

Expertise and insight for the future

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A discussion of the factors affecting a potential market for CBD products in Finland

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The goal of this thesis was to investigate factors affecting the potential market for CBD products in Finland. Due to the trend of legalisation around the world, especially North America, the Cannabis and Cannabidiol (CBD) market has grown exponentially and has started to spread across Europe. With new research, more information about CBD and the current approved applications as well as possible future applications emerge. This shows a positive outlook for the CBD market in future. As the sale of CBD is prohibited in Finland due to it being on a medication list, there is currently little to no market for CBD products.

The research examines points for and against CBD, the current situation in Finland, different versions of legalisation in Europe and North America and potential future uses for CBD.

The findings of this research show that currently there is a little risk with CBD itself, the risk comes more from the lack of regulation and testing for the product. As there are no clear requirements and oversight for CBD products in many markets, the issue that has risen is the impurity of the products. People still tend to be more inclined to use CBD products than before and some researchers have been surprised by the amount of people that had already tried CBD when researching the subject. Currently the future looks optimistic for CBD products in Finland as they exist as approved products to some extent, but with future research the regulators should be confident enough to allow more open use of the product and regulate the market. This would lead to superior products with less impurities and would also open up an avenue for new type of innovation in Finland with CBD products.

| Keywords | Cannabidiol (CBD), Hemp, Market Research | |
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Appendix 1. Letter from Kela sent to doctors in Finland (2019)



Glossary

Broad spectrum

A product containing all elements of the cannabis plant other than THC.

CBD

Cannabidiol (CBD) is one of two major cannabinoids found in cannabis. It is a non-psychoactive compound that does not produce the same "high" as THC but has other beneficial uses.

CBD-A

CBD-A is the form of CBD that it exists in before it has been decarboxylated, which means it has to be heated to a certain degree for it to be converted into CBD.

ECS

Endocannabinoid System (ECS) is a biological system that is composed of different types of endocannabinoids that are lipid-based retrograde neurotransmitters that bind to cannabinoid receptors and cannabinoids and which can be found all over the central nervous system which includes the brain and peripheral nervous system.

Full spectrum

A product which contains all elements of the cannabis plant including THC.

THC

Delta-9-tetrahydrocannabinol (THC) is the main psychoactive compound in cannabis that produces the "high" feeling of cannabis.



1 Introduction

The topic of cannabidiol (CBD) is very fresh and a large part of the population is not aware of the product itself or the possible benefits it can provide. I myself was first introduced into CBD after being hospitalized with an auto-immune sickness called Henoch-Schönlein Purpura. The disease affects vascular- and intestinal systems causing them to become inflamed. The available treatments were strong medications that lasted for a long time and had side effects which required other medicines, in order to handle them. In order to alleviate the symptoms of the illness and the side effects of these medications I started to research the disease online and I stumbled onto CBD. CBD was something I had heard a little of beforehand, due to the legalization of cannabis in Canada and United States, but I really had no idea what it was or what were its intended uses. After some research I decided to try it out as I thought "there seems to be no listed negatives anywhere I, might just give it a shot". At first, I was skeptical about the effects but after using it for a few weeks I noticed that I required less pain medication and was able to sleep better. This was amazing as the main side effect of my medication was stress and loss of sleep. Although the author h

The object of this study is to investigate whether there is a possible market for hemp-based cannabidiol (CBD) products in Finland. CBD is one of two major cannabinoids found in cannabis. It is a non-psychoactive compound that does not produce the same "high" as Tetrahydrocannabinol (THC) but has other beneficial uses such as dietary supplements, skin care products or medication. The studies suggest that CBD has multiple effects on human physiology through the endocannabinoid system. The endocannabinoid system influences the body through the endocannabinoid receptors: CB1 and CB2 which can be found within many tissues including the brain, gastrointestinal system, reproductive and urinary tracts, spleen, endocrine system and heart. The endocannabinoid system affects pain, inflammation, appetite, digestion, metabolism, circadian cycle, immune system, hormonal balance and mood affecting hormones such as: serotonin, dopamine and glutamate (Hamppumaa 2019). The major benefit of CBD over other alternatives is that it is entirely natural, has very minor side effects compared to other medication, such as anticonvulsants that are used to treat the same diseases and issues as CBD. Anticonvulsants have multiple side effects



whereas with CBD the side effects are limited to; dry mouth, light headedness, low blood pressure and minor stomach aches.

The hemp, CBD and cannabis industry is one of the fastest growing industries within the US, the CBD and THC market together combined can be estimated at \$20 Billion by 2024 a study says (Dorbian 2019). CBD alone was estimated by Cowen Outperform to grow to a 16-billion-dollar industry by 2025. Cowen itself was surprised that in a survey the conducted (n= ~ 2500) nearly 7% of the respondents had used CBD products within the past month as a supplement (Cowen 2019). Other publications such as Bourque (2019), has mentioned that: "the market projected to hit \$22B by 2022 - up from \$190M in 2017". The growth is as well supported by the reduction of stigma around cannabis and the realization that the war on drugs all around has been a failure, which has led people to form their own, better informed opinions regarding cannabis, hemp and CBD. The potential of CBD as a medication has been realized and the first ever FDA approved CBD medications have been allowed on to the market in the United States. The study conducted by Cowen in 2019 also supports the proposition that CBD has become more widely acknowledged and used as a supplement to aid people with recovery, inflammation and anxiety. The United States already patented some of the cannabinoids as an antioxidant. There is also interest in CBD products by multiple different retailers in the US (Skelly C 2019). Multiple northern American companies have already branched out into Europe in order to capitalize on the future hemp and cannabis market. Aphria is one of the North American companies that has started operations in Europe with multiple partners such as: ASG Pharma Ltd, FI-Group, CC Pharma, Schrolll Medical and Aphria Europe (Aphria Inc).

2 Methodology

The methods used for completion of this thesis consist of qualitative research methods such as; scientific publications, news articles, legislative publications, expert interviews, visit to manufacturing sites and survey results. Due to the nature of the subject and it being very recent there is a limited amount of publications regarding the potential uses



and effects of CBD. New studies can be used to determine the usefulness of CBD and therefore determine potential applications and a possible future market. Legislative publications can provide a view into the potential of future market size. During the research, the writer had an opportunity in the summer of 2019 to tour the manufacturing site of a company that produces CBD. This was an excellent opportunity to see the manufacturing process first hand and to learn what is required in order to refine the original product into a market approved CBD product. The visit to the manufacturing site itself was unstructured yet nevertheless fruitful and yielded a wide amount of knowledge regarding the manufacturing of CBD products. The main take-away information was with the purity required for products in Finland and what is required to achieve that. Visit also gave information regarding different strains of hemp to be grown for CBD and that there are strains that are very suitable to growing conditions in Finland. (Hempaattinen)

Although CBD is under heavy legislative scrutiny, there has been a trend of liberalization regarding the subject, which seems to continue. This would be good news for the industry. The main consideration of this research is to remain ethical and unbiased with regard to the findings presented. This can be achieved through researching reliable variety of different sources that provide information for the case and against the case of CBD, after validating and compiling the data from different sources an idea regarding the future of CBD should become clearer. (Saunders 2016).

The main idea of this research is to address a theoretical research problem whether there is a potential market for CBD products in Finland. To qualify this, the research will discuss the potential positives and negatives that CBD can provide and whether people would be willing to use CBD after learning about it. As information regarding the subject can be scarce it is necessary to use variety of different sources to compile information on a scale required for the investigation. Using the methods mentioned above, this research should provide a better view into the research question.

