



Affinity
GROUP

An Affinity Group eBook:
**The Rise of the Regulated Cannabis
Industry and the Isle of Man Advantage**

An eBook on the flourishing regulated cannabis industry and the unique position of the Isle of Man in the marketplace.

Learn about the remarkable transformation of cannabis from a prohibited substance to a high growth industry and the role the Isle of Man is playing in regulating and promoting opportunities within the dynamic space.

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Introduction

Once overshadowed by stigma and debate, the cannabis industry is currently experiencing a period of evolving attitudes and remarkable growth. Global legal reforms have transformed cannabis from a contentious subject to a blossoming, regulated sector. Countries are proactively shaping regulations to harness the expanding opportunities in the industry, while entrepreneurs, investors, and startups are keenly searching for jurisdictions that offer a secure and stable environment for cannabis investment.

Cannabis for healthcare is leading this charge. In 2022, the global medicinal cannabis market reached \$30 billion, with over 6 million registered medical cannabis patients in the United States. Most projections see this as just the beginning, with forecasts for the industry to double by 2028.

Enter the Isle of Man, a self-governing British Crown dependency in the Irish Sea. Known for its political stability and steadfast legal landscape, the Isle of Man is swiftly establishing itself as a premier jurisdiction for medicinal cannabis companies to develop their operations.

In 2021, the Isle of Man undertook progressive steps to regulate the cultivation, extraction, manufacturing, importation, and exportation of medical and industrial-derived cannabis products. Its robust regulatory framework, managed by the GSC Cannabis, a part of the Gambling Supervision Commission (GSC), offers a myriad of licences, providing much-needed flexibility for entities with varying industry backgrounds and expertise.

Companies looking to capitalise on the Isle of Man's thriving cannabis sector must comply with the E.U.'s Good Manufacturing Practice (GMP) guidelines, ensuring the production processes meet certain quality standards. This emphasis on quality and innovation has created an optimal environment for industry innovation, research, and product development.

With its progressive outlook and robust regulatory environment, the Isle of Man is poised to ride this 'green wave', promoting opportunities for cannabis organisations of all forms within this dynamic space.

Cannabis in growth mode

The rise of the legal, regulated cannabis market marks a pivotal shift in the global marketplace. Historically associated with countercultural movements and largely prohibited by authorities, cannabis has, in recent years, transformed its perception and utility. Driven predominantly by its medicinal applications, the global cannabis industry has witnessed a surging demand projected to continue.

Medicinal cannabis, backed by increasing research, is heralded for its potential therapeutic properties in treating chronic pain, epilepsy, and anxiety disorders. The allure of these applications is matched by the increasing investments streaming into research, development, and commercialisation efforts. Ground-breaking research is not only substantiating the medical claims of cannabis but is also broadening the horizons for its potential therapeutic use.

Countries at the forefront of the cannabis revolution serve as forerunners in the global trend of cannabis legalisation and commercialisation. With their proactive action, the pioneering nations have paved the way for others to reconsider their stance on the substance. Investment flows mirror the promise the industry holds. The rapid evolution from a shadowed, contentious market to a regulated, high-growth sector bears testament to changing societal perceptions and the undeniable economic potential of the industry.

The leading and challenging markets

Globally, the cannabis regulatory landscape is diverse and rapidly evolving. While complete legalisation exists in some jurisdictions, others have adopted more conservative stances. Yet, the trend leans towards more liberal cannabis policies, influenced by changing public opinion and growing awareness of the plant's therapeutic potential.

Promising Jurisdictions:

- **Canada, Malta, South Africa & Uruguay:** These countries have legalised cannabis for adults for medicinal and recreational purposes, marking them as pioneers in the global cannabis industry.
- **Australia, Germany, the Isle of Man, Israel, the Netherlands, and the United Kingdom:** With robust medical cannabis programmes and comprehensive insurance coverage schemes, these nations present promising business opportunities in the cannabis sector.
- **Chile, Greece, Italy, Peru, Poland, Portugal & Thailand:** These countries have all legalised medical cannabis to varying degrees. Thailand decriminalised marijuana and hemp in June 2022, positioning itself as a potential "herbal centre" in Southeast Asia.
- **Brazil, Denmark, Greece, Ireland, New Zealand, Norway, and Sweden:** These countries take a forward-thinking approach toward medicinal cannabis. However, recreational use is illegal and strictly prohibited.

