

# MEDICAL CANNABIS IN EUROPE:

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# MEDICAL CANNABIS IN EUROPE



**Alfredo Pascual**  
MJBizDaily International  
International Analyst

With international cannabis companies trying to scale globally and publicly listed organizations justifying their valuations with their access to overseas markets, Europe has become an increasingly important market.

The European Union has more than 500 million inhabitants, and non-EU countries situated entirely within the boundaries of geographical Europe add almost another 100 million.

The population, per capita gross domestic product (GDP) and health insurance coverage of cannabis at least in certain EU countries mean many in the industry estimate that Europe will be a larger market long term than the U.S. and Canada combined.

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

This report provides industry leaders and investors interested in the European markets a realistic estimate of its 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 with no basis in data.

In 2018, only three countries—Germany, Italy and the Netherlands—had meaningful sales of medical cannabis in Europe. Many other countries showed positive signs, advancing with legislation that either allowed national production or prescription, but those markets are far from established.

The immediate opportunities in Europe consist of:

- Export to Germany, which will depend on imports until at least the end of 2020 to meet its domestic demand.
- Setup of cultivation or production facilities in the countries that allow it or are preparing for it, including Cyprus, Denmark, Greece, Malta, North Macedonia and Portugal.

This report covers:

- International policy considerations at a United Nations and European Union level.
- The Big Markets: Germany, Italy and the Netherlands.
- Countries that developed a framework with a primary goal of exporting.
- Countries that have smaller national programs.
- The next big European countries that could tip the scales.

It's important to note that whenever we mention medical marijuana or medical cannabis, we are referring to either flower or full-spectrum derivatives of cannabis, such as oils or capsules that are prescribed by a physician. We do not include Sativex or other pharmaceutical products with marketing authorization, nor dronabinol or any other semisynthetic or synthetic cannabinoid, unless otherwise specified.

The report also does not include analysis of industrial hemp or the low-THC CBD consumer products markets, as these are not sold as medicine under prescription in Europe.

Because of the ever-changing nature of cannabis regulations, information in this report should be assumed to be updated through 2018 unless otherwise specified.

If you have any questions or comments, feel free to reach out to me at [alfredop@mjbizdaily.com](mailto:alfredop@mjbizdaily.com).

**Alfredo Pascual**  
International Analyst

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## beyond pioneering

Since 2003 Bedrocan has cultivated and produced standardised cannabis of pharmaceutical quality to the Dutch government. Bedrocan is the oldest legal company in the world providing several, chemically different cannabis varieties to be used by patients on doctor's prescription and as a raw material for the pharmaceutical industry (API).

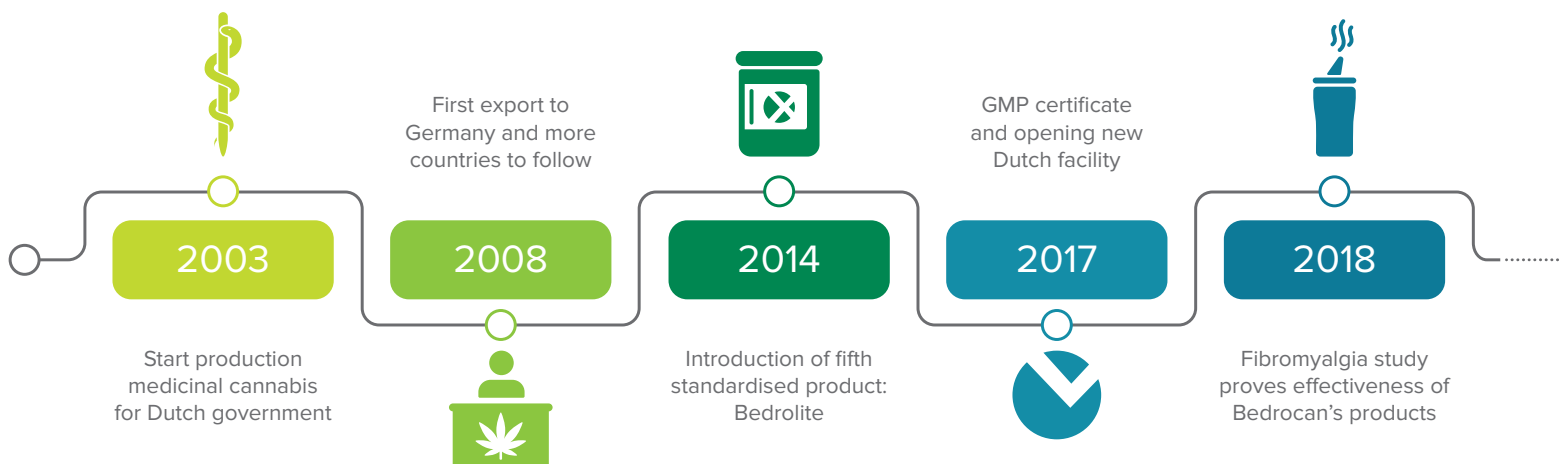
Over the past 25 years Bedrocan has developed and standardised unique methods of producing cannabis to pharmaceutical standards to a level achieved by no other company until today. This makes Bedrocan the industry leader in cannabis cultivar standardisation. Each product has a distinct chemical profile, with a consistent, defined active ingredient composition of delta-9-tetrahydrocannabinol (THC), cannabidiol (CBD) and terpenes, the aromatic compounds. Its cannabis is guaranteed free of microbial contaminants (moulds, fungi, and bacteria), pesticides and heavy metals.

A strong commitment to product quality resulted in the Dutch Bedrocan production facilities being approved for GMP/API (Good Manufacturing Practice/Active Pharmaceutical Ingredients) by the Dutch Health Authorities in 2017.

Bedrocan's products are currently exported to – amongst others – Australia, Denmark, Finland, Germany, Italy, Israel, Macedonia and Poland.



“It is my strong belief that there should be a clear distinction between medicinal and recreational use of cannabis and that patient needs for safe and consistent cannabis is a priority”, **founder and CEO Tjalling Erkelens** says when talking about the company's mission and vision. He is convinced that this can be achieved by going through the formal drug approval process. “Only fully standardised medicinal cannabis is the foundation on which such approval can be achieved.”



# CHAPTER 1

## REGULATORY FRAMEWORK

### INTERNATIONAL DRUG CONTROL TREATIES AND TRADE

For companies interested in doing business beyond a single country, the importance of the United Nations drug control treaties that allow – but also restrict – medical cannabis trade can't be ignored.

International law mandates control of cannabis plants and products. Provided the right controls, medical, scientific and industrial use may be permitted, but recreational use is not.

The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971 have classification systems that include different cannabis categories, based on risk and therapeutic value.

These two conventions largely provide the mechanisms for international trade.

In practice, the conventions establish that national authorities should report the following to the UN every year:

- Estimate of drug quantities required for medical and scientific use.
- Statistics of production, consumption, import/export (quarterly), plant stocks and total land use.
- Seizure and confiscation of cannabis products.

The cannabis authority for each country must establish rules for:

- Provisions for manufacturing.
- Limits on quantities manufactured for export based on market needs.
- Prevention of misuse and illicit trade.
- Licensing manufacturers and overseeing producers.
- Controls for international trade and distribution.
- Requirements for supervision and inspection of the manufacture of cannabis products.

Following the basic procedure for shipping cannabis internationally, the importing country issues a permit to the exporting country that details the quantities approved, the companies involved, the period of validity for the transaction and the entrance point into the country.

Reports are submitted to the International Narcotics Control Board (INCB), which is “the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions.”

In its 2018 report, the INCB heavily criticized what they consider “poorly regulated” medical cannabis programs in North America, including Canada's framework, which could lead to international challenges for these markets. Other countries that have a special-access schemes, such as Israel or the Netherlands, were mentioned in the report without criticism. The president of the INCB noted that European medical cannabis programs could use improvements but are generally in line with the conventions.

## THE MOST RELEVANT ARTICLES OF THE CONVENTIONS

Article 28 of the 1961 Convention describes the system of controls required if a country decides to permit the cultivation of cannabis that is not for industrial or horticultural purposes. The 1971 Convention controls THC<sup>1</sup>.

### **Article 28**

#### **CONTROL OF CANNABIS**

- 1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.**
- 2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.**
- 3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.**

Article 23, which is referred to in Article 28, applies the same framework for control as is applied to “opium” or “opium poppy.”

### **Article 23**

#### **NATIONAL OPIUM AGENCIES**

- 1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.**
- 2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:**
  - a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.**
  - b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.**
  - c) Each licence shall specify the extent of the land on which the cultivation is permitted.**
  - d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.**
  - e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.**
- 3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.**

<sup>1</sup> [https://www.unodc.org/documents/commissions/CND/Int\\_Drug\\_Control\\_Conventions/Ebook/The\\_International\\_Drug\\_Control\\_Conventions\\_E.pdf](https://www.unodc.org/documents/commissions/CND/Int_Drug_Control_Conventions/Ebook/The_International_Drug_Control_Conventions_E.pdf)

## POSSIBLE INTERNATIONAL REFORM AHEAD

Advocates for legalization have been arguing for decades that cannabis scheduling was a political, not a scientific, decision. And indeed, the scheduling of cannabis and cannabis products under the international drug control conventions was not based on scientific review.

The Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO), which is the institution responsible for carrying out scientific reviews of the substances considered within the scope of the international drug control conventions, recently completed its first scientific review of cannabis. Those results were presented to the United Nations Commission on Narcotic Drugs (CND) at the end of January 2019.

Those recommendations included:

- Removing cannabis from Schedule 4 of the 1961 Convention, the category reserved for the most dangerous substances.
- Removing THC in all forms from the 1971 Convention, placing it together with cannabis in Schedule 1 of the 1961 Convention, significantly simplifying cannabis classification.
- Clarifying that pure CBD and CBD preparations containing no more than 0.2% THC should not be included in any way in the international drug control conventions.
- Adding that pharmaceutical preparations containing THC, if they follow certain criteria, would be added to Schedule 3 of the 1961 Convention, recognizing the unlikelihood of abuse of these specific products.

	<b>Cannabis and cannabis resin</b>	<b>THC</b> (delta-9-THC and other isomers)	<b>CBD</b>	<b>Specific pharmaceutical cannabis preparations</b> (ex Sativex, Marinol, Syndros)
<b>Current scheduling</b>	I, IV of the 1961 Convention	II (delta-9-THC) and I (other isomers) of the 1971 Convention	-	-
<b>Recommendation</b>	I of the 1961 Convention* <small>*not including CBD preparations with less than 0.2% THC, which, like CBD, would not be scheduled</small>	I of the 1961 Convention	No scheduling	Schedule III of the 1961 Convention

The recommendations were mostly welcomed by the industry, as the suggestion to remove cannabis from Schedule 4 of the 1961 Convention signals more acknowledgement of medicinal value than what the current scheduling suggests.

"The evidence presented to the committee did not indicate that cannabis plant and cannabis resin were particularly liable to produce ill-effects similar to the effects of the other substances in Schedule 4 of the 1961 Single Convention on Narcotic Drugs," the recommendation report said.

The CND was expected to vote in March 2019, but because the recommendations were sent to member states later than planned, the decision of the CND was delayed. It's highly unlikely the vote will take place before the reconvened CND session of December 2019 or the next regular CND session of March 2020.

## MEDICAL CANNABIS AT A EUROPEAN LEVEL

The lack of continent-wide regulations and definitions is one of the main challenges international cannabis companies face in Europe.

There are three routes in which medicines can obtain a marketing authorization in Europe:

- Centralized procedure.
- Decentralized procedure in individual states.
- Mutual recognition.

A centralized procedure means a medicine obtained an EU-wide marketing authorization from the European Medicines Agency (EMA).

The decentralized procedure in individual states is, as the name suggests, a marketing authorization obtained for a specific country from its health agency. This process is usually used for new medicines that haven't yet obtained authorization in other EU countries.

Mutual recognition is when an EU country grants marketing authorization of a product that already obtained authorization in another EU country.

For obtaining marketing authorization through any of the three routes, efficacy, quality and safety need to be proved, usually with full clinical trials.

As of today, no cannabis medicine has EU-wide authorization, but Sativex and Canemes have been authorized in many EU countries.

Several EU countries also allow special programs under which physicians can prescribe products without marketing authorization. Special-access schemes are usually set up for providing access to products still undergoing clinical trials to terminal patients or patients who failed to respond positively to conventional treatments. This is the way many European countries established their medical cannabis programs.

Access to medical cannabis without marketing authorization differs from country to country.

Some countries allow only certain physicians to prescribe – for instance, the United Kingdom – while others allow any physician to do so – as in Germany, where any doctor other than dentists and veterinarians can prescribe cannabis. Some countries have a specific list of conditions for which cannabis can be prescribed, while others leave it to the discretion of the doctors.

For these special programs that allow access to medical cannabis, companies selling are usually required to demonstrate quality and consistency of their products, for instance, by having EU-GMP certification, but no proven efficacy to treat specific conditions is demanded.

## AN ATTEMPT TOWARD HARMONIZATION

The European Union Parliament recently passed a resolution seeking to address the lack of an EU-wide framework, emphasizing “the need for the standardization and unification of products containing cannabis-based medicines.”

The resolution calls on the European Commission and member states to engage with issues such as research, medical education, access and more, also stressing “the importance of close cooperation and coordination with the World Health Organization.”

While not binding, this opinion of the EU Parliament could pave the way for a larger and more harmonized European medical cannabis market.

However, some industry participants have questioned one part of the resolution, Article 14, which “calls on the commission to work with Member States to ensure that safe and controlled cannabis used for medicinal purposes can only be in the form of cannabis-derived products that have gone through clinical trials, regulatory assessment and approval.”

Were this suggestion followed by member states, it is likely that only Sativex and Canemes would be allowed in a few European countries and all the medical programs that allow the prescription of medical cannabis that has not gone through clinical trials wouldn't exist.

# CHAPTER 2

## EU MARKET ESTIMATES

### NO PERFECT ESTIMATION

There isn't any straightforward way to know how much medical cannabis was sold in the European Union in 2018. No central agency keeps track of sales, and even within individual countries, finding accurate information is challenging. Of the Canadian companies selling medical cannabis internationally, only Canopy Growth discloses how much and the average price, and that's only for Germany.

The problem is exacerbated by the lack of harmonized definitions of medical cannabis. Products sold in 2018 in Europe as medical cannabis without a marketing authorization included

- Whole flower
- Flower used for magistral preparations dispensed in pharmacies
- Ground flower
- Full-spectrum extracts
- Magistral preparations that contain dronabinol.
- Sativex and Canemes are sold in several European countries as registered medicines.

Lack of transparency into several of these markets makes the exercise of estimating future market sizes very speculative. Experience shows that different countries evolve at different paces, with certain countries growing rapidly, such as Germany, and others showing limited implementation even after many years, such as the Czech Republic.

