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ACRONYMS

AEMPS: Agencia Española de Medicamentos y Productos Sanitarios

B2B: Business To Business

B2C: Business To Consumer

CBD: Cannabidiol

CEO: Chief Executive Officer

CJEU: Court of Justice of the European Union

COO: Chief Operating Officer

EFSA: European Food Safety Authority

EU: European Union

EU-GMP: European Union Good Manufacturing Practice

THC: Tetrahydrocannabinol

UN: United Nations

I. INTRODUCTION

CBD, or cannabidiol, is currently creating hype and anticipation on many fronts. From holistic health and wellness circles, to legislative reforms, this compound found in the cannabis plant is gathering significant attention both globally and locally. In recent years, Europe has seen CBD store-fronts pop-up from Member State to another. However, the emerging industry is navigating turbulence as it is trying to establish itself. The unstable legal landscape and regulatory hindrances are widely felt from business operators to the growing group of consumers. Nevertheless, as the industry growth expands across the continent, the opening up and development of markets presents new opportunities for businesses. According to Murphy, Pastori & O'Brien (2023), the combined European market size of all CBD categories in 2023 is over €2 billion, and projected growth by 2030 is over 400% (Murphy et al., 2023). The European CBD industry is in its infancy, yet the potential for its growth is anticipated to be significant.

Despite the growing hype around the emerging industry, there is a lot of confusion regarding the current state of European CBD, and a need for research to address it. The lack of research, together with fast paced regulatory changes and industry advancements, businesses as well as regulators are struggling to address the priorities to ensure smooth development. Furthermore, as a derivative of the cannabis plant, CBD invigorates further conversation of certain social issues, and out-dated drug policies, that could have significant influence on the overall development of the European social environment.

This research seeks to address the gap in knowledge through giving a brief overview of the current state of the European Union's CBD industry, and looks at it specifically through the lens of a CBD business based in Spain. The research objective of this study is to shed light on the development of this industry, and provide a resource for industry experts, as well as the regulatory bodies. This research is guided by the following research questions; what are the challenges for CBD business growth in Europe? And specifically in Spain? How can businesses improve their market position? And, what are we expecting from the Spanish CBD market?

In order to understand the research objectives, this study conducted a qualitative research that would allow an open-ended data-collection of a European CBD business, namely: a semi-structured interview. The interviewee was sampled by looking at industry expertise within Spanish CBD industry. Findings are related with the results obtained from the CEO of a successful local CBD business. The coding and analysis is conducted through an thematic approach, as the interview is analyzed and discussed through the main three themes, namely, legislative landscape, transparency issues and competition.

Finally, this research will present and discuss the results and why the main hindrances of the European CBD industry relate to weak legal clarity, transparency issues, the saturated competition landscape and restrictions on advertisement. In terms of limitations, the scope of

European CBD: challenges and growth. Spanish case study

this research is limited into studying one Spanish CBD business and, for future research, more businesses should be interviewed and studied for more conclusive results.

II. THE EUROPEAN CBD INDUSTRY

Upon doing the research, this study was able to distinguish the most prominent elements influencing the European CBD sector. In this dissertation, I argue that the main obstacles EU based CBD businesses are faced with can be summarized in three, namely; regulatory uncertainty, transparency issues and high competition.

The regulatory landscape is, to say the least, confusing. European CBD businesses do not only have to stay aware of the supranational legislation, namely the EU legislative framework - but also that of the respective Member States. National legislations differ from one country to another, which causes further confusion for businesses looking to grow on the international stage. Furthermore, the Covid-19 pandemic and war in Ukraine sent any pending legislation on the backburner, significantly slowing down or even halting many business operations (Murphy, Pastori & O'Brien, 2023). As the reforms of the cannabis laws have been sent down on the list of priorities and the governing bodies have not been educated on the subject, CBD industry struggles with a general stigma about the nature of the product. For instance, obstacles in shipping CBD products across European borders are commonly reported (IHS Markit, 2021). The lack of education of custom authorities and scarcity of import guidelines for CBD products has resulted in products being seized at borders. The longer the products and materials are halted, the shorter their shelf-life becomes. Consequently, having a disruptive impact on the overall supply chain of European CBD businesses.

In addition to the legal uncertainty the industry faces, the lack of standardized practices creates transparency issues. As an emerging industry, the absence of clear guidelines and regulatory oversight has resulted in challenges to distinguish quality in case of product and production. As the pace remains slow at the regulatory level, the industry practitioners lack an uniform definition of terms for concentrated extract products (CBD products), such as 'full-spectrum', 'distillate' (Murphy, Pastori & O'Brien, 2023). In practice, buyers have no certainty on the purchase as terms can mean different things to different operators, which subsequently leads to breakdown in trust between companies. As the buyer can be easily misled, whether intentionally or unintentionally, disappointment in the product further creates distrust in industry and the industry operators. Implications of such transparency issues can have a negative influence on industry reputation, and public support.

According to Sanja Bonelli, the CEO and Founder of Herbliz; "for consumers, terms such as cosmetic oral care oil are confusing, as well as not knowing what effect a product may have on their body. Unfortunately, this often results in a poor consumer experience. Legal clarity is needed to ensure standards around product quality and claims so that we can provide the right education and marketing strategy to attract consumers and positively influence any purchase decisions" (Murphy, Pastori & O'Brien, 2023).

Finally, European businesses in the CBD industry face a high-level of competition on many fronts. First and foremost, the industry funding is tight due to the current economic landscape. As an aftermath of the pandemic, and the Russian invasion in Ukraine, the economy experienced a transfer of capital towards risk-averse investment. As Europe is experiencing a growing demand, and global policy reforms around cannabis are taking place, it has motivated a highly saturated business growth. Furthermore, many businesses that are not primarily concerned with CBD products, but are anticipating law reforms regarding recreational use, are also crowding the industry. According to the Prohibition Partners 2023 Cannabis Report, "the European market as a whole is heading towards oversupply" (Murphy, Pastori & O'Brien, p.59, 2023). However, due to the recent reforms on the European scale, a high barrier of entry has been established through necessary certifications and quality requirements (Murphy et al., 2023). Therefore, the dynamic and shifting economic landscape and high competition within the CBD industry requires businesses to adapt quickly, innovate and stay resilient in the face of changing regulatory landscape.

In summary, European CBD businesses are still faced with many obstacles despite the growing industry. The nearly quarterly changing legislative element, together with emerging market's challenge of establishing trust, and the increasing diversity of supplies, is creating tension for European CBD entrepreneurs and businesses. In the next section, we will look into the past regulatory framework governing the industry's development, and the most recent predictions for the future of European CBD.

2.1. History & legislative development

To gain an understanding of the current legislative landscape regarding CBD, we have to refer to the Treaty that has had the most significant impact on global drug control policies; UN Single Convention on Narcotic Drugs in 1961. "Concerned with the health and welfare of mankind", the UN classified a number of substances as narcotics, including cannabis and its derivatives, like CBD. The UN Treaty remains as a significant resource for legislators globally. Nonetheless, the Cannabis plant remained a curiosity for the scientific community, and was subject to many scientific inquiries particularly within the last decade.

CBD, a derivative cannabinoid of the Cannabis plant, started gaining increasing attention in 1990's, and was promoted for its health supporting properties. The increasing funding on further studies made positive correlations between CBD usage in treating conditions such as epilepsy, scoliosis, anxiety, endometriosis and arthritis (Grinspoon, 2021). Some studies are also making claims on its benefits when added topically, which has paved the way for the emergence of CBD cosmetic products.

In 2014, the U.S. Farm Bill (Agricultural Act of 2014) allowed the cultivation of industrial hemp, which is a legal source of CBD. This led to a widespread popularity and market presence

of CBD products in the United States, which in turn contributed to an increasing availability of CBD products globally (Corroon & Kight, 2018).

In the mid-2010s, Europe saw a wave of CBD store fronts opening. The lack of regulation led to a very self-directed market growth, which continued steady with the increasing understanding of CBDs potential therapeutic benefits. This growth was further supported through global legislative reforms regarding Cannabis and Hemp plants, e.g. in Canada, United State and Mexico. The changing attitudes have had a positive impact on customer curiosity, which in turn has resulted in gradually increasing demand and diversifying customer personaalso in Europe. From 2010 to 2018 European CBD business growth was steady, yet hindered by the delayed governmental processes.

In June 2018 EU Council (the decision making body) announced the Novel Food Act (Regulation 2015/2283), where any food or food ingredient that had not been commonly consumed before May 1997, requires assessment and authorization before it can be legally sold within the EU. Since the use of CBD had no palpable historic evidence of use, it fell under the scope of the regulation. Thus, all orally taken food supplements were to be taken off shelves until further authorization of the relevant bodies. This included all CBD oils, extracts and other CBD-infused products (Ministry of Hemp, 2020). As a non-binding act, the enforcement between Member States has been varying, with some more strict than others. Nonetheless, the Novel Food Act had a significant impact on the emerging CBD industry, as many businesses had to halt the sale of CBD food products, while raising the barrier of entry for many other businesses.

