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Cultivating Sustainable Cannabis in the Danish Medicinal Cannabis Pilot Programme: A Case Study at OC CARE ApS

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Abstract

In my research I explore the Danish Medicinal Cannabis Pilot Programme (Pilot Programme). The study was done with the case of OC Care ApS' (OC Care) Envision Concept, a legislation-compliant growth facility with a controlled environment, designed to produce sustainable medicinal cannabis. OC Care was chosen as the single case for this study because they are the only licensed company with the aim to produce organic cannabis within the Pilot Programme. OC Care's Envision Concept is analyzed through an agroecological perspective, by considering the economic, environmental, and social components that together make a system. To understand the context and set the boundaries for the study, the Pilot Programme is analyzed through system thinking methodology. To reach a holistic understanding of the case and its context, data was gathered through multiple sources: participant observation, informal conversations, and semi-structured interviews. Findings indicate that the Pilot Programme has a cautious approach towards legalization, and aims to produce scientific evidence to validate the benefits of medicinal cannabis and regulate its cultivation, processing, and distribution. Due to its pharmaceutical paradigm, hybrid framework, and Denmark's competitive advantages, Denmark is becoming a leader in the European medicinal cannabis market. To produce organic and sustainable medicinal cannabis OC Care have developed the Envision Concept, a controlled environment cultivation and processing facility, compliant with the European Union's (EU) Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. The Envision Concept is a system that integrates economic, environmental, and social interests to provide patients with an organic, standardized, and sustainable pharma-grade product.

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Introduction

Cannabis is beginning to be recognized for its therapeutic benefits rather than feared for its adverse effects after decades of prohibition. Although cannabis remains prohibited worldwide, some countries have started legalizing its use, as research reveals benefits when treating illnesses such as neuropathic pain. It may also improve multiple sclerosis spasticity, reduce chemotherapy-induced nausea and vomiting, and ease many chronic conditions (Grant, et al., 2012; Borgelt et al., 2013; Whiting et al., 2015; Isaac, Saini, & Chaar, 2016). Although there is scientific evidence for the positive effects mentioned above, physicians and health authorities worldwide ask for more studies regarding cannabis' long-term effects and use of smoking as an administration form (Hakkarainen et al., 2015). Despite this knowledge gap, international support for the legalization of medicinal cannabis is increasing.

In North America, the approach towards medicinal cannabis legalization developed through a bottom-up approach, where medicinal cannabis was approved through citizen initiatives. In contrast, European countries are updating their health systems to provide patients with medicinal cannabis, which means that the medicinal cannabis industry in Europe counts on support from health agencies, patient advocacy groups, pharmaceutical firms, and insurance companies. For this reason, medicinal cannabis in Europe must be produced under high-quality standards and is subjected to the same regulations as any other medicine production. Cultivation and post-harvest transformation are controlled by the EudraLex (2015); The rules governing medicinal products in the EU, Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use (EU-GMP). This legislation provides a good manufacturing practices (GMP) framework to produce medicinal products. Among the requirements included in EU-GMP, we find; Quality System Requirements, Personnel, Premises and Equipment, Documentation, Production, Quality Control, Outsourced Activities, Complaint/ Defect/ Recall and Self Inspection (Lahnakoski, 2019).

The rising interest in cannabis legalization has set the scene for developing the global medicinal cannabis industry, one of the fastest-growing markets in the world (Keenan & Murphy, 2018). If legalization continues to expand across Europe, the demand for medicinal cannabis is expected to increase (Lubbe & Verpoorte, 2011) and Europe will become the world's largest medicinal cannabis market, projected to be worth €55.2b by 2028 (Attwood et al. 2019).

As described by the Invest in Denmark department of the Danish Ministry of Foreign Affairs, Denmark is becoming an attractive entry point into the European medicinal cannabis market due to its proximity to the main EU markets, pharmaceutical know-how, and transparent regulatory regime (Prytz & Light, 2020). Thus, providing Danish and European farmers vast opportunities in this emergent market with excellent growth potential (Prytz & Light, 2020; Lubbe & Verpoorte, 2011).

My study aims to provide exploratory knowledge about the Danish Medicinal Cannabis Pilot Programme (Pilot Programme) through the case of one of the producers; OC Care ApS (OC Care). I follow Yin's (2017) case study methodology to explore OC Care's Envision Concept and its aim of delivering sustainable medicinal cannabis. I also analyze and map the Pilot Programme according to Checkland's (1999) system thinking methodology.

Research Questions

- *How is the medicinal cannabis Pilot Programme structured in Denmark?*

- *How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?*

Context

This section sets the stage for the research by explaining the legal state of medicinal cannabis and the overall context. As Yin explains (2017), the case cannot be distinguished from its context, allowing me to explain its setting and boundaries.

Cultivation

Cannabis has been cultivated since ancient times, and archaeological findings have evidenced its use as a fiber, food, oil, and medicine source since the Neolithic period - 10,000 BCE until 3,000 BCE (Russo, 2007; Piluzza et al., 2013). However, at the end of the 19th century, its use started declining due to the development of new fibers such as cotton and synthetic fibers and the decline in rope and sails production due to the rise of steamboats (Piluza et al., 2013). Kynett (1895) published an editorial in the *Medical and Surgical Reporter* journal of New York in 1895 titled *Cannabis Indica,* where he pointed out that, unlike with many other drugs, there had never been a documented poisoning case from cannabis. The medicinal use of cannabis started to decline at the beginning of the 20th century with the development of analgesic drugs such as aspirin, which did not have psychoactive effects and offered reliable treatment with predetermined dosages. Simultaneously, worries about uncontrolled access to recreational cannabis started emerging (Pisanti & Bifulco, 2019).

Prohibition

The first signs of prohibition appeared in 1925 due to the pressure exerted by Egypt, the United States, and China, to include cannabis among the controlled drugs in the Second International Opium Convention (Pisanti & Bifulco, 2019). Nevertheless, it was not until 1961 that cannabis became illegal when the Single Convention on Narcotic Drugs classified cannabis as a Schedule I, a dangerously addictive psychoactive drug, and Schedule IV, a limited or no therapeutic value drug (Lande, 1962). Since then, many countries have opposed cannabis prohibition. India objected to the 1961 Convention and defended the use of *bhang*, a preparation of cannabis leaves and seeds used during religious celebrations (Bewley-Taylor, Blickman, & Jelsma, 2014).

Despite the prohibition, cannabis research continued and in 1967 Ashurst et al. identified the chemical structure of cannabinoids, the active substance in cannabis. In the early 1990s, scientists discovered the endocannabinoid system, the endogenous physiological system in charge of regulating body processes (Pisanti et al., 2007, 2015; Proto et al., 2012). These findings validated the medicinal properties of cannabis, opening the door to new research and the publication of hundreds of papers supporting its use (Aquila et al., 2009; Kaur, Ambwani & Singh, 2016; Pisanti et al., 2009; Pisanti et al., 2013). These findings also contributed to more lenient cannabis policies. Today, more than 20 countries are allowing cannabis medicinal use (Figure 1 below). Moreover, other countries such as Canada (Cox, 2018) and Uruguay (Cerdá & Kilmer, 2018), and more than 15 states in the United States have decriminalized or legalized its use for recreational purposes (Rense, 2020).

Control

Denmark has signed the main international conventions on drug and cannabis control, including the 1961 UN Single Convention that adds cannabis to the list of illegal drugs, although use was not criminalized. Additionally, Denmark has also signed the 1971 Psychotropic Substances Convention and the 1988 United Nations Convention Against Illicit Traffic of Drugs and Psychotropic Substances (Laursen & Jepsen, 2002; Frank, 2008: Nygaard-Christensen & Frank, 2019). Danish drug policy is built around the 1955 law on Euphoria-inducing Substances; which enforces minor drug crimes, and section §191 added to the Penal Code in 1969; which enforces sales and possession of large amounts of drugs (Laursen & Jepsen, 20022; Storgaard, 2005, Nygaard-Christensen & Frank, 2019). According to these laws, possession, production, import, and buying or selling of cannabis can lead to prison penalties from two to ten years (Frank, 2008).

Danish drug policy has traditionally been liberal, with laws differentiating dealers from consumers and classifying drugs; hard or soft. Thus, police target drug dealers and health agencies to provide harm reduction services to consumers (Nygaard-Christensen & Frank, 2019). However, in 2001 the liberal-conservative coalition came into power, and in 2003 they launched *'the fight against drugs*'; an action plan institutionalizing a zero-tolerance

policy towards drugs. This new drug policy amended the law on euphoria-inducing substances and section §191 of the Penal Code, introducing penalties for possession of small quantities of cannabis (Frank, 2008). Thus, ending the distinction between consumers and dealers and between soft and hard drugs.

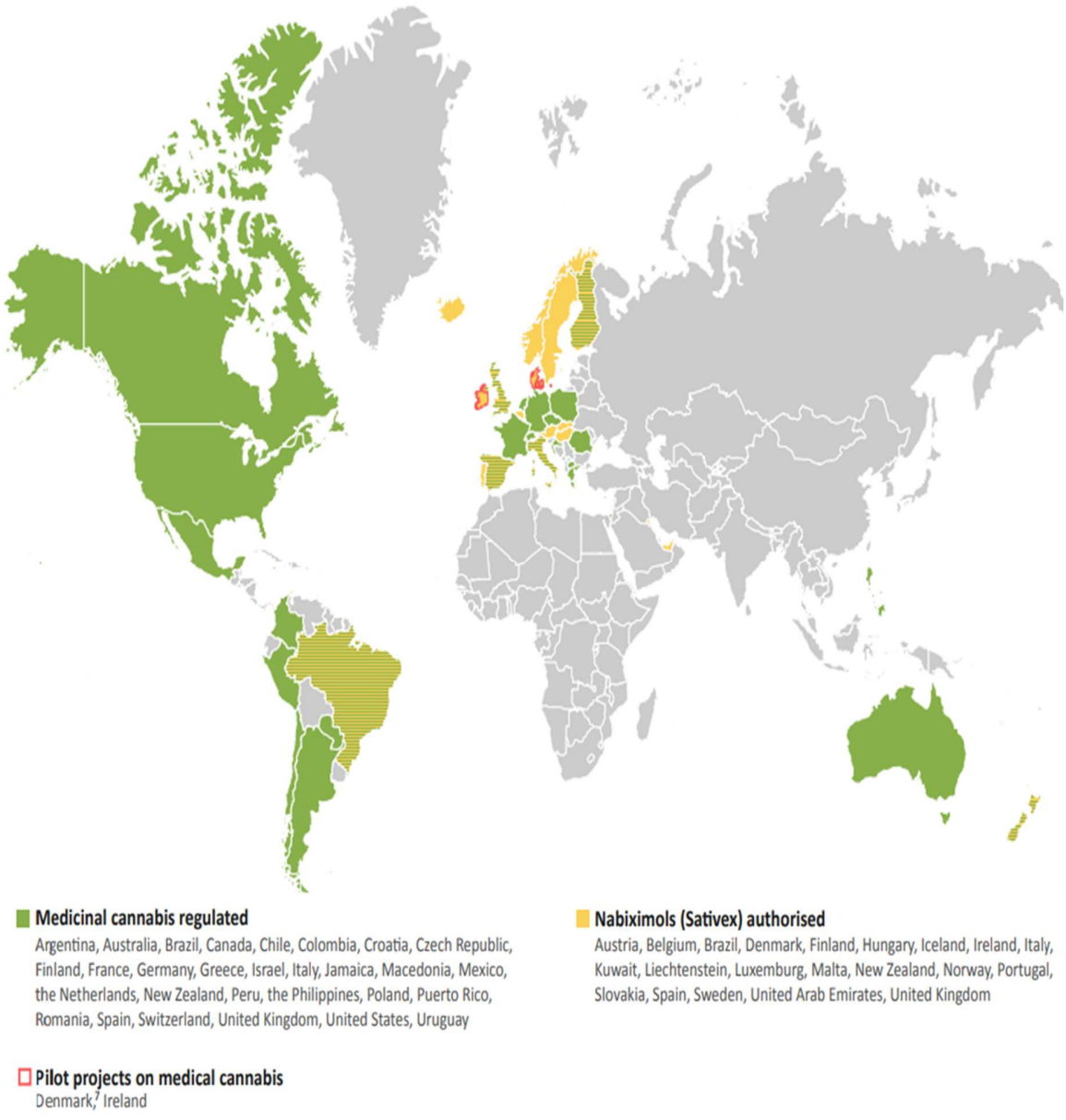

Figure 1. *Map of countries with approved medicinal cannabis (International Drug Policy Consortium, 2018)*

Danish Medicinal Cannabis Pilot Programme

In December 2017, Denmark approved the *Medicinal Cannabis Pilot Programme* (LOV nr 1668 of 26/12/2017), a four-year Pilot Programme allowing prescriptions of medicinal cannabis for patients suffering from: multiple sclerosis, spinal cord injury, chronic pain, and pain relief for patients undergoing chemotherapy. Thereby opening the market for licensed growing companies through the *Development Scheme* (BEK nr 695 of 03/07/2019); executive order regulating the cultivation, production, and distribution of cannabis bulk and cannabis products.

