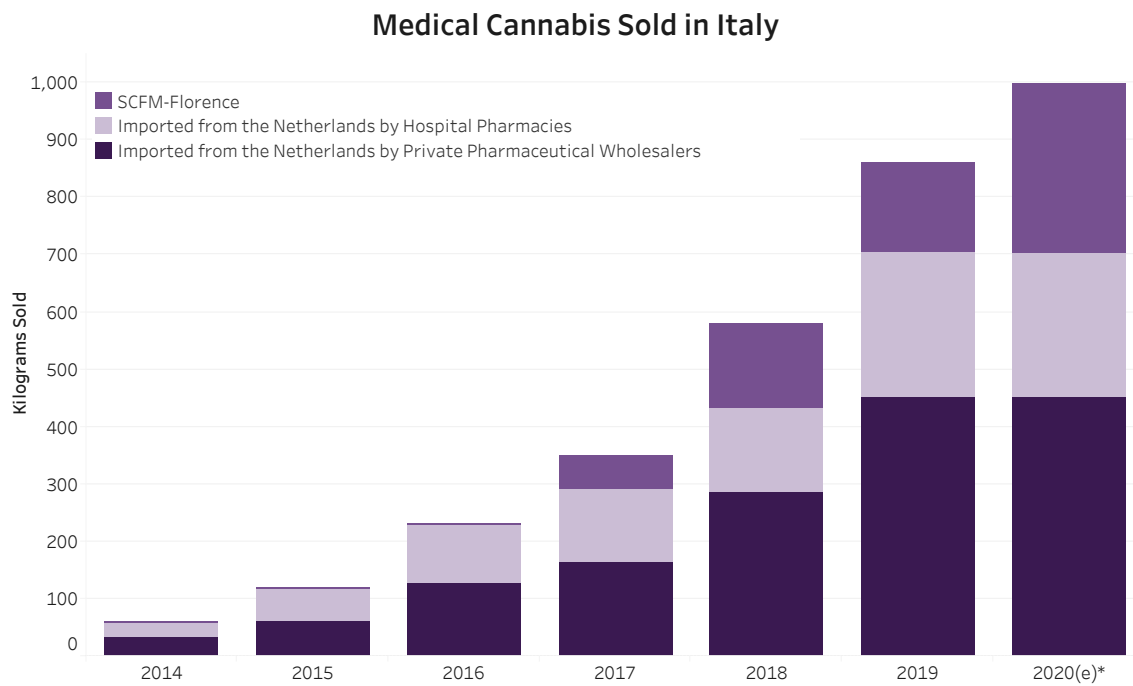
MARKET SIZE AND SUPPLY

The medical cannabis market in Italy has steadily grown since 2014. The first sales started before that year but were largely insignificant. We predict the market will continue to expand in 2020, albeit at a slower pace.

Pharmacists in Italy have the following supply options:

- Private pharmaceutical wholesalers that import from the Netherlands.
- Direct imports from the Netherlands by hospital pharmacies.
- SCFM distribution to pharmacies with its own production and with what it buys from Aurora.

Chart 1: Medical Cannabis Sold in Italy



*Estimates based on data available in early 2020.

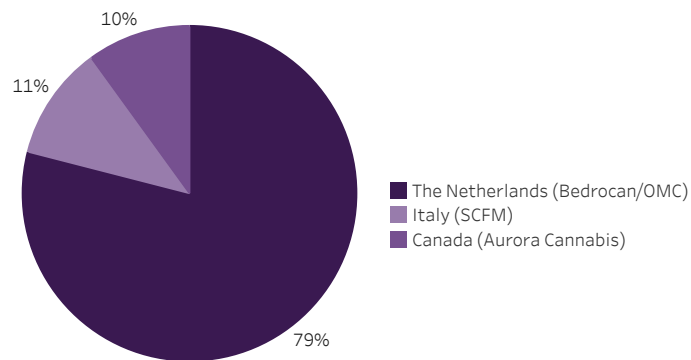
Source: Italian Ministry of Health and the Dutch Office of Medical Cannabis
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COUNTRY OF ORIGIN

Marijuana Business Daily estimates that only about 10% of the total supply of medical cannabis in Italy in 2018 and 2019 was produced in Canada, 11% was produced domestically by the SCFM and the rest was imported from the Netherlands.

Chart 2: Country of Origin for Italy's Medical Cannabis 2018-19

**Country of Origin for Italy's Medical Cannabis:
2018-19**



Source: Italian Ministry of Health, Italian Ministry of Defense, Dutch Office of Medical Cannabis (OMC) and *Marijuana Business Daily* estimates.
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DUTCH IMPORTS

The governments of Italy and the Netherlands agreed in 2018 that the Netherlands would ship 700 kilograms to Italy in 2019.

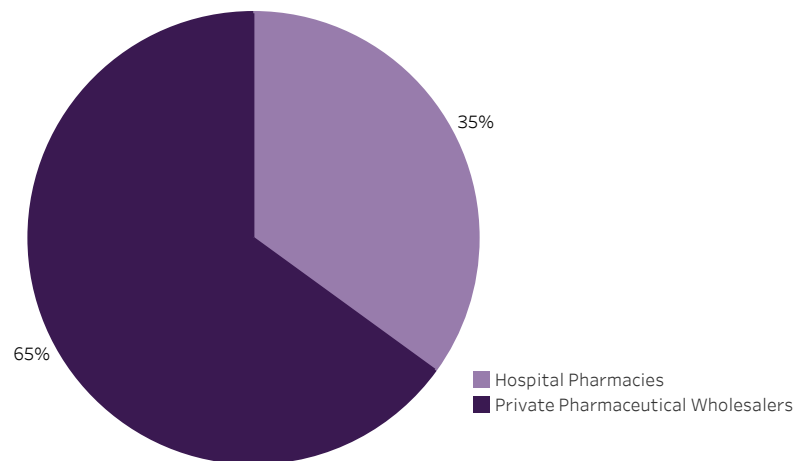
MJBizDaily is not aware of an extension to the agreement being officially announced nor any changes in quantities, but we expect it to continue with another 700 kilograms in 2020.

There are two ways in which medical cannabis from the Netherlands is imported into Italy:

- Pharmaceutical wholesalers buy from the Dutch OMC and distribute to pharmacies across the country. The number of companies actively importing and distributing in this manner is about half a dozen.
- Hospital pharmacies, which are part of the Ministry of Health, import directly from the OMC for the needs of their patients.

Chart 3: Italian Importers of Medical Cannabis from the Netherlands: 2018-19

Italian Importers of Medical Cannabis from the Netherlands: 2018-19



Source: Italian Ministry of Health, Dutch Office of Medical Cannabis (OMC) and Marijuana Business Daily estimates.
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SCFM-FLORENCE

Only the Ministry of Defense through its SCFM grows medical cannabis in Italy for patients. Its first products became available in 2017.

The SCFM also started buying from Aurora in 2018 to have more product available to supply pharmacies.

We estimate that, in 2020, the SCFM will play a larger role supplying pharmacies as it increases domestic production and buys more from Aurora, while Dutch imports will remain the same.

A decree published at the end of 2019 in Italy's official Gazette signaled the intention of the government to rely to a lesser degree on imports to serve growing domestic demand for medical cannabis.

As per the country's psychotropic-substances estimates, which cover medical cannabis, the health ministry allowed the SCFM to produce 500 kilograms of cannabis flower in 2020.

However, this is a maximum quantity and doesn't necessarily mean the SCFM can achieve that production output in 2020.

Another sign that the SCFM intends to increase its production is the joint venture it signed with the Italian region of Tuscany to produce medical cannabis and to generate evidence on the efficacy and safety of the drug.

That decision in November 2019 is a continuation of an ongoing collaboration between the two entities. The project was approved by a resolution presented by Councilor for Health Stefania Saccardi and approved by the regional council.

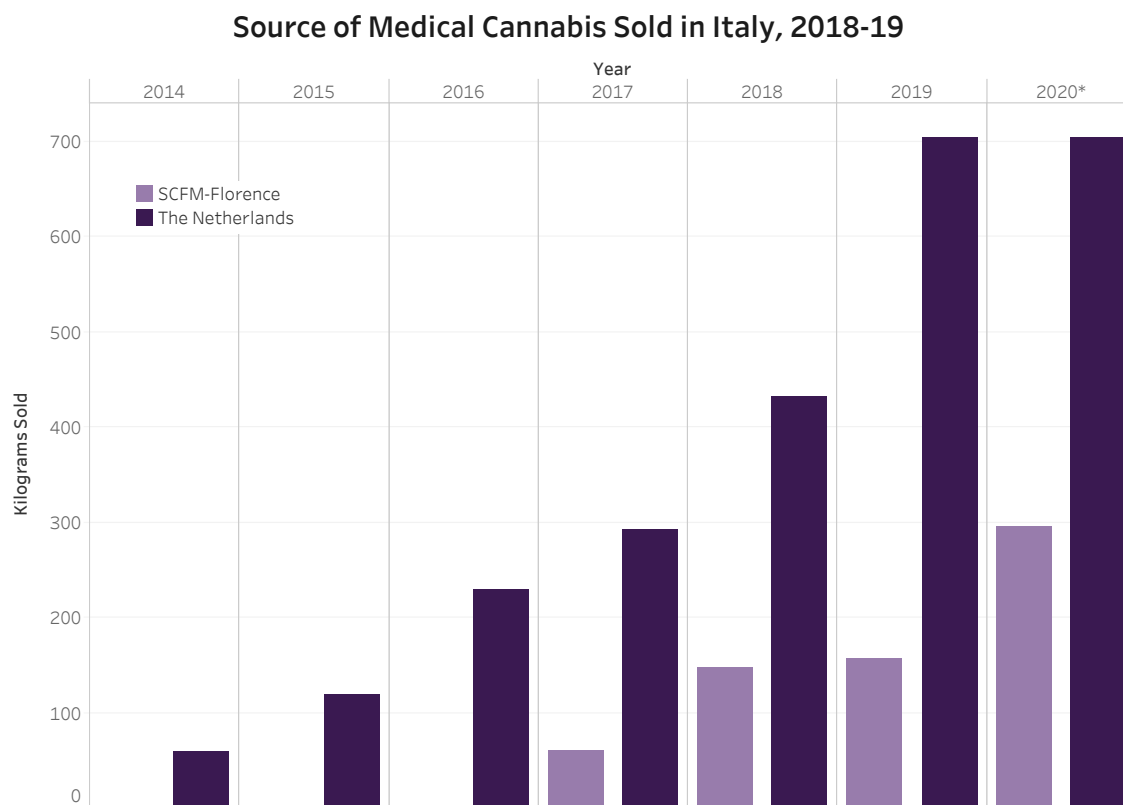
The three-year project—which might be extended—will focus on three areas:

- The production of cannabis flower for medical use.
- The standardization of oil extracts.
- The design and conduct of clinical trials.

The total investment amounts to 1.4 million euros. Of that total, the SCFM will contribute 600,000 euros and the region of Tuscany 795,000 euros, starting with 397,000 euros in 2020 followed by 198,750 euros in each of the following two years.