However, in 2020 Europe took steps towards a further development of its CBD industry with the KanaVape case ruling, and later with the UN vote. The Court of Justice of the European Union ruling was made in relation to a prosecution in France of KanaVape, a vaporiser company that sells CBD oils made from whole hemp plants (Guardian, 2020). In November 2020 the CJEU ruled on Case C-663/18 (KanaVape) that CBD cannot be considered as a narcotic substance, as it does not contain a psychoactive ingredient or any harmful effect on human health. Therefore, the CJEU ruled that the French ban on the marketing of hemp-derived CBD products was contradicting EU law on the free movement of goods (Guardian, 2020). Many CBD industry professionals saw the KanaVape case as a victory for the industry. The Court's decision set a binding precedent to other European institutions and governments, while also demonstrating a formal separation of CBD, in law, from Cannabis (The European CBD Report, 2023). Consequently, the KanaVape case ruling led to greater regulatory harmonization and legal certainty across the EU (Allen & Overy, 2020).

Furthermore, in December 2020, the UN voted on the recognition of the medicinal and therapeutic potential of Cannabis, and urged to remove it from the Schedule IV of the Single Convention on Narcotic Drugs. Schedule IV includes the most dangerous substances with limited or no medical value, such as heroin (Romero De Alba, Martín Martín, & Abogados, 2022). Currently, cannabis and cannabis resin (including CBD) is classified under Schedule I

with substances that are not deemed harmful to health and have a therapeutic value, despite their addictive potential (Romero De Alba et al., 2022). Despite the regulatory hindrances the industry is faced with, many CBD industry professionals have been optimistic of the potential consequences of the above mentioned 2020 events.

The next step for CBD in Europe is the admission of CBD products into the Novel Food Catalog (Regulation 2015/2283) under each jurisdiction. Currently only cosmetic products are officially available, but all ingestibles such as oils, gummies and teas are prohibited until registered. The EU application process is described to be arduous and costly, which dwindles the competition, as the products are unmarketable while the process is ongoing (Murphy, Pastori & O'Brien, 2023). Furthermore, mid-2022 the novel foods assessment process got delayed for another year or two as the EFSA is doing inquiry for more data on CBD safety for humans (ibid, 2023).

However, as laws and regulations are lagging behind the self-led CBD market evolution, the majority of European CBD remains to be sold in a legally 'gray' area. Apart from the legal uncertainty, the lack of standardized practices has posed the industry issues in transparency with potentially several undesired consequences.

2.2. The European CBD Industry - Transparency

One of the commonly acknowledged challenges for emerging industries are issues with transparency. These issues could manifest as difficulty in legal and regulatory compliance, which can have implications on product safety, consumer confidence and the overall reputation of the industry. Miller and Lamoreaux (2015) refer to transparency as a process of defining clear policies and operating procedures. There should be available printed documentations and reasoning for decisions of the parties concerned. However, the current landscape of the European CBD market is rather 'opaque' as described by Murphy, Pastori & O'Brien, which is causing several difficulties for businesses within the sector (2023). Currently the European cosmetic CBD market has to follow, apart from national regulations, the European Good Manufacturing Practices, while ingestible CBD products are subject to the EU Novel Food authorizations.

The legal framework for European CBD is often described to be in a constant process of catching up with the market development. The frequent regulatory changes are casting doubt on the legal status and public image of CBD. Furthermore, what is adding to the confusion are the country specific legal frameworks for international operators. The most significant current trend in Europe is the rise of CBD flower products, which poses many legal questions across European courtrooms (Murphy, Pastori & O'Brien, 2023). Moreover, the pace of change being rapid puts pressure on operators to adapt their business models to the ever-changing environment. Therefore, as Jaime Muñoz, CEO of Natureight says, the industry has a lot of

self-regulating operators administering their own practices (Ministry of Hemp, 2020). Trust and transparency is valued more highly in CBD than in most industries in Europe due to the lack of official comprehensive oversight. However, in the absence of standardized protocols, there is a danger of unethical business practices. Antonin Cohen, the founder and CEO of Harmony and former co-director of KanaVape, argues that "the lack of clear regulations prevents safe market development" (Allen & Overy, 2020).

Testing and analysis of the products has become more important and affordable for businesses and the industry has adopted a greater focus on transparency and quality of the products, as said in the Prohibition Partners CBD report (Murphy, Pastori & O'Brien, 2023). Philipp Hagenbach, the COO of Cannavigia says that "The safety of consumers is vital. Ensuring transparency and traceability in the supply chain and consumers must know the products they are purchasing and consuming." (Murphy, Pastori & O'Brien, 2023). Nevertheless, transparency issues can have a negative repercussion on consumer confidence and it is fundamental to develop strict quality standards in the interest of consumers.

On the European level, a part of CBD being classified as a Novel Food in 2019, CBD businesses are subject to comply with the European Union Good Manufacturing Practice. EU-GMP establishes a set of quality standards and guidelines to ensure the quality and safety of products from production to distribution (Murphy, Pastori & O'Brien, 2023). The compliance of this is assessed through potential inspections and audits by regulatory authorities into the manufacturing facilities. However, as the enforcement relies mostly on member states and national bodies with individual cannabis laws, it can create confusion among both operators and regulators. This confusion in turn can translate to bad practices and negative industry reputation.

2.3. The European CBD Industry - Competition

The European CBD competition landscape is greatly affected by the regulatory variations. This does not only affect European businesses operating in other EU countries, but also influences the incoming competition from other regions and continents. Due to the recent reforms on the European scale, a high barrier of entry has been established through necessary certifications and quality requirements (Murphy, Pastori & O'Brien, 2023). Since regulations, such as permissible CBD/THC levels, vary significantly between different countries, it can affect the quality of the product and the overall cost of production. This can give an upper hand on the global market for producers manufacturing outside the European regulatory framework. For instance, the EU-GMP, which European producers have to strictly adhere to throughout the lifecycle of the product, while outside competitors do not have similar restrictions in developing products. The EU-GMP standard is recognized worldwide, but only EU producers are supposed to adhere to it.

However, as the global demand and popularity of CBD grows, the market is getting increasingly saturated with new players joining. Among these, a new development is taking place within the competitive landscape. Already compliant bigger established companies and Big Pharma are now seeing the potential of this emerging market and rely on more initial capital to manage the risky environment. This in turn has raised the barriers of entry even higher.

Furthermore, the European CBD business faces competition regarding investment and financing. The cannabis industry often faces limited access to banking services, which in turn makes secure financing challenging. Because of this, CBD businesses generally do not have direct access to business loans, financial support or infrastructure improvements. Moreover, the Russian invasion of Ukraine saw global stock market prices fall around 25% in 2022 while Cannabis stocks experienced an overall decline of 60% with nearly four times the volatility (Murphy, Pastori & O'Brien, 2023). Because of the war and change in priorities, investors are investing in more risk-averse industries than the one of cannabis. Therefore, competition for investment within the industry has also increased as a recent development.

Looking at the European CBD market, there are a few themes that stand apart when studying the challenges that the companies are faced with. Firstly, the regulatory uncertainty, with the constantly changing framework, confuses business operations. Secondly, the battle with transparency issues that all individual operators are faced with. And finally, the competition landscape, which is highly saturated and lacks public funding.

2.4. European CBD in figures

To further illustrate the current state of the European CBD industry, below is presented figures, for instance, on some of the market value estimates, usage, and legal clarity. As earlier stipulated and depicted on the graphs, despite the consistent growth trajectory regarding interest, usage and revenue, the industry still struggles with legal uncertainty.

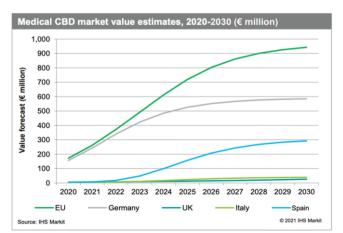


Figure 1: Medical CBD market value estimates, 2020-2030 (€ million)

Figure 1: Medical CBD market value estimates, 2020-2030 (€ million). Source: IHS Markit (2021)

As seen in Figure 1, the CBD market value is estimated to have a consistent upwards trajectory through the 2020's. One of the explanations given is the post-pandemic emerging interest in more holistic and natural health solutions (Romero de Alba, Martín Martín & Abogados, 2022). This theory would also explain Figure 2. of the Total Revenue of publicly operating European CBD companies. As concluded in the Prohibition Partners 2023 report, the total revenues experienced significant increases from 2020 to 2021 and tripled its total revenue from 2019 (Murphy, Pastori & O'Brien, 2023). This trend is present in Member State revenue developments as well.

