IRISgroup

Medical Cannabis in Denmark

An Industry Analysis - 2022

Danmarks Erhvervsfremmebestyrelse

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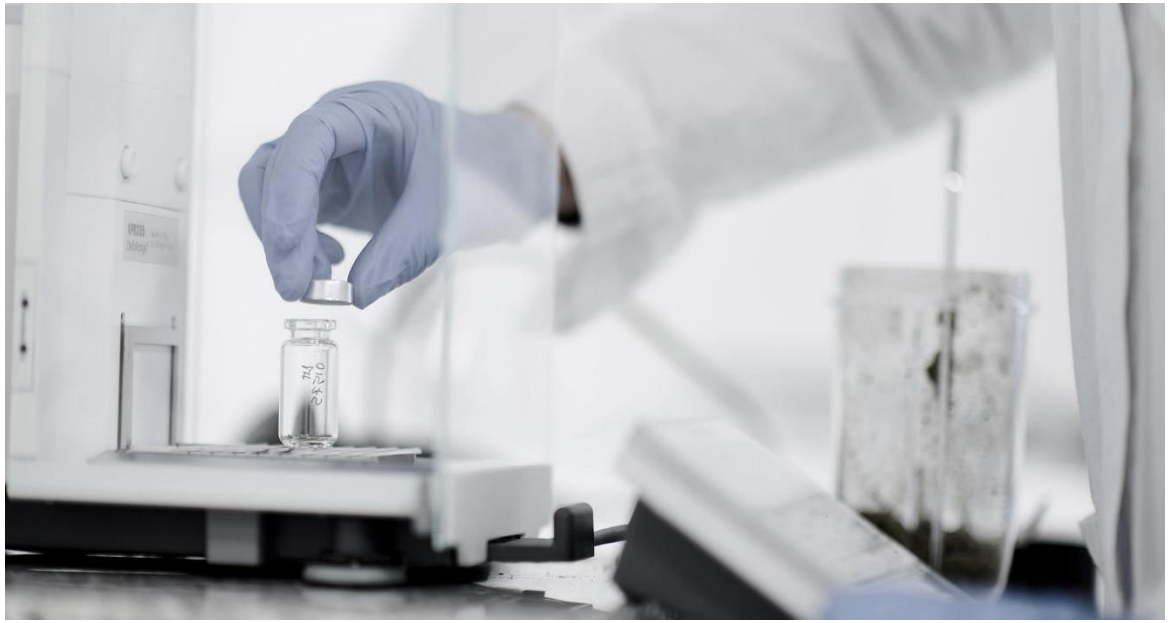
Preface

In January 2018, the Danish government authorised a four-year pilot programme for medicinal cannabis. The pilot permitted doctors in Denmark to prescribe cannabis-based medicines. Companies were also licenced to cultivate cannabis and use it to manufacture medical products. During the pilot, the Danish cannabis industry developed rapidly, and in December 2022 the Danish Parliament unanimously passed new legalisation which will transform the Danish medical cannabis sector from a pilot project to a permanent industry. Denmark is therefore well-placed to see further growth and development in the medical cannabis industry. However, the industry is at present in an early and emergent phase, and there is a need to obtain a better overview of both its current status and future growth potential.

With this in mind, Invest In Odense has commissioned an analysis of the Danish medical cannabis industry that has been prepared in collaboration with the organisation for the medical cannabis industry in Denmark. The analysis was carried out by IRIS Group in the autumn of 2021, and its results are presented in this report.

The analysis is based on a questionnaire presented to all Danish medical cannabis companies licensed by the Danish Medical Agency to cultivate cannabis and produce medical cannabis products, interviews with Danish company representatives and key actors, and desk research into existing studies and growth forecasts.



Reading guide

The report contains an executive summary and four chapters:

- Chapter 1 presents an introduction to medical cannabis and an overview of the legal framework in Denmark and Europe.
- Chapter 2 details the companies currently operating in the industry, and how they view the framework conditions and ecosystem for medical cannabis in Denmark.
- Chapter 3 focuses on the industry's future growth potential, including potential barriers to expansion, and highlights initiatives that would strengthen the Danish medical cannabis industry and ecosystem.
- Chapter 4 presents four cases from different parts of the Danish medical cannabis ecosystem. An appendix is attached with fuller details of the data and the methods used in the analysis.

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IRIS GROUP

CHRISTIANS BRYGGE 28, 1. SAL

DK-1559 KØBENHAVN V

IRISGROUP@IRISGROUP.DK

WWW.IRISGROUP.DK

Executive Summary

An overview of the Danish medical cannabis industry

- The Danish medical cannabis industry comprised around 36 companies in the fall of 2021. These included a few large medical cannabis producers, plus a large group of small and newly established companies.
- The large companies and producers are mainly concentrated on the isle of Fyn. Many of the small and newly established companies are in the Capital Region of Denmark.
- The industry employs 286 full-time employees, many of whom work in companies located on Fyn.
- Between 2019 and 2021 the number of full-time employees grew from 152 to 286, an increase of 88%, showing that the industry has expanded considerably since its establishment.

The Danish companies cover all parts of the value chain

- The companies in Denmark cover the entire value chain of the medical cannabis industry.
- Almost half of the Danish companies cultivate medical cannabis, and more than 40% have activities connected with product development.
- Additionally, 30% of the companies are active in genetics or plant breeding, indicating that the Danish medical cannabis industry is grounded in a strong horticultural tradition in Denmark.

An emerging industry with high export potential

- The medical cannabis business remains an emerging industry, and therefore many of the younger companies do not yet have products on the market from which they can generate revenue.
- A large proportion of the industry's revenue derives from export activities, particularly to the German market.
- The Danish market is important for several of the smaller and newly established companies. However, their future growth will primarily be driven by increased exports.

Several large investments in the Danish medical cannabis industry

- Two-thirds of Danish medical cannabis companies (65%) have been able to attract capital investment in the last three years, with 25% receiving either share capital, or seed, venture capital, or loan capital.
- The companies have sourced external capital of approx. DKK 850 million (excluding their founders' own investments) in total over the last three years. Several of the Danish companies are also listed on the stock exchange in Denmark or Sweden.

High growth expectations both globally and in Denmark

- Experts forecast significant international growth in the global medical cannabis industry. It is predicted that on average there will be annual growth of around 19% between 2020 and 2026.
- Danish medical cannabis companies are also expecting to grow significantly over the next few years. By 2024, it is anticipated that the companies operating in Denmark will employ 410 full-time employees. This amounts to a 43% increase in the number of full-time employees in 2021.

Executive Summary

Unique strengths of the Danish medical cannabis industry

- Fyn has a range of local strengths and competencies. These offer a solid foundation for the growth of the Danish medical cannabis industry.
- The strengths lie especially in a robust horticultural tradition, a strong research environment with widespread collaboration between research, industry and the authorities, as well as a broad-based local support.
- At national level, Denmark's vibrant life science sector and the presence of a regulatory framework permanently allowing companies to cultivate and produce medical cannabis without any limits on production capacity will also become important strengths of the cannabis industry.

Extensive collaboration within the Danish medical cannabis ecosystem

- There is extensive collaboration within the Danish medical cannabis ecosystem.
- Nearly all of the Danish medical cannabis companies have participated in a collaborative project on medical cannabis over the past three years.
- There is in general a high level of professionalism within the collaborative project, with a very large majority (approx. 90%) of those surveyed confirming that the cooperative nature of the project has strengthened their business to a great or moderate extent.

The medical cannabis industry is developing towards life science

- Medicinal cannabis is still a relatively young and emerging industry in comparison with the pharmaceutical industry as whole and the life science sector in Denmark.
- However, it is developing fast, and within the sector new evidence and understanding of the efficacy of medical cannabis treatments for various different health conditions is constantly being generated.
- In the next few years, the medical cannabis industry is therefore expected to develop further towards pharmaceutical products and the life science sector.
- This is also reflected in international forecasts, which predict that the primary growth of the medical cannabis industry in Europe in the future will be in sales of extracts and isolates rather than dried flowers.

The Need for more research and harmonised regulation

- Although several clinical studies of the effects of medical cannabis are ongoing, there remains a significant need to initiate and maintain more research and further clinical trials to improve our understanding of the conditions under which medical cannabis works best.
- Access to qualified labour and the harmonisation of regulatory conditions within the EU are also critical factors in the future growth of the Danish medical cannabis industry.

1. Introduction to medicinal cannabis

This chapter gives an overview of medical cannabis from a clinical perspective. It opens with an explanation of what medical cannabis is. That is followed by a brief introduction to the Danish and European legal framework governing medical cannabis. Following this, the prevalence of clinical studies within the field is examined.

The following points can be highlighted:

- Medical cannabis products contains several component chemicals from the cannabis plant, including a wide range of cannabinoids and other chemically active substances. These components are believed to act together in a complex synergy and boost the effectiveness of the medicine. However, this so-called "*entourage effect*" has still not been proven scientifically. Several studies are investigating the mechanism.
- In 2018, the Danish government enacted a four-year pilot programme that allowed doctors in Denmark to prescribe new kinds of medical cannabis product to their patients. In December 2021, the programme was extended for an additional four years.
- Between 2018 when the pilot began and 2020 total sales of cannabis-based medical products in Denmark doubled from DKK 30 million (EUR 4 million) to nearly DKK 60 million (EUR 8 million) in 2020, equivalent to an increase of 100%.
- Germany is the largest European market for medicinal cannabis. In 2021, German doctors issued more than 300,000 prescriptions for cannabis-based medicines.
- The number of clinical studies on medical cannabis has increased significantly over recent years. Between 2014 and 2017 there were around 15 clinical studies per year. These focused on cannabidiol. In 2021, by contrast, there were more than 90 clinical studies taking place around the world, primarily in the US.

Defining medical cannabis

Medical cannabis products contain either parts of the cannabis plant or active substances derived from the plant, including a wide range of cannabinoids and other chemically active substances such as terpenes and flavonoids.

Medical cannabis is used to alleviate illness and to improve patients' quality of life. The effects of the cannabis plant arise from chemicals know as cannabinoids. There are more than 100 types of cannabinoid present in the plant. These have different effects on the human body when consumed. The two best-known cannabinoids are tetrahydrocannabinol (THC) and Cannabidiol (CBD). THC is the psychoactive compound in the cannabis plant, whereas CBD does not produce any psychoactive effects when consumed.

Medical cannabis products range from dried cannabis flowers to cannabis oils, capsules, tablets etc., as illustrated in the figure. The commonest product is dried flowers. Patients can consume these in various ways. It's also possible to extract cannabis oils from dried cannabis flower to produce oil-based products and tablets or capsules. Additionally, it's possible y to manufacture cannabinoids isolates.

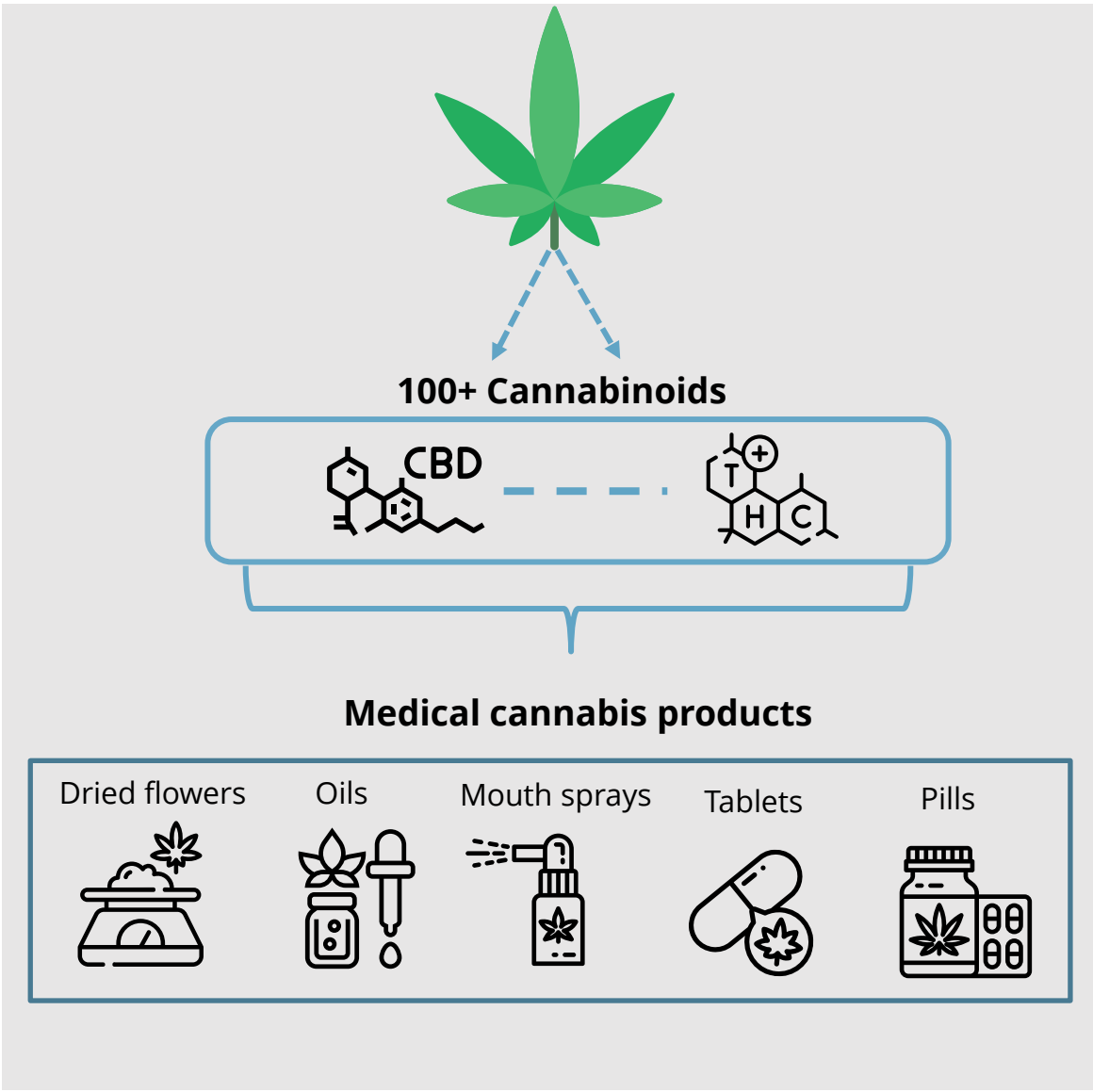
Medical cannabis and pharmaceutical cannabis

It is important to distinguish between two broad categories of medicinal cannabis product:

- **Pharmaceutical cannabis products** consist of individual components found in the cannabis plant. They may incorporate synthetically produced THC or CBD. Examples here are the medicines Sativex® and Epidyolex®. These are authorised medicines that have been tested in controlled laboratory conditions and approved by national health authorities as medicines.
- **Medical cannabis products** contain various components from the cannabis plant, including a wide range of cannabinoids and other active substances such as terpenes and flavonoids. Full-spectrum medical cannabis products with these active substances may boost the effectiveness of a medicine via an entourage effect.

The entourage effect refers to potential synergistic effects given by combinations of different components - cannabinoids, terpenes and flavonoids – in medical cannabis products. Such an effect has still not been proven scientifically, but several ongoing studies are investigating the mechanism.

Illustration of medical cannabis products



Regulatory Framework for prescribing medical cannabis in Denmark

In January 2018, the Danish government launched a four-year pilot programme for medicinal cannabis during which doctors in Denmark would be permitted to prescribe cannabis-based medicines. In December 2021, the pilot programme was extended by the government for four more years. Doctors in Denmark have several options when prescribing cannabis-based medicines:

- **Authorised medicines:** Authorised cannabis-based medicines are products that have been tested under controlled conditions in a laboratory. Two medicines of this kind (Sativex® and Epidyolex®) are currently available on the Danish market.
- **Non-authorised medicines issued by doctors on compassionate grounds:** Products that are authorised in other countries but not in Denmark.
- **Magistral preparations of cannabis:** A magistral preparation is made by a pharmacy for a specific patient according to the doctor's instructions.
- **Medicinal cannabis products under the pilot programme:** Medical cannabis products admitted on the Danish Medicines Agency's list of approved products.

Between the start of the trial period in 2018 and 2020, total sales of cannabis-based medical products in Denmark rose from DKK 30 million to nearly EUR 60 million. The majority of sales in Denmark involve magistral products, followed by authorised medicines.

Framework for medical cannabis in Europe

In recent years, several European countries have moved towards the legalisation of medical cannabis. However, the European market for cannabis-based products is still relatively young and there is significant variation in the legislative frameworks of different European countries. The differing rules and regulations make it very difficult for medical cannabis companies to navigate the European market.

