



THE NEW LEAF:
BEYOND BREXIT, COUNTERING COVID

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volteface

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Executive Summary

The New Leaf Opportunities campaign has highlighted the economic benefits, innovations and investment opportunities that medical cannabis and CBD can bring to the UK. It has also focused on how celebrating this will lead to a more vibrant cannabis sector.

This report has honed in on the opportunities that medical cannabis and CBD bring through an economic, innovation and regulatory lens.

Chapter one focuses on the economic opportunity, using existing evidence to paint a clear picture as to why the UK is an attractive jurisdiction for business. An analysis of the major cannabis companies was performed to showcase the global opportunity for medical cannabis. Using a number of countries and US states, a market estimate was calculated for the UK, which stands at **£1.2 billion**. Using job statistics from US states with only a medical cannabis industry (i.e. no adult-use market), an estimate for the UK was formed; **over 41,000 jobs could be created in the UK medical cannabis sector with an additional approximate 17,000 ancillary jobs**.

Chapter two examines the opportunities for innovation through a case study analysis of two cannabis companies: Kanabo and CiiTECH.

As the barriers to prohibition break down, the industry requires evidence-backed, indication-specific and consistent products.

Research and development must sit at the core of the industry to legitimise products, ensuring consistency and reputability for cannabis to be used as a medicine.

Chapter three discusses the UK's CBD advantage. The UK has a unique headstart compared to the rest of Europe, bringing a period of regulatory uncertainty to an end. Clear regulation encourages investment and innovation as a serious and reputable industry. A clear path to compliance is a necessary step for moving the industry forward and ensuring consumer safety.

Chapter four highlights the next steps for the industry. There is rising competition in the European medical cannabis sector in the form of pilot programmes and new emerging markets. As the continent prepares for a booming industry, it is essential to move quickly in order to capitalise on a valuable opportunity. More importantly, to continue growing the medical cannabis sector, patient access must be expanded as the industry cannot sustain itself without more patients.

Key Findings

Estimated predicted value of the UK medical cannabis market is **£1.2 billion.**

Number of jobs to be created in the UK medical cannabis sector is estimated at **41,437.**

Number of ancillary jobs to be created in the UK medical cannabis sector is estimated at **17,000.**

Recommendations

1. The appointment of a 'cannabis tsar' or the creation of a governmental body in the UK to oversee the expansion of the UK medical cannabis industry. At the moment, regulatory matters must be processed through the Home Office.

This is slowing down development due to a lack of a streamlined approach. A governmental body reserved for cannabinoid regulation, licensing and innovation funding is a necessary step towards further harmonising development in the sector.

2. The Food Standards Association should provide clarity around the amount of THC to be permitted in CBD products. Such regulatory clarity must be done in a way to ensure it encourages further investment and innovation.

3. The industry should engage with the British Chambers of Commerce in efforts to invest in innovation for the cannabis sector. This would further legitimise cannabis as a growth sector and contribute to research and development for expanding access to medicine. There should also be engagement with the National Farmers Union to represent producer interest as a means of diversifying crops.

4. As per the recommendation in the recent Volteface report Pleasant Lands, allowing hemp seed varieties with a THC percentage above 0.2% and up to 1% would improve the health of the plant and increase the yield of CBD per acre, and would not affect the end product, which could still have undetectable levels of THC present.

This would allow the UK to compete with other non-EU countries, which are not bound by EU registered seed varieties, and would support the UK to become a hub of research and development.

5. Simple amendments to legislation to facilitate the flow of products. Currently, customs and other legislative bodies are slowing down supplies and increasing costs. If these processes are simplified, costs will be reduced and patient access will be improved.

6. Amend the regulation requiring medical cannabis prescriptions to be made by doctors on the specialist register. This could be replaced by doctors undertaking a suitable CPD qualification. Ensuring that all doctors can prescribe medical cannabis is a huge and achievable win. The UK should follow in Germany's footsteps in regards to how quickly the sector can grow if allowed. The UK should aim to help private patients achieve reimbursement on insurance.

7. Increase the evidence base for cannabis-based medicinal products in the UK in order to expand patient access on the NHS; this is essential to fully unlock the UK market. The only way of successfully achieving this would be through a government-funded national trial. Forming strategic partnerships with well-regarded UK medical establishments is essential in bringing cannabis medicines into the mainstream medical ecosystem.

Foreword - Written by Daniel Pryor

Suppose someone told you that two innovative industries were poised to revolutionize healthcare and create tens of thousands of jobs in the process. They would contribute billions to our COVID-stricken economy whilst attracting global talent and investment to our shores. They would also showcase the benefits of divergence from the European Union. Anyone would take advantage of such an opportunity with open arms.

The industries in question are medical cannabis and CBD. The UK has already begun to embrace the potential of these nascent, fast-growing markets: undoubtedly accelerated by the legalisation of medical cannabis in 2018. Cannabis listings opened on the London Stock Exchange earlier this year, an advanced regulatory framework has created significant opportunities for future growth in domestic CBD businesses compared to their continental counterparts and the UK remains the largest exporter of medical cannabis in Europe.

The European market for medical cannabis is the fastest growing in the world and our unique position gives us the prospect of becoming a leading player in medical cannabis and CBD. This paper provides a fascinating overview of the state of play in these markets, opportunities for growth and the regulatory questions that face the sector. It shows how the UK is in a prime position to become the centre of the European medical cannabis and CBD industry, as well as the significant economic benefits that would result.

It also examines the innovation opportunity inherent in these markets: embracing these sectors will help to attract the best and brightest scientists to the UK. We are internationally acclaimed for our leadership in research and development in countless sectors, and through two case studies this paper shows how medical cannabis and CBD are both fertile ground for driving innovation in medical and health products.

The UK has led the charge in ensuring our CBD industry is one of the first in Europe to be fully compliant with Novel Foods regulation while allowing the market to grow. The paper shows that companies involved in this space stand to benefit from the regulatory clarity this provides, as well as the associated boost to investment and consumer confidence through establishing high standards. The risks to competition from onerous regulatory burdens pushing out smaller businesses have also been mitigated through the European Industrial Hemp Association's (EIHA) Novel Food Consortium, which has helped to reduce the cost of compliance by pooling applications for Novel Foods certification.