Denmark's Pilot Programme has a cautious approach towards legalization, following the International Narcotics Control Board's (INCB) recommendations, which in its 2018 report alerted that poorly planned medicinal cannabis programmes might increase cannabis consumption due to a weakened public perception of associated risks (INCB ANNUAL REPORT 2018 - Board, I. 2018). Furthermore, the Pilot Programme aims to collect evidence of the effects and side-effects of cannabis use after the Danish College of General Practitioners expressed concerns regarding the lack of knowledge around the impact of medicinal cannabis on chronic nerve pain and potential side-effects of cannabis use (DSAM, 2018). The Pilot Programme regulates medicinal cannabis and complies with the drug control treaties signed by Denmark. It is based on public health knowledge and thereby setting an example for other countries seeking to legalize medicinal cannabis.

Case Selection and Presentation

To select a case, I visited the Danish Medicines Agency website and reviewed the list of companies authorized to cultivate and handle cannabis (see Appendix 1). When I proceeded to do a web search, I found that most of the companies do not have an active website. I then narrowed my list of potential candidates to those with an active website. I further developed the case selection criteria to make the project relevant in Agroecology and included the following: a small-scale case, family-run enterprise, and an interest in sustainable practices, i.e., producing organic, using renewable energy, and reducing

waste. This process led me to the case of OC Care, as the only organic producer of cannabis within the Pilot Programme.

The Case: OC Care ApS

OC Care is in Aabybro, North Jutland (Figure 2). On December 15, 2018, the Danish Medicines Agency granted OC Care license to cultivate and handle medicinal cannabis. Unlike most companies taking part in the *Development Scheme*, OC Care is a family-owned company. The family has 27 years of experience in organic farming and raising beef cattle. Since its founding, the company has focused on sustainability, only using certified organic growing media, pesticides, and fertilizers. They are also committed to renewable energy, recycling, and waste sorting.

***Figure 2**. OC Care ApS location (Google, n.d.)*

To achieve sustainable production of medicinal cannabis, they developed the Envision concept, a multi-layer system combining production modules into a single facility powered by renewable energy. The Envision facility was designed to comply with the EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use (EU-GMP). The Envision concept is still in the research- and design phase, and specialized methods are being fine-tuned in their 110sqm test facility. OC Care has partnered with leading horticulture stakeholders to integrate new technologies, artificial intelligence (AI), data science, and robotics into the concept. These technologies streamline cannabis production by providing reliable data and automatizing the processes. This way environmental factors are replicated during cultivation, ensuring a consistent product in every batch.

Theoretical Framework

Methodology

As an agroecology student I believe that to improve our current unsustainable and globalized agri-food systems, research must lead to concrete actions that empower those involved in changing the system (Lewin, 1946). Thus, I framed my research in action research methodology (Lewin, 1946; Hodgkinson, 1957; Hult & Lennung, 1980; Checkland & Holwell, 1998; Greenwood & Maguire, 2003; Lieblein et al., 2012) and decided to explore OC Care, a company addressing the rising concerns over the highly energy-intensive cultivation methods of the emerging global medicinal cannabis industry (Mills, 2012). For example, OC Care uses a controlled environment facility that is more energy efficient than a greenhouse.

Data was collected in close collaboration with stakeholders from the Pilot Programme, especially with the CEO of OC Care. The use of participatory methods such as participant observation and semi-structured interviews allowed me to share, contrast and reflect on my findings with participants, which again lead to a deeper understanding of the situation (Hult & Lennung, 1980).

Research Strategy

I realized during the preliminary stages of the research that if I wanted to reach my goals, I needed a strategy to develop this study. To deal with the continuous inflow of information and to structure my analysis, I followed recommendations from Checkland´s (1999) soft system methodology (SSM). This action research methodology based in systems ideas provides flexible principles to understand and facilitate change in real-world problematic situations. Additionally, SSM is a valuable methodology for novice researchers like me because it provides a framework to systemize the process of inquiry (Checkland and Haynes, 1994).

I was able to adopt and adapt the methodology to fit my needs (Checkland and Poulter, 2006). Due to my inexperience as a researcher, time constraints, and the project's scope, it was not feasible to use the entire SSM methodology and build purposeful activity models

to suggest a change for the Pilot Programme. Instead, I used SSM to conceptualize my understanding of how the Pilot Programme is structured and to discuss how the Envision Concept integrates economic, environmental, and social interests to achieve sustainable production of medicinal cannabis.

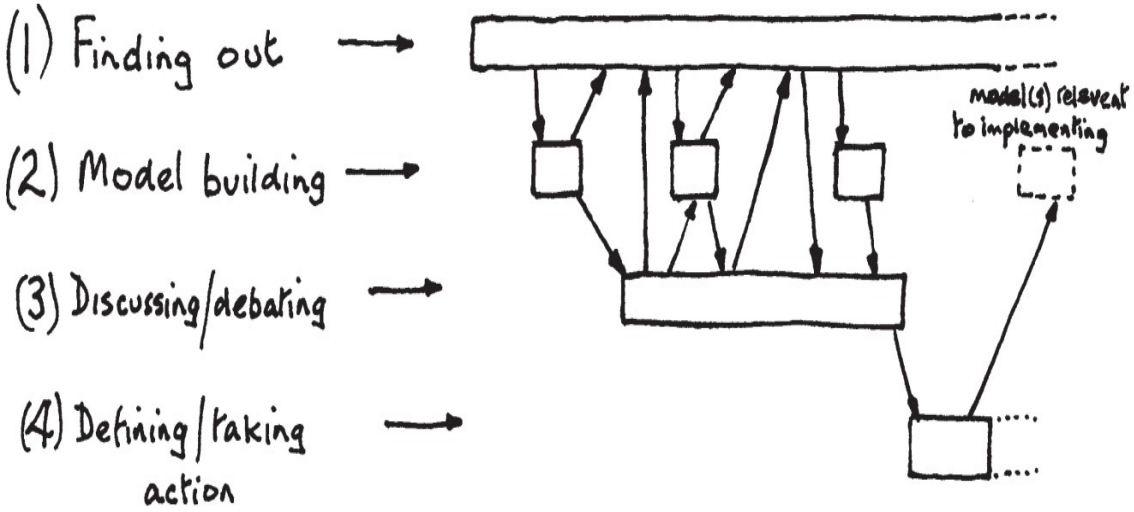

Figure 3. *Typical pattern of activity during an SSM investigation (Checkland & Poulter, 2006)*

As seen above in Figure 3, my research process was cyclic. I started by reviewing news articles, industry reports, archival records, and public records to learn about the Pilot Programme and the Envision Concept. To make sense of the information I had gathered I started building system maps and rich pictures (Checkland, 1999; Reynolds and Holwell, 2020). I used system maps as a tool to conceptualize my understanding of how the Pilot Programme is structured (see *Figure 5.*), while rich pictures were used to understand and describe the development of OC Care's Envision Concept (see Appendix 2).

However, the process of developing system maps and rich pictures was not linear. After developing a system map or rich picture new questions and themes were revealed, so I was constantly finding out new information to deepen my understanding of the situation to prepare a more robust diagram (Checkland and Poulter, 2006). For example, during my first visit to OC Care's facility I learned that the Pilot Programme consisted of two parallel programmes: A Pilot Programme regulating medicinal cannabis prescriptions and a

Development Scheme regulating cultivation, processing, and distribution of medicinal cannabis.

After getting a sense of the whole, I started sharing my system maps and rich pictures with my interviewee, using them as a tool to structure our discussions regarding the Pilot Programme and the Envision Concept (Reynolds and Holwell, 2020). For example, during these discussions I learned that the company had to change its name from “Organic Cannabis Care” to OC Care because there is no organic certification for medicinal cannabis.

In line with systems thinking, I used an “agroecological lens” to analyze OC Care’s efforts to achieve a sustainable production of medicinal cannabis (Gliessman, 2004; Bland and Bell, 2007). I therefore studied the economic, environmental, and social interests that integrate the Envision Concept, basing my analysis on Wezel et al.’s (2016) term "agroecology territories"; places transitioning into sustainable agri-food systems. I acknowledge that Wezel uses the term “territory” to refer to a larger territorial scale, but when I analyzed OC Care, I recognized that the Envision Concept integrates the three domains of an "agroecology territory"; production based on organic principles, use of renewable energy, and embedded in a larger system; the Pilot Programme. Furthermore, as reflected in my research questions, this strategy allowed me to shift the scale of the study from the Pilot Programme system to the Envision Concept system (Bland and Bell, 2007; Wezel et al., 2016).

Research Design

To achieve my goals of attaining a holistic understanding of the Pilot Programme and developing an in-depth analysis of the economic, environmental, and social interests of OC Care’s Envision Concept, I designed this study following Yin’s (2017) single holistic case study recommendations. Consequently, the Pilot Programme sets the context of the research, as the case cannot be understood without its context (Baxter & Jack, 2008; Yin, 2017)

To maintain the research scope, I bind the case by placing the Pilot Programme, its stakeholders and events held during the duration of this study as the case boundaries

(Baxter & Jack, 2008). These boundaries guided my line of inquiry and supported my exploration and analysis by keeping the case embedded in its context.

Methods

Data Collection

Following Yin's (2017) recommendations, I gathered data through multiple sources: secondary data (news articles, industry reports, archival records, and public documents), participant observation, informal conversations, and semi-structured interviews. This strategy allowed me to reach a holistic understanding of the case embedded in its context and strengthen data validity through triangulation (Baxter & Jack, 2008). Data collection stretched over the fall and winter of 2020, starting with a preliminary phase in August where I reviewed secondary data. Most of the data collection took place between September 2020 and January 2021 through semi-structured interviews.

Secondary data

I reviewed news articles and industry reports from the Invest in Denmark office of the Danish Ministry of Foreign Affairs, Cannabis Danmark advocacy group and reports covering the Pilot Programme from Prohibition Partners and First Wednesday's. I also reviewed the Danish Medicines Agency and the Danish Civil Agency archival records and public documents. These data helped me to get a holistic understanding of the Programme and were of great help for developing the system diagram (Figure. 5) which I will later present in the results chapter.

Participant Observation

After getting an initial understanding of the Pilot Programme I visited the OC Care facility in September 2020 for three days, to observe their day-to-day operation and establish the collaboration for the project. During this visit, I immersed myself in their efforts to develop the Envision Concept, observed their cultivation methods and aimed at understanding the motives that drive them to attain a sustainable production (Bryman, 2012). Also, having this visit early in the project was valuable because it allowed me to reflect on my role as a researcher and helped me to identify the skills I needed to improve for the upcoming interviews.