Tuscany justified the investment as a way to acquire clinical data to validate the safety and efficacy of cannabis and its derivatives covered by its health services.

Chart 4: Source of Medical Cannabis Sold in Italy, 2018-19



Source: Italian Ministry of Health, Italian Ministry of Defense, Dutch Office of Medical Cannabis (OMC) and Marijuana Business Daily estimates.
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APPLICATION PROCESSES

Italy complements imports from the Netherlands and its domestic government-run production with specific supply application processes.

Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practice (GMP) are part of the quality requirements to successfully apply, limiting to only a handful the number of companies that have a realistic chance of winning.

The technical specifications also include strict limits on pesticides and heavy metals as well as stability data to support the proposed shelf life.

At the end of 2017 and early 2018, Aurora and fellow Canadian producer Canopy Growth, via their respective German subsidiaries, Pedanios GmbH and Spektrum Cannabis GmbH, applied and were the finalists of the first application process to supply the SCFM with 100 kilograms of medical cannabis flower in one year, distributed as follows:

- 75 kilograms of medical cannabis flower high in THC.
- 10 kilograms with a similar content of THC and CBD.
- 15 kilograms of high-CBD flower.

Ultimately, Aurora was granted the contract for all three lots, for a total price offered by the company of 320,900 euros (not including value-added tax VAT), meaning an average price of 3.21 euros per gram.

Aurora's first shipment under the contract was made in April 2018, but the company did not complete the 100 kilograms in calendar year 2018. We assume the remainder shipped in early 2019.

The second application process took place in mid-2019. Originally, it was for 400 kilograms divided into three lots:

- 320 kilograms of high-THC flower.
- 40 kilograms of THC/CBD-balanced flower.
- 40 kilograms of high-CBD flower.

As in the previous application process, the award criteria was the lowest offered price for each individual lot. Companies needed to qualify for their offers to be considered, something only Aurora achieved.

Five companies—four of which are based in Canada—originally applied:

- Aurora Cannabis (through its German subsidiary).
- Canopy Growth (through its German subsidiary).
- Medicinal Organics Cannabis Australia.
- Tilray (through its Portuguese subsidiary).
- Wayland Group (through its Italian subsidiary).

The technical documents opened July 3, and the evaluating commission immediately disqualified Wayland after an irregularity was detected that could not be remedied because the company declared that it does not apply radiation—or an equivalent treatment—to its products.

All other companies also had irregularities but, unlike Wayland, were given an opportunity to remedy them.

However, neither Canopy, Medicinal Organics Cannabis Australia nor Tilray submitted the documents required by the government and were subsequently disqualified.

Because Aurora was the sole company qualifying with acceptable documentation, only its envelopes with economic offers for the three lots were opened. The prices offered by the other companies were not published.

Aurora offered the following prices:

- 1.78 euros per gram for the first lot of 320 kilograms of high-THC flower, totaling 569,600 euros, a 56% discount over the tender reference price.
- 1.29 euros per gram for the second lot of 40 kilograms of THC/CBD-balanced flower, totaling 51,600 euros, a 57% discount over the tender reference price.
- 1.77 euros per gram for the third lot of 40 kilograms of high-CBD flower, totaling 70,800 euros, a 41% discount over the tender reference price.

Aurora was granted the contract for all three lots, for a total price offered by the company of 692,000 euros (not including VAT), meaning an average price of 1.73 euros per gram.

Forty of the 400-kilogram supply was subsequently canceled by the Italian Ministry of Defense, which justified the decision by saying one of the lots originally tendered was “not necessary.”

At the end, Aurora will be able to sell 360 kilograms to the SCFM at an average price of 1.73 euros per gram for the two-year period that started in mid-2019.

PRICE, HEALTH-INSURANCE COVERAGE AND REGIONAL DIFFERENCES

The price that pharmacies pay the SCFM for flower is fixed at 6.88 euros per gram, plus VAT of 22%, for a total of 8.39 euros per gram. The SCFM also charges a shipping cost of 20 euros.

The price that a pharmacist pays a private pharmaceutical company isn't fixed, but it's typically in the range of 9-11 euros per gram, plus shipping.

Pharmacies pay a VAT of 22% when buying flower, which is considered raw material, but they must sell the magistral preparations with a VAT of 10%.

MJBizDaily estimates the average wholesale price that pharmacies pay, including VAT and shipping, is about 10 euros per gram.

The final costs patients pay are based on a fixed tariff but might vary wildly depending on the individual prescription, such as flower prescribed for vaporizing or prepared as oil or cream.

The prescription, particularly the type of product that needs to be prepared, quantities and dosage, will determine the final cost.

The retail price that patients pay includes 9 euros per gram of flower, plus the cost of the preparation, a narcotics fee and a VAT of 10%. With all those fees, the final price could end up double or more than the cost of the flower. We estimate an average retail price of at least 20 euros per gram of flower that was used in the prescription.

Italy has 20 administrative regions with some level of autonomy for health policies. The majority of those regions offer patients some insurance coverage for medical cannabis, but the qualifying conditions and reimbursement rules vary.

Cannabis supplied to patients by hospital pharmacies is typically covered by health insurance, but that's not always the case when purchases are made in non-hospital pharmacies.

The Tuscany region, in the center of the country, leads Italy in medical cannabis sales. It is followed by:

- Liguria, Lombardy and Piedmont in the northwest.
- Emilia-Romagna in the northeast.
- Apulia in the south.

2020

There are three ways the medical cannabis supply in Italy might increase in 2020:

- More imports from the Netherlands.
- The SCFM ramps up domestic production.
- The SCFM starts a new application process and the winner starts shipping before the end of the year.

As of the publication deadline for this report, no agreement between the Dutch and Italian governments has been made public regarding an increase of the yearly quantities that the OMC sends to Italy. *MJBizDaily* expects that the Netherlands will ship 700 kilograms to Italy in 2020, as it did in 2019.

The SCFM has struggled to increase its domestic production for years. While 2020 could mark the year it finally does so, we have only limited expectations that it will drastically increase supply.

Aurora already started shipping some of the quantities agreed upon in the second supply-application process it won.

We view this optimistically and expect the company will deliver roughly 180 kilograms in 2020, which would be in line with the 360 kilograms over a period of two years that the contract it won establishes.

With our assumptions, unless unexpected catalysts occur during the remainder of the year, Italy will have slower market growth in 2020—15%-20%, by our estimates.

Media reports that the Italian government is considering allowing public/private partnerships to increase national production are, for now, not much more than stated intentions of some government officials.

THE NETHERLANDS

The Netherlands remains the export powerhouse of Europe and has a more mature domestic market than any of its neighbors.

Several European countries are gearing up to challenge the Netherlands as exporters, but as of early 2020, the only meaningful export from a European Union country to another not involving the Netherlands was a 500-kilogram shipment from Portugal to Germany at the end of 2019.

The Dutch medical program, which is overseen by the country's Office of Medical Cannabis (OMC), was one of the first ones in the world, beginning more than 15 years ago.

Here are some key medical cannabis market facts from the Netherlands in 2019:

- The country exported 3,370 kilograms (7,430 pounds) of flower for pharmacy dispensing.
- Exports for dronabinol manufacturing or for research purposes are not included in the 3,370 kilograms figure. *Marijuana Business Daily* estimates exports for dronabinol represented roughly 1,000 kilograms.
- We estimate the retail value of the Netherlands' domestic market at 12 million euros (\$13.1 million). It has not grown meaningfully during the past three years.
- Full-spectrum oils prepared in individual pharmacies represented more than half the prescriptions.

Bedrocan is currently the only medical cannabis grower in the Netherlands, selling exclusively to the OMC. The OMC has an ongoing application process for a maximum of two suppliers.

The agency is responsible for all exports as well as domestic sales to pharmacies.

The OMC has two significant flower export agreements:

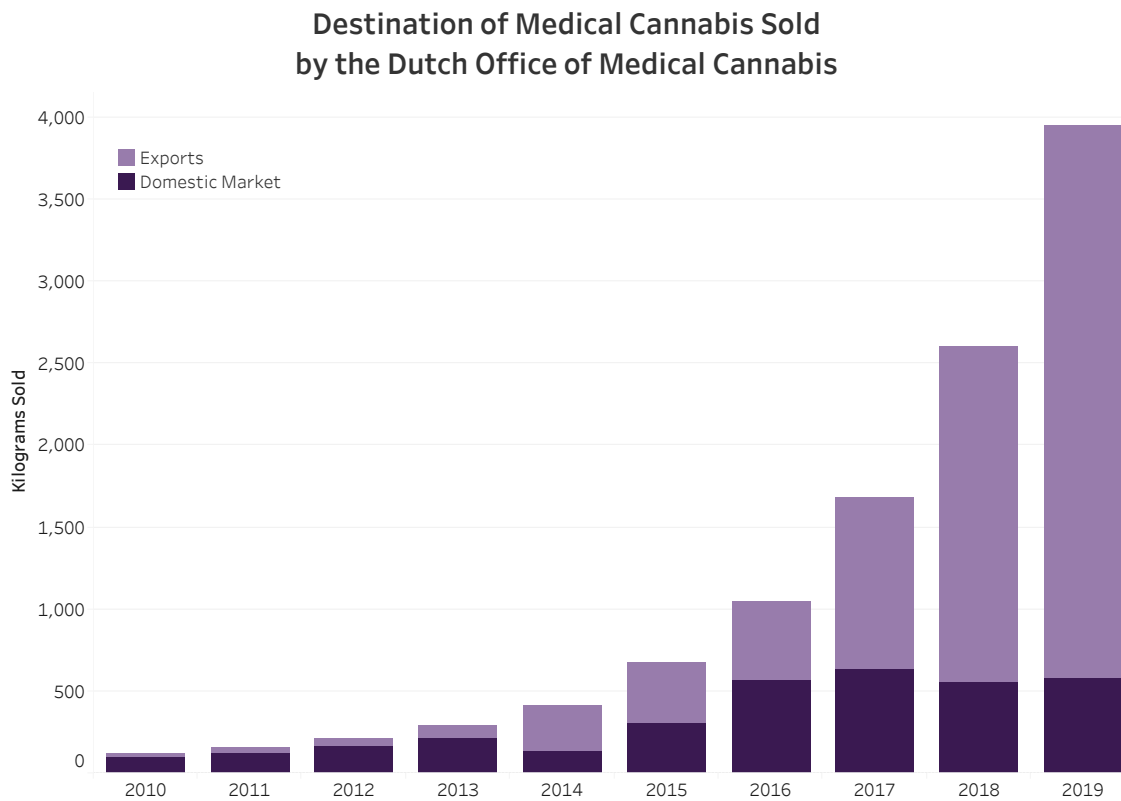
- 2,500 kilograms per year to Germany in 2019 and 2020.
- 700 kilograms per year to Italy in 2019, which we assume continues in place in 2020.

The government agency also exports smaller quantities to several other European and non-European countries that totaled 170 kilograms in 2019.

That year, 580 kilograms of flower were sold in the Dutch domestic market, up 5% from 2018, when 553 kilograms of flower was sold.