Despite our achievements to date in this area, we cannot rest on our laurels. There are still questions to be answered around appropriate legal limits on naturally occurring THC content in CBD products. If the limits are too harsh, we risk hamstringing the market just as it has the greatest opportunity to flourish and grow.

For medical cannabis in the UK, the elephant in the room is the challenge of widening patient access. As the paper highlights, there are still substantial barriers facing those in need of prescriptions. Sensible regulation, encouraging investment into the sector and conducting further research on cannabis-based medicinal products are all vital components of ensuring the UK becomes a centre of excellence for medical cannabis in a way that benefits patients, not just the economy at large.

Daniel Pryor
Head of Programmes
Adam Smith Institute



Introduction: Turning Over A New Leaf

Medical cannabis and CBD are undoubtedly coming of age in the UK. Despite Brexit and Covid bringing a substantial amount of economic insecurity, 2021 is proving itself to be a year of promising opportunities.

As one of the few growth sectors, cannabis has demonstrated itself to be a viable opportunity to combat economic uncertainty. Recently, cannabis has witnessed incredible global reform breakthroughs. Whether it is the UN's historic vote, the EU court's CBD ruling, more states legalising in the US or the introduction of medical cannabis programs across Europe - the world is warming to the idea of cannabis.

As the world's fastest growing market, Europe is set to become a leader in cannabis. Looking closer to home, we witness the first cannabis company listings on the London Stock Exchange (LSE). By doing so, the UK has shown it is open for business.

Though many see cannabis as a niche industry, this is far from the truth. Cannabis is an interdisciplinary sector, requiring a wide-range of job roles for a variety of skill sets. Within a legal cannabis industry, everyone gets to profit with a massive ancillary revenue for all involved professional services. The opportunities for employment are vast and must be welcomed.

Investment in the cannabis sector is also a vessel for innovation development through improving product quality, access and advancing our understanding of cannabis. Through this, the UK will be able to further its influence in research and development (R&D) in the sector.

The more the industry expands and diversifies, the more affordable products become for consumers. Greater product variety through innovation ensures consumers have a larger selection of products to choose from. This also prevents large players from monopolising the market, instead celebrating diversity.

The UK has a booming CBD industry. It also stands in a unique and advantageous position for CBD regulation. The recent regulatory clarity and compliance with Novel Foods authorisation processes places the UK in an excellent place for innovation and investment. The clarification paves the way for normalising the industry, guaranteeing product quality and makes the UK an attractive jurisdiction to do business in.

The UK cannabis sector holds promise for 2021 and beyond. Regulatory clarity and R&D are allowing for a vibrant and dynamic industry to develop. Industry growth with investment will continue to expand our knowledge of cannabis and greater knowledge will expand the industry. This two way process is poised for success.

Chapter 1. The Economic Opportunity

There is no doubt that cannabis holds immense economic benefits. Recent developments are allowing the UK to become a hub for medical cannabis investment.

The UK is the largest exporter¹ of medical cannabis in Europe. The first license to cultivate medical cannabis was issued in 1998 to GW Pharmaceuticals. Medical cannabis was legalised in 2018, though access still remains limited

On 18 September 2020, the Financial Conduct Authority (FCA) released an important statement² outlining a new approach for listing medical cannabis companies. This statement provided the necessary clarity for medical cannabis companies in the UK. This news was open and supportive of the market, allowing for investment and expansion of operations in the sector.

In February 2021, the LSE opened its doors to medical cannabis companies. Listings have provided the necessary step for medical cannabis

to become a legitimate and serious industry in the UK. Public investment is a huge step forward, opening up a new pool of capital. Successful listings have demonstrated the UK investor community is interested in cannabis, giving the green light to an immense opportunity.

Over the last few years, North America has paved the way with medical cannabis with investment, vast job creation and taxable revenue. Although Europe is developing quickly, at present it has no obvious medical cannabis leader. The UK has the opportunity to take this position. As it works toward creating a new identity post-Brexit, the UK is no longer tied to EU decision making. This can be viewed positively for this space, allowing the UK to move faster and lead on a whole new level.




Recent news certainly positions the UK as an attractive jurisdiction to do business in for the medical cannabis sector. In due time we can expect this to result in higher quality and cheaper cannabis medicines for patients.

Major global players analysis

In order to give a tangible estimate of what the UK's cannabis industry could look like, an analysis of the largest global cannabis companies was conducted.

The analysis highlights why the UK should be focused on becoming an investment hub given the profitability of the sector.

Table 1. Analysis of 10 Largest Cannabis Companies. Note: all values in GBP.

Company	Number of Employees	Highest Value Lowest Value	2020 Revenue	Taxable Revenue*	Number of Countries Active in
 aphria inc	303	14.76 (19.2.2021) 1.82 (12.3.2020)	390.4 million ³	58.56 million	9 ⁴
 AURORA	2,779	94.96 (12.10.2018) 3.07 (16.10.2020)	51.8 million ⁵	7.77 million	25 ⁶
 CANOPY GROWTH CORPORATION	1,462	38.77 (26.4.2019) 9.83 (20.3.2020)	286.9 million ⁷	43.04 million	2 ⁸

Company	Number of Employees	Highest Value Lowest Value	2020 Revenue	Taxable Revenue*	Number of Countries Active in
	721	5.49 (15.1.2021) 1.04 (20.3.2020)	58.8 million ⁹	12.34 million	3 ¹⁰
	813	11.55 (19.2.2021) 2.04 (20.3.2020)	110.2 million ¹¹	24.14 million	1 ¹²
	329	16.83 (8.3.2019) 4.08 (30.10.2020)	26.7 million ¹³	26.7 million	17 ¹⁴
	1,108	20.30 (30.11.2015) 4.08 (26.4.2018)	450.9 million ¹⁵	4 million	1 ¹⁶
	708	155.03 (8.3.2019) 27.66 (11.3.2016)	379.2 million ¹⁷	94.69 million	42 ¹⁸
	106	11.26 (12.2.2021) 1.15 (20.3.2020)	36.6 million ¹⁹	72.04 million	1 ²⁰
	750	106.65 (12.10.2018) 2.63 (20.3.2020)	151.4 million ²¹	5.49 million	18 ²²
Total	9,099		1.94 billion	343.78 million	
Average	910		194.3 million	34.37 million	12

* Taxable revenue was calculated based on the percentage of taxable company revenue in each country (i.e. 21% USA, 15% Canada, 19% UK).