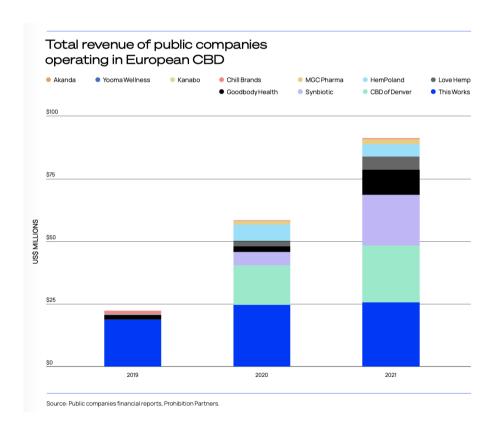


Figure 2. Total revenue of public companies operating in European CBD. Source: Murphy, Pastori & O'Brien (2023)

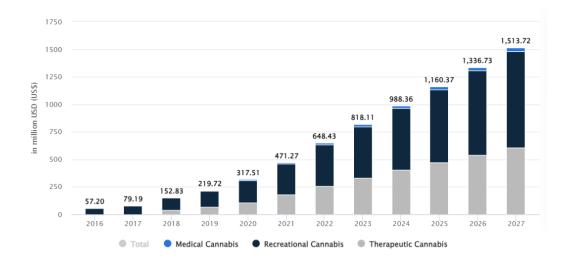


Figure 3. Revenue of Cannabis in Spain. Source: Statista Market Insights (2023)

This growth trend can also be identified on the Member State level, as with the Spanish market (Figure 3.), where the projected Cannabis-related revenue shows a steady increase. Based on the figures above, it can be concluded that the European CBD industry has created a lot of anticipation for the products growth and future potential.

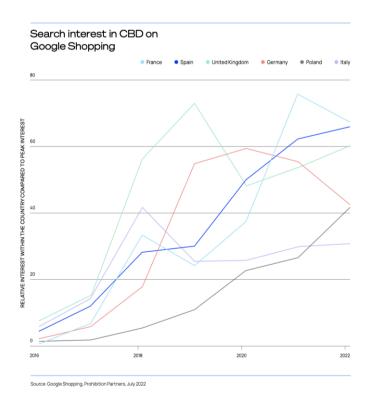


Figure 4. Search interest in CBD in Google Shopping. Source: Murphy, Pastori & O'Brien (2023)

Regarding the growing public interest, Figure 4. illustrates the search interest in CBD on Google Shopping in European countries. Overall, all stipulated countries are shown to have an increased search interest. Furthermore, except for the UK, all countries also experienced an increment during the pandemic. In France, we can see the interest peaking during the KanaVape case. This can be assumed to relate to the media-attention CJEU court ruling attracted. The Spanish and Polish slow yet steady increase in search hits could relate to both governments being described as more conservative regarding the legislative reforms.

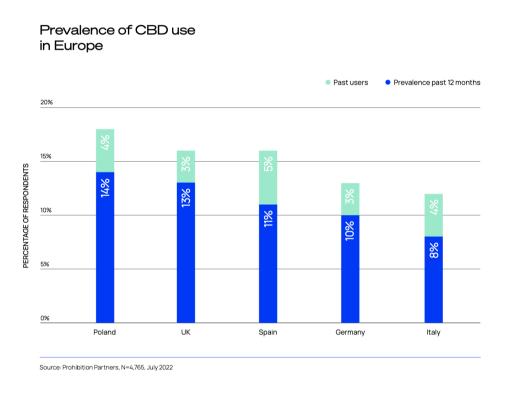


Figure 5. Prevalence of CBD use in Europe. Source: Murphy, Pastori & O'Brien (2023)

In Figure 5, the graph shows the prevalence of CBD use in Europe, aiming to show the contrast between the past users and the new users in the last 12 months. Again, we can see the increasing relevance of CBD. Within the last year, new users have increased by doubling or more than past users. The graph shows the growth of new users from 4% to 14% in countries like Poland, or from 3% to 13% in the United Kingdom over the last 12 months. This is further supportive of the experts predictions on the emerging industries exponential and continuous expansion over the few years.

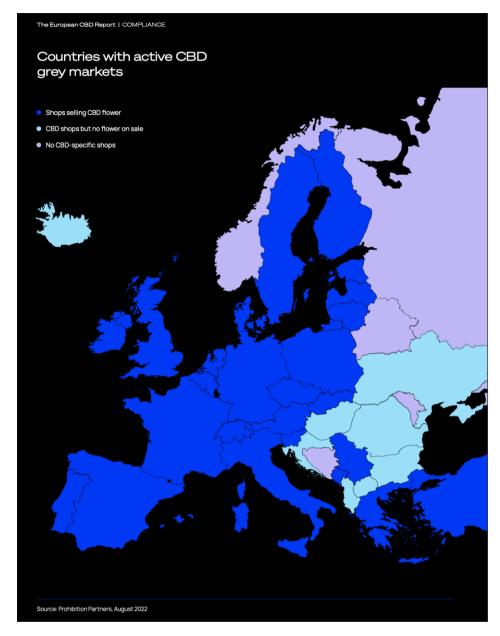


Figure 6. Countries with active CBD gray markets. Source: Murphy, Pastori & O'Brien (2023)

In order to further understand the contemporary status of CBD flowers in the European market, the map shows the different countries with active CBD gray markets. Figure 6 is divided according to three criterias; countries where CBD shops sell flowers, countries where CBD shops do not have flowers and sale, and countries where there are no established CBD shops. Upon observation, the majority of Western Europe offers flowers at their shops in contrast to Eastern Europe. Whether this relates to the nature of the government, or some other factor, it presents another interesting avenue for further research. However, the implication of the grey

business markets; suppose risks for consumers' safety since the legislative status of certain countries establishes that flowers are not suitable for consumption, yet flowers can be found for sale. Furthermore, the risk for businesses facing fines, seizures and, in worse cases, imprisonment. In Europe, this can also complicate B2B operations as each country allows different percentages of THC in their flowers.

Legal clarity of THC limits in CBD products (particularly hemp flower) & risk for businesses

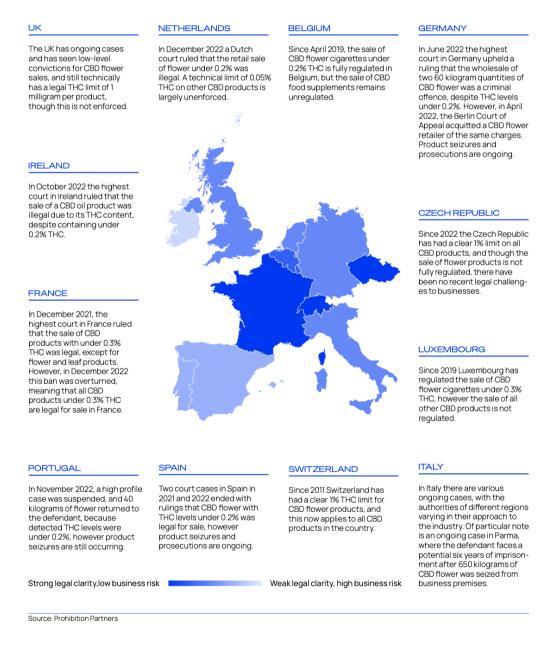


Figure 7. Legal Clarity of THC limits in CBD products & risk for business. Source: Murphy, Pastori & O'Brien (2023)

Figure 7 displays the legal clarity of THC limits in CBD products and its risk for businesses. Strong legal clarity allows businesses to operate at a lower risk. Countries like Switzerland and the Czech Republic have a limit of 1% of THC in their products, resulting in a lack of legal challenges for the businesses. Furthermore, countries like France can now profit from safer business operations as the legislation has gone under multiple updates in recent years. On the other hand, in countries where there is low legal clarity, businesses are subject to higher risk. Countries such as Spain, Portugal or Germany, CBD operators are faced with product seizures. Moreover, in countries like Italy, product seizures can lead to imprisonment, as the example in Figure 7 states. The graph illustrates how, despite businesses efforts to comply with the local regulations, CBD operators deal with complications.

Risk and unpredictability are both factors many European CBD businesses have to take into account when running their operations. The figure above illustrates the need for increased legal clarity, as it shows to smoothen business operations in countries that have regulated the market. Nevertheless, so far I have only discussed the EU environment for the CBD sector. In order to gain deeper insight into the realities and challenges of a European CBD business, it is important to look at it on a Member State level. For this reason, I am focusing on Spain and its local setting, aiming to understand how the current state of the European industry is affecting the local operators.

III. METHODOLOGY

In an effort to analyze and understand the contemporary state and challenges of the Spanish CBD market, I have conducted an interview as part of the research. The focus and methodology of this dissertation is a qualitative interview with an industry expert and CEO of a successful Spanish CBD company. The next section will present the reasoning for the chosen methodology by explaining the overall research design, describe the sampling strategy, why I decided to use a semi-structured interview protocol, and how the interview was conducted. Following that, I will provide a description of the data analysis process, and briefly reflect on the limitations, validity and the reliability of this method.