Moreover, assuming that flower grown in a field will be the main medicinal cannabis product of consumption in 10 years is questionable, as advances in technology will provide consumers with new formats and producers with new cannabinoid production techniques.

### THE 2018 EUROPEAN MARKET

For 2018, almost all sales of medical cannabis flower<sup>1</sup> or full-spectrum extracts in the European Union were products that originated in either the Netherlands or Canada. Small cultivation operations also exist in Italy, Switzerland and the Czech Republic, each for domestic markets only.

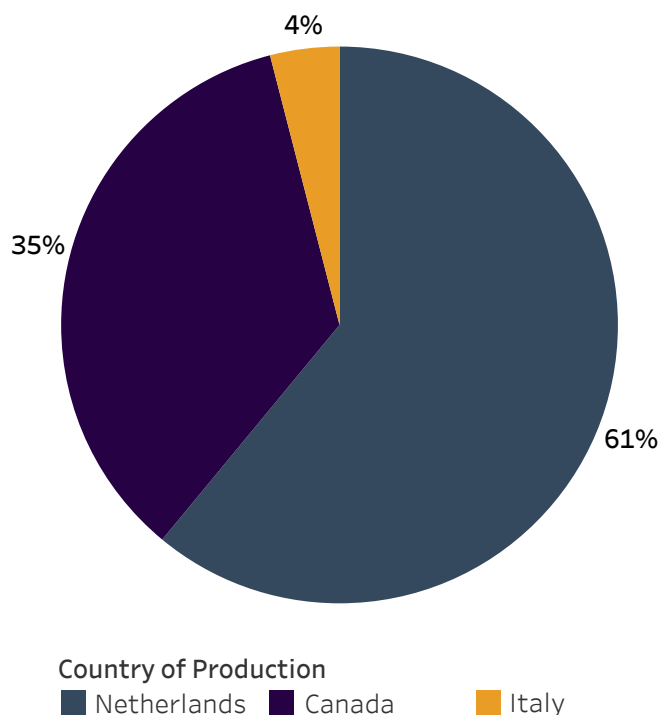
Marijuana Business Daily estimates that a total of 4,165 kilograms of cannabis flower was sold in 2018 in the EU, from the following sources:

- Canadian exports to the EU: 1,465 kilograms
- National market of the Netherlands supplied by local producer Bedrocan: 550 kilograms
- Exports from the Netherlands to other EU countries: 2,000 kilograms
- Other national productions (with Italy the only significant one): 150 kilograms

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<sup>1</sup> When we say sales of flower, we refer to whole flower, ground flower or oils prepared with flower in the pharmacies for individual patients (for example, in Italy).

## Country of Production of Medical Cannabis Sold in the EU in 2018



Source: Health Canada, Office of Medical Cannabis of the Netherlands, Italian media.

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\* Our estimate includes unprocessed flower, ground flower and the flower used by pharmacies to produce oils. It doesn't include sales of imported full-spectrum extracts, dronabinol preparations, Sativex nor any ready pharmaceutical product.

Our estimate is well below forecasts published by other analysts. Canaccord Genuity estimated 5.5 tons in 2018 annual sales in a report published in August. BMO's Global Opportunity Report published in January 2019 placed the total at 7,200 kilograms.

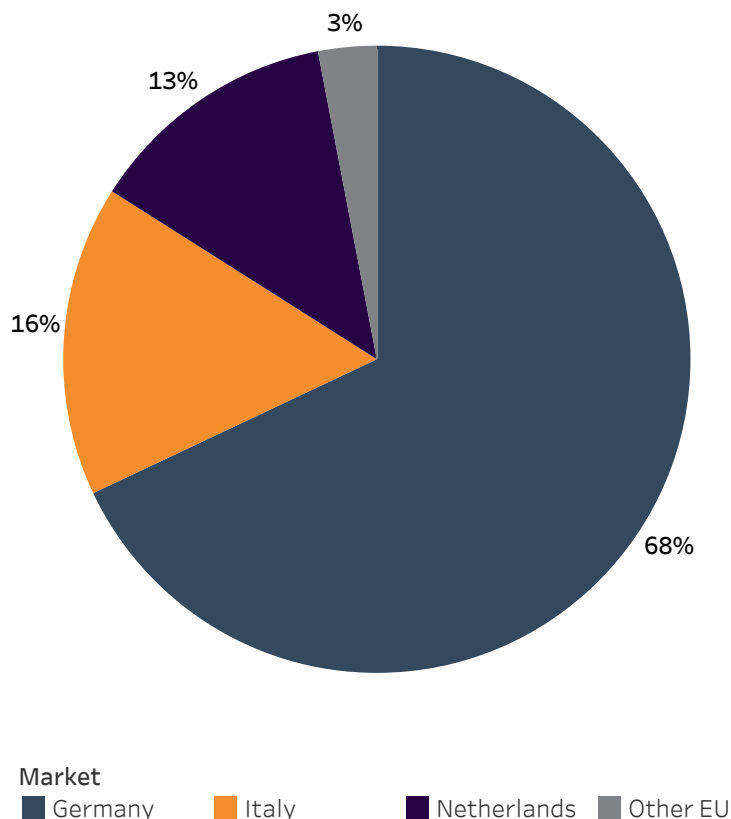
The Austrian Agency for Health and Food Safety has a small cultivation facility in Vienna whose production is exported to Germany in its entirety exclusively for the firm Bionorica Ethics to manufacture dronabinol<sup>2</sup>.

Sales of those 4,165 kilograms by jurisdiction were distributed as follows:

- Germany: 2,845 kilograms
- The Netherlands: 550 kilograms
- Italy: 650 kilograms
- All other European countries: 120 kilograms

<sup>2</sup> [https://www.parlament.gv.at/PAKT/VHG/XXVI/J/J\\_02588/imfname\\_729972.pdf](https://www.parlament.gv.at/PAKT/VHG/XXVI/J/J_02588/imfname_729972.pdf)

## Amount of Medical Cannabis Flower Sold in Europe (measured in kilograms)



Source: GKV-Spitzenverband, Office of Medical Cannabis of the Netherlands, Italian media.  
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### RETAIL ESTIMATE

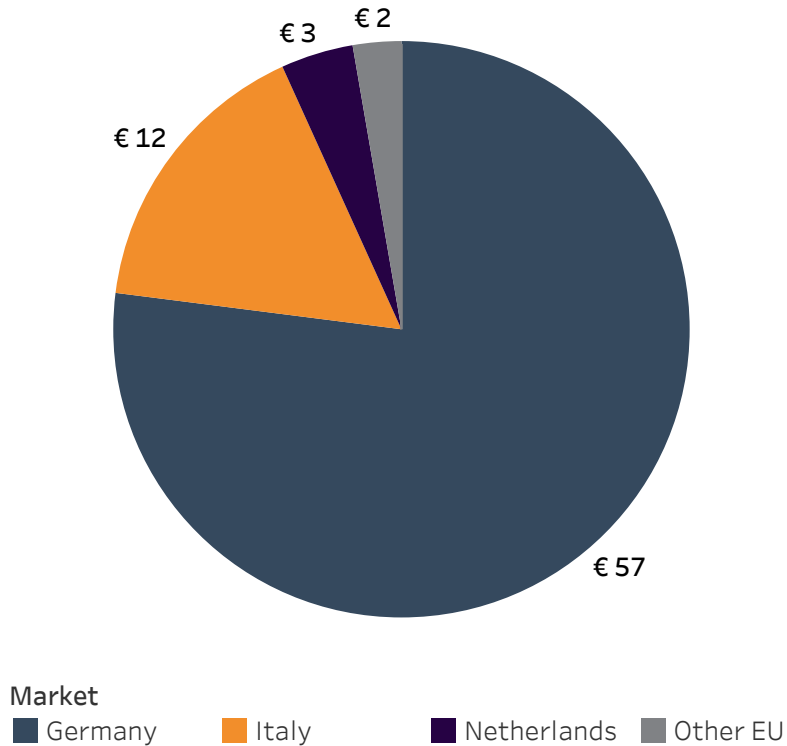
Marijuana Business Daily estimates that total sales of medical cannabis flower within the EU amounted to roughly 74.4 million euros (US\$83.8 million), based on quantities and reported average price:

- Germany: 56.9 million euros with an average price of 20 euros per gram.
- Italy: 11.7 million euros with an average price of 18 euros per gram.
- The Netherlands: 3.4 million euros with an average price of 6.15 euros per gram.
- Other: 2.4 million euros with an average price of 20 euros per gram.

Our estimates include flower when sold unprocessed by pharmacies or when used by individual pharmacies to prepare other products. It does not include sales of full-spectrum extracts not prepared by the pharmacist.

We're only aware of only two companies that sold full-spectrum extracts in Europe in 2018: Tilray and CannTrust. The total international revenue of Tilray was about 2.6 million euros. At our publication deadline, the international revenue of CannTrust wasn't available, but we don't consider it meaningful as it only consisted of oils shipped to Denmark – a nascent market – during the second half of the year.

## Amount of Medical Cannabis Flower Sold in Europe (millions of euros)



Source: GKV-Spitzenverband, Office of Medical Cannabis of the Netherlands, Italian media.  
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While Germany represented 68% of the total sales in kilograms of flower, it represented 76% of the total revenue from cannabis sold, as retail value in Germany is significantly higher than in the Netherlands.

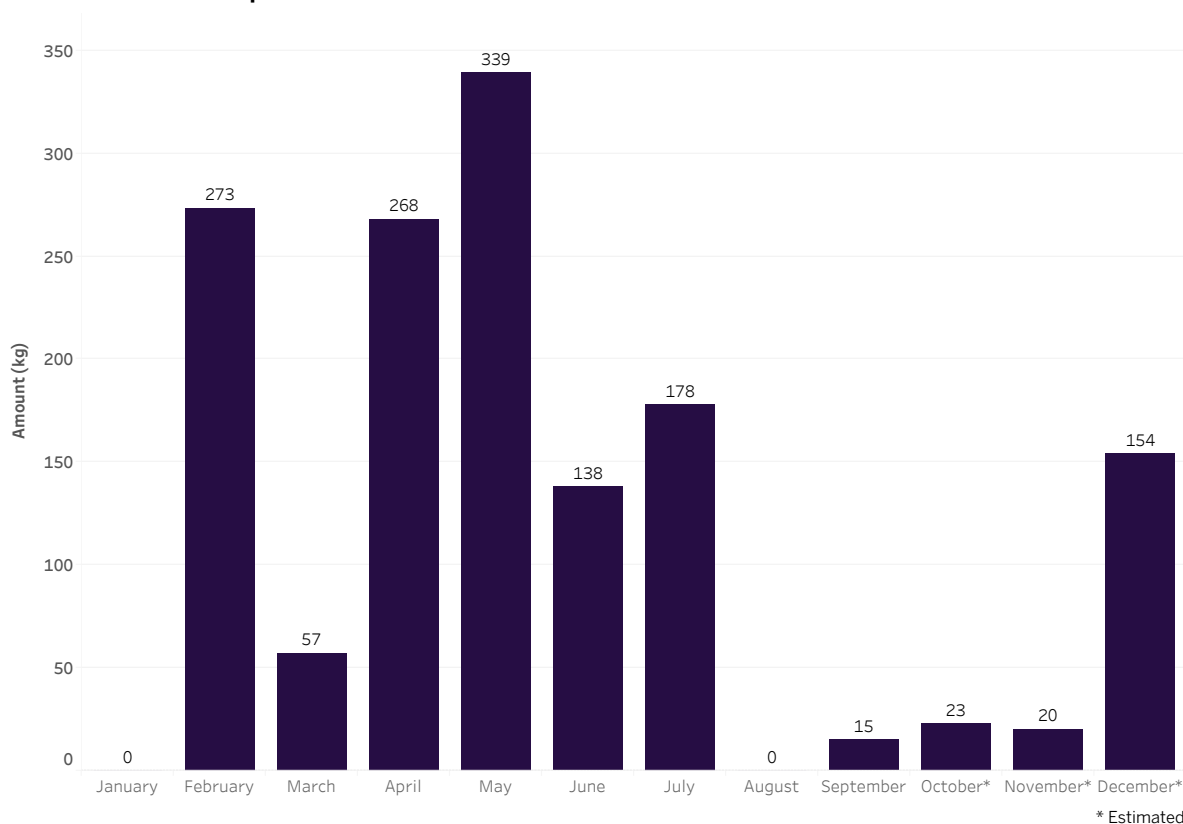
About half the total market retail value is captured by pharmacies' markup and value-added tax (VAT), as can be seen in the respective sections about Germany and Italy in this report.

## CANADIAN EXPORTS, DISAGGREGATED BY EXPORTER

Canada exported a total of 1,465 kilograms of flower and 911 liters of oil in 2018.

	Dried cannabis (kilograms)	Cannabis oil (liters)
January	0	0
February	273	0.025
March	57	0.27
April	268	67
May	339	36
June	138	28
July	178	25
August	0	203
September	15	1
October	23	2
November	20	126
December	154	423
<b>TOTAL</b>	<b>1,465 kilograms</b>	<b>911 liters</b>

## Dried Cannabis Exports from Canada in 2018



Source: Health Canada.

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Canopy Growth is the only Canadian licensed producer that specified in its public filings how many kilograms of flower it sold in Germany. Canopy's sales in Germany totaled 791 kilograms of flower in 2018 at an average selling price of 13.46 Canadian dollars per gram:

- 175 kilograms at an average price of CA\$13.35 per gram in Q1
- 248 kilograms at an average price of CA\$13.62 per gram in Q2
- 164 kilograms at an average price of CA\$13.58 per gram in Q3
- 204 kilograms at an average price of CA\$13.28 per gram in Q4

All quarters refer to calendar year 2018, not the company's fiscal year.

Canopy's 791 kilograms sold in Germany leaves 674 kilograms exported from Canada to be supplied by other producers, Aurora Cannabis and Cronos Group.

We assume that all product exported to Germany in 2018 was also sold within the year – a likely scenario because lack of available product was a problem in German pharmacies toward the end of 2018 and beginning of 2019.

For Aurora Cannabis, which doesn't report the number of kilograms sold in Germany or EU, we estimate that international sales of medical cannabis totaled CA\$10.628.

Calendar Year	Aurora Cannabis		Canopy Growth	
	Intl cannabis revenue	Total net revenue	Intl cannabis revenue	Total net revenue
Q1 2018	2,331	16,100	2,336	22,806
Q2 2018	2,641	19,147	3,378	25,916
Q3 2018	2,803	29,674	2,235	23,327
Q4 2018	2,853	54,178	2,702	83,048
<b>TOTAL 2018</b>	<b>10,628</b>	<b>119,099</b>	<b>10,649</b>	<b>155,097</b>

In 2018, Aurora exported 100 kilograms of flower to Italy for 320,900 euros [CA\$484,275].