These figures demonstrate that the cannabis sector holds promise for the UK given the large sums of total and taxable revenue per company.

The number of employees simply acts as an indicator for the size of these companies. This is an indicator for the extensive size UK companies could grow to. The number of countries these global players are active in demonstrates the cannabis sector is a global opportunity for exporting and expanding internationally. Market values and yearly revenue per company demonstrates the sector's profitability. If the UK positions itself as the focal point of Europe, a significant pool of capital awaits for publicly listed companies. The more companies that list, the greater the pool of capital. This is also a compelling argument for a free market approach to the cannabis industry, which would further boost the economic opportunity.

UK market size estimate

The following analysis of the major cannabis players gives an indication of the extent of the global opportunity. In order to calculate an accurate estimate for the UK market, a scale of the medical cannabis market was used for Germany, Italy, The Netherlands and several US states that only have a medical market. The UK population currently stands at 66.65 million. This existing market size was used and adjusted to the UK to give an accurate estimate, proportionate to the population.

Table 2. UK Medical Cannabis Market Estimate. Note: All values in GBP

Country ²³ / US State ²⁴	Market Size (million)	Population (million)	UK Market Size Equivalent (million)
Germany	105.79	83.02	84.93
Italy	15.7	60.36	17.34
The Netherlands	9.36	17.28	36.10
Arkansas	34.3	3.018	757.49
Arizona	507	7.279	4,643.33
Connecticut	42.9	3.565	802
Delaware	26.4	0.974	1,806.5
Florida	572	21.48	1,774.9
Hawaii	25	1.416	1,176.7

Country ²³ / US State ²⁴	Market Size (million)	Population (million)	UK Market Size Equivalent (million)
Iowa	4.29	3.155	90.63
Louisiana	3.57	4.649	51.18
Maryland	231.86	6.046	2,546.5
Minnesota	27.9	5.64	329.7
Montana	65.8	1.069	4,102.5
New Hampshire	16.1	1.36	789
New Jersey	85.8	8.882	643.84
New Mexico	92.9	2.097	2,952.69
New York	89.39	19.45	306.32
Ohio	157.3	11.69	896.84
Pennsylvania	290.3	12.8	1,511.6

Average calculated UK medical cannabis market estimate: £1.265 billion

This analysis used 20 medical cannabis markets in the US and Europe to predict a UK medical cannabis market size. As this analysis uses inputs from a range of markets, the estimate has a certain amount of validity.

This UK market estimate demonstrates the immense economic opportunity the cannabis sector holds. By developing the UK into a European cannabis industry leader, this will hold a significant amount of capital, in the realms of £1.265 billion.

Job estimation

The medical cannabis industry is clearly a profitable sector. The breadth of innovation is an attractive opportunity for businesses to flourish. Not only is it appealing for companies to make a large profit, it is an industry that employs a large number of people across all skill-sets.

As various figures have been thrown around, it is worth investigating what a profitable industry in the UK could look like for widespread job creation.

This report has used existing, recently published data on the number of people employed in the US legal cannabis industry. In order for estimates to be as accurate as possible, US states that only have a medical cannabis market were included. Including states that also have a recreational market would not accurately represent the number of potential jobs in the UK.

The UK population currently stands at 66.65 million²⁵. The number of cannabis sector jobs and population for each state was included in the analysis. This was used to estimate an equivalent figure for the UK, proportionate to the population.

As is visible in the table below, the number of jobs in the medical cannabis sector varies massively across states. Though population plays a role, so does the number of patients and extent of the industry's development.

In order to have the most reliable job estimate, an average for all 22 states that have only a medical cannabis market were included, to paint the most realistic estimate for the UK market. All job estimates have been multiplied by their population factor, then averaged to give a final estimate.

Table 2. Number of Jobs in the Medical Cannabis Industry by US State & Estimated UK Equivalent²⁶

US State	Number of Jobs	Population (million)	UK Market Size Equivalent (million)
Arkansas	1,777	3.018	39,243
Arizona	15,059	7.279	137,887
Connecticut	1,372	3.565	25,650
Delaware	720	0.974	49,268
Florida	15,498	21.48	48,088
Hawaii	745	1.416	35,066
Iowa	120	3.155	2,535
Louisiana	90	4.649	1,290
Maryland	6,353	6.046	70,034

US State	Number of Jobs	Population (million)	UK Market Size Equivalent (million)
Minnesota	764	5.64	9,028
Missouri	1,100	6.137	11,946
Montana	1,800	1.069	112,226
New Hampshire	441	1.36	21,612
New Jersey	2,356	8.882	17,679
New Mexico	2,549	2.097	81,016
New York	2,941	19.45	10,078
North Dakota	200	0.762	17,493
Ohio	2,475	11.69	14,111
Oklahoma	9,412	3.957	158,531
Pennsylvania	8,765	12.8	45,639
Utah	100	3.206	2,078
West Virginia	30	1.792	1,115

Average number of jobs potentially created in the UK: 41,437

Using estimates and averages from 22 US states with medical cannabis programs, the UK medical cannabis market could create over 41,000 jobs in the sector.

This is only an estimate based on data from the US. However, the larger the market and the more patients in the UK the greater the potential number of jobs in the industry.

This analysis is strengthened by using inputs from a range of US medical cannabis markets, giving this estimate a greater validity.