3.1. Research Design: Semi-structured interview

As this research is concerned in exploring and understanding the contemporary CBD market in Spain, the research is inherently qualitative in nature. As Creswell (2014) states, qualitative research aims to understand the phenomena in their natural settings and contexts through observation. In order to comprehend the market experience in depth, I had to choose a method that would allow an open-ended data collection. Therefore, a semi-structured interview was deemed the most appropriate method. A semi-structured interview refers to a combination of a pre established set of open questions and the freedom to use improvised probes and follow-up questions to explore particular themes or some responses further. Rubin and Rubin (2012, p.6) argue that an effective way to gain an in-depth and detailed understanding of the subject, is to structure the interview around three types of questions; main questions, probes, and follow-up questions. "Qualitative interviewers listen to hear the meaning of what interviewees tell them. When they cannot figure out the meaning, they ask follow-up questions to gain clarity and precision."

In terms of the used sampling strategy, I wanted to intentionally select an individual who has industry expertise and has been successful within the Spanish CBD market for the most relevant insights. Creswell (2014) calls this method purposeful sampling. Purposeful sampling allows research to focus on individuals that can provide unique insights, such as that of a CBD operator in Spain. Therefore, I reached out to the CEO of a first-wave Spanish CBD company, SoytuCBD. This proved to be a great choice as it provided a deeper understanding of the current state and challenges of this emerging industry in Spain.

Regarding the interview itself, the questions were derived from my earlier research on the state of the CBD market in the European landscape. As mentioned earlier, the interview took the form of a semi-structured approach in order to achieve comprehensive insight. My strategy for

questions was to generate them within three themes that I identified during my earlier research. Namely, legislative, transparency and competition. These three themes were crucial elements in the analysis process. The final questions used in the interview can be found in Annex I: Interview Transcript.

3.2. Data-collection and analysis

For the data collection, I contacted the participant through a mutual contact and we maintained a brief email exchange to gain consent and agree on a date, platform and time reserved for the interview. In terms of efficient data collection, and due to mutual time constraints, I agreed with the interviewee to conduct a phone interview in Spanish. This implied that I had to translate the questions, as well as the transcript in the analysis phase of the research. Creswell (2014) does suggest that observation can also serve as an alternate tool for additional information, such as physical behaviors or reactions. Despite the lack of visual content, thanks to our mutual contact, the participant was at ease throughout the interview and was verbally expressive for me to obtain a detailed account of his perspective being an operator of the CBD market in Spain. The interview lasted for one hour and was recorded on the computer for transcript and later analysis. The interviewee gave consent to use his name and company for this research.

In order to analyze the data, I first had to transcribe the recorded interview and translate it to English. The software used was Transcribe, an application leveraging AI technology to transcribe audio into text. However, I had to examine and correct the computer generated transcript as I was translating the content into English. Bazeley (2013) encourages to combine traditional methods with technology to navigate the 'messiness' of qualitative data analysis. For content analysis and coding, I used a thematic approach, which refers to identifying common themes within the analyzed data (ibid, 2013). I used both, deductive and inductive, approaches as I had already three preconceived themes based on existing research of the European CBD market. Namely, legislative, transparency and competition. However, upon coding the transcript, I identified new themes from the data, namely, marketing related, which later helped me dissect the data.

As a limitation of this research, I see the number of interviewees. For a more accurate overview of the contemporary state of the Spanish CBD market, a larger sample of different actors within the industry would be desirable. However, due to the scope of this research, it was not feasible and I hope that this dissertation can serve as a reference for future research and inquiry into deepening our understanding of this emerging industry.

For the validity and reliability of this research, I used the data source triangulation method as stipulated by Creswell (2014). This implies the collection of data from multiple sources to acquire better comprehension of the studied subject. The interview findings were analyzed

alongside the analysis of the European CBD market data for conclusions and future recommendations for research.

IV. ANALYSIS AND RESULTS

In this section of the study, I will present the case study of Spain and analyze the current challenges for the European CBD industry's growth. The analysis will address the following research questions:

- RQ1. What are the challenges for CBD business growth in Europe? And specifically in Spain?
- RQ2. How can businesses improve their market position?
- RQ3. What are we expecting from the Spanish CBD market?

The analysis is divided into four main themes: legislative landscape, transparency, competition, and other findings. I used an inductive strategy during the interview coding and was looking to find evidence within the three preconceived themes; legislative landscape, transparency and competition. However, during the coding, other themes that were important emerged along with the earlier findings. Therefore, they were grouped together in the fourth theme, other findings.

As mentioned earlier, for a better understanding of the realities and challenges of a European CBD business, this research will focus its analysis on the Member State, Spain. Specifically, a local business operator, SoytuCBD.

Spain is known for its thriving cannabis culture, from social clubs to favorable climate conditions for the plant. However, in regards to its cannabis and CBD regulation, the Spanish government is described as conservative (Romero de Alba, Martín Martín & Abogados, 2022). Spain ratified the 1961 UN Convention and passed its general law of controlled substances, including the cannabis plant in 1967 (Ley 17/1967). To date, the Spanish government has not amended this law nor provided secondary legislation for clear view on some of the contemporary aspects regulating today's cannabis industry (Romero de Alba et al., 2022). Despite the 2020 events on European scale (KanaVape ruling and UN vote), their effects remain to be seen in Spain. So far, unlike some other EU Member States, Spain lacks a specific approach in regulating cannabis, apart from the international drug control treaties and Law 17/1967. However, the Agencia Española de Medicamentos y Productos Sanitarios, a State agency within the Spanish Ministry of Health, is the regulatory body regarding cannabis and CBD. Consequently, it has the authority to issue the relevant licenses (Eurogrow, 2023). The AEMPS strictly follows the EU framework for cannabis, namely, the Novel Food Act 2019. Therefore, officially, the Spanish market is limited to CBD cosmetic products. As a result, most Spanish market activity still operates in the gray area of Law.

4.1. Spanish legislative landscape

In this section, I will analyze the interview with a focus on the challenges of CBD businesses in the light of the Spanish legislative landscape. As an emerging industry, the legislation is still in the making, although the degree of it varies between countries. The scarce regulatory landscape creates both obstacles and hindrances for CBD operators.

Despite the fact that CBD is fully legalized at the European level, and there are certain European countries that have properly regulated it, Spain lags behind in regulatory issues due to other factors (...) the biggest challenge we have is the scarce regulation that exists. It is a legal product, but you have to sell it in certain ways that complicate the growth of the company (p. 37)

When analyzing the above statement, one could argue over the disconnect between the European level and the national level legislation regarding CBD. Although we have seen developments on the European scale, the Spanish legal framework remains stagnant since the 1967 Law. The regulatory uncertainty in this case creates hindrances in the market growth.

The Spanish market is in an uncertain situation, because the body that is in charge of regulating is the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) and it is not willing to facilitate the regulation of CBD. (...) Although over a year ago the Congress regulated and authorized the use of medical marijuana, in particular THC, the products are still not available as the AEMPS has postponed signing the final documents and thus, not allowing the market entry. (p. 43)

Furthermore, according to the CEO, the governing body controlling the growth of the Spanish CBD market has been unpredictable and unreliable, pushing further the predicted time frames of completion. Interestingly, the CEO argues that the delay is purposeful as it relates to AEMPS's private political and economic interest:

(The AEMPS) is issuing licenses exclusively to parties that are of benefit for them. I believe that regarding CBD, it will eventually be fully regulated but it will happen very slowly. What is the problem with this? CBD businesses will end up buying the products from the AEMPS. I am not in favor of this because they are going to put a middleman, and if you do not buy from them, you will not be able to sell your product. Since the beginning we have had control over the process by working directly with growers and the laboratories. It would feel like taking a step back. However, these are the rules of the game. Even the largest companies in the industry could not do anything if things evolve in this direction. Here we are talking about political and economic issues that go beyond our understanding. (p. 44)

As quoted above, the Spanish regulator seems to be guided by a biased interest, and priority is placed elsewhere away from industry growth and consumer benefit. Furthermore, by adding a

new agent to the supply chain, the freedom of operators is narrowed down. Currently, Spanish CBD businesses operate under the AEMPS discretion without a stable legal framework to refer to. One could argue that this is one of the main struggles of the present day Spanish CBD operators.

There have been moments that have been hard due to regulatory issues, specifically with the AEMPS, which, even if you have done everything right, can create problems for your company. (...) I take it calmly, because in a year from now the AEMPS may change something and put the business in a difficult position once again. (p. 44)

Legal unpredictability disrupts the organic growth potential of the market. This can lead to the danger of lack of innovation as operators refrain from taking unnecessary risks in an inherently risk prone market.

At the European level it is different. It keeps steadily progressing, which eventually benefits us. As we are a member state of the EU, if conflicts arise in Spain they will be taken to European trials. In our country, you have to patiently follow along, doing what you can do in the market as it is now. I think it will change, but it is a slow and an expensive process. (p. 44)

As the interviewee expresses, the market has a growing interest, yet the legislation moves at a slower pace. This requires patience from CBD entrepreneurs and businesses, which can become costly if industry growth is constantly hindered.

As an advice to other businesses in the space, the CEO highlights as a primary key for success to remain on top of the regulation:

Take a good look at all the information on the internet regarding how to sell the product so as not to make mistakes regarding the Law: how to sell it, how to explain the product, because in the future, mistakes can translate into fines or public bodies going after them. (p. 45)

Alongside with the business operations, marketing and sales, this industry requires agility and dedication of owners to stay on top of the regulation, by having the ability to read between the lines to avoid financial consequences.