Several large countries in the EU, such as the United Kingdom, adopted legalisation in 2018 making it legal to prescribe medical cannabis products. Last year France initiated a two-year trial of these products. Germany is the largest European market (see p. 9) for medicinal cannabis. In Germany, there is a limitation on production capacity and they therefore import medical cannabis products from several other European countries.

Widespread use of cannabis-based medicines in Germany

Looking at Europe, we see that Germany is the country with largest sales of cannabis-based medicines. In 2019, Germany accounted for more than half of the total sales of cannabis-based medicinal products in Europe. Italy is the second largest European market, followed by Denmark and the Netherlands.

The use of cannabis-based medicines in Germany has increased over recent years. Between 2018 and 2020 the number of prescriptions for cannabis-based medicines increased from approx. 185,000 prescriptions to more than 340,000.

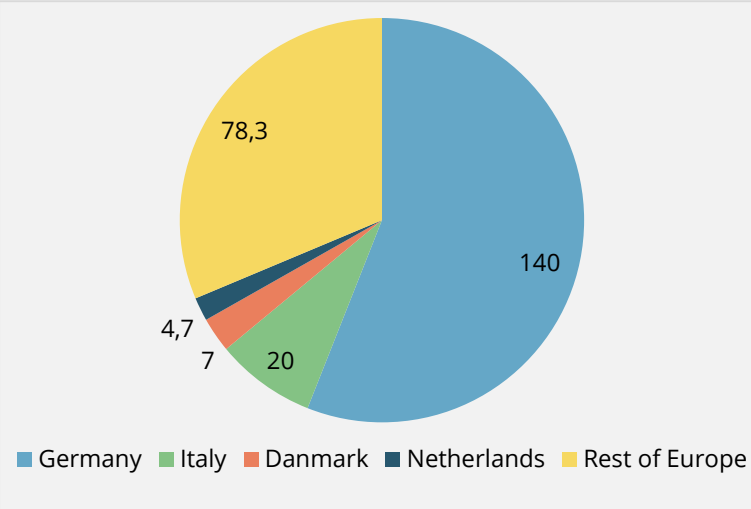
The main product sold in Germany is dried cannabis flower. This makes up just over half (54%) of the German market, as shown in the figure (bottom, left).

This is followed by isolates, which account for 28% of the market, while authorised products and (especially) full spectrum extracts occupy more minor shares of the market.

Germany relies on imports of large volumes of medical cannabis products as there is a limitation on the amount national companies may produce. A large share of the products sold on the German market are imported from other European countries.

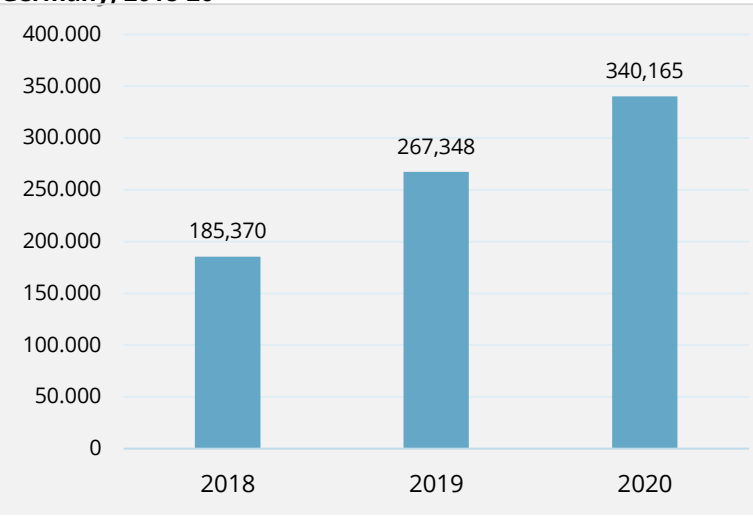
Cannabis flowers produced by Danish companies make up 19% of German imports of cannabis flowers, as shown in the figure (bottom, right).

Retail sales of cannabis-based medicine, Europe, million euros, 2019



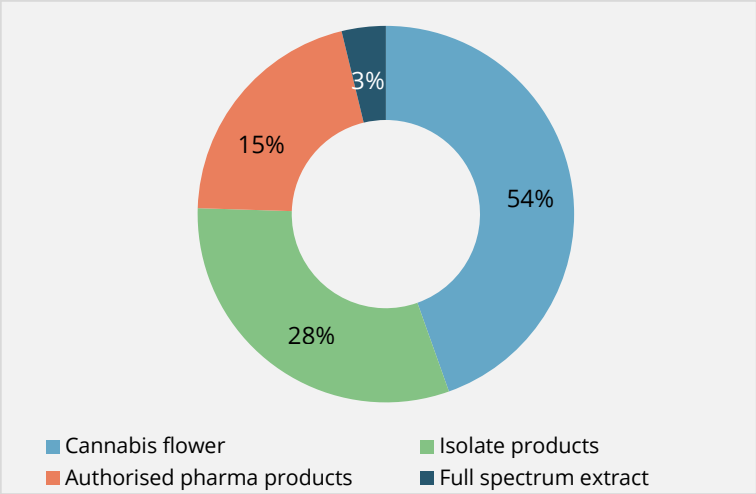
Source: KOMAND Consulting (2020).

Total numbers of cannabis-based medicine prescriptions, Germany, 2018-20



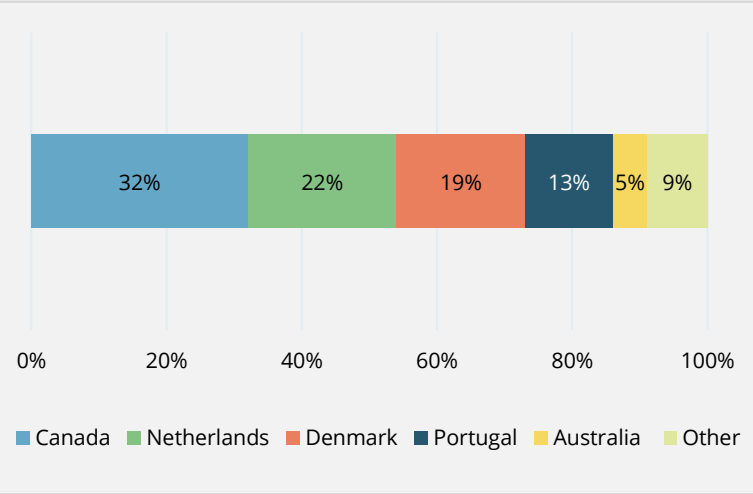
Source: Branchenverband Cannabiswirtscha e.V. (2021).

Retail sales of cannabis-based medicine, Germany, by product type, million euros, 2019



Source: KOMAND Consulting (2020).

German imports of cannabis flowers in the first half of 2021, by exporting country, percentages



Source: Cannabis Business Industry Association e.V. (2021).

Increased interest in cannabis-based medicine as a treatment for patients

There is increasing interest in cannabis-based medicines, both in Europe and around the World.

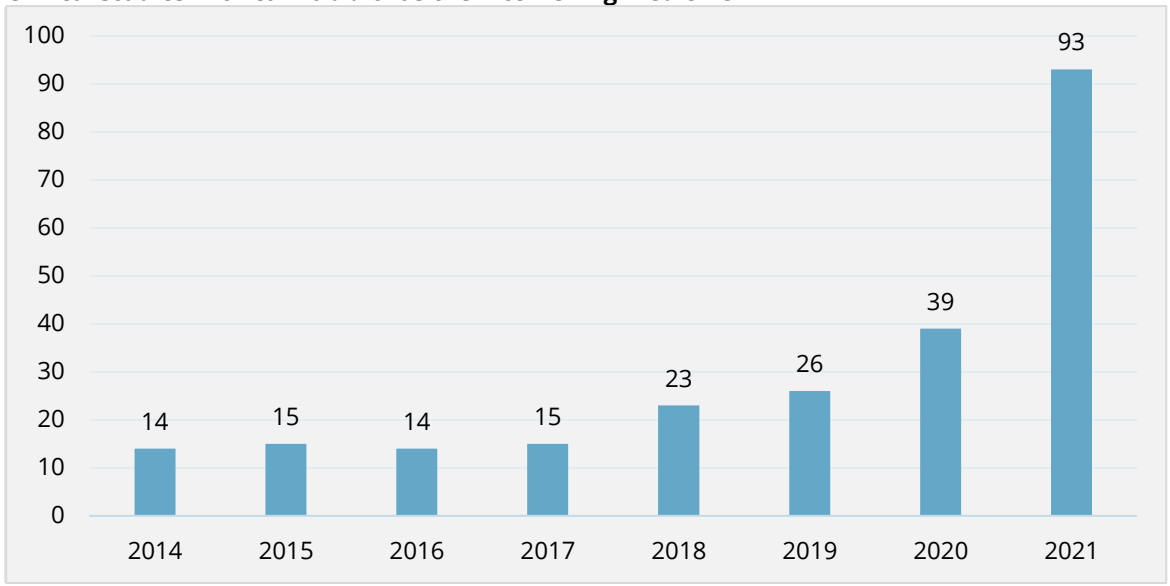
Many countries have integrated medicinal cannabis into their health care scheme or initiated regulatory pilots in order to assess the potential advantages of medical cannabis, as described on the following page.

The increased interest is evident from the number of clinical studies on cannabis, i.e. trials in which cannabidiol is used as the intervening medicine. The figure to the right shows numbers of these over an eight-year period.

The following points can be highlighted:

- In the period 2014-17 there were around 15 clinical studies using cannabidiol per year.
- From 2018 onwards the number of studies increased significantly. In 2021, there were more than 90 clinical studies taking place around the world.
- The majority of studies (approx. 60%) are being conducted in America. This is not surprising as several US States legalised cannabis some years ago.
- In Europe, most of the studies are conducted in the UK, France, Germany, Spain and the Netherlands.

Clinical studies with cannabidiol as the intervening medicine



Source: Clinicaltrials.gov
Note: The figure is based on clinical studies registered in the Clinical Trial database, where cannabidiol is used as an intervening medicine. The database contains both private and publicly funded clinical trials conducted worldwide. However, it should be noted that the database does not cover all clinical trials of medical cannabis products in the world.

About clinical trials

In clinical trials of medicinal cannabis products human volunteers are given cannabidiol in accordance with a protocol, outlined by the research leader, and are then evaluated for effects on biomedical or health outcomes.

The major advantage of clinical trials is that they typically involve a control group of patients who receive a placebo. This makes it possible to better isolate the effects of the cannabis-based product, and to attribute any positive effects on the patients to it. Because of this, clinical trials play a major role in the advancement of medical cannabis products, since it is essential that we improve our understanding of the effects of the medicines.

The clinical studies focus on ill-health of various kinds. A large share of them investigate issues related to psychotic and mental disorders as well as pain management. Many of the studies involve authorised medicines such as Epidiolex ®. The studies focus primarily on cannabis-based medicines containing synthetically produced THC or CBD.

2. The Danish medical cannabis industry

In the overview of the Danish medical cannabis industry that we present in this chapter, the results to which we refer are based on a survey of Danish companies.

First, we describe the value chain and ecosystem for medical cannabis in Denmark. We then offer an analysis of the typical company profile in this sector, covering age, size and geographical location. The chapter also looks at the collaborative relations between medical cannabis companies and other actors, and it considers the amount of capital attracted by Danish companies.

The following points can be highlighted:

- In the fall of 2021, 36 Danish medical cannabis companies were licensed by Danish Medical Agency to cultivate and handle cannabis. The companies occupied points throughout the entire value chain of the medical cannabis industry.
- Most of the medical cannabis companies were established in Denmark in 2017, 2018 or 2019, after the Danish government introduced the medicinal cannabis trial programme.
- The industry consists of a few large medical cannabis producers together with a large group of small and newly established companies. Half the companies have up to 5 employees and only 15% have more than 25 employees.
- The large companies and producers are concentrated on Fyn. Many of the smaller, newly established companies are in the Capital Region of Denmark.
- In total, the industry employs 286 full time employees, many of whom work in companies on Fyn. Between 2019 and 2021 the number of full-time employees rose from 152 to 286, an increase of 88%, showing that the industry has expanded considerably since its establishment.
- Just over half of Danish medical cannabis companies (65%) have been able to attract capital of various kinds over the last three years. In total, Danish companies have received external capital of approx. DKK 850 million (excluding founders' own investments) over this period.

The regulation of medical cannabis in Europe

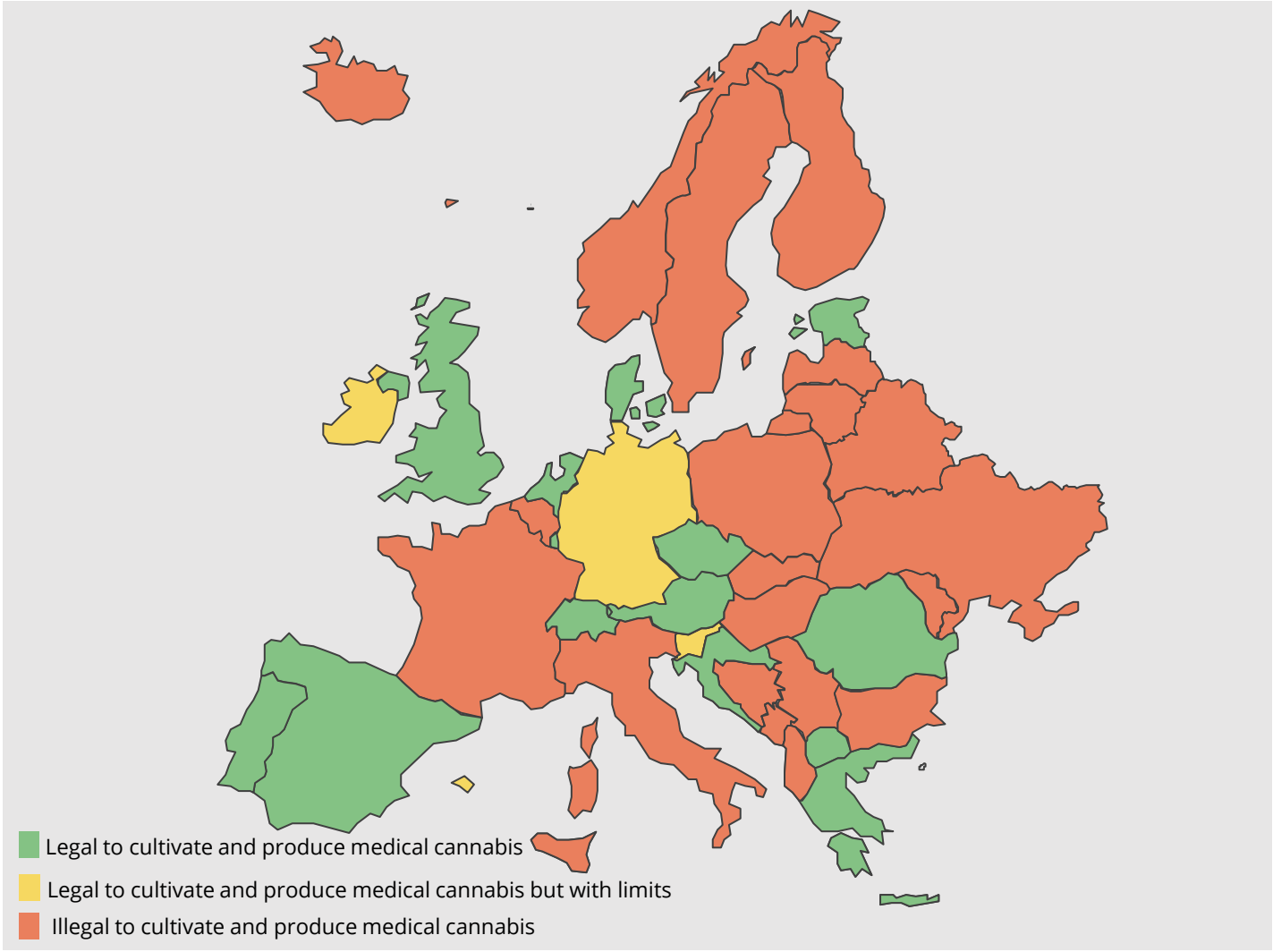
This reports presents an analysis of the medical cannabis industry in Denmark, but we also make some international comparisons. In 2021, the Danish government passed new legalisation making the cultivation and production of cannabis products permanently legal in Denmark. Danish companies can therefore cultivate cannabis plants and produce medical cannabis products in Denmark without any legal constraint on production capacity.

Looking across Europe, there is still significant variation in national legislation relating to the cultivation and production of medical cannabis. This figure (right) provides an overview of the current legal framework in European countries.