All these purchases in pharmacies were either of unprocessed flower or compounded by pharmacists into oils.

Chart 1: Destination of Medical Cannabis Sold by the Dutch Office of Medical Cannabis

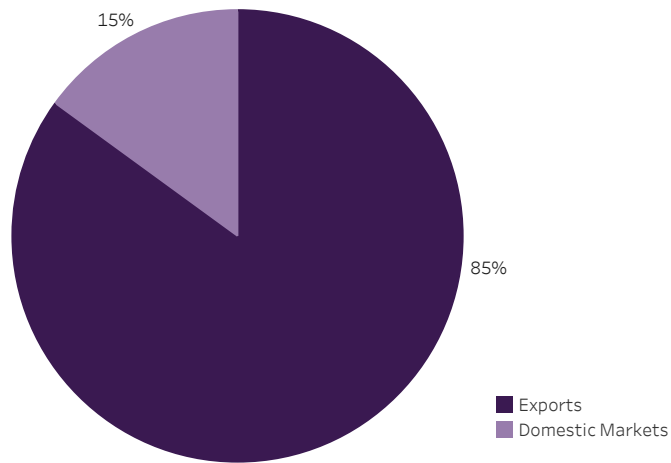


Data does not include sales for use in the manufacture of dronabinol or for research purposes.

Source: Dutch Office of Medical Cannabis
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Chart 2: Dutch Office of Medical Cannabis Sales in 2019

Dutch Office of Medical Cannabis Sales in 2019



Source: Dutch Office of Medical Cannabis
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DUTCH MARKET SIZE

With 580 kilograms sold, domestic sales in the Netherlands remained largely unchanged in 2019 from the 553 kilograms sold in 2018.

According to the Dutch Foundation for Pharmaceutical Statistics (SFK), approximately 51,000 cannabis prescriptions were issued in 2018. That total decreased to roughly 48,500 in 2019.

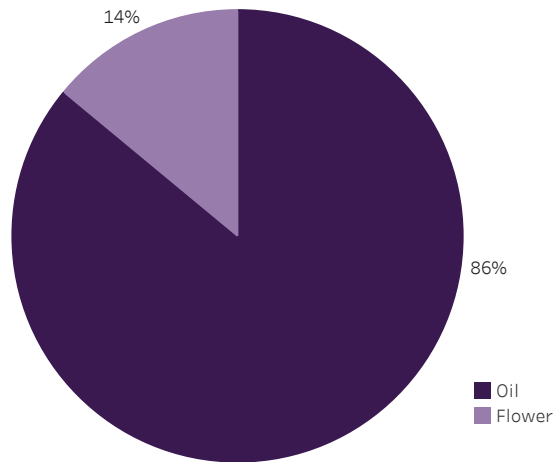
A larger average prescription size helps to explain the 5% increase in kilograms sold while the number of prescriptions decreased about 5%.

We estimate the retail value of the domestic market in 2019 at 11.9 million euros.

While oils represent about 55% of the prescriptions, we estimate they account for 86% of the retail value of the market. This is because pharmacies sell flower at approximately the same price at which they buy it plus a fixed fee, but the oils they prepare cost considerably more.

Chart 3: Estimated Domestic Retail Sales in 2019

Estimated Domestic Retail Sales in 2019



Source: Dutch Office of Medical Cannabis, Dutch Foundation for Pharmaceutical Statistics (SFK), pharmacies that prepare oils & Marijuana Business Daily estimates.
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Since the Netherlands is the most mature medical cannabis program in Europe, it might serve as humbling real-world example of how markets in European countries without generalized health-insurance coverage could evolve.

When the market hit its peak in 2017, patients received 53,300 prescriptions. According to SFK figures, prescriptions decreased 4% in 2018 and 5% in 2019, stabilizing at just below 50,000 prescriptions per year.

With a population of 17 million, this translates to roughly three prescriptions per 1,000 people per year.

This is in stark contrast with predictions of explosive and apparently unending growth that several analysts expect across Europe.

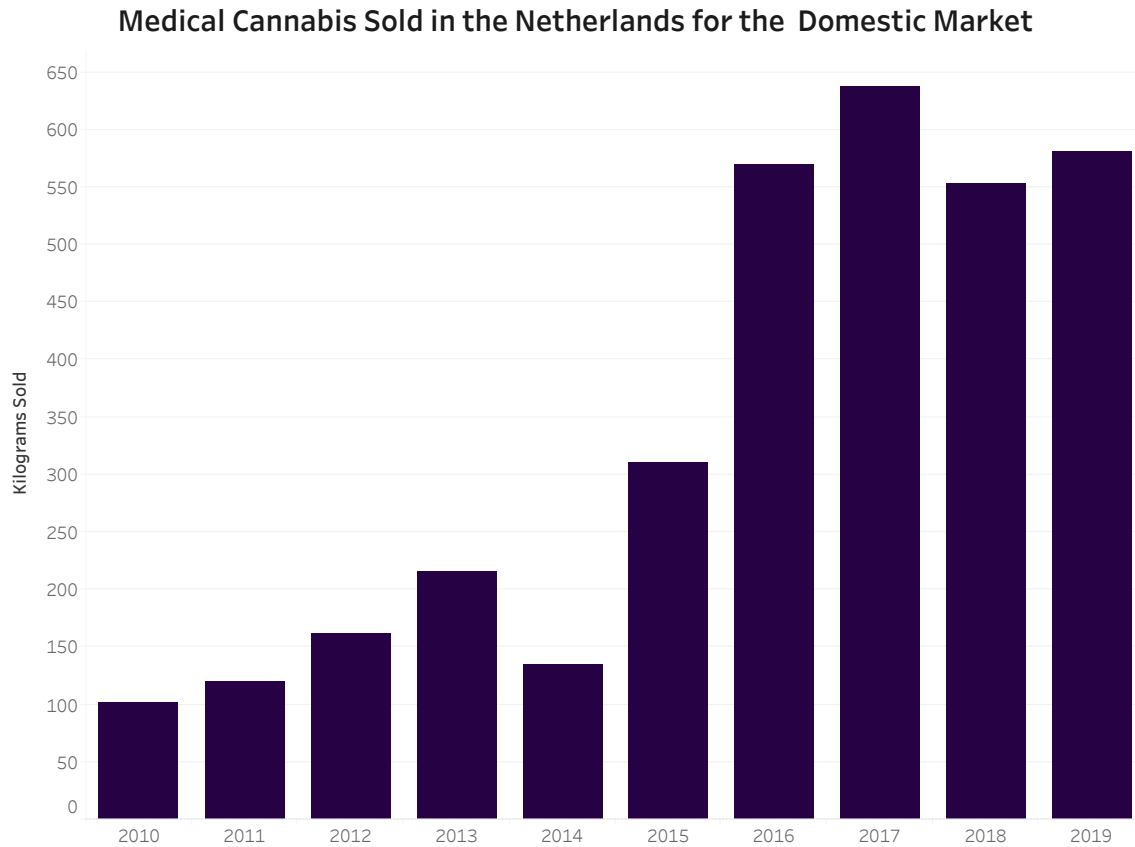
If Germany, with a population of a little more than 80 million, were to follow the Netherlands' lead, prescriptions would top out at 245,000 more than a decade after the program started in 2017.

However, German doctors wrote more than 267,000 prescriptions in 2019 in the statutory health system alone.

The number would be higher if we could account for the unknown number of private prescriptions. What this simple exercise shows is Germany already surpassed the Netherlands in per capita prescriptions.

While several factors can explain the stark growth difference, a big part of the equation is Germany’s mandate that medical cannabis must be covered by statutory health insurance if certain conditions are met while Dutch insurers are free to decide whether to cover cannabis.

Chart 3: Medical Cannabis Sold in the Netherlands for the Domestic Market



Source: Dutch Office of Medical Cannabis
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PRODUCTS AND DISTRIBUTION

Only pharmacies can sell medical cannabis to patients in the Netherlands, and it must be treated like any other substance that falls under the Dutch Opium Act.

Five of the following chemovars are available to patients, which can be prescribed for making tea or vaporizing. Smoking is discouraged.

Type	Tetrahydrocannabinol (THC)	Cannabidiol (CBD)	Characteristics
Bedrobinol	13.5%	<1%	Sativa/whole flower
Bedrocan	22%	<1%	Sativa/whole flower
Bedica	14%	<1%	Indica/granulated
Bediol	6.3%	8%	Sativa/ granulated
Bedrolite	<1%	9%	Sativa/ granulated

The Bedrocan variety is the highest seller for both the export and domestic markets.

Prescriptions of medical cannabis in the Netherlands, as in Germany, must include the specific variety, quantity and dosage, among other information.

We know of at least three pharmacies that prepare oils from medicinal cannabis in the Netherlands:

- Transvaal Pharmacy in The Hague.
- GMP Apotheek Mierlo Hout/Infinity Pharma in Helmond.
- Clinical Cannabis Care BV in Breukelen.

The following are just some examples of commonly sold oils:

- Bediol CBD 2.0%/THC 1.3% oil, 10 milliliters.
- Bedica THC 2.0% oil, 10 milliliters.
- Bedrocan THC 2.0% oil, 10 milliliters.
- Bedrolite CBD 2.0% oil, 10 milliliters.
- Bedrolite CBD 10% oil, 10 milliliters.

In addition to oils, at least one pharmacy sells an ointment prepared with Bediol, containing 1% CBD and 0.65% THC.

The five strains mentioned previously are the same as those exported to other countries.

Specification sheets of the different varieties and release certificates of previous batches produced in the Netherlands are available on the OMC website.

Three firms are directly involved in the production process:

- Bedrocan BV is the grower and dryer.
- Synergy Health performs gamma irradiation.
- Fagron BV completes the packaging.

The OMC certifies that each batch is “cultivated and manufactured, including packaging and quality control,” in compliance with Dutch Good Agricultural Practices (GAP) requirements, and that processing, packaging and analysis complies with GAP and Good Manufacturing Practice (GMP).

PRICE AND REIMBURSEMENT

The OMC typically sells cannabis flower for between 5.40 and 5.80 euros per gram plus value-added tax (VAT). To calculate this price, the agency includes not only the cost of the flower but also its irradiation, testing and administrative costs.

The final price per gram of medical cannabis in pharmacies is about 6.5 euros, but that might vary based on the size of the purchase. Pharmacists charge a fixed fee that typically depends on whether it's a first prescription or a renewal.

Flower is sold in 5-gram containers.

The prices patients pay for oils are usually about 50 euros for a 10 milliliter bottle of 2% THC, with prices increasing for higher cannabinoid concentrations.

At least one pharmacy offers larger bottles—30 milliliters—for some products at a cheaper price per milliliter than the smaller version with the same cannabinoid concentration.

Unlike Germany, where statutory health insurers must cover medical cannabis if certain conditions are met, insurers in the Netherlands are free to set their own rules when it comes to marijuana coverage.

In the past, several insurers have reimbursed on a case-by-case basis, with conditions that vary among insurers. Only part of the total cost is covered and only for patients who have premium types of insurance.