Furthermore, I also made direct observations during a symposium on medicinal cannabis: From Plant to Patient, on November 11. 2020, organized by the Danish Technical Institute and the Invest in Denmark office of the Ministry of Foreign Affairs of Denmark. During this symposium I attended talks from different stakeholders from the Pilot Programme. These talks were very informative, highlighting the main stakeholders within the Pilot Programme and revealing the different types of interrelations that link stakeholders in the Pilot Programme. During the symposium I met a special advisor from the Invest in Denmark Life Sciences team and a coordinator from the Danish Technological Institute AgroTech department. During the symposium, I was able to clear doubts I had regarding the Danish Medicinal Pilot Programme. In addition, they gave me their view of OC Care's Envision Concept.

Semi-structured Interviews

Since most of my data was collected through interviews with OC Care founder and CEO, I decided to follow Yin's (2017) prolonged case study interview strategy and stretched the interview process over five monthly sessions from September 2020 to January 2021. The first interview took place at the OC Care facility and the following 4 sittings took place in Copenhagen.

The prolonged interview with OC Care's CEO and founder started with an introductory sitting to gather background information and learn about his motivations for participating in the Pilot Programme and developing the Envision Concept. The next two sittings explored his thoughts, impressions and perceptions related to the Pilot Programme. While the last two sittings focused on OC Care's economic, environmental, and social interests, the Envision Concept roadmap, and OC Care's future projects.

This strategy allowed me to keep sittings under two hours long and structure my inquiry line to gather in-depth information to answer both of my research questions. Furthermore, this strategy enabled me to preserve the quality of the data by, including reflection sessions in between sittings, corroborate findings by contrasting them with secondary data and data gathered from the informal conversation with a special advisor

from the Life Sciences team of Invest in Denmark and a coordinator from the AgroTech department of the Danish Technological Institute (Yin, 2017).

Finally, this flexible method allowed me to follow my line of inquiry while letting participants freely express their experiences and insights regarding the Pilot Programme and the development of OC Care's Envision Concept (Rubin & Rubin, 2011;Yin, 2017). As seen in Appendix 3 where I present one of my interview guides, I framed interviews in a conversational context, using unbiased and open-ended questions so participants felt comfortable expressing their experiences, perceptions and impressions and I only intervened when the conversation was going off-topic (Bernard, 2006).

Data Analysis

I analyzed data from the interviews following Graneheim and Lundman's (2004) content analysis method. This method assisted me in reducing the data volume by analyzing the manifest content (*what the text says*), and then get into a deeper interpretation level by analyzing the data's latent content (*what the text talks about*), to identify relationships and meaning in the interview.

I started my analysis by immersing myself in the data, listening, transcribing, and rereading the interviews several times. Thus, transcripts became the unit of analysis. First, I identified and extracted meaning units: "words, sentences or paragraphs containing aspects related to each other through their content and context" (Graneheim and Lundman, 2004, p.106), from transcripts. Later, I reduced data volume by interpreting and categorizing meaning units through condensation into codes, sub-themes, and themes, as my level of understanding reached a higher logical level. Thus, shifting the analysis from the particular to the general to answer my research questions.

In Table 1 below, I present how I developed the *Environmental Interests* theme to answer research question 2 (*How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?)*. I started by listing meaning units extracted from interviews, which were then coded to reduce the volume of data. Then, I create sub-themes by grouping codes that share the same focus.

Finally, as my analysis reaches a higher logical level, I condense these sub-themes into themes (Economic Interests, Environmental Interests and Social Interests). These themes were deliberately selected to develop my analysis of the Envision Concept through an "agroecological lens".

Table 1. *Content Analysis for Environmental Interest theme*

Meaning Unit	Code	Sub-Theme	Theme
Now, we are only using energy from wind turbines in our test facilities, and we will continue to do this	wind turbines energy	Green Energy	Environmental Interests
we want to create some energy as well and we are looking into biogas reactors to try and make some green energy that way and by using wind turbines.	Bioreactor to create green energy		
we want to produce an organic product, even though we cannot get it certified organic. But still, we use organic methodology to differentiate and have a positive impact on the environment and to provide the patients with the best possible product…	*Organic production*	Organic DNA	
because they are closed, we will not have the impact on the environment, and we won't have any excess fertilizers going into the ground water streams lake or the ocean.	No pesticide runoff		
The role of OC CARE, our vision was to differentiate us from other companies producing cannabis in the Pilot Programme. A lot of companies are doing it inorganic; they are using other types of media and they are using conventional methods producing in greenhouses mostly.	Organic is healthier		
when growing organic you know you must use certified organic products. You cannot use mineral fertilizers or liquid fertilizers that aren't organic.	*Only organic inputs*		
We can recapture the water inside the facilities, so, all the water that the plants are transpiring…. We can recapture that	Recapture water	Closed Loop Water System	

water and keep it in a close loop system, so we can feed it to the plants again.			
The runoff that we have from the irrigation of the plants, we can recapture again and reuse.	Recapture water		
We can collect rainwater not to need some of the scarce freshwater resources.	Collect rainwater		
When you are growing in greenhouses you need a lot of heat to warm up the climate inside the houses, our production facility is insulated. We don't have to apply as much heat	Insulated facility	Reduce Energy Footprint	
In the way that the vertical cultivation system is being made, is a bit different. But we can still integrate a lot of lines and we can easily, collect the waste product from that production…	Reduce waste		
we want to reduce our energy supply or use in the facility, and we do that by using technologies like LED lights and the ground cooling system that I told you	Technology to reduce energy footprint		
it is sustainable, because we can keep on doing the same thing for ever after we have had the first input into the facility. It is a never-ending circle that never stops, just like the environment in the world.	Closed loop	Sustainable Mindset	
We want to secure a better for coming generations by being aware of how we produce and producing sustainable… sustainability is one of our core values.	Sustainable company		
The way things are looking now, if we keep producing foods and energy on the same way, we have been doing until now there will not be a good world to live now in 80 years.	Agriculture needs to transform		

Ethical Considerations

Since the project involves human subjects, I followed rigorous ethical considerations to protect participants' integrity (Yin, 2017). Data collection started after receiving approval from NSD - Norwegian centre for research data. Before each interview, I presented a brief

description of the research project and gathered permission through an informed consent form (Appendix 4). Participation was voluntary and entailed the option of withdrawing from the project at any moment without having to give a reason. I processed personal data following the General Data Protection Regulation and Personal Data Act to ensure confidentiality.

Results & Discussion

In this section, I present my results and discuss my findings. I start by using system thinking to encapsulate the essence of the Pilot Programme embedded in its context. Then I shift the focus towards OC Care's Envision Concept and present my findings through an agroecological lens, exploring OC Care's economic, environmental, and social interests and how they merge in the Envision Concept to achieve their goal of producing sustainable medicinal cannabis.

Results

How is the Danish Medicinal Cannabis Pilot Programme structured?

Danish Medicinal Cannabis Pilot Programme System

The Pilot Programme was unanimously backed by the Danish Parliament in 2018 and it is based on two parallel four-year trials: Pilot Programme: *regulating medicinal cannabis prescription*, and Development Scheme: *regulating medicinal cannabis cultivation, processing, and distribution*. The programme is designed to provide patients with legal access to medicinal cannabis when medicines authorized by the Danish Medicines Agency have not benefitted them.

After reviewing secondary data (news articles, industry reports, public documents, and archival records), participating in the symposium on medicinal cannabis: From Plant to Patient and organized the information gathered during interviews, I developed the systems maps presented bellow (See Figure. 4), to conceptualize the dynamic system that is developing around the Pilot Programme.

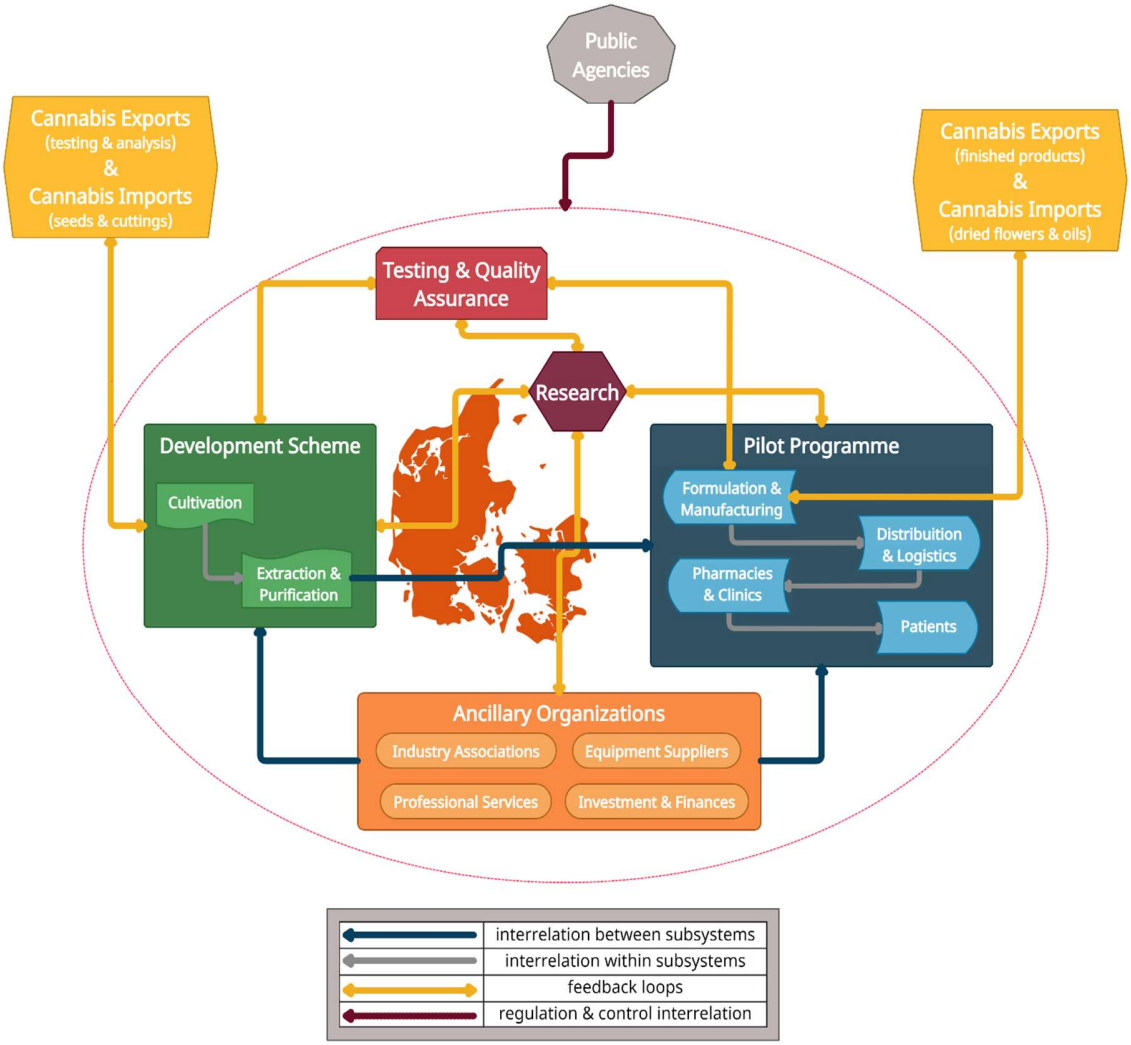

Figure 4. *Systems maps Danish Medicinal Cannabis PIlot Programme*

The Pilot Programme is based on pharmaceutical standards to ensure patients' safety, minimize risks, and produce scientific evidence concerning cannabis medicinal properties. Although these pharmaceutical standards increase the barriers for producers to enter the industry, they ensure high-quality standards, encourage participation from the renowned biotech industry and the Danish horticultural industry and promote collaboration between stakeholders from the system to develop innovative processes and products. A clear example of this is the collaboration between the Danish Technological Institute and

licensed cultivators like OC Care for developing methods for meristem tissue culture propagation for cannabis (See Figure. 5).