Due to the topical nature of the subject, new information keeps surfacing as studies are published. Furthermore, governments tend to show a trend towards liberalization in terms of removing the penalties of having THC or CBD products or even going so far as to legalize the substance and open up the market for variety of products. Due its



topical nature, a variety of news outlets and expert websites prove to be a good source of information when used critically especially in terms of bias of the information.

This trend towards liberalization also allows the chance to conduct descriptive research into the different ways of decriminalization or legalization of CBD products, and how the market has evolved with different types of legislation in control of it. The study will examine the systems of Canada, United States, Estonia, Spain and the Netherlands in order to gain an idea of what the market could look like in Finland. The reasoning behind looking at these countries is that they all have different types of models for legalization or decriminalization, all of which operate differently. The author wanted to include countries from within the EU as they face the same EU legislation as Finland. (Saunders 2016).

Legislative publications that concern the research of this study are taken from worldwide sources due to the scarcity of available research within Finland and Europe. Studies used are generally produced in North America due to the recent legalization of the products in Canada and in parts of the United States. Many of the studies regarding the market are not available to consumers at this time but should be considered as material for future research. This study also draws on expert interviews to obtain information from people who deal with producing and selling CBD hands on. A visit was conducted to Hempaattinen, which produces Finnish hemp products such as oils and salves to begin with. Hempaattinen was also expecting the market to start growing and for them to start producing also different products out of Hemp that include CBD.

However, the writer made the decision not to include a survey as part of his research due to the nature and the topicality of the subject. The reason for not using a survey was mainly concerned with bias and the complexity of conducting a survey within the time frame of this thesis. It was decided that it is better to focus on variety of secondary sources of information such as news articles, research studies and legislative publications. After more information is available regarding the subject and some time has passed, conducting a survey among the general public could provide more accurate data in order to have better confidence in the findings of the study.



2.1 Research Hypotheses

To complete the study, three hypotheses were made, against which to reflect the findings of this research.

Hypothesis A1; there is a significant market for CBD products to be sold either as a medicine or supplement; the extent of the market and the profitability is widely affected by legislation. Expectation is that the highest market value is in the supplement and cosmetics market: considering the daily applications of these products.

Hypothesis A2; there is a market for the products but due to legislative issues it is difficult to compete with international markets.

Hypothesis A3; there is only a small or little to no market for these products in Finland.

The conclusion will go over the findings and compare the outcome to the hypotheses.

3 Literature Review

Literature on the subject is limited. However, an increasing amount of publications is surfacing due to the topicality of the subject. Older publications prior to the cannabis prohibition exist which can prove helpful. It is important to review the potential positives and negatives regarding CBD's effects, potential of market size for variety of CBD products such as; cosmetics, supplements and medication.

3.1 Criteria for finding and choosing the research

Due to the nature of the subject, several sources of research information are utilized. These include news articles, research publications, legislative publications, a possible



survey and blog texts. Because of the scarcity of research publications from reputable and peer-reviewed sources such as universities and journals, additional focus shall center upon the validity and bias of the sources found. It is also essential to make sure that the literature is relevant to the field as well as enough research into the relevant material is conducted. When assessing the relevance of the literature, the research question must be kept closely in mind while remembering that the author is looking for relevance in the subject of matter and "not critically assessing the ideas contained within." (Saunders 2016).

3.2 Nature of available research

Research is primarily focused on the potential health effects of CBD and the potential dangers of it, whereas legislative publications tend to focus on the issue of legality regarding CBD in terms of purity and safety of the products that are potentially emerging on to the market. Legislative publications, in this case mainly from the European Union, provide an understanding of the issue of legality regarding medicinal and recreational cannabis and hemp products and on the required research that will be necessary for legislative changes to take place that would allow cannabis products to be legal. This means more research into the potential negatives of cannabis products as well as more research into the positive aspects of the plant, overall, more understanding especially of long-term effects is required.

Grotenhermen states in The Medical Use of Cannabis in Germany that the interest in therapeutic use of cannabis strongly increased in the 1990s. Despite it having a long history of medicinal use, it was almost completely forgotten after the 1950s. This is mainly due to the legislative issues (Grotenhermen 2002).

A World Health Organization (WHO) report states that CBD can be useful for several medical conditions, mainly epilepsy and other seizure disorders such as Dravet and Lennox-Gastaut syndromes. CBD has also been shown to be helpful for treatments for multiple other illnesses such as anxiety, drug addiction but more research is required to establish a direct link between CBD and its help to these diseases (World Health Organization 2018).



What many sources seem to have in common is that there are multiple purposes for the use of CBD. So far, it is an approved treatment for seizures, but other applications would require more research to prove causation between CBD and health benefits. Another connecting factor is that CBD is not addictive, and it is not possible to become dependent on it. This has been proven in animal and human trials. Indications are that there is no abuse potential in CBD, "While the number of studies is limited, the evidence from well controlled human experimental research indicates that CBD is not associated with abuse potential." (World Health Organization).

The Finnish Institute for Health and Welfare (THL) has also suggested that all drugs should be decriminalized. Hakkarainen and Tammi (2014) from THL suggest that certain methods need to be revaluated from time to time, this goes for the drug policy as well. They state that the usage of drugs should be controlled by the jurisdiction of health and social services rather than criminal law and punishments. They state that multiple different organizations support the notion that drug users should not be punished. Organizations such as WHO and Global Commission on Drug Policy have stated that the usage of drugs should be interfered with in other ways than punishment. This also is in support of the trend towards liberalization regarding mainly hemp and cannabis. (Hakkarainen et al 2014).

Publications that study the effects and applications of CBD are also useful in determining the potential applications and therefore potential market for CBD products. These studies have been produced abroad mainly in North America. As Saunders states when a subject is relatively new there is higher possibility of scarcity of closely related material to the actual subject, then it is necessary to widen the scope of research (Saunders 2016).

Multiple online sources were used as literature regarding this subject was not widely available. Some online sources can include bias as expected the main concern was with sources that advocate for CBD heavily. In order to minimize the effect of this bias writer compared sources against each other and also included sources that is critical of the subject.



3.3 Ethical aspects of the research

The aim of the thesis is to remain as open, unbiased, honest, objective and careful to provide an accurate as possible result of the research to increase and provide knowledge in the subject and to support collaborative work. The current situation regarding Cannabis products is difficult since it is mostly considered as just a recreational "drug". There is a stigma regarding it which can hold people back in speaking about it. This is why the researcher has made efforts to use sources that provide a view from both sides of the aisle, so that both positives and negatives of the subject are considered.

4 The case for CBD

4.1 Medicinal Use

CBD has multiple different medicinal uses and can be produced for use as a medication for different diseases. Currently it is FDA approved for a few seizure inflicting diseases and is under research to be approved for other diseases and symptoms that include anxiety, chronic pain and insomnia. Currently there are two main Cannabis products that are approved on the Finnish medicinal market, Sativex and Epidiolex although in rare cases more options are available such as product in flower form like Bedrocan.

The first one to be approved is Sativex, which was approved in 2012 and was introduced to the markets the following year. It includes two active cannabis compounds both THC and CBD. The use of Sativex is meant for patients with MS disease to alleviate the spastic symptoms that it causes. Sativex is used as an additional medicine when other more common medications are not effective enough.