Any doctor can prescribe cannabis for any condition—but only when conventional treatments and medicines failed, not as a first option.

COMMERCIAL OPPORTUNITIES

Even though the Netherlands has had a domestic medical cannabis program for more than 15 years and is the leading European exporter of medical cannabis, business opportunities in the country remain limited for new players.

The government strictly applies the 1961 Single Convention on Narcotics Drugs, with the OMC enjoying a monopoly over most of the market. However, the agency occasionally publishes application processes requesting service providers for different activities in the supply chain.

As of early 2020, only one grower—Bedrocan—supplies the OMC with flower. A handful of pharmacies prepare oils with them.

Unlike countries such as Italy and Germany, where local entrepreneurs found business opportunities importing medical cannabis to supply the domestic market, imports into the Netherlands—although possible—are extremely rare.

The OMC will occasionally import cannabis for holders of an exemption to the Opium Act for scientific research.

In the European context, several companies are connected with the Netherlands because of what dozens of importers—particularly in Germany—buy from the OMC to distribute in other countries.

As of early 2020, only one licensed grower was contracted by the OMC to supply cannabis flower for distribution, but several other companies hold licenses to grow for noncommercial research purposes.

Those research opportunities—and other to come—may provide interesting opportunities for businesses looking to participate in the Dutch cannabis market.

DOMESTIC CULTIVATION TENDER

In early 2018, the Dutch OMC started a European application process to select a maximum of two growers. The application process consisted of two lots, one to cultivate the five existing varieties and another to grow new ones.

The OMC halted the process in July 2018, based on questions applicants raised during the tender and suitability requirements that would have included trial crops for all applicants to take place in the Netherlands. The OMC published a detailed explanation in December 2018.

With the unsuccessful attempt to expand cultivation in 2018, Bedrocan's contract with the OMC was extended.

The new application process was restarted in July 2019—again to select up to two service providers to grow cannabis for the OMC—but with somewhat different rules than in the previous, canceled edition.

In the current process, it is possible to grow the trial crops abroad as long as it's legal in the foreign country. With that, the contracting authority aims to avoid unnecessary barriers for foreign applicants to participate.

Although participating in the application process with a trial cultivation performed in a foreign country is permitted, the winners of the process will have to cultivate the contracted quantities in the Netherlands.

The final results of the current application process are expected in the second half of 2021.

In the trial cultivation, applicants must show that they can grow two varieties—one high in THC and the other one with balanced THC and CBD—in standardized quality.

Only testing of single batches from three consecutive trial harvests—not blends—is permitted to qualify.

The initial duration of the contract for up to two winners will be four years. After that, there are two options to extend the agreement for a maximum of 12 months at a time.

Because of the difficulties determining future demand, the government guarantees only a minimum purchase of 250 kilograms per year per supplier at a fixed price of 2.35 euros per gram.

This means a guaranteed turnover of 2.35 million euros per contractor per year over a four-year period if the supplier is able to meet its obligations.

The OMC expects—but cannot guarantee—much higher demand, estimating the maximum value of the contract at 5,000 kilograms per year at the fixed price of 2.35 euros per gram per contractor.

Because the price is fixed, the criteria for determining winners of the application process will be entirely dependent on quality. When explaining the rationale for that decision in the application-process documents, the Dutch government noted it wanted to avoid the “price dumping” seen in the German supply application process, which could affect the quality of the products.

Two sources can provide the points to win the application process: 80% from trial cultivations and 20% from various documentation.

The application process of 2018 was designed to use both price and quality as criteria.

One of the quality requirements is that the THC and CBD content be between 85% and 115% of the declared value.

The OMC highlighted that growers must be capable of complying with more stringent rules—including a range between 90% and 110%—if so dictated by a future European monograph for cannabis flower.

The application process to select up to two suppliers of medical cannabis is strictly separated from the recreational marijuana system of coffee shops and an upcoming experiment to supply the recreational market.

RECREATIONAL CANNABIS

The Netherlands is internationally known as the country where recreational marijuana is sold in “coffee shops,” which came from a culture that emerged with decriminalization in the 1970s. Though consumption, possession and sales in these coffee shops are tolerated under certain circumstances, production and wholesale of recreational cannabis remain illegal.

In fact, thousands of police raids occur at grow operations in the Netherlands every year.

The contradiction in this approach is that the coffee shops must obtain supply from the illicit market to operate, commonly referred to as the “backdoor” problem.

In the second half of 2019, the Netherlands approved a pilot program that will allow 10 Dutch municipalities with 79 coffee shops to receive access to a legal supply of recreational marijuana for the first time. The suppliers will be domestic growers that have undergone a selection process.

The selected cities for the experiment were Almere, Arnhem, Breda, Groningen, Heerlen, Hellevoetsluis, Maastricht, Nijmegen, Tilburg and Zaanstad.

The program, though modest in scope and magnitude, will create some business opportunities to supply participating coffee shops.

Cannabis cultivators do not necessarily have to grow in the selected municipalities, but they would supply only the selected areas.

Price, THC and CBD content will not be determined by the government and will largely depend on supply and demand.

The government expects a timeline of one year of preparation and four years of implementation for the program. Companies could apply for cultivation licenses during that time.

An independent committee will assess the results after the experiment is concluded.

None of the top-five Dutch municipalities by population joined the program. The main reason is that all coffee shops in a participating municipality must abandon their illegal supply—something not every coffee shop owner is ready to do.

2020 OUTLOOK

With the OMC holding a monopoly over most activities in the Netherlands' medical cannabis market, opportunities largely depend on application processes to be a service provider to the agency.

The ongoing application process for cultivating medical cannabis is an example of that.

As the documentation of the process suggests, it is hard for the OMC to estimate demand, in part because the vast majority of cannabis in recent years has come from export destinations.

Industry watchers will carefully follow if the Netherlands' export numbers will see an impact from Germany—the main export destination—which expects its first domestic harvest by the end of 2020.

Also, more countries are trying to become exporters of medical cannabis within and outside Europe, which could challenge the rapid growth of exports that the Netherlands has seen in past years.

The current agreement to supply Germany with 2,500 kilograms of Dutch flower is valid for 2019 and 2020, so it will also be important to see how that changes for 2021.

Another important trend to keep an eye on is the number of patients from neighboring countries who travel to the Netherlands with a prescription issued by their doctor in their home country to buy medical cannabis in Dutch pharmacies.

While hard to quantify, conversations *MJBizDaily* had with Dutch patients associations and pharmacies suggest this is an increasing trend. We expect it could have policy implications in the Netherlands or neighboring countries if this were to continue to grow.

Finally—and while not the focus of this report—it will be interesting to see how the recreational pilot program to create a legal cultivation program to supply coffee shops evolves and if it will have any implications for the separately regulated medical market.

DENMARK

At the end of 2017, the Danish Parliament unanimously voted in favor of a four-year trial period for medical cannabis, creating a new domestic market and export possibilities.

Before the start of the trial program, sales of isolated THC and/or CBD as magistral preparations have been possible as have sales of Sativex and other finished pharmaceutical products.

In 2018, Denmark started to implement the pilot program in a surprisingly efficient way, at least when compared to other jurisdictions that often take years after the approval of a law to grant medical cannabis licenses or allow the first patients to access products.

Some Danish domestic patients already had access in the first quarter of 2018 to medical cannabis products from the pilot program, and sales ramped up by the end of the year.

Growth in the domestic market continued during the first half of 2019, but the trend abruptly changed by the third quarter. Sales of the only full-spectrum oils that had been available in the market—exported from Canada by CannTrust and imported into Denmark by Stenocare—had to be interrupted because of regulatory misconduct by CannTrust.

In terms of domestic production, dozens of licenses have been granted, many of which are operational. But as of the end of 2019, no company had been able to supply domestic patients with Danish production, nor had they been able to export commercially to other countries.

Because the focus of this report is to provide an overview of medical cannabis sales in Europe—not production opportunities—this chapter focuses on domestic sales in the Danish market and not on how to obtain a license to grow.

2019 key market facts in Denmark include:

- The pilot program brought in nearly 2 million euros (\$2.2 million) from products sold. This includes almost 30 kilograms (66 pounds) of flower and about 3,600 units of full-spectrum oils.
- Almost 4 million euros of isolated cannabinoids (pure THC and/or CBD) were sold as magistral preparations (not part of the pilot program).
- A little more than 1 million euros of finished pharmaceutical products were sold (Sativex, Marinol and nabilone, also not part of the pilot program).
- A drastic decrease in sales occurred in the pilot program from the first quarter to the third, when the only full-spectrum oils became unavailable. Sales in the fourth quarter continued to decrease.
- More than 40 licensed domestic producers exist.

DOMESTIC MARKET PRODUCTS

The domestic market can be divided into medical cannabis products that are part of the pilot program and those that are not.

In 2019, products offered under the pilot program consisted of only flower and full-spectrum oils, including:

Three chemovars of flower—Bedica, Bediol and Bedrocan—which are produced by Bedrocan in the Netherlands and imported into Denmark by CannGros. More information about the chemovars is available in the Netherlands chapter of this report.

Three oral solutions produced by CannTrust in Canada and imported into Denmark by Stenocare. Sales of these declined drastically in the third quarter of 2019 and became completely unavailable by the fourth quarter.

In early 2020, as part of the Danish pilot program, Canada-based Aurora Cannabis started importing softgel capsules into Denmark.

Products that are not part of the pilot program but have been available since before 2018 include:

- Products with marketing authorization. Sativex is currently the only product in this category.
- Other finished medicines without marketing authorization in Denmark but whose imports could be allowed with an exception from the government. This category includes Marinol and nabilone capsules.
- Magistral preparations with isolated cannabinoids such as THC and CBD, alone or combined.

PILOT-PROGRAM SALES

The first products available under the pilot program, in the first quarter of 2018, were flower chemovars imported from the Netherlands.

The first oils became available in the third quarter of 2018 and contributed to a meaningful increase in sales in the fourth quarter of 2018—a trend that continued until mid-2019.