Figure 5. *OC Care´s Facebook post collaboration with Danish Technological Insitute (OC Care, 2021)*

This dynamic system has caught the attention of local and foreign investors, positioning Denmark as one of the world's largest medicinal cannabis producers, with more than 270,000 square meters of built cultivation facilities (Prytz & Light, 2020). To enter the Danish market, the global leaders in the industry (e.g., Aurora Cannabis, Aphria, Canopy Growth, and The Green Organic Dutchman) have already launched cultivation and processing projects or have partnered with local investors through joint ventures. During email communication with a special advisor from Invest in Denmark office of Life Sciences, he touched upon the investments in the Pilot Programme: *"Invest in Denmark has facilitated more than half a billion euros of direct investment into the cultivation of medical cannabis from international investors, which is matched by additional local*

investment through joint ventures. Within the active pipeline of Investment Projects (Active IPs), we estimate an additional round of international investment this year."

After establishing cultivation facilities, the Pilot Programme is now attracting companies from the biotech and horticultural industries to create an efficient supply chain to meet pharmaceutical standards (See, figure. 6). This has encouraged partnerships and investments to fine-tune methods for developing pharma grade products. As commented by a special advisor from Invest in Denmark office of Life Sciences during our email communications:*"In 2020, we see the investment and increased activity in downstream activities, such as in extraction, processing, drug development, and applied research. This is the stage where medical cannabis meets the traditional pharmaceutical industry. We now have a pipeline of IPs in; genetics research and cannabinoid profiling, small batch cultivation for research and development, extraction technologies, import and white labelling, cannabinoid biosynthesis, manufacturing, product development and clinical trials".*

***Figure 6**. Main Stakeholders in the Danish Medicinal Cannabis Pilot Programme*

On May 25, 2021, a majority in the Danish Parliament reached an agreement to permanently approve cultivation and production of medicinal cannabis and extend prescriptions of medicinal cannabis for another four years (Appendix 5), confirming Denmark's commitment to become a global leader in the rising European medicinal cannabis industry. This announcement provides confidence to investors while keeping a cautious approach towards medicinal cannabis legalization in Denmark.

Pharmaceutical Standards

Denmark's Pilot Programme is designed under pharmaceutical standards and has one of the strictest quality standards in the world. Thereby ensuring patients' safety, minimizing risks, and providing scientific evidence concerning cannabis' medicinal properties. Producers must comply with the World Health Organization (WHO) and European Medicines Agency (EMA) standards. Consequently, it is required that producers meet Good Agricultural Collection Practices (GACP) during cultivation and Good Manufacturing Practices (GMP) during manufacturing, processing, packaging, and storing. These procedures ensure that producers maintain high standards by implementing quality risk management (QRM) to minimize and mitigate risks inherent in pharmaceutical R&D (World Health Organization, 2013). Furthermore, there are additional standards imposed by the Danish Medicines Agency (i.e., pesticide ban during cultivation and ±10% TCH and CBD content standard deviation).

"The Danish model is based on a pharma paradigm that requires serious planning to achieve minimum standards, with clear requirements and a transparent regulatory framework but with significant scope to explore business models, breeding approaches, and improving cultivation techniques. In Denmark, these standards are enforced in a strict yet predictable approach that prepares industry participants to meet European and global standards for medical cannabis." Email communication with special advisor from Invest in Denmark office of Life Sciences.

In line with the Danish pharmaceutical industry's principles, the Pilot Programme stresses the importance of carrying out research to validate the medicinal properties of cannabis

(See Table 2) and consider feedback from patients and doctors for the development of pharmaceutical products. To ensure patient feedback, the Danish Medicines Agency in January 2019 announced a special reimbursement scheme for patients of the Pilot Programme (Appendix 6). The amount of financial aid to buy medicinal cannabis varies according to patients' illnesses; 100% reimbursement for terminal patients and a maximum 10,000 DKK annual reimbursement covering 50% of costs for other patients.

The doctors' participation and feedback have been more difficult after the Danish College of General Practitioners expressed concerns regarding the lack of scientific knowledge around the benefits of medicinal cannabis. Cannabis Danmark, an NGO and advocacy group connecting the industry's stakeholders, launched the Klinisk Cannabis Forum to address this concern. The forum aims to co-create and disseminate knowledge about medicinal cannabis between doctors and researchers. Klinisk Cannabis Forum advocates the need for developing doseable pharmaceutical products and further research on cannabinoids and how these can be used to treat specific illnesses (Kvamme, Pedersen, et al., 2021).

Table 2. *Denmark´s medicinal cannabis research (adapted from Cannabis Danmark, n.d.)*

Research Study	Research Center	Research Type
Does CBD help with sleep and inflammatory pain in fibromyalgia patients?	Frederiksberg Hospital	Double-blind, randomized, placebo-controlled study
Nordjysk Medical Cannabinoid Project – Cancer patients´ reaction to cannabis as a supplement to conventional palliative treatment	Center for Clinical Research, Region Hospital Nordjylland	Double-blind, randomized, placebo-controlled study
Effect and safety of cannabis in rheumatoid arthritis and back pain. CBD and THC.	King Christian X's Gigthospital Project CAN-ART.	Double-blind, randomized, placebo-controlled study

The effect of medical cannabis on neuropathic pain and spasticity in patients with MS and patients with spinal cord injury	Neurological Department Aarhus University Hospital	Double-blind, randomized, placebo-controlled study
THC / CBD for pain relief in peripheral neuropathic pain	Department of Neurology Odense University Hospital	Double-blind, randomized, placebo-controlled study
CBD's effect on pain and inflammation in patients with palpitations and psoriasis arthritis.	Rheumatologist Department of Aalborg University Hospital	Placebo-controlled study
Beyond the high: Mapping patterns of use and motives for use of cannabis as medicine	Center for Drug Research, Aarhus	Questionnaire study
Doctors and Patients' Experiences, Knowledge and Attitudes towards Medicinal Cannabis	Research Unit for General Practice, Odense	Questionnaire study

Denmark's Competitive Advantages

Denmark's social welfare model and stable political system paved the way for the country to become Europe's most accessible place for doing business (World Bank, 2019). Denmark offers investors competitive advantages such as a transparent regulatory framework, low renewable energy prices, strategic geographical location, and a highly developed logistical infrastructure. These are all positioning Denmark as an optimal location for entering the emerging EU medicinal cannabis market.

"As a launch pad for entering the European market, the availability of a strong business ecosystem offers investors a plug-and-play model for establishing and rapidly scaling up in the pharma oriented European market. This includes experienced project design and validation expertise, deep pools of Quality Assurance professionals and a specialized set of suppliers that can meet the highest standards for planning through to construction,

process optimization, facilities management and beyond." Email communication with special advisor from Invest in Denmark office of Life Sciences.

Furthermore, Denmark's know-how in the pharmaceutical and horticulture sectors also provides competitive advantages to companies within the Pilot Programme. Denmark's biotech and pharma clusters are driven by a collaboration between universities, the public health sector, and private companies. This collaboration has created a system for the country to become a global leader in biotech and pharma R&D and base for significant pharmaceuticals companies. Proof of this is that Denmark has ranked in the top five of the Scientific American Worldview Scorecard since its creation in 2008 (Scientific American, 2016).

Additionally, Denmark is also known for its sustainability-oriented horticulture industry. Grounded in its century-old cooperative model, Denmark's Horticulture Association *"Dansk Gartneri"* has led the development of cutting-edge technology in plant genetics, plant breeding, automated production methods, and a highly educated labor force. Therefore, Denmark has an extensive network of horticultural suppliers that meet the high standards needed to comply with the EU-GACP and EU-GMP regulations.

Denmark's Hybrid Framework

When analyzing the European medicinal cannabis industry, there are two predominant frameworks: 'export-focused' and 'patient-focused'. As its name states, the 'export-focused' framework aims to supply medicinal cannabis to foreign markets. This framework has mainly been adopted by southern European countries (e.g., Greece, Malta, North Macedonia, and Portugal), where climate conditions are favorable for cultivation and production costs are low. Under this framework, the goal is to generate economic growth by producing a profitable commodity. Therefore, there are no caps on production and supply chains are built to comply with target market regulations.

On the other hand, the 'patient-focused' framework aims to regulate and provide patients with legal access to medicinal cannabis. Medicinal cannabis is seen as a novel pharmaceutical drug, and as such, it is controlled by competent public agencies. For this

reason, production in countries that have adopted this framework (e.g., Czech Republic, France, Germany, Netherlands, and Italy) is managed via a state-monopoly or through commercial state-tendered licenses. Licenses and production tend to be lower than patient demand, so demand is complemented through state-controlled imports. Additionally, this framework considers patients' and doctors' feedback. Thus, encouraging research and pharmaceutical drug research and development.

Instead of following any of these trends, Denmark is trailblazing with a unique "hybrid" framework built around the know-how of its world-known biotech and horticulture industry. This hybrid framework is based on two parallel four-year trial programmes; *Pilot Programme which* is grounded within a "patient-focused" framework. As highlighted by a special advisor from Invest in Denmark office of Life Sciences during our conversations: *"cultivators need to engage with the local ecosystem of plant scientists, breeders, AgTech, and pharma engineering firms to bring the standards up to higher levels of medical grade cultivation*". While the *Development Scheme* is built around an "export-focused" framework, as corroborated by a special advisor from Invest in Denmark office of Life Sciences during our conversations *"In Denmark, the cultivation is structured in an open-ended system with no cap on production volumes and no limit to the number of licensed producers."*

This hybrid framework is the main reason why Denmark is expected to become a global leader in the rising medicinal cannabis industry. It is offering investors a system centered around the renowned biotech and AgTech Danish industries to develop pharma-grade products complying with the European Medicines Agency (EMA) standards. Furthermore, the open-ended system with no cap on production combined with the country's competitive advantages make Denmark the ideal location for supplying the rising European medicinal cannabis market.

How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?

Envision Concept, a game-changer within the medicinal cannabis industry

After acquiring the cultivation license, the company has focused on designing a sustainable cultivation system that fulfills the Danish Medicines Agency's high-quality standards. To do so, they are developing the Envision Concept, a GACP & GMP compliant controlled environment cultivation and processing facility. The Envision Concept is a revolutionary system seeking to produce organic medicinal cannabis and reduce the environmental footprint of the highly energy-intensive indoor cultivation methods that predominates in the medicinal cannabis industry (Mills, 2012). To do so, it combines the latest technologies in the industry with the company's holistic, sustainable mindset.

"The role of OC CARE, our vision was to differentiate us from other companies producing cannabis in the Pilot Programme. A lot of companies are not doing it organic; they are using other types of growth media and they are using conventional methods, producing in greenhouses mostly. And our vision was to make a facility where we do not have any impact in the environment. Actually, the opposite, having a positive impact on the environment…" OC Care's CEO

I developed the diagram presented below (See Figure. 7), to summarize the economic, environmental, and social interests that converge in OC Care's Envision Concept to provide patients with an organic, standardized, sustainable pharma-grade product. It is worth mentioning that Figure. 7 is a simplification of the real world, because most of the presented sub-themes are simultaneously present in other themes. Though, to rationalize the analysis, the sub-themes have been listed in the theme that best describes them.