Some of the main points to note are:

- Besides Denmark, only a handful of Western European countries permit companies to produce medical cannabis. These include England, Spain and Portugal.
- Cultivation and production of medical cannabis is also legal in some Eastern European countries such a Estonia and Romania as well as in Cyprus.
- In Germany the amount of medical cannabis that can be legally produced is limited. The country therefore imports large quantitates of medical cannabis.
- France recently initiated a two-year medical cannabis trial. However, cultivation of high-THC cannabis is still illegal in France and the country therefore imports medical cannabis products.
- Italy is one of the largest medical cannabis markets in Europe (see p. 9), but the military is the only licensed producer in the country and it has a monopoly on the cultivation cannabis in the country.

Regulatory regimes on medical cannabis Europe



Source: Based on desk research of information obtained from the national health authorities.
Note: There can be large differences in national regulatory frameworks in relation to a variety of requirements for companies applying for permits to cultivate and produce medical cannabis. It is therefore be difficult to compare the national schemes directly with each other. The segmentation of countries is based on IRIS Group's assessment of the available information found online.

Companies operating in the medical cannabis industry in Denmark

The present mapping and analysis of the Danish medical cannabis industry is based on an examination companies in Denmark that are licensed to cultivate and handle cannabis under either the development scheme or the pilot programme.

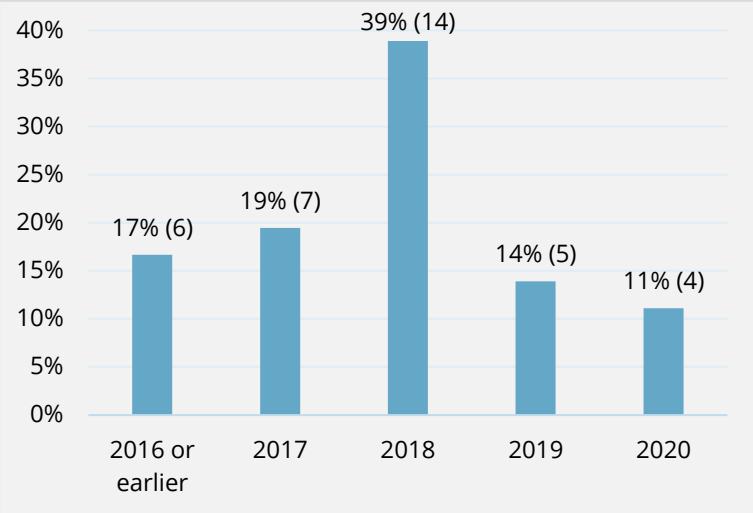
In total, 36 companies are included in the analysis. The following analysis is based on a survey of these. Note that 20 companies participated in the survey.

In addition to the survey, we have conducted a series of interviews with representatives of the medical cannabis companies, universities and hospitals (see Appendix for details).

The figures to the right show the year of establishment and current size of medical cannabis companies in Denmark. The following insights stand out:

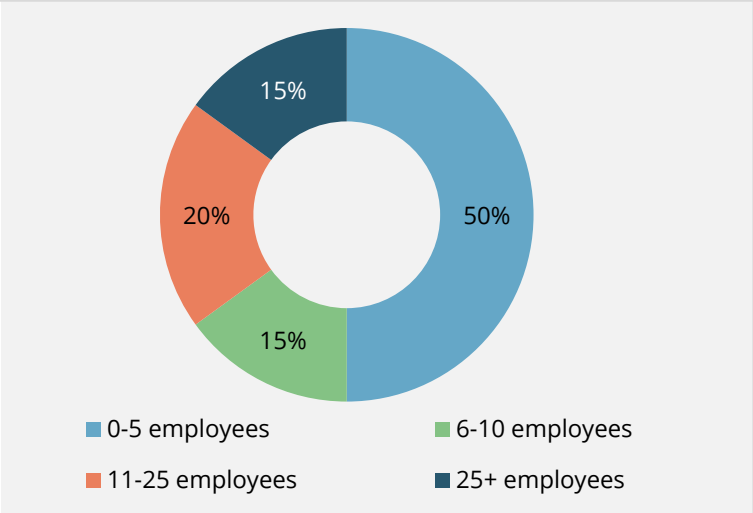
- The majority of Danish medical cannabis companies were established in 2017, 2018 or 2019, as shown in the figure (top, left). This was due primarily to the fact that the Danish government introduced the medicinal cannabis trial programme in 2018.
- Half the companies have up to 5 employees, and only 15% have more than 25 employees . It can be seen, therefore, that the industry is still emerging and consists chiefly of small companies.
- Most Danish companies are licenced under the development scheme, as shown in the figure (bottom, right). They are typically small start-ups.
- A quarter of Danish companies are licensed under both the development scheme and the pilot programme. Only 15% are licenced under the pilot programme alone, and these tend to be the larger and more established producers.

Year of establishment in Denmark



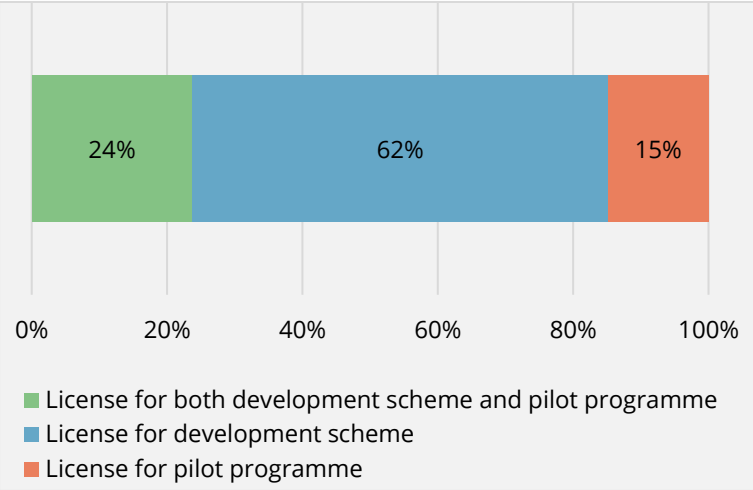
Source: Bisnode.
Note= n=36.

Companies by number of employees, 1st October 2021



Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20.

Type of license from the Danish Medical Agency



Source: Bisnode.
Note= n=36.

Types of licence for handling medical cannabis

In January 2018, the Danish government introduced a four-year medical cannabis pilot programme allowing companies to cultivate and produce medical cannabis. Companies could apply for two types of licences:

- **Development scheme**: Companies can develop medicinal cannabis products. These cannot be dispensed to patients, but the company can cultivate, develop and test its medical cannabis products.
- **Pilot programme**: Companies can cultivate, manufacture and import medic cannabis products. These can be sold on the Danish market and exported to foreign markets.

In December 2021, the Danish government made the legislation permanent, allowing Danish companies to produce medical cannabis products in Denmark without any production gaps.

Danish companies occupy the entire value chain of the medical cannabis industry

The Danish ecosystem for medical cannabis includes more than just the companies that cultivate cannabis and develop medical cannabis product.

This is illustrated in the figure (above, right) offering a visual summary of the Danish ecosystem.

In the following analysis we cover companies positioned throughout the entire value chain for medical cannabis.

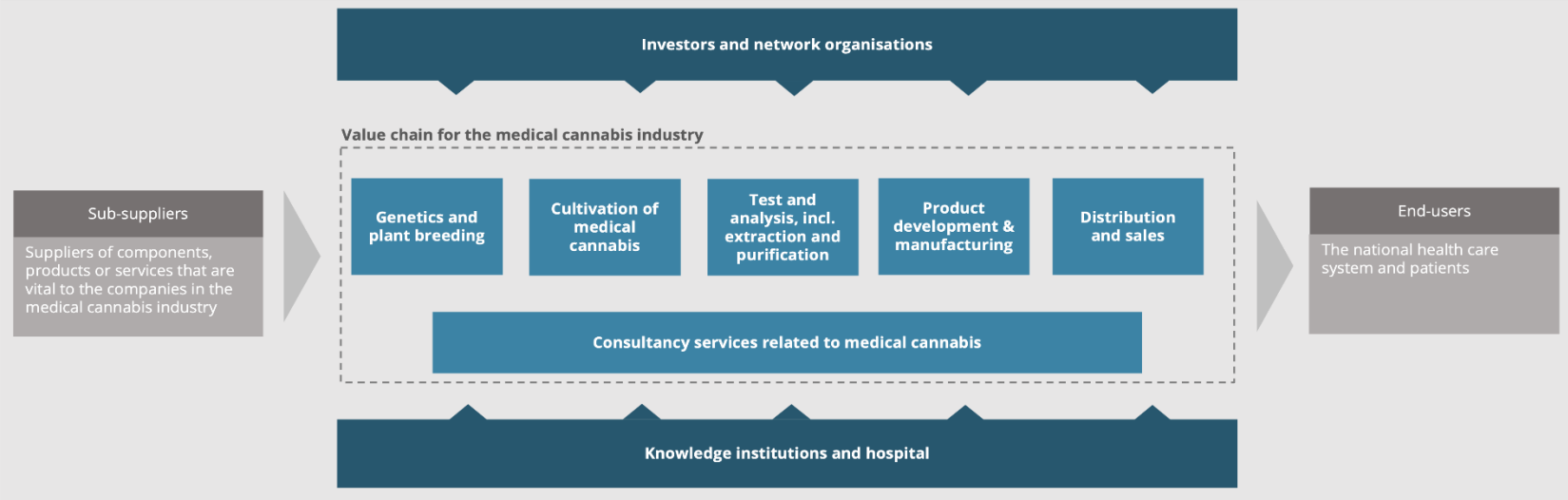
Activities along the value chain span from plant breeding to the distribution and sale of medical cannabis products.

Danish companies in the medical cannabis ecosystem occupy the entire value chain for the industry, as shown in the second figure (below, right).

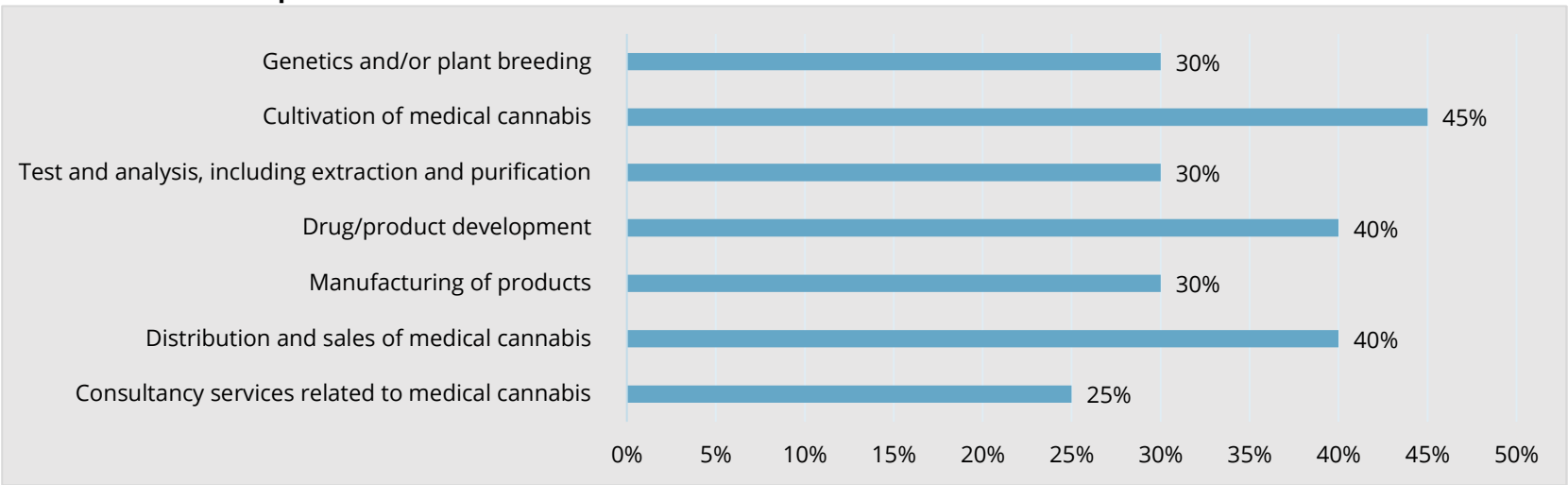
The following points can be highlighted:

- Neary half (45%) of Danish companies cultivate medical cannabis.
- 40% of Danish companies have activities related to drug/product development as well as distribution and sales.
- 30% of the companies are active in genetics and/or plant breeding, showing that the Danish medical cannabis industry is grounded in a robust horticultural tradition in Denmark.
- Danish companies include 30% with test and analysis activities and 30% which manufacture products.

Ecosystem for the Danish medical cannabis industry



Shares of Danish companies in different activities within the value chain of medical cannabis



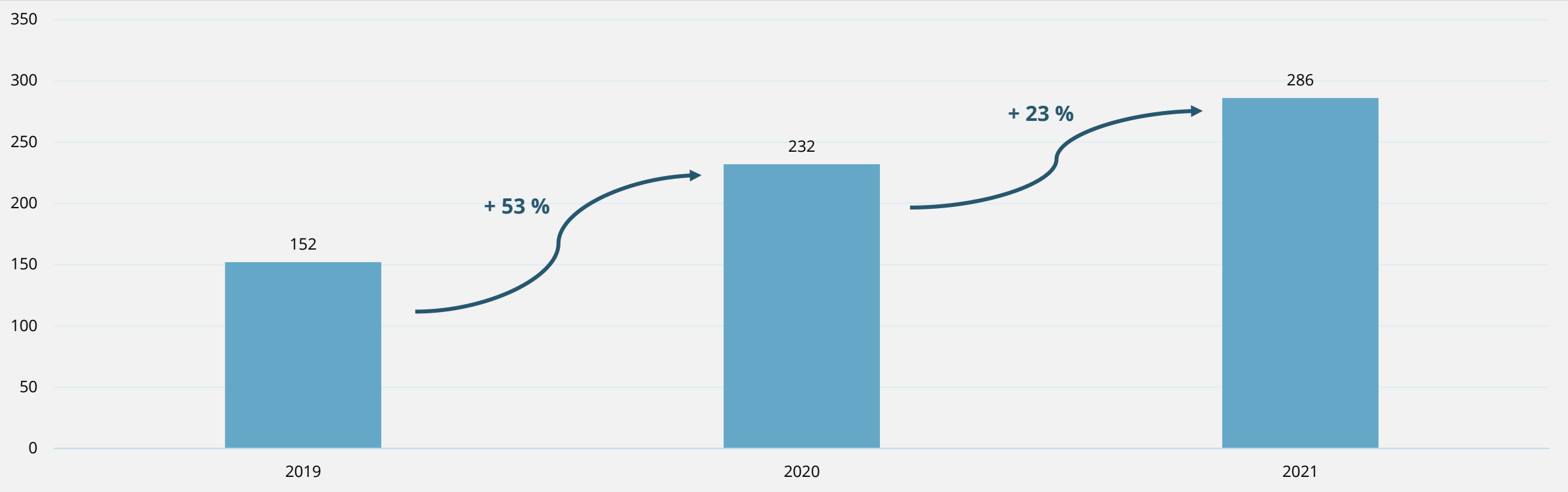
Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20. Companies were allowed to tick of several activities.

Rapid growth of the Danish medical cannabis industry over recent years

Between 2019 and 2021 the number of full-time employees grew from 152 to 286, an increase of 88%, showing that the industry has expanded considerably since its establishment. The largest growth in numbers was seen between 2019 and 2020, when there was an increase of 80 full-time employees. The significant growth in employment is to a large extent driven by a few large companies in the industry such as Aurora Nordic, Little Green Pharma and Schroll Medical.

Employees in the medical cannabis industry are diverse and range from unskilled labour, to those with vocational training, to specialised employees with higher education. The medical cannabis industry lies at the intersection of horticulture and the pharmaceutical sector. Companies may therefore employ horticulturalists who work on cannabis flower cultivation, biochemists with expertise in plant breeding, and scientists with a pharmaceutical background who focus on the formulation and development of products and perform the required tests and analysis needed for product certification.

Numbers of full-time employees in the Danish medical cannabis industry, 2019-2021



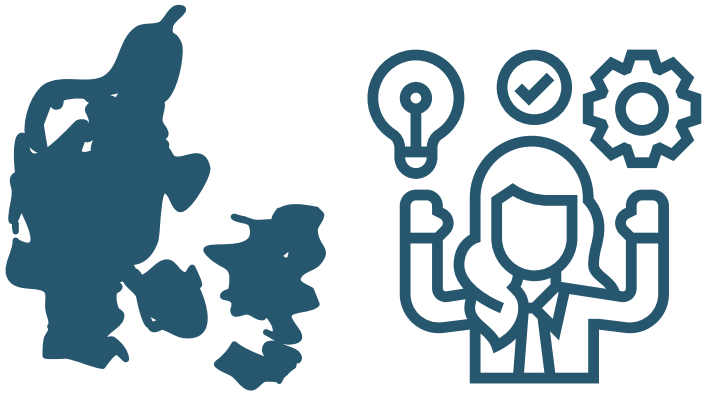
Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20.

