

RELM RISK BRIEFING: **CANNABIS** 2026



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I FOREWORD

The global cannabis sector has moved from experiment to enterprise. What began as a patchwork of early medical markets now operates at international scale, shaped by regulation, investment, and public demand. Yet, as the industry matures, its exposure to operational, financial, and reputational risk has become clearer.

At Relm, we've seen this evolution up close. As one of the first insurers dedicated to cannabis and other emerging industries, we've underwritten through the sector's growing pains, and watched risk management become the measure of long-term stability. Operators that prioritize governance, compliance, and transparency, not only protect their balance sheets, but also build the trust needed for sustained growth.

This *Risk Briefing: Cannabis 2026* shares what we've learned from that experience. It analyzes how regulation, insurance, and operational practice intersect across the global supply chain, drawing on data and conversations with market leaders who are setting new standards in safety, sustainability, and accountability.

Relm remains committed to supporting that progress. Through tailored coverage, data-driven insight, and collaboration with regulators and innovators, we continue to help cannabis enterprises manage uncertainty and build lasting resilience as the sector enters its next stage.



Claire Davey,

PhD, ACII, CISSP

SVP, Head of Product Development & Emerging Risk

Claire Davey leads Relm's Product Innovation & Emerging Risk team, overseeing product development and emerging risk strategies. With over 13 years in the London insurance market, she specializes in cyber and technology risks, as well as financial and professional lines.

Prior to joining Relm in 2021, she worked as a Lloyd's broker, advising large corporations on cyber and contractual technology risks. Claire holds ACII and CISSP qualifications and continues to expand Relm's insurance portfolio.



EXECUTIVE SUMMARY

Global legal cannabis sales are projected to exceed \$55 billion by 2030, with medical markets accounting for about 27% of total revenue. While this growth signals maturity, it also exposes the sector's uneven regulation and persistent operational risk. Few jurisdictions offer full alignment with Good Manufacturing Practice (GMP) standards, and contamination or quality failures caused 40% of all cannabis product recalls in 2024.

Relm's *Risk Briefing: Cannabis 2025* analyzes these challenges across six stages of the supply chain. Drawing on interviews, case studies, and data from the United Kingdom, Europe, the United States, and Canada, the report outlines where risk concentrations are highest and how leading operators are building stability and trust.

KEY FINDINGS INCLUDE:

- **Cultivation:** Highly vulnerable to biological contamination, environmental instability, inconsistent genetics, and security breaches. Operators are addressing these issues through controlled-environment agriculture, tissue culture propagation, integrated pest management, and strict hygiene protocols.
- **Manufacturing and Extraction:** Variability in raw materials and inconsistent oversight remain leading causes of production risk. Adherence to GMP standards, in-house testing, and selective supplier relationships are emerging as reliable control points.
- **Testing:** Ensuring product quality and regulatory compliance depends on rigorous testing. Operators are increasingly combining in-house laboratories with accredited third-party testing to maintain consistency, traceability, and faster release cycles across markets.
- **Packaging and Labeling:** Stability and safety rely on validated packaging materials, sterile processing, and long-term shelf testing. These measures help ensure accurate regulatory labeling and reduce spoilage.
- **Distribution and Logistics:** Exposure to temperature fluctuation, theft, and fragmented rules continues to disrupt operations. Good Distribution Practice (GDP)-aligned transport protocols, route monitoring, and cargo insurance remain essential safeguards.
- **Retail and Pharmacy:** Market accessibility and reimbursement policies vary widely. Initiatives that stabilize domestic supply and expand pharmacy training are helping to improve patient and consumer access.

The report also highlights insurance as a driver, and more importantly, an indicator of risk maturity. Coverage options remain limited and new solutions are needed, but capacity is expanding across particular lines of insurance, including general liability (GL) directors and officers (D&O) liability. As regulatory clarity improves and operators adopt stronger governance and data transparency, insurers are beginning to price and structure policies with greater precision. The importance of insurance and the role it plays in developing the cannabis sector cannot be overstated, and this report demonstrates how it is a critical step toward greater financial resilience.

COMMERCIAL INSIGHT

The next phase of cannabis growth will belong to operators that act first to professionalize risk. Those who build insured, transparent operations now will define standards, secure capital, and outpace slower competitors.



I INTRODUCTION

The cannabis industry has grown into a complex global market spanning medical, pharmaceutical, and adult-use products. Expansion has created commercial opportunity but also magnified the operational and regulatory pressures that distinguish cannabis from established sectors.

Companies face irregular policy frameworks, mercurial product standards, and continued financial and social scrutiny. These factors compound common supply chain challenges like crop failure, contamination, and security risk, which demand disciplined governance and risk management at every stage.

This *Risk Briefing: Cannabis 2026* report serves two purposes:

1. To provide detailed economic and regulatory analysis of the largest and fastest-growing cannabis markets.
2. To examine the risks operators encounter when transacting within these markets and outline practical strategies to mitigate them.

The report focuses on developments across the United Kingdom, Europe, the United States, and Canada. It analyzes both upstream and downstream operations through six critical stages of the supply chain: cultivation, manufacturing and extraction, testing, packaging and labeling, distribution and logistics, and retail and pharmacy.

Section Two draws on interviews with operators, case studies, and regulatory insights to identify where risk concentrations emerge and how effective governance and insurance can reduce exposure. The findings highlight not only the areas of highest vulnerability but also examples of risk maturity that are shaping standards across the sector.

By mapping these dynamics, the briefing aims to equip regulators, investors, and operators with practical knowledge for strengthening compliance and improving resilience across the global cannabis value chain.



SECTION 1: MARKET OVERVIEW

Throughout 2024 and 2025, major developments in the international cannabis sector have provided a fairly positive outlook for future growth, with total global cannabis sales (medical and adult-use) forecasted to reach \$42 billion in 2025 and \$56 billion by 2030.

On a global scale, the industry continues to benefit from legislative developments toward the legalization of medical and adult-use cannabis, yet businesses continue to face daily challenges with regard to regulatory requirements, competition, demand, and patient access, all of which prevent growth while signifying future potential.

When evaluating the sales forecast for the global cannabis industry, it is evident that the adult-use market significantly surpasses the medical market. This disparity is primarily due to a broader consumer base, regulatory liberalization in key markets, and higher per-capita consumption rates associated with recreational use. Adult-use markets in North America have established pathways for large-scale commercial cultivation and retail, leading to rapid growth in product availability, branding, and consumer choice. While in Europe, recent adult-use legalization developments in the Netherlands, Germany, and Switzerland all provide a growing future for the market internationally.

Conversely, the medical market encounters limitations due to stricter prescribing regulations, fragmented regulatory frameworks, insufficient public reimbursement in crucial markets, and prolonged processes for patient onboarding, especially in Europe and developing markets. Additionally, as legal adult-use sectors develop in various markets, the medical cannabis market contracts as patients transition their purchasing behavior from medical avenues to adult-use options, driven by greater ease of access and a wider range of products.

Looking ahead, continued legalization efforts in major economies are expected to strengthen the dominance of the adult-use cannabis market. Meanwhile, the medical segment is likely to grow more gradually, influenced by pharmaceutical standards, clinical evidence requirements, and reimbursement pathways. However, since cannabis regulations vary significantly from country to country, the growth of both the medical and adult-use sectors will depend on how commercially open the regulatory frameworks are.

Given the significant variations across markets, the following sub-sections will provide a country-and state-level examination of the key European and North American cannabis markets. This is due to considerable differences in regulatory frameworks, market maturity, and consumer access across jurisdictions. Each market presents unique challenges and growth drivers, encompassing everything from licensing models and reimbursement policies to supply chain structures and cultural acceptance.