4.2. Spanish transparency

The transparency issues the CBD sector is faced with manifest in several different ways. From the unclear regulation, making business operations difficult, to the inadequate research and wild claims, putting the consumer trust and industry image in test. CBD operators have to remain vigilant and proactive to counter any transparency issues.

(...) there is always the risk of spending money stupidly because you don't know the industry in depth and the challenges it poses. (p. 43)

There is no existing legislation. The current laws are vague and can have several interpretations, so it becomes complicated for small companies that do not have a law firm's support. Lawyers, who do not particularly work within the sector, can make mistakes even when doing their best. (p. 44)

The CEO claims that, as a complex industry with poor visibility in many aspects, the lack of regulatory guidelines creates confusion between both lawyers and CBD operators. Consequently, the constantly changing industry makes companies more likely to make mistakes, as well as having unnecessary expenses. In absence of clear regulation, while businesses are subject to greater vulnerability, there is a greater risk of unethical behavior regarding their activities:

(CBD) is an emerging industry that lacks research and the big problem is that, since it is effective and is growing at a fast rate, some companies label it as if cannabis cures everything. (p. 40)

There have been recent investigations of a distributor that gained strength here in Spain because it sold very cheaply, and they have had problems later on because the analysis of these products proved to be of very poor quality. (p. 45)

Since the Spanish government has no standardized processes in place, businesses can make unfounded claims about the product or its processes, which in turn can be disadvantageous for the industry relationships, customer confidence and the overall industry reputation. False allegations regarding product quality is not only a potential health hazard for customers, but it can also create distrust within an already sensitive industry.

To conclude, the interviewee clarifies the most important elements for the transparency issues of the industry:

This is the most complicated phase that the sector is currently in, they do not let us operate in a correct manner. Since it is a new product, I understand that the regulation is more advanced for topical use. For instance, food carries several sanitary controls, but that is because it is not a new product. It is a standardized process and they know the steps to go through when launching new foods into the market. Similarly it happens here, but since it's a new product that is orally consumed, they have to fully understand all quality processes. There are also other economic interests that make the process even slower. Since these are regarded as issues of the health sector, the pharmaceutical industry has huge influence and control. Truth be told, lately the Department of Health has started investigating the market more extensively. However, by delaying its regulation, they are putting the population at risk. As there is no analysis or quality control of these products for human consumption, it results in the quality of the products sold worldwide is poor and inadequate. CBD can no longer be stopped because the product is regulated in certain aspects, although they have to completely regulate the real use that is being given to the product. (p. 38)

The government has control over how the products are being sold, yet usage of the product is up to the customers. Due to the current regulation, CBD is officially being sold as a cosmetic product. However, it is commonly consumed as ingestible. With the present situation, if customers wish to do so, the shops that guide them take a risk of being sanctioned. On the other hand, if consumers proceed to its consumption without proper guidance, they are putting their own safety at risk. The situation is disadvantageous for all parties involved. Because of this, much of the Spanish CBD market happens between loopholes and legally gray areas, hence businesses are often required to stay more careful about what they sell and how they sell it.

4.3. Spanish competition

In this part of the analysis, we examine the challenges of the competitive landscape. As an emerging industry, with a lot of anticipation from a growing customer pool, the industry struggles with a crowded marketplace to the point of oversupply. Moreover, as bigger established businesses are entering the market, the competition is in danger of becoming increasingly monopolized. In Spain, the regulatory body (the AEMPS) has the potential to jeopardize small business operations fully under its control. In addition, European CBD products struggle with competition in the global market due to the strict yet unclear regulatory product requirements.

During the second and third waves, a year after the pandemic, there was a boom in companies entering the sector, as well as multiple growers. Every week we would come across new companies and suddenly everyone was talking about CBD. (...) Why have these companies closed? Because, even though it was great for a marketing campaign, there was an excess of supply and there was not enough demand for all companies to survive in the Spanish market. (p. 41)

As the industry gained popularity and built hype, many young entrepreneurs saw the business opportunity, which eventually led to a crowded marketplace. However, the demand could not meet the supply and many businesses were unable to stay afloat.

Many of those companies have failed and will continue to fail. The main change is that the sector is increasingly becoming more professionalized. The first companies to enter the market were run by young people believing in this market, but lacking entrepreneur experience or investment support. (p.41)

Now, you see companies that enter the market through the alliance of four businessmen getting together and trusting one person to set up this project with a capital of $\in 100,000$ or $\in 200,000$. What capacity does that give them? From the beginning they start stronger and with more money, which facilitates faster growth. (p. 43)

Indeed, as stated above, the competition landscape regarding CBD has evolved as more prepared competitors are entering the market. Despite this, the market remains crowded and highly saturated and the problem with oversupply persists:

It is hard to give an estimate since there is no specific category in which the cannabis sector is registered, as it currently sits within the cosmetic sector. Within this sector there are millions of companies, so you cannot differentiate one from the other. However, the one figure I have heard of frequently is approximately 2000 companies. Within those 2,000 companies, I would classify about 100 companies with a proper structure, that is, with employees and physical stores, and the remaining 1,900, are rather a website managed by a freelancer who buys a product from one of these 100 companies and puts it on the market. Respectfully, they are competing players, but I would say there are about 100 well structured companies. (p. 42)

The cosmetic category is the most regulated one. Why? Because it is of topical use. Here I refer to muscle ache and moisturizing creams. Thanks to this regulation, big companies like L'Oréal are getting into this sector and selling it without a problem. (p. 38)

Since the CBD industry continues developing, the marketplace is attracting other players apart from the existing freelancers and well-structured CBD companies. As the market potential is recognized by industry giants, they are now starting to look into adding CBD products to their shelves.

In Spain, the most influential public institution regarding CBD regulation is the AEMPS. It is important to note that the Spanish public healthcare and all day-to-day medicines are financed by the State, hence the AEMPS has a lot of power. CBD, as a product, is directly competing with the products this institution profits from the most. This explains their hesitancy and delays in the regulatory processes. I don't think they are interested in seeing the CBD market grow, at least not until they have it under their control. (p. 43)

The unpredictability of the Spanish regulatory body poses challenges for the local operators. According to his statement, the interviewee sees the AEMPS as a strong potential future competitor, which could also explain the hesitancy to advance cannabis laws in Spain.

Finally, the CEO discusses global competition and the challenges it presents:

It is of low profitability for us to compete with local companies from the outside. In the US, according to each state, both CBD and THC are totally legal and, by not altering the growing process to comply with regulations, the quality is far better than in Spain or Italy. So, why are you going to buy poorer quality products from another country, having to deal with shipments, customs, etc.? (...) At the B2C level, exporting our product to countries outside of Europe is not profitable (p. 39).

Again, we see how the confusing regulatory landscape is perceived as a hindrance, also in competition outside of Europe. The strict product requirements have resulted in advantages of product quality for outside operators, which limits European CBD growth on the global stage.

4.4. Other findings

During the coding process of the interview, another major theme emerged, namely, advertisement. The research had previously overlooked a crucial aspect of the European CBD market development, and therefore, one of the key challenges operators have within the industry. The CEO of SoytuCBD brought this theme forth in several instances and although, as a consequence of the Spanish regulatory landscape, I decided to analyze it separately for the sake of this research.

The second would be advertising. Today, without advertising, it is difficult for a company to grow (...). And now there has been a rise of private companies like Facebook, Instagram, Google and TikTok. What about these major advertising companies? They do not allow paid advertising of cannabis products, since they cannot ensure that what you are advertising is totally legal. That is, they cannot audit that my product has all the licenses, analysis, and that it is correctly regulated. Therefore, when in doubt, they restrict all advertising. (...). Since the advertisement issue is a consequence of the current regulation, we could say that the regulatory landscape is the biggest problem for the growth of CBD businesses in Spain (p. 37).

Interestingly, due to the nature of the product, the CBD industry does not have the same advantage that many other sectors have, namely, access to social media platforms advertisement. Furthermore, when given the opportunity to advertise, businesses have to be specifically careful how their product is promoted due to the strict yet ambiguous legislation.

Since you can't advertise, your best communication channel is a satisfied customer who tells another customer - it's the only way to grow. What's happening now? In the last three years, this has significantly grown, a great deal of people have tried it, and those who have not tried it, have already heard about it (p. 40).

Currently, the CBD business in Spain relies mostly on word of mouth advertising and, although it can create customer loyalty and growth, it is a relatively slow marketing strategy. However, the CEO puts emphasis on the importance of creative marketing, and advises that it should be one of the primary focuses for CBD operators:

First, having a good marketing team, agency or partner that takes care of it well, because with the difficulties that advertising has, it's going to be the most important thing. (p. 45)

V. DISCUSSION

In the discussion section of this research, the analysis and results are discussed, as well as the research question regarding the challenges and growth of Spanish CBD is answered. Post-interview analysis, it becomes evident that Spanish CBD struggles relate mainly to the current state of the regulatory framework, transparency issues, an increasingly saturated competition landscape and a lack of marketing opportunities.