Several strengths and competencies within the Danish medicinal cannabis sector

Denmark has a number of national strengths and competencies which have has played an important role in the establishment and development of the medical cannabis industry.

Some of the key national features that were highlighted in interviews with Danish medical cannabis companies and researchers are described to the right.

These features offer a solid foundation for the continued development and growth of the Danish medical cannabis industry.



Strong horticultural tradition

There is a large and robust horticultural sector in Denmark. On Fyn alone, there are more than 330 companies and 14,000 employees within the sector. Fyn has one of the strongest concentrations of commercial horticultural activity in Denmark.

Danish horticulture has provided a vital foundation in the development of a successful ecosystem for medical cannabis. The availability of highly skilled workers with extensive horticultural experience has enabled companies to quickly establish production facilities for the cultivation of medical cannabis in Denmark.

Established knowledge institutions

In Denmark, knowledge institutions with expertise in the field of medical cannabis have played an important role for the development of the industry. Researchers working at the University of Southern Denmark and Copenhagen University, for example, perform high-level research into medical cannabis and contribute new and important knowledge. Universities also deliver courses and qualifications in essential areas of expertise such as biology and bioengineering.

Danish university hospitals are also involved in the medical cannabis arena and collaborate with both companies and universities.

Governmental support and cooperation

The government strongly supports the development of the medical cannabis industry in Denmark. Invest in Denmark, which is part of the Danish Ministry of Foreign Affairs, has played an important role in attracting companies to Denmark and has supported a international symposium on medical Cannabis.

At the local level, Invest in Odense has helped to nurture the medical cannabis industry by providing financial support for network activities.

Strong governmental support has been important in the establishment and development of the medical cannabis industry.

Extensive collaboration in the ecosystem

There have been a consistently high level of cooperation in the Danish medical cannabis ecosystem since its establishment. This extensive collaboration between key actors has strengthened and enlarged the ecosystem significantly.

The collaborative projects have involved a number companies, knowledge institutions and hospitals. The projects provide vital connections for medical cannabis companies positioned along the entire value chain from plant breeding and cultivation to the formulation and development of products.

Fyn is a regional stronghold for medical cannabis in Denmark

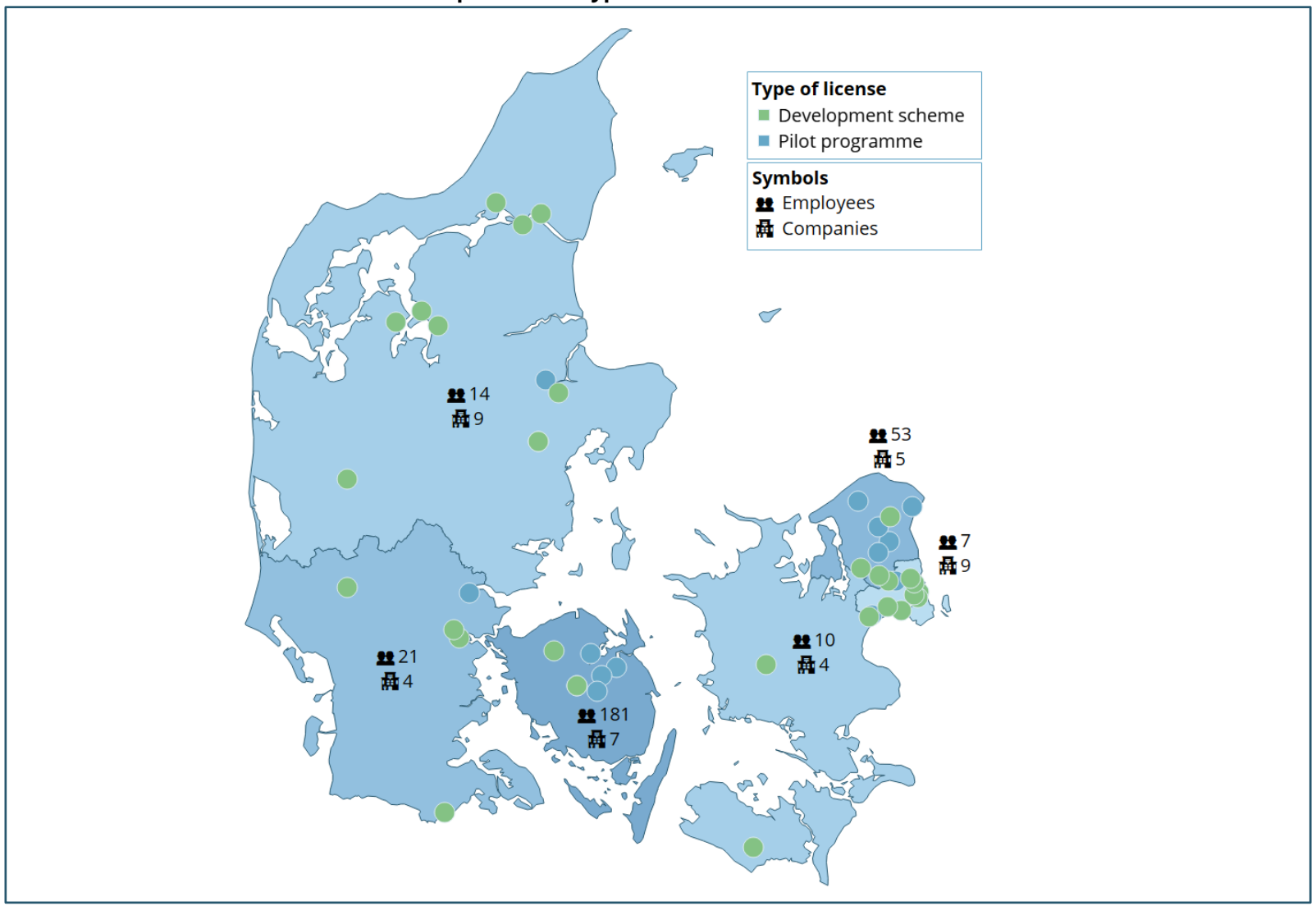
The figure to the right shows the location of the Danish medical cannabis companies and numbers of full-time employees. The number of employees are based on the 20 companies that completed the survey.The map shows that:

- Medical cannabis companies operate in several regions across the country, although a large share of them are located either around the Capital City Region or on Fyn.
- Seven companies are located on Fyn. Together these employ more than 180 people. The companies on Fyn are mainly producers and developers of medical cannabis.
- Nine companies are located in and around the city of Copenhagen. These companies are rather diverse and work with distribution as well as the production and development of medical cannabis products.
- Five companies, with a total of 53 employees, are located in North Zealand. Almost all of the companies in this area have a licence for the pilot programme.
- Thirteen companies are located in Jutland. They employ 35 people. These companies are somewhat scattered. In the main they are smaller companies on the development scheme.

It is clear that Fyn has played an important role in building and developing the medical cannabis industry in Denmark. Several large international companies established themselves on Fyn early on and entered into partnerships with local horticulturalists.

Today, several of the largest producers, such as Aurora Nordic, Schroll Medical and Little Green Pharma, are still located close to Odense.

Location of Danish medical cannabis companies and type of license



Source: Danish Medical Agency and survey of companies in the Danish medical cannabis industry.
Note: The number of employees is based on the survey of Danish medical cannabis companies and therefore does not cover all full-time employees in Denmark. The overview is based on the Danish Medical Agency's list of companies with a licence to work with medical cannabis extracted the 1st of February 2022.

Germany is the largest market for the Danish companies

In the survey, we asked the companies about the shares of their revenues generated domestically and from exports to different European countries in 2020. The results, shown in the chart to the right, are based on the combined revenues of the 20 companies that completed the survey.

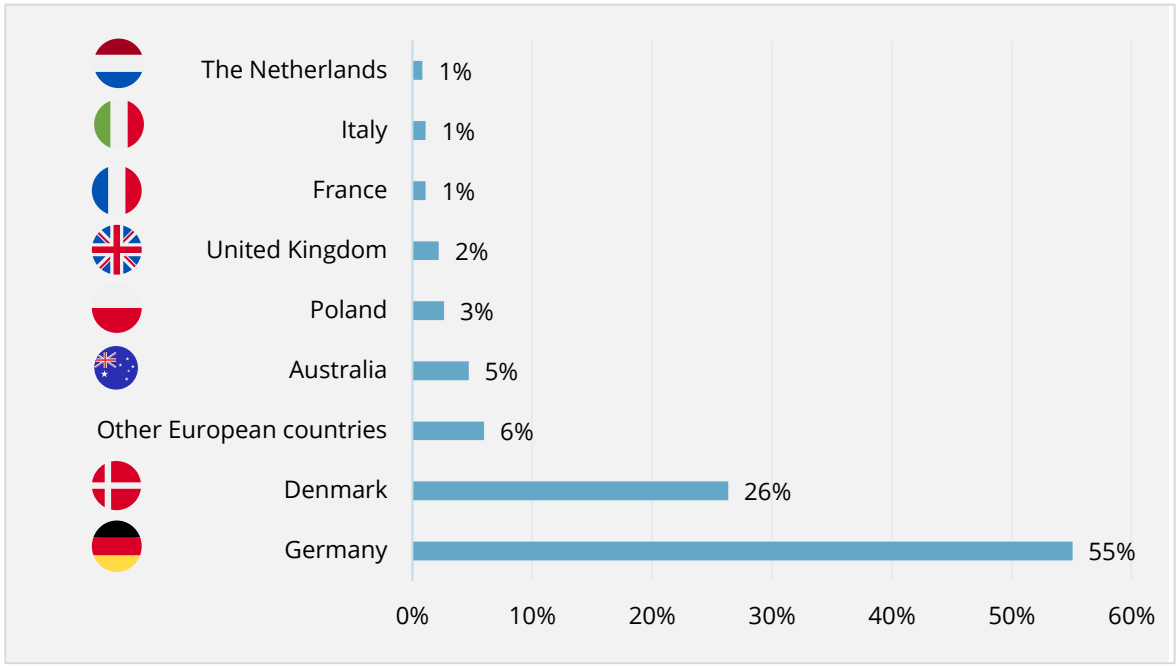
The following findings can be highlighted:

- Germany is the largest market for Danish medical cannabis. More than 50% of the combined revenues were generated from sales to the German market in 2020. As we have already indicated (p. 9), Germany is also the European country with the highest sales of medical cannabis in Europe.
- The Danish market is also important for the companies. A quarter of the companies' revenues in 2020 were generated from the domestic market.

Germany is the largest market for the Danish cannabis companies in part because there is a cap on the volume of domestic production of cannabis there. This means the country is obliged to import large substantial volumes of medical cannabis in order to meet domestic demand.

It should be noted that several of the companies that participated in the survey had not generated any revenue in 2020, because they were still in the process of developing their products or setting up production. Several companies highlight in the interviews that they expect to able to market their products within the next year, after which they will begin to generate revenue.

The primary markets for medical cannabis companies based on revenue in 2020



Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20. The figures are only for companies with revenue in 2020.

The companies we interviewed emphasised the following points:

- In the short run (within the next few years) the Danish market is expected to play a significant role, as companies in Denmark are developing new products and introducing these to the home market.
- For the companies, access to the Danish market plays a role in supporting their export activities. Having products on the Danish market helps to create credibility and legitimacy in relation to international sales and the marketing of products.
- In the long run, the other European markets are expected to grow and make up a much larger share of the Danish companies' revenues. It is anticipated that the Danish market will account for a minor share of revenues as Danish companies introduce their products to European and international markets.

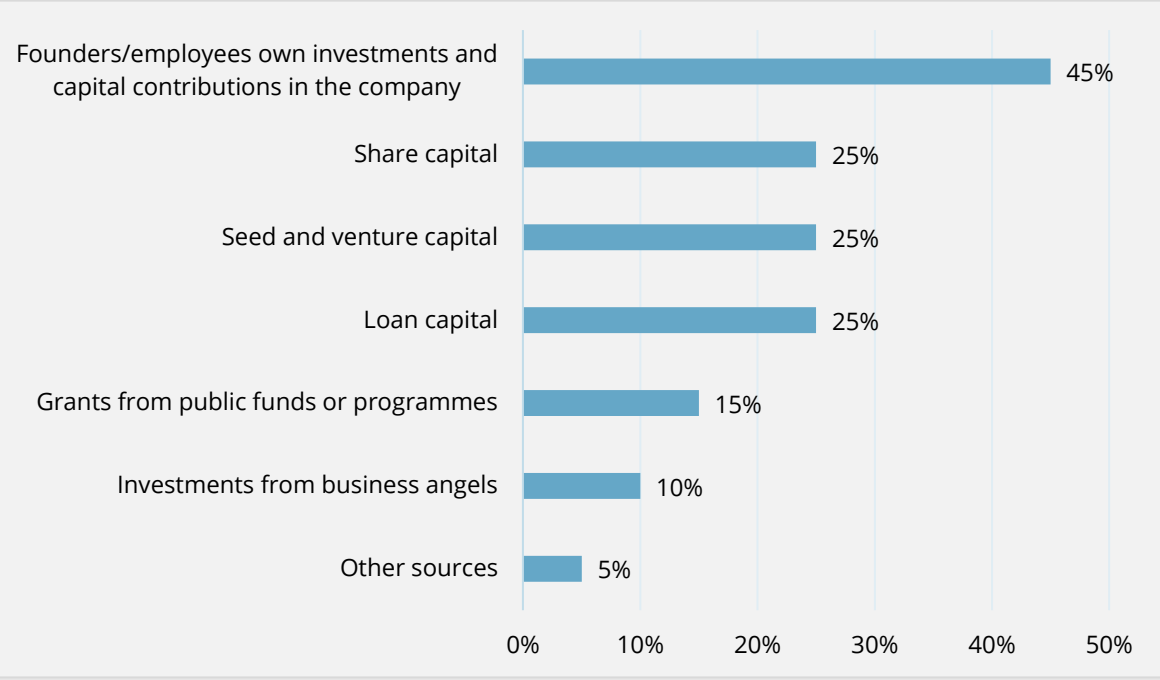
More than DKK 1.5 billion invested in the Danish medical cannabis industry

A key prerequisite of growth for many Danish medical cannabis companies is the ability to attract capital to finance their investment in infrastructure and their development activities. Therefore, we asked the companies how much capital they had received over the last three years and from what sources.

The first figure (below, left) shows the shares of companies which have attracted capital from different sources over the last three years. The majority of the Danish companies (65%) have been able to attract some form of capital investment, and 25% have attracted either share capital or seed, venture capital, or loan capital. In almost half of the companies (45%) founders or employees have invested in the company themselves. Over the last few years, several medical cannabis companies have also been listed on the stock exchanges in Denmark and Sweden.

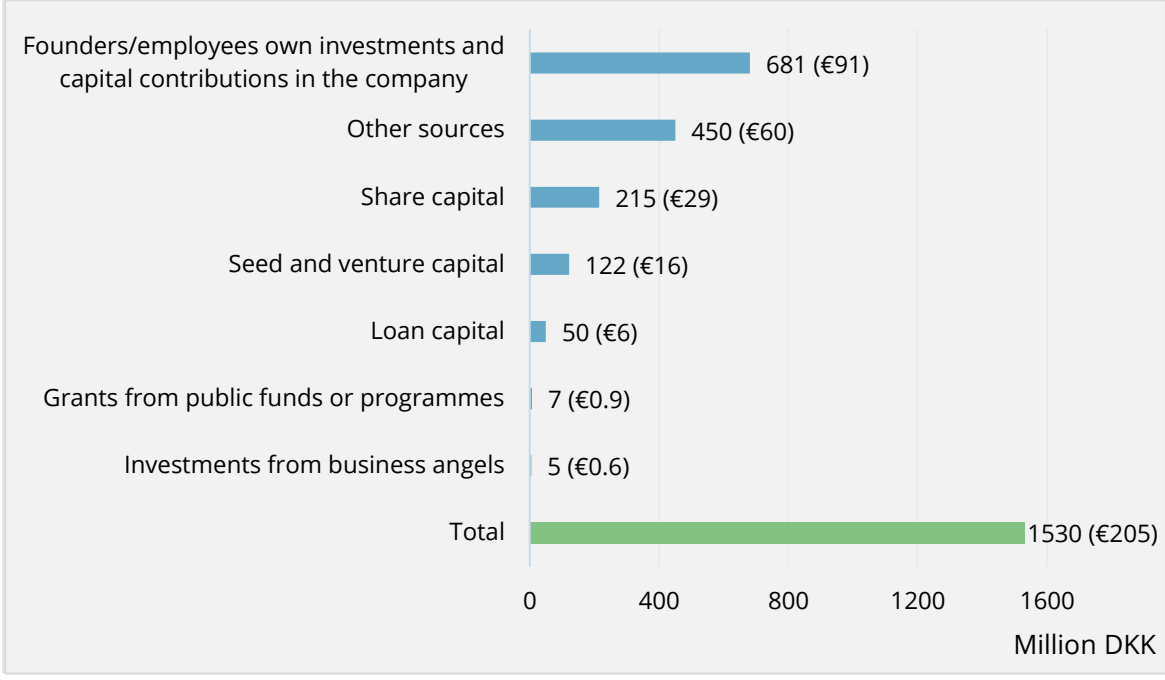
As the second figure (below, right) shows, in total Danish companies have attracted external capital of approx. DKK 850 million (excluding founders' own investments). This corresponds to an average of DKK 42 million per company. However, it should be noted that the average conceals considerable variation among the companies. The largest investments came from founders or employees, who invested DKK 680 million. Investments from founders or employees comprise 44% of the total investment.