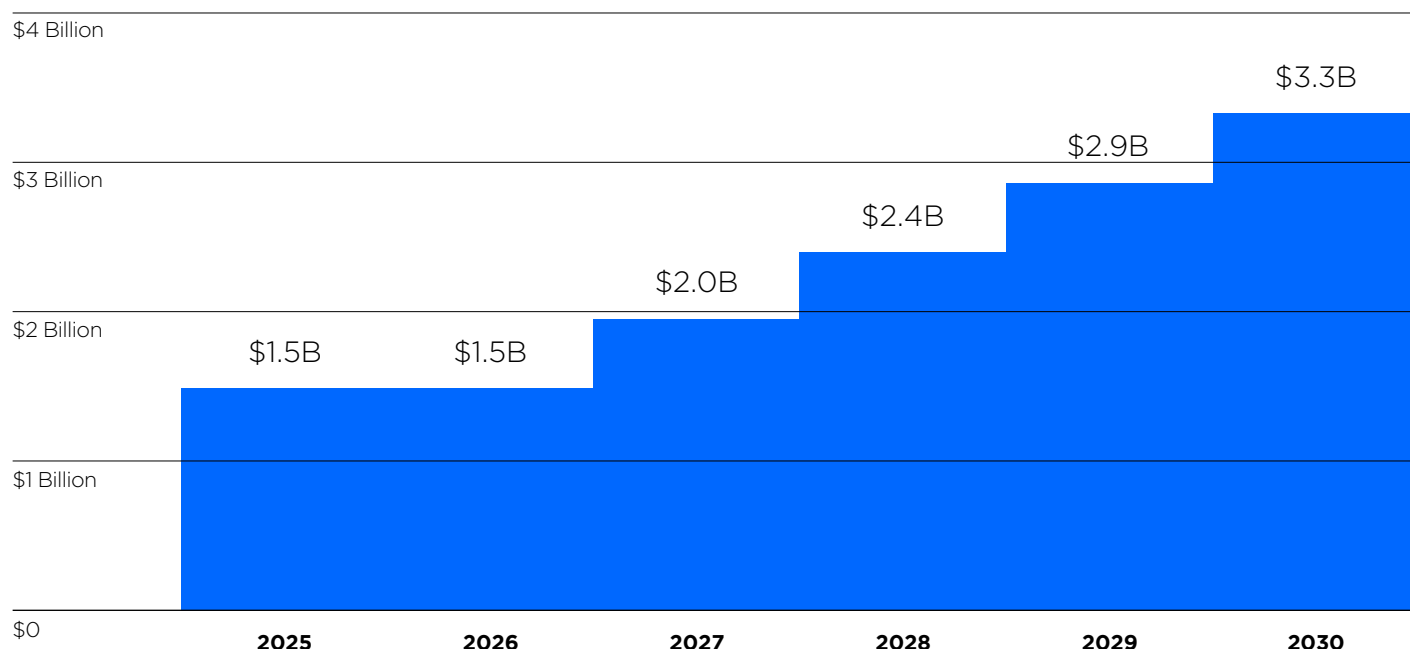
Nevertheless, shared themes such as managing oversupply, navigating international and domestic law, and balancing public health with economic opportunity offer valuable parallels. A regional comparison not only highlights these differences and similarities but also provides critical insight into the risks, opportunities, and operational hurdles cannabis operators encounter when expanding across diverse legal and commercial landscapes.

Graph 01 **Global Medical and Adult-Use Cannabis Sales Forecast (2025-2030)**



EUROPE

Graph 02 **European Medical Cannabis Sales** (2025 - 2030)



Source: Prohibition Partners, 2025

It is forecasted that total European cannabis sales (medical and adult-use) will reach \$1.5 billion in 2025 and \$3.3 billion by 2030. The growth of the adult-use market is driven by recent developments including Switzerland planning to fully regulate the nonprofit sale of adult-use cannabis in 2026, the Netherlands launching regulated cannabis sales through its pilot project, cannabis associations distributing cannabis in Malta and Germany, while the Czech Republic implemented an adult-use framework that legalizes personal possession and home cultivation. In terms of the medical cannabis market, Europe continues to see strong growth as medical operators benefit from the establishment of permanent medical cannabis frameworks in Denmark and France, the growth of the UK and German markets, and the further adoption of medical cannabis frameworks by European nations.

To understand the future growth of the European cannabis market, it is important to consider the varying medical cannabis frameworks and market dynamics across European countries. This includes examining the commercial freedom available to operators and the specific trends and challenges each market faces.



Europe is opening up, with Germany and France leading the way. Portugal has also positioned itself as a key export hub. Beyond that, other EU countries are up-and-coming, but again, it depends on clear and stable regulations. The companies that win will be those who deliver consistent, pharmaceutical-quality cannabis medicines at scale.



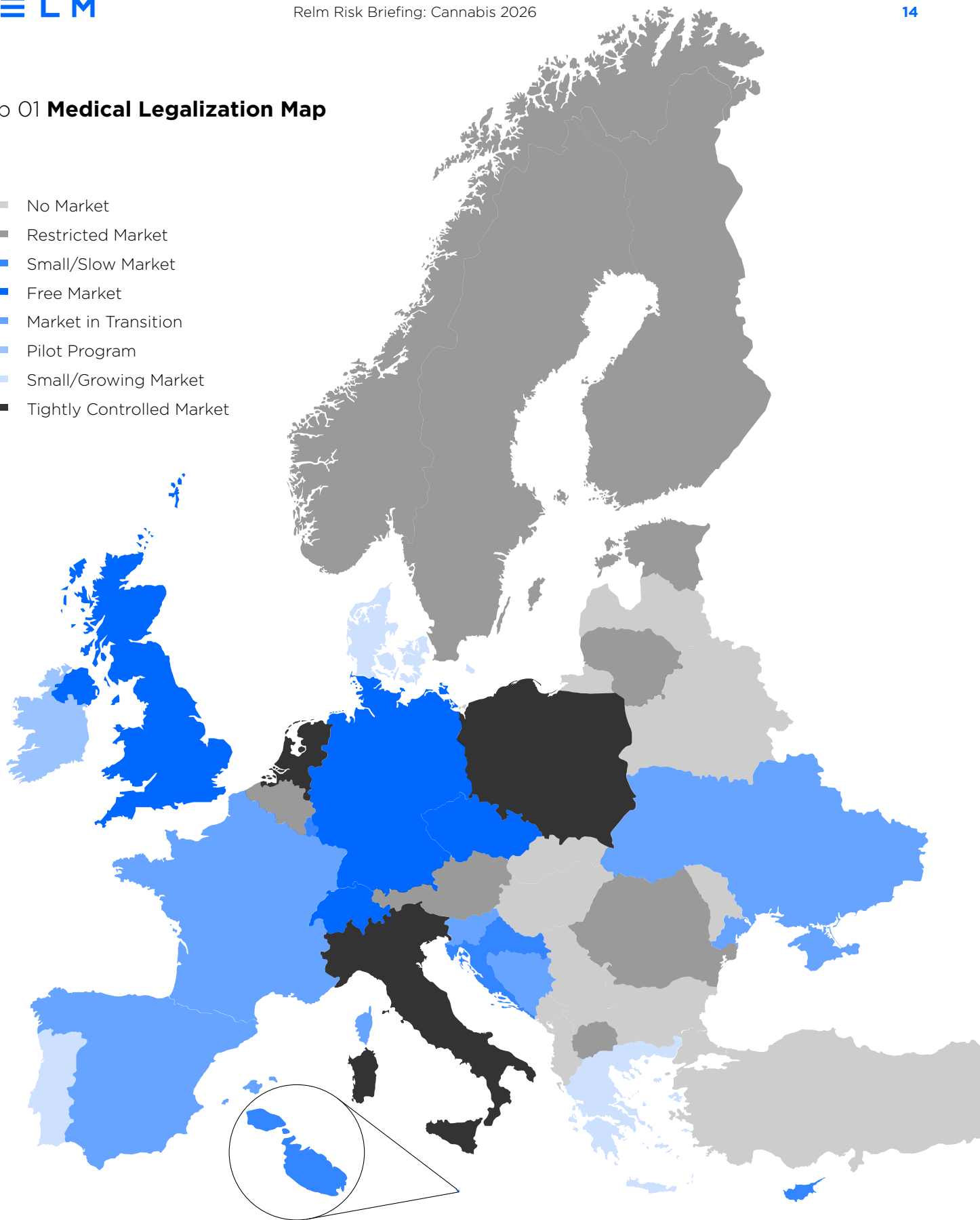
Michael Sassano,

CEO and Founder, SOMA Pharmaceuticals
(See Appendix for full interview.)



Map 01 Medical Legalization Map

- No Market
- Restricted Market
- Small/Slow Market
- Free Market
- Market in Transition
- Pilot Program
- Small/Growing Market
- Tightly Controlled Market



Medical Framework

Free Markets

Markets in Transition

Pilot Programs

Restricted Markets

Small/Growing Markets

Small/Slow Markets

Tightly Controlled Markets

Markets and Details

Germany: Reimbursement by public health insurers is available. Intense competition stems from a large number of suppliers. The market is dominated by imports.