The only other Canadian licensed producer in addition to Canopy and Aurora that exported meaningful quantities of medical cannabis flower to Europe in 2018 was Cronos. Cronos reported total international revenue of CA\$1.2 million for 2018.

Based on the available data, we estimate that exports from these three Canadian companies to the EU break down as:

- Canopy – 791 kilograms, without any meaningful sales in the rest of Europe.
- Aurora – 455 kilograms sold in Germany, 100 kilograms sold in Italy and 20 kilograms in the rest of Europe.
- Cronos – 99 kilograms sold in Germany, without any meaningful sales in the rest of Europe.

\* We acknowledge this estimate is based on assumptions and subject to error, but neither Aurora nor Cronos agreed to disclose the amounts it sold in Germany or the EU.

At the time this report was compiled, one other Canadian cannabis producer in addition to Canopy, Aurora, Cronos and Tilray had EU-GMP certification: Wayland. In October 2018, Wayland announced a supply agreement with Cannamedical, but as of mid-January, no shipment had been made.

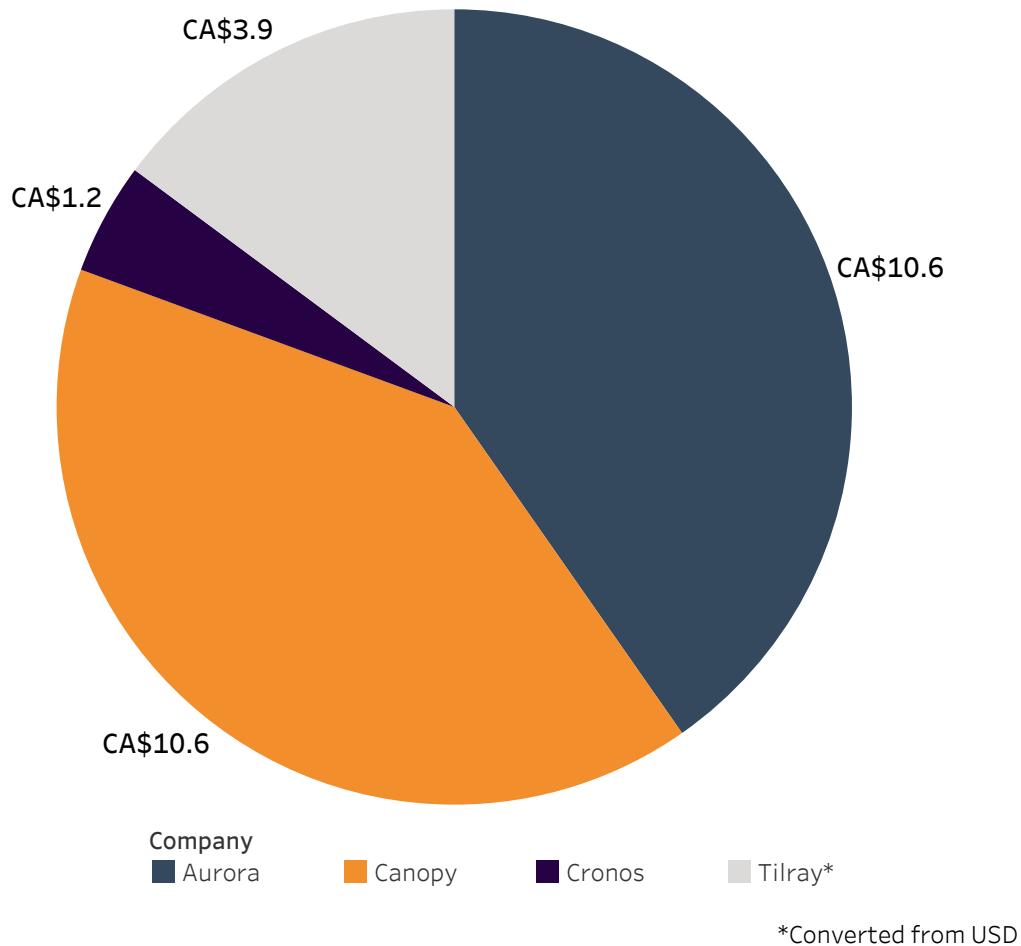
In the case of Tilray, the company announced in September 2018 that it would start selling flower in Germany, but German specialized media reported that the first flower arrived in 2019,<sup>3</sup> so we did not include the company in our calculation of the flower market for 2018.

Tilray reported US\$2.9 million in international revenue, a little more than one-third that of Canopy or Aurora in the same period. The company doesn't disaggregate international revenue by jurisdiction, and Australia is a significant non-EU export destination for the company.

CannTrust, despite not having EU-GMP certification, shipped oils to Denmark during the second half of 2019. Because Denmark is a nascent small market, we don't consider those quantities relevant.

3 <https://www.pharmazeutische-zeitung.de/cannabisblueten-als-rezepturazneimittel-verfuegbar/>

## International Revenue of Largest Canadian Cannabis Companies in 2018

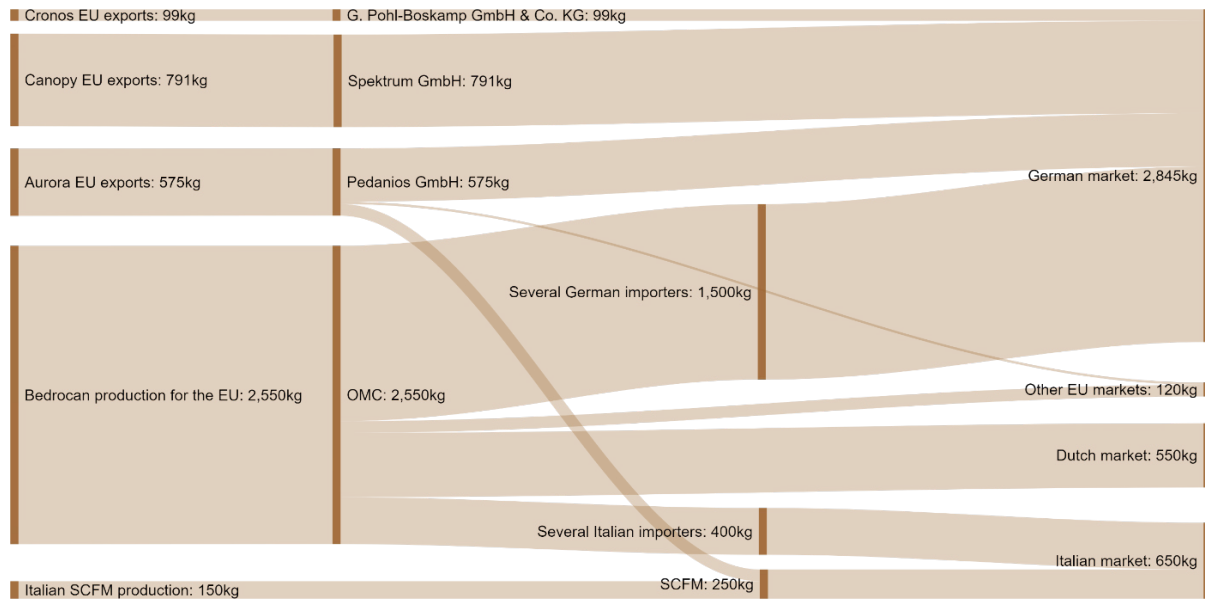


Source: Company regulatory filings.

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## THE FLOW OF MEDICAL CANNABIS FLOWERS

Based on the research in previous chapters, this graph shows how many kilograms of medical cannabis flower were sold in the EU in 2018 and where they originated.



\*Kilograms of flower sold in different jurisdictions, including estimated sales of unprocessed flower, grinded flower and the flower used by pharmacies to produce oils. Not including sales of imported full-spectrum extracts, dronabinol preparations, Sativex nor any ready pharmaceutical product.

# CHAPTER 3

## GERMANY

### THE EUROPEAN POWERHOUSE

In 2018, Germany had more sales of medical cannabis than all the other European countries combined, representing by far the most important marijuana market outside North America.

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 supposed to cover the cost of medical cannabis.

Until March 2017, the country had a limited framework that only exceptionally allowed the import of medical cannabis. This changed when an amendment to the narcotics law expanded access.

No domestic cultivation currently takes place in Germany, and the first German harvest is not expected until the end of 2020, meaning the market is fully dependent on imports. Even when domestic production starts functioning, it isn't expected to be enough to meet actual demand, so imports likely will be needed to cover the gap.

### DOMESTIC MARKET SIZE

Germany has no registry of patients nor any centralized database showing the total number of prescriptions or sales. The total market can only be inferred from multiple incomplete sources.

Estimates of the numbers of patients vary wildly, from 12,000<sup>1</sup> to as high as 40,000<sup>2</sup>. These figures are loosely based on previous disclosures by certain insurers of the number of applications for coverage that they received and approved. When insurers accept an application, it's for a specific product. If that product isn't available – as is often the case – the prescribing doctor needs to submit a new application. This translates to the possibility of a single person having several applications approved but not filled.

The statutory health insurance agency publishes the total number of prescriptions they reimbursed, but this doesn't include sales to patients with private health insurance (about 10% of the German population) or those who were denied coverage by their insurer and still buy with “private prescriptions” and pay for it themselves.

Further complicating the situation, the statutory health insurance discloses total prescriptions and amount reimbursed for a category that includes only unprocessed flower and separately for another category called “preparations” that includes:

- Flower, when ground in pharmacy on instruction of a doctor.
- Tilray extracts, the only full-spectrum extracts in the market in 2018.
- Dronabinol preparations, manufactured by German firm Bionorica Ethics.

How much of the preparations category that each of those products represents is unknown. Because flower is included in the two categories—unprocessed flower and preparations—there's no straightforward way of knowing the amount of flower being reimbursed in Germany from the data that the statutory health insurance publishes.

However, in 2018, all medical cannabis flower and full-spectrum extracts prescribed in Germany were fulfilled from either the Netherlands or Canada.

According to the Office of Medical Cannabis of the Netherlands, the only exporter from that country, 1,500 kilograms of cannabis flower produced by Bedrocan were exported to Germany.

In addition, the majority of the 1,465 kilograms of Canadian flower exported went to Germany, with the exception of 100 kilograms sold in Italy and 20 kilograms that were sold in other EU countries.

Our estimate of 2,845 kilograms is significantly higher than what the statutory health insurance agency reports was reimbursed in 2018. According to the German statutory health insurance, a total of 32.9 million euros of unprocessed flower was reimbursed, which at an average price of 20 euros per gram would be 1,647 kilograms. The difference can be explained with flowers sold ground (which are reimbursed in another category) and private prescriptions, which aren't

1 [https://www.aerztezeitung.de/praxis\\_wirtschaft/rezepte/article/965036/deutschland-bis-14000-patienten-erhalten-cannabis-rezept.html](https://www.aerztezeitung.de/praxis_wirtschaft/rezepte/article/965036/deutschland-bis-14000-patienten-erhalten-cannabis-rezept.html)

2 <https://www.handelsblatt.com/unternehmen/industrie/cannabis-medizin-immer-mehr-schmerzpatienten-bekommen-marihuana-auf-rezept/23125754.html>

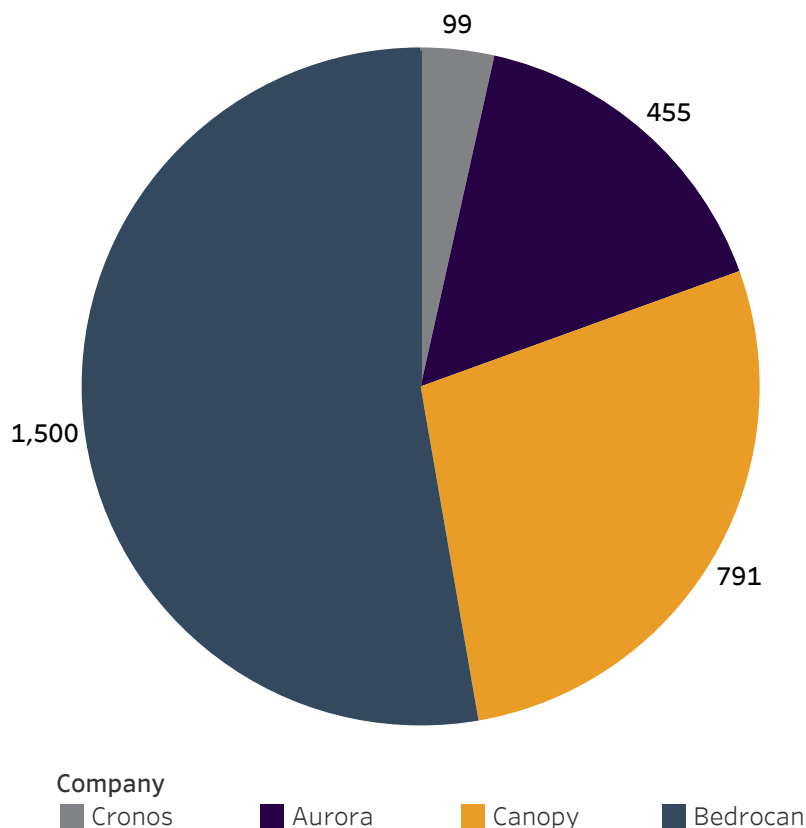
included in the reimbursement data at all. A recent report in German media<sup>3</sup> assessed the amount of cannabis imported into Germany in 2018 at 3,130 kilograms. This figure is beyond any that we could confirm, but it highlights the challenge is pinpointing the exact amount of medical cannabis making its way into Germany.

Flower sales in 2018 were 137% higher than in 2017. From March 2017, when the German government expanded the medical program, until December 2017, a total of 1,200 kilograms were imported<sup>4</sup>.

The only Canadian companies that shipped meaningful quantities of medical cannabis flower to Germany in 2018 were Aurora Cannabis, Canopy Growth and Cronos Group. Tilray didn't export any flower to Germany, but it was the only company to export oil.

Wayland is the only other Canadian company with EU-GMP certification. The company became the new supplier of German importer Cannamedical with an agreement signed in October 2018 but told us via email that as of January 2019, no shipment had yet been made.

## Sources of Medical Cannabis Flower for Sale in Germany in 2018 (kilograms)



Source: Company regulatory filing, GKV-Spitzenverband.

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<sup>3</sup> <https://www.dw.com/de/frankfurter-start-up-sagt-kanada-beim-cannabis-den-kampf-an-und-will-in-europa-anbauen/a-48100533>

<sup>4</sup> <https://www.aerzteblatt.de/nachrichten/97413/Bundesregierung-erhoeht-Importmenge-fuer-Medizinalhanf>

## BEFORE 2017

The current cannabis framework in Germany became effective in March 2017. Before that, only the finished pharmaceutical products Sativex and Canemes could be prescribed normally, and about 1,000 German patients had a special permit from the Federal Institute for Drugs and Medical Devices [BfArM] to buy imported cannabis flower under a very strict regime of case-by-case exceptional authorizations.