Share of companies attracting capital from various sources over the last three years



Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20.

Sums of capital received by medical cannabis companies over the last three years, in million DKK (million EUR)



Source: Survey of companies in the Danish medical cannabis industry.
Note: n= 20.

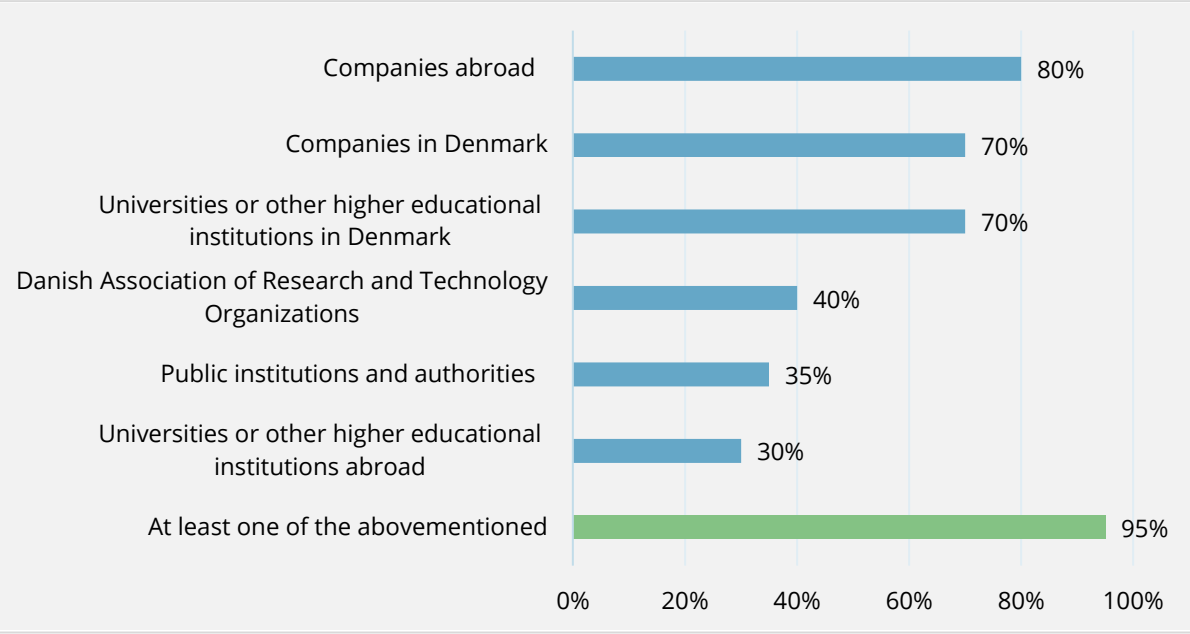
Extensive collaboration in the Danish medical cannabis ecosystem

Nearly all (95%) of the Danish medical cannabis companies had participated in a collaborative project in the last three years. This confirms that within the ecosystem there is a high degree of collaboration between actors. The survey also showed that:

- 80% of the companies had collaborated with companies abroad. This reflects the fact that the medical cannabis industry is international and Danish companies are oriented towards export markets. A large share of the collaborative partners are companies located in Germany, which is also the primary market for the Danish sector.
- 70% of the companies had collaborated with other companies in Denmark, and with universities and institutions of higher education. This wide collaboration was also highlighted in the interviews with company representatives, who emphasised the importance of collaboration with universities for the acquisition of new knowledge of the effects of medical cannabis. For an example of a research project involving the collaboration of industry and a Danish university, see the case presented on p. 40.

Early on, the medical cannabis companies, along with subcontractors in Denmark, founded the industry association *Medicinsk Cannabis Industri*. One of the association's goals is to support constructive dialogue and collaboration between key stakeholders .The association has facilitated several networking activities and plays and important role in strengthening cooperation between Danish medical cannabis companies.

Share of companies participating in a collaboration project on medical cannabis over the past three years



Source: survey of companies in the Danish medical cannabis industry.
Note: n = 20.

Companies derive considerable value from collaboration

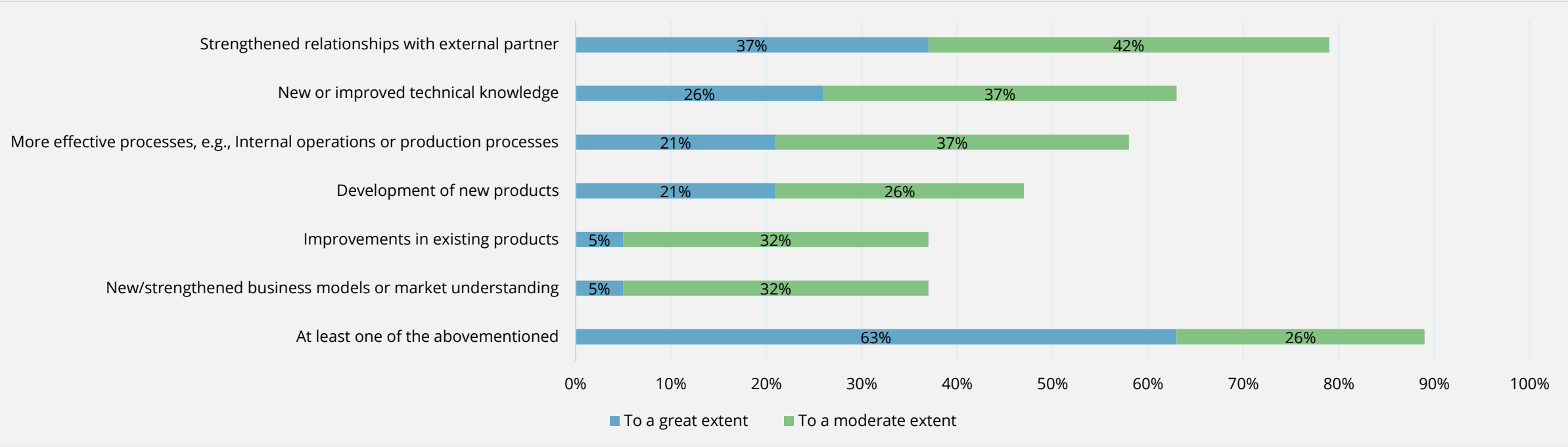
The Danish medical cannabis companies generally assessed that collaboration had strengthened them in one or more areas, as shown in the figure below. Approx. 90% of 19 companies questioned stated that to a great extent or a moderate extent cooperation had strengthened their business in at least one aspect.

The following more detailed results of the survey can be highlighted:

- Almost 80% of the companies assessed that to great or moderate extent their relationship with external partners had been improved by their collaboration.
- About two-thirds of the companies stated that to a great or moderate extent their collaboration had generated new or improved knowledge. Almost the same share reported that collaboration activities also contributed to more effective processes in their company.
- Nearly half the companies said that collaborative projects had contributed to the development of new products.

These factors indicate that there is a high degree of professionalism in the collaborative projects.

Shares of companies which, to some extent or a great extent, assess that collaborative projects have contributed to new competencies, insights, and business relationships



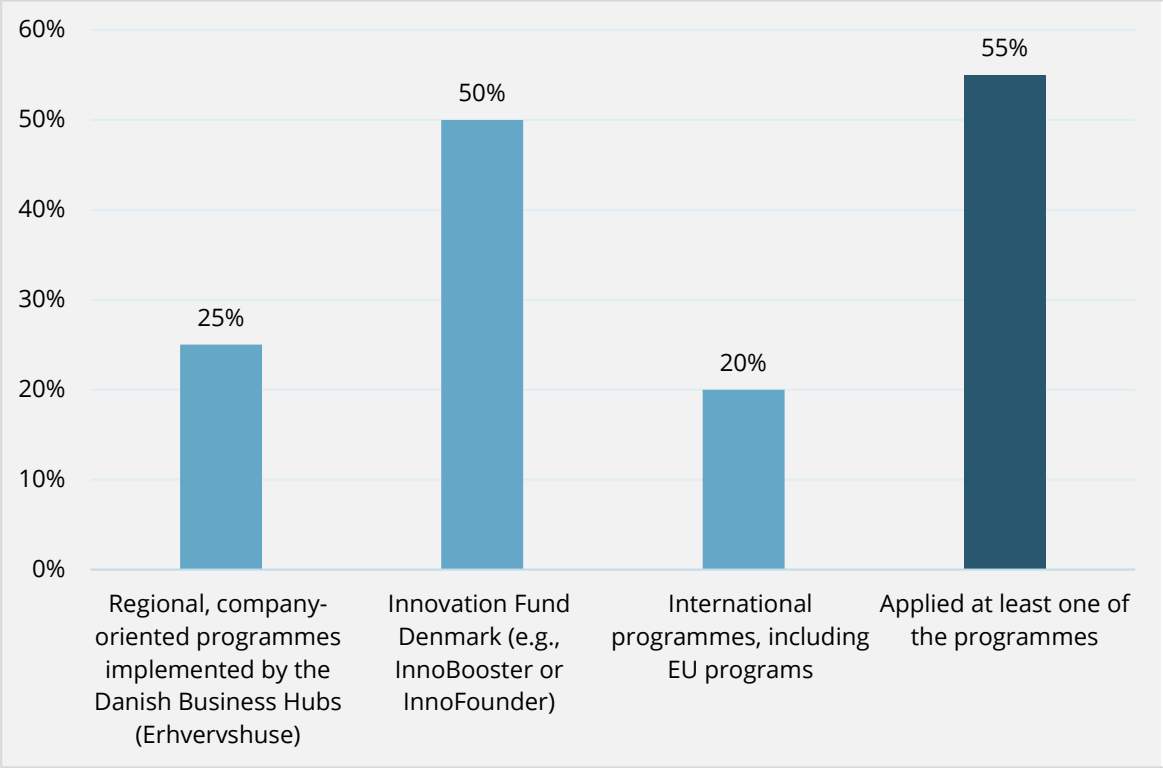
Source: survey of companies in the Danish medical cannabis industry.
Note: n= 19.

Danish medical cannabis companies focus strongly on innovation

More than half of the Danish medical cannabis companies had applied for funding for innovation activities in the last three years. This shows that the industry has a strong focus on innovation and product development.

The highest proportion of companies (50%) applied for funding to Innovation Fund Denmark, while 25% applied to the Danish Business Hubs and 20% applied to various international funding schemes.

Share of companies applying for support/grants for innovation activities from different actors over the past three years



Source: survey of companies in the Danish medical cannabis industry.
Note: n= 20.

The success rate for innovation applications to the Danish Business Hubs and Innovation Fund Denmark are 40% and 30%, respectively. The success rate for applications to international funding schemes is 10%.

Although these rates are healthy, the companies we interviewed stressed that it can be difficult to obtain for funding to support their innovation activities.

The companies pointed to the fact that medical cannabis is rarely a prioritised area in publicly supported schemes, and that therefore it can be challenging to work out which programme to apply to for funding.

3. Growth potential for the medical cannabis industry

This chapter first summarises several international forecasts for the global medical cannabis industry.

Next, it shows the Danish medical cannabis companies' assessment of the framework conditions that are vital to their future expansion, together with the companies' expectations as regards growth and development in the coming years. The chapter than provides an overview of the barriers and challenges the Danish medical cannabis industry foresees, and possible actions and initiatives that would help strengthen the industry.

The following conclusions can be highlighted:

- The medical cannabis industry is an emerging industry. Therefore, many younger companies do not yet have products on the market from which they can generate revenue.
- International forecasts are of significant growth in the global medical cannabis industry. On average, there is expected to be annual growth of approx. 19% over the period 2020-2026.
- The Danish medical cannabis companies also have optimistic growth expectations for the next few years. By 2024, the Danish companies expect to employ 410 full-time employees. This equates to a 43% increase on the number of full-time employees in 2021.
- Several local strengths and competencies on Fyn offer a solid foundation for future growth of the medical cannabis industry in Denmark. They include a well-established horticultural tradition, a strong research environment and wide collaboration between research, industry and the authorities, as well as robust local support.
- The medical cannabis industry is developing fast. It is constantly generating and sharing new evidence and knowledge regarding the efficacy of treatments for different conditions with medical cannabis, and it is expected to become more fully integrated with the life science sector in the coming years.
- Although several ongoing clinical studies are investigating the therapeutic effects of medical cannabis, there still is a need for more research. In addition, access to qualified labour as well as harmonisation of regulatory conditions across the EU were highlighted as some of the most important factors in future growth in the sector.

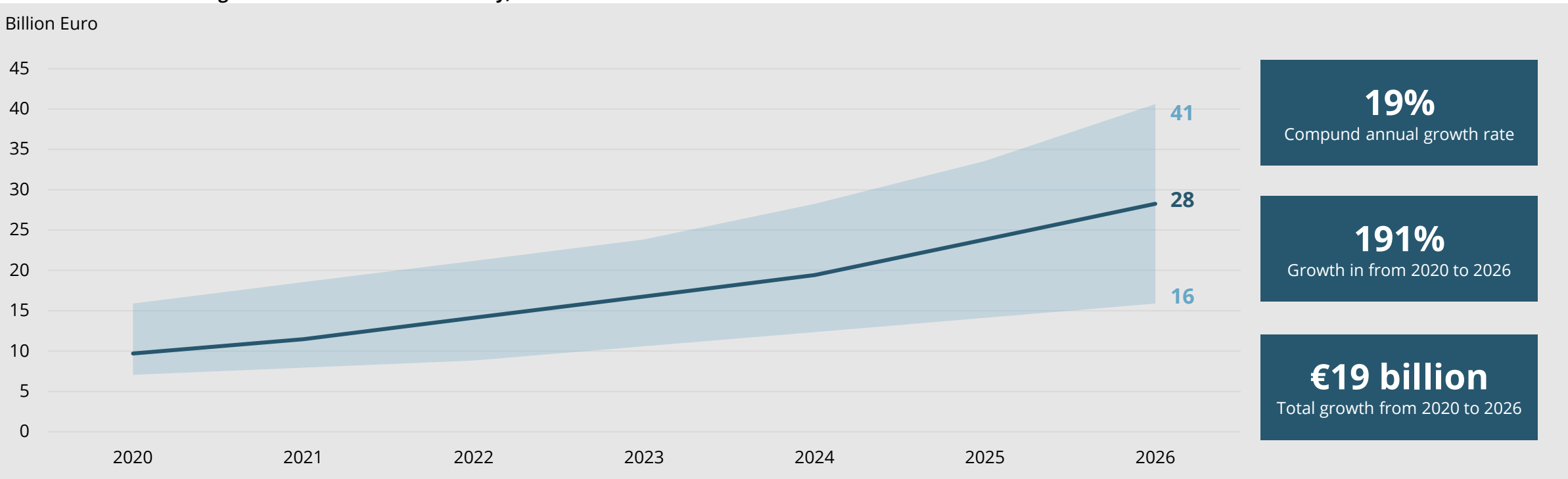
International forecasts point to significant growth in the global medical cannabis industry

Several international research institutes have conducted forecast analyses for the medical cannabis industry. In the figure below, we combine analyses from a number of international institutes. The dark blue line indicates the mean value of the forecast analysis, while the light blue area shows the span between the different analyses.

All of the international forecast analyses anticipate substantial growth in the industry globally over the coming years. By 2026, international forecast analysis assesses that the market value of the world's medical cannabis sector will be approx. EUR 28 billion. This equates to an average compound annual growth rate in the industry of approx. 19%, corresponding to total growth of EUR 19 billion between 2020 and 2026.