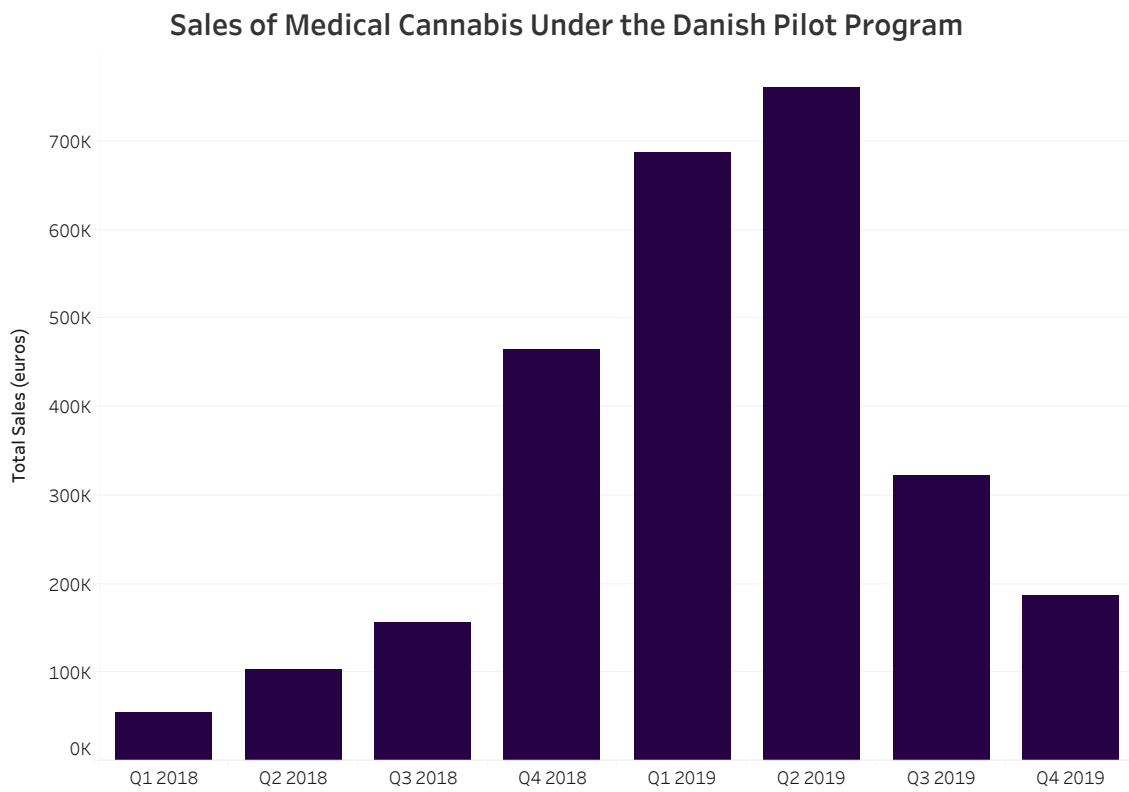
However, sales of those imported oils were interrupted because of Canadian producer CannTrust's noncompliance with Health Canada regulations, and purchases under the pilot project drastically fell in the third quarter of 2019.

Only flower remained available by the last quarter of 2019, and the quantities sold didn't increase meaningfully from the third quarter to the fourth. That means flower sales weren't able to make up for the sales lost from not having any oils available.

On the other hand, sales of isolated cannabinoids—which are not part of the pilot program—drastically increased in the last quarter of 2019.

This could mean that many patients who had access to full-spectrum oils under the pilot program switched to isolated cannabinoids sold as magistral preparations once the full-spectrum oils became unavailable, instead of switching to the available flower.

Chart 1: Sales of Medical Cannabis Under the Danish Pilot Program

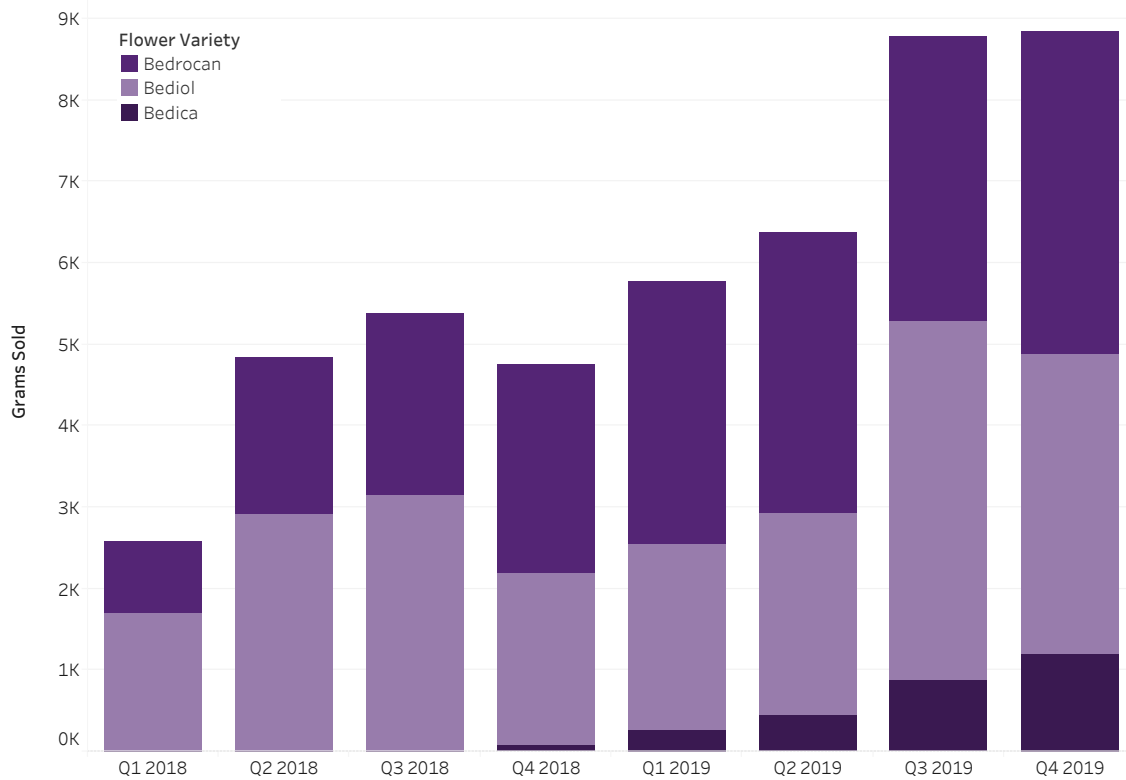


Note: Value converted from Danish krone using 1 euro = 7.46 Danish krone.

Source: The Danish Health and Medicines Agency's database of health data (eSundhed) & Marijuana Business Daily estimates
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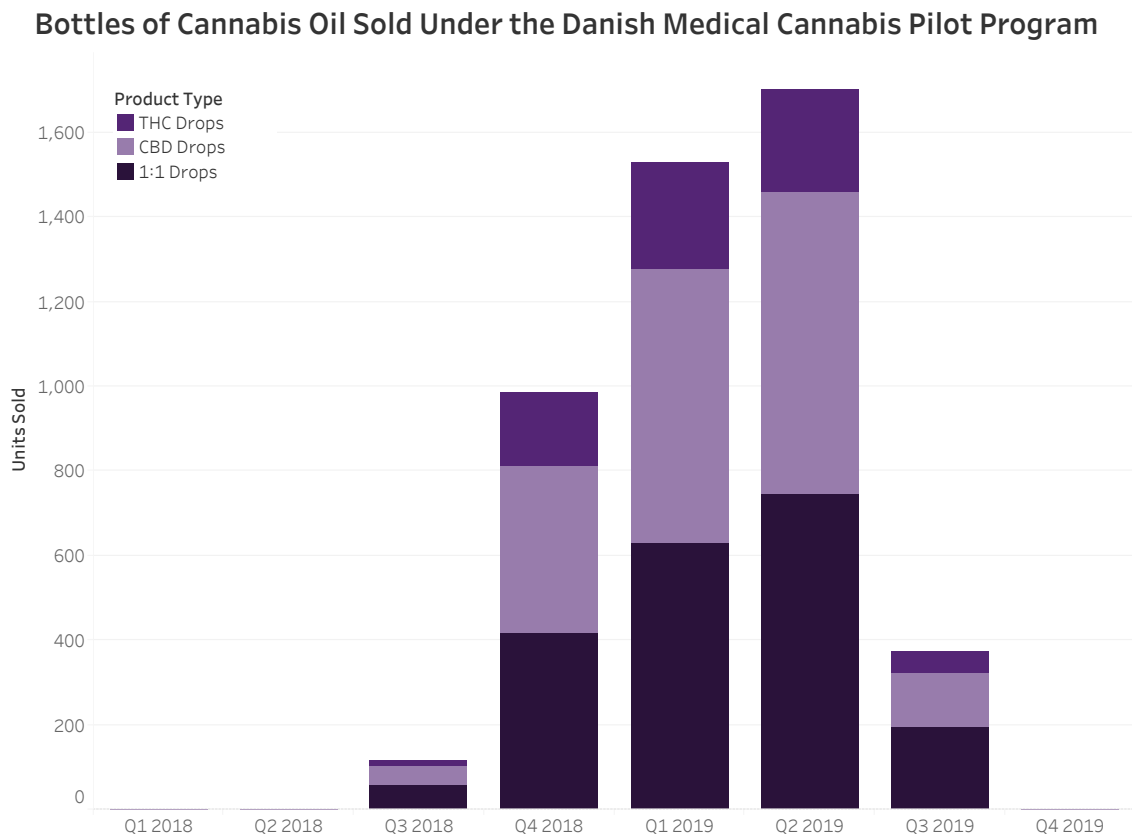
Chart 2: Grams of Medical Cannabis Flower Sold Under the Danish Pilot Program

Grams of Medical Cannabis Flower Sold Under the Danish Pilot Program



Source: The Danish Health and Medicines Agency's database of health data (eSundhed) & Marijuana Business Daily estimates
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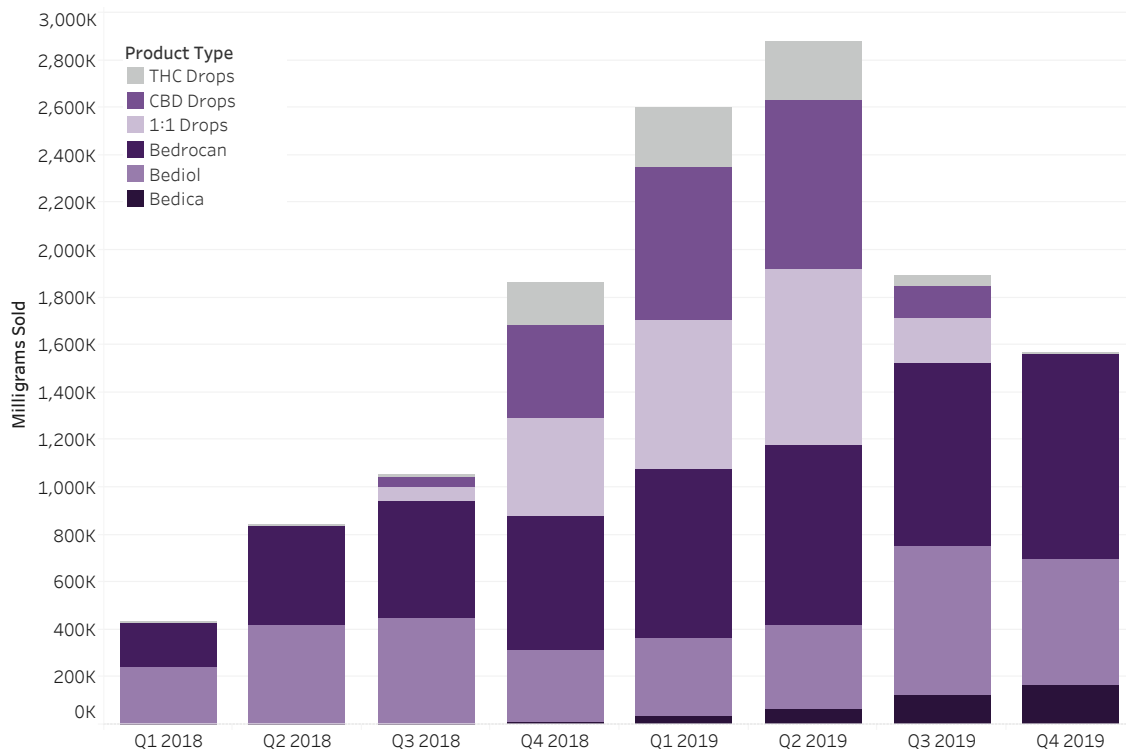
Chart 3: Bottles of Cannabis Oil Sold Under the Danish Medical Cannabis Pilot Program