About half those special authorizations were granted 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, a handful of patients obtained a permit from the judicial system to grow their own cannabis for medicinal purposes at home. Their argument, in a nutshell, was that they couldn't afford the imported products, so they didn't have access to the constitutional right to health.

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

## THE CURRENT FRAMEWORK

A cannabis agency [Cannabisagentur] was created under the BfArM to regulate the supply of medical cannabis.

The agency doesn't cultivate, manufacture, import, store, deliver or sell medical cannabis.

Under the new framework, statutory health insurers are expected to cover the cost of prescribed cannabis. Refusals to reimburse should be exceptional, but because the law wasn't clear enough when determining when a patient qualifies for medical cannabis or not, in practice about one-third of the applications for reimbursement are rejected.

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

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

- It's a serious disease.
- Cannabis is used as a last resort.
- There's a not-too-distant 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 anonymized study about the treatment, with the BfArM collecting the data.

According to information provided by the German government<sup>5</sup>, the most common condition for which cannabis is prescribed is chronic pain [68%], followed by anorexia [15%], spasticity [8%] and nausea and vomiting [6%]. All other conditions represent less than 1% of prescriptions.

These figures need to be taken with caution, as the percentages are based on only 398 patients that interrupted treatment. Doctors need to report to the BfArM after a patient interrupts treatment or after a year of therapy.

## PRODUCTS

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

- Sativex, which has a close to 1:1 ratio of THC:CBD. The marketing authorization in Germany is to treat multiple sclerosis.
- Canemes, containing the active ingredient nabilone, a synthetic cannabinoid that mimics THC. The marketing authorization in Germany is to treat nausea and vomiting of patients with cancer undergoing chemotherapy, if other medicines don't work. It's sold in 1-milligram capsules.

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<sup>5</sup> <http://dipbt.bundestag.de/doc/btd/19/012/1901230.pdf>

Semisynthetic dronabinol preparations are among the most commonly prescribed products. Dronabinol is produced in Germany by Bionorica Ethics and delivered to the pharmacies in its pure form. Pharmacists must prepare it for a patient according to a doctor's prescription, usually in the form of capsules or drops.

Other pharmaceutical products such as Marinol, without marketing authorization in Germany, can also be imported, but this is rarely done because locally produced generic dronabinol is less expensive.

Finally, cannabis flower and full-spectrum extracts, the focus of this report, are also prescribed. Flower may be sold as unprocessed or the doctor may prescribe them ground or packaged for use as tea.

When prescribing flower, doctors need to specify in the prescription the cannabis chemovar (strain). Chemovars differentiate themselves according to their THC and CBD content.

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

Tilray was the only company with full-spectrum extracts in the market in 2018: 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. THC10:CBD10 has 10 milligrams/milliliters of THC and 10 milligrams/milliliters of CBD.

Aurora announced it will begin selling oils in Germany in 2019.

## IN-COUNTRY CULTIVATION APPLICATION PROCESS

While Germany has relied solely on imports to meet demand for medical cannabis to date, the cannabis agency has been working to establish a domestic cultivation program since 2017.

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

A new application process, started in mid-2018, drew 79 applicants for 13 available lots. Winners will be determined by a points system, with 40% of the points determined by price and 60% by technical documents. Results are expected in the second quarter of 2019.

The agency will issue contracts for 10,400 kilograms, distributed across the 13 lots at 200 kilograms per year for a period of four years. A single applicant may obtain a maximum of five lots, meaning there will be a minimum of three and a maximum of 13 companies cultivating in Germany. The government may also increase the quantities by 30% if deemed necessary.

Only dried flower of three different THC:CBD ratios will be produced by the winners; no other products will be manufactured. Any excess harvest must be destroyed.

The cap of 2,600 kilograms a year is not enough to meet the 2018 demand, and the gap between domestic supply in demand is only expected to grow. Imports will be possible and likely necessary beyond 2020, unless the German government dramatically increases the quantities.

Winners of the application process will have significant capital requirements and production costs. Only indoor cultivation is permitted, and extreme security measures are required. Because of limits on the available lots, economies of scale may be difficult to achieve. Cannabis will need to be cultivated under Good Agricultural and Collection Practices (GACP).

The cannabis agency will buy the agreed quantities and resell them to manufacturers of cannabis medicines, wholesalers or pharmacies, with only the necessary markup to cover operating expenses; no profit can be made.

## DISTRIBUTION

Germany claims to import medical cannabis only from cultivations that take place under state control and comply with the 1961 Single Convention on Narcotic Drugs. This claim may be challenged after the International Narcotics Board, in its 2018 report, singled out Canada for contravening the international drug control treaties by allowing recreational marijuana use and because of their “poorly regulated” medical framework.

EU-GMP is necessary to export to Germany. The official public database of EU-GMP certifications shows that all Canadian cannabis licensed producers with EU-GMP-certified facilities obtained the certification after inspections that occurred in 2017.

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

These Canadian producers and facilities have received EU-GMP certification:

- Maricann (Wayland) in Langton, Ontario.
- MedReleaf Corp. (Aurora) in Markham, Ontario.
- Tilray Canada (Tilray) in Nanaimo, British Columbia.
- Aurora Cannabis Enterprises (Aurora) in Cremona, Alberta.
- Tweed (Canopy) in Smiths Falls, Ontario.
- Tweed Farms (Canopy) in Niagara-on-the-Lake, Ontario.
- Peace Naturals Project (Cronos) in Stayner, Ontario.

Producers that want to distribute in Germany also need to either own or have an agreement with a German importer. Importers sell to pharmaceutical wholesalers or pharmacies. Only pharmacies are allowed to sell to patients.

German importers must have the following:

- A registered business with commercial register entry through the Handelsregister.
- A pharmaceutical wholesaler license, applied for on a regional (Bundesland) level.
- A license for dealing with narcotics at the federal level.

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

Three of the major Canadian companies looking to serve the German market have acquired importers in the country.

- Canopy acquired Medcann GmbH, which had already been importing Canopy products, in November 2016. Medcann GmbH was renamed Spektrum Cannabis GmbH.
- Aurora acquired Pedanios in May 2017. Pedanios had previously been importing Cronos products.
- Aphria bought CC Pharma in January 2019. Aphria does not have EU-GMP-certified facilities, so it currently can't export to Germany. In the meantime, CC Pharma imports cannabis from the Netherlands.

The other two Canadian cultivators that export to Germany, Cronos and Tilray, have supply agreements with German companies. Cronos has an exclusive supply agreement with importer Pohl Boskamp, while Tilray has agreements with pharmaceutical wholesaler Noweda and service provider Paesel & Lorei.

Wayland has a supply agreement with Cannamedical but has yet to ship any cannabis into Germany.

Regional German GMP inspectorates issue part of the necessary import permits and certify foreign manufacturers that intend to export to Germany.

As of August 2018, the German government received 23 applications to import, of which 14 had been approved.

Depending on the activities that the importer intends to conduct, different types of certifications are needed:

- Manufacturing and importation authorization.
- Compliance with Good Manufacturing Practice.
- Wholesale distributor authorization.
- GDP compliance.

Those certifications can be consulted in the public database EudraGMP. Neither online sales nor advertising to patients is allowed. Outreach to doctors is restricted.

## PRICE

Import prices are hard to establish, as there are only a few exporters and a few importers with little incentive to disclose the prices at which they sell or buy. However, conversations with different industry stakeholders, including importers and exporters, revealed that the price range paid to import medical cannabis flowers was between 3 euros and 7 euros per gram, with anything under 5 euros considered an extremely good deal.

The price paid by pharmacies to wholesalers also isn't fixed nor publicly available.

Conversations with wholesalers and pharmacies place the price range between 8 euros and 14 euros per gram, with most transactions in the range of 8-10 euros per gram.

The markup by pharmacies is regulated by law.

If flower is sold as "unprocessed," the pharmacy marks up the price by 100% and adds the price of the container, a narcotic prescription fee and value-added tax (VAT).

If a pharmacist purchases 10 grams of whole flower for 85 euros, the retail price would include:

- 85 euros (example of price the pharmacy pays for the flower).
- 85 euros (100% markup).
- 2.60 euros (container price)
- 32.79 euros (19% VAT)
- 2.91 euros (narcotic prescription fee)
- 208.30 euros (total price for 10 grams)

If the prescription is covered by statutory health insurance, the pharmacy must provide a discount of 5% over the final price.

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

For 10 grams of ground flowers at 85 euros:

- 85 euros (example of price the pharmacy pays for the flowers).
- 76.50 euros (90% markup).
- 2.60 euros (container price).
- 3.50 euros (Rezepturzuschlag, a fixed formula fee that could be as high as 6 euros).
- 8.35 euros (Festzuschlag, a fixed fee).
- 33.43 euros (19% VAT).
- 2.91 euros (narcotic prescription fee).
- 212.29 euros (total price for 10 grams).

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

## 2019

The German Parliament is considering a bill that would eliminate the need for approval from statutory health insurers for reimbursement of medical cannabis.

If the bill becomes law, statutory health insurers would be required to cover the cost of prescribed cannabis, and the paperwork and application for approval would disappear. This would eliminate one of the disincentives for doctors to prescribe, potentially increasing access and patient numbers.

- Germany still has room for growth. For that to happen, the following bottlenecks need to be addressed:
- Doctor education and simplification of the extra paperwork they need to do to prescribe cannabis.
- Clearer rules for reimbursement. The law establishes that statutory health insurers should reject coverage only in justified exceptional cases, so when they reject one-third of the cases, it's a signal that something isn't working.
- Availability of products, specifically flower. Many companies claim to export to Germany, but patients can't find the specific products they've been prescribed.
- Unnecessarily high price of flower. Patients without statutory health insurance coverage for medical cannabis report that the imported products are too expensive. Planned domestic cultivation could help bring prices down, but it's not expected to be enough. Several countries beyond Canada and the Netherlands—including Denmark, Portugal, Israel, Colombia, Uruguay and Australia—are also eyeing exports to Germany, which could help with the supply issues.

# CHAPTER 4

## ITALY

As the second-largest European medical cannabis market and mostly dependent on imports, Italy attracted significant attention from Canadian companies in 2018. However, only 100 kilograms of the total 650 kilograms sold during the year was produced by Canadian companies.

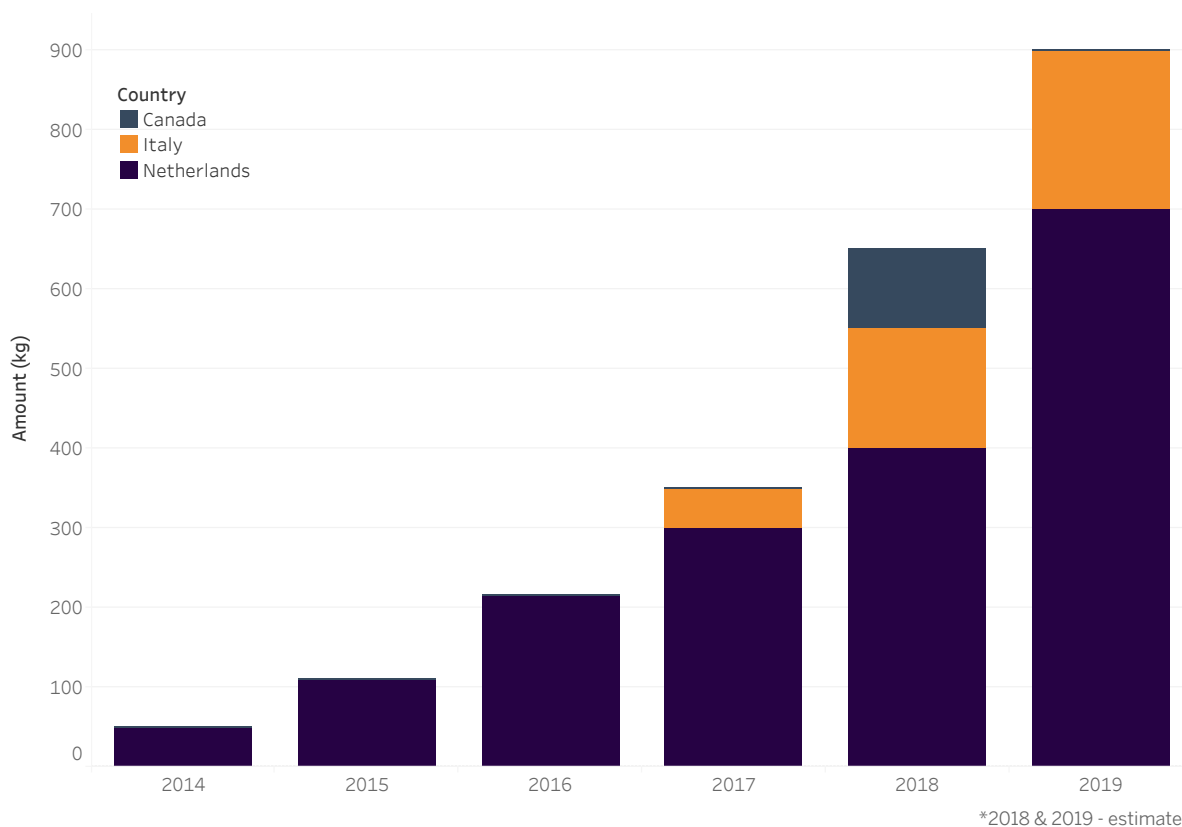
As in Germany, Bedrocan – exporting via the Office of Medical Cannabis (OMC) of the Netherlands – provided the bulk of the medical cannabis for the country, with 400 kilograms of Dutch-grown product making its way to the southern European nation.

The Italian armed forces, which have a monopoly on production through the Stabilimento Chimico Farmaceutico di Firenze (SCFF) grow EU-GMP-certified flower. In 2018, it's estimated the armed forces produced between 100 and 150 kilograms of flower.

A total of 10 different strains were sold in Italy in 2018:

- Bedrocan provided 400 kilograms of five strains.
- SCFF produced 100-150 kilograms of two strains.
- Aurora Cannabis – the only Canadian company approved to import to Italy – provided 100 kilograms of three strains.

### Medical Cannabis Sold in Italy



Source: Office of Medical Cannabis of the Netherlands, company regulatory filings.  
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*\*Our estimate*

## HOW IT WORKS

Medical cannabis flower is sold only as magistral preparations in pharmacies and under a special prescription. Pharmacists must either grind the flower and sell it ready for making tea or vaporizing or prepared in an oil, depending on doctors' instructions.