As previously mentioned in the Research Design section, I based this diagram and analysis on Wezel et al. (2016) "agroecology territories" concept. I choose this framework because of its holistic and systemic approach. It guarantees not only the analysis of environmental aspects usually associated with sustainability, but also considers economic and social aspects such as consumer-producer relationships and efficiency of the supply chain. Due

to its holistic approach, this framework makes it possible to analyze initiatives that can provide alternatives to tackle the wicked challenges the food and agriculture system are currently facing.

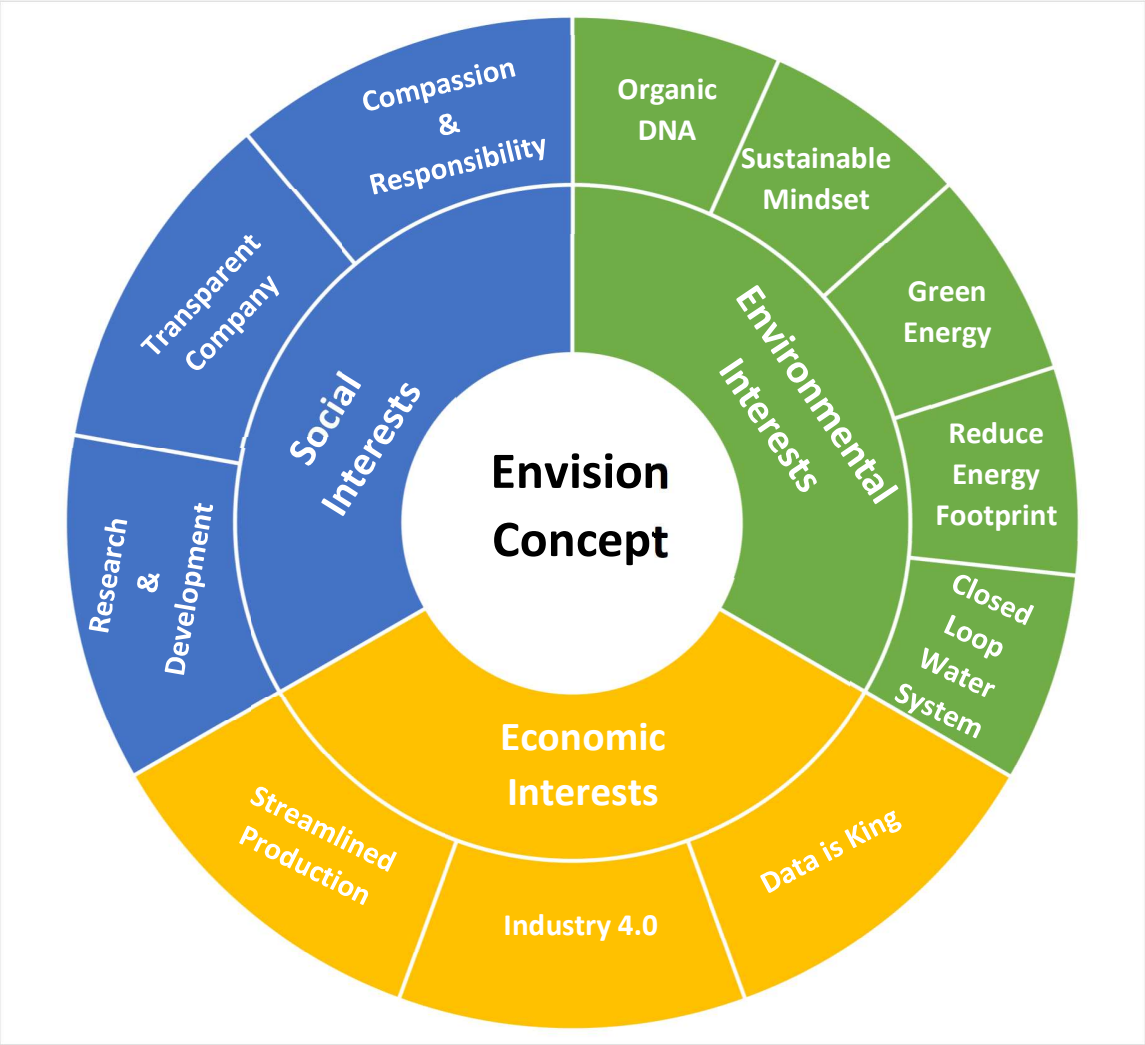

Figure 7. *Agroecology analysis of the Envision Concept (adapted from Hollensen, 2020)*

Economic Interests

Streamlined Production

The Envision Concept optimizes space and time in cultivation and processing to create economic value. This streamlined production is achieved by creating a modular system that boosts efficiency and decreases downtime and bottlenecks. To do so, the Envision Concept integrates production modules into the facility (germination, seedling, vegetative, flowering, harvesting, processing). Each production module is tailored to the needs of the

plant in its several growth stages. For example, as seen during my visit to OC Care, when plants are in the vegetative stage production module, the light cycle is 16 hours. Once they are moved into the flowering production module, the light cycle is reduced to 10 hours to encourage flower production.

Cultivation and processing modules are fully compliant with GACP-GMP. To remove airborne particles, the processing production module will be Cleanroom certified (ISO 14644). Te idea behind this module-based system, is to have the flexibility to meet the standards of the different countries with approved medicinal cannabis.

Following the Danish medicinal cannabis industry trend, OC Care has partnered with key stakeholders to develop the Envision Concept. Merging OC Care's industry know-how with services and products from leading Danish AgTech suppliers to conceive this innovative controlled environment facility warrants optimization and standardization in production. Thus, ensuring that Envision Concept facilities are always running at a fine-tuned capacity, diminishing downtimes and bottlenecks to increase productivity and profitability.

Industry 4.0

As previously commented, the Envision concept is merging different technologies to achieve a controlled environment. The Envision Concept integrates automation, AI & robotics, and LED lighting, to ensure standardization and streamlined production. Automation is vital in the Envision Concept, as it guarantees efficiency and standardization in the production. For this reason, conveyor belts are used to transport plants around the facility to avoid handling and stress. AI is used to control and monitor these automated processes, as it was explained by OC Care CEO in one of the interviews, *" each little component inside the facility is monitored and we know when it needs to be replaced and we can tell by the data collected inside the facility"*

Data is King

Collecting data on the production is vital in the medicinal cannabis industry as it facilitates achieving pharmaceutical quality standards. One of the benefits of the controlled environment is that it allows for reliable data collection. This is particularly important

when implementing a quality management system to ensure consistency and optimize processes. Therefore, the Envision Concept has an integrated cloud-based centralized management system that is packed with sensors to collect data throughout the facility. This system has been of great help during the production, because it has been possible to record and analyze how the different growing mediums, light cycle and irrigation methods affect the plants.

Furthermore, OC Care is also implementing an identification system to record the life cycle of the plants with the intention of minimizing deviations and ensure traceability of all products. During one of the interviews, the CEO of OC Care commented *"There will be a QR code on plants and we can scan that and tell that it has been propagated from this date and this date, when it came into the vegetative state and when it flowered and was harvested and processed in the different kind of processing processes."*

Environmental Interests

Organic DNA

With more than 27 years of experience in organic farming, this family-owned company has witnessed how pesticides and toxins destroy nature. They know that to provide a quality and healthy product, it is imperative to work hand in hand with nature. For this reason, the company has always adhered to the organic principles; health, ecology, fairness, and care (Luttikholt, 2007), as was stated by OC Care CEO in one of our meetings "*We want to produce an organic product, even though we cannot get it certified organic. But still, we use organic methodology to differentiate and have a positive impact on the environment and to provide the patients with the best possible product…"*

After getting their growing license, OC Care contacted the Danish Medicines Agency to inquiry about the procedure for certifying their production as organic. They were informed that there is no organic certification for pharmaceutical products. The lack of a Danish organic certification for medicinal products has proven to be a challenge for OC Care, because there aren't clear guidelines for growing and processing. Though, as medicinal cannabis is regulated across Europe, it is expected that an EU organic

certification for cannabis will be presented. For example, Switzerland announced that in their medicinal cannabis trial programme, production must be organic, but there is still no clear framework on how this will be adopted.

In the meantime, OC Care is fine-tuning its cultivation methods and testing different certified organic inputs to accomplish tailored standard operating procedures (SOP) for their Envision Concept. However, positive results have started to come from their test batches, achieving yields above the industry average.

Sustainable Mindset

Growing up on an organic farm shaped the mindset of OC Care's founder, granting him a critical perspective towards the current unsustainable global agri-food system. In his surroundings, he experienced the negative environmental impact of conventional agriculture, opening his eyes to the urgency of this complex situation, as it was mentioned during one of our conversations: *"the way things are looking now, if we keep producing foods and energy on the same way, we have been doing until now there will not be a good world to live now in 80 years"*. Ultimately, this encouraged him to become a steward of the environment and inspire and challenge others to accelerate sustainable innovations to transform the agri-food system.

For this reason, when deciding to enter the Pilot Programme, he aimed to establish a highly sustainable company and conceive the Envision Concept as a sustainable alternative to the energy intensive greenhouse methods that dominate the industry. Based on mimicking nature by creating a closed-loop system, inputs are constantly recycled and reused to keep the facility running, as it was highlighted during one of the interviews: "*it is sustainable, because we can keep on doing the same thing for ever after we have had the first input into the facility. It is a never-ending circle that never stops, just like the environment in the world."*

To achieve this goal, OC Care's approach has been to choose technologies with less energy consumption. Secondly, to minimize waste from production and, thirdly, generate energy from renewable sources.

Green Energy

One of Denmark's competitive advantages to Pilot Programme participants is access to affordable green energy. According to the 2019 Annual Energy Statistics report from the Danish Energy Agency, renewable energy supply increased 7% compared with the 2018 report, representing 67.5% of the domestic energy supply, with wind turbines contributing 46.8% (Energistyrelsen, 2020).

Since its beginning, the Envision Concept test facility has been powered by wind turbines. Furthermore, as proof of its commitment to sustainability and responsibility towards the local community, OC Care is starting to explore the possibility of integrating bioreactors into Envision Concept facilities to produce and supply green energy to its surrounding communities.

Reduce Energy Footprint

One of the visions of the Envision Concept is to provide a sustainable alternative to the current energy-intensive greenhouse production facilities that dominate the cannabis industry. In line with its values, OC Care knew that it needed to reduce its energy footprint to become a sustainable company. As mentioned before, the Envision Concept relies upon technology to control the facility's energy input and output, e.g., LED lights and groundwater cooling systems. Also, as commented in one of the interviews by the CEO of OC Care, the Envision Concept test facility is insulated; this drastically reduces the need for heat to warm up the climate inside the facility. "

Furthermore, OC Care is starting to invest in R&D to tap into the full potential of the cannabis plant, aiming to reduce waste and use the entire plant, not only its active substance. The goal is to make use of the leftover plant material to transform it into fiber or for feeding the planned bioreactor to heat the facility.

Closed Loop Water System

Water plays a crucial role in supporting life on earth and is becoming scarce due to unsustainable management, ongoing climate change, increasing human demands, and intensified land-use change (Falkenmark, 2020). Therefore, an integral part of the Envision

Concept is creating a closed-loop water system to capture and reutilize as much water as possible.

To achieve this, the Envision Concept test facility was designed to capture rainwater from the roof and the runoff from irrigation, which is then fed again to the plants, aiming to mimic natural closed-loop systems.

Social Interests

Compassion & Responsibility

OC Care is committed to help patients improve their quality of life, and its business model is oriented towards reaching this goal rather than generating profit. Their view is that the conventional pharma industry is not focusing on making the best medicines for patients and instead focus on profit-generating drugs. That is why they are committed to provide an organic product that meets pharmaceutical standards and create initiatives to participate in patients' healing processes. That is why OC Care wants to create relationships with patients to understand their healing process and develop products that increase their quality of life.