Firstly, regarding the challenges for CBD business growth in Spain, but arguably also applicable to the European CBD industry, can be summarized in the following manner. The Spanish regulatory body (AEMPS) has been postponing advancement of the regulatory reform, which has caused the industry uncertain market conditions. Mismatch between the European and local regulatory standards creates frustration in CBD business operations, and increases the emerging market's transparency issues. Consequently, businesses are required to remain agile in interpreting the Law and stay compliant. The lack of clear industry standards raises discussion over health hazards, consumer trust and industry reputation. Despite the hype around the industry and the growing supply, with restrictions on CBD and its advertisement, the industry cannot advance to its greatest potential.

Secondly, in order for CBD businesses to improve their market position, they are required to stay on top of the changing legislatory landscape and find creative ways to increase visibility of their products. Furthermore, a strategic allocation of resources and educating the public will overall be beneficial for the industry. All CBD businesses are encouraged to have focus on improving the industry's transparency. This implies that businesses should be open and cooperate among others in the industry in order to increase customer confidence, and industry reputation. The whole industry will benefit from a positive public image as it has the potential to push regulators to respect the agreed timelines regarding industry's deliverables.

Lastly, regarding the future of the CBD market, on a European level, steps are being taken, although slow, public support for cannabis reform is growing. Thus, pushing change also on a national level. However, so far the pace of change has been slow and Spanish CBD operators have to remain patient for legislative clarity. The market will continue its growth and will eventually become fully regulated. Meanwhile, businesses should ensure compliance while remaining innovative and developing the products.

Finally, as an emerging industry, it can be assumed that the businesses within it are passionate about the industry's growth. This implies that companies also care about the legal compliance, product quality and safety, public image, and an overall positive customer experience. In the absence of legal frameworks, CBD businesses have shown proactivity to create standardized practices around product origin, supply chains, testing and analysis as it remains the primary means for the CBD operators to determine the quality, as well as safety of the product (Murphy,

Pastori & O'Brien, 2023). However, with the lack of regulatory oversight, the industry remains vulnerable to exploitation by unethical business practices and greed for profit at the expense of the industry's reputation. Much of the industry continues operating on the gray area of law until further regulatory clarity.

This brief overview of the current state of the European CBD sector remains insufficient to fully grasp the intricacies of this emerging industry and I would urge for future research to uncover more. For future research, it would be intriguing to better understand the differences between progressive and conservative governments regarding the legislative reforms around cannabis or the increasing lobbying of Big Pharma within the medical cannabis space. Furthermore, studies on CBD itself should be encouraged, as well as inquiry into other natural remedies. The European CBD industry is in its infancy and it will be interesting to see how it keeps on developing and affecting the modern understanding of health and wellbeing.

VI. CONCLUSION

This research addressed the current state of the European CBD industry, and specifically that of Spain. The purpose of the research was to understand the contemporary challenges of European CBD businesses and therefore, was guided by answering the questions of: what are the challenges for CBD business growth in Europe? And specifically in Spain? How can businesses improve their market position? And, what are we expecting from the Spanish CBD market?

The key insights the analysis revealed were that the main struggles of the Spanish CBD industry development are tied to the unclear and unpredictable legislative landscape, which in turn leads to subsequent transparency issues that have implications on the legitimacy of the industry. Furthermore, the restrictions on advertisement are leading to an oversupplied marketplace, and hence, the competition is becoming increasingly saturated. Despite the growing industry practitioners, due to the restrictions on advertisement, the industry lacks visibility and has resulted in issues with oversupply. Furthermore, issues in transparency can lead to varying product quality, which can affect trust between companies and customers. Overall, on the EU level, the legislative reforms are slowly advancing, yet the industry professionals are still at large faced with many regulatory hindrances compared to their global competitors. The current state of EU regulation is disadvantageous for European CBD operators looking to export the product outside of Europe. With the growing interest towards natural remedies and holistic health solutions, EU CBD struggles to compete with the global suppliers.

In order for the European CBD to grow organically to its full potential, this research highlights the need for legislative clarity, both on European and Member State level. Moreover, to ensure the safety of the consumers and good business conduct, the creation of standardized processes within the CBD industry is urgent. The industry and demand for the product already exists and therefore, it is important that regulators understand what is being regulated and the true consumption patterns of the product. In addition, a deeper inquiry into the CBD substance and overall education of the public and the governing bodies is encouraged for a thriving market and potentially EU wide improved wellbeing.

This study is an important contribution to the growing body of research surrounding CBD, and specifically useful resource for those looking to understand more about the European CBD market and its development. By providing both practical business insight and potential future avenues for further research, this study is dedicated to support the European CBD industry development.

The European CBD industry is in its early days and due to its dimensional complexity, it will serve as an interesting example for any other emerging industries and provide many lessons to be learned from theoretical to practical.

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ANNEX I

INTERVIEW TRANSCRIPT

26th of June 2023

Taipei - Madrid

Daniel Sánchez Diago and Manuel Samper

[00:00:01.340] - Daniel Sanchez Diago

June 26, 2023. My name is Daniel Sánchez Diago and I am with Manuel Samper for the interview about CBD in Spain in 2023. Manuel is the CEO of SoytuCBD. Could you start by telling us a bit about your business, why CBD and why you started when you did?

[00:00:37.390] - Manuel Samper

Our business is in the cannabis sector, which has been gaining traction worldwide for the last ten years. It all depends on each country. The cannabis business is divided into two main areas. There is the recreational area and then the medical area. In our case it would be medicinal, since the recreational one contains THC, and THC in Spain is not legal. Perhaps in a few years it will be, but that part would not fall within our cannabis sector.

Why did I start it and why then? SoytuCBD started during the pandemic, a few months after the most critical moment of Covid19. I had already been looking into the business plan a year and a half or two before the pandemic. The reason was that, due to other jobs that I was doing, I accumulated high levels of stress that I did not know how to properly manage. This led to serious problems of chronic and continuous anxiety. At the time, I did not know that what I was suffering from was anxiety. Consequently, as happens here in Spain, doctors solve these things with benzodiazepines. I didn't know what this was either, but researching on the Internet I realized that benzodiazepine is a substance that you have to be careful with and especially when used daily. For a while it worked fine for me, but I started looking for natural remedies. Among these remedies, I learned about CBD, which is another of the molecules found in the cannabis plant and where this industry gets its name from, and which also has anxiolytic properties. I tried it, and it worked very well for me. In Spain this did not exist back then, so I had to have it delivered from Italy and, thanks to this, I began to see that there were more products, such as balms and oils, that covered a number of health issues that seemed very interesting to me. From there, I started testing it on family members without completely telling them what it was. The feedback was very good and there I began to study and prepare the business in depth. I tried to enter the market a year and a half or two before the pandemic, but it was impossible because I did not find the right partners. I was working in the nightlife industry at the time, and this was shut down due to the pandemic, therefore I had run out of options. That's when I decided to launch the cannabis company.

That's why we started at that time and that's why it was CBD, for a personal health issue that many people suffer from, and I was at a good time and had a good product to launch.

[00:04:10.250] - Daniel Sanchez Diago

Once the CBD business was launched, what have been the biggest challenges that you and CBD operators have encountered in Spain? Especially in regards to promoting growth?

[00:04:43.810] - Manuel Samper

Among several, the main one is regulation, which is where the rest of the problems derive from. Being a new product and originating from a plant that is still not well regarded in certain parts of society, the regulation of this product is slow. This plant is cannabis, specifically marijuana, which produces THC and is used both, recreationally and medicinally. Despite the fact that CBD is fully legalized at the European level, and there are certain European countries that have properly regulated it, Spain lags behind in regulatory issues due to other factors, which we will discuss later. To comply with the law, it must have low levels of THC, which in this case Spain allows a maximum THC level of 0.2%. But the biggest challenge we have is the scarce regulation that exists. It is a legal product, but you have to sell it in certain ways that complicate the growth of the company, like any normal business would.

The second would be advertising. Today, without advertising, it is difficult for a company to grow. The purpose is to reach people, and doing it in an organic way such as social networks or in the press is complicated, slow and expensive. You need large amounts of money to make your campaigns work. That is, Instagram allows you to purchase their services to display ads. I mean that kind of paid advertising. First, television advertising is out-of-reach for a company of our size; and second, there is the press, which is not the best of channels for advertising, good in reputation but not in efficiency. And now there has been a rise of private companies like Facebook, Instagram, Google and TikTok. What about these major advertising companies? They do not allow paid advertising of cannabis products, since they cannot ensure that what you are advertising is totally legal. That is, they cannot audit that my product has all the licenses, analysis, and that it is correctly regulated. Therefore, when in doubt, they restrict all advertising. And of course there is organic advertising, this is uploading posts and is barely controlled, which is not a problem unless the content is reported.

Those would be the two main problems. Especially for growing companies: the regulatory problem to advance, and the advertising problem to grow. Although there are none yet in Spain, large companies have it easier because they are already known, as is often the case in the United States.