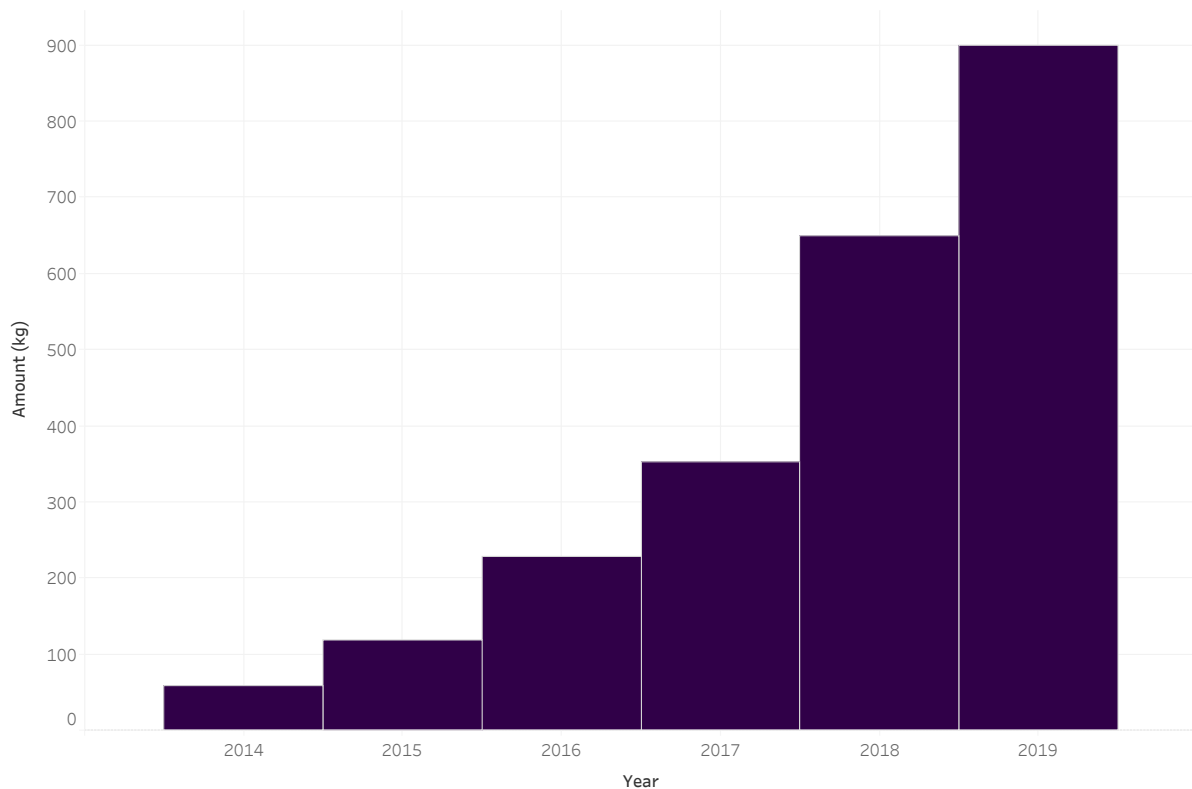
Because cannabis is being sold as magistral preparation, not as registered medicines, patients must sign a consent form acknowledging they're getting an unregistered product. The types of conditions for which cannabis could be prescribed isn't limited.

Most of the medical cannabis in Italy is purchased in the regions of Tuscany, Emilia-Romagna and Apulia.

Sales have steadily grown since 2014, and we predict that it will continue to do so in 2019:

- 2014: 59 kilograms
- 2015: 119 kilograms
- 2016: 228 kilograms
- 2017: 352 kilograms
- 2018: 650 kilograms
- 2019: 900 kilograms

### Medical Cannabis Sold in Italy (kilograms)



\*2018 & 2019 - estimates

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## IMPORTS

The OMC of the Netherlands has been exporting to Italy since at least 2014.

Until 2017, the Italian government served as the importer for about half the products from the Netherlands for distribution to hospital pharmacies. The other half was imported by private parties to distribute in the rest of the pharmacies.

At the end of 2017, Aurora and Canopy, via their respective German subsidiaries, Pedanios GmbH and Spektrum Cannabis GmbH, applied and were the finalists of the first – and, so far, the only – application process to supply the SCFF with 100 kilograms of medical cannabis flower, 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 a total price of 320,900 euros [not including VAT]<sup>1</sup>.

Aurora's first shipment under the contract was made in April 2018.

## PRICE

The price pharmacies pay the SCFF for flower is fixed at 9 euros per gram (6.88 euros per gram + VAT and shipping). Private importers could raise the price to 11 euros per gram. Pharmacies pay a VAT of 22% when buying flower, which is considered raw material, but sell the preparations with a VAT of 10%.

Sales prices to patients are also fixed but may vary wildly depending on whether the flower is sold ground [ready for tea preparation or vaporizing] or prepared as oil. The prescription, specifically the dosage, will determine the amount of materials needed and the final price. Retail price tends to be 15-19 euros per gram of flower used in the preparation [10% VAT included].

Most prescriptions are sold as oil, which garners a higher price than ground flower.

Reimbursement depends on the region. As of the end of 2018, 14 of the 20 Italian regions had some legislation to reimburse medical cannabis.

## 2019

According to Italian media and local industry stakeholders, the main bottleneck that needs to be addressed for Italy's market to develop are supply issues.

National production hasn't been able to keep up with demand, imports from the Netherlands are not enough to fill the gap, and the government hasn't allowed large-scale imports of Canadian-produced cannabis nor private production within Italy.

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

For 2019, it's expected that the Italian SCFF will produce up to 200 kilograms of cannabis and imports from the Netherlands will increase to 700 kilograms.

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<sup>1</sup> [https://www.difesa.it/AID/Bandi\\_di\\_gara/Documents/2017/100\\_kg\\_cannabis\\_firenze/verbale\\_valutazione\\_offerte\\_cannabis.PDF](https://www.difesa.it/AID/Bandi_di_gara/Documents/2017/100_kg_cannabis_firenze/verbale_valutazione_offerte_cannabis.PDF)

# CHAPTER 5

## NETHERLANDS

The Netherlands is internationally known as the country where recreational marijuana is sold in “coffee shops,” 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.

The contradiction in this approach is that the coffee shops must obtain supply from the black market to operate, commonly referred to as the “back door” problem. Certain political segments have been trying to resolve the issue, introducing a bill to Parliament in 2018 that would allow up to 10 municipalities to regulate marijuana cultivation in a pilot project. The bill was passed in early 2019, but it remains uncertain if, and when, the pilot project could start.

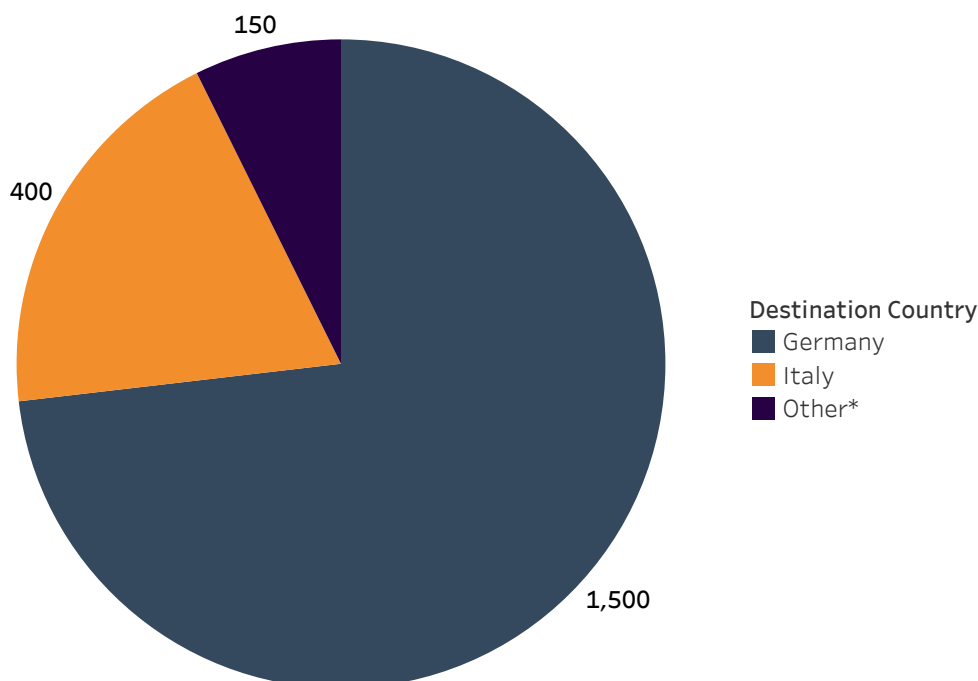
For medical cannabis, however, the Netherlands plays an even more critical role in Europe:

- It's the most mature European medical cannabis market, which could be an indicator of how neighboring countries could evolve.
- Considering only flower or full-spectrum oil, the Netherlands was the third-largest European market in 2018, with 550 kilograms sold for an estimated 3.4 million euros in retail value.
- With more than two metric tons exported in 2018, the country was the largest exporter of medical cannabis in the world. (This does not include export numbers of GW Pharmaceuticals' Sativex from the United Kingdom.)

The Dutch medical program began more than 15 years ago, overseen by the Office of Medical Cannabis (OMC). Bedrocan is currently the only supplier to the OMC.

The OMC has agreements with two countries for exports of more than 100 kilograms per year, Germany and Italy. As of March 2019, exports to Germany this year are expected to total 1,500 kilograms while exports to Italy will increase to 700 kilograms.

## Destination Countries for Netherlands Exports of Medical Cannabis (kilograms of flower)



\* Includes exports to EU countries such as Denmark, Finland, Poland, Sweden and the U.K., and non-EU countries such as Australia, Israel, Norway, North Macedonia and Switzerland. None of these received more than 100 kilograms.

Source: Office of Medical Cannabis of the Netherlands.

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*\*Included exports to EU countries such as Denmark, Finland, Poland, Sweden and the UK and non-EU countries such as Australia, Israel, Norway, North Macedonia and Switzerland. None of these received more than 100 kilograms<sup>1</sup>.*

## DOMESTIC MARKET SIZE

Dutch patients bought 550 kilograms of medical cannabis flower with 49,500 prescriptions in 2018. These purchases were either of unprocessed flower or compounded by pharmacists into oils<sup>2</sup>.

At a retail price of 6.15 euros per gram<sup>3</sup>, the total retail value of the market in 2018 was 3.4 million euros.

Contrary to other reports that predict exponential growth in every European market, the Netherlands may serve as a real-world example for how these markets may evolve. The Dutch market is the most mature one in Europe, but after growing year-after-year until 2017, the number of prescriptions declined in 2018.

<sup>1</sup> Email communication with the OMC.

<sup>2</sup> Information received via email from the OMC.

<sup>3</sup> <https://english.cannabisbureau.nl/medicinal-cannabis/types-of-medicinal-cannabis>

When the market was at its peak in 2017, patients received 53,300 prescriptions; the number of prescriptions in 2018 declined to 49,500. Part of this drop may be attributed to a change in attitude by medical practitioners, as the Dutch General Practitioners Association [Nederlands Huisartsen Genootschap] in June 2018 recommended against prescribing medical cannabis because of lack of evidence.

The Netherlands, with a population of 17 million, had roughly 50,000 prescriptions at its peak. That translates into roughly three prescriptions per 1,000 people per year.

If Germany, with a population of roughly 80 million, were to follow in the Netherlands' wake, prescriptions would peak at 240,000. In 2018, the total number of reimbursed prescriptions in Germany was 185,370<sup>4</sup>, so anyone expecting exponential growth should be concerned.

However, this exercise has many limitations, including insurance reimbursement for medical cannabis. In the Netherlands, such prescriptions are rarely reimbursed, while in Germany about two-thirds of the applications for reimbursement are successful, which could be a catalyst for more rapid growth.

## PRODUCTS AND DISTRIBUTION

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

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

Type	% tetrahydrocannabinol [THC]	% cannabidiol [CBD]
Bedrobinol®	approx. 13,5	<1
Bedrocan®	approx. 22	<1
Bedica®	approx. 14	<1
Bediol®	approx. 6,3	approx. 8
Bedrolite®	<1	approx. 9

A few pharmacies prepare oils with the flower.

The five strains mentioned above are the same as those exported to other countries. Bedrocan cultivates them under Good Agricultural Practices [GAP]. 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 only grower and drier, Synergy Health performs gamma irradiation and Fagron BV completes the packaging. The OMC certifies that each batch is "cultivated and manufactured, including packaging and quality control," in compliance with the Dutch GAP requirements, and that processing, packaging and analysis complies with GAP and Good Manufacturing Practices [GMP].

<sup>4</sup> [https://www.gkv-gamsi.de/media/dokumente/gamsi\\_statistiken/2018/q4\\_19/Bundesbericht\\_GAmSi\\_201812\\_konsolidiert\\_Sonderbeilage\\_Cannabis.pdf](https://www.gkv-gamsi.de/media/dokumente/gamsi_statistiken/2018/q4_19/Bundesbericht_GAmSi_201812_konsolidiert_Sonderbeilage_Cannabis.pdf)

## PRICE AND REIMBURSEMENT

The final price per gram of medical cannabis in pharmacies is 6.15 euros (including VAT), but that may vary based on the size of the purchase.

In 2003, the Dutch National Health Care Institute was asked to consider the evidence of medical cannabis and concluded it wasn't enough to include medical cannabis in the basic health insurance. The position was reaffirmed in 2016.

In 2017, the institute once again concluded that the lack evidence for medical cannabis didn't justify a change. But it also stated that sales to patients who pay for medical cannabis out of pocket should continue to be available and that the government could consider a strategy to make prices in pharmacies lower than those in coffee shops.

Several insurers have reimbursed in the past on a case-by-case basis, with conditions that vary among insurers. Only part of the total cost is covered and only to patients that 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 medical cannabis program for more than 15 years and is the leading exporter of medical cannabis, business opportunities in the market remains limited for new players.

In early 2018, the OMC started a European application process to select another cultivator. The application process consisted of two lots, one to cultivate the 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. The OMC published a detailed explanation in December 2018<sup>5</sup>.

Although the Netherlands are recognized as the primary cannabis supplier to the rest of Europe, imports into the country are also possible—albeit rare. The OMC will sometimes import cannabis for holders of an exemption to the Opium Act for scientific research.

## 2019

With the unsuccessful attempt to expand cultivation last year, Bedrocan remains the sole grower in the Netherlands. The OMC expects to open the application process again during the first half of 2019. It will be available in [www.tenderned.nl](http://www.tenderned.nl).

Unlike other European countries – such as Germany, Italy and the Czech Republic – that allow private importers to import and distribute, the OMC holds a monopoly in the Netherlands.