It is evident that medical cannabis is a lucrative industry with the potential for immense job creation. The larger the UK industry becomes, the more job opportunities. Though the US industry is several years ahead of the UK, the cannabis industry already employs more people than computer programmers²⁷ in the country.

However, job creation goes beyond direct employment in the cannabis sector. Ancillary revenue and job creation is another contributor to the economy.

The development and growth of the cannabis sector has a direct beneficial impact to other industries. A thriving market benefits professional services involved in the industry.

Ancillary jobs include roles such as lawyers, accountants, consultants, media companies and marketing firms that service the industry. These jobs support the industry without direct involvement, demonstrating the widespread benefits of the sector stretching beyond the parameters of medical cannabis.

A report published by [Leafly in 2019](#) estimated the number of indirect ancillary jobs created as a result of the legal cannabis industry to be 85,000. This figure will have grown since 2019. Performing a rough estimate equivalent to the UK population, this would result in the creation of approximately 17,000 ancillary jobs for the medical cannabis industry.

With over a potential 41,000 direct and 17,000 indirect jobs created by the medical cannabis industry, the UK stands in a strong economic place.

Estimates and predictions highlight the present economic opportunity for the UK is massive. However, for the time being the industry remains in a nascent stage. There is a clear appetite for investment in the UK but there is a paradox for patient access remaining difficult across the country.

As the UK emerges from Brexit and Covid, there is no better time to embrace cannabis and encourage investment.

Chapter 2. The Innovation Opportunity

The cannabis industry undoubtedly holds immense opportunity for innovation. Currently, the UK is primed for innovation opportunities if it embraces the business case for cannabis. Coupling the evidence-base behind the efficacy of products and creative applications, innovation is a key driver for the expansion of the cannabis industry. This leaves the UK in a promising spot, especially as it has a global reputation for excellence in scientific research. However, remaining at the forefront involves furthering research and development (R&D) in the cannabis sector.

Cannabis brings unique opportunities for product development within a variety of existing innovations, which increase the effectiveness and appeal of medicines. Despite overlap, medical cannabis and CBD are each uniquely positioned with product development holding specific requirements to foster innovative thinking. As consumers within these markets have differing requirements, it is most appropriate to discuss medical cannabis and CBD separately.

Case Study 1: Kanabo

The Israeli R&D company, Kanabo²⁸ was founded in 2016. Kanabo's commitment to research has led to the development of high-quality cannabis extract formulas, innovative medical grade vaporisers and various non-smoking consumption solutions. They have recently become the centrepiece for medical cannabis innovation as the first company to be approved to list on the LSE, making their market debut on February 16 2021.

The present case study is based on insights from Michelle Tamir, Marketing and Sales Manager at Kanabo.

"The importance of innovation in the cannabis sector comes down to taking something that has been an illicit, agricultural product used throughout the millennia and consumed through rudimentary ways. These are Tier 1 Products and have been around for a long time. 80 years of cannabis prohibition has not let this process evolve at all. Whereas, regulation allows us to apply a framework to the market with supply chains and a scientific method. This allows for the

This chapter highlights the way forward for innovation and branding in the cannabis sector. This section of the report hones in on two case studies examining medical and wellness products.

Case Study 1 examines Kanabo and their groundbreaking medical cannabis 'VapePod'. The focus on Kanabo originates from the success of their recent listing and their proven investment clamour.

Case Study 2 examines leading company CiiTECH, exploring why R&D must sit at the core of brand development to legitimise CBD as a health product. CiiTECH is a relevant case study with their approach to innovation through research in the sector.

development of products that are medical, placing us in the same territory as doctors. This permits us to go down to the molecular level, understand how the cannabis plant works and how it can be applied in different ways to create new products."

Innovation is a means of advancing medicine. Known for their development of the VapePod, the history behind Kanabo's product comes from Avihu Tamir, Kanabo CEO Founder's personal story. After being prescribed medical cannabis, Avihu was sent to a nurse to learn how to roll cannabis cigarettes. Finding this medically unacceptable, it sparked a Eureka moment, with Tamir realising that there must be a better way of consuming the plant. This led to the founding of Kanabo and the journey to develop proper formulated medicine.

What makes cannabis unique as a medicine is the way in which it is most effectively consumed.

This is reflected in the consumer choice to smoke cannabis, due to the fast onset of effects.

However, this unhealthy method of consumption is one of the key reasons why doctors fail to see cannabis as a medicine.

Bioavailability is one of the most important aspects to cannabis innovation. Bioavailability is determined by the properties of the drug dose, referring to the extent and rate at which a drug enters the circulation when it is introduced in the body and thus is able to have an active effect.

Smoking cannabis gives high bioavailability, absorbing a high amount of the product with a rapid onset of effects; hence reflecting the consumer choice to smoke. Whereas edibles only absorb approximately 5-10% of the product. The effects of edibles are also experienced differently by individuals, meaning there are a range of different effects, which for a medicinal product can be problematic to administer.

Innovation for medical cannabis derives from developing "Tier 2" products that offer high bioavailability and a fast onset without necessarily being inhalation and edible products. Kanabo has taken this effective consumption method and applied it to the "VapePod", to medicalise smoking. This gives not only a healthy alternative but also a more accurate dose.

"Once we advance the bioavailability, cannabis medicine moves into the language that doctors speak. If these products can offer a consistent measure, much like taking an aspirin pill with the same effect every single time, the product has succeeded as a medicine. Medicines require consistent packaging and consistently the same effects for each person that consumes it. When that has been achieved, physicians can prescribe cannabis. Consistency is what allows it to become mainstream, breaking down the barriers to prohibition and unlocking the therapeutic benefits of the plant."

Ensuring product consistency and reputability is essential for any medicine. There are plenty of cannabis vaporizers on the US market. Although these are increasing in popularity, regulation has yet to catch up. Companies want a quick product, without necessarily considering the consumer,

which leads to the creation of under-researched products with sub-par materials.