UK: There is almost no public health reimbursement available, and patient access is almost exclusively conducted through private clinics. As with Germany, the market faces intense competition due to numerous suppliers importing into the market. However, domestically cultivated products have begun to enter the market.

Czech Republic: Reimbursement by public health insurers is available. Strong competition driven by imports and domestic production. Growth is limited by the number of patients.

Switzerland: The market liberalized in 2022, yet there is no public reimbursement. Any doctor can prescribe, but patient use is low. Supplied by imports and domestic production.

France: Currently undergoing a transitional period, whereby generalized medical cannabis access is planned by April 2026, as a result of a successful pilot project.

Spain: Authorities are currently developing their first medical cannabis access framework. Timeline for effective access unclear.

Slovenia: Legislation was introduced in April 2025 to regulate medical cannabis cultivation, production, trade, and supervision. License structures for cultivation, manufacture, and exports are proposed.

Ukraine: Legalized medical cannabis in February 2024, established a regulatory framework in August 2024, and saw the first products listed in January 2025. The market will initially be reliant on imports, with domestic production forecasted to launch by 2028.

Bosnia and Herzegovina: In December 2025, the Council of Ministers of Bosnia and Herzegovina adopted the decision to legalize cannabis for medical purposes. The country plans to implement a monitoring system and licensing requirements for the production, distribution, transportation and dispensation of medical cannabis.

Ireland: Currently, running a pilot program of <100 patients that concludes in 2026. There are six approved products from four producers; growth is slow.

The following countries allow access to medical-use cannabis only under exceptional circumstances, via individual authorization and minimal imports:

Austria, Belgium, Estonia, Finland, Lithuania, North Macedonia, Norway, Romania, Sweden

Denmark, Greece and Portugal have an emerging patient base for medical cannabis, but full growth limited by population size.

Legal, but extremely low patient numbers due to small population and limited infrastructure. Countries include: **Croatia, Malta, Cyprus, Luxembourg**

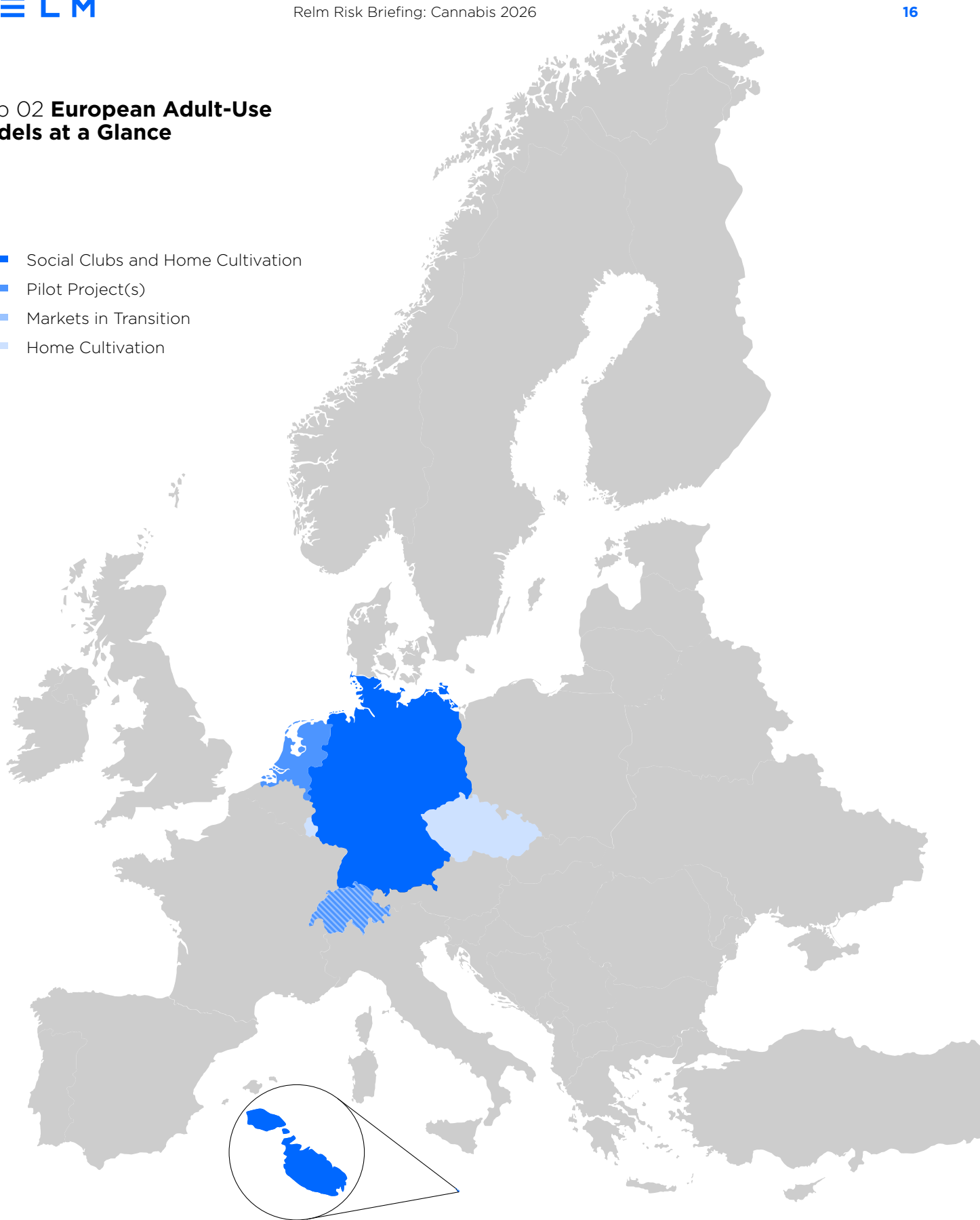
Netherlands: A single domestic producer operates under a tight supply agreement with the government, which controls distribution.

Italy: The medical-use market is supplied by tenders for government-negotiated agreements (five producers supply ~15 products). Limited domestic production exists, which is cultivated by the Italian military.

Poland: All products must go through an application process, which can take two to three years. Currently, 50 products are on the market. No public reimbursement and treatment is prohibitively expensive for patients.

Map 02 **European Adult-Use Models at a Glance**

- Social Clubs and Home Cultivation
- Pilot Project(s)
- Markets in Transition
- Home Cultivation



Adult-Use Framework

Pilot Project(s)

Switzerland: Development of adult-use cannabis through the expansion of its pilot studies. These controlled pilots are designed to gather crucial data on the impact of various regulatory models before a broader implementation.

The Netherlands: The controlled supply chain experiment has launched. Whereby, all steps of the cannabis supply chain are controlled. Participating coffeeshops in 10 municipalities are now exclusively stocking regulated products, allowing the government to closely monitor the entire supply chain, from cultivation to sale.

Social Clubs and Home Cultivation

Malta: The first country in Europe to allow home cultivation and initiate sales of adult-use cannabis in cannabis associations. The framework is facilitated through a unique model of nonprofit associations, emphasizing a community-focused and regulated approach to distribution.

Germany: Possession and home cultivation of cannabis has been legalized, which will facilitate the industry's growth. This reform also includes provisions for the establishment of cannabis associations, mirroring elements of the Maltese model.

Home Cultivation

Czech Republic: As of January 2026, adults at the age of 21 and above are legally allowed to cultivate three cannabis plants and possess 100 grams of cannabis at home.

Luxembourg: Adults over 18 are legally permitted to cultivate up to four cannabis plants per household.

Markets in Transition

Switzerland: The country stated its ambition to implement a comprehensive legal adult-use framework by 2026, informed by evidence and careful planning.

The table provides an overview and market dynamics of established adult-use cannabis frameworks in Europe.

In summary, Europe's cannabis landscape is undergoing a complex and transformative shift, shaped by both fragmented medical frameworks and evolving approaches to adult use. On the medical side, each country operates under its own regulations governing access, prescriptions, importation, exportation, domestic production, and dispensation.

This fragmentation has produced divergent outcomes: 'Free Markets' such as the UK and Germany are witnessing growth, while 'Tightly Controlled Markets' like Italy and the Netherlands remain stagnant.