Interesting opportunities in the medical sector could become available if the application process for cultivating medical cannabis starts again – or in the recreational sector if the pilot project to create a legal cultivation program for recreational marijuana is approved.

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5 <https://www.cannabisbureau.nl/documenten/besluiten/2018/12/20/motivering-intrekking-aanbesteding>

# CHAPTER 6

## AUSTRIA

Austria allows the prescription of pharmaceutical products Sativex and Canemes. Since 2015, dronabinol (exclusively imported from Germany) and CBD may be prescribed for magistral preparations in pharmacies as drops or capsules.

Unlike Germany, patients in Austria can't access full-spectrum extracts or flower, limiting market opportunities to registered medicines and dronabinol preparations.

Despite those limits, the Austrian market is one of the largest in Europe, according to our estimates, with a retail value of 10 million euros in 2018.

### DOMESTIC MARKET SIZE

Health insurance reimburses dronabinol preparations under certain conditions, but Sativex and Canemes are covered only in exceptional cases.

For the first half of 2018, 7,325 patients received at least one reimbursement for a cannabis product through 22,337 prescriptions totaling 5 million euros. This suggests that the total retail value of the market in 2018 will most likely exceed 10 million euros.

Private purchases are allowed, but it's unaffordable for most people, as the typical price for 20 milliliters of dronabinol drops with 500 milligrams of THC is 450 euros.

### COMMERCIAL OPPORTUNITIES

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

Reliable information about AGES is hard to find, and the agency replied to our request for basic information such as amount produced and destination of the production by saying that such information was confidential.

According to German media, AGES produced 250 kilograms of cannabis in 2017 in a 3,000-square-meter facility<sup>1</sup>. The harvest was shipped to Germany for Bionorica Ethics to manufacture dronabinol. Dronabinol is primarily sold in Austria, Germany and Switzerland.

Considering the increased demand in Germany in 2018, we assume AGES produced more than 250 kilograms in 2018, again selling all its production to Germany for the manufacture of dronabinol.

### 2019

We don't expect any liberalization of the current cannabis laws in 2019, but the market for dronabinol will probably expand further, benefiting Austrian state-owned grower AGES and Bionorica Ethics, the German manufacturer of the dronabinol that Austrian patients have access to.

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<sup>1</sup> <https://www.bz-berlin.de/deutschland/oesterreich-produziert-cannabis-fuer-den-deutschen-markt>

# CHAPTER 7

## CZECH REPUBLIC

The Czech Republic is not one of the largest medical cannabis markets in Europe – its pharmacies sold less than 5 kilograms in 2018 – but it is one of the oldest.

Until recently, developments were very slow and limited in scope, but at the end of 2018 and into 2019, more prescriptions were being issued and more grams were being sold.

The country has a small domestic cultivation and allows imports.

### DOMESTIC MARKET SIZE

Compared to the quantities usually sold in North America, the Czech Republic market is still in its infancy.

In 2018, 4,801 grams were prescribed, which, at an estimated average price sold of 8 euros per gram, means a total retail value market of less than 40,000 euros in 2018.

Of those 4.8 kilograms sold, 1.8 kilograms were produced locally and 3 kilograms were imported, according to the Ministry of Health.

### LEGAL FRAMEWORK

The first cannabis law dates from 2013 with Act No. 50/2013 Coll<sup>1</sup>. Only a handful of patients had access at the time, approved on an exceptional basis. Things slightly changed in 2015 with Decree No. 236/2015 Coll<sup>2</sup>, which stipulated conditions under which medical cannabis could be prescribed and distributed.

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 the product for distribution.

SAKL is one of the most transparent European cannabis agencies, though most of the information is available only in Czech. The agency provides detailed information about the number of grams sold monthly, prescriptions issued, the conditions for which those grams were prescribed, the number of patients, doctors and authorized pharmacies. No other health authority in Europe publicly provides such comprehensive information.

### PRODUCTS

Medical cannabis is legal in the Czech Republic as magistral formulas under electronic prescription for patients older than 18. It can be prescribed only in the form of dry flower, with a defined maximum cap of 21% THC and 19% CBD. A deviation of up to 20% of the value specified by the grower is tolerated.

Some of the products prescribed are produced domestically, and the rest are imported from the Netherlands or Canada.

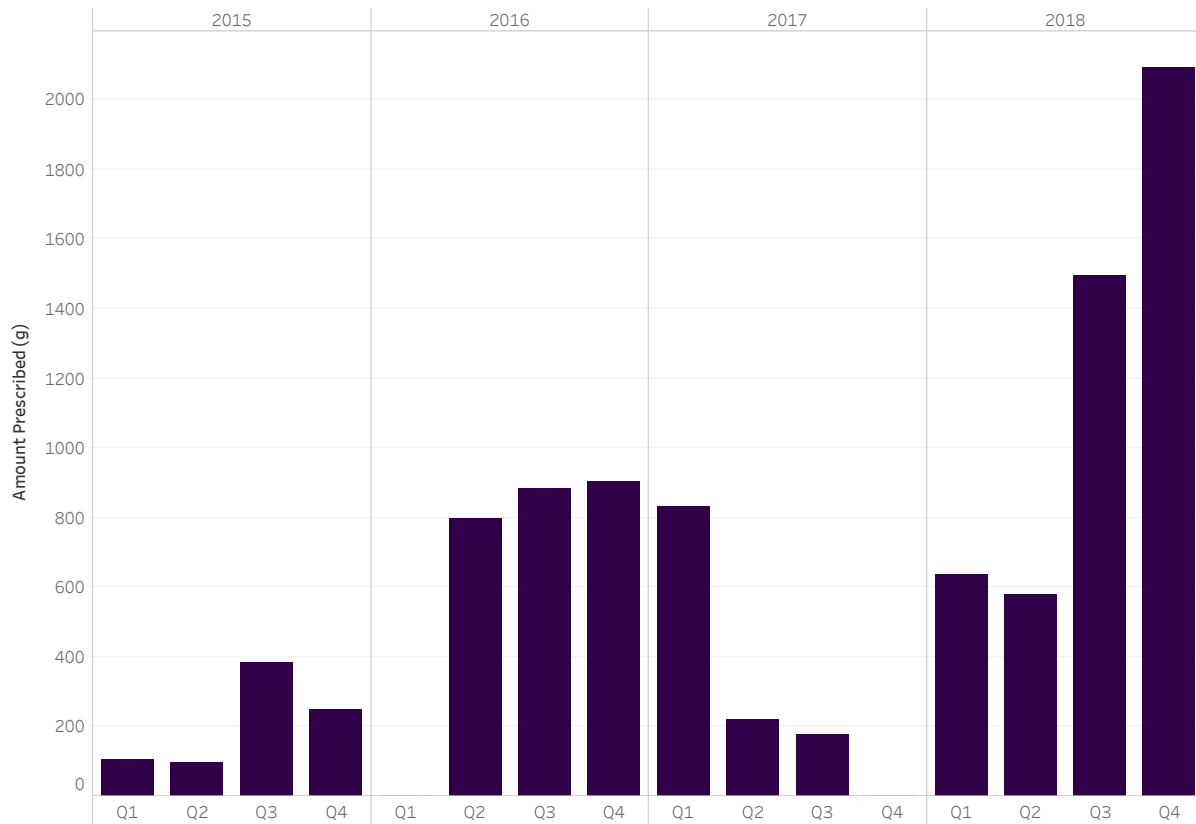
Sativex is also approved in the Czech Republic, but in practice, the drug is rarely prescribed because of its price tag.

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<sup>1</sup> <http://ftp.aspi.cz/opispdf/2013/022-2013.pdf>

<sup>2</sup> <http://www.sakl.cz/assets/user/Decree No 236-2015.pdf>

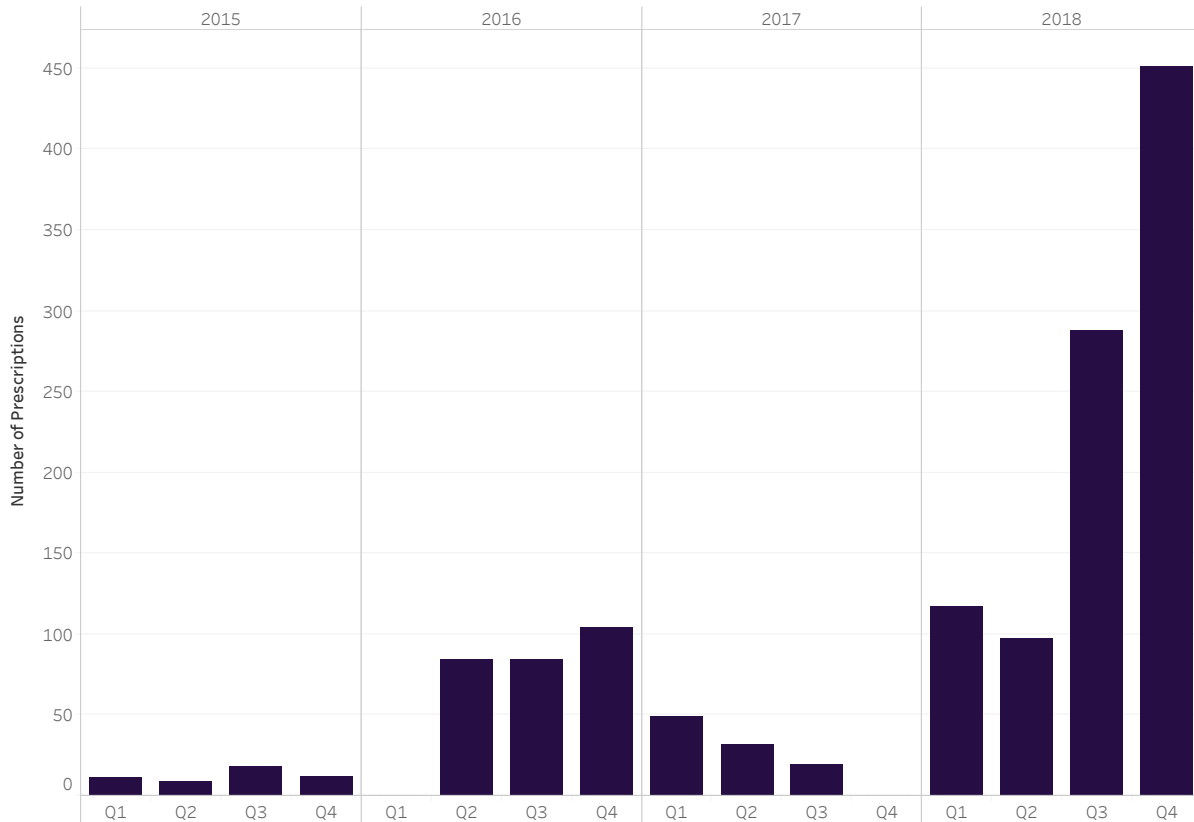
### Amount of Medical Cannabis Prescribed in the Czech Republic (grams)



Source: State Agency of Medical Cannabis (SAKL).

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## Number of Medical Cannabis Prescriptions in the Czech Republic



Source: State Agency of Medical Cannabis (SAKL).  
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## COMMERCIAL OPPORTUNITIES

As of today, there is only one producer within the Czech Republic: Elkoplast Slušovice, s.r.o, winner of the most recent public tender.

That tender had only one participant, and there were cases of tenders that had to be canceled because no company applied.

Elkoplast Slušovice sells its production to the State Institute for Drug Control. The total production is stored in the warehouse of the only authorized distributor, Alliance Healthcare sro.

As of February 2019, 56 pharmacies were authorized to buy from that single distributor, and patients are allowed to buy only from those pharmacies.

Despite total sales in the Czech Republic being below 5 kilograms in 2018, several Canadian cannabis companies have tried to establish a presence in the country:

- Tilray announced its first export to the Czech Republic in December 2017.
- Canopy acquired a Czech importer in April 2018.

Aurora announced its first shipment to the Czech Republic in November 2018.

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

Pharmacies typically pay 172.50 koruna (value-added tax included) for a gram of domestically produced cannabis, selling it to patients for 207 koruna a gram [about 8 euros or US\$9]. Only domestically grown cannabis has a fixed price, but imported cannabis generally sells at the same or a lower price, as of early 2019.

The maximum dose a patient can be prescribed is 180 grams per month, regardless of THC content.

Public health insurance doesn't cover medical cannabis, but the Ministry of Health recently proposed a change that would have health insurance cover 90% of the price of up to 30 grams per month per patient<sup>3</sup>. If approved in 2019, as expected, medical cannabis reimbursement would go into effect in 2020.

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<sup>3</sup> [https://www.mzcr.cz/dokumenty/ministerstvo-zdravotnictvi-navrhuje-uhradu-lecebneho-konopi-z%C2%A0verejneho-zdravotn\\_16737\\_1.html](https://www.mzcr.cz/dokumenty/ministerstvo-zdravotnictvi-navrhuje-uhradu-lecebneho-konopi-z%C2%A0verejneho-zdravotn_16737_1.html)

## CONDITIONS AND CONTROLS

As of March 2019, 80 doctors in a country of more than 10 million people were listed as prescribers of medical cannabis.

Decree 236/2015 established the following list of conditions for which only certain specialists can prescribe medical cannabis:

Indication	Doctor's 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"> <li>• Clinical oncology</li> <li>• Radiation oncology</li> <li>• Neurology</li> <li>• Palliative medicine</li> <li>• Treatment of pain</li> <li>• Rheumatology</li> <li>• Orthopedics</li> <li>• Infectious diseases</li> <li>• Internal medicine</li> <li>• Ophthalmology</li> <li>• Dermatovenerology</li> <li>• Geriatrics</li> </ul>
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"> <li>• Neurology</li> <li>• Geriatrics</li> </ul>
Nausea, vomiting, stimulation of appetite in association with cancer treatment or HIV treatment.	<ul style="list-style-type: none"> <li>• Clinical oncology</li> <li>• Radiation oncology</li> <li>• Infectious diseases</li> <li>• Dermatovenerology</li> <li>• Geriatrics</li> </ul>
Tourette syndrome.	<ul style="list-style-type: none"> <li>• Psychiatry</li> </ul>
Surface treatment of dermatoses and mucosal lesions.	<ul style="list-style-type: none"> <li>• Dermatovenerology</li> <li>• Infectious diseases</li> <li>• Geriatrics</li> </ul>

About 90% of current prescriptions are for chronic pain.

## 2019

Despite being a small market, the Czech Republic's recent exponential growth should not be ignored. In January and February 2019, 1,748 grams were dispensed, which means the exponential growth of the latest quarter of 2018 is likely to continue in 2019.

The recent proposal of the Ministry of Health to reimburse medical cannabis could be a key factor in this growth, as price is usually a bottleneck for the legal market.

# CHAPTER 8

## THE FUTURE EXPORTERS

The Netherlands and Canada are the current global leaders in exporting medical cannabis, with most exports going to Germany, Italy and Australia. But several other countries may be in line for challenging export dominance in Europe.