For these exact reasons, Kanabo's VapePod is an exciting and relevant cannabis innovation. Though it may look similar to standard products on the market, the VapePod sets itself apart as a vaporizer that ensures patients receive a metered dose, providing exactly 1mg of cannabinoid extract. This is more precise than smoking cannabis flower where it is impossible to ensure consistency.

The mechanism is essentially the same as an e-cigarette. However, the VapePod uses sealed tamper-proof cartridges that cannot be manipulated, ensuring consistency and safety from additives. The device also has an automatic stop function. When the consumer inhales there is haptic feedback indicating the dose has been administered; the device then shuts off automatically. No matter how hard or soft the consumer drags, the VapePod delivers the exact same amount of product each time. This ensures a specific amount can be prescribed, whilst remaining easy to administer. The VapePod is a necessary innovation, which effectively medicalises vaping.

"What is also unique is that the VapePod was developed with the consumer in mind. It is very easy to use with no buttons and minimal cleaning required. To clean the VapePod, one simply needs to take a cotton swab with a drop or two of rubbing alcohol and wipe away dust particles from the connection components every once in a while. Whereas other devices, especially those meant for dry flowers, require a deep cleaning that can be rather time consuming and would require a set of tools to do so. It uses a simple design with a place to insert the cartridge and is light to hold in your hand. This user friendly design is essential, particularly for patients that have dexterity or mobility issues."

Developing the VapePod resulted in several years of getting the product to a level where it would be accepted by the medical establishment with a process of approvals. Materials and manufacturing processes had to be GMP production approved. The device also had to be tested by a third party, setting itself apart from other products on the market.

The VapePod can be used to treat a range of conditions. As an R&D company, Kanabo plans to perfect formulas to cater to specific conditions.

Cannabis medicines are not a “one size fits all” paradigm. Thus, developing specific formulations for conditions will be the next step for product innovation.

With a lot of conservatism still surrounding the cannabis industry, there are certainly challenges ahead. However, innovations like the VapePod will be the gateway for demonstrating the worthiness of conducting research to medicalise current methods of consumption and making physicians more comfortable prescribing cannabis. Ultimately, this leads to more prescriptions being offered to patients, broadening the access to and acceptance of cannabis medicines.

Case Study 2: CiiTECH

CiiTECH²⁹ is a leading consumer-focused CBD company engaged in ongoing cannabinoid research, focused on discovering and commercialising cannabis products. Founded in 2017, in the midst of a growing yet unregulated CBD industry, CiiTECH aims to create strong consumer connections by bringing research-led formulations and innovations directly to consumers. They created Provacan³⁰, a leading CBD brand both in the UK and across the globe. Through this, CiiTECH aims for regulation and standardisation within the industry, recognising the differing regulatory frameworks in each territory.

CiiTECH has remained at the forefront of the CBD industry through cannabinoid research conducted in collaboration with The Hebrew University. This investment in clinical research has helped generate a body of knowledge on cannabis health by partnering with scientific and medical communities. All of CiiTECH's endeavours are inspired by science and driven by data insight.

This case study is based on insights from Clifton Flack, Founder and CEO of CiiTECH.

“The most innovative aspect to this industry has been transforming cannabis into a health product by approaching it through a new lens. This means, taking something that has been around for centuries and

Kanabo continues to think of ways of developing user-friendly, medical-grade products. Moving forward, we can expect to see a wider spectrum of products that further accommodate for mobility issues. Kanabo is successfully spearheading innovation frontiers for medical cannabis.

As we slowly break down the global barrier of cannabis prohibition, incredible innovations will continue to emerge. The renaissance currently being experienced will allow the cannabis sector to flourish.

transforming it into something new and regulated that holds multiple uses. Innovative thinking gives cannabis incredible potential by allowing the industry to continue developing new and more effective cannabis healthcare products.”

CiiTECH is focused on addressing the problem cannabis currently faces as medicine, which is a lack of clinical research and evidence. This makes it important to change how the problem is approached to see results - innovation is this realisation. CiiTECH has done an incredible job at recognising where cannabis sits and how it should be regulated - from this, products that fit this criteria can be developed.

CiiTECH's philosophy stresses innovative thinking for the cannabis sector, particularly honing in on brand development. This is a particularly important aspect for CBD as it remains a consumer choice. This highlights the different considerations required for CBD, compared to medical products.

Building a trustworthy brand is essential for innovation. To build interest in CBD, brands must be founded on trust and support. This can be accomplished through the industry engaging in innovative thinking to develop CBD's reputation as a health product based on evidence, science and medicine.

“The CBD space needs regulation but not necessarily anything new or innovative. Instead, the industry requires transparency and standardisation. This is exactly what novel food certifications are for, formalising the process for CBD to be regulated as a food supplement.”

If CBD is to be as large as it is forecasted to be, synthetic lab-based products will be the most appropriate means for approaching the market as a large company. This will not only allow products to be safely regulated but further expedite the process at which they are produced.

“Full spectrum products certainly have a place in the industry. However, among large industry players it is difficult to ensure a safe and secure format. The industry is currently under a significant amount of pressure around regulation, making synthetic lab-based products a viable alternative to continue formalising the sector to allow the industry to scale up and wide. The cosmetics industry will certainly be the heaviest users of synthetic cannabinoids.”

This highlights the broader issue of control and regulation for CBD products. CBD is one compound of many and the only way to effectively isolate it is synthetically. This means we can expect to see more isolated products on the market. This will allow CBD to begin fusing with the medical world as individual compounds are regulated.

CiiTECH sees the innovative mechanism behind CBD as encompassing brand development. The scalable nature of this industry is down to building trustworthy brands; ones that are dynamic and flexible to meet consumer needs and ensuring strong product market fit in each local territory or target market.

CBD is an interesting product as it sits right in the middle of ‘recreational’ and ‘medical’, as a therapeutic product. Research has shown CBD’s efficacy, most commonly to treat anxiety, insomnia, pain and depression.