The second medication is Epidiolex. This is extracted from the Cannabis plant and has CBD as the active component. It was approved by European Union legislation in 2019 but was introduced to European markets in 2020 as GW Pharmaceuticals reported a successful commercial launch within the Europe and UK. (Globenewswire 2020).



Epidiolex is used for hereditary childhood epilepsy along with Clobazam (Epidiolex 2019b).

In some individual cases when Sativex treatment has not been effective enough, with the doctor's consideration, patients can apply for special permission in order to consume cannabis flower as a medicine. Although the flower-based medicine must be approved by the authorities, the cultivator must also have permission to cultivate and produce the said products. The main cannabinoid contents (CBD and THC) of these plant-based medicines are standardized as much as possible in order to provide a consistent product. The plants must be cultivated, packaged and analyzed according to good cultivation habits; this includes the GACP and GMP regulations. In Finland, the governance of medicines is under the scrutiny of Fimea. Fimea controls that all products within the Finnish medicinal market fulfill the set requirements with regard to efficacy, safety and quality. Fimea's jurisdiction lies with the control of pre- and after supervision as well as guiding and overseeing the manufacturing of medicines (Fimea/2015). Considering all this supervision there still is no agreement for the products' quality or proven efficacy that is approved by Fimea, which means that the medicinal applications are very limited even abroad where the products originate from. There is not sufficient evidence that would support wide variety medicinal use of currently unapproved cannabis products. Both the European Parliament and WHO have stated that any cannabis product used for medicinal purposes must go through clinical trials, regulatory evaluation and approval.

From the view of the medicinal authorities, the medicinal use of unapproved medicinal cannabis products is concerning because these products are often untested which means that the efficacy, safety and quality has not been confirmed as being on the same level as other products that have been approved for sale. The safety of the treatment, as well as the proper use of the unapproved products, is left up to the responsibility of the single prescribing doctor. It should be noted that the use of these unapproved products can cause dependency as well as significant social and health issues. However, if the medicinal use of unapproved cannabis products is seen as necessary, it would be beneficial to have a definition of policy on the federal level and make proper changes to the existing laws, including the statute for the special permission applications. Currently it is difficult for the consumer to be confident



regarding the legality of the means of acquiring their unapproved medicinal cannabis products. Multiple products are available, with a large variety of suppliers. Fimea has notified consumers on its website not to order CBD products from abroad because of the inconsistency in quality. Additionally, unapproved CBD products are illegal in Finland and there is no guarantee regarding the safety of these products (Pihlainen K, Sofia E, Näveri L, Pellas Kr, Koski S.. 2020).

4.1.1 Established uses

Multiple different medicinal uses of CBD have been discovered. It has been FDA approved as a medication under the name of Epidiolex for a few seizure inflicting conditions such as: Lennox-Gastaut syndrome and Dravet syndrome (Epidiolex)

One major benefit of CBD is that the side effects are minor compared to alternative medications such as opioids or anticonvulsants. So far no studies have proved the efficacy of CBD for human use to be beneficial for arthritis although it has been discovered that cannabinoid acid (CBDA) seems to work in similar ways to NSAID medications often taken by arthritis patients. The European Parliament acknowledges that scientific evidence suggests therapeutic effects of cannabis and cannabinoids regarding certain diseases such as chronic pain, nausea and multiple sclerosis and that they are effective in the treatment of people with anxiety, PTSD and depression (European Monitoring Centre for Drugs and Drug Addiction 2018).

Cannabis products, which include both CBD and THC, have been used as a medication in Finland since 2008, which means they already have a small controlled market. These are mainly used to treat people with multiple sclerosis who have not had success with other forms of treatment (Fimea 2015). The medicine that is used in Finland carries the name of Sativex; currently the price is very high as a package with 3 times of 10 ML doses costs € 642,75 (€ 20824,83/L) (Yliopiston Apteekki 2019). According to this, there would most certainly be a market share for Cannabis products that include both THC and CBD as well as individual CBD or THC products since the current price is very high. It should be noted that it is much more expensive to produce a medicine than a supplement or a recreational product. Finland also has cannabis available as a medicine in flower form under a few different names such as: Bedrocan,



Bedrobinol, Bediol, Bedica, Bedrolite. The difference between these products is the amount of CBD and THC concentrations which vary from 1 to 22% of THC and 1 to 9% CBD, depending on the strain.

4.1.2 CBD as pain medication

The European Journal of Pain has conducted research into the CBD and CBD/THC medications used for treating pain. One study included strictly CBD as a transdermal medicine to alleviate joint pain in rats. The second test concluded by European Journal of Pain researched a medicine that included CBD/THC mixed together, as a way to relieve pain and increase sleep in patients with peripheral neuropathic to further increase recovery and life quality (Hammell D.C, Zhang L.P, Ma F., Abshire S.M, McIlwrath S.L, Stinchcomb A.L and Westlund K.N., 2016.).

A study into the efficacy of transdermal CBD to treat inflammation and joint pain in rats provided positive results, as "Transdermal CBD gel significantly reduced joint swelling, limb posture scores as a rating of spontaneous pain, immune cell infiltration and thickening of the synovial membrane in a dose-dependent manner." Another major factor to point out is that "Exploratory behavior was not altered by CBD indicating limited effect on higher brain function." (Hammell Et Al.). Although conducted in rats, this would suggest that CBD could be applicable as an alternative to widely used inflammation medicines such as ibuprofen. The research shows that CBD is a safer choice with fewer potential side effects than many other medications used to treat inflammation and arthritis. As ibuprofen side effects include stomach pain, heartburn, nausea, vomiting, gas, constipation, diarrhea, as well as other more serious side effects after long-term use, these side effects include decreased kidney function, increased blood pressure, ulcers and bleeding in the stomach and intestines (Healthline 2020).



4.2 Supplemental Use

CBD has been shown to have many benefits as a daily supplement for athletes and people who are suffering from different conditions such as inflammation, anxiety, stress and sleep problems. It is relatively safe to use as it there is no risk of addiction as shown in a study conducted by the World Health Organization (WHO 2018).

CBD has been shown to alleviate the stress of hard exercise and increase the rate of recovery. As recovery is just as important as the workout, it is essential for athletes and people with active lifestyles to make sure they are recovering while they are resting in which case CBD is an ideal supplement. As people train and work out, muscle fibers break down which leads to the growth of the muscle after the muscle has recovered. This is where CBD steps in as an anti-inflammatory that helps with the recovery and reduces the resting time required allowing for the athlete to perform in full capacity faster (Kelly 2020).

4.3 Recreational Use

The common belief is that CBD is just medicinal, and THC is only recreational, when both compounds can be applied to both uses. Recreational usage for CBD has different varieties as a sleep aid, a relaxant and a stress reliever. An advantage of using CBD is that it is not intoxicating so can be used very safely. Although CBD use can include some psychoactive components, it is proven to help with stress, anxiety and sleep.

4.4 Cosmetic Use

CBD has been proven to have multiple cosmetic applications in skin cream, lotions and moisturizers. With already multiple different types of products available to customers, the global CBD cosmetic market was estimated to be worth around \$580 million (Grand view research 2019. This market is expected to be worth \$1.7 billion by 2025 with the North American market leading the way (Nazish 2019).