Additionally, OC Care also feels responsible towards the local community around them. Since their beginnings, they have taken precautions to have a good relationship with neighbors. For example, make sure there are no complaints regarding smells. In the future, the company's aim is that the Envision Concept will be used to cultivate crops in schools or hospitals, ensuring nutritious food and minimize greenhouse emissions from transportation.

Transparent Company

In line with their sense of responsibility towards patients, OC Care strives to be a transparent company. As mentioned above, OC Care wants to build a close relationship with patients based on clear and transparent communication. To achieve this, they plan to show patients how products are produced by showing them the production line, how the products come alive from clones to a finished product on the shelf of pharmacies. Thus, patients can be made aware of how OC Care produces value for their products.

This plan cannot be developed right now, because due to the current legislation, cannabis is still considered a narcotic drug, and it is not possible to advertise it. It is still uncertain if this restriction will be lifted anytime soon, especially if smoking is still approved as an administration form. Currently, participants in the Danish Medicinal Pilot Programme are in talks with the Danish Medicines Agency to find a way for advertising. In the meantime, they will start with CBD products containing less than 0,2% THC, which by law are considered nutritional supplements, and therefore are possible to advertise.

Research & Development

As previously mentioned, the *Pilot Programme* fosters an industry based on a pharmaceutical paradigm, encouraging R&D throughout the entire supply chain. As commented in a conversation with a member of the Invest in Denmark Life Science department, OC Care's Envision Concept is a leading example of commitment to R&D. This effort can be found through its entire value chain, accelerating innovative and sustainable initiatives to improve cultivation, and improving patients' quality of life through innovative products.

Currently, OC Care is devoting a lot of its effort to fine-tune its substrate blend for its organic production and developing a thriving substrate environment to encourage microbiologic activity and plant nutrient uptake. As previously mentioned, it is working hand in hand with its suppliers to tailor its products and services to meet the high-quality standards for the cultivation and processing of medicinal cannabis in Denmark. Furthermore, they have started to collaborate with the Danish Technological Institute to work with plant genetics to develop strains and products that can target specific illnesses.

Limitations

My inexperience as a researcher limited the project as this was my first time carrying out an academic research project. I am still a novice researcher who needs to further develop my research skills, especially as an interviewer. Therefore, I acknowledge that my ability to collect and analyze relevant data within the given time to develop the research impacted results and findings. Nevertheless, the case study methodology provided a guide for achieving trustworthiness by exploring the case through multiple perspectives and

triangulating data sources and data types (Baxter & Jack, 2008). I also experienced difficulties maintaining an unbiased view, distancing my beliefs and motivations for the research. I tackled this issue by following Baxter & Jack's (2008) advice on member checking after collecting and analyzing data by sharing my data interpretation with my interviewee/participant, allowing him to clarify his views. Additionally, I kept a reflection journal throughout the project. This tool, which I have used since the start of the Agroecology program, was of great help because it enabled me to keep track of my thoughts throughout the process, allowing me to distance myself from the research and identify biased views.

The small size of informants also limited the research. Most of the companies participating in the Pilot Programme are big corporations, and their opinions might provide valuable insights. I decided to explore the case with an Agroecology lens; therefore, I considered it appropriate to do research on a family-owned company with an agriculture background and an owner with a sustainable mindset. I believe this did not affect the research quality because in a case study credibility is achieved by collecting multiple perspectives and systematically analyzing data rather than by the size of the sample (Patton, 2014).

Language also limited the research because the pilot program laws are published in Danish. Although all relevant information is available in English at the Danish Medicines Agency website, I contacted them to clarify doubts. This language barrier prevented me from analyzing all available information.

Reliability and Validity

As commented in the previous section, I acknowledge that my inexperience as a researcher impacted the project's quality. To tackle this issue, I integrated Yin's (2017) tests for judging the quality of research design. These tests allowed me to examine each step of the research and "to ensure enough detail is provided so that readers can assess the validity or credibility of the work" (Baxter & Jack, 2008, p. 556). Because I developed an exploratory case study I omitted the internal validity test, and instead focused on the remaining three tests: construct validity, external validity, and reliability.

To construct validity during data gathering, I used multiple sources of evidence. Using semi-structured interviews and participant observation strengthened a convergent line of inquiry and gave room for triangulating data (Yin, 2017). Also, feedback from my advisor, peers, and participants helped me construct validity during the writing process. Feedback received from my advisor and peers contributed to adding multiple perspectives into the project. At the same time, the review by participants helped to corroborate results.

In terms of external validity, I focused on highlighting how my findings corroborated the theory used to design the case study. The selection of 'how' questions during the research design phase helped shed empirical light on the selected theory and reach analytic generalizations (Yin, 2017).

I developed a case study protocol (Appendix 7) and a case study database to ensure reliability. These tools allowed me to document the data collection process and target the case study topic (Yin, 2017). Thus, ensuring replicability of results when following research procedures. The case study protocol proved essential when carrying out data collection because it provided a guide for data gathering and prepared me for the interviews. When developing the case study protocol, I had the opportunity to review and practice my interview skills. On the other hand, using a case study database helped me keep data organized. The process of building this database also helped me to make sense of all the collected data.

Conclusion & Recommendations for Further Research

This study aimed to explore the Pilot Programme and OC Care's effort to produce sustainable medicinal cannabis through its Envision Concept. As legalization spreads worldwide, research will be fundamental so governments legislate under a public health approach and ensure this energy-intensive industry will develop sustainably. The Pilot Programme and OC Care's Envision Concept are initiatives seeking to achieve these objectives. A proof of this is that the majority of the Danish Parliament reached an agreement to permanently approve cultivation and production of medicinal cannabis and extend prescriptions of medicinal cannabis until 2025.

After immersing myself in the Pilot Programme system, I corroborated that the program's approach is based on public health knowledge and seeks to produce scientific evidence for the Danish parliament to legislate the use of medicinal cannabis. Furthermore, it seeks to regulate medicinal cannabis from plant to product by creating an ecosystem integrating the country's horticulture and biotech industry expertise to position Denmark as a hub in the rising European medicinal cannabis market. For these reasons, the Pilot Programme positions itself as a model case for other countries seeking to regulate and integrate cannabis into their health systems.

OC Care's Envision Concept, a growing and processing facility is a leading example of the enterprises the Pilot Programme fosters. OC Care stands out as a company seeking to produce sustainable medicinal cannabis. Since its beginnings, the company has striven to create innovative solutions to attain this goal by merging the latest horticultural technological advances with a humane and transparent philosophy. The Envision Concept is still in its development phase and needs to become a proof of concept, but their test batches already prove that high yields can be achieved with a low environmental impact.

To establish a reliable medicinal cannabis industry, global prohibition needs to end, and research to be encouraged throughout the entire supply chain. Thus, ensuring medicinal cannabis is correctly legislated, ensuring patient safety, and transforming it into a sustainable industry.

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Appendix

Appendix 1 – List of licensed companies to cultivate and handle cannabis

Adapted from the Danish Medicines Agency website. Accessed 14/11/2020. https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis/companies/development-scheme/applicants-having-applied-for-permission-to-cultivate-and-handle-cannabis/

Updated October 19, 2020

To accommodate the considerable interest from the industry and the media, the Danish Medicines Agency has decided to publish the names of the companies that have applied for authorization to cultivate and handle cannabis to develop cannabis for medicinal use.

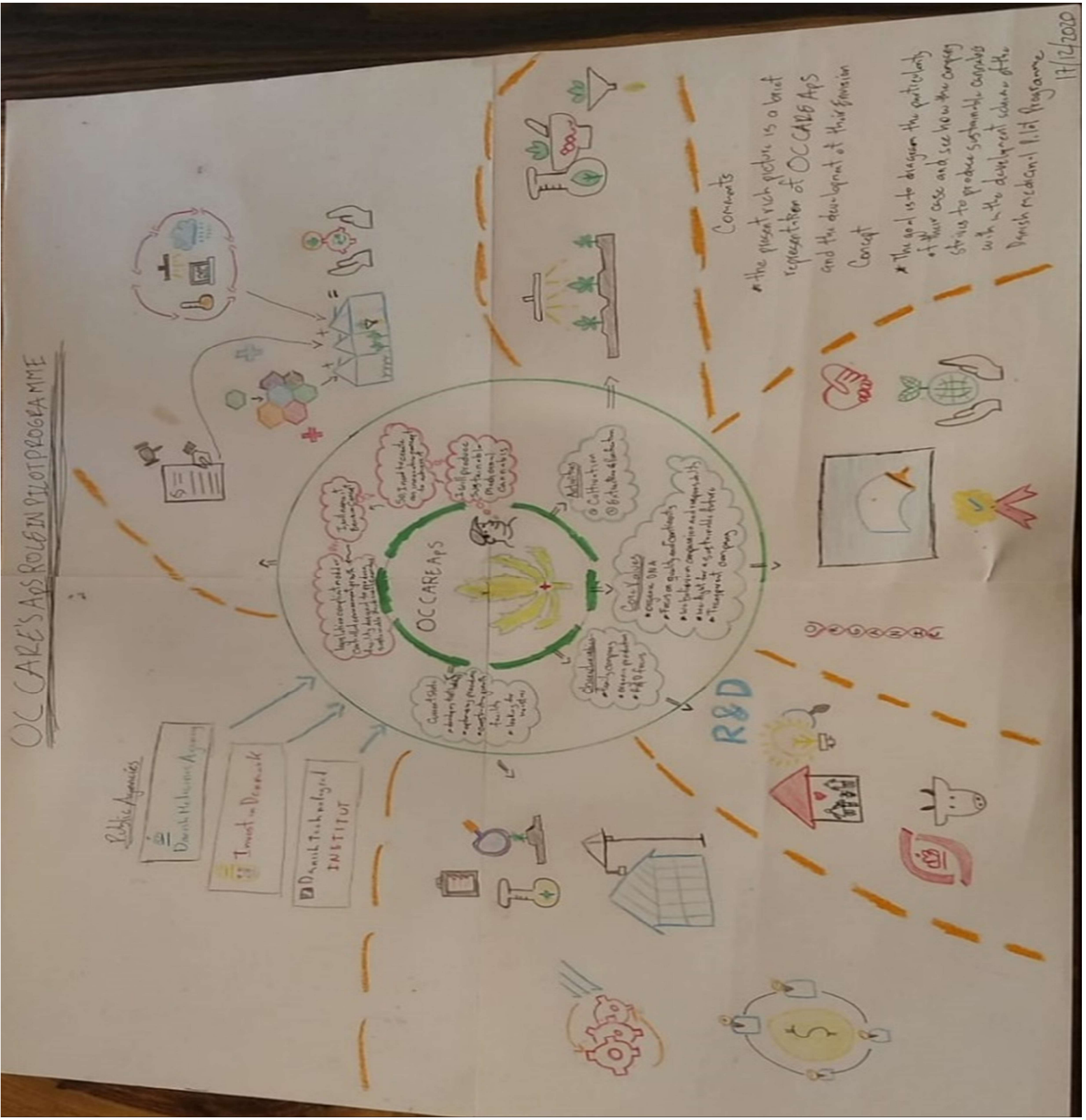
The following companies have (as of October 19, 2020) applied for permission to cultivate and handle cannabis to develop cannabis for medicinal use:

Applicants who have been granted authorizations:

- Tetra Pharm Technologies ApS (authorization sent September 22, 2020)
- Nordicann I/S (authorization sent September 22, 2020)
- Cannabis Pharm (authorization sent August 13, 2020)
- Solural Pharma (authorization sent April 23, 2020)
- MariMedic ApS (authorization sent March 2, 2020)
- Poulsen Roser A/S (authorization sent February 28, 2020)
- Weeco ApS (authorization sent January 24, 2020)
- Medical Cannabis Denmark ApS (authorization sent January 17, 2020)
- CanAct ApS (authorization sent 11 November 2019)
- Sereni IVS (authorization sent November 11, 2019)
- TGOD Denmark Production A/S (authorization sent October 11, 2019)
- Carham ApS (authorization sent October 11, 2019)
- ProCann ApS (authorization sent October 10, 2019)
- Tikun Olam Scandinavia ApS ("formerly Copenhagen Cannabis IVS" first authorization sent March 23, 2018, updated September 18, 2019)