Source: The Danish Health and Medicines Agency's database of health data (eSundhed) & Marijuana Business Daily estimates
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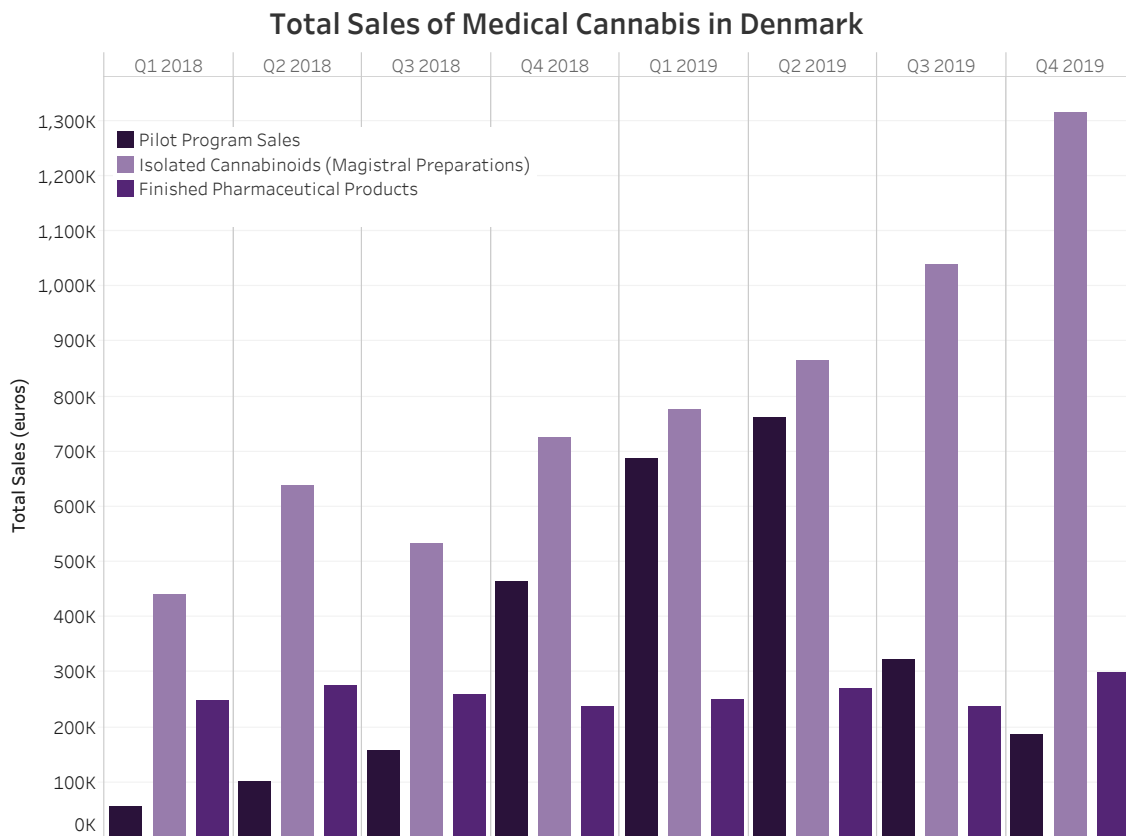
Chart 4: Milligrams of Cannabinoids Sold Under the Danish Medical Cannabis Pilot Program (By Product Type)

Milligrams of Cannabinoids Sold Under the Danish Medical Cannabis Pilot Program (By Product Type)



Source: The Danish Health and Medicines Agency's database of health data (eSundhed) & Marijuana Business Daily estimates
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Chart 5: Total Sales of Medical Cannabis in Denmark



Source: The Danish Health and Medicines Agency's database of health data (eSundhed) & Marijuana Business Daily estimates
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PRICE AND REIMBURSEMENT

Companies are free to set their own prices under the pilot program. Once wholesalers set their prices, they cannot change them for 14 days, and all pharmacies across Denmark are expected to sell the products for the same price.

Bedrocan flower imported from the Netherlands is sold to patients for 157 Danish krone (about 21 euros) per gram.

The 40-milliliter Stenocare drops, which had a cannabinoid concentration of 25 milligrams per milliliter, previously sold for about 2,742 krone.

Aurora softgel capsules—which became first available in 2020—are sold for 1,489 krone. The package has 100 capsules with 5 milligrams of THC and a maximum of 0.2 milligrams of CBD in each one.

Since 2019, and retroactively for 2018, terminal patients are eligible for full reimbursement of these purchases by the national health-insurance program.

Other patients may get 50% coverage capped at 10,000 krone a year—if they do not spend more than 20,000 krone per year. Exceeding the spending cap results in no reimbursement.

Products covered by the pilot program cannot be advertised.

DOMESTIC MARKET CHALLENGES

Skepticism from the Danish College of General Practitioners (Dansk Selskab for Almen Medicin) has been notorious since the beginning. They generally discourage doctors from prescribing products that have not undergone clinical trials.

In January 2019, one year after implementation of the medical cannabis program, Anders Beich, the chair of the Danish College of General Practitioners, said he doesn't believe it's a good idea that any doctor can prescribe cannabis, as not all general practitioners have the proper skills, and with so few patients, it's hard to determine the effects of cannabis treatments.

In an interview with a local newspaper in early 2020, Beich considered the already two years of trial as “wasted” and “harmful.”

Other renowned physicians criticize the pilot program for being a political and not scientific decision. They complain that, after two years, physicians in Denmark still don't have the tools to make the best use of the program since no treatment guides or enough evidence are available.

DOMESTIC PRODUCTION

Since 2018, companies can apply for licenses to grow and manufacture cannabis in Denmark.

Judging from the number of projects, their estimated capacities and the meager quantities being sold in Denmark, it seems that most producers are focused on exporting than on the limited domestic market.

Especially during 2018 and early 2019, several companies had announced massive production-facility plans. Some of these plans failed to materialize as of early 2020, or, in some cases, their scale was reduced.

Unlike in countries such as Germany or the Netherlands, Danish authorities receive applications for cultivation and manufacture on an ongoing basis.

As of March 2, 2020, Denmark had:

- 44 granted licenses (double the number of as of March 2019).
- Three pending licenses.
- 10 refused or expired licenses.
- Five withdrawn licenses.

At the end of 2019, no Danish-produced medical cannabis had reached domestic or foreign patients.

2020

The fact that the country was able to quickly provide access to domestic patients, even if limited, differentiates Denmark from other European markets such as Greece or Portugal that so far have mainly focused on exporting but whose domestic patients still have no access to medical cannabis products.

However, in 2019, the Danish domestic market suffered significantly when sales of the only full-spectrum oils that had been available had to be interrupted.

Sales of isolated cannabinoids—THC and/or CBD—increased, and it seems that a number of patients who had previously accessed full-spectrum oils under the pilot program turned to isolated cannabinoids preparations.

The sales figures by the end of 2019 are worrisome for the domestic trial because it shows that, when compared to the other categories of cannabis products, flower and full-spectrum oils are losing relevance.

Aurora's softgel capsules became available as part of the pilot program in early 2020, but the first sales figures were unavailable when this report was published.

The pilot program depends to a large extent on Aurora's softgel capsules sales getting back to the trial patients who previously used CannTrust oils imported by Stenocare.

If other new products become available under the trial, it could also help revive the experiment. At the end of 2019, only 3 kilograms of flower per month were being sold under the pilot program.

2020 will also likely mark the year in which domestically produced cannabis starts being sold to patients in Denmark and abroad.

CZECH REPUBLIC

The Czech Republic is not one of the largest medical cannabis markets in Europe—its pharmacies sold only 17 kilograms (37.5 pounds) of flower in 2019—but it is one of the oldest, with recorded sales since at least 2015.

Through the end of 2018, developments in the market were slow and limited in scope. But 2019 saw many more prescriptions issued, and sales more than tripled when compared with the 5 kilograms sold in 2018.

It's important to note a sales trend into 2020 in which the first quarter showed a sales record in the Czech Republic.

The country has a small domestic cultivation and allows imports.

Here are 2019's key market facts for the Czech Republic:

- 17 kilograms of flower were sold at a retail value of 100,000-150,000 euros (\$109,000-163,500).
- New reimbursement rules are generating more sales, with almost 12 kilograms sold in the first quarter of 2020.
- Small domestic grow, but no export-oriented industry.

To comply with United Nations drug control treaties, the State Agency of Medical Cannabis (SAKL, Státní agentura pro konopí pro léčebné použití) oversees tasks such as granting licenses and purchasing all medical cannabis product for distribution.

DOMESTIC MARKET

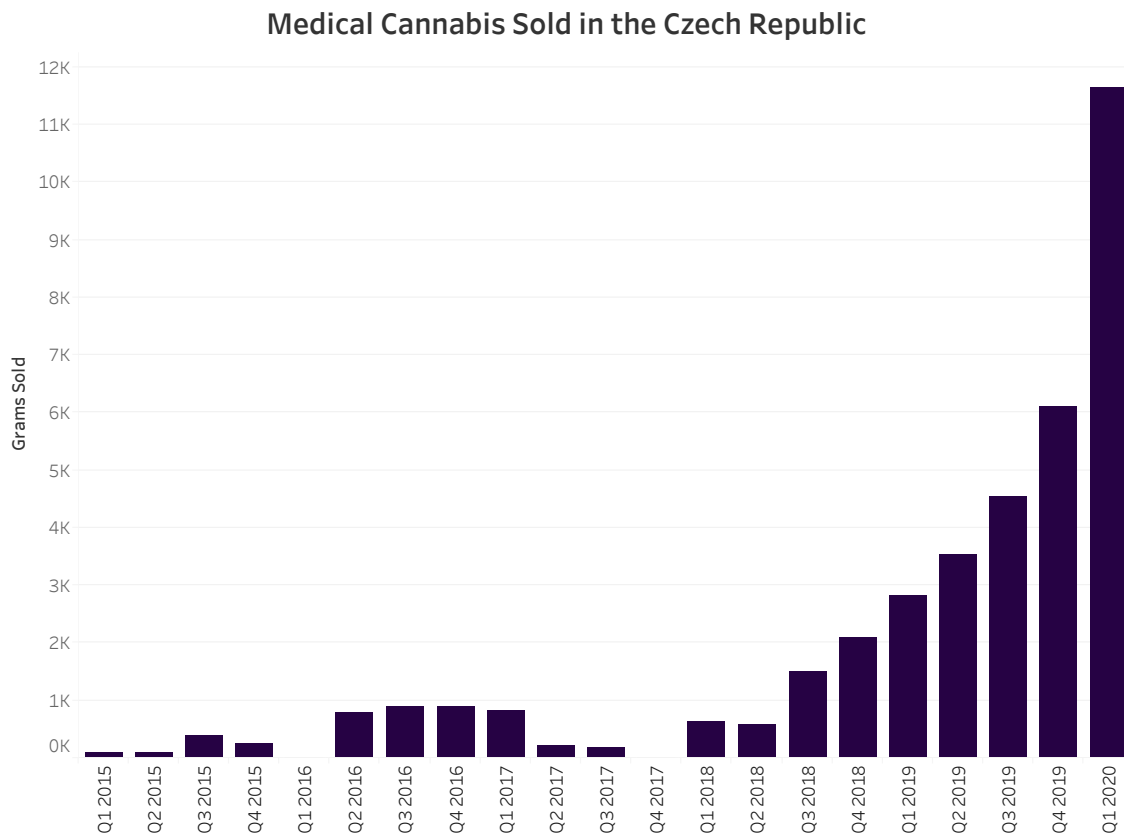
Medical cannabis is legal in the Czech Republic as magistral preparations sold in pharmacies under electronic prescription for patients older than 18.