The opportunity created by Germany, as a comparatively big market totally dependent on imports, is incentivizing other European countries to develop frameworks to allow exports, including Denmark, Greece, Malta, Spain and Portugal.

### DENMARK

Denmark is an exception within the comparatively restrictive Scandinavian countries. In December 2017, the Danish Parliament unanimously voted in favor of a four-year trial period for medical cannabis, creating a domestic market and future export possibilities.

Denmark is also an exception on a continent with several examples of countries that approve a medical cannabis law but fail to establish and develop their markets. Its pilot program started in January 2018, and in just one year, a small internal market was developed and a comparatively solid framework with domestic and export sales was created.

### PRODUCTS AVAILABLE AND PRICE

Cannabis products available to Danish patients are categorized as follows:

- Pilot project (forsøgsordning): As of the second half of 2018, two Bedrocan chemovars of flowers (imported from the Netherlands) and three Stenocare oral solutions (produced by CannTrust and imported from Canada) were available to patients as part of the program<sup>1</sup>. CannTrust is the only case we're aware of that has medical cannabis sold in the European Union that isn't manufactured in an EU-GMP-certified facility.
- Dronabinol preparations (magistrel).
- Products with marketing authorization (godkendt). Sativex is currently the only product in this category.
- Compassionate-care products (udleveringstilladelse): Marinol and nabilone are included in this category.

### PRICE

Bedrocan flower is imported from the Netherlands and sold under the pilot project for 157.20 Danish krone (21 euros or US\$24) and 40-milliliter Stenocare drops are sold for 2742.30 krone.

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 that spending cap will result in no reimbursement.

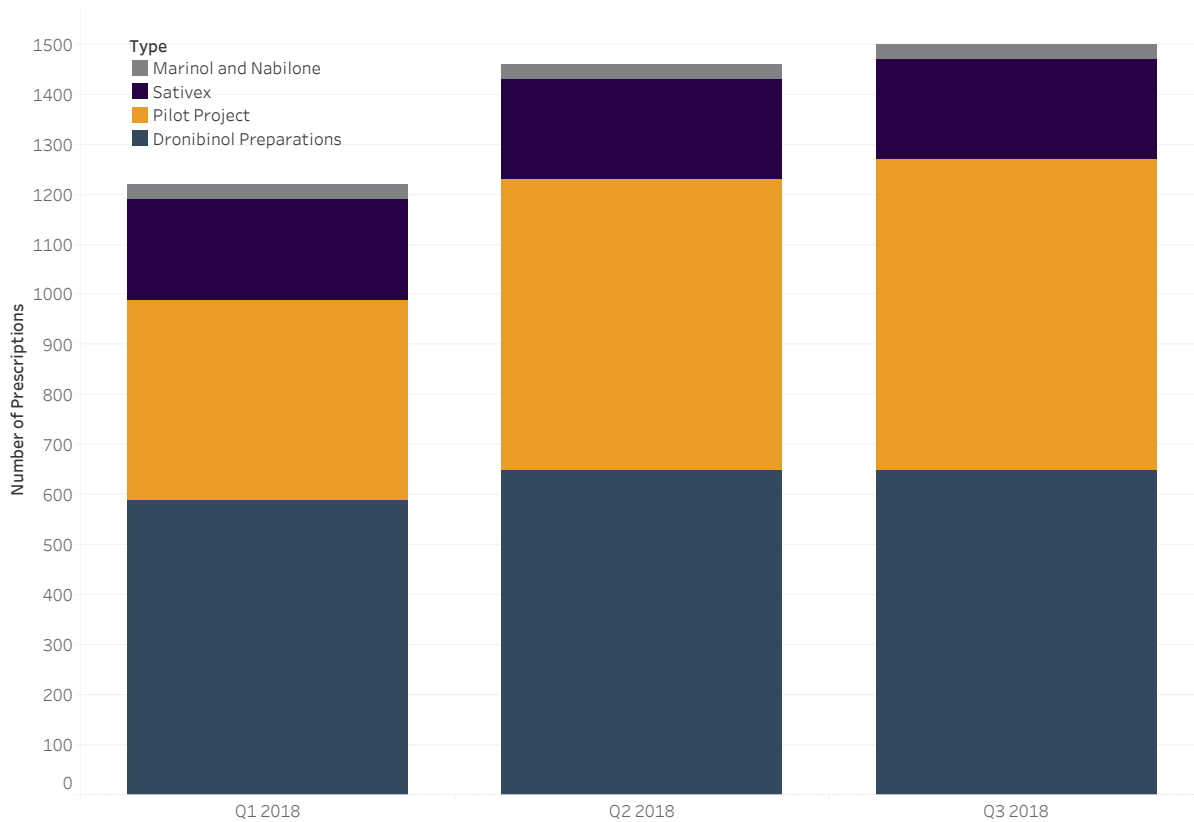
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<sup>1</sup> <https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis/companies/pilot-programme/list-of-admitted-cannabis-products/>

## DOMESTIC MARKET SIZE

For the first nine months of 2018, 700 patients received a prescription for flower or full-spectrum oil under the pilot project, while 800 patients received prescriptions for dronabinol preparations and 268 patients were prescribed a finished pharmaceutical product. [Data for the fourth quarter was not available at deadline for this report.]

### Number of Medical Cannabis Prescriptions by Type in Denmark



Source: Denmark's Health Data Agency (Sundhedsdata-styrelsen)  
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Opposition from the Danish College of General Practitioners (Dansk Selskab for Almen) has been notorious since the beginning. They discourage doctors from prescribing products that have not undergone clinical trials.

In January 2019, one year after implementation of the medical cannabis program, Andreas 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 right skills and, with so few patients, it's hard to gain experience about the effects of cannabis treatments.

In theory, 24,000 doctors could prescribe, but as of February 2019, the position of doctors remained largely against prescribing.

## COMMERCIAL OPPORTUNITIES

Imports to Denmark for the domestic market is possible. Companies wishing to do so must apply to be included in the Danish Medicines Agency's list. This is how the Danish Medicines Agency describes the import process<sup>2</sup>:

Most companies, especially international ones, are focused on exporting from Denmark to the rest of the EU, setting up large production facilities to achieve this. By amending the pilot-project law at the end of 2018, bulk exports were approved to begin in January 2019.

<sup>2</sup> <https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis/citizens/graphical-overview-of-the-medicinal-cannabis-pilot-programme/>

Unlike the Czech Republic, Germany or the Netherlands, applications for cultivation and manufacture in Denmark are received by authorities on an ongoing basis at least during the four-year pilot project. According to Danish authorities, it usually takes two to three months to grant a license after receipt of an adequate application.

As of March 6, 2019, Denmark had:

- 22 granted licenses.
- 10 pending licenses.
- 8 refused or expired licenses.
- 3 withdrawn licenses.

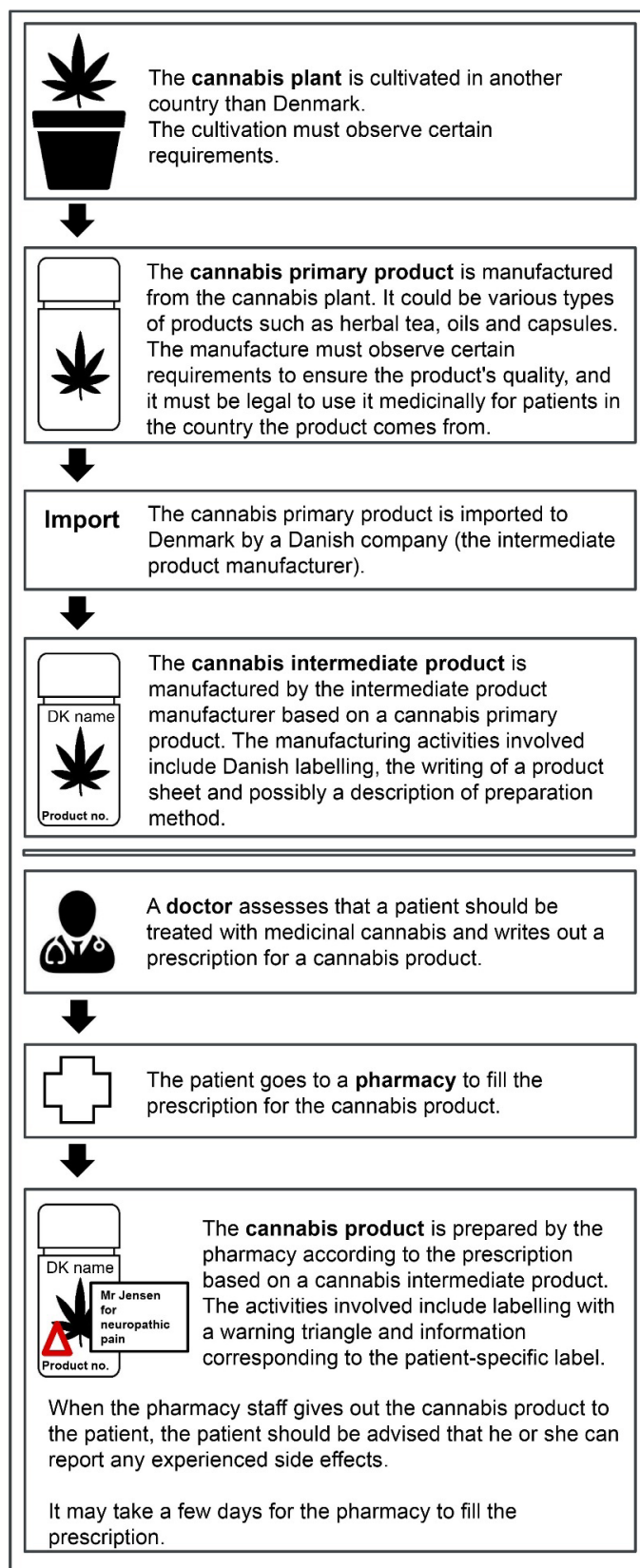
Canadian companies with Danish projects include:

- Canopy announced in December 2017 a joint venture with Danish Cannabis ApS. In June 2018, it shipped the first clones from partner Alcaliber in Spain to Canopy's Danish facilities.
- CannTrust announced in March 2018 a joint venture with Stenocare. In July 2018, the company received approval to sell CannTrust products in Denmark, and the first oils were shipped from Canada to Denmark in September 2018.
- Aurora announced in January 2018 a joint venture with Alfred Pedersen & Son. The company shipped the first cultivars from Canada to Denmark in August 2018.
- Aphria announced in September 2018 a partnership with Schroll Medical. The first clones were shipped from Canada to Denmark in February 2019.
- Indiva signed a nonbinding letter of intent to acquire a medical cannabis cultivation and handling license in Denmark from AEssence Europe.
- The Green Organic Dutchman announced in June 2018 a joint venture with Knud Jepsen. The company received its license in January 2019.

## 2019

As of early 2019, Denmark has a framework that allows imports for the domestic market as well as cultivation, manufacture and distribution—both for the domestic market and for export.

Several international cannabis companies are setting up large facilities in Denmark with the objective to export to the rest of Europe. Good Agriculture and Collection Practices (GACP) certification for cultivation and GMP for manufacture is necessary, so it remains to be seen which companies are successful in obtaining it within 2019 to start sales of domestically produced products.



# PORTUGAL

Portugal, internationally known for its pioneering drug policy reform that in 2001 decriminalized all drugs, had no medical cannabis framework until very recently.

In June 2018, a bill presented in the Parliament in January became law, legalizing medical cannabis, including the prescription of medical cannabis and sales in pharmacies. It did not allow for cultivation at home. The law was regulated in January 2019 with Decree 8/2019.

The National Authority of Medicines and Health Products [Infarmed] is responsible for regulating and implementing most aspects of the framework, including the types of products that may be prescribed, the conditions, all licensing issues, imports and exports.

Several companies claim to be at some stage of licensing in Portugal. Tilray, already operational, appears to be the leader, but the company still must obtain EU-GMP certification for its facility to be able to sell—which it expects to obtain from Infarmed in 2019.

While Canopy, Aurora and Aphria expect to use Denmark as a European export hub, Tilray has been working in Portugal since 2017, with the goal of having their Portuguese facilities to be the “primary supply source for patients in the European Union.”

Flower, another Canadian firm, acquired a stake in Holigen, a Portuguese company that said in December 2018 that it was “in the final stages of obtaining a license.”

Aurora announced in February 2019 that it acquired 51% of a “license applicant.”

The first company to be licensed, under a previous framework, was Terra Verde. The company was created with the goal of shipping cannabis to the United Kingdom for GW Pharmaceuticals to manufacture medicinal products. The deal fell apart, and the company never grew any cannabis.

Cannabis may be prescribed only as a last-resort option and only for seven conditions that were approved in January 2019:

- Spasticity associated with multiple sclerosis
- Nausea and vomiting caused by chemotherapy or radiotherapy
- Appetite stimulant for cancer or HIV patients in palliative care
- Chronic pain associated with oncologic disease or to the nervous system
- Tourette syndrome
- Refractory epilepsy in children
- Drug-resistant glaucoma

Smoking is discouraged.

## 2019

The domestic market still is nonexistent as of early 2019, as no product has been imported or made locally available for prescription.

# GREECE

In March 2018, Greece legalized medical cannabis with an amendment to its law on addictive substances. The reform allows the integrated cultivation and production of high-THC cannabis. The products may be sold only to the state monopoly for Greek patients or exported to countries that allow medical imports of cannabis.

In mid-2018, two important regulations were issued:

- The Joint Ministerial decision, 51483/700/ 15, defined the terms and procedures for cultivation and processing of medicinal cannabis.
- The Ministry of Health decision, Δ3[ ]52588, on the terms and conditions for the production and distribution of medicinal cannabis end products.

Companies must be vertically integrated, and licenses are nontransferable.

The Scientific Committee of the National Organization of Medicines (EOF) concluded that medical cannabis end products can be prescribed for:

- Prevention and treatment of side effects of chemotherapy.
- Neuropathic or cancer pain that does not respond to other treatments.
- Spasticity and pain in patients with multiple sclerosis.

Dozens of companies have applied for licenses, including Israeli company Tikun Olam and Canada's The Green Organic Dutchman and HEXO.

As of early 2019, no company is fully operational. Companies that claim to have licenses are permitted only to set up facilities to become operational (which includes obtaining EU-GMP certification) and produce cannabis for commercial purposes.

Greece still doesn't have a domestic market, as no products are available and nothing has been prescribed.

## 2019

This will be the year in which leading companies will likely be able to become fully licensed, as opposed to those that are just starting the process. Access to patients, now unavailable, likely will also see changes, but it's unrealistic to expect fully licensed and operational companies harvesting for the national market or export before the end of the year.