The advantage of CBD is that it is considered safe and effective for all skin types, but it is extremely more useful for people with skin issues such as sensitivity, inflammation, acne and dryness. CBD acts by helping the skin in its natural healing process, which means a shorter lifespan for breakouts, rashes and eczema. An added benefit is that CBD can help with the pain associated with inflammatory skin conditions. (Scheau, et. al. 2020)

4.5 Legal considerations

4.5.1 Finland

In Finland, it is illegal to produce and withhold any type of Cannabis. However, having CBD products is legal if they contain a THC level of under 0.2%. Depending on the CBD product, it might come under the scrutiny of the Finnish Medicines Agency (Fimea), the National Bureau of Investigation (Keskusrikospoliisi) or the Customs.

Fimea is in control of investigative use of illegal narcotics as well as medicinal use of these products. This means that Fimea oversees cannabis products in the same manner as any other product that is under Fimea's jurisdiction. If the products are on the markets illegally, they are under the jurisdiction of the National Bureau of Investigation and customs. (Pihlainen Et Al. 2020).

According to an article released in Sic! (2020), the term "Medicinal Cannabis" does not exist in Finland and is misleading. It does not have an official determined definition in the Finnish language and no products exist that would match the term. It is not recommended to use the term for this reason and because it cannot be used unambiguously. (If a Cannabis product is aiming for permission to be sold as a medication, it must meet the same legal requirements as any other medicinal products. A company must apply for permission to sell if it wants to bring a product to the markets. Permission is granted if the company can present a research study according to which the medicine can be expected to have more positives than negatives for the population, when it is used in accordance with the instructions and when the existing permission of sale requirements are met. As earlier stated in section 4.1, Fimea also oversees all already approved medications and guarantees the safety to the user as



long as the product may be in use. It should be noted that the authorities cannot initiate the permission of sale process, nor can they have any effect on initiating the permission of sale process for medicines that are already approved abroad. (Pihlainen et al. 2017).

According to medicinal law, Fimea can categorize CBD as a medicine even though it is sold outside the medicinal supply chain. If a compound is categorized as a medicine, it has limitations regarding the production, distribution, sale, marketing and importing of the product. After Fimea has categorized a compound as a medicine and it has been approved, marketing the product is illegal and it can no longer be sold in Finland. Fimea has categorized products that include CBD as a medicine but according to Fimea the categorization as a medicine does not prove that a compound or product has medicinal effects or value as a medicine. The categorization is often used to protect consumers from what the authorities can describe as harmful products as there might not be enough information regarding the quality of the products or knowledge about all the possible ingredients and compounds that are included in the product. As is the case with CBD, the products can also often include THC that has been categorized as an illegal narcotic. The same rules apply to the personal importation of cannabis products as well as for any other medicinal products. As CBD is listed on the medicine list in Finland, any product that contains CBD can be compared to a prescription medicine. This means that ordering any CBD products online is prohibited. Importing products against the rules is breaking the law and is considered a medicinal crime; if the products contain any amounts of THC it is also considered a drug crime. The importation of illegal narcotics comes under the jurisdiction of the Finnish Customs (Pihlainen et al. 2017).

4.5.2 Europe

Legislation towards Cannabis and CBD has started globally which has led to a wave of liberalization that started in Northern America and has spread to the Europe, where it is still largely illegal to grow Cannabis and Hemp. Consuming and carrying small amounts of THC or CBD products are allowed depending on the country.



In November 2020, the European Court of Justice (ECJ) issued a ruling on a pivotal case concerning the legality of CBD in the European Union and the potential future of the Union's CBD market. The background of the case is that KanaVape, a French CBD company, came under prosecution in France for importing CBD to be marketed in vaporizer cartridges. The issue was whether the European Union can ban the marketing of a product that is still legal in another state of the Union. To solve the case the judges had to rule whether CBD was considered a narcotic under EU law, as it is considered a narcotic under the UN Single Convention on Narcotic Substances. (O'Conor 2020).

The judges ruled that CBD should not be considered a narcotic because CBD does not "have any psychotropic effect or any harmful effect on human health." It was noted that technically CBD could have been considered a narcotic according to the legislation within the UN convention, but banning CBD according to that legislation would have been: "contrary to the general spirit of that convention and to its objective of protecting 'the health and welfare of mankind". The court also made a big ruling regarding the marketing of CBD that: "A decision to prohibit the marketing of CBD, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other [EU] member states, can be adopted only if that risk appears sufficiently established." (CVRIA 2020).

Robert Jappie, a partner at a law firm Ince, confirmed to The Guardian newspaper that this ruling was a "big win" for the industry:

"By confirming that there was no scientific evidence to suggest that CBD has a harmful effect on the human body, the court has made it very difficult for the European commission to pursue their proposed classification of CBD as a narcotic," he said." (Guardian 2020)

4.5.3 Germany

Germany recently took the initiative towards liberalization and allowed the medicinal use of cannabis products. The spread of medicinal cannabis markets to a state in Europe with half a billion citizens can be expected to lead to broader public acceptance, which could then set the stage for adult use legalization in a pattern that



would probably repeat itself across the globe (Adams T./2019). Back in 2017, Germany allowed the use of Cannabis products for severely ill patients and since then around 60,000 patients have received cannabis prescriptions through their health insurance. Recreational use is still prohibited, although legislation concerning the possession of cannabis products varies from state to state. In Hamburg, Lower Saxony and Bavaria you can carry under 6 grams of Cannabis and avoid prosecution while some other states such as Rhineland-Palatinate and Thuringia have set the limit at 10 grams and Berlin at 15 grams effectively. (Healtheuropa 2020).

The German Federal Institute for Drugs and Medical Devices (BfArM) founded The Cannabis Agency to purchase

"take possession and sell medical cannabis cultivated in Germany so that it meets the international requirements as stated in the United Nations Single Convention of Narcotic Drugs of 1961 to manufacturers of medicinal products, wholesalers or pharmacies." (ECA-Academy 2019).

The BfArM is in position to issue licenses to producers hoping to grow cannabis in Germany, as it is currently completely dependent on imported products. The first licenses have been issued as of June 2020 and Germany is looking to receive the first harvest by the end of 2020. The BfArM has been looking for 13 state distributors of cannabis products and is accepting tenders for the positions. The companies that succeed in winning the tender shall oversee the distribution of all domestically grown product to German pharmacies (Healtheuropa 2020). A total of 79 distributors applied for the positions and all 13 positions were awarded to Canadian groups such as Aphria and Demecan who won the last four spots that were available. The BfArM will not be a part in storing the Cannabis. When BfArM arrived at the conclusion of the award procedure, it issued a press release where Dr Karl Broich, the President of the BfArM, stated that: "this step is an important contribution to the improvement of the supply situation. The successful finalization of the award procedure means that the cultivation of cannabis of pharmaceutical quality in Germany can now be fully and rapidly implemented" (ECA-Academy 2019).



4.5.4 Estonia

In Estonia, medical Cannabis has been legal for well over 10 years. However, when it was legalized by the government, it was made challenging for patients because no medical marijuana programme had been implemented that would support the cultivation, distribution and recommendation of medical cannabis. Instead of having a medical cannabis programme, the state permits the use of cannabis products on a perpatient basis. To be approved, patients must go through an extensive and complicated process that can in some cases can involve the Estonian Ministry of Social Affairs, as well as some other official departments in some cases. Qualification for medical cannabis in Estonia is very different compared to other countries such as Finland or Northern American counties, since no medical cannabis program exists, there are no defined qualifications for medical cannabis. This gives physicians the authority to determine whether a patient requires medicinal cannabis. By December 2018, only one patient had received approval to use medical cannabis.