The past four years have seen a clear trend toward various forms of adult-use legalization. These developments collectively highlight a dynamic and evolving regulatory environment, where approaches vary. Still, the overall direction is toward more formalized and regulated frameworks that will facilitate the growth of the industry over the next five years.

This ongoing shift reflects a complex interplay of public health priorities, economic opportunities, social justice concerns, and efforts to curb the illicit market. However, despite wider acceptance of cannabis legalization, the overarching framework of the UN Drug Conventions continues to limit the scope and pace of commercial adult-use implementation across Europe.

To provide more granular insights into Europe, the following section will examine the recent developments, trends, and challenges of key cannabis markets in the region. Countries have been selected based on their size and commercial activity in the medical and/or adult-use sectors.

GERMANY



ADULT-USE FRAMEWORK:

Social Clubs and Home Cultivation -
Pilot Projects Planned



LAUNCH OF ADULT-USE FRAMEWORK:

April 2024 (personal and home cultivation)
and July 2024 (Cultivation Associations)



DATE OF FIRST ADULT-USE SALES

(DISTRIBUTION TO MEMBERS):
November 2024



NUMBER OF LICENSED CULTIVATION ASSOCIATIONS (2025):

>360



LAUNCH OF MEDICAL FRAMEWORK:

March 2017 and
April 2024



ESTIMATED PATIENT SIZE

(2025):
600,000 - 700,000



NUMBER OF MEDICAL PRODUCTS:

>1,200

MEDICAL

Germany's new law governing the country's cannabis framework, the Cannabis Act (CanG) which consists of the laws regarding adult-use and medical cannabis, came into effect on April 1 2024, dramatically changing the medical and adult-use cannabis landscape in the country. Through the CanG, cannabis has become 'quasi-legalized' for adult-use consumption, while simultaneously widening the medical market by easing patient access as well as eliminating regulatory and operational barriers for medical cannabis operators.

Germany was already Europe's largest cannabis market, however the implementation of MedCanG in April 2024 significantly boosted growth and streamlined the commercial medical cannabis industry.

Medical cannabis is now classified as a prescription drug, simplifying doctor processes and patient access. Companies in the supply chain still need permits but face fewer restrictions. Strict tender requirements for domestic cultivators have been abolished, allowing expansion and diversification. New cultivators can enter the market.

Germany's medical cannabis imports have been steadily increasing from 2017 to 2023, averaging an annual growth of 4,000 to 8,000 kilograms. In 2024, imports surged to 72,000 kilograms due to new regulations, and by the first three quarters of 2025, import volumes were already nearly double the total for 2024. Telemedicine platforms are the main growth driver, boosting patient access and market expansion through online clinics and pharmacies. However, in June 2025, a bill amending the MedCanG was introduced that proposed banning telemedicine for initial prescriptions and prohibiting the online pharmacy delivery of cannabis flowers. On 18 December 2025, the Bundestag held its first reading of the proposed amendments and will now undergo a detailed examination and revision by the parliamentary health committee. Further readings and votes in the Bundestag are expected in spring 2026. Depending on the level of restrictions, the market's growth and size could be significantly impacted.



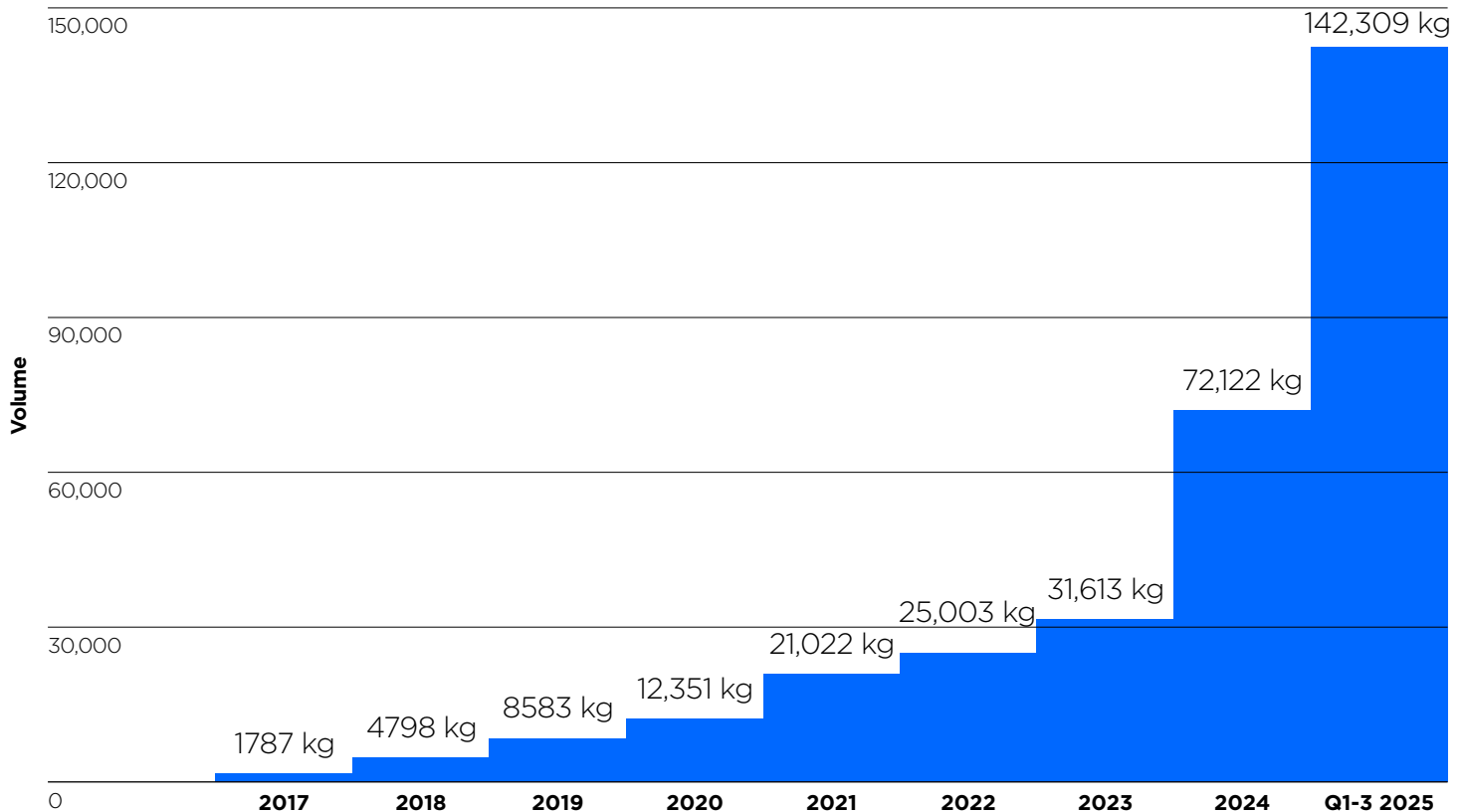
First, we must register each new product name with the authorities, which can take up to three months. Other challenges include the limited availability of qualified logistics partners and rapidly evolving market expectations. Success depends on close teamwork between our supply chain, product, and quality teams to ensure compliance and smooth market entry.



Justin Stenchly,

Supply Chain Manager, Enea
(See Appendix for full interview.)