- Gistrup Green Grow (first authorization sent December 15, 2017, updated September 18, 2019)
- Atlas Growers Denmark A/S (authorization sent September 6, 2019)
- DK Cannabis Europe ApS (authorization sent August 2, 2019)
- Cannabis-International ApS (authorization sent July 15, 2019)
- Sterigenics Denmark A/S (authorization sent June 18, 2019)
- Solace Denmark ApS (authorization sent June 6, 2019)
- Vertanical Denmark A/S (authorization sent May 29, 2019)
- Orenda ApS (authorization sent May 29, 2019)
- Valeus IVS (authorization sent May 7, 2019)
- Cronus APS (authorization sent May 7, 2019)
- Aureum A/S (authorization sent May 6, 2019)
- OC Care (authorization sent May 3, 2019)
- Teknologisk Institut (authorization sent May 3, 2019)
- TGOD Genetics A/S (authorization sent April 5, 2019)
- MM Danish Cannabis (authorization sent March 21, 2019)
- Canna Therapeutic ApS (authorization sent January 3, 2019)
- Pharmacan IVS (authorization sent November 22, 2018)
- Vibegårds Gartneri A/S (authorization sent July 24, 2018)
- DANCANN (authorization sent June 20, 2018)
- Drizzle Grow IVS (authorization sent May 23, 2018)
- Schroll Medical ApS (authorization sent April 12, 2018)
- Nordic Cannabis ApS (authorization sent March 23, 2018)
- Æssense Europe ApS (authorization sent January 12, 2018)
- Cannabis Pharm, earlier MM Bureau v/Morten Nøhr Mortensen (authorization sent December 15, 2017)
- Aurora Nordic Cannabis A/S, earlier Scandinavian Cannabis A/S (authorization sent December 15, 2017)
- DW IVS (authorization sent December 15, 2017)
- Canopy Growth Denmark ApS, earlier Spectrum Cannabis Denmark ApS (authorization sent December 15, 2017)
- Hemp Valley ApS (authorization sent December 15, 2017)
- MEDICAN ApS (authorization sent December 15, 2017)
- StenoCare A/S, earlier StenoCare IVS (authorization sent December 15, 2017)

Appendix 2 – Rich Picture describing the development of the Envision Concept



Appendix 3 – Interview Guide

Semi-Structured Interview Guide

Research Objective

To provide knowledge about (exploratory research of) the Danish Medicinal Cannabis Pilot Programme focusing on producing sustainable medicinal cannabis.

- How is the Danish Medicinal Cannabis Pilot Programme structured?
- How does OC Care ApS integrate economic, environmental, and social interests in the Envision concept to achieve sustainable production of medicinal cannabis?

Interview Guide

1. **Briefing**

• Start by presenting myself and thanking the participant for taking time to contribute to this study

• Explain the scope of the study and how data will be treated.

• Clarify any doubt or question from the participant.

• Obtain written consent to proceed with the interview and use a recording device.

2. **Warm-Up Questions**

- How is your day going so far?
- What is your role in OC Care?

3. **Interview Questions**

1. Can you tell me about OC Care role in the Danish Medicinal Cannabis Pilot Programme?

2. Could you describe how the process for obtaining the cultivation license was? Did you face any challenges during the procedure? If yes, what were they?

3. What is the relationship between OC Care and stakeholders from the Pilot Programme? To what degree is there collaboration to further develop the industry in Denmark?

4. Do you know organic certifications/labels to produce medicinal cannabis? If so, what are they? Are they internationally recognized/approved?

5. Does OC Care use organic practices during cultivation? If so, which ones and what are the motives behind them?
6. Looking at your experience during the Pilot Programme, describe the supporting and hindering forces for the organic production of medicinal cannabis in Denmark?

I would now like to move on to a different topic and know more about the Envision concept.

7. Please describe OC Care´s values and priorities for growing sustainable medicinal cannabis and incorporating these into daily activities?

8. How does the Envision concept differ from standard, GMP-compliant medicinal cannabis facilities?

9. How does the Envision concept impact communities regarding environmental, economic, and social wellbeing?

Appendix 4 – Consent Form

Are you interested in taking part in the research project?
Exploratory case study of medicinal cannabis Pilot Programme in Denmark?

This is an inquiry about participation in a research project where the main purpose is to explore the development scheme in the Danish Medicinal Cannabis Pilot Programme to determine the supporting & hindering forces for organic production of medicinal cannabis. In this letter, we will give you information about the purpose of the project and what your participation will involve.

Purpose of the project

This research project is conducted as a master thesis for the Agroecology MSc. program at the Norwegian University of Life Sciences. The objective of this research project is to explore the development scheme in the Danish Medicinal Cannabis Pilot Programme and identify and analyze the supporting and hindering forces to produce organic medicinal cannabis in Denmark.

To achieve this objective, the following research questions will be answered.

- *How is the medicinal cannabis Pilot Programme structured in Denmark?*
- *What is the supporting and hindering forces for the organic production of medicinal cannabis in Denmark?*
- *How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?*

Who is responsible for the research project?

The Norwegian University of Life Sciences is the institution responsible for the project.

Why are you being asked to participate?

You are being asked to participate in the project because you are one of the companies with a license to produce medicinal cannabis under the Danish Medicinal Cannabis Pilot Programme.

The selection criteria for choosing the participant for this project is interested in organic production of medicinal cannabis. For this reason, after reviewing the list of licensed companies your company has been selected.

What does participation involve for you?

- If you chose to take part in the project, this would involve that you will be interviewed. It will take approx. 45 minutes. The interview includes questions

about your participation in the development scheme in the Danish Medicinal Cannabis Pilot Programme, questions about your interest and attempts to produce organic medicinal cannabis. Furthermore, there will be questions about how your company integrates economic, environmental, and social interests to achieve sustainable production. The interview will be recorded, and I will take notes.

- If you chose to take part in the project, this would involve that you will be observed through the participant observation method. It will take approx. 60 minutes. The observation will take place in the production facility of the company. During the observation, questions about production methods, legislation compliance, and the Danish Medicinal Cannabis Pilot Programme will be included. Photos of the production facility will be taken during observation; there will be no identifiable persons in the pictures. Additionally, I will take notes.

Participation is voluntary
Participation in the project is voluntary. If you chose to participate, you could withdraw your consent at any time without giving a reason. All information about you will then be made anonymous. There will be no negative consequences for you if you chose not to participate or later decide to withdraw.

Your personal privacy – how we will store and use your personal data
We will only use your personal data for the purpose(s) specified in this information letter. We will process your personal data confidentially and following data protection legislation (the General Data Protection Regulation and Personal Data Act).

- Access to the personal data collected will only be available to Nelson Avila (student research) and the thesis supervisor, Anna Marie Nicolaysen, Researcher at the Norwegian University of Life Sciences.

- To ensure that no unauthorized persons can access personal data, I will replace your name and contact details with a code. The list of names, contact details, and respective codes will be stored separately from the rest of the collected data.

The participant will be recognizable in the research project since the research project is a case study. The participant's identity will remain anonymous, but information about the company's name will be published.

What will happen to your personal data at the end of the research project?

The project is scheduled to end on 01/06/2021. All data, including personal data, digital recordings, and pictures, will be deleted at the end of the project.

Your rights
So long as you can be identified in the collected data, you have the right to:

- access the personal information that is being processed about you
- request that your personal data is deleted
- request that incorrect personal data about you is corrected/rectified
- receive a copy of your personal data (data portability), and
- send a complaint to the Data Protection Officer or The Norwegian Data Protection Authority regarding the processing of your personal data

What gives us the right to process your personal data?
We will process your personal data based on your consent. Based on an agreement with the Norwegian University of Life Sciences, NSD – The Norwegian Centre for Research Data AS has assessed that the processing of personal data in this project follows data protection legislation.

Where can I find out more?
If you have questions about the project or want to exercise your rights, contact:

- NMBU – The Norwegian University of Life Sciences via
    - Student Researcher – Nelson Avila, by email; nelson.avila@nmbu.no
    - Thesis Supervisor – Anna Marie Nicolaysen; anna.marie.nicolaysen@nmbu.no
- NMBU Data Protection Officer: Hanne Pernille Gulbrandsen, by email: personvernombud@nmbu.no
- NSD – The Norwegian Centre for Research Data AS, by email: (personverntjenester@nsd.no) or by telephone: +47 55 58 21 17.

Yours sincerely,

Project Leader (Researcher/supervisor) Student (if applicable)

Consent form

I have received and understood information about the master thesis research project, an exploratory case study of organic medicinal cannabis production in Denmark and have been allowed to ask questions. I give consent:

- ☐ to participate in an interview
- ☐ to participate in participant observation
- ☐ for information about me/myself to be published in a way that I can be recognized. The name of the company will be published.

I give consent for my personal data to be processed until the end date of the project, approx. 01/06/2021

(Signed by participant, date)

Appendix 5 – Danish Parliament Press Release - Agreement on the continuation of the trial scheme with medical cannabis

Retrieved from the Danish Ministry of Health. Accessed 12/08/2021.
https://sum.dk/Media/637575573334068173/Aftale%20om%20videref%C3%B8relse%20af%20fors%C3%B8gsordningen%20med%20medicinsk%20cannabis,%2025.%20maj.pdf

Regeringen (Socialdemokratiet)
Venstre
Dansk Folkeparti
Socialistisk Folkeparti
Enhedslisten
Nye Borgerlige
Liberal Alliance
Alternativet
Kristendemokraterne
Frie Grønne

København, den 25. maj 2021

Aftale om videreførelse af forsøgsordningen med medicinsk cannabis

Regeringen (Socialdemokratiet), Venstre, Dansk Folkeparti, Socialistisk Folkeparti, Enhedslisten, Nye Borgerlige, Liberal Alliance, Alternativet, Kristendemokraterne og Frie Grønne har den 25. maj 2021 indgået aftale om at videreføre forsøgsordningen med medicinsk cannabis.

Det er aftalt, at forsøgsordningen med medicinsk cannabis forlænges i fire år for så vidt angår lægers mulighed for at ordinere medicinsk cannabis til patienter. Det er aftalt, at forsøgsordningen gøres permanent for så vidt angår virksomheders mulighed for dyrkning af cannabis til medicinsk brug. Formålet med at gøre dyrkningsdelen permanent er at skabe afklaring og sikkerhed for de investeringer, der er foretaget i branchen.

Det bemærkes, at omkostningerne ved forsøgsordningen for så vidt angår virksomheders mulighed for dyrkning af cannabis til medicinsk brug er gebyrfinansieret. Partierne er enige om at drøfte eventuelle ændringer af ordningen fx tilskud i efteråret.

Aftalepartierne er enige om, at justeringer af ordningen kan foretages på et senere tidspunkt.

Aftalepartierne er enige om at drøfte en videreførelse af tilskud til patienter ved køb af medicinsk cannabis i forsøgsordningen til efteråret.

Den gældende forsøgsordning med medicinsk cannabis ophører ved udgangen af 2021, og videreførelsen af forsøgsordningen skal derfor ske ved lov. Regeringen vil fremsætte

lovforslag i efteråret 2021 med henblik på vedtagelse inden udgangen af 2021. Aftalepartierne er enige om at stemme for lovforslaget. Der kan i forbindelse med lovforslagsprocessen blive foretaget mindre tekniske justeringer i ordningen.