Nevertheless, more than 13% of Estonians between the ages 15 to 34 use cannabis. Since the early 2000s, Estonia has worked to reduce the penalties for having recreational or medical cannabis; penalties for having up to 7.5 grams of cannabis flower are most often fines, only around 10 to 20 percent of offenders receiving an administrative arrest for up to 30 days. However, cultivating and distributing cannabis will lead to strict and higher penalties such as imprisonment that will last from 3 to 20 years depending on the amount (Rosado 2018).

According to Estonia's Ministry of Justice, patients are only allowed to use cannabis-based medications such as Marinol. This means that regular cannabis in its flower form is prohibited. In order to apply for the use of traditional medical cannabis, the patient and physician must make a request to the State Agency of Medicines which will in coordination with the International Narcotics Control Board (INCB) determine if the need for this medicine is justified. This complex system makes it very difficult for patients to acquire flower-based cannabis medicine in Estonia. On top of this, the imported cannabis medicine is not covered by insurance. The positive element regarding the complicated process is that it protects both the patient and the physician as the multi-step vetting process as it ensures the potential benefits and dangers of medicinal cannabis compared to other treatment options. Furthermore, by confirming



the product with INCB you are assuring that it meets the qualifications of medicinal cannabis (Rosado 2018).

Recreational CBD arrived in Estonia in 2019 where it is legal to use. In Tallinn you can find multiple stores that sell Hemp CBD in multiple forms such as: seedling, flowers, seeds and hemp protein. The vendors have been positively surprised as sales have been higher than expected. Yle (Finnish broadcasting association) interviewed a shop owner who stated that the customer base is wide and there are customers from all age groups, Estonian and from abroad and that people come in with their kids and pets. He also mentioned that Finnish tourists who visit the shop are very common (Massa 2019). In addition, some pharmacies in Tallinn carry CBD products as supplements for consumers to get their hands on. (420CBD).

4.5.5 The Netherlands

The Netherlands is known for its liberal view on marijuana and cannabis. The capital Amsterdam is also a major tourist destination partly for this reason. The Dutch law concerning cannabis products is primarily based on the Dutch Act on Drugs / Opium Act (Opiumwet). It includes the distinction between hard drugs and soft drugs. List 1 includes all the hard drugs whereas list 2 includes the soft drugs. Cannabis, hemp and hashish are on list 2. Cannabis products such as beverages, edibles are allowed with certain conditions: the THC amount is limited to 0.05%, the product does not bear any medical claims and that the consumers are advised to take maximum 160mg of CBD per day. Products made with THC extracted from cannabis plants are not allowed and depending on the product, it may be better to consult with The Netherlands Food and Consumer Product Safety Authority (NVWA).

Any use of THC or hemp oil that is extracted from the cannabis plant is not allowed in the Netherlands since they are listed on List 1 of the Opium Act. Due to the list 2 drugs being deemed less dangerous to consumers than those on list 1, the government has allowed the controlled sale of cannabis within coffee shops for recreational purposes (Weeren M. 2017). In article 5 of the Opium Act the jurisdiction of coffee shops is granted to municipalities. Article 8 of the Opium Act states that for certain purposes, exemptions can be granted (Overheid 2009).



Other regulations regarding cannabis also exist as there are secondary legislations such as: Foodstuffs and Cannabis regulation, medicines regulation, cosmetics and CBD regulation, tobacco related products and cannabis regulation. These secondary regulations regulate the markets that are using refined cannabis in some form such as edibles, medications or cosmetics. The foodstuffs and cannabis regulation are primarily of European origin as the General Food Law (European Food Regulation 178/2002) regulates food stuff where the main topics are the contents of food, labeling them, advertisement as well as packaging. Medicines regulation is applicable to any product that is marketed as having medicinal benefits according to the Medicines Act and European Medicines Directive 2001/83/EC. However, if a product is marketed as being a medicine, these regulations will be applicable which means that it has to undergo scrutiny and pass the criteria of presentation ("aandieningscriterium") or the criteria of administration ("toedieningscriterium").

If a cannabis product qualifies as a cosmetic product, the Cosmetic Products Decree 2011 and the European Cosmetics Regulation 1223/2009 apply. According to these regulations, the distributor and producers of the product must meet certain obligations such as safety, label guidelines, identification and notification requirements. For tobacco and related products such as vaping, smoking the tobacco regulation must be taken into consideration. This is The Dutch Tobacco and Related Products Act (Tabaks- en rookwarenwet) which, along with the European Directive 2014/40, these legislations regulate tobacco and related products and can apply even though tobacco is not included in the products. This is why it is also taken into the consideration with CBD products. These regulations impose certain restrictions that must be considered regarding the advertisement, sponsoring and age verification systems. (Weeren M. 2017.)

4.5.6 Spain

In 1967, Spain ratified the international treaties that were formed in the Single Convention of 1961, which meant cannabis was classified as a narcotic drug. This classification does not prevent the production, export, import, distribution, trade, use and possession of cannabis as long as it is meant for "medical and scientific purposes"



(Single Convention, Article 4). Spanish Law 17/1967 supports this as regarding cannabis it states that "authorized therapeutic, scientific and teaching uses in accordance with this Law" along with the Royal Degree 1/2015 that allows the sale of plants that have been traditionally considered as medicinal plants, like cannabis.

In Spain, up to 2.2 million (7.3%) people had dmitted to the use of cannabis as reported in a survey conducted between December 2015 and April 2016 by the Ministry of Health. This was a rise on earlier reports from 2013 where the number was 6.6%. Recreational use of cannabis products is still illegal but decriminalized.

Some approved cannabis-based medications in Spain include Sativex, which has been approved since 2010 (Navarre-Varo 2018). Medical cannabis is not regulated in Spain but high amounts of cultivation in Spain mean that the product is exported to other parts of the world where it is legal for medicinal and recreational purposes.

Regarding CBD there is no regulation at all for the use of CBD as food since it cannot be classified as a food supplemens along with vitamins and minerals. This means that it is not legal to register food items that have CBD in them. Although there is a loophole where CBD-based products are produced within an EU country where CBD is legal, it can be sold in Spain according to the principle of mutual recognition (Sativasana 2019). The principle of mutual recognition is a principle applying to the field of free movement of goods. "Where no harmonized rules exist at European level, products lawfully marketed in one Member State can be sold in other Member States regardless of complying or not with the national technical rules of these member states" (European Commission 2020).

4.6 Risks associated with CBD use

Legislation towards Cannabis and CBD has started around the world. It started in Northern America and has spread to Europe where it still is illegal to grow Cannabis and Hemp for the most part it is allowed to consume and carry small amounts of THC or CBD products. It is considered illegal to produce and withhold any type of Cannabis, but having CBD products is legal if they contain under 0.2% THC level. Although the



sale of these products is illegal as well as importing these products, CBD is classified as a prescription medicine in Finland.

The use of banking services for industrial hemp businesses has also been allowed in the US since November 2019. This previously was an issue due to the hemp industry having no access to banking and financial services, which made operating difficult. It also held back potential investors and business partners.