It should be noted that behind these forecast analyses there lie considerable uncertainties. For example, the analyses do not take into account unforeseen developments, such as changes in the regulatory framework, economic crises or shifts in the public perception of medical cannabis. Nevertheless, the analyses provide useful insights into market expectations for the medical cannabis industry.

Market forecasts for the global medical cannabis industry, 2020-26



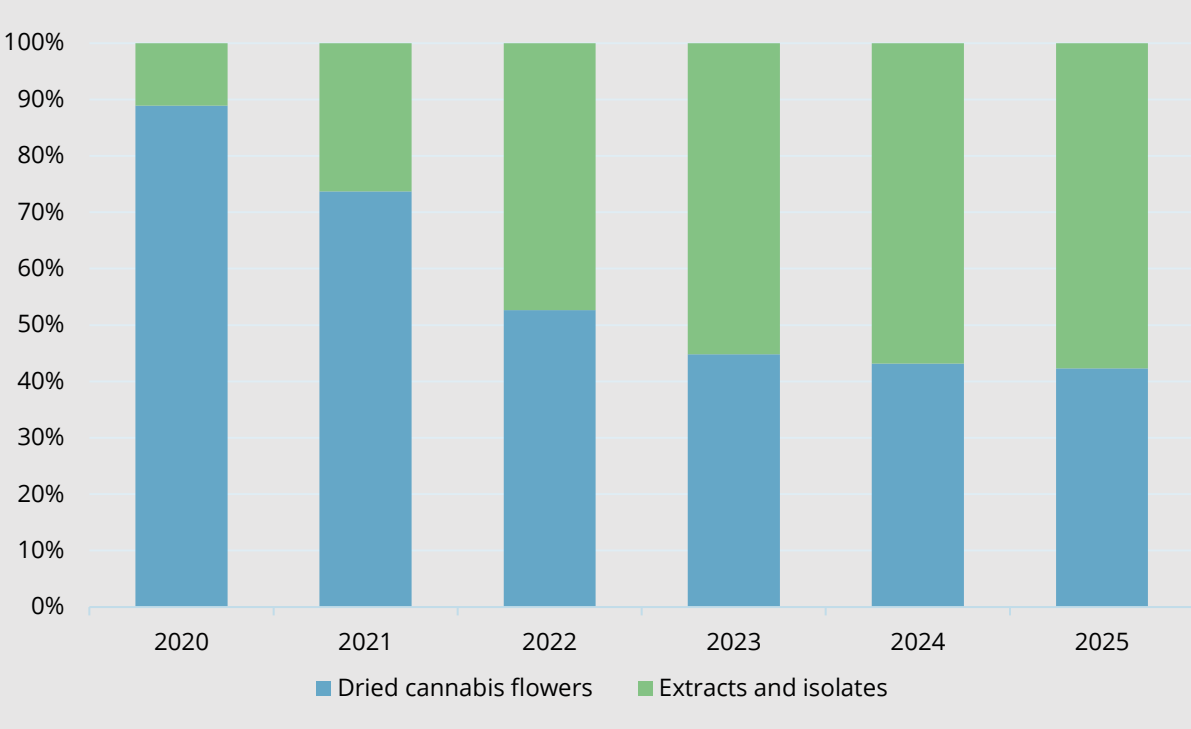
Source: IMARC Group; Grand View Research, 2021; Research and Markets, 2021; Facts and Factors, 2021; Market Data Forecast, 2021; Market Research Future, 2021; Emergen Research, 2021.

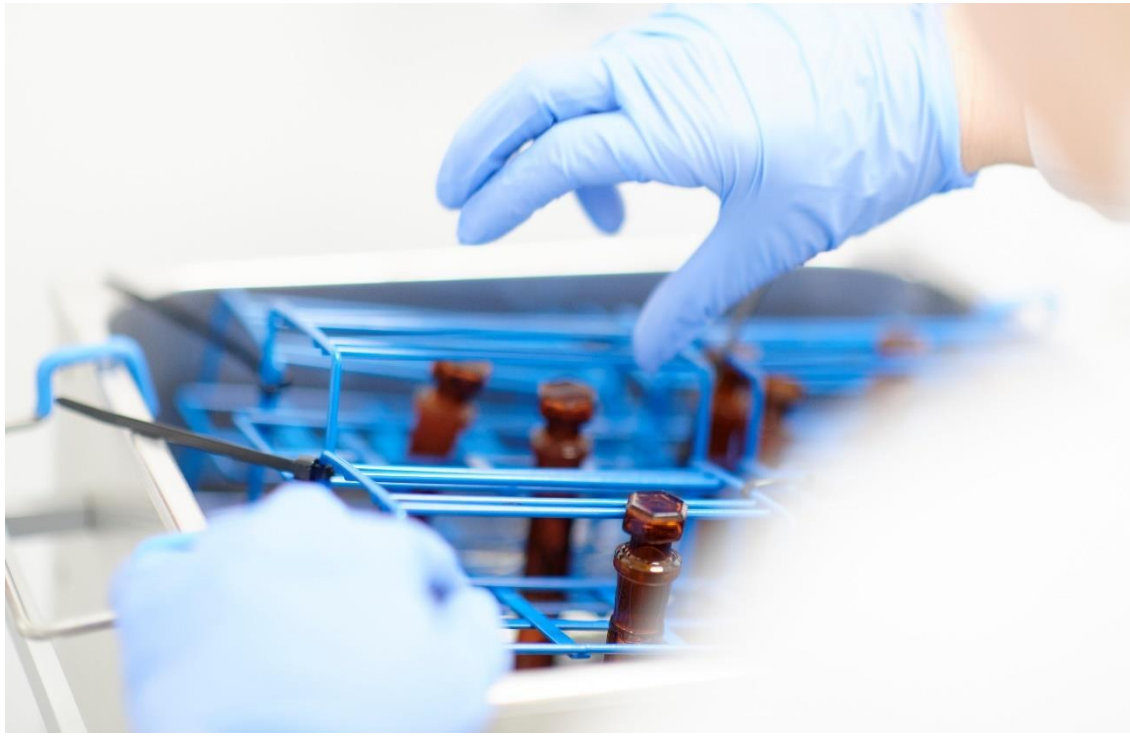
The market for medical cannabis is moving towards more pharmaceutical products

European medical cannabis markets are expected to grow considerably over the next few years in comparison with the other markets. A range of analyses suggest that the European market will expand by between 52% and 67% annually (Brightfield Group, 2020; Prohibition Partners, 2021). The primary driver of the growth is the ongoing liberalisation of cannabis-based medicine through new legislation across Europe.

The analyses suggest that most of the growth in the European medical cannabis sector will be generated by sales of extracts and isolates rather than dried flowers, as the figure below illustrates. Sales of the former are expected to overtake dried flower sales in the next couple of years. Dried flowers have traditionally been the most commonly used form of medicinal cannabis in Europe. However, in recent years there has been a growing demand for extract products and isolates. This represents an opportunity for Danish companies to further develop their product lines by building on the strong pharmaceutical sector and know-how in the country.

Projected sales of medical cannabis products in Europe, product types





Source: Prohibition Partners (2021): "The European Cannabis Report, 6th edition."

Medical Cannabis and the Danish life science sector

The medical cannabis industry is developing towards life science

Medical cannabis is still a relatively young and emerging industry. However, in the coming years, the industry is expected to develop products further towards pharmaceutical products and move closer to the life science sector. Medical cannabis has also been embedded in the Danish government's strategy for further development of the Danish life science sector from 2021.

The Danish industry, in collaboration with universities and clinical researchers, is generating new knowledge about medical cannabis. It is exploring the efficacy of treatments for a range of medical conditions and improvements to patients' quality of life. Ways of incorporating medical cannabis into new treatments are constantly evolving, and scientific evidence and knowledge regarding the effects of medical cannabis is evolving rapidly.

The companies interviewed for this report indicated that the medical cannabis industry will move closer to the life science sector over the next years and begin to export high-quality medical cannabis products to the European and global markets.

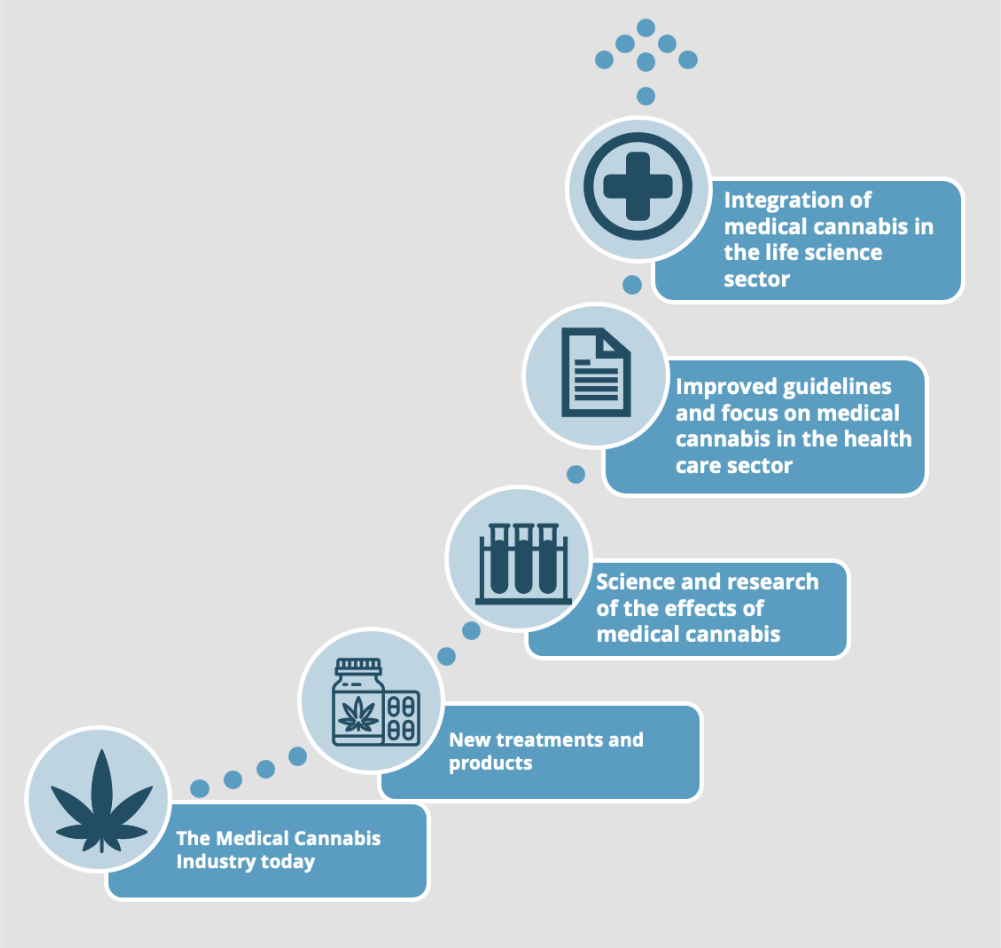
Synergies between the medical cannabis industry and life science

The Danish approach and legal regulations surrounding medical cannabis are based largely on the same principles as those governing the pharmaceutical sector. There is a strong focus on transparency and high standards that medical cannabis producers must meet in their production process. These standards are described in The European Good Manufacturing Process (GMP) published by the European Medicine Agency. They help to ensure that products are of high quality.

As the medical cannabis industry takes its lead from the pharmaceutical sector, there are significant synergies between it and the Danish life science industry. Among other things, researchers and clinicians in the two sectors work with the same types of methods and indicators, whether they are investigating traditional pharmaceutical products or medical cannabis products.

Denmark is a leading country in life science and has a long tradition of developing high-quality pharmaceutical products. Synergies are therefore created both by the access to competencies in the country and by Denmark's international brand within life science. These synergies will facilitate exports of cannabis products.

A path to the integration of medical cannabis with the life science industry



The pathway towards integration of medical cannabis into the life science industry shown above is based on interviews with companies from the Danish medical cannabis industry. Overall, the interviewed companies indicated that they expect their industry to be more closely integrated in the life science sector over the coming years.

Several framework conditions are important for the industry's future growth

In the survey, the companies were asked what framework conditions will be important for their future growth and development. The results are shown in the figure to the right. Below key themes are described.

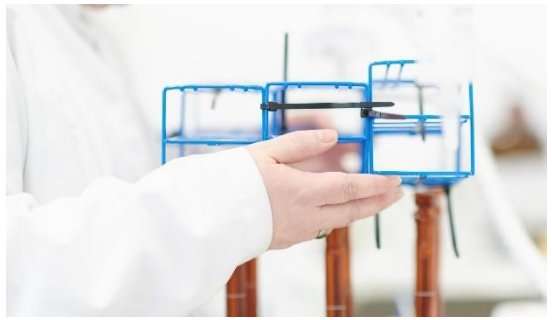
- **Access to capital and labour:** 60% of the companies agreed to a great extent that access to capital and suitably qualified labour are important for their future growth and development.

  The companies pointed to the need for additional investments in infrastructure as they begin to further develop their products. The medical cannabis industry, like the pharmaceutical industry, is very capital intensive.

- **Scientific evidence:** 60% of the companies indicated that accessible scientific evidence and knowledge about the effects of medical cannabis are an essential framework condition. Several also pointed to the need for more scientific evidence to promote better understanding of when and how medical cannabis is most efficacious.

  Improved scientific evidence and clinical trials are essential in order to integrate medical cannabis products fully into the existing health care system. In this connection, some companies pointed to the opportunities to collect further high-quality data in the new four-year trial period for medicinal cannabis.

- **Harmonisation of regulatory mechanisms in the EU:** Half of the companies believed that harmonisation of the EU's regulatory conditions is very important for their future growth. This finding related in particularly to a more uniform interpretation of EU Good Manufacturing Practices (EU-GMP) across member states.



Companies assessment to what extent different framework conditions are important for the company's future growth and development

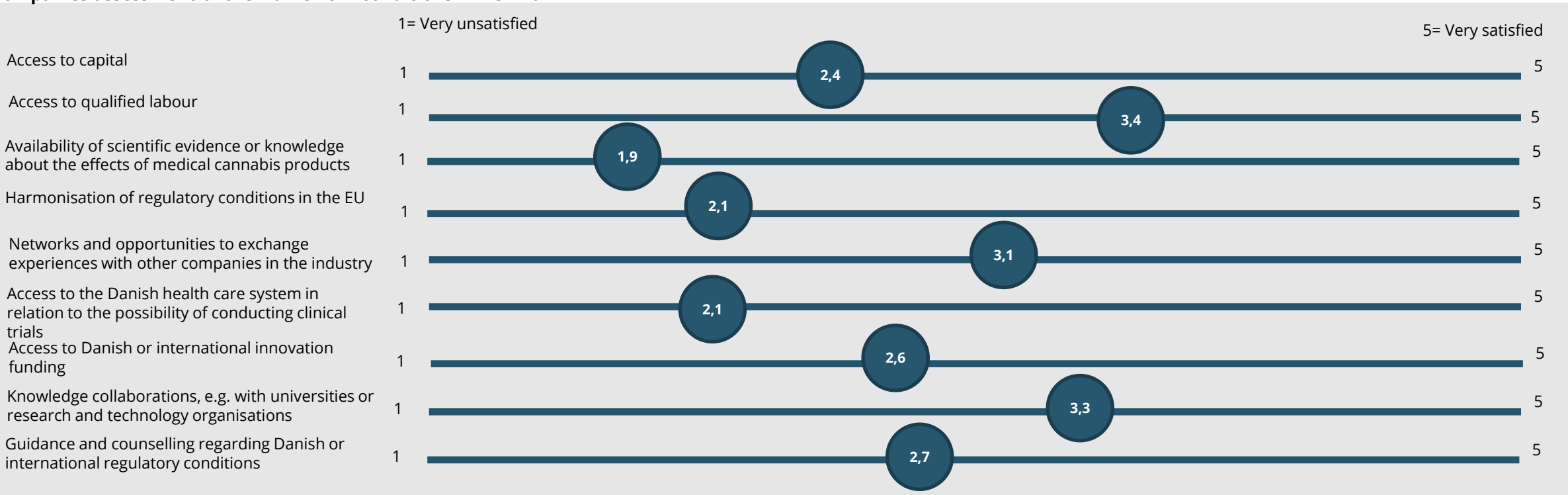
Source: survey of companies in the Danish medical cannabis industry.
Note: n= 20.