Appendix 6 – Danish Medicines Agency Information Sheet - Reimbursement of medicinal cannabis of the Pilot Programme

Retrieved from the Danish Medicines Agency website. Accessed 25/07/2021. https://laegemiddelstyrelsen.dk/en/special/medicinal-cannabis/citizens/reimbursement-of-medicinal-cannabis-of-the-pilot-programme-effective-as-of-1-january-2019/

Den 1. januar 2019 indføres en særlig tilskudsordning for medicinsk cannabis omfattet af den 4-årige forsøgsordning med medicinsk cannabis. Ordningen gælder med tilbagevirkende kraft for køb foretaget fra 1. januar 2018.

Borgere, som har en gældende terminalbevilling får 100 % i tilskud. Andre borgere får 50 % i tilskud til et årligt forbrug af medicinsk cannabis, der ikke overstiger 20.000 kr. Når det samlede forbrug overstiger 20.000 kr. ydes der ikke længere tilskud, og der er derfor fuld egenbetaling til hele produktets pris. Tilskud til køb fra 1. januar 2019 fratrækkes automatisk på apoteket i ekspeditionsøjeblikket.

De særlige tilskudsgrænser og tilskudsprocenter er vist i tabellen nedenfor:

Samlet udgift per tilskuds-periode (12 måneder)	Tilskud	Egenbetaling
0 - 20.000 kr.	50 %	Op til 10.000 kr.
Over 20.000 kr. -	0 %	Hele produktets pris
For patienter med gældende terminalbevilling	100 %	Ingen egenbetaling

Grænserne kan blive justeret 2 gange om året.

Køb foretaget i 2018
Har du købt medicinsk cannabis i forsøgsordningen i 2018, vil Lægemiddelstyrelsen automatisk beregne og udbetale dit tilskud til din NemKonto senest i første kvartal af 2019.

Lægemiddelstyrelsen indberetter oplysninger om dine køb i 2018 til det Centrale Tilskudsregister for Cannabis. Derfor kan din tilskudsperiode og din saldo allerede være aktive den 1. januar 2019.

Eksempel på beregning af tilskud til medicinsk cannabis i 2018:

Købsdato	Købspris	Tilskud	Egenbetaling	CTR-C saldo
15. juni 2018	920 kr.	50 %	460 kr.	920 kr.
17. juli 2018	2.300 kr.	50 %	1.150 kr.	3.220 kr.

Saldo for køb af cannabis: 3.220 kr.
Tilskud i alt 1.610 kr.
Egenbetaling i alt: 1.610 kr,
Startdato for tilskudsperiode: 15. juni 2018
Slutdato for tilskudsperiode: 14. juni 2019

4 hurtige om den særlige tilskudsordning:

- Tilskuddet til medicinsk cannabis beregnes separat fra tilskuddet til din almindelige medicin.
- Lægemiddelstyrelsen har oprettet et separat tilskudsregister til beregning af tilskud til medicinsk cannabis:

  Det Centrale Tilskudsregister for Cannabis.
- Du skal være opmærksom på, at du nu kan have to CTR saldi og to tilskudsperioder.
- Oplysninger om det ydede tilskud til cannabisslutprodukter og tilskudsperioden fremgår af din kvittering fra apoteket.

1 enkelt om den almindelige tilskudsordning:

Der ændres ikke i det normale behovsafhængige medicintilskudssystem. Det fortsætter, som du kender det og omfatter al anden tilskudsberettiget medicin.

Lægemiddelstyrelsen version 1

Klip ud og gem dine CTR oplysninger. Du kan få dem oplyst på apoteket og kan altid se dem på dine kvitteringer.

Medicinsk cannabis

Saldo for køb af cannabisprodukter	
Slutdato for tilskudsperiode	

Mine andre lægemider

Saldo for køb af anden medicin	
Slutdato for tilskudsperiode	

Appendix 7- Case Study Protocol

Section 1 – Overview

The project is a master thesis for the Agroecology program at NMBU. The primary purpose is to provide exploratory research on the Danish Medicinal Cannabis Pilot Programme, system mapping the Pilot Programme, and analyzing a company committed to producing sustainably. To achieve this objective, the following research questions will be answered.

- *How is the medicinal cannabis Pilot Programme structured in Denmark?*
- *How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?*

The study will take place in Denmark, between Aalborg and Copenhagen. Preparation, fieldwork, data processing, and writing will occur in Copenhagen. Visits to the case test production facility in Aalborg will be scheduled to observe and take an active part in their operation, with the intent of validating findings from interviews.

Key readings

Board, I. (2018). Report of the International Narcotics Control Board for 2018. *United Nations, Vienna*

EudraLex. (2015). The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use; Annex 1–Manufacture of Sterile Medicinal Products.

Executive order on the cultivation, manufacture, and distribution of cannabis bulk and the manufacture of cannabis starting products, BEK nr 695 af 03/07/2019. Accessed September 5, 2020, at https://www.retsinformation.dk/eli/lta/2019/695

Frank, V. A. (2008). Danish drug policy-shifting from liberalism to repression. *Drugs and Alcohol Today*, *8*(2), 26.

Nygaard-Christensen, M., & Frank, V. A. (2019). Cannabis Regulation in Europe: Country Report Denmark.

Lande, A. (1962). The Single Convention on Narcotic Drugs, 1961. *International Organization*, *16*(4), 776-797.

Law on the experimental scheme with medical cannabis, LOV nr 1668 af 26/12/2017. Accessed September 5, 2020, at https://www.retsinformation.dk/eli/lta/2019/695

Section 2 – Data Collection Procedure

Case screening – The Danish Medicines Agency made public and published the list of authorized applicants to cultivate and handle cannabis under the *development scheme* on their website. I then proceeded to do a web search and found that most of the authorized applicants do not have an active website, which narrowed potential candidates. After reviewing the websites, I developed the case selection criteria. To make the project relevant under an Agroecology scope, the case had to be a small-scale, family-run, or coop enterprise. Moreover, have an interest in sustainability, i.e., producing organic, using renewable energy, reducing waste.

OC Care was one of the first 12 companies that received the license and approval to cultivate medicinal cannabis in Denmark. Unlike most pilot project companies; OC Care is a family-owned company with 22 years of organic agriculture experience. Since founding the company, they have focused on producing sustainable organic medicinal cannabis.

Ethics – I will follow ethical guidelines to protect participants' integrity and ensure that the information they provide will reflect their views. I will start interviews and participant observations by delivering an information letter with a brief description of the research project and getting informed consent. Hence, participants know that their privacy is protected. Before the data collection process, I will register my project at Data Protection Official for Research and file the notification form for personal processing data (https://nsd.no/personvernombud/en/index.html).

Contact Persons

Contact person	Organization	Role	documents to review
Christian O. Hollensen	OC Care ApS	CEO	OAG article April edition
Derek James Light	Invest in Denmark	Special Advisor	OAG article January edition First Wednesdays Nov. report

Data Collection Plan -

Contact person	Method	Date	Location
Christian O. Hollensen	Informal conversation	03/09/2020	OC Care ApS
Christian O. Hollensen	Informal conversation	30/10/2020	Copenhagen
Christian O. Hollensen	Interview	30/11/2020	Copenhagen
Christian O. Hollensen	Interview	10/12/2020	Copenhagen

Christian O. Hollensen	Interview	26/01/2020	Copenhagen
Derek James Light	Informal conversation and Emails	04/11/2020	Symposium on Medical Cannabis
Karin Wiborg	Informal conversation and Emails	04/11/2020	Symposium on Medical Cannabis

Section 3 – Protocol Questions

Research Question 1 - *How is the medicinal cannabis Pilot Programme structured in Denmark?*

- How OC Care participates in the Pilot Programme?
- With which stakeholders from the supply chain does OC Care collaborates?
- OC Care story; founding members, milestones, etc.?
- Difference between Pilot Programmes and development scheme licenses?
- Describe the process for getting seeds or clones?

Research Question 2 - *How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?*

- How far is the development of Envision Concept?
- How much renewable energy is used to power test facilities?
- Do you have plans to produce your growing media?
- How do you plan to close the loop in production?
- How do you plan to provide CSR projects for patients?
- Where do you plan to share your growing and handling protocols?
- Do you integrate SDGs in management?

Section 4 – Case Study Report Outline

- Introduction
  - Research question
  - Context
  - Case Selection
- Methodology
  - Methodology
  - Research Strategy
  - Research Design
  - Methods
- Results and Discussion
  - Results
  - Discussion
  - Limitations

    - Reliability and Validity
- References
- Appendix

Section 1 – Overview

The project is a master thesis for the Agroecology program at NMBU. The primary purpose is to provide exploratory research on the Danish Medicinal Cannabis Pilot Programme, system mapping the Pilot Programme, and analyzing a company committed to producing sustainably. To achieve this objective, the following research questions will be answered.

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Section 2 – Data Collection Procedure

Case screening – The Danish Medicines Agency made public and published the list of authorized applicants to cultivate and handle cannabis under the *development scheme* on their website. I then proceeded to do a web search and found that most of the authorized applicants do not have an active website, which narrowed potential candidates. After reviewing the websites, I developed the case selection criteria. To make the project relevant under an Agroecology scope, the case had to be a small-scale, family-run, or coop enterprise. Moreover, have an interest in sustainability, i.e., producing organic, using renewable energy, reducing waste.

OC Care was one of the first 12 companies that received the license and approval to cultivate medicinal cannabis in Denmark. Unlike most pilot project companies; OC Care is a family-owned company with 22 years of organic agriculture experience. Since founding the company, they have focused on producing sustainable organic medicinal cannabis.

Ethics – I will follow ethical guidelines to protect participants' integrity and ensure that the information they provide will reflect their views. I will start interviews and participant observations by delivering an information letter with a brief description of the research project and getting informed consent. Hence, participants know that their privacy is protected. Before the data collection process, I will register my project at Data Protection Official for Research and file the notification form for personal processing data (https://nsd.no/personvernombud/en/index.html).

Contact Persons

Contact person	Organization	Role	documents to review
Christian O. Hollensen	OC Care ApS	CEO	OAG article April edition
Derek James Light	Invest in Denmark	Special Advisor	OAG article January edition First Wednesdays Nov. report

Data Collection Plan -

Contact person	Method	Date	Location
Christian O. Hollensen	Informal conversation	03/09/2020	OC Care ApS
Christian O. Hollensen	Informal conversation	30/10/2020	Copenhagen
Christian O. Hollensen	Interview	30/11/2020	Copenhagen

Christian O. Hollensen	Interview	10/12/2020	Copenhagen
Christian O. Hollensen	Interview	26/01/2020	Copenhagen
Derek James Light	Informal conversation and Emails	04/11/2020	Symposium on Medical Cannabis
Karin Wiborg	Informal conversation and Emails	04/11/2020	Symposium on Medical Cannabis

Section 3 – Protocol Questions

Research Question 1 - *How is the medicinal cannabis Pilot Programme structured in Denmark?*

- How OC Care participates in the Pilot Programme?
- With which stakeholders from the supply chain does OC Care collaborates?
- OC Care story; founding members, milestones, etc.?
- Difference between Pilot Programmes and development scheme licenses?
- Describe the process for getting seeds or clones?

Research Question 2 - *How does the Envision Concept integrate economic, environmental, and social interests to achieve sustainable production of medicinal cannabis?*

- How far is the development of Envision Concept?
- How much renewable energy is used to power test facilities?
- Do you have plans to produce your growing media?
- How do you plan to close the loop in production?
- How do you plan to provide CSR projects for patients?
- Where do you plan to share your growing and handling protocols?
- Do you integrate SDGs in management?

Section 4 – Case Study Report Outline

- Introduction
    - Research question
    - Context
    - Case Selection
- Methodology
    - Methodology
    - Research Strategy
    - Research Design
    - Methods
- Results and Discussion
    - Results

    - Discussion
    - Limitations
    - Reliability and Validity
- References
- Appendix

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