4.7 Potential Market

Cannabidiol products can be consumed in multiple different ways: CBD products exist in beverages, smokables, vapes, flower medicines, edibles along with cosmetics. With so many different options, it is easy for a customer to find an appropriate method of consuming the products. This is beneficial especially because many people want to avoid smoking flower due to the damage that inhaling smoke causes to the lungs (National Institute on Drug Health 2020). A recent report produced by New Frontier data showed that infused products such as edibles and beverages accounted for 14% of total cannabis sales in the US. It is the third largest category after flower which accounts for 37% and vape which accounts for 32%. (Furnari C. 2020).

"BDS Analytics' has predicted that the US sales of cannabis- and hemp-derived CBD products to rise from \$1.9 billion in 2018 to \$20 billion in 2024, a compound annual growth rate of 49%." (BDS Analytics 2019a) Whereas the worldwide cannabis market is expected to rise to 42.7% billion, with 26.9% compounded annual growth rate from 2018. (BDS-Analytics 2020).

The increasing amount of sports injuries along with growing geriatric population would also support the growth in the CBD market as joint pain and inflammation accounted for around 10% of the market share in 2019. This is expected to follow a similar trend during the market forecast period. Joint pain and inflammation affect up to 15 million patients in the US every year and are mostly prominent in the geriatric population (Ugalmugle, Rupali 2020). These statistics also apply in Finland where the amount of people over 65 years old is expected to rise from 16% to 26% by the year of 2030, according to a forecast by Statistics Finland back in 2007 (Tilastokeskus 2020). In 2019



there were 874 000 people that were over the age of 70. The amount has increased by 100 000 within 3 years (Findikaattori 2020). This shift of population aging would suggest that there may be a need for products that help with joint pain, inflammation such as CBD.



Graph 4.1: Displays the purchasing factors of CBD buyers, according to the information gathered by New Frontier Data.

New frontier studies show the purchasing factors for CBD products among people questioned. The most important factors are price and potency of the product. As the new frontier report stated: "In both the CBD and marijuana markets, consumers consistently listed ingredients, dosage, and testing results as the most important factors." (Furnari 2020).

Total sales of CBD products have grown exponentially since legalization in United States and Canada. As the market has grown and expanded into new products, the CBD market has evolved from "cannabis sub-category into a full-blown industry of its own" stated BDS Analytics (2019). Major retailers have also announced their stocking and private level development of CBD products. BDS Analytics expects the majority of CBD sales to move to retailers from dispensaries and that the success of the products is dependent on dosing, consistent labeling of the products along with education and understanding of the consumers. The consumer profile of CBD users is also more widespread than the regular marijuana consumer base, as the CBD consumer base



tends to be around half women half men whereas the regular marijuana consumer base is just around 1/3rd women. CBD sales have grown at faster rates than overall cannabis sales within dispensaries (BDS Analytics 2019). This implies that the CBD market can possibly become bigger than the regular marijuana market that is aimed mainly at THC products. Since BDS Analytics have tracked sales of dispensaries, CBD sales have increased from 5% in 2017 to 11% in 2018.

5 The case against CBD

5.1 Medicinal Use

CBD is not suitable for everyone and the mechanisms of how it affects the body are yet to be fully understood. The producers of the first FDA approved CBD medication, called Epidiolex, say that the medication is not suitable for people under 2 years of age and has a variety of side effects such as; sleepiness, diarrhea, loss of appetite, sleep problems and infections (Epidiolex) It should be noted that generally medicines known as anticonvulsants are used to treat the same diseases as CBD, also have multiple side effects such as: drowsiness, dizziness, nausea, vomiting, diarrhea, constipation, trouble sleeping, loss of coordination, headache, blurred/double vision, hiccups, or loss of appetite (WebMD 2019). Cannabis products, which include both CBD and THC, have been used as a medication in Finland since 2008, which means they already have a small controlled market. They are mainly used to treat people with multiple sclerosis who have not had success with other forms of treatment (Fimea). The medicine that is used in Finland carries the name of Sativex; currently the price is very high as a package with 3 times of 10 ML doses costs € 642,75 (€ 20824,83 /L). (Yliopiston Apteekki) You are required to have special authorization from a doctor in order to receive medicinal cannabis in Finland. The amount of people being granted the authorization was on the rise from 2014, where 223 people had acquired the authorization, up until 2017 where 373 authorizations were granted. After this, there was a drop in 2018 where 269 authorizations for medicinal cannabis were granted. Suomen Kuvalehti, a Finnish journalism magazine, ran an investigation into this.



According to the magazine, the reason for the reduced amount of authorizations was a note sent from Kela (Finnish social insurance institution), that it will send the information of every doctor Valvira (National Supervisory Authority for Welfare and Health) (Malin 2019).

Appendix one shows the note from Kela sent to the doctors. This is a clear indication of stigma that still exists around CBD and cannabis products overall.

5.2 Supplemental Use

Finland has already seen its share of different CBD supplements such as dietary supplements. Multiple stores had already stocked up on CBD or so called "cannabislight" but the Finnish food authority (Fimea) ordered the shops to stop selling these products. This is because "The agency cited that the products do not have the right authorization to be marketed as a foodstuff." (Green 2020).

5.3 Recreational Use

Generally, CBD has little to no recreational value compared to THC products as it does not alter a person's consciousness and produce the same "high". However, some people might find it useful in recreational use for multiple different purposes such as relaxation, or sleep aid. There are some studies regarding the potential uses of CBD but these mainly focus on the medical field on the treatment of people with pain and convulsive disorders. More research is required into the effects of CBD, especially in long-term use to determine the effects it might have. The research so far suggests that abuse potential is extremely low even in polydrug users. Research published in Epilepsy and Behavior showed that:

"CBD is associated with minimal abuse potential and low cognitive/psychomotor impairment over a range of doses up to a supratherapeutic dose of 4500 mg in a highly sensitive population of recreational polydrug users. These findings are consistent with the published literature, which indicates few euphoric effects of



the active ingredient CBD in multiple different trial populations" (Schoedel et al. 2002).

5.4 Cosmetic Use

The use of CBD in cosmetics is defined in the European Cosmetic Regulation 1223/2009, under the entry 306 "Narcotics, natural and synthetic" of Annex II. This regulation prohibits the use of cannabis and cannabis extracts in cosmetics as it is banned in the Single Convention of Narcotic Drugs, signed in New York in 1961. CBD is not referenced in this convention specifically which has created confusion in the industry. For this reason, the European Commission added two entries to its database of cosmetics ingredients regarding CBD. CBD is divided into two categories; natural CBD derived from tincture, extract or resin of cannabis and synthetic CBD. Both of these entries contain the text:

"Cannabidiol (CBD) as such, irrespective of its source, is not listed in the Schedules of the 1961 Single Convention on Narcotic Drugs. However, it shall be prohibited from use in cosmetic products (II/306), if it is prepared as an extract or tincture or resin of Cannabis in accordance with Single Convention. Please note that national legislations on controlled substances may also apply" (Trilla, 2002).

Essentially, this means that CBD derived from plants or parts of plants of cannabis, other than seeds and leaves without tops, that might include traces of other substances that are included within the plant other than CBD, are banned. Synthetically produced CBD is allowed for use within the EU states. It is worth mentioning that while EU law is applied to every member country, including Finland, interpreting and enforcing the law is left up to the individual country's responsibility. This is important because the EU acknowledges that there are certain instances in which the EU will accept CBD within the cosmetic market. In Finland, all sorts of cannabidiols are currently included in the medicine lists, which means that cannabidiol cannot be legally marketed in Finland as a cosmetic or used within cosmetic products.