A key way to remain at the forefront of the CBD industry through the incorporation of scientific research into products. Investment and revenue can then go directly into funding more research. As already highlighted, this is what makes CiiTECH a unique and reputable company.

Revenue is directly invested back into ongoing research projects and partnerships, that then spearhead new product development.

Two exciting products that are due for market release in the US have been created with patent pending formulations developed with the Hebrew University. These are CBD products in pill form to treat a) fatty liver disease and b) symptoms of the alcohol hangover. They are unique in their scientific backing and their use of existing remedies coupled with CBD. Both products are in high demand for consumers.

CiiTECH invested in a clinical trial examining the effects of CBD and CBG for fatty liver disease. Studies investigated how these compounds would improve obesity invitro and in mice and found that obese mice lost weight.

These findings are not necessarily new, as cannabis formulas are already being used for weight loss. However, CiiTECH’s research discovered which cells absorb and store fat and which genes in the cell influence this. The formula CiiTECH have developed mirrors this, not absorbing or storing fat as energy. What this means for CiiTECH is a product that is a non-psychoactive and not controlled patented formula with CBD/CBG.

The food supplement formula will be marketed as a unified weight management product. What makes the product unique is that it contains CBD/CBG but with added compounds that are already being used for weight management, such as apple cider vinegar. Essentially, what CiiTECH has done is create a weight management pill using zcompounds that are known to benefit weight loss.

CiiTECH’s hangover product follows the same concept as the weight-loss formula. A scientific method was used at the Hebrew University utilising the benefits of CBD along with other compounds known to alleviate hangover symptoms.

These products highlight CiiTECH’s philosophy of using innovative thinking which encompasses already commonly utilised scientific methods, rather than something entirely new. These products are reinventing and rebranding solutions that already exist on the market, adding a patented CBD formula.

Products such as these are indication specific and are not medical. There is no expectation for doctors to prescribe remedies, but what makes them unique and appealing is that they are backed up by well-researched evidence, combined with existing compounds that are known to work.

“This is generally where we will see the CBD industry move toward, using CBD and other compounds to harvest a further effect. This will further distinguish between what products are aiming to achieve. The potential effects CBD can have are vast. By having an indication specific purpose, this allows products to be branded easier if they have a targeted function.”

In summary, CiiTECH’s science-led approach to building brands, product development and consumer connections is innovative, as it is both underpinned by existing scientific and medical approaches whilst utilising CBD.

The way forward

Innovation is a crucial element in developing the cannabis industry and unlocking further opportunities. Innovation is the only way to recover from decades of cannabis prohibition, fostering new growth.

As a highly interdisciplinary field, development must occur within the appropriate parameters. The First Wednesday’s European Medical Cannabis Ecosystem³¹ has done an excellent job highlighting how the industry can effectively operate within interdisciplinary parameters; innovation within each section of the ecosystem leads to a flourishing industry.

There is certainly a continued focus on innovation in the UK. A recent policy paper³² published by the UK government has formed a new Task Force on Innovation, Growth and Regulatory Reform.

Taking existing ingredients already known to consumers and combining them with CBD means that consumers already associate the formulations with certain indications, pump revenue into funds for further research and view it to be a reputable company with trustworthy products.

CiiTECH is a unique CBD company with its dedication to an evidence-driven approach for CBD innovation. This is a sustainable model which uses data-driven insights to fuel brand value. For a CBD company to successfully immerse itself in the health industry they must establish credibility and display similarities with a healthcare company. This means looking further than simply sticking products on shelves. Involvement in research and grassroots education is imperative.

This will identify and develop proposals in a range of areas to drive innovation for the UK economy. This demonstrates that innovation opportunities and areas for growth are being taken seriously by the UK government.

As an emerging market, R&D has the real potential to flourish. The renaissance and recognition of the potential cannabis has, demonstrates how investment and fresh thinking will continue to benefit the sector. We can expect to see further innovation in the sector, bringing new products to the market. This is a necessary advancement, particularly alongside much needed regulatory clarity in the sector to legitimise the industry.

Chapter 3. The UK CBD Advantage

The UK has a booming CBD industry. As it is currently worth £300 million³³ and estimated to grow to £1 billion in the next five years, the sector is poised for positive development. The cannabis sector has witnessed the transformation of CBD into a mainstream industry with products available on every high street corner in the UK, including in well-known chains such as Holland & Barrett and Boots over the last few years. The implementation of novel foods will likely see a number of major high-street players enter the space.

Novel Foods explained

Before this report delves into the practicalities around why the UK is at an advantage for CBD regulation, it is important to unpick what the novel foods process means.

A novel food under European Law³⁵ is a product that does not have a history of human consumption prior to May 1997. The regulation³⁶ was introduced to establish safety mechanisms to control newly developed foods.

In January 2019, the European Commission³⁷ reaffirmed that CBD extracts and isolates were to be listed in the novel food catalogue. The hemp plant itself and related products (i.e. seeds and cold-pressed oils) were not included in this ruling, as they have a history of human consumption prior to 1997 in European markets. However, once those raw extracts are placed through additional refinement processes, then a novel product is created, and novel food approval is required to prove product safety. Though the UK has left the EU, the UK government continues to implement the novel food regime and therefore the ruling on the novel food status of CBD stands.

Compared to the rest of Europe, the UK has an advanced and lucrative CBD market. More importantly, the regulatory clarity provided by the Food Standards Association³⁴ (FSA) on novel food authorisation guidance for CBD, places the UK in a unique position and ahead of Europe.

The following chapter was constructed and guided by insights from Robert Jappie. Robert is a Partner at Ince Gordon Dadds LLP, specialising in life science and cannabinoid regulation for the UK and Europe.

Novel food regulations are ultimately about consumer safety. A common misconception around the novel food process is that it is a legal submission, when in fact a novel food dossier application is entirely a technical, scientific submission. As CBD products are marketed to be consumed every day as a food supplement, then consumers need to be confident that it is safe to consume such a product daily. This is the purpose of the novel food regulations. The central part of a novel food submission is a detailed toxicology study, which provides a clear route to establishing safety data, enabling laboratories to establish the long-term impacts of CBD consumption by extrapolating data from studies lasting a matter of months.