A deviation of up to 20% of the THC and CBD value specified by the producer of the flower is tolerated, unlike Germany, which allows only a 10% deviation.

The demand is covered by a mix of flower produced domestically and imports of flower grown in Canada or the Netherlands.

Sativex is also approved in the Czech Republic, but in practice, the drug is rarely prescribed because of its price.

Chart 1: Medical Cannabis Sold in the Czech Republic



Source: Czech State Institute for Drug Control (SUKL)
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COMMERCIAL OPPORTUNITIES

As of early 2020, the Czech Republic continued to have only one domestic producer: Elkoplast Slušovice, s.r.o, which won a supply application in 2017.

The company is expected to supply the State Institute for Drug Control (SUKL) with 40 kilograms of cannabis flower over a period of four years.

That tender had only one participant, and there were cases of previous application processes that were canceled because no company applied.

In 2019, Elkoplast Slušovice supplied about 25 kilograms to the government. With total sales in pharmacies in the year reaching 17 kilograms. This probably means some of the production of the domestic grower in 2019 remained in stock in early 2020.

The total production is stored in the warehouse of the only authorized distributor, Alliance Healthcare s.r.o.

As of early 2020, 90 pharmacies were authorized to buy Czech-grown cannabis from that Alliance.

Despite 2019 total sales in the Czech Republic being less than 20 kilograms—the majority of that seems to have been produced by a domestic grower—several Canadian cannabis companies have tried to establish a presence in the market.

Canadian producer Canopy Growth acquired a domestic wholesaler so that a subsidiary is importing its products.

Aurora Cannabis and Tilray export to independent domestic distributor Czech Medical Herbs.

Any company that wishes to import medical cannabis to the Czech Republic for distribution must obtain the following permits:

- Authorization to distribute medicinal products, obtained from the State Institute of Drug Control.
- Authorization to handle addictive substances, obtained from the Ministry of Health.
- An import authorization from the Ministry of Health.

PRICING AND COVERAGE

Through the end of 2019, pharmacies typically paid 171 koruna (6.28 euros), value-added tax (VAT) included, for a gram of domestically produced cannabis. The retail price was about 207 koruna a gram (about 8 euros).

Only domestically grown cannabis has a fixed price, but imported cannabis generally sells at a similar cost.

The maximum dose for which a patient can obtain a prescription is 180 grams, regardless of THC content.

Since Jan. 1, 2020, patients are entitled to insurance coverage of 90% of the retail price for 30 grams of flower per month for medical use.

Doctors may authorize reimbursement of quantities exceeding the monthly limit of 30 grams in exceptional cases, but the total limit still cannot exceed 180 grams.

CONDITIONS AND CONTROLS

As of March 2020, 152 doctors in the Czech Republic were listed as prescribers of medical cannabis. That total includes only physicians who agreed to share their contact information through government agency websites. The number of doctors prescribing could be higher than reported.

Physicians are expected to prescribe cannabis for medical use only after a thorough examination and only if they consider it could prove beneficial to supplement existing, standard treatments.

A special electronic prescription is used in all cases. Pharmacies are the only places where patients can obtain cannabis medicine, individually prepared by the pharmacist according to the prescription.

A decree in 2015 established the following list of conditions for which only certain specialists can prescribe medical cannabis:

Indication	Physician Specialization
Chronic continuing pain (particularly in cancer conditions, pain associated with degenerative motor diseases, with systemic connective tissue diseases and immunopathological conditions, neuropathic pain, glaucoma-related pain).	<ul style="list-style-type: none"> • Clinical oncology • Radiation oncology • Neurology • Palliative medicine • Treatment of pain • Rheumatology • Orthopedics • Infectious diseases • Internal medicine • Ophthalmology • Dermatovenerology • Geriatrics
Spasticity and related pain in multiple sclerosis or spinal cord traumas, painless intractable spasticity essentially restricting movement and mobility of the breathing of the patient, involuntary kinesis caused by neurological conditions, and other medical complications arising from underlying neurological conditions or spine trauma with spinal cord damage or brain trauma, neurologic tremor caused by Parkinson's disease and other neurological problems as per the judgment of the treating doctor.	<ul style="list-style-type: none"> • Neurology • Geriatrics
Nausea, vomiting, stimulation of appetite in association with cancer treatment or HIV treatment.	<ul style="list-style-type: none"> • Clinical oncology • Radiation oncology • Infectious diseases • Dermatovenerology • Geriatrics
Tourette syndrome	<ul style="list-style-type: none"> • Psychiatry
Surface treatment of dermatoses and mucosal lesions.	<ul style="list-style-type: none"> • Dermatovenerology • Infectious diseases • Geriatrics

More than 80% of medical cannabis sales in the Czech Republic in 2019 were for chronic pain.

2020

While medical cannabis sales in the Czech Republic in 2019 look small when compared to larger European markets, we note a positive growth trend.

In 2020, it will be key to see how the newly implemented reimbursed scheme fuels further growth and whether that new demand will be covered by domestic production or imports.

AUSTRIA AND SWITZERLAND

Austria and Switzerland have had limited medical cannabis programs for many years, but neither allows for patient access to flower.

Instead, the primary mechanism for accessing medical cannabis is dronabinol. In Austria, only finished pharmaceutical products or isolated cannabinoid preparations are allowed. Switzerland offers those products as well as full-spectrum tinctures and oils.

We were not able to obtain updated official sales data for the two countries before publishing this report. But based on data from previous years, official patient numbers and product prices in both countries, we estimate that the retail values of the two markets in 2019 was 10 million-12 million euros (\$11 million-\$13.1 million) each.

AUSTRIA

Austria allows the prescription of finished pharmaceutical products Sativex and Canemes, which have marketing authorizations just as they do in Germany. (See the Germany chapter of this report for more information about these two products.)

Since 2015, physicians have been permitted to prescribe isolated THC and CBD for any condition and the products dispensed as magistral preparations in pharmacies as drops or capsules.

Unlike Germany and other European countries, patients in Austria cannot access full-spectrum extracts or flower, a situation that limits market opportunities to registered medicines and isolated cannabinoids preparations.

Despite those considerations, the under-the-radar Austrian market is larger than many other countries in Europe where there is a lot of talk about medical cannabis, but sales are far less significant in those areas.

The latest official available data for Austrian sales shows that during the first half of 2018, 7,325 patients received at least one reimbursement for a medical cannabis product through 22,337 prescriptions totaling 5 million euros.

This suggests that the total retail value of the market in 2019 most likely exceeded 10 million euros.

Health insurance reimburses dronabinol preparations under certain conditions, but Sativex and Canemes are covered only in exceptional cases. CBD preparations are not covered by insurance.

Patients cannot always use their health coverage for cannabis products. But private purchases are allowed.

There are no medical cannabis commercial production opportunities in Austria. One organization has a monopoly on production through a special authorization: the government Agency for Health and Food Safety (AGES).

AGES grows a few hundred kilograms of cannabis flower per year. The harvest is shipped to C3 in Germany to manufacture dronabinol. That dronabinol is primarily sold in Austria, Denmark, Germany and Switzerland. (For more information about dronabinol production, see the subchapter in the Germany section of this report.)

Marijuana Business Daily does not expect any liberalization of the current cannabis laws in 2020. In 2019, the government reviewed the current evidence and decided not to expand the existing limited medical cannabis access.

Exporting pharmaceutical, isolated THC and CBD to Austria remains a business opportunity.

SWITZERLAND

Switzerland has had a limited medical cannabis program for nearly 10 years. Cannabis above 1% THC is a prohibited narcotic. Medical cannabis products require registration, and Sativex is the only authorized medicine. However, the Federal Act on Narcotics and Psychotropic Substances allows the Federal Office of Public Health (FOPH) to issue exceptional permits under special circumstances.

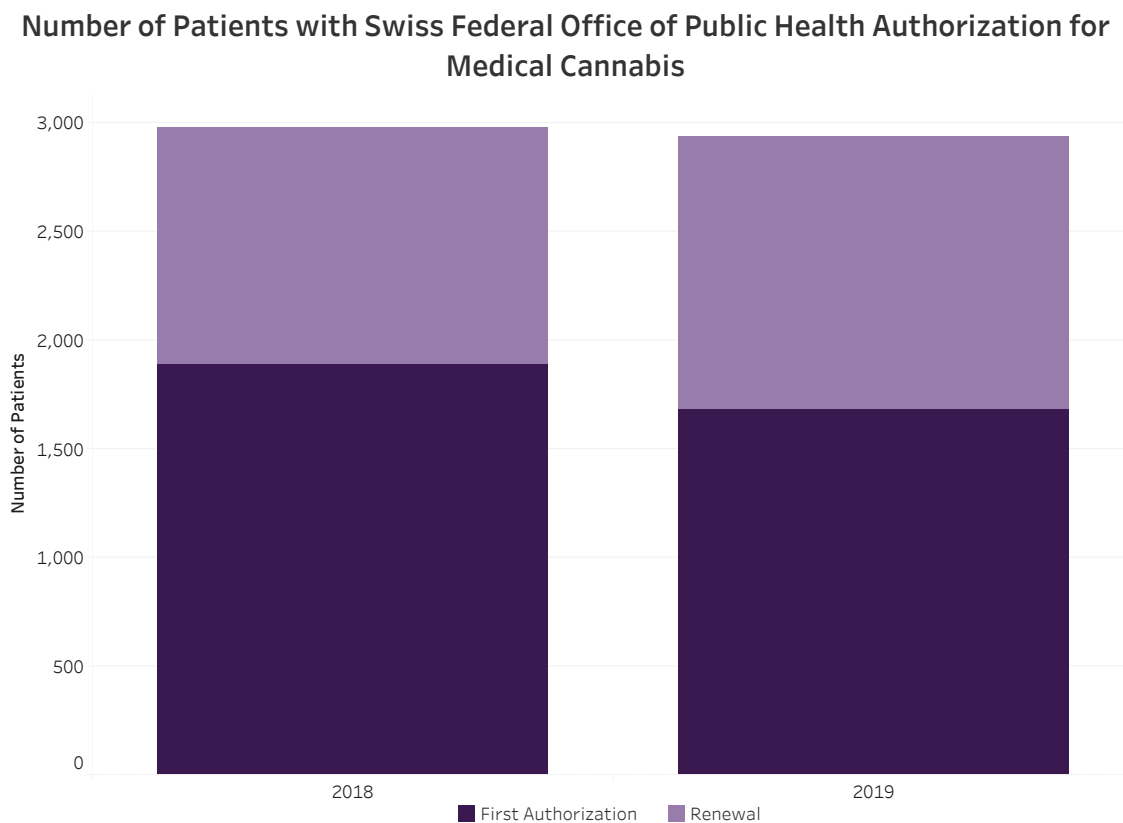
Doctors can apply for a special authorization from the FOPH on behalf of their patients to access medical cannabis magistral preparations under prescription. Patients must consent to the treatment. The applications must justify the need for using medical cannabis, such as when other standard therapies have failed.