Graph 03 **Medical Cannabis Imports** (2017 - Q3 2025)



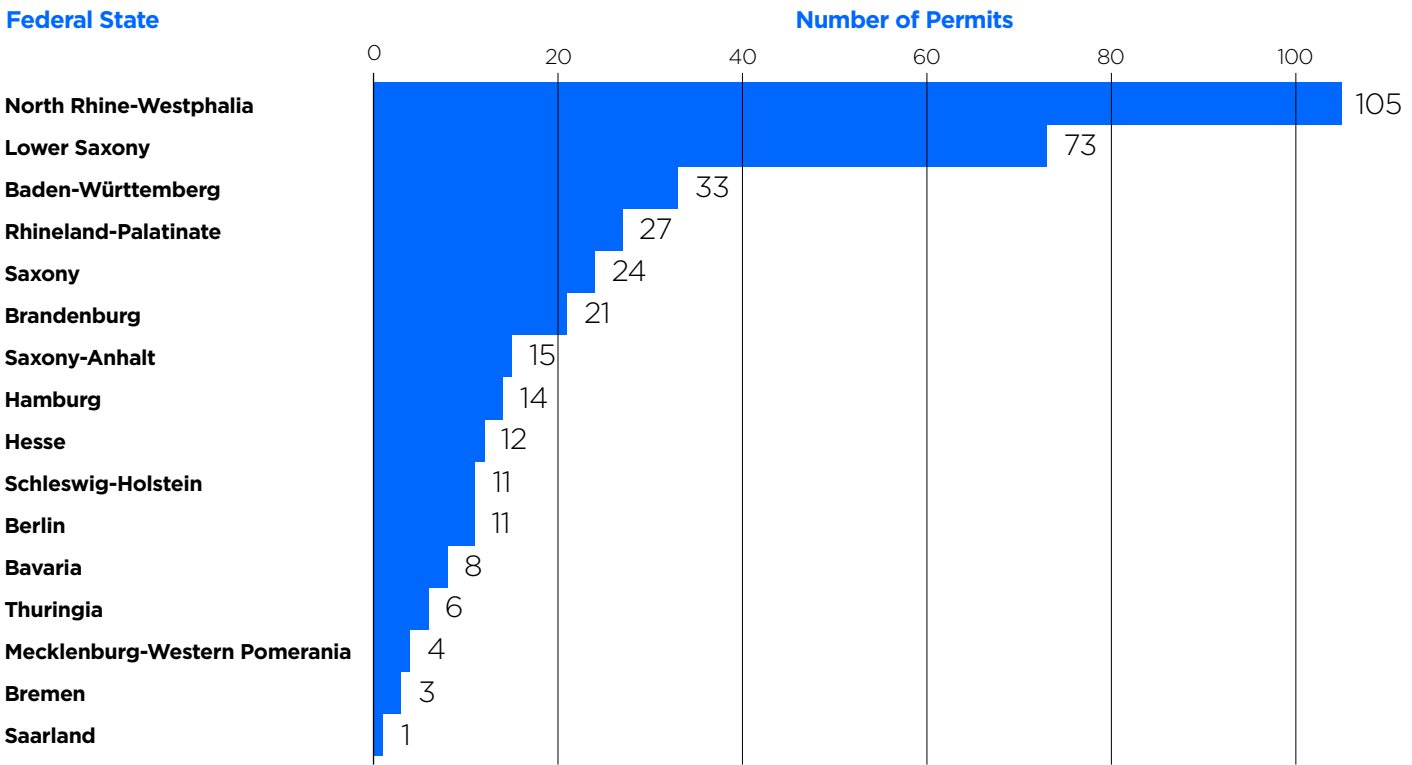
ADULT-USE

Germany’s Consumer Cannabis Act (KCanG), effective from April 1 2024, allows adults to possess, consume, and cultivate cannabis at home with restrictions. Since July 1 2024, cannabis cultivation associations can obtain permits to supply members, with initial associations already active. This ‘quasi-legalization’ is the first pillar of Germany’s Two-Pillar model. Progress on the second pillar, commercial cannabis supply chains, is uncertain due to the change in

government. Several German cities have expressed interest in scientific pilot projects for commercial supply chains.

Since July 1 2024, German cannabis associations can apply for operational permits, but inconsistent state-level issuance has led to disparities. As of December 2025, 806 applications resulted in 368 permits. Associations set fees and prices.

Graph 04 Cannabis Associations’ Permits by Federal State (December 2025)



Source: Prohibition Partners and BCAv, 2025

KEY CHALLENGES

POLITICAL ENVIRONMENT

Following the change in government, cannabis has become a highly contentious subject, with politicians seeking to restrict or reverse legalization. This presents significant uncertainty for the industry and its investors.

FEDERAL STATE DIFFERENCES

Germany’s federal state laws create varied regulatory frameworks, rules, and requirements for cannabis associations and users. This makes it more challenging for operators and other industry players to establish themselves.

HIGHLY COMPETITIVE

With over 1200 products and over 50 distributors, the medical cannabis market is oversaturated with an abundance of products, leading to a lowering of prices and capturable market share.



SWITZERLAND



ADULT-USE FRAMEWORK:

Pilot Projects



LAUNCH OF ADULT-USE FRAMEWORK:

May 2021



NUMBER OF ACTIVE PILOT PROJECTS (2025):

7



NUMBER OF ACTIVE PILOT PARTICIPANTS:

>10,000



LAUNCH OF MEDICAL FRAMEWORK:

2011 and August 2022



ESTIMATED PATIENT SIZE

(2025):

4000 - 5000



NUMBER OF MEDICAL PRODUCTS:

>130

Switzerland's cannabis market is evolving, balancing a slow medical sector with ambitious adult-use plans. Medical cannabis was legalized in 2011 and expanded in 2022; however, patient numbers have not seen significant growth due to the lack of prescribing doctors and reimbursement issues. The market generally relies on domestic producers and dronabinol imports, with recent efforts to increase exports.

Since launching its first adult-use pilot project in 2023, the country has expanded to seven operations, with implementation proceeding smoothly and without major concerns. Policymakers are moving toward full legalization, with a draft bill having been approved in February 2025. The bill would allow adults to grow, buy, possess, and consume cannabis, with canton-controlled sales. Taxation would be based on THC content and product form, with revenues funding health insurance. Individuals could cultivate three plants, and possession limits are pending. Cantonal authorities would retain oversight. If passed, the law is expected in 2026, making Switzerland the first European country to have a fully regulated adult-use market.



Stronger patient access to cannabinoids is hindered by a lack of trained doctors and pharmacists. Although reimbursement is technically available, obtaining it is challenging for patients. Implementing clearer reimbursement policies, similar to those in Germany, would significantly improve access.



Susane Caspar,

CEO, Linnea

(See Appendix for full interview.)

ADULT-USE PILOT PROJECTS

In May 2021, Switzerland enacted a legal framework for adult-use cannabis ‘pilot trials’, allowing small-scale sales for scientific purposes. Currently, seven trials are active, all run by public entities, and involving approximately 10,000 participants. The table that follows illustrates that each study focuses on distinct research questions and tests various dispensation models and products.

Pilot Project	Research Question(s)	Location(s)	Number of Products	Current Sample Size	Max. Sample Size	Dispensation Model	Launch Date	End Date
WeedCare	Examine the effects regulated sales will have on consumption behavior of cannabis users.	Basel-Stadt	4 Flowers 2 Hashes 2 Vapes 1 Oil 1 Spray	299	378	Pharmacies	January 2023	January 2027
Züri Can	Investigating the health effects of regulated cannabis sales to consumers, comparing three different sales models.	Zurich	11 Flowers 3 Hashes	2280	3000	Pharmacies, cannabis social clubs, Drug Information Center	August 2023	October 2026
Grashaus Projects	Examine whether structured and controlled sales of high-quality, organically grown cannabis in specialized stores with trained sales staff can achieve a change in consumption toward harm reduction, a reduction in illegal use, and the associated problems.	Liestal Allschwil	15 Flowers 2 Hashes 2 Vapes 3 Edibles 2 Oils	>1000	3950	Specialized dispensaries	December 2023	October 2028

Pilot Project	Research Question(s)	Location(s)	Number of Products	Current Sample Size	Max. Sample Size	Dispensation Model	Launch Date	End Date
Cann-L	Examines the feasibility of a controlled sales model, its acceptance by participants, and what impact this has on the illicit market. It also examines the extent to which participation in the pilot project leads to more responsible and lower-risk cannabis consumption.	Lausanne	Flowers Hashes Oils	>1400	1600	State sponsored specialized dispensary	December 2023	Summer 2027
La Cannabi-nothèque	Investigating the extent to which a program for regulated access to cannabis can improve knowledge about cannabis use and the associated problems. It is also investigating whether participation in the trial has an impact on the amount of cannabis consumed and the choice of cannabis products.	Vernier	Flowers Pollen Hashes Oils	1100	1200	Nonprofit Dispensary	December 2023	June 2027
SCRIPT	Examines the effects of regulated cannabis sales at selected pharmacies on the consumption behavior and health of cannabis users. Also examining the tobacco consumption related to cannabis consumption.	Bern Biel Lucerne	4 Flowers 2 Hashes 2 Sprays 2 Vapes	1090	1091	Pharmacies	April 2024	April 2026
Cannabis Research Zürich	Examines the social and economic consequences of legalizing recreational cannabis use in Switzerland. In addition, the effects of a self-regulation program for the prevention of excessive cannabis use are to be studied.	Canton of Zurich	10 Flower 2 Hashes 5 Vapes 4 Oils 2 Edibles	>4400	7500	Specialized dispensaries, pharmacies	May 2024	December 2028

KEY CHALLENGES

QUALITY AND LACK OF DIVERSITY

Although access to adult-use cannabis through a pilot project remains straightforward, participants are still bound to products available to a specific project, which has led to many being dissatisfied with the quality and formats available.