- In the **United States**, where medicinal cannabis use is legal in thirty-seven states, four territories, and D.C., and recreational use in nineteen states, two territories, and D.C., the demographic of consumers is skewed towards individuals aged 50 and above. This trend is attributed to the higher risk of chronic diseases post-50 and the efficacy of cannabis in treating such conditions.

Challenging Jurisdictions:

- **Russia, China & South Korea:** Despite the global trend towards liberalising cannabis laws, these nations maintain stringent regulations on the use of cannabis. Particularly in Russia and China, severe legal penalties make them challenging jurisdictions for cannabis businesses.
- **Japan:** Similar to the nations above, Japan has strict drug laws, with cannabis use, except CBD, being illegal, whether for medical or recreational purposes. The legal ramifications for cannabis-related offences are severe, which creates a highly challenging market.

The global cannabis industry

- There are more than **6 million** registered medical cannabis patients in the United States alone, according to a study by the Marijuana Policy Project (ASA).
- Medical cannabis is used therapeutically by patients for a wide range of conditions, including chronic pain, anxiety, depression, seizures, nausea, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), Crohn's disease, glaucoma, multiple sclerosis, and muscle spasms.
- **Over 13,000 physicians** in Canada prescribe medical cannabis, with an average administration of 2.1 grams of cannabis per day (CBC).
- **72%** of British adults said they strongly support the legalisation of cannabis-based medicines by the British Government, while 18% disagree (Hill Dickinson).
- At the end of 2019, there were less than 250 active medical cannabis users in the U.K. By the end of 2024, that number is expected to rise to 400,000 (Statista).
- A 2018 report from the Cannabis Consumers Coalition found medical cannabis patients come from all walks of life, ages, and backgrounds.



A closer examination of uses and applications

Medicinal cannabis, with its history spanning millennia, has undergone a significant revival in recent years. The modern era has seen the transition of cannabis from primarily anecdotal applications to a rapidly growing field backed by research and clinical trials.

Cannabis: Uses and applications:

1. Chronic pain management

Chronic pain affects millions globally, severely impacting sufferers' quality of life and overall well-being. Studies have demonstrated that cannabinoids, particularly CBD and THC, possess analgesic properties that can be utilised for effective pain management. These compounds interact with the body's endocannabinoid system, alleviating pain and reducing inflammation. This has led to the widespread use of medicinal cannabis products for conditions such as arthritis, fibromyalgia, and endometriosis.

2. Epilepsy and seizures

The potential of medicinal cannabis to reduce the frequency and severity of seizures, especially in treatment-resistant forms of epilepsy, has garnered significant attention. In 2018, the U.S. Food and Drug Administration approved Epidiolex, a CBD-based drug, which is a testament to this potential. In 2019 the European Medicines Agency followed suit with the U.K. approving Epidiolex in 2021 and 2022. Patients, particularly children with severe epilepsy, have experienced significant relief with cannabinoid-based treatments.

3. Anxiety and depression

Mental health has taken centre stage in recent healthcare discussions, and the role of cannabis in managing disorders like anxiety and depression is promising. Specific cannabinoids have demonstrated anxiolytic effects, helping to calm the nervous system and potentially reduce symptoms. Ongoing research continues to explore the full scope and optimal dosages for such applications.



4. Nausea and appetite stimulation

Chemotherapy-induced nausea and vomiting are among cancer patients' most distressing side effects. Medical cannabis, especially THC-dominant strains, has been beneficial in reducing nausea and stimulating appetite. This dual action provides crucial support for patients undergoing debilitating treatments.

5. Neurodegenerative diseases

Conditions such as Parkinson's, Alzheimer's, and Multiple Sclerosis are marked by the degeneration of nervous tissue over time. Preliminary research has indicated that cannabinoids possess neuroprotective properties. They may play a role in slowing disease progression, managing symptoms, and improving the quality of life for patients with these conditions.

6. Glaucoma

Traditionally one of the primary reasons for medicinal cannabis prescriptions, glaucoma results in increased intraocular pressure, which can lead to vision loss. Cannabis has been shown to reduce this pressure, providing symptomatic relief. While not a definitive cure, it offers another tool in the arsenal against this eye condition.

The challenges of the cannabis industry

While the cannabis industry is experiencing rapid growth, it faces significant global challenges. These range from legal constraints to societal views and operational difficulties. This section provides a clear overview of these challenges and their implications for the sector.