The UK's Head Start

In normal circumstances, full marketing authorisation is required before a novel food can be lawfully sold. The UK has set out a unique position for CBD novel food compliance. The FSA has granted an exemption for CBD products, which requires CBD companies to achieve compliance via a validated novel food submission. A deadline for submission of the novel food dossier was set for March 31 2021. This pragmatic approach allows existing products to continue being sold, with the expectation of achieving novel food compliance by the deadline.

“Novel food compliance should be viewed positively as it has imposed regulation via a phased approach which allows the industry to continue developing. This regulatory clarity has given the UK a route to compliance for CBD products. Though it has been extremely difficult, costly and a time consuming process, it is undoubtedly a necessary step in moving the industry forward”

The European Dilemma

The UK's novel food regime has diverted away from European procedures. This has had a positive impact on the UK industry, whilst creating obstacles for the rest of Europe.

Regulatory compliance is a complex space to navigate. This makes clarity all the more important and is what currently sets the UK apart from the rest of Europe. This lack of clarity across Europe creates problems for regulation in individual countries. There are two recent cases that highlight this.

The landmark KanaVape case is an example of why clear regulation is essential for the CBD industry, which would act as a catalyst for sector growth.

The Kanavape ruling

In November 2020, the European Court of Justice ruled that CBD should not be classified as a narcotic. This ruling was in relation to the prosecution in France³⁸ for KanaVape, a company selling CBD products containing oil extracted from the whole hemp plant. Under French law,

It is important to highlight the advantage novel food regulations provide for the industry. There is no higher standard in the world for food quality and safety than novel food certification. By requiring CBD companies to engage in this process, it ensures consumer confidence and market stability; both of which are a necessary step for legitimising the industry, attracting both further investment and mainstream interest.

The advantage of novel food regulations has been a neglected aspect to the debate. Whilst the drawbacks of regulatory hurdles have been stressed, the long-term implications these regulations have for the CBD sector have not been considered in detail. Achieving novel food compliance will allow CBD companies to set the highest standards in the global industry.

only the fibre and seeds of hemp can be used for commercial use, not the flower. The ECJ ruled that the French ban on CBD extracted from the whole plant contradicted EU law on the free movement of goods.

“The KanaVape case is an excellent example of how a seemingly small and insignificant case can have huge ramifications on the industry. Although very positive, and a relief to the industry, every member state is still responsible for its own legislation meaning the case was not a direct game changer for CBD. It further highlights that need for a clear route of compliance for CBD companies across Europe”

This case is already having an impact, forcing the European Commission to recommence consideration of Novel Food applications. We can expect to see more decisions like this, as the ruling highlights the need to establish a streamlined European market for CBD products as many products are still being sold in a regulatory grey area in the EU.

The Little Collins case

The ongoing case of Little Collins CBD Dispensary in Ireland perfectly highlights the problem a lack of regulatory clarity creates. Little Collins is an independent business selling CBD oil and hemp flower products, including herbal remedies, teas and oils. The shop has been raided several times by the police. The case has been taken to the Irish Higher Court, challenging the prosecution that selling certain hemp products is invalid under EU Law.

Due to such regulatory grey areas, the situation in Ireland is profoundly incoherent and difficult to navigate. This has meant that small and independent businesses are unfairly targeted in these raids. Unfortunately, these businesses have little protection from such raids.

What's happening in Ireland is indicative of the risk for all European countries, as authorities have a wide discretion on whether to crack down on novel food regulations. Cases like this could have posed a risk for the UK without the FSA exemption. As a result of this, raids like this should not occur in the UK. However, so far no other European countries have followed the UK's example.

Although there is a growing CBD market in the EU, due to a lack of regulatory clarity, there is still a great deal of risk associated with this sector. If the CBD industry is to be sustainable, regulation must be addressed. The clarity provided by novel food regulations in the UK is the first step in removing risk from the sector.

Positive developments

Though Europe faces challenges in terms of CBD regulation, there have been positive developments in the sector.

Whole plant-derived CBD has been added as a legal ingredient in cosmetics in the EU. Although some forms of CBD were previously allowed, only CBD extracted from the seeds and stems were permitted. This was unnecessarily restrictive. With whole plant extracts now allowed in cosmetics, this is a positive for the European cosmetics industry.

Strict regulations can, of course, be accompanied by the sad reality that smaller companies are pushed out of the market. However, the European Industrial Hemp Association³⁹ (EIHA) has encouraged smaller companies to join

their membership. As this is a legally complex area, the EIHA plans to achieve security for the industry by leveling the playing field for SMEs. This has been achieved by creating a novel food consortium, which allows companies to submit a joint application and share the costs burden. For an individual company to prepare a dossier submission, the costs can be as high as €300,000, thus this consortium offers SMEs a helping hand in achieving novel food compliance.

Although the enforcement of the novel food regime will undoubtedly reduce the number of companies in the market, we don't want this industry to be the preserve of only big companies. The EIHA initiative is an example of how an inclusive, supportive and reasonable approach to keep the market open can be achieved.

How will compliance be enforced?

Although the pathway to regulatory compliance is now known in the UK, the level of enforcement that will take place is still to be determined.

“Post-deadline, products not covered by a validated novel foods application face the risk of being removed from sale. Companies that have spent significant amounts of money for novel food applications, will be expecting enforcement to take place. Enforcement will fall to Trading Standards, who will have been briefed by the FSA to intervene in relation to non-compliant CBD companies. It remains to be seen what resources will be made available to local authority trading standards to carry out enforcement actions”

From April 1 2021, we may start to see some self-regulation within the industry taking place, with compliant companies on the lookout for non-compliant competitors. Of course, there has to

be a balance between regulatory compliance and free market flexibility. We don't want compliance obligations to be so onerous and expensive that only the biggest companies can survive.