5.5 Legal considerations

5.5.1 Finland

Currently CBD products are not legal for sale and marketing in Finland as they fall under the jurisdiction of Fimea. According to Fimea: "the current research does not support wide use of unapproved cannabis products" while they also mention that "clear international definitions of policy regarding the use of cannabis products is necessary (Pihlainen etc. 2020).

The legality of CBD in Finland is somewhat complicated and illogical, since 15 January 2019 the European Commission updated the novel food status list so that all extracts made from hemp are deemed novel foods. These products require the state's novelty food permission. This update is illogical because Hemp has been used as a food in earlier ages and has also been deemed non harmful by the World Health Organization. The issue here is that the use of Hemp as a food and supplement source has been proven in 3rd world countries which is not accepted within the European Commission even though every other ingredient is accepted (EIHA / European Industrial Hemp Association 2019). So, the current situation is:

"The marketing of food as having medicinal properties is always prohibited. Foods produced from hemp cannot be marketed using medicinal claims. Only approved claims complying with legislation can be used for the marketing of hemp. Nutritional claims can be used for nutrients that the hemp contains. Health claims have only been applied for hemp seed oil. The Commission has not yet made a decision on whether to approve or reject the health claims in question. Health claims for which the assessment process is not yet finished can be used in marketing for the time being." (Ruokavirasto 2019)

According to Fimea, the classification of CBD is still illegal medicine due to safety reasons. This allows for quick removal of any unapproved CBD products from the Finnish market in accordance with the Finnish Medicines act and Decree. Given the classification of medicine, CBD is under tighter scrutiny, which limits the production, distribution, sale, marketing and importation of said products.

Fimea has classified multiple CBD products as medicines. Even if a product is classified as a medicine, it does not mean that the product has applications as a medicine. More so Fimea most often uses the medicine classification in situations.



when the authorities see that safety of consumers might be threatened (Pihlainen etc. 2020).

The increased consumption of unapproved cannabis products for medicinal purposes is worrisome to the authorities from the point of view that there is no confirmed information regarding the strength, safety and quality of these products (Pihlainen etc. 2020).

Currently the only form CBD that can be sold in is CBD-A. This is not ideal for the CBD market as CBD-A has not been decarboxylated thus leaving multiple ingredients inactive and reducing benefits of the product in question. This is contradictory as current research is unable to present CBD as having any negative effects (WHO 2018). CBD-A has been studied less than CBD, but current research has not been able to prove dangers with CBD-A, although the general consensus is that more research is required. In 2019 Hamppumaa Oy reported that it had pulled products that included CBD and CBD-A from the Finnish market. This was due to them not being listed as novelty foods. Although CBD is considered illegal, it is still being sold in a variety of health food stores across Finland as a tincture or as a cosmetic (Ruohonjuuri 2021).

5.5.2 Europe

The European Commission suspended the applications for including CBD in the Novel Food Catalogue with the argument that CBD and any other extract coming from the hemp plant would be better suited to be regulated under the United Nations Single Convention on Narcotics of 1961. If this "preliminary conclusion" moves forward, it will have devastating effects for the CBD market within Europe. The ruling would make it impossible for any CBD market to exist. The ruling would also prevent innovation and research of CBD products on the European continent.

5.6 Risks associated with CBD use

CBD has potential risks such as side effects, limited research, inadequate regulation, drug interactions and pre-and post-fatal unknowns. Possible side effects include dry



mouth, low blood pressure, lightheadedness, drowsiness and possible signs of liver injury have been reported by NIH (U.S National Library of Medicine). Limited research is another issue as CBD has been classified as a drug for a long time which has limited the extent to which CBD could be studied. In the era of liberalization regarding CBD and cannabis in general, information should be available in future. What is currently known is good, but future research is required to properly understand the potential positive and negative effects and applications of CBD in order to fully maximize its effectiveness. Inadequate regulation is another issue, since the era of liberalization started most states have yet to find an effective way to regulate the CBD market which is a major issue. Researchers from Penn Medicine found that about 70% of the CBD products they tested contained less CBD than stated in the label (Bon Miller Et Al 2017). Drug interactions provide another issue with CBD. If a person is taking other medication there might be ways in which it interacts with CBD which could cause some issues. Some drug interactions with CBD are known but more research is required to determine all the interactions. Pre- and post-natal unknowns also provide a risk; it is recommended that women do not use CBD while pregnant or nursing to avoid any issues.

5.7 Potential Market

The potential market applications of CBD products have been increasing so dramatically in recent years that CBD has become more available and sought after. This is mainly due to the implementation of the Farm Bill 2018 in the United States and the product approvals that followed (Ugalmugle et al. 2020). CBD and cannabis products in general have been available in flower or oil form for quite some time but in recent years they have become available as: flower, oil, transdermal patches, tablets, vape pens, isolates, capsules, creams, gummy candies, supplements and pet foods. Different forms of CBD are generally used within certain fields such as transdermal patches and tablets in the medical field when gummy bears are often used within the recreational market section.



Out of all the product types, tinctures have seen the largest growth in sales valued at 0.39 Million USD in 2015 to sales valued at 389 million in 2019.

Within Finland, the current market is very restricted due to the confusing legislation at state level that contradicts EU laws but is entirely legal as Finland since an EU state has the right to determine which compounds are considered as medications. This has led to a confusing situation where CBD-A products are allowed within the market whereas CBD products are not. This is contradicted by the authorities still allowing the sale of certain forms of CBD-A products which might include CBD as well.

6 Conclusion

As there are multiple different applications of CBD that are already known, it clearly shows that there most certainly is demand for products made of hemp given the unique qualities that CBD offers in variety of products such as cosmetics or supplements compared to the currently available ones. As CBD is still being researched and all its potential applications are still unknown, so far, the biggest achievements are the medications made for compulsive disorders. However, current research already shows possibilities of other applications such as pain medication and arthritis medication. It must be remembered that for new medications to get onto the market, they faced high amount of scrutiny which means that new research is required for each new CBD product that is about to enter the market.

As stated earlier, the recent trend of liberalization regarding hemp and CBD products paints an optimistic view of the direction the CBD market in Finland could be heading to. As liberalization started to spread from Northern America to Europe, the law in Europe did not make a clear distinction whether CBD is a narcotic or a novelty food. It was necessary for the European Union to investigate CBD and its properties. The ruling made by the European Court of Justice in November of 2020 gave a clear distinction that CBD shall not be considered a narcotic. This ruling was in accordance with reports from WHO that show CBD to be non-psychoactive and have no potential to cause dependence. As Fimea is in control of CBD in the Finnish market, it has ruled that CBD be listed as a medication, which means that there are still obstacles for CBD



within the Finnish market. Although Fimea has stated that it has been waiting for clearer international instructions regarding the uses and effects of CBD, given the new ruling by European of Court Justice, this would also indicate a positive future for a CBD market. While this trend is clearly visible, the negative stigma around cannabis still predominates, as shown in the letter sent by Kela to doctors in Finland. The letter claimed that there are no proven benefits for cannabis as a medication other than in the treatment of convulsive disorders. This is in fact an outright lie as several studies have outlined the multiple different benefits of CBD in the treatment of many different ailments such as cancer and arthritis.