The need for more scientific evidence on the therapeutic effects of medical cannabis

In the survey, the companies were also asked to asses the quality of the Danish framework conditions on a scale of 1-5. The results are shown below, but note the following:

- The availability of scientific evidence on the effects of medical cannabis is ranked lowest, followed by harmonisation of the regulatory conditions in the EU and access to the Danish health care system in relation to the possibility of conducting clinical trials. These are clearly the three conditions the Danish medical cannabis companies surveyed were most dissatisfied with.
- In the interviews, the companies expressed the view that the availability of scientific evidence and harmonisation of EU regulation are broader global issues, rather than specifically Danish challenges.
- In general, the companies believed that assess to qualified labour in Denmark is good, a finding that was confirmed in the interviews. Some companies, however, are experiencing difficulty attracting employees with a pharmaceutical background to support the development of new cannabis products.
- Overall, the companies were satisfied with the networks in the Danish medical cannabis sector and indicated that they were able to initiate knowledge collaborations.

Companies assessment of the framework conditions in Denmark



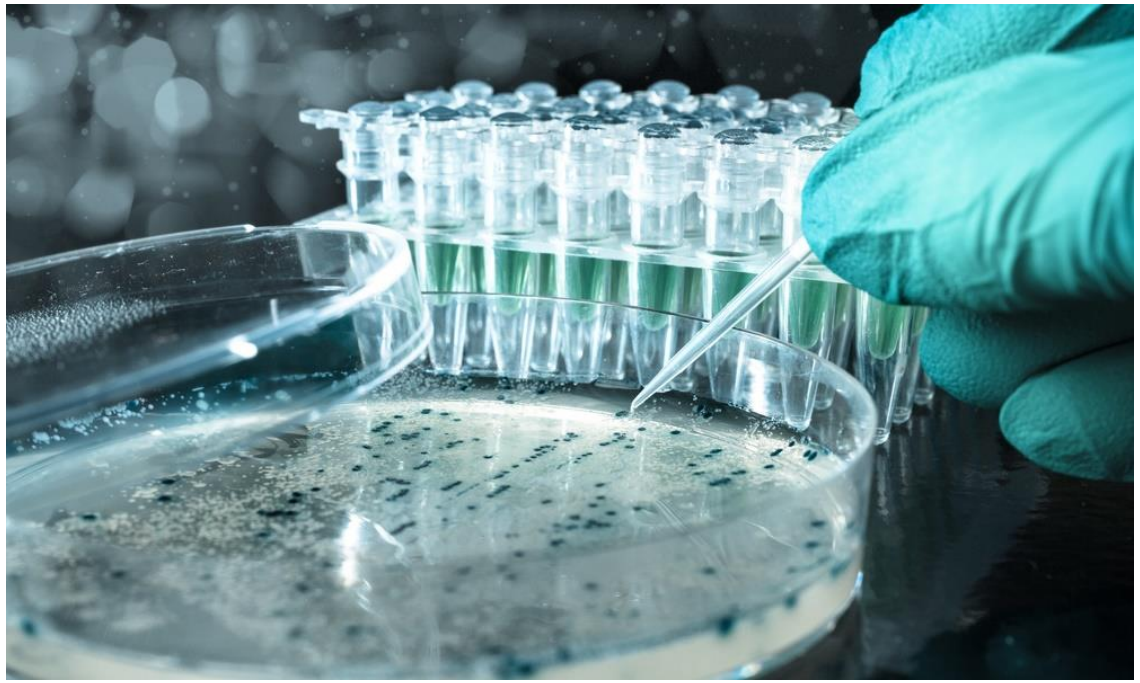
Trends and scenarios for the Danish medical cannabis industry

The Danish medical cannabis industry is still a very young, emerging industry. It has only operated in Denmark since the introduction of the pilot programme in 2018. Therefore, several of the companies have not yet begun to generate revenue from sales activities. For that reason, and out of respect for the companies' wish for anonymity, the industry revenues do not form part of this analysis.

Instead, in the survey we asked the companies to assess developments in their employment capacity in three different scenarios:

- **The optimistic scenario:** At the national level, the medical cannabis industry is further embedded as a part of the Danish life science strategy[1], and dedicated public funds are allocated to support development of the Danish ecosystem, including funding for research and innovation collaboration with universities and hospitals. At EU level, the rules and regulations governing use of medical cannabis are harmonised with a focus on ensuring that medical cannabis products are covered by the health insurance schemes in different countries.
- **The neutral scenario:** The medical cannabis industry has the same status/position as it has today in Denmark, and no significant changes are made to national and international regulation or funding schemes.
- **The pessimistic scenario**: At the national level, the political focus on the medical cannabis industry is diminished. Therefore, no further public funding is allocated to support the development of the ecosystem, and the processing time for applications to the Danish Medicines Agency grows. At EU level, there is no regulatory harmonisation, and market conditions vary wildly across Europe, meaning that many patients will be unable to access medical cannabis products under their country's health insurance schemes.

1. Medical cannabis was integrated in the Danish Governments 2021 national strategy for life science.



Several companies in the medical cannabis industry are still in the process of product development and approval. As the industry has a pharmaceutical approach and is developing products for human use, the time to market is lengthy. For comparison, time to market for pharmaceutical products can be 10+ years. Consequently, at present only a handful of companies have products on the market from which they generate sales revenue.

Some of the companies we interviewed confirmed that they expect to start making revenues from sales in the coming years. Several were in the process of introducing their products to various markets.

Generally, the companies had very positive expectations in relation to sales in the coming years and were expecting to expand their business as they gained access to the Danish and European markets.

Large differences in employment growth in the three scenarios

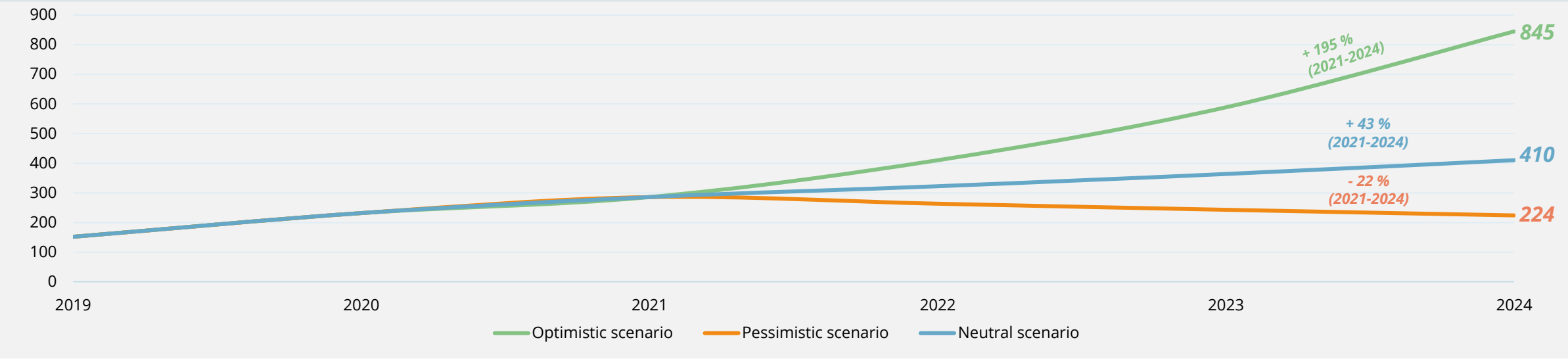
The figure below shows developments in full-time employment needs for the medical cannabis companies we interviewed across the three scenarios. In the neutral scenario, the companies expected to employ 410 full-time people in 2024. In the optimistic scenario, they anticipated hiring additional employees and employing 845 people in 2024. Relative to today's numbers (286 employed full-time) this represents an increase of approx. 196%.

When presented with the optimistic scenario, a number of companies underlined the embedding of the industry in the Danish life science sector as a vital factor. Several are currently working on developing their product portfolios to include more extracts and isolates and would therefore benefit greatly from closer integration between the medical cannabis industry and the life science sector. The interviewed companies also pointed to harmonisation of the regulatory conditions at EU level as an essential factor. Additionally, they stressed the need for ongoing research and clinical trials, indicating that this was an important feature of the optimistic scenario . There is a need to generate new knowledge and understanding of how medical cannabis works upon different health conditions if the industry is to be fully integrated into national health schemes.

In the pessimistic scenario, the companies expected to reduce the number of full-time employees from the 286 employed today to 224 in 2024. They believed the lack of harmonisation of rules across Europe and diminishing political prioritisation of medical cannabis would be the main causes of the decline in employment numbers. As the industry is very export-extensive, companies are dependent on access to European markets if they are to achieve their growth potential.

The large differences in employment capacity in the three scenarios show the potential gains of further support for the Danish medical cannabis industry. However, it should also be noted that the analysis only covers companies that are active within the industry today and responded to the survey questionnaire.

Expected numbers of full-time employees working for companies in the Danish medical Cannabis industry in 2024



Source: survey of companies in the Danish medical cannabis industry.
Note: n= 20

How to strengthen the Danish medical cannabis industry

In what ways could the Danish medical cannabis industry be strengthened? The companies that are active in the sector differ considerably in size, primary business area, product portfolio, and so on. However, the preceding analysis points to six general barriers, and therefore to six opportunities to strengthen. We elaborate these on this and the next page. In the three boxes below we consider aspects of regulation and market access. Although the barriers we consider relate mainly to the industry itself, several companies also highlighted uncertainties in the Danish market created by the ongoing temporary framework for prescribing medical cannabis products. They stressed the need for a long-term strategy and vision for medicinal cannabis in Denmark that engages with both the industry and the health care system.

Regulatory conditions in Denmark

In general, companies are very satisfied with the new legislation, which has provided a permanent legal basis on which the industry can operate and solved several of the regulatory barriers inherent in the previous trial programme.

Potential regulatory issues remain, however. Going forward, several companies highlighted the regulatory conditions surrounding contract processing with companies in the EU.

Currently, Danish companies are not permitted to enter into contracts with other companies, for instance, in relation to the extraction of cannabis bulk. If Danish companies are not able to work with other European manufactures, the development of a strong ecosystem may be held back.

Additionally, with the introduction of the new legislation, an application fee when applying for approval of products has been introduced.

This, in combination with the fact that the programme allowing doctors to prescribe medical cannabis has not yet become permanent, could deter companies from introducing products on the Danish market.

Easier access to the Danish market

Several of the interviewed companies stressed the importance of having easier access to the Danish market.

One of the reasons for the limited number of Danish-produced products, according to companies, is the highly complex regulatory conditions under which market approval is currently granted for medical cannabis products in Denmark. Going forward, more guidelines should be developed by the Danish Medicines Agency to help to ensure that the case processing of product approvals is smoother and more uniform.

Under the new legislation it is also possible for the companies to get their products approved as magistral medicines (i.e. medicines prepared in a pharmacy for individual patients). However, this requires a separate permit that differs from those issued under the medical cannabis pilot programme, and this is expensive and time-consuming.

To ensure that more Danish-produced products can enter the Danish market, the Danish Medicines Agency may consider creating a FastTrack scheme for companies that have already been granted approval in the pilot programme.

Harmonisation of European regulation

In the coming years, European markets for medical cannabis are expected to grow significantly. Therefore, harmonisation of the regulatory conditions for medical cannabis across the continent is important.

In Europe there is at present a rather fragmented regulatory approach to medicinal cannabis across the different countries. It will be important to harmonise the regulatory framework in line with EU Good Manufacturing Practices and to avoid divergent interpretations. If products throughout the European market are to be of the highest quality it is vital to secure uniformity: it must be ensured that countries interpret the rules in the same way.

A harmonised European publication providing information on ingredients and active substance content in medical cannabis products would also help to ensure that the market maintains high-quality products. Such a publication would make it easier to get products accepted on the different markets as the standards and test requirements would be similar.

Going forward, its therefore important to continuously promote European harmonisation through international lobbying and advocacy.

How to strengthen the Danish medical cannabis industry

As well as expressing concerns about regulatory conditions, the Danish companies we interviewed pointed to the need for further research offering an improved understanding of the effects of medical cannabis. The industry will need to attract highly qualified employees with experience and competencies gained in the pharmaceutical sector as the companies begin to develop their products further. They will also need access to capital. Finally, the conditions for prescribing cannabis products on the Danish market should be strengthened by improving the guidelines for Danish doctors.

Further scientific and clinical studies

Medical cannabis is still a relatively new arena, and there is a need to generate more knowledge about how medical cannabis products affect patients.

The interviewed companies and actors highlighted that more research is needed to improve our understanding of the circumstances in which medicinal cannabis is most efficacious. Therefore, universities, hospitals and companies in the sector need to initiate and conduct more research and clinical trials.

Clinical studies in focusing on the effects of medical cannabis are ongoing in Denmark, but according to the companies, and in the view of some researchers, it can be difficult to acquire financial support for research projects from the private and public research funds.

When the legislative framework for medical cannabis was introduced in 2018, DKK 10 million was allocated to the development of scientific knowledge during the medicinal cannabis pilot programme. To further increase knowledge generation within the arena of medicinal cannabis, a similar model, with dedicated research funds for basic research and clinical trials, could be implemented. The dedicated funds could support additional international collaborations with relevance to medicinal cannabis.

Access to qualified labour and capital

Several interviewed companies saw access to skilled labour and capital as important growth prerequisites.

As the medical cannabis industry is still in a phase of product development, several companies highlighted increased demand for employees with experience from the pharmaceutical sector. This included employees with competencies within drug discovery, protocol development and clinical studies. The fact that Danish medical cannabis is still in its infancy means that companies have limited resources to recruit specialised pharmaceutical employees. It can therefore be difficult for some companies to attract the right employees.

To meet the growing demand for qualified labour, some actors stressed the need for more collaboration between the industry and educational institutions. Some companies already work with university students, who write their candidate theses in collaboration with the company. Going forward, this type of collaboration could be developed and strengthened further.

Additionally, the companies point to the need for more capital and investment in infrastructure enabling the continued development of novel pharmaceutical products.

Improved guidelines for doctors on the prescription of medical cannabis

A number of interviewed actors talked about the reluctance of doctors to prescribe medical cannabis remedies. They saw this as a significant barrier to progress with medical cannabis in Denmark.

Research suggests that the Danish doctors' reluctance is due to a lack of sufficient evidence on the effects of medicinal cannabis and the absence of professional guidelines on how to prescribe the medicine.[1]

Several actors we interviewed pointed to the necessity for strengthened and detailed guidelines for doctors on cannabis prescription. These should be developed by the Danish Medical Agency. They could take, as their starting point, existing guidelines from countries such as France and Canada, as well as material developed by the Danish Clinical Cannabis Forum.

Additionally, there is a need to facilitate and run new educational courses for doctors focusing on medical cannabis, and advising, in particular, on how to use cannabis as a course of treatment increasing the patient's quality of life.

1. Budchwald et al. (2019) "*Clinicians view of cannabis to cancer patients – a qualitative interview study*"

4. Four Cases

This chapter presents four case studies. Each represents a different part of the Danish medical cannabis ecosystem:

- The first case focuses on a global leader in medical cannabis production that has located its largest European production facility in Odense.
- The second case looks at a Danish medical cannabis company based on strong horticultural expertise and know-how within breeding and plant production.
- The third case is a company specialising in performing highly advanced pharmaceutical testing and analysis for the medical cannabis industry.
- The fourth case concerns a Danish research group based at the University of Southern Denmark conducting research into how cannabis can be used to fight antibiotic-resistant bacteria.

Case 1: A global medical cannabis company located in Denmark

About Aurora Nordic

Aurora Nordic was founded in 2018 as a joint venture between the Danish horticulture company Alfred Pedersen & Son and the Canadian company Aurora Cannabis Inc. In 2020 Aurora Cannabis Inc. took on full ownership of the Aurora Nordic facility.

Aurora is a global leader in medical cannabis production with state-of-the-art facilities in Canada and Europe. Aurora's facilities are designed and operated to ensure the highest level of quality and consistency for the benefit of patients. Aurora Europe's largest production facility is Aurora Nordic, in Odense, Denmark. Aurora also operates South America's first GMP compliant science lab in Uruguay, known as ICC Labs, which provides cultivation and processing capacity for high quality medical cannabis concentrates.

Since its foundation in 2018, the Aurora Nordic facility has grown considerably from around 27 employees to almost 80 employees today. Those working at the facility range from unskilled and vocationally trained workers to highly educated specialists such as biologists, process engineers, who typically come from a background of employment in the pharmaceutical industry.

Aurora's production facility in Odense, Denmark

With more than 9,200 m² production space and a maximum capacity of up to 10,000 kg of high-quality medical cannabis per year, the Aurora Nordic facility is well positioned to serve European and international markets. Today, the high-tech cultivation facility in Odense produces dried flowers as well as full spectrum medical cannabis extracts. It will expand its product offerings in the near term. EU-GMP certification was granted in 2020.