Legal challenges

One of the most significant hurdles confronting the cannabis sector is the complex and often incongruent legal landscape. Regulatory obstacles exist at the national and international levels, creating a challenging labyrinth for businesses to navigate. Variances in legislation across countries can complicate matters further. For instance, while a country like Canada has completely legalised cannabis, it remains strictly controlled in many nations. Such discrepancies create uncertainties for businesses looking to expand across borders, requiring them to understand and comply with the different regulations, which can often be daunting and resource-intensive.

Social challenges

Despite the increased acceptance of cannabis, particularly for medicinal use, stigma remains a considerable obstacle. Negative stereotypes associated with cannabis use continue to pervade societies worldwide. This can influence individual attitudes and behaviours, making potential users hesitant and impacting market growth. Therefore, there is a compelling need for social perspective shifts through education and increased awareness about the potential benefits of regulated cannabis.

Operational challenges

The cannabis industry's operational challenges are manifold. Ensuring quality control and maintaining compliance with GMP guidelines is critical, as substandard or non-compliant products can lead to regulatory actions and harm the business's reputation. But meeting these stringent standards requires a skilled workforce, often scarce in this emerging industry. The ability to attract and retain trained personnel, from cultivation experts to lab technicians, poses a unique challenge for businesses in the cannabis sector.



Choosing the Isle of Man

In the centre of the Irish Sea, nestled between Great Britain and Ireland, the Isle of Man is not just an idyllic island escape but a dynamic hub for international cannabis companies. Known for its favourable tax structure, the island entices businesses with a 0% corporate tax rate, positioning it as a tax-advantageous jurisdiction.

Beyond fiscal benefits, with its strategic location, the Isle of Man offers businesses unparalleled access to major markets across Europe and beyond. Its reputation as a licensing authority is bolstered by a forward-thinking regulatory framework, reflecting its prowess in cryptocurrency, eGaming, and FinTech. Its inviting landscape and rich cultural tapestry make it an appealing destination to live, work, and innovate.

Geographical location

The Isle of Man provides easy access to U.K. and European markets, making it an ideal location for companies seeking to expand their operations in these regions. The island can also serve as a gateway to worldwide markets in North America, South America, and Asia.

Regulation

The Isle of Man is well-known for its forward-thinking approach and is a recognised hub for other industries, including cryptocurrency, eGaming, and FinTech. Regulators create an effective public-private partnership that helps new companies grow quickly while remaining 100% compliant.

Favourable tax policies

With a 0% corporate tax rate, the Isle of Man has a very pro-business-friendly environment.

People power

The Isle of Man has a highly skilled workforce with a strong emphasis on technology and innovation.

Stability

The island's robust legal framework creates a stable and secure environment for medical cannabis companies. The Government has proactively established a supportive regulatory environment for the emerging cannabis industry. An example is introducing the Misuse of Drugs (Cannabis) Regulations 2020, the Transfer of Functions (Cannabis) Order 2020, and the Misuse of Drugs (Cannabis Licences) (Data Processing) Regulations 2022, which supplement the Misuse of Drugs Act 1976.



Setting up a cannabis company

As the cannabis industry witnesses significant growth, establishing a cannabis company offers a prime opportunity to tap into this expanding market. This section provides essential steps and considerations for setting up a business, ensuring a solid foundation in this promising sector.

1. Setting up the company

For those looking to start a cannabis company in the Isle of Man, the first step is to create a business under the Isle of Man Companies Act 2006. This means picking a unique company name, choosing a director, and having a company secretary. Once these steps are done, the business can be registered with the Isle of Man Companies Registry. After paying the necessary fees and getting approval, the business will receive a certificate of incorporation to confirm it's officially set up.

2. Getting the business ready

After establishing the company, selecting an optimal location in compliance with local regulations becomes paramount for cultivating and producing cannabis products. This location must also be strategically chosen to attract top talent – from botanists and laboratory technicians to security personnel – especially considering the niche skill set demanded in the cannabis industry. Equally crucial is implementing robust operational protocols, ensuring meticulous oversight from cultivation stages to distribution tracking.

3. Applying for a licence with the GSC

To legally operate, businesses need a licence from the Gambling Supervision Commission (GSC) in the Isle of Man. When applying, companies should provide a detailed business plan, explain their operations, show they have enough money to run the business and describe their security measures. They also need to provide information about the people who work for them.