ILLICIT MARKET

The illicit market remains a strong channel for access, as prices are lower and there are more formats and varieties available.

DISPENSATION INFRASTRUCTURE

In Switzerland, patients can purchase medicines directly from their prescribing general practitioners (GPs) and specialists. The self-dispensing doctor model in Switzerland is a revenue channel for many practitioners. As physicians cannot generate revenue from medical cannabis sales due to its restrictive classification, doctors tend to prescribe medicines which are more commercially lucrative.

STRICT REIMBURSEMENT STRUCTURE

In Switzerland, reimbursement for medical cannabis is usually only provided to patients who have exhausted all other forms of treatment. Additionally, approximately 50% of all reimbursement applications fail, leading many to access cannabis through illicit channels or seek other medicine, as prices for medical cannabis treatment in Switzerland are high.

UNITED KINGDOM



ESTIMATED PATIENT SIZE
(2025):
70,000 – 80,000



LAUNCH OF MEDICAL FRAMEWORK:
November 2018

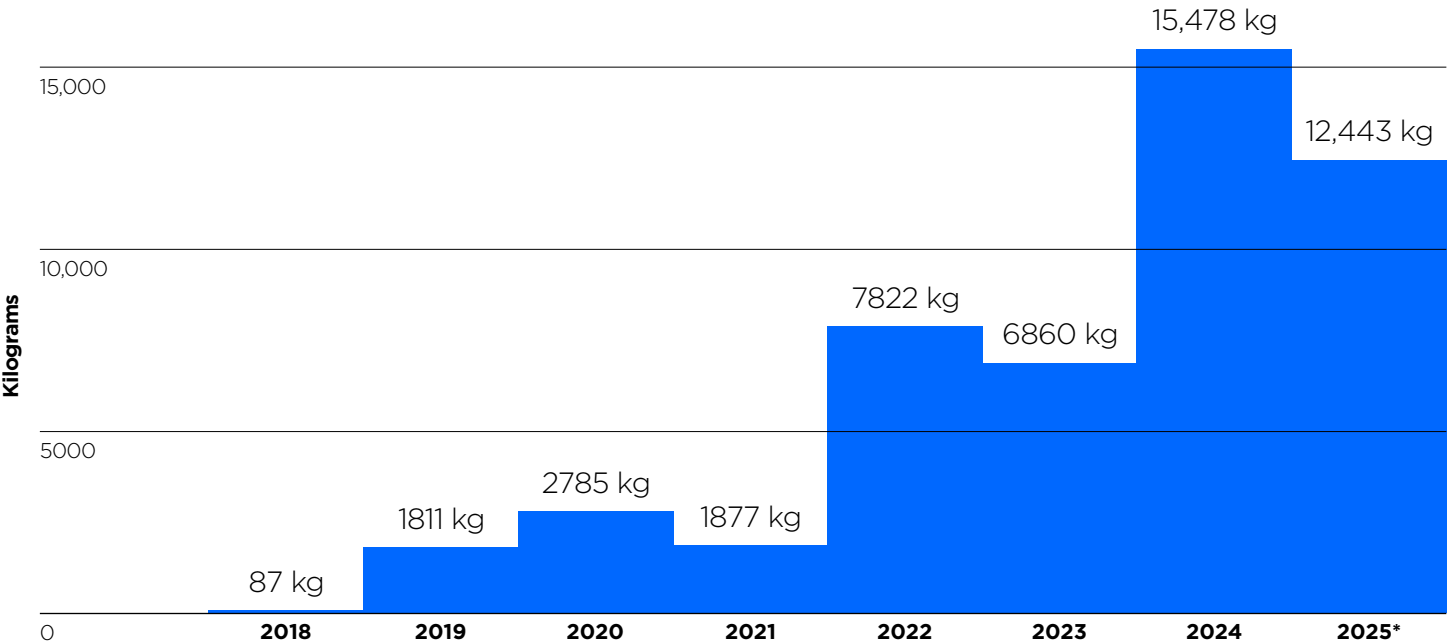


NUMBER OF PRODUCTS:
>690

The UK’s medical cannabis market, Europe’s second-largest, boasts an infrastructure of cultivators, importers, manufacturers, clinics, and pharmacies. Despite being a fraction of the size of the German market, it is experiencing growth in patient numbers. This growth is facilitated by specialized clinics offering accessible services through telemedicine platforms. Furthermore, the

establishment of a fully functioning domestic supply chain has begun, with UK-grown medical cannabis now being dispensed to patients by the first operational cultivators. However, the UK still relies heavily on imports, having brought in approximately 15.5 tons in 2024 and over 12 tons for the first 8 months of 2025.

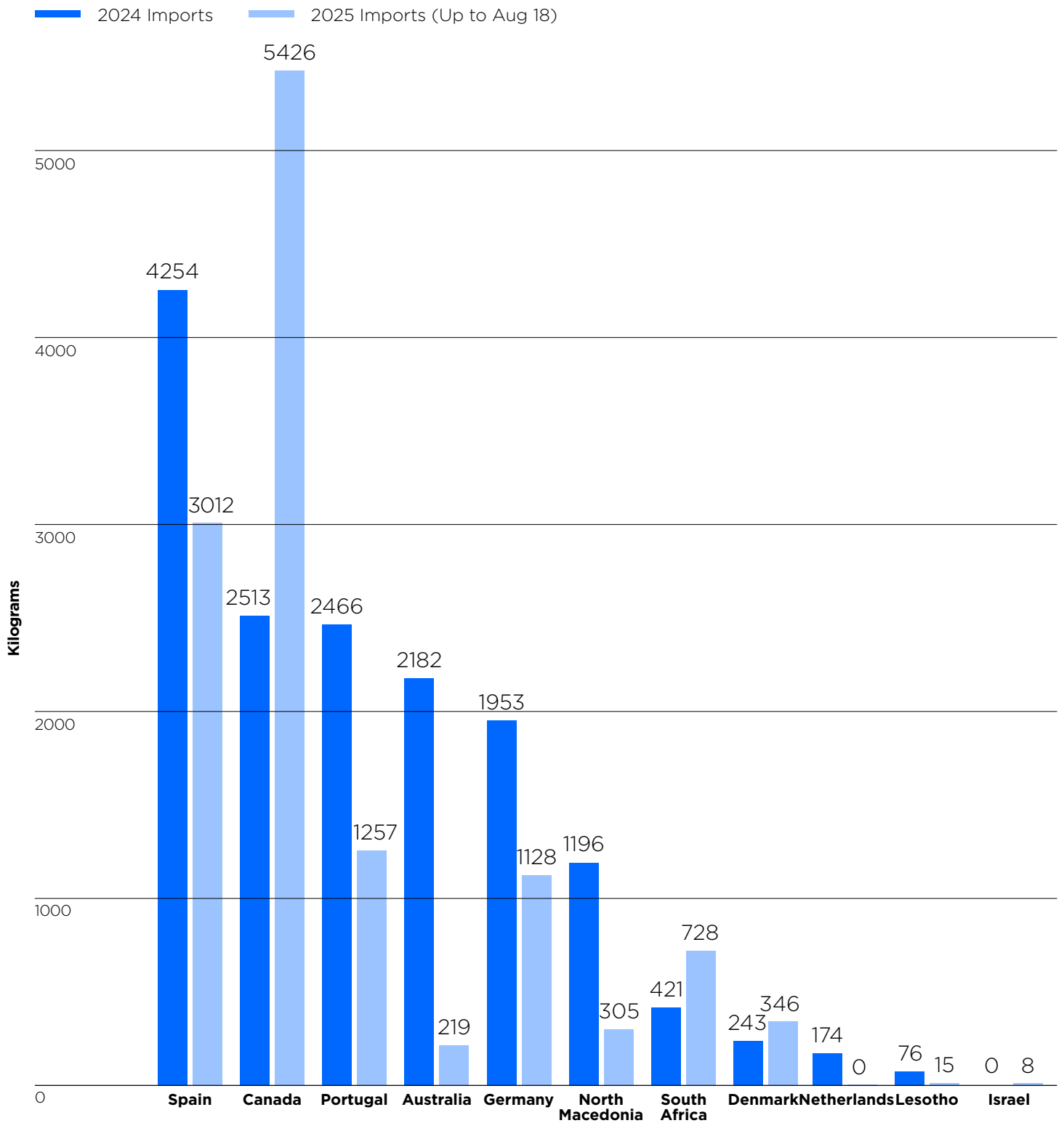
Graph 05 **UK Medical Cannabis - Annual Import Volume** (2018 - August 2025)



Source: Home Office FOI Request, 2025 | *As of August 2025



Graph 06 **UK Medical Cannabis Imports by Country** (2024-2025)





The industry is under the control of four regulators: the Home Office, the Medicines and Healthcare Products Regulatory Agency (MHRA), the General Pharmaceutical Council (GPhC), and the Care Quality Commission (CQC). They cover overlapping areas from cultivation to pharmacies.