Only a handful of pharmacies sell medical cannabis. The only products available under the special authorization program are dronabinol preparations, cannabis tinctures and cannabis oils. No flower is sold to patients without processing.

Health insurance isn't obligated to cover the cost of medical cannabis magistral preparations. On-label prescription of Sativex does not require FOPH approval. Dronabinol is mostly imported from Germany, but tinctures and cannabis oils are prepared with plant material sourced domestically.

As of early 2020, the government is considering expanding access to medical cannabis in the county and possibly allowing exports, but this is still far from materializing.

Chart 1: Number of Patients with Swiss Federal Office of Public Health Authorization for Medical Cannabis



Source: Bundesamt für Gesundheit (Federal Office of Public Health)
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OTHER SMALL EUROPEAN MEDICAL CANNABIS MARKETS

Germany, Italy and the Netherlands were the only three European countries where we found significant sales of flower and full-spectrum products in 2019. But there are several other countries where medical cannabis legislation exists.

Denmark and the Czech Republic received individual coverage in this report because they play important roles in the European medical cannabis industry despite the small size of their markets. Moreover, their authorities are transparent when disclosing details about sales.

Austria and Switzerland have comparatively meaningful sales when dronabinol preparations are included.

Because of lack of official information available, it is near impossible to provide real data on sales in many European markets.

However, we are confident none of the countries included in this chapter had larger markets in 2019 than the top three—Germany, Italy and the Netherlands.

POLAND

An amendment to the Prevention of Drug Abuse Act of 2005 came into force in Poland on Nov. 1, 2017. It allowed distributors to import cannabis as a medical raw material and to provide it to pharmacies, which were authorized to use it in preparing prescription drugs.

The Polish framework does not regulate domestic cultivation, so all products are imported.

The amended law requires cannabis products be approved by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) before being sold to patients. Approvals remain valid for five years. Additionally, applicants are required to file for an import permit from the Chief Pharmaceutical Inspectorate.

Imported products are distributed through wholesalers to pharmacies which, as is common in Europe, are expected to process it as magistral preparations.

There is no list of conditions for which medical cannabis can be prescribed.

Patients also may apply for a permit that allows them to import individually.

Patients who wish to import medical cannabis individually can apply to the Health Ministry for reimbursement if they receive a positive opinion issued by Agency of Evaluation Medical Technologies and Economy—but actual cases of reimbursement are rare.

Sativex is registered as a medicine and has been available in Poland since 2012, but its high price makes it unaffordable for most patients.

At the end of October 2018, the first permit to distribute cannabis flower to Polish pharmacies was issued to Spectrum Cannabis, an arm of Canadian producer Canopy Growth.

In mid-January 2019, the first delivery of dried cannabis flower arrived in Poland.

In October 2019, Canadian producer Aurora Cannabis announced four product registries, with the first import taking place in early 2020.

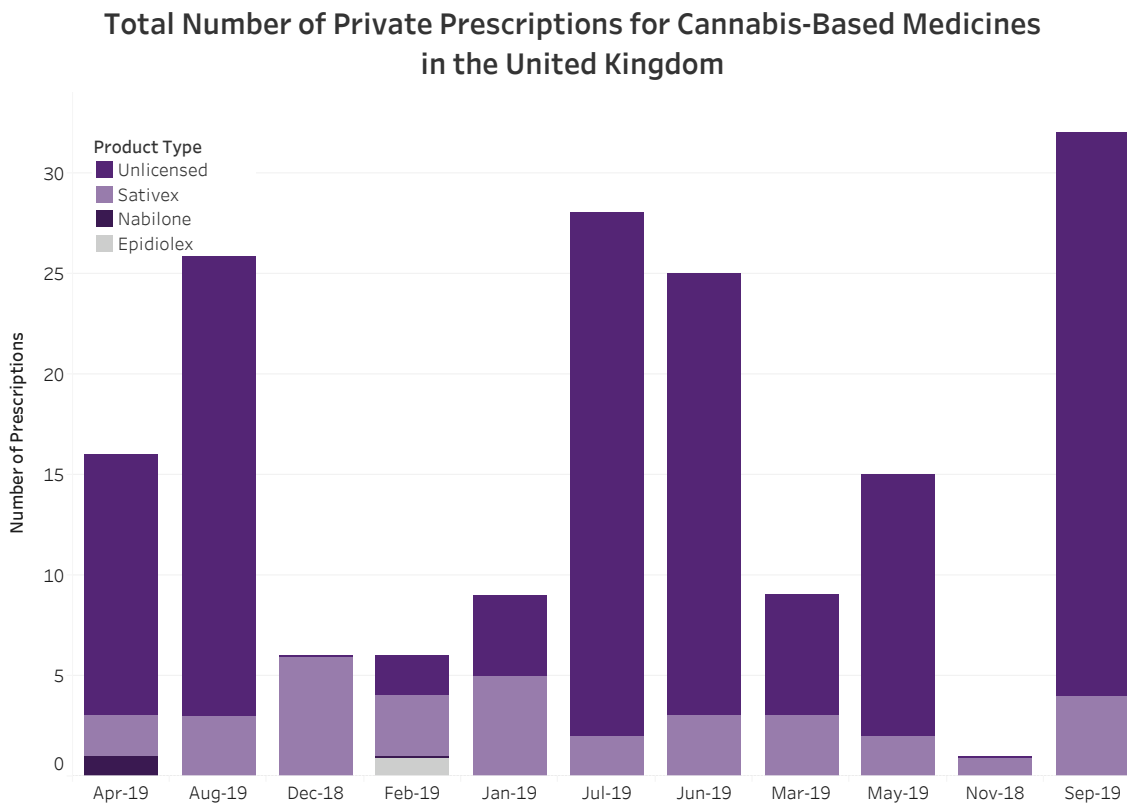
We were not able to obtain official data about quantities imported into Poland in 2019, but local sources estimate it was about 70 kilograms (154 pounds).

UNITED KINGDOM

In November 2018, the U.K. became one of the latest European countries to allow doctors to prescribe medical cannabis. But access has been extremely rare based on official data available as of September 2019—the latest information available.

Only 18 National Health Service (NHS) prescriptions are known to have been issued through the end of September 2019, and the number of private prescriptions was below 30 per month as of the end of the third quarter of 2019.

Chart 1: Total Number of Private Prescriptions for Cannabis-Based Medicines in the United Kingdom



As of this report’s publication date, official data was available only through September 2019.

Source: National Health Service
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It's possible that sales ramped up since October 2019, but even if they're now 10 times more, it would mean a market of just a few hundred patients.

Additionally, news about cannabis clinics opening in the United Kingdom in recent months might result in expanded access to medical cannabis.

Aspects of the regulations were recently simplified to allow better access. The changes include easing of some import restrictions to allow larger quantities to be imported and maintained in stock.

Domestic cultivation is legal only if carried out under a license from the U.K. Home Office.

The country is home to GW Pharmaceuticals, the company that manufactures Sativex and Epidiolex.

Sativex is a registered medicine in several European countries and around the world. Epidiolex obtained U.S. Food and Drug Administration (FDA) approval in the United States in 2018, and the European Commission granted marketing authorization for the product in September 2019.

In November 2019, U.K. health regulators recommended that plant-derived Sativex and Epidiolex as well as the synthetic drug nabilone be covered through the NHS if certain conditions are met.

LUXEMBOURG

Luxembourg legalized medical cannabis in mid-2018.

The law mandates that doctors can prescribe cannabis only to treat patients with serious diseases who meet at least one of the following criteria:

- Live in Luxembourg.
- Are beneficiaries of a Luxembourg's health insurance.
- Have Luxembourg nationality.

Only doctors who have undergone special training may prescribe medical cannabis.

The following restrictions also apply:

- Maximum coverage of 30 days.
- Maximum quantity of 100 grams of flower per 30 days.
- THC content in cannabis extracts may not exceed 1,000 milligrams per 30 days.

Canadian producer Aurora Cannabis became the first company to export to Luxembourg in December 2018. According to local media reports, the shipment was 20 kilograms of flower sold for 2.50 euros per gram.

In October 2019, Canadian producer Canopy Growth announced that it became "the exclusive supplier of medical cannabis" to Luxembourg without detailing already shipped quantities or quantities it expects to ship.

The current government in Luxembourg promised to legalize recreational cannabis within the current parliamentary period. The next election is scheduled for 2023.

FRANCE

As of early 2020, France did not have a medical cannabis program.

The French Agency for the Safety of Medicines and Health Products (ANSM) created a scientific committee to write certain rules ahead of the launch of a two-year medical cannabis experiment.

The areas of focus of the committee are:

- The products that will become available to patients during the trial.
- The training of doctors and pharmacists who will prescribe and dispense medical cannabis, respectively, as well as information for patients.
- A registry of patients to evaluate the experiment at the end of the two-year period.

While the ANSM communication doesn't specify whether the committee will be responsible for actually selecting the medical cannabis products, it appears that it will at least play a significant role in establishing the requirements.

The pilot project isn't expected to start before the second half of 2020.

OTHER COUNTRIES

Several other European countries, including Croatia, Cyprus, Malta and North Macedonia have had limited medical cannabis programs for years.

Ireland launched its limited pilot project in mid-2019.

Many Belgian patients travel to neighboring Netherlands with their prescriptions to buy medical cannabis in Dutch pharmacies.

Some Nordic countries also grant importation permits to certain patients from other nations, and there might be other European countries that allow some access.

We are not aware that any of these countries represent significant commercial opportunities in the medical cannabis sector when it comes to selling in their domestic markets because access is extremely limited, their populations are small or a combination of both.

Other European countries, including Greece, Portugal and Spain, have an exclusively export-oriented industry so far, with dozens of companies already licensed in some way or attempting to obtain licensing in each of these jurisdictions. But the three countries had no patients as of early 2020, though they might have some limited access to Sativex or Epidiolex on a case-by-case basis.