# MALTA

As of early 2019, Malta has one of the most favorable European governments to medical cannabis. The Drug Dependence Act [treatment not imprisonment] was amended in March 2018, creating a medical cannabis framework that allows patients to access medical cannabis with a doctor's prescription. One month later, the Production of Cannabis for Medicinal Use Act was approved, creating the production framework that allows companies to apply for licenses to produce medical cannabis in Malta.

## DOMESTIC MARKET

Only 3.55 kilograms of cannabis was imported in 2018 by the following Maltese pharmaceutical importers and distributors:

- Cherubino imports from Aurora's German subsidiary Pedanios.
- PharmaMT imports from Bedrocan, through the Office of Medical Cannabis of the Netherlands.

## COMMERCIAL OPPORTUNITIES

Any company can apply for an import permit, but as is the case in all EU countries, the products to be imported must have EU-GMP certification.

The comparatively favorable corporate environment, an English-speaking population and a government that promotes the development of the industry attracted several international cannabis companies to the small island in 2018, including several Canadian producers, companies traded in Australia, Israeli companies and even one U.S. operator.

Investors should be aware that several companies drafted news releases after obtaining letters of intent from Malta Enterprise without clarifying that it's just the first step in the process. A license from Malta Medicines Authority is also required before companies will be allowed to produce for commercial purposes.

These were a few of the announcements of 2018 and early 2019:

- MGC Pharma in April 2018.
- Wayland [formerly known as Maricann] in July 2018.
- Aurora Cannabis in July 2018.
- Columbia Care in November 2018.
- Affinity Energy & Health in December 2018.
- Supreme Cannabis in March 2019.

Of all these announcements, only the last one, Supreme, was fully transparent about the stage in the licensing process. All the other companies were misleading with the titles and/or content of their news releases.

Israeli company Alvit LCS Pharma claims on its website to also have a letter of intent (LOI) with Malta Enterprise.

Aphria, through the acquisition of Nuuvera, owns ASG Pharma, an EU-GMP-certified Maltese laboratory. ASG Pharma's GMP certificate allows the company to import, but the manufacturing certification includes only "batch certification" and "quality control testing," which suggests the company could use Malta as an import/export hub. Unless they also secure an LOI with Malta Enterprise and a manufacturing license, they won't be able to manufacture in Malta.

Zenabis claims in its website to have a "conditional approval to develop production and processing facility in Malta."

Cultivation and manufacture of cannabis in Malta must be carried out within designated industrial zones and under strict security measures. EU-GMP certification is needed for manufacturing, and cultivation of cannabis to be used for manufacturing in Malta, whether domestic or foreign, must be GACP certified. Export from Malta of finished products intended for medicinal use is also possible.

To obtain a license to produce medical cannabis for commercial purposes in Malta, the following three steps must be followed:

1. Obtain a letter of intent from Malta Enterprise, the Maltese government's agency focused on attracting investment. As of November 2018, 10 companies had LOIs and another 10 were rejected.
2. Have facilities fully compliant with all relevant regulations, including operationally ready for EU-GMP certification.
3. Apply for a license to Malta Medicines Authority.

## 2019

Several companies have already signed LOIs with Malta Enterprise and are preparing their facilities, meaning the market may see its first fully licensed cannabis manufacturers before the end of the year. Malta's small domestic market will also continue to evolve.

# NORTH MACEDONIA

North Macedonia legalized medical cannabis in early 2016, becoming another country with a small national market but a framework that could turn it into a key European exporter.

The reform allowed for the cultivation, production and distribution of medical cannabis by amending the existing Law on Control on Opioid Drugs and Psychotropic Substances.

Instead of passing a new law, the existing statute that regulates drug control was amended, meaning that cannabis regulations ended up being similar to those that allow the cultivation of opium, with few additional requirements. After obtaining a license, companies must ask for special permission from the Ministry of Agriculture before planting.

Active companies include NYSK Holdings, Freyherr, Replek Farm, Oaza Alkaloidi and 5 Letters. Macedonia isn't part of the European Union, which means a Macedonian GMP certification is unlikely to be sufficient to export to an EU country. The European Medicines Agency doesn't show any mutual recognition agreement with North Macedonia<sup>3</sup>.

Applications for licenses are accepted on an ongoing basis. Applicants must employ at least four people, including a pharmacist and an agriculturist with a minimum of three years of experience.

Cultivation must take place in an area with atmospheric protection and adhere to strict security requirements, including:

- A 4-meter-high fence, topped by three rows of barbed wire.
- 24-hour video surveillance over the entire space.

The Ministry of Health is responsible for the applications.

Oncologists, neurologists and infectious disease specialists who work in the public health system (not in the private system) are allowed to prescribe medical cannabis. Only four conditions are approved: HIV, multiple sclerosis, epilepsy and cancer.

Small quantities of Bedrocan products are imported to North Macedonia through the Dutch Office of Medical Cannabis.

## 2019

With several companies already fully licensed and operational, 2019 may be the year in which the first companies in North Macedonia obtain EU-GMP certification, which would allow them to export medical cannabis to EU countries.

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<sup>3</sup> <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra>

# CHAPTER 9

## OTHER MARKETS

### NEW MARKETS TO WATCH FOR IN 2019

There are several markets that we haven't addressed yet that have the potential to make a significant difference in the European medical cannabis landscape. These include the United Kingdom, Poland, France and Spain, not only because of their combined gross domestic product (GDP) and populations but also because:

- Poland already has a framework in place that allows imports, but the program is in its very early stages. 2019 will be crucial to assess how it will evolve.
- The U.K. surprised many when it legalized medical cannabis in 2018. Like Poland, the country is still in a very early stage. The final guidelines for prescription are expected in October 2019, which will significantly impact the market's development, as they are expected to include a cost-benefit analysis of cannabis products.
- France has no medical cannabis program, but a government-mandated committee is studying the issue. Preliminary recommendations included creating a medical cannabis framework. Final recommendations are expected in November 2019.
- Spain has no domestic medical cannabis program allowing doctors to prescribe, but a few companies have production licenses. With neighboring Portugal advancing more rapidly with cannabis regulations, we expect in 2019 to gain more clarity regarding the licensing system in Spain.

### POLAND

Medical cannabis was legalized in November 2017 through an amendment of the law on prevention of drug abuse [Ustawa o przeciwdziałaniu narkomanii]. Imports are regulated by a pharmaceutical law [Prawo farmaceutyczne].

The Polish framework allows for import of medical cannabis but not local cultivation. Hemp for industrial purposes is the only cannabis product allowed to be grown in country.

Importers must get a license for the products they want to import, which is valid for five years.

Imported products are distributed through wholesalers to pharmacies which, as is common in Europe, are expected to process it as magistral preparations. Grinding the flower, performing physical and chemical operations or repackaging is enough to comply with this requirement.

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

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

In the case of individual importation, patients can apply to the Health Ministry for individual 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 tag makes it unaffordable for most patients.

Cronos announced a distribution agreement with a Polish pharmaceutical wholesaler, Delfarma, in June 2018. The company's latest management discussion and analysis, filed March 26, clarified that the "Company and Delfarma are currently in the process of obtaining the necessary regulatory approvals to sell cannabis products in Poland."

Aurora announced in October 2018 that it had received approval for a first shipment of cannabis products to Poland.

Canopy announced its first import to Poland in January 2019. Local media reported that the shipment consisted of 7 kilograms. The retail price in pharmacies would be 65 Polish zloty [15 euros or US\$17], and pharmacists can order from a central warehouse only after patients show the necessary prescription.

## UNITED KINGDOM

In November 2018, the U.K. became one of the latest European countries where it is legal for doctors to prescribe medical cannabis, but access has been extremely rare as of March 2019. No National Health Service (NHS) prescriptions are known to have been issued so far, and only a handful of patients have accessed it privately.

In June 2018, the Home Office launched a review of medical cannabis, and one month later, the Home Secretary announced the rescheduling of cannabis to “help patients with exceptional clinical need.” While the initial rules were developed, doctors could apply to a panel on behalf of patients to seek authorization for import. Only limited cases were successful.

“Cannabis-based product for medicinal use in humans” was defined as:

“a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which—  
[a] is or contains cannabis, cannabis resin, cannabidiol or a cannabidiol derivative (not being dronabinol or its stereoisomers);

[b] is produced for medicinal use in humans; and—

[c] is— (i) a medicinal product, or (ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product.”

And the following the three ways of access were defined:

1. “A special medicinal product for use in accordance with a prescription or direction of a doctor (who has made the decision to prescribe) on the Specialist Register of the General Medical Council;
2. An investigational medicinal product without marketing authorisation for use in a clinical trial or;
3. A medicinal product with a marketing authorisation.”

In practice, all products other than Sativex are considered “unlicensed medicines,” restricting the prescription capability to only clinicians listed on the Specialist Register of the General Medical Council.

In November 2018, guidelines about the burdensome importation requirements were published by the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>1</sup>.

The final guidelines for prescription are expected to be published in October 2019 by the National Institute for Health and Care Excellence and will largely determine the future of the market.

Domestic cultivation is legal only if carried out under a Home Office license.

The U.K. 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 company is currently pursuing European marketing authorization.

Sativex is authorized in the U.K. but not covered by the NHS in England, as it is not considered “a cost-effective treatment.”

## FRANCE

As of early 2019, France doesn’t have any medical cannabis program. Only Sativex is allowed, but it is not commercialized.

Authorities are considering adopting regulations to create a comprehensive medical cannabis framework. In September 2019, the French National Agency for the Safety of Medicines and Health Products (ANSM) tasked a committee with:

- Evaluating scientific data related to medical cannabis.
- Assessing the experiences of other countries that have implemented such a program.
- Considering patient experiences and feedback in other markets.

<sup>1</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/752796/Cannabis\\_Guidance\\_-\\_unlicensed\\_CBPMs\\_-\\_Final\\_311018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/752796/Cannabis_Guidance_-_unlicensed_CBPMs_-_Final_311018.pdf)

The committee reached its first conclusions in December 2018, recommending the use of medical cannabis in certain restrictively defined cases.

Final recommendations are expected in 2019, which could be a turning point for France. After the final recommendation, a parliamentary process to create a law will likely be needed, so implementation of a medical cannabis program before the end of the year is unlikely.

## SPAIN

No doctor can prescribe nonpharmaceutical medical cannabis in Spain and no products are available, but the country allows the cultivation of medical cannabis in certain cases.

Law 17/1967 allows cultivation in Spain as long as authorization from the Ministry of Health – in practice, the Spanish Agency of Medicines and Medical Products (AEMPS) – is obtained.

Because Spain has no medical cannabis program, what's produced for commercial purposes would have to be exported, but as of early 2019, we're not aware of any exports of cannabis other than clones sent by Alcaliber, Canopy Growth partner in Spain, to Denmark.

According to a government reply to parliamentary questions, as of the end of 2018, the AEMPS had granted eight authorizations to seven companies or organizations:

- Five for research, of which one was for hemp.
- One for educational purposes.
- Two for medicinal purposes, of which one was for the production and export of seeds and clones, and the other for the production and manufacture of cannabis and its derivatives.

Of all the previous authorizations, only these were valid as of end of 2018:

- Cáñamo y Fibras Naturales, S.L. [Cafina]
- CIJA Preservation, S.L.
- DJT PLANTS
- Phytoplant Research, S.L.
- Universidad Politécnica de Valencia
- Alcaliber S.A.–the only company with a license for production of medical cannabis and its derivatives

Canopy Growth announced in September 2017 a supply agreement with Alcaliber and transferred genetics to the Spanish pharmaceutical company in March 2018.

Different media outlets have reported that thousands of hectares are licensed in Spain for the cultivation of cannabis, but the AEMPS said in January 2019 that for the period 2018-2019, the agency had authorized a total cultivation area of 4.03 hectares (40,326 square meters).

- 2.31 hectares for research purposes, in the regions of Andalusia, Catalonia and Valencia.
- 1.72 hectares for medicinal purposes in the region of Murcia.

Sativex is the only product with a marketing authorization in Spain. Epidiolex, nabilone and dronabinol may be imported in exceptional cases.

Decriminalization in Spain allowed the culture of cannabis social clubs to thrive, especially in Catalonia. These nonprofits work within a legal gray area and don't represent a fully legal, scalable business opportunity.

## OTHER SMALL MARKETS

### Switzerland

Switzerland generally allows any product with less than 1% THC to be sold legally, which has created a comparatively big CBD market.

The country also has a medical cannabis program, and doctors have been able to prescribe medical cannabis since 2011, though only in exceptional cases.

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 to the FOPH on behalf of their patients to access medical cannabis magistral preparations under prescription. Patients must consent to the treatment.

Very few pharmacies sell medical cannabis. The only products available under the special authorization program are dronabinol preparations, cannabis tinctures and cannabis oils. The last two of these products are prepared with plant material sourced from a small domestic cultivation.

Official data about the number of patients, prescriptions or quantities sold isn't publicly available, but we estimate that only a few hundred patients actively access medical cannabis, as the paperwork for the exceptional authorization is burdensome and health insurers are not obligated to cover the cost.

On-label prescription of Sativex does not require FOPH approval.

### Croatia

Croatia has a comparatively old medical program, having passed a law in October 2015.

The first shipments of medical cannabis from Canada to Europe occurred in June 2016 and included two varieties of capsules being shipped to Croatia.

Without health insurance coverage, the market has been slow to develop. We estimate that sales in 2018 were insignificant.

According to recent local media reports, a handful of doctors prescribe for only a few patients because most cannot afford legal products. No product was available in pharmacies as of early 2019.

## Luxembourg

Luxembourg legalized medical cannabis in mid-2018.

The law mandates that cannabis can be prescribed only to treat serious diseases of patients who fulfill at least one of the following:

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

Only doctors that have undergone special training may prescribe.

The following restrictions also apply:

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

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 for 50,000 euros, which should be enough for the country until April 2019.

The current government promised to legalize recreational cannabis within the current parliamentary period.

## Cyprus

Cyprus has had a medical cannabis law since 2017 and an insignificant market that never truly developed.

In May 2017, Tilray's first shipment arrived in Cyprus.

A new law was approved in early 2019, which, according to local media reports<sup>2</sup>, will allow for three licenses to be granted to private companies to produce cannabis in Cyprus to distribute to pharmacies.

## Other countries

In February 2019, a bill was submitted to the Belgian Parliament that would create a "cannabis agency" to retain a monopoly on cultivation and trade.

We're also aware that other European countries, such as Ireland and certain Nordic countries, allow the prescription and importation of medical cannabis for individual patients in very specific cases.

We estimate that this represents no more than a handful of cases in each country and that these jurisdictions don't represent any immediate commercial opportunities in the medical cannabis sector.

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<sup>2</sup> <https://cyprus-mail.com/2019/02/15/house-passes-law-on-medical-cannabis/>