James Duckenfield,

CEO, Glass Pharms

(See Appendix for full interview.)

In the first half of 2025, UK imports of medical cannabis from Canada reached over 5.4 tons, followed by Spain (3 tons), Portugal (1.3 tons) and South Africa (0.7 tons). All of the imports stemming from Germany are imported products (Canada, Spain, Portugal, etc.), which have undergone final production and packaging processes in Germany.

The graphs show that imports are rising sharply to cater to increasing levels of demand, solely fueled by the medical-use market.

In the UK, specialist General Medical Council (GMC) registered doctors can prescribe cannabis-based medicines using an FP10 prescription pad after a multidisciplinary peer review, typically for patients unresponsive to conventional treatments. There's no fixed list of qualifying conditions, but common ones include: anxiety, chemotherapy-induced nausea/vomiting, Crohn's disease, neuropathic pain, multiple sclerosis, fibromyalgia, and PTSD. This is permitted by the Misuse of Drugs Regulations 2001, amended in 2018, but is prescribed predominantly through private clinics.

Patients who are prescribed cannabis are paying significant sums for the products. Import permits add expense to the supply chain, which should encourage domestic manufacturing. UK production licensing is stringent but open, fostering industry growth.

KEY CHALLENGES

LACK OF PRESCRIBING DOCTORS

There are roughly 200 doctors prescribing medical cannabis in the UK. The lack of doctors severely hinders the growth in the market as doctors can only treat a finite number of patients a day.

SLOW REGULATORY CHANGE

The medical cannabis regulatory framework in the UK is a significant bottleneck for the market's growth. Due to tightly controlled restrictions based on cannabis' classified status, operators in the sector are bound to strict requirements limiting overall productivity and expansion in the market.

LACK OF PATIENT AWARENESS

A large proportion of the UK public remains unaware that medical cannabis treatment is available in the UK, perhaps due to the strict advertising regulations imposed on operators.

NETHERLANDS



ADULT-USE FRAMEWORK:

Controlled Supply Chain Pilot Project



EXPERIMENTAL PHASE LAUNCH DATE:

April 7 2025



COMPLETION DATE:

April 2029



LAUNCH OF MEDICAL FRAMEWORK:

September 2003



ESTIMATED PATIENT SIZE (2025):

>6000

The Netherlands was the first country in Europe to establish a domestic medical cannabis framework, allowing patients to access medical cannabis supplied through a monopolized domestic supply chain. For several years, the Netherlands dominated the international export market for medical cannabis globally.

However, the country has not significantly evolved its framework, which has stymied patient access and production. It therefore remains a relatively small market when compared to other European countries.

In terms of adult-use cannabis, the Netherlands implemented a tolerance policy in the 1970s, allowing coffeeshops to sell small amounts of cannabis to customers. However, as the supply of cannabis was sourced from illicit channels, Dutch authorities increasingly regulated coffeeshop operations to address rising potency, crime risks, and societal concerns through formal limits and zoning restrictions. This led to the establishment of the 'Weed Experiment' (Wietexperiment), which is an ongoing multiyear trial aimed at establishing legal domestic supply chains for adult-use cannabis. Its core

objective is to provide coffeeshops with legally produced Dutch cannabis, replacing current illicit market sources. Test phases commenced in December 2023, with the main experiment officially launching on April 7 2025.

However, the change of government in 2024, may result in changes or barriers to this process, leading to relative market uncertainty.

KEY CHALLENGES

HASH PRODUCTION

Producing hash at the required scale proved technically challenging. Many certified growers either declined to produce it or delivered lower-quality products compared to traditional illicit varieties like Moroccan hash.

QUANTITY AND DIVERSITY

A limited number of producers and high demand have resulted in insufficient stock for coffeeshops. Additionally, as not all cannabis producers for the experiment have launched products onto the market, product diversity remains limited.

LIMITED PRODUCERS

Participation in the experiment is limited to a select group of growers. A new grower from the waiting list can only join the experiment if a current participant withdraws.

POLAND



ESTIMATED PATIENT SIZE (2025):

30,000-40,000



LAUNCH OF MEDICAL FRAMEWORK:

November 2017



NUMBER OF PRODUCTS:

52

Poland legalized medical cannabis in 2017, but its initial regulatory framework limited commercial activity, and there is no public reimbursement model. From 2022 to the end of 2024, Poland's medical cannabis market experienced substantial growth. This expansion was driven by several factors: an increase in product authorizations, the establishment of more robust import and distribution supply chains, a decrease in product prices, greater awareness of medical cannabis among healthcare professionals, and the rise of telemedicine.

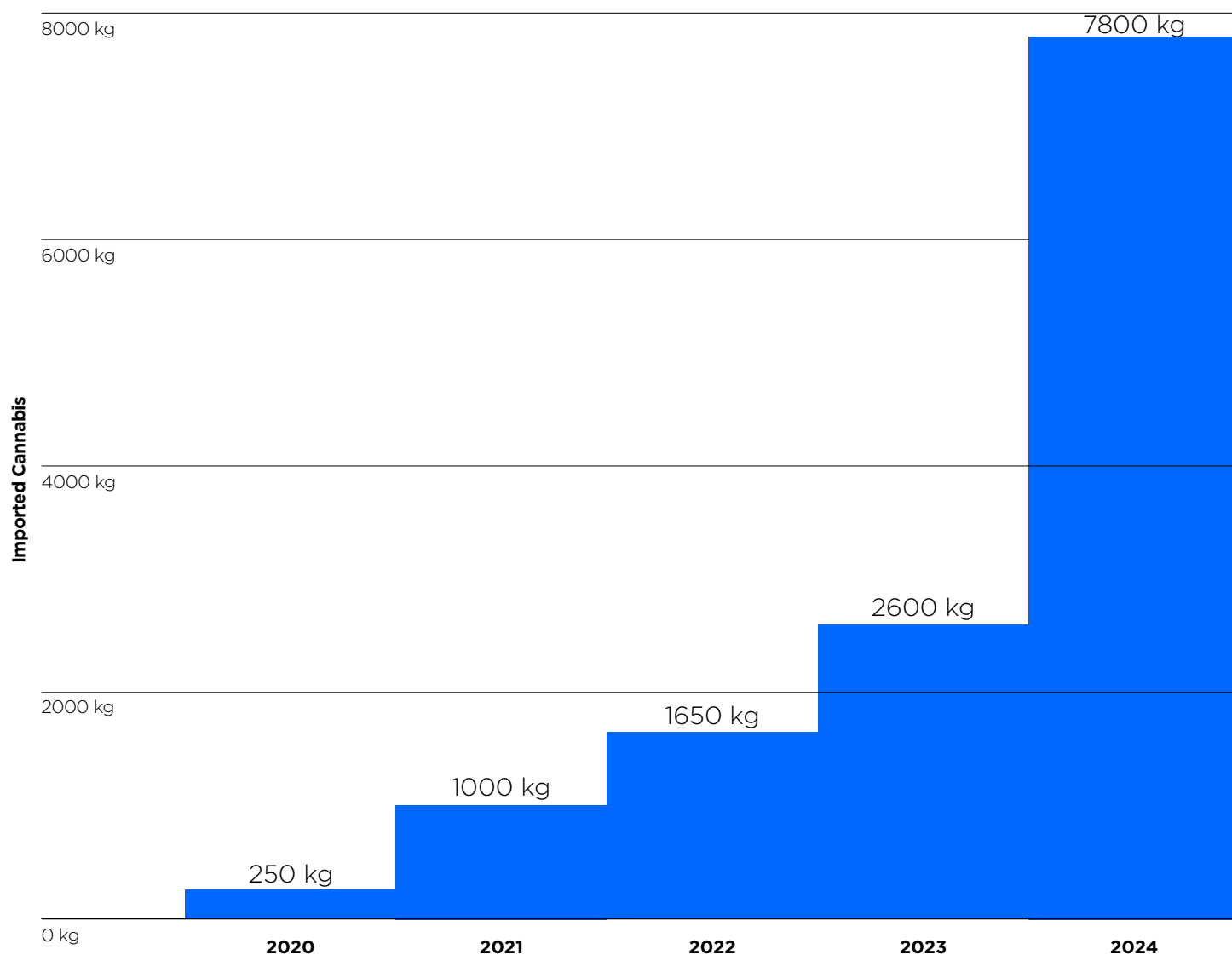
In November 2024, the Polish Ministry of Health imposed restrictions on online consultations for medical cannabis. Regulations now require prescribers to conduct an initial in-person examination, with remote consultations only permitted subsequent to this initial physical assessment. This policy change has resulted in an oversupply of medical cannabis in many Polish pharmacies, as fewer patients are able to fulfill prescriptions. Consequently, prices have dropped considerably as pharmacies try to sell expiring stock. However, Polish patient numbers and prescriptions are starting to rebound due to the establishment of dedicated physical and mobile medical cannabis clinics, offering in-person consultations.