[00:09:09.470] - Daniel Sanchez Diago

Since the advertisement issue is a consequence of the current regulation, we could say that the regulatory landscape is the biggest problem for the growth of CBD businesses in Spain. Then, what would be the requirements to operate a CBD business in accordance with regulation in Spain?

We can divide this part into the three most common product categories here in Spain. On the one hand, we have the cosmetics; CBD oils, which is a subgroup of cosmetics; and then there would be the bud, which is the flower of the plant

Regarding the buds, which is what the consumer purchases the most, it works like this. In Spain, human consumption of this product is still not allowed. In order to comply with the law, the product is sold as a collector's product, which contains a specific amount of flowers and is not suitable for human consumption. This is how we sell it. Now, the improper use that each person makes of the product is not the company's responsibility.

The cosmetic category is the most regulated one. Why? Because it is of topical use. Here I refer to muscle ache and moisturizing creams. Thanks to this regulation, big companies like L'Oréal are getting into this sector and selling it without a problem.

And lastly, the category of oils, which as a product of topical use, are a subgroup of cosmetics. This is a product that society uses as a consumable, specifically sublingually, but in Spain it cannot legally be sold that way. There they enter the same category as flowers and hence why I have separated it as a subgroup of cosmetics. To be legal in Spain, the oils are sold as a cosmetic product for topical use not suitable for human consumption, just like the cosmetics. However, on the Internet one will only find information on the real use that is given to it and none about it being a topical product. In Spain, to avoid problems, cannabis companies cannot publicly label it as such on platforms like the Internet.

This is the most complicated phase that the sector is currently in, they do not let us operate in a correct manner. Since it is a new product, I understand that the regulation is more advanced for topical use. For instance, food carries several sanitary controls, but that is because it is not a new product. It is a standardized process and they know the steps to go through when launching new foods into the market. Similarly it happens here, but since it's a new product that is orally consumed, they have to fully understand all quality processes. There are also other economic interests that make the process even slower. Since these are regarded as issues of the health sector, the pharmaceutical industry has huge influence and control. Truth be told, lately the Department of Health has started investigating the market more extensively. However, by delaying its regulation, they are putting the population at risk. As there is no analysis or quality control of these products for human consumption, it results in the quality of the products sold worldwide is poor and inadequate. CBD can no longer be stopped because the product is regulated in certain aspects, although they have to completely regulate the real use that is being given to the product.

[00:14:35.210] - Daniel Sanchez Diago

Taking into account all these limits that the current regulation in Spain supposes, what is your current supply chain like? Are there international imports or exports? Do you encounter problems at the borders?

[00:15:03.680] - Manuel Samper

Europe has a law of European free trade. If something is legal in a specific country and they have not banned the sale of it, then it is legal to move it freely between European countries. For example, in Spain the use of CBD is legal. What is illegal is the process of extracting components from the plant. Spanish growers do not work the flowers, because there is a law that prohibits separating the bud from the cannabis plant. For this reason, we cannot buy from local growers in Spain. So we rely on Italy for instance, where handling the plant is not prohibited and a completely manicured product arrives here. Since this is legal there and it is not banned to export flowers or buds outside the country, that product automatically becomes a legal product in Spain. This, of course, as long as it is sold as unsuitable for consumption and as a collector's item. Therefore, the company constantly operates with imports. As for the flowers, we buy them from Italy, and the oils and cosmetics, we work with a large specialized cannabis laboratory in Poland.

[00:20:26.340] - Daniel Sanchez Diago

And as for the final consumer, in other words, B2C, how do you handle international trade? What are some of the challenges that arise? And what are the differences with B2B?

[00:20:58.210] - Manuel Samper

At the B2C level it is different because, if the company has followed all the necessary steps, the product is already completely legal. In Europe there is no problem, because you do not have to go through customs as long as you provide an analysis that certifies that it is not marijuana and it is hemp. It was a complication in the past but it no longer happens. I have had routine checks at airports and there have been no problems. It may be that someone does not know what CBD is, the analysis makes it clear. Except for a couple of countries in Europe that are more restrictive with CBD, such as Sweden, today within the EU there is no problem.

The problem begins in countries outside the European Union. For example, through a collaboration, at SoytuCBD we are trying to enter the American market. The problem with the USA is that I have to submit documentation for the FDA for my product to be registered and avoid complications. Moreover, each country has its own regulations in South America. We've recently started in Mexico and it is a similar process to the one in the United States. So, at the B2C level, exporting our product to countries outside of Europe is not profitable. In fact, it is common that even large American multinationals do not sell in Spain. Therefore, by finding a Spanish collaborator to whom they send their product, they work at the B2B level and then it is sold at the B2C level by local companies, which is something that we are currently exploring. For now, we are focusing on South America because it is a collaboration with a specific

influencer and an exclusive product. If it weren't for this, it is of low profitability for us to compete with local companies from the outside. In the US, according to each state, both CBD and THC are totally legal and, by not altering the growing process to comply with regulations, the quality is far better than in Spain or Italy. So, why are you going to buy poorer quality products from another country, having to deal with shipments, customs, etc.? This happens with exclusive products that can only be found in a specific location, which is not the case of CBD.

At SoytuCBD, we are operating nationwide. In two weeks, we are crossing borders into Europe thanks to our collaboration, and this will not be problematic. Later on, the USA and Mexico. We will meet our demand, but I believe the best results will be in Europe, and particularly in Spain. There is already a significant market in Spain and, until the market becomes more mature and regulation is facilitated, there is no need to create unnecessary trouble. Since it is already quite complicated in Spain, there is no interest in opening fronts in markets where laws remain unclear.

In other words, for the international markets, we rely on B2B, to then sell to B2C.

[00:27:27.930] - Daniel Sanchez Diago

Since you mentioned that there is a large market in Spain, let's focus on the Spanish landscape. How would you describe the public image that people have of the CBD industry in Spain?

[00:27:44.900] - Manuel Samper

To this day, quite good. When the industry started, the image was neither good nor bad. There was an initial talk of this product having nothing to do with marijuana, but the population did not comprehend this. This is not a drug. People did not have a prejudice, but they were rather cautious when it came to what they were buying. What happened? This product works, and that is why it is growing and it is quickly spreading through word of mouth. Since you can't advertise, your best communication channel is a satisfied customer who tells another customer - it's the only way to grow. What's happening now? In the last three years, this has significantly grown, a great deal of people have tried it, and those who have not tried it, have already heard about it.

So now there isn't as much prejudice as we thought there would be when we started the company. Some companies specialize in one type of product, which may avoid more complications, for example, within the pharmaceutical sector, and others that, although it is not marijuana, are in a sector focused on flowers and a younger audience. The latter may be faced with more prejudice. It all depends on how your company communicates. Regarding the oils and creams I have not experienced any prejudice.

[00:30:07.840] - Daniel Sanchez Diago

Why do you think it's been so good from the start? What have been the success factors?

[00:30:17.830] - Manuel Samper

Today, there are already several studies on CBD. But the scientific community still needs years of investigation to have truly conclusive studies.

CBD was discovered in the 1990s, as a result of the research of marijuana for cancer treatment. Research has shown that, just as we have a respiratory or circulatory system, all mammals have an endocannabinoid system. Cannabinoids are also produced by other fruits and plants, but it is abundant in the cannabis plant. Today, about 120 have been discovered, but new cannabinoids are always being discovered. Among them, THC, which is psychoactive and also not legal in Spain, followed by CBD, which is how our industry is recognized. And then CBG, CBN and so on, infinite acronyms up to 120. So, each of these has a peculiarity that opens or closes receptors of the endocannabinoid system. What do you have to be careful about? This is an emerging industry that lacks research and the big problem is that, since it is effective and is growing at a fast rate, some companies label it as if cannabis cures everything. A recent study comes out claiming that cannabis reduces stomach problems, and consequently X companies are already saying that if your stomach hurts, you should consume cannabis. There are some studies but they are very small and other larger ones, such as for pain purposes, which are far more conclusive.

[00:34:09.180] - Daniel Sanchez Diago

You mentioned that the public image has been positive and I wanted to ask you if you could describe the current behavior of the consumer and how the way of seeing SoytuCBD has changed since the beginning of your business.

[00:34:50.340] - Manuel Samper

There has not been a radical change. The biggest change is that at the beginning there were many doubts to be cleared. Their main behavior was to resolve their questions that, although it continues to happen with new consumers, it was more common at the beginning. It is where the industry has had to work the most in its early years, more focus on information than on selling. The primary behavior was to collect information and afterwards to acquire the product. As a result, now consumers are more relaxed and trusting thanks to the effects of word of mouth of someone close to them. CBD products can also be found in pharmacies and, since it is the place where the medicines are sold, people believe in what they are being recommended.

[00:36:48.470] - Daniel Sanchez Diago

With this high volume of demand, there must be a large amount of supply. What is the competitive landscape like in Spain? Where do you find your biggest competitors?