In the production facility, Aurora Nordic has invested in state-of-the-art extractors. These allow cannabis oils to be extracted from dried cannabis flowers and thus facilitate the manufacture of a variety of oil-based products. Aurora Nordic is in the process of further developing its product portfolio to include capsules, tablets, etc., as well as isolates which contain CBD or THC alone as highly purified active pharmaceutical ingredients (API).

Strong interest in research and collaboration with knowledge institutions

Aurora Nordic believes there is a strong need to improve our knowledge of the effects of medical cannabis. For that reason, they collaborate with several Danish universities, including the University of Southern Denmark, as well as with the various Danish health professions and hospitals. The purpose of the research collaborations is to acquire new and improved knowledge about the effects of medial cannabis on patients.

Aurora Nordic also collaborates with universities and companies abroad. Last year, the company worked with Humboldt University in Germany, funding a course on which no fewer than 15 students worked with different perspectives on medical cannabis.

Case 1: A global medical cannabis company located in Denmark

Denmark as the main supplier of medical cannabis in Europe

Aurora Nordic sees great potential in the European medical cannabis market. It expects to experience significant growth over the next few years, with rising exports to the larger European countries. The high-tech cultivation facilities in Denmark are expected to be the main supplier of medical cannabis to the entire European market. Aurora Nordic therefore expects to significantly increase its revenues and facility employees over the coming years. Within the European market, Aurora Nordic sees the largest growth coming from formulated products rather than dried flowers.

Going forward, Aurora Nordic therefore sees considerable potential in embedding the medical cannabis industry in the strong Danish life science sector. There are significant synergies to be had in the interplay of the medical cannabis industry and the research environments of traditional life science. A stronger integration of these two could strengthen the medical cannabis sector significantly.

Another important element going forward is the regulatory framework in Denmark. The Danish legislative framework for medical cannabis is based on a special national scheme which is exempt from the Medicines Directive.

Case 2: A company based on strong horticultural expertise

About Schroll Medical

Schroll Medical is a Danish medical cannabis company located on Fyn. Established in 2018, Schroll Medical has its origins in Schroll Flowers, a breeding and plant production company that is one of the world's leading suppliers of hydrangeas.

Schroll Medical was given approval to join the Danish medical cannabis pilot in 2018 and received a license for its cannabis development programme the following year. Due to its extensive horticultural experience and know-how, it was quickly able to establish efficient, high-quality production facilities.

The company's production facilities were awarded EU Good Manufacturing Practice (EU-GMP) certification early on. Currently, they produce up to approx. 7 tons cannabis a year, which they export to countries such as Germany, Australia and England. Besides producing medical cannabis, Schroll Medical works intensively with plant breeding, and specifically on the modification of various traits of the cannabis flower to produce desired characteristics such as higher concentrations of CBD or THC.

Today the company has around 35 employees, ranging from trained labour to highly educated specialists, including biologists who breed the cannabis plants.

Strong local support and collaboration in the ecosystem

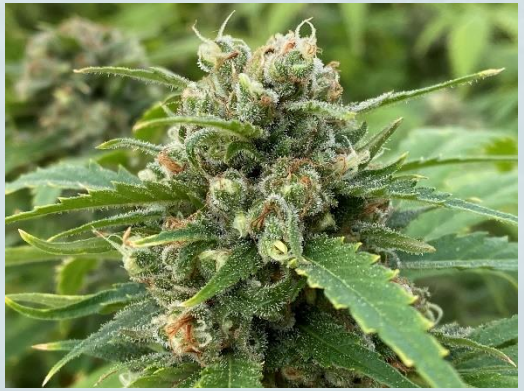
The local ecosystem, and strong collaboration between various actors on Fyn, has played an important role in Schroll Medical's positive development. The company has worked with several Danish companies and knowledge institutions, as well as with public authorities, since their establishment.

Over recent years, Schroll Medical has collaborated with researchers from the Department of Green Technology at the University of Southern Denmark. The projects have focused on gene-rating new knowledge about various active substances in the cannabis flowers such cannabinoids and terpenes.

Besides being an active collaborator with local knowledge institutions, Schroll Medical is a member of the industry association for manufacturers of medical cannabis and associated subcontractors in Denmark (Medicinsk Cannabis Industri).

Medicinsk Cannabis Industri has facilitated several networking and collaborative events and activities involving Danish medical cannabis companies. The widespread cooperation with other companies has played an important role when it comes to understanding and interpreting legislation correctly.

Local authorities - particularly Invest in Odense - have also played a significant role in building a strong ecosystem with collaborative activities on Fyn. From the beginning of the pilot scheme, they have launched a variety of initiatives aiming to bring together relevant actors and improve the business framework for companies on Fyn.



Case 2: A company based on strong horticultural expertise

Great growth potential on the European markets

Schroll Medical sees substantial future potential in the European market for medical cannabis. It expects demand for cannabis products to increase continuously over the coming years. It anticipates that it will need to double its workforce in the next 3-4 years.

To meet future demand for medical cannabis products on the European market, Schroll Medical is developing its product portfolio, adding further extracts of cannabis flowers and oil-based products.

The company sees considerable growth potential in oil-based products and cannabinoid isolates on the European market. Among other things, it is much easer to control dosage accuracy and consistency of content in oil-based products than it is with dried flowers.

Potential growth barriers

Looking forward, a well-functioning domestic market of Danish products is highlighted by Schroll Medical as a good starting point for opening up new export markets. Denmark is known globally for its high-quality pharmaceutical products. The Danish origin of medical cannabis products would signal to buyers that they are safe and of high-quality.

A stronger domestic market could also support better and more systematic collection of patient treatment data, which can in turn be integrated with existing Danish health data. This would allow Denmark to be a frontrunner in Europe in generating new knowledge about the effects of medical cannabis.

In this context, Schroll Medical highlights the need to develop new and more detailed guidelines for Danish doctors on the uses of medicinal cannabis. The current guideline and material provided by the Danish Medicines Agency are insufficient. They have not been updated in years. In other countries, such as Canada and France, the medical agencies have published more detailed and precise guidelines.

Finally, Schroll Medical draws attention to the harmonisation of regulatory conditions within the EU and the EU-GMP. There are currently significantly divergent interpretations of the standards set out in the EU-GMP across the European countries, and this poses a serious challenge for the industry. To ensure that the sector maintains high-quality products, it is vital that European countries interpret the rules uniformly.

Case 3: Advanced analytical laboratory

About QNTM Labs

QNTM Labs is a high tech analytic laboratory located in Odense that specialises in performing highly advanced pharmaceutical testing and analysis for the medical cannabis industry. Their services cover advanced testing and analysis for regulatory compliance, advising and consulting, as well as contract research.

QNTM Labs was founded in 2020 by Connor Murphy and Justin Ihnken. They established QNTM Labs as they saw a need for a more advanced and specialised laboratory targeting the medical cannabis industry. Danish producers, like many around the world, have struggled to find reliable laboratories with the ability to perform analyses on new cannabis-based products of the kind that is vital in the product development life cycle and particularly in acquiring EU-GMP approval for pharmaceutical product registration.

The two founders pivoted from successful corporate careers to apply their skills and experience to create QNTM Labs within a year. Today their company has a range of robust cannabis focused analytical methods and is working hand-in-hand with multiple medical cannabis producers in Denmark and internationally. QNTM's team is currently around 10 employees, including PhDs in Analytical Chemistry with experience in R&D, quality control, and quality assurance.

QNTM Labs' ability to establish robust operations within an accelerated timeline has attracted the attention of the international investment community, and in September 2021 the company secured EUR 3.5 million in funding from a consortium of private investors. Based on the investment, QNTM Labs is scaling existing lab operations and commercial relationships. It is in the process of expanding into a new 1,000 m² flagship laboratory that will be used to cover a broad range of EU-GMP pharmaceutical analysis as well as innovative R&D projects.

The new, highly specialised laboratory will make it possible for QNTM Labs to focus more intensively on developing cannabis specific analytical standards for the Danish and global medical cannabis industry.

Strong ecosystem and network important for the development of the company

The strong ecosystem on Fyn, with several key medical cannabis producers and knowledge institutions located there, was one of the main reasons QNTM chose to locate in Odense. Additionally, the support and involvement of local actors like Invest in Odense has been an important factor in the laboratory's establishment on Fyn and has accelerated growth.

Case 3: Advanced analytical laboratory

The strong ecosystem on Fyn has also played an important role in supporting the development of QNTM Labs, as they have been able to utilise the local network to initiate a range of collaborative projects, including several with researchers at the University of Southern Denmark. The local network was also important for QNTM Labs because it helped the company to establish relationships with licensed medical cannabis producers based around Fyn. Additionally, they have been able to recruit core employees with specialised competencies locally on Fyn. Their Head of R&D is one such.

"With QNTM, we have been able to construct a laboratory, develop robust analytical methods, and start working with clients in under a year, and the ecosystem for medical cannabis on Fyn has been a crucial factor. We leveraged strong support from Invest in Odense and Invest in Denmark, who helped us connect with key stakeholders and find a location for our company. In addition, we were able to hire several critical employees locally from Fyn, which is a major advantage."

- Connor Murphy, COO and Founder of QNTM Labs

In addition to offering compliance testing services to medical cannabis companies, QNTM labs also has a strong focus on advancing research and development within the field of medical cannabis. The company therefore participates in extensive collaborative activities with departments at the University of Southern Denmark including Chemical Engineering, Biotechnology, and Environmental Technology.

QNTM Labs places a strong emphasis on working with students to develop their analytical skills and promote their educational development within the field of cannabinoids. In the future, they expect to continue and expand research collaborations with scientists from the University of Southern Denmark to drive further advances in the field of medicinal cannabis.

Strong demand for advanced testing and analysis

QNTM Labs says there is strong demand for its robust analytical services, and that it expects significant growth in the coming years as the medical cannabis sector matures in Denmark and abroad. As the medical cannabis industry begins to adopt a more pharmaceutical approach, the need for advanced studies and laboratory testing grows. Only with these can companies live up to the high-quality control standards.

In both Denmark and other European countries, producers are working on developing more advanced medical cannabis products. This requires significant analytical data and documentation for approvals by the national medicine's agencies.

With its highly specialised EU-GMP approved facilities, QNTM Labs is positioned to deliver robust and reliable scientific analysis for the industry. Within the next 4-5 years, the company therefore expects to be able to double its number of employees.

Going forward, QNTM Labs points to the legislative and regulatory conditions for medical cannabis as an important factor. Currently, there is little harmonisation across EU Member States in relation to medical cannabis, and increased efforts to harmonise the standards for medicinal cannabis products at EU level will be important for the future development of the industry.

Case 4: Danish researchers fighting resistant bacteria using cannabis

Janne Kudsk Klitgaard is an Associate Professor at the Institute of Clinical Research and Department of Biochemistry and Molecular Biology at the University of Southern Denmark. Janne Kudsk Klitgaard and her research group conduct research within the field of clinical microbiology with a focus on the ways in which antibiotics can be combined with helper compounds to combat resistant bacteria. The helper compounds typically do not have any antibacterial properties themselves, but they are able to boost the effect of the antibiotics.

The development of bacterial resistance to conventional antibiotics is becoming a major problem and a threat to global health. Antibiotic resistance means that minor infections which used to be cured easily can become very difficult to treat – potentially, they might be life-threating for patients. Therefore, there is a strong need to develop new antibiotics that better combat the resistant bacteria.

CBD from cannabis can boost the effect of antibiotics on bacteria

In 2018, Janne Kudsk Klitgaard entered into a research collaboration with the Danish medical cannabis company Canna Therapeutic to investigate whether cannabidiol (CBD) could be used as a helper compound to improve the effectiveness of antibiotics. Professor Klitgaard was joined by the Canna Therapeutic CEO, Steen Pontoppidan, and a PhD student, Claes Søndergaard Wassmann, also participated in the project, which was co-funded by Canna Therapeutics.

The research attempted to identify the most efficient combination of CBD and antibiotics, and to isolate the mechanism of the helper action. It indicated that CBD is able to enhance the effectiveness of antibiotics against a variety of resistant bacteria. Additionally, when the combination treatment is used, it is possible to reduce the quantity of antibiotics given to fight the bacteria, which in turn reduces the risk of further resistance development.

Very challenging to attract research funding

Although the research study found evidence of the positive effect of combining CBD with antibiotics, the exact underlying mechanisms of this effect are still unknown and call for further research. Despite the significant promise of her research, Janne Kudsk Klitgaard has found it very difficult to find research funding for her work on cannabidiol.

"There is a great potential in additional research to further clarify how cannabinoids such as CBD can strengthen the effectiveness of antibiotics against resistant bacteria. However, its very difficult to find funding in Denmark for research related to the field of medical cannabis. The research area is generally under-prioritised in both public and private research funding organisations in Denmark."

- Janne Kudsk Klitgaard, Associate Professor, University of Southern Denmark

Researchers working in the field of medical cannabis confirm that it can be difficult to attract funding, both from public and private research funding organisations. Most of the research into medicinal cannabis is funded by companies in the industry. However, as the medical cannabis industry is still relatively young, it can be difficult for the companies to initiate and fund large research projects spanning over several years.

There is, therefore, is a pressing need at present for dedicated research funds capable of supporting more basic research into medical cannabis. Overall, knowledge and evidence of the various effects cannabis is not well developed in the scientific community, and dedicated funding could increase levels of knowledge here significantly.

A strengthening of basic research into medical cannabis would not only be advantageous for the researchers. Potentially it could also lead to the discovery of new business areas for the medical cannabis companies.

From left: Janne Kudsk Klitgaard, Steen Pontoppidan and Claes Søndergaard Wassmann

Appendix: Methods and data

Survey of medical cannabis companies

The quantitative analysis underpinning this report was based on a survey of medical cannabis companies in Denmark that are licensed to cultivate and handle cannabis under the pilot programme or the development scheme.

The survey involved 36 companies and was conducted in September-October 2021. All companies received an invitation to participate in the survey by email. To raise the response rate, we also attempted to contact the companies by telephone. In total 20 of the 36 companies completed the survey (response rate 55%).

Of the 20 companies, 13 had a licence under the pilot programme. The survey therefore includes most of the largest companies within the Danish medical cannabis sector.

International literature

The fowling national and international reports and analysis have been used in the report:

- Prohibition Partners (2021*): "The European Cannabis Report, 6th edition."*
- KOMAND Consulting (2020). *"The European Medical Cannabis Market - Investment in strategy."*
- Brightfield Group (2020): *"Succeeding in European Cannabis."*
- IMARC Group (2021). *"Medical Cannabis Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2021-2026."*
- Grand view research (2021): *"Legal Marijuana Market Size. Market analysis report."*
- Research and Markets (2021): *"Medical Cannabis Market Forecast to 2028."*
- Facts & Factors (2021): *"Medical Marijuana Market By Application, By Route Of Administration, By Distribution Channel: Global & Regional Industry Analysis Report, Regional Outlook, Application Potential, Price Trends, Competitive Market Share & Forecasts, 2021 – 2026."*
- Market Research Future (2021): *" Medical Cannabis Market."*
- Market Data Forecast (2021): *"Global Medical Cannabis Market Size, Share, Trends, COVID-19 impact, Growth Analysis Report – Segmented By Species, Derivatives, Application, Route of Administration & Region – Industry Forecasts (2021 to 2026)."*
- Emergen research (2021): *" Medical Cannabis Market."*
- Danish Ministry of Health (2020) "*Evaluering af forsøgsordningen med medicinsk cannabis."*

Interviews

Further input to the analysis was obtained in 13 interviews. The participating interviewees are listed in the table below.

Company/organisation	Interview
Schroll Medical	Mariolla Dolleris Schroll, Public Relations Officer
Aurora Nordic	Marianne Hundtofte Nielsen, Vice President Business Development & Medical Affairs Europe
QNTM Labs	Connor Murphy, Founder and COO
OC Care	Christian Hollensen, CEO
Canngros	Henrik Uth, CEO
DanCann Pharma	Jeppe Krog Rasmussen, Founder and CEO
Valon Medical	Peter Emil Sigetty, Chief Operating Officer
QNTM Labs	Rime Bahij, Head of Research
University of Southern Denmark	Jette Kudsk Klitgaard, Associate Professor
University of Southern Denmark	Lars Duelund, Executive Officer
Regional Hospital Nordjylland	Dorte Buchwald, palliative care nurse
Regional Hospital Nordjylland	Peter Christian Leutsche, Head of Centre for Clinical Studies
Psykiatrisk Center København	Carsten Hjortshøj, Senior Researcher
Horsted Institute	Tina Horsted, Owner, M.D.

IRIS GROUP
CHRISTIANS BRYGGE 28, 1. SAL | DK-1559 KØBENHAVN V
IRISGROUP@IRISGROUP.DK | WWW.IRISGROUP.DK