In 2024, Poland imported roughly 7.8 tons of medical cannabis. This is a threefold increase compared to the previous year, highlighting growing demand. This increasing reliance on imports is caused by the restriction of cultivation to research institutions only. Currently, only one entity holds a permit for cultivation.

However, all companies engaged in manufacturing, processing, import, and distribution must secure both a regular business authorization and a narcotic authorization from the Chief Pharmaceutical Inspectorate.

Establishing a presence on the Polish market is fairly difficult as the product authorization process can often take over two years.

Graph 07 **Polish Medical Cannabis Imports (2020-2024)**



Source: Polska Agencja Prasowa, 2025

KEY CHALLENGES

TELEMEDICINE RESTRICTIONS AND SMALL NUMBER OF DOCTORS

The restriction on telemedicine prescriptions for first-time patients may hinder the further growth of the Polish market, especially since there is already a shortage of physicians willing to prescribe medical cannabis.

LONG LICENSING PROCEDURE

It can take up to two years to place a medical cannabis product on the Polish market. This process can be time-consuming and costly, leading many European operators to focus on other markets.

NO REIMBURSEMENT

Public health insurers do not provide medical cannabis reimbursement in Poland, thus patients face a financial barrier when seeking treatment and may turn to other reimbursable medications instead.

PORTUGAL



ESTIMATED PATIENT SIZE (2025):

400 - 500



LAUNCH OF MEDICAL FRAMEWORK:

November 2018



NUMBER OF PRODUCTS:

9

Portugal is one of the largest medical cannabis producers in the world, exporting medical cannabis to international markets, and export volumes growing consistently year-over-year.

Over 50 companies are currently authorized to export medical cannabis substances and preparations from Portugal. In the first three quarters of 2025, Portugal exported over 33 tons of medical cannabis, an over 2 tons increase when compared to the total cannabis (31 tons) exported in the whole of 2024.

Despite its role as a medical cannabis production, processing, and re-export hub for the international market, domestic patient access to medical cannabis in Portugal remains severely limited.

Portugal regulated the use of cannabis-derived medicinal products in 2018, and in 2019 set out the legal framework for market authorization, prescription, and dispensation procedures.

Non-pharmaceutical medical cannabis products (unlike Sativex and Epidyolex) require a market placing authorization (ACM) from the Portuguese National Medicines Authority (INFARMED), before they can be prescribed. Obtaining an ACM is a complex, expensive, and lengthy process, deterring many companies.

In Portugal, medical cannabis can be prescribed by any doctor, but only for specific conditions and when conventional therapies have proven ineffective or caused unwanted side effects. Despite this, few doctors are willing to prescribe it due to a lack of sufficient education and training regarding medical cannabis and the endocannabinoid system.



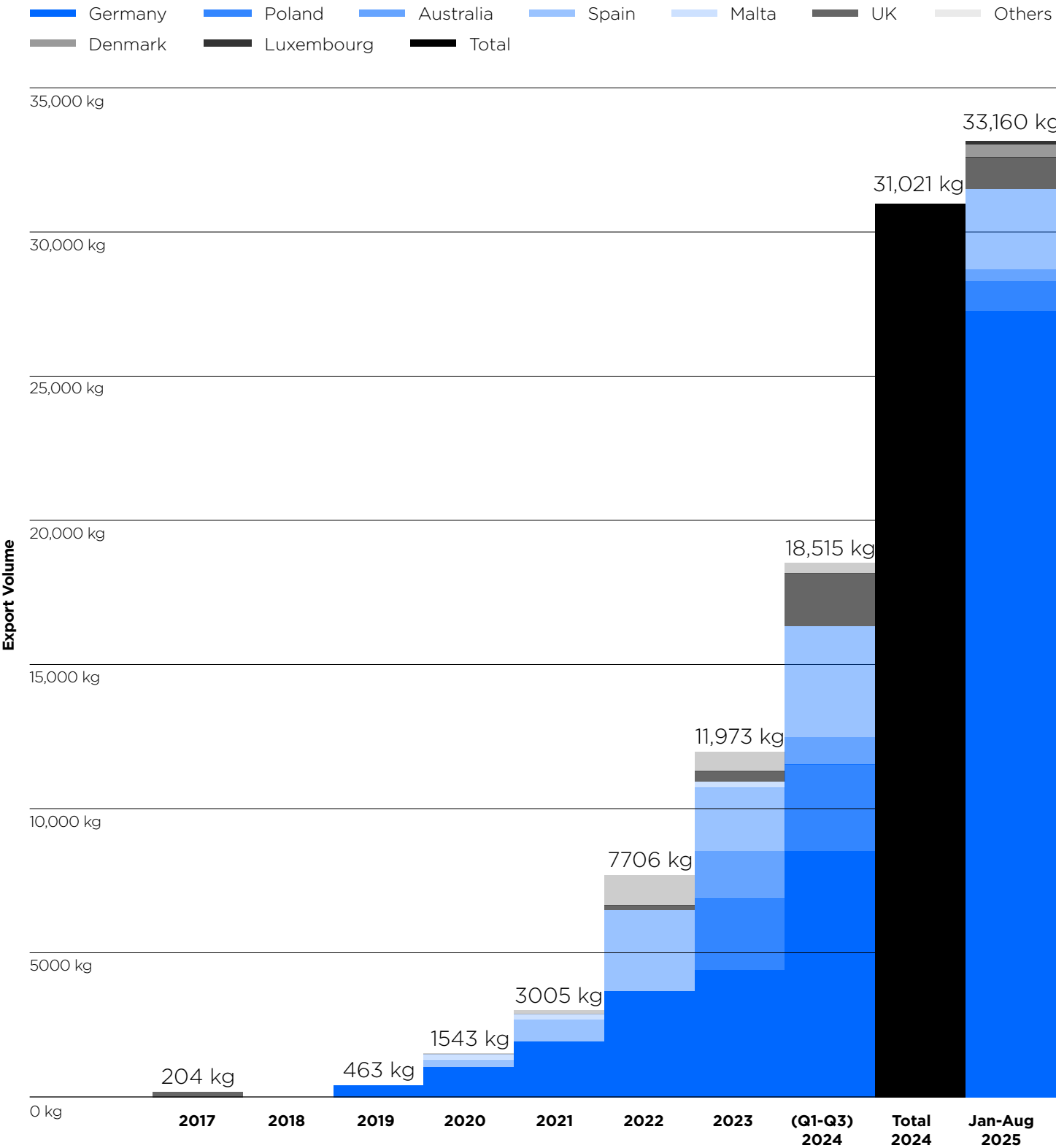
Portugal is the second-largest exporter to Europe after Canada because of