As the CBD industry now employs a lot of people, the government should be encouraging businesses to grow whilst operating in a compliant fashion. Regulation of the CBD industry will feed into the broader topic of market consolidation that is taking place across the cannabis sector. Thus, the UK CBD industry must look for steady and sustainable growth, which may mean looking for synergies with like-minded companies.

Where do we go from here?

Post-novel foods, the next issue for the UK CBD market is THC content. The question around the amount of THC, which should be permitted in CBD products is certainly a discussion occurring in government. However, it needs to be addressed in a way that supports businesses rather than hinders them. If harsh restrictions are put in place for THC content, then the expense and effort used up in achieving novel food compliance will be for nothing.

We are already seeing the industry prepare for this, with the EIHA launching a clinical trial to establish safe THC levels⁴⁰ in CBD products. This will be the largest study of the toxicological impacts of human ingestion of trace levels of THC in foods. This evidence will help establish a base for regulators of permitted levels of THC.

THC content is an area that requires clarity, but must be conducted in an open and positive manner. The Home Office has been looking into

what is an acceptable amount of THC to have in products; this is evidenced by the recent letter to the ACMD on THC content from Kit Malthouse⁴¹, who is the relevant under secretary as Minister for Crime and Policing. In the letter, he highlights why this is an issue that needs to be taken seriously and needs addressing.

Though there have been many arguments for and against novel food compliance, the UK's CBD advantage hopefully brings a period of regulatory uncertainty to an end. A clear path to compliance is undoubtedly necessary for consumer safety and moving the industry forward.

We hope that regulatory certainty will encourage further investment and innovation in the cannabis space. Mainstream companies will be increasingly likely to enter the sector, creating new jobs and revenue, ultimately boosting the UK cannabis industry.

Chapter 4. Increasing European Competition

Europe is rapidly becoming a central hub for medical cannabis as the fastest growing⁴² market globally. This is driven by the opening of new markets and an increased demand for medical cannabis reform.

Recently, the industry has witnessed fast developments which have capitalised on cannabis across Europe. It is clear the continent is preparing for a booming industry.

Given the advantages highlighted in this report, the UK has the opportunity to become a medical cannabis leader in Europe. Though in a strong position, there is work to be done.

Denmark

Denmark launched their four-year medical cannabis pilot programme in 2018⁴³. The programme permits doctors to prescribe cannabis products that were previously illegal in Denmark. The purpose was to offer a legal way to test medical cannabis treatment and expand access, to provide a better basis for assessing its use and efficacy. This established a controlled framework by which medical cannabis could be prescribed.

Following this, in November 2018 the government allowed bulk exports of medical cannabis. This makes the Danish model unique as it has a trial for medical use and cultivation in progress. Patients have been prioritised for the trial, but emphasis has also been placed on exporting cannabis for economic benefits. This has allowed Denmark to make a big name in the space once the programme is over.

The Danish medical cannabis industry continues to thrive as a safe entry-point for companies wishing to enter the European market. Denmark's

Work must be centred around increasing the number of medical cannabis prescriptions and expanding access. The UK must move quickly to ensure a valuable opportunity is not missed as European competition continues to increase.

This chapter sheds light on Denmark and France. Both have been chosen as examples for how medical cannabis pilot programmes are being implemented. This will be used to highlight what this means for the European market and for UK expansion.

high but transparent regulations have been an excellent means for establishing themselves, further highlighting the benefits of a regulated market. The programme has established expertise in pharma and horticulture, whilst maintaining commitment to innovation and sustainability.

Under the programme, companies can obtain a license to cultivate, manufacture, import and sell cannabis medicine. So far, the pilot has been a resounding success⁴⁴ with an increase in doctors prescribing and patients receiving medicine.

Through their pilot programme, Denmark has been established as a key, leading player in the European medical cannabis industry. This has been an excellent 'foot in the door' for a thriving medical cannabis market through attracting leading industry players. The programme has had a domino effect on the rest of Europe with other countries adopting medical cannabis programmes.

France

France is due to commence their two year national medical trial targeting 3,000 patients suffering from a range of conditions including cancer, epilepsy, multiple sclerosis, palliative care and pain.

As the first nationally authorised non-commercial patient trial in Europe, this is bound to advance the medical market. If successful, the trial could be a big step for developing the French sector.

As one of the centrepieces for European cannabis discussions in 2021, France could become a significant player in expanding patient access. This could lead to expanding operations in Europe as the result of meaningful data gathered from the trial.

With the trial only just starting, there is no guarantee that the programme will be a success, but this is certainly a step forward for market development and increased access.

Call to action

Investment in the nascent UK cannabis sector is undoubtedly booming. More listings are making a positive splash for the industry. The case has been made for the UK opportunity through an economic, innovation and regulatory lens. With growing interest in the European medical cannabis sector, the UK must move fast to ensure they don't miss out.

However, if the medical cannabis industry really wants to make a difference and witness widespread reform, access for patients must be expanded. The industry cannot sustain itself if patient numbers do not increase.

The UK medical cannabis landscape is still filled with barriers. There is a reluctance to prescribe cannabis, with only a handful of prescriptions issued by the NHS since the law changed in 2018. Approximately 2,500 patients access cannabis through a private prescription. However, this is financially inaccessible to most, reflected in the 1.4 million⁴⁵ ill people who have illicitly accessed cannabis to self-medicate.

The medical cannabis industry cannot and will not continue expanding without more patients. Thus, expanding access for patients must be a priority and investment can help make this happen. Pouring money into the industry can broaden access and drive down the price for patients.

Another barrier for the sector is that cannabis does not look or feel like a medicine to doctors. The variety and lack of control when prescribing flower-based products means cannabis is not viewed as a medicine. The incredible innovations emerging are a key way for improving the efficacy, regulation and control over cannabis medicines.

The UK industry is taking off with a quickly changing landscape. Though things are looking good, there is more work to be done. If the UK wants to continue developing into a key industry leader, it must look into a controlled framework for medical cannabis access. Access must be expanded to get medical cannabis properly off its feet and see long term development.

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