Types of licences available

There are different licences for different activities in the cannabis industry on the Isle of Man:

- **Cultivation Licence:** For growing cannabis indoors. It costs £47,250 for the first year and £36,750 every year after.
- **Research Licence:** For studying new types of cannabis. It's £21,000 the first year and £12,600 every year after.
- **Transport & Storage Licence:** For moving and storing cannabis products. It's £5,250 for the first year and £2,625 every year after.
- **Manufacture Licence:** For making cannabis products. It's £23,625 for the first year and £15,750 every year after.
- **Extraction Licence:** For getting ingredients from the plants. It's £23,625 for the first year and £18,375 every year after.
- **Import & Export Licence:** For bringing in and sending out cannabis products. It's £10,500 for the first year and £7,875 every year after.
- **Analysis Licence:** For labs testing cannabis samples. It's £13,125 for the first year and £8,400 every year after.

4. Compliance with good manufacturing practice (GMP)

Ensuring adherence to GMP standards is critical, guaranteeing that products are produced and controlled to the highest standards of quality. Implement rigorous testing procedures, regularly audit operational compliance and address any non-compliance swiftly and comprehensively.

5. Working with a Corporate Service Provider (CSP)

A CSP can help companies handle tasks like setting up the company, keeping track of rules, and other services. This lets the company leaders concentrate on running the business and making key decisions.

The role of a Corporate Service Provider (CSP)

Navigating the complexities of the cannabis industry requires specialised knowledge and expertise. A CSP is integral in guiding businesses through regulatory, compliance, and operational challenges.

1. Regulatory assistance

A CSP ensures that companies remain updated and compliant with the ever-evolving legal framework surrounding cannabis. This involves assisting with licensing applications, periodic renewals, and ensuring adherence to local and international standards.

2. Financial oversight

By managing accounting, auditing, and tax-related matters, these providers play a pivotal role in the financial health of a cannabis enterprise. They help businesses optimise their financial operations and ensure compliance with tax obligations.

3. Business structuring

For companies new to the cannabis industry, corporate service providers offer guidance on optimal business structures, whether it's a sole proprietorship, partnership, or limited liability company. Their insights can prove invaluable in mitigating risks and enhancing operational efficiency.

4. Strategic guidance

These providers can offer strategic advice by keeping a pulse on industry trends and shifts, enabling businesses to adapt, grow, and capitalise on emerging opportunities.



"We approach the cannabis sector with the same commitment as other sectors, providing bespoke and tailored services. Our team members hold exceptional expertise in licensing and the regulatory environment on the Isle of Man, and we welcome all enquiries from both the medicinal and industrial cannabis space."

Andy Morgan, CEO, Affinity Group

GrowLab Organics: An Isle of Man success story

Affinity Group assisted GrowLab Organics with bespoke corporate services to structure their entity in the Isle of Man.

GrowLab Organics is revolutionising how companies grow, process and utilise cannabis in the British Isles. The company brings together an interdisciplinary team of experts with backgrounds in agriculture, pharmaceuticals, marketing, and business, using the most advanced growing methods and cutting-edge equipment to produce the highest-grade medicinal cannabis.

The company built its blockchain software to trace all its plants from soil to oil. It has already grown hemp under licence in England with a sister company and is about to begin the construction phase for a fully licensed medicinal cannabis research facility.

GrowLab Organics is thriving on the Isle of Man. Alex Fray, CEO of GrowLab Organics, credits much of the firm's success to its location.

"The legal cannabis industry is highly regulated and exceptionally complex. As the first licence holder in the Isle of Man, and one of the first in the British Isles, we are walking a largely untrodden path, and as a result, our business requirements are diverse and often time critical.

Working with Affinity feels like a partnership, as they go above and beyond to deliver for us. They took the time to understand our unique business model and provided bespoke structuring to meet our needs. The team are committed to our success and are technically strong, professional and personable.

I can highly recommend Affinity's services."

Learn more about GrowLab Organics at:
<https://growlaborganics.com/>



Affinity Group: Leading the way in the Isle of Man

With a 100% success rate in licensing applications at Affinity Group, we have proven expertise in navigating the Isle of Man's regulatory framework.

Our established relationship with the Gambling Supervision Commission, the Government and our network of intermediaries, including banks and law firms, places us in an excellent position for the regulated cannabis sector on the Isle of Man, and our previous success in emerging sectors indicates our ability to adopt innovative services.

We are convinced the newly regulated cannabis sector holds huge potential, and clients can benefit from our bespoke structuring services.

Our services include:

- Cannabis consultancy
- Business plan assistance
- Licence application compilation
- Assistance with government grant applications
- Establishment of bank accounts
- Liaison with regulators, lawyers and auditors
- Local employment assistance and guidance
- Company incorporation and administration
- Provision of directorship services
- VAT registration
- Completion of VAT returns
- Provision of Company Directors and Secretary

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