Although these recent events present an optimistic view of the direction the situation is heading, it is still essential to keep in mind that the current ruling of listing CBD as a medication will make it impossible for a market to currently exist in Finland. Past research shows positive results for CBD in the treatment of different illnesses, for use as a cosmetic or as a supplement. Given that any harsh negative side effects are yet to be discovered, future research might give authorities the confidence to reduce restrictions on CBD products. The situation currently is conflicting as CBD products are still being sold in a variety of shops across Finland. The majority of these products consist of CBD-A while some are just CBD-A based with CBD in there as well. It should also be noted that CBD is affected by EU legislation along with Finnish legislation which might in some cases contradict each other, but according to EU rules, Finland has the ability to control its internal markets as it sees fit. This has led to a situation in which CBD is widely available across Europe while in Finland it is in the "grey zone" where some types of products are legal and can be sold whereas different versions of the product are not accepted. Tinctures and flower are a good example, given that both products contain THC under the legal limit of 0.2%, a tincture with CBD-A is legal and can be sold but flower with CBD-A cannot be sold.

Considering the research hypotheses after the research, hypothesis A1 - there is a significant market for CBD products to be sold either as a medicine or supplement; the extent of the market and the profitability is widely affected by legislation. Expectation is that the highest market value is in the supplement and cosmetics market; considering the daily applications of these products. Research supports the idea that there is a market for CBD products and people are clearly interested in them. The data regarding



CBD products is not substantial enough to draw a clear distinction that the highest market valuation for CBD products would be within the supplement or cosmetics section. In order to make a reliable statement on this matter, more research is required in the future.

Research hypothesis A2 states "there is a market for the products but due to legislative issues it is difficult to compete with international markets". This is correct, as there clearly is a market for these products but due to Finnish legislation, the marketing and sale of products that are listed in the medicine list is not allowed which disrupts the sale of products with CBD but not CBD-A. As stated in section 5.5.1 this is heavily contradictory as there are still some products that contain CBD within the market.

Hypothesis A3 states "there is only a small or little to-no market for these products in Finland". Considering the evidence presented in this study, there is growing interest in CBD. Finland has seen variety of different products reach the market, only to be pulled from the market due to legislation. There is still quite a selection of CBD-A products on shelves in Finnish stores such as Ruohonjuuri, which shows that there clearly is a market for these products, although the market is heavily limited by regulation. Other factors need to be taken into consideration such as the stigma around the product that still clearly exists.

Overall, the topic has evolved during the actual time of writing the thesis. The situation with CBD has been moving slowly forward within Finland and the EU, taking steps slowly forward while taking a step or two backward. This has made it challenging to draw a clear distinction into the future of CBD. Nevertheless, the recent openness towards the subject along with the positive conclusion from the majority of completed research provide an optimistic view regarding the future of CBD market.

The author believes that this research was able to depict the current complex situation of CBD and bring out the clear advantages of CBD while also acknowledging existing issues and providing data for future research of CBD and hemp related work. The author acknowledges that more research is required especially into the applications and safety of CBD. As more information becomes available, a clearer distinction can be



drawn into what the actual market size could be and which products could be competitors of CBD in different fields such as supplementation, medicines, cosmetics and pet food.

Entertaining the idea of Fimea relieving the regulation of CBD products, a model which would be ideal for the perfect market to exist, all out legalization would provide most of the benefits with increased tax revenues for the state, while also providing the consumers with more certainty that the products they are using meet the quality requirements as they should. If Fimea went down the route of "decriminalization", which in this case would mean removing CBD from the medication list, it would allow for the fast access of products to the market but would also leave the market unregulated. As earlier shown in section 5.5.1, unregulated CBD products have often not met quality and safety requirements. Comparing Finland to the examples of other EU countries, it would be widely beneficial for the state and consumers that CBD would be legal. A controlled market would bring in tax benefits; regulation would guarantee the quality of products for customers and open up a completely new industry for business, which would then also benefit employment. Given that Finns are known for innovations such as Nokia, the removal of regulations would allow for companies to develop and manufacture new products made of or consisting CBD. As there are multiple different applications for CBD such as supplements, cosmetics along with medication and with all the potential applications that can become available as more research into CBD is conducted. There can potentially be many avenues for businesses to pursue regarding CBD, but it is very dependent on the Finnish authorities and legislation whether a market can exist. With that said a after more research into CBD is conducted all the future applications along with the safety of use can be determined.



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Letter from Kela sent to doctors in Finland (2019)

Arvoisa lääkäri

Tämä kirje on lähetetty niille lääkäreille, joiden on Kelassa perustoimeentulotuen toimeenpanon yhteydessä vuonna 2017 havaittu määränneen lääkekannabisvalmisteita potilailleen.

Toimeentulotuesta annetun lain mukaan perusosalla katettaviin menoihin kuuluvat mm. vähäiset terveydenhuoltomenot. Perusosalla katettavien menojen lisäksi muina perusmenoina otetaan tarpeellisen suuruisina huomioon mm. muut kuin perusosaan sisältyvät terveydenhuoltomenot, joita esimerkiksi terveydenhuollon ammattihenkilön määräyksellä hankitut ovat Perustoimeentulotuesta korvattavan lääkkeen tulee olla asiakkaan hoidon kannalta tarpeellinen ja välttämätön. Kela voi edellyttää asiakasta toimittamaan lääkärin tai erikoislääkärin lausunnon hoidon tai lääkkeen tarpeellisuudesta. Epäselvissä tapauksissa lääkevalmisteen tarpeellisuus ja arvioidaan moniammatillisessa välttämättömyys asiakkaalle tapauskohtaisesti Kelan toimeentulotuen terveydenhuoltomenojen asiantuntijaryhmässä ottaen huomioon lääketieteellinen tutkimusnäyttö sekä yleisesti hyväksytty hoitokäytäntö.

Lääkekannabisvalmisteissa väärinkäytön vaara on ilmeinen, minkä vuoksi niiden määräämiseen on kiinnitettävä erityistä huomiota. Tutkimusnäyttö ja kansalliset hoitosuositukset eivät tue lääkekannabiksen käyttöä minkään kiputilan hoidossa. Cannabis Flos –valmisteen käyttöä ei voida pitää yleisen hoitokäytännön mukaisena minkään sairauden hoidossa, vaan kyseessä on kokeellinen hoito. Ainoastaan myyntiluvallisen lääkekannabisvalmisteen käytöstä MS-taudin spastisuuden hoidossa on tutkimusnäyttöä, mutta siitäkin hyötyy vain osa MS-potilaista. Kela nojautuu tähän lääketieteelliseen tutkimusnäyttöön ja kansallisiin hoitosuosituksiin arvioidessaan yksilökohtaisesti lääkevalmisteen korvaamista perustoimeentulotuesta.

Kela muistuttaa, että koska asiaan liittyy huolta asiakkaiden potilasturvallisuuden toteutumisesta, Kela voi ilmoittaa Sosiaali- ja terveysalan lupa- ja valvontavirastolle ilman erillistä pyyntöä sekä salassapitosäännösten estämättä seikasta, joka voi vaarantaa asiakas- tai potilasturvallisuutta, elinympäristön tai väestön terveellisyyttä tai turvallisuutta taikka joka voi vaikuttaa valvottavan toiminnanharjoittajan luotettavuusarviointiin (Laki Sosiaali- ja terveysalan lupa- ja valvontavirastosta 6 §).

(Pikkarainen 2019)