[00:37:04.020] - Manuel Samper

This has also changed remarkably. SoytuCBD was not the first company to start operating in Spain, but we were among the first wave of CBD businesses. During the second and third waves, a year after the pandemic, there was a boom in companies entering the sector, as well as multiple growers. Every week we would come across new companies and suddenly everyone was talking about CBD. This was a highly powerful marketing campaign. What happened next? That many of those companies have shut down. Why have these companies closed? Because, even though it was great for a marketing campaign, there was an excess of supply and there was not enough demand for all companies to survive in the Spanish market. Many of those companies have failed and will continue to fail. The main change is that the sector is increasingly becoming more professionalized. The first companies to enter the market were run by young people believing in this market, but lacking entrepreneur experience or investment support. However, the new companies that are currently entering the market do so in a more relaxed and organized approach. The team that makes up these companies are adult people, who come from having previously set up several businesses, and starting with high levels of capital. Thus, they enter the market as a solid competitor, while knowing that they may not make money in the first years, and simply want to take their market share.

To this day, many companies remain in the market. Furthermore, the problem in this industry is that the product is the same or similar for all companies. What changes is how that company acquires their product and how much they sell it for. But in regards to the quality aspect, there is low variation, meaning there is no company that stands out for having the best product in the sector. Companies are similarly tied and the one that does the best marketing wins. And once again, the obstacle of advertising comes into place. Although in the last 10 years all sectors have evolved towards marketing through social networks, the exception is for sectors like ours and others, such as sex toys, which also cannot advertise.

As a result, they rely on complicated marketing strategies, and since the budget is limited, businesses have to generate campaigns that people share, find fun, and associate with.

[00:41:22.700] - Daniel Sanchez Diago

Due to the lack of regulation, it is difficult to say an exact number of businesses that currently operate in Spain, but do you have an estimated number of CBD businesses operating in Spain in 2023?

[00:41:45.620] - Manuel Samper

It is hard to give an estimate since there is no specific category in which the cannabis sector is registered, as it currently sits within the cosmetic sector. Within this sector there are millions of companies, so you cannot differentiate one from the other. However, the one figure I have heard of frequently is approximately 2000 companies. Within those 2,000 companies, I would classify about 100 companies with a proper structure, that is, with employees and a physical store, and the remaining 1,900, are rather a website managed by a freelancer who buys a product from one of these 100 companies and puts it on the market. Respectfully, they are competing players, but I would say there are about 100 well structured companies.

[00:43:10.040] - Daniel Sanchez Diago

You mentioned before that, while at the beginning entrepreneurs with low capital and little preparation entered the market, now companies with a high level of capital are doing so. So I would like to know, how is the financing in Spain? Where do CBD companies go for funding? And how has SoytuCBD done it in the past?

[00:43:37.200] - Manuel Samper

This is similar in all sectors. Companies have two ways of raising funds. If they are companies from abroad, and they cooperate with a Spanish company or try to set up their own headquarters, it implies they already come with their own financing. It may be because in their country they are already a large player, to the extent of being listed on the stock market. The second alternative is with a small own financing. Later on, as it starts to grow, a round of capital takes place, which is making the business proposal attractive to people close to you or to small investors, in order to raise a certain amount of money. When that first round falls short, which could have been €200,000, the next one could need more, for instance a million euros.

Then, venture capital companies or investment funds take over. These are companies specialized in investing in projects that, later in the future, sell their part and profit from the growth the company has had. Of this kind, a few players can be found in the market, which are neither many nor large. The first two or three enterprises that started are the ones currently going through this phase. These are the models for funding: either come from outside with a strong investment because you have the capacity to do so; or start from the bottom, like any other company, and grow.

However, as I mentioned before, the differentiator between the first wave of CBD businesses is that we started as young people, with limited experience in previous businesses. In spite of starting from scratch, the contrast factor between first wave companies and the newcomers is the level of preparation and budget. SoytuCBD started with a capital of €10,000, which is little to no money to start a company where you have to buy products, set up a website, and certain

tasks that ensure the budget is finished in the first few months. Now, you see companies that enter the market through the alliance of four businessmen getting together and trusting one person to set up this project with a capital of €100,000 or €200,000. What capacity does that give them? From the beginning they start stronger and with more money, which facilitates faster growth. But there is always the risk of spending money stupidly because you don't know the industry in depth and the challenges it poses. SoytuCBD, starting with a small capital, has occasionally wasted large sums of money stupidly simply because you make mistakes. One should always test with small amounts of money. Let me give the example of our radio campaign. We spent what was a lot of money for us at the time on radio advertising, but that money was not converted into sales. It was not 100% throwing money away, because it gave us recognition in Madrid, but it was not our advertising model. If you do this with a €100,000 campaign, you may notice your mistake too late and you will have spent €100,000 of your budget. So it depends on the company.

[00:48:46.740] - Daniel Sanchez Diago

Looking ahead, what do you expect from the CBD market in Spain and Europe?

[00:49:01.140] - Manuel Samper

The Spanish market is in an uncertain situation, because the body that is in charge of regulating is the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) and it is not willing to facilitate the regulation of CBD. Why? This mainly depends on each country and how their internal public bodies are constituted. In Spain, the most influential public institution regarding CBD regulation is the AEMPS. It is important to note that the Spanish public healthcare and all day-to-day medicines are financed by the State, hence the AEMPS has a lot of power. CBD, as a product, is directly competing with the products this institution profits from the most. This explains their hesitancy and delays in the regulatory processes. I don't think they are interested in seeing the CBD market grow, at least not until they have it under their control. For instance, although over a year ago the Congress regulated and authorized the use of medical marijuana, in particular THC, the products are still not available as the AEMPS has postponed signing the final documents and thus, not allowing the market entry.

So far, they are issuing licenses exclusively to parties that are of benefit for them. I believe that regarding CBD, it will eventually be fully regulated but it will happen very slowly. What is the problem with this? CBD businesses will end up buying the products from the AEMPS. I am not in favor of this because they are going to put a middleman, and if you do not buy from them, you will not be able to sell your product. Since the beginning we have had control over the process by working directly with growers and the laboratories. It would feel like taking a step back. However, these are the rules of the game. Even the largest companies in the industry

could not do anything if things evolve in this direction. Here we are talking about political and economic issues that go beyond our understanding.

At the European level it is different. It keeps steadily progressing, which eventually benefits us. As we are a member state of the EU, if conflicts arise in Spain they will be taken to European trials. In our country, you have to patiently follow along, doing what you can do in the market as it is now. I think it will change, but it is a slow and an expensive process.

[00:52:15.830] - Daniel Sanchez Diago

How do you see the future of SoytuCBD?

[00:52:20.020] - Manuel Samper

The future of SoytuCBD is looking bright as of today. There have been moments that have been hard due to regulatory issues, specifically with the AEMPS, which, even if you have done everything right, can create problems for your company. Like any business, you will always encounter problems. The CBD industry faces a tad more unusual problems, and as it is something totally new, there is no existing legislation. The current laws are vague and can have several interpretations, so it becomes complicated for small companies that do not have a law firm's support. Lawyers, who do not particularly work within the sector, can make mistakes even when doing their best

The future of SoytuCBD is currently very good, time is passing and we are growing. We came to have three stores of our own, and we had to close one of them due to this boom. Just as there was a boom at the online level, there was a boom at the level of physical stores and we had to close it because it could not keep afloat. Now, we have the opening of three new stores, but we are changing our model to a franchise. Online growth continues and today the company looks better than in recent years. I take it calmly, because in a year from now the AEMPS may change something and put the business in a difficult position once again.

That is for SoytuCBD and the rest of the companies in the sector. The industry is growing strong, but from time to time every company encounters problems with a public body. Those self-employed do not necessarily deal with these issues, as they have their own website, manage their social media, and buy and sell products to make some profit. It is the large companies that are having problems for being in the spotlight.

[00:55:39.340] - Daniel Sanchez Diago

And the final question, what do you think are the essential requirements for a CBD business to succeed in Spain in 2023?

[00:55:57.420] - Manuel Samper

First, having a good marketing team, agency or partner that takes care of it well, because with the difficulties that advertising has, it's going to be the most important thing.

Second, if you do not have enough capital at the beginning to hire lawyers, take a good look at all the information on the internet regarding how to sell the product so as not to make mistakes regarding the Law: how to sell it, how to explain the product, because in the future, mistakes can translate into fines or public bodies going after them.

Third, although all products are similar, ensure to have a good product. You have to try to avoid looking for the cheapest product because sometimes it is also the worst quality. There have been recent investigations of a distributor that gained strength here in Spain because it sold very cheaply, and they have had problems later on because the analysis of these products proved to be of very poor quality. I would summarize it in these three principles. Lastly, I would add that before going for money, I would recommend setting up a good team of partners: one to be in charge of the web, another in advertising marketing, one in operations and another in sales. It will be more effective to cover the fundamental areas of a company regarding partners in order for it to be successful.

[00:58:38.390] - Daniel Sanchez Diago

Brilliant. The interview ends here and thank you very much for your time, Manuel.

[00:58:44.460] - Manuel Samper

You are welcome, Daniel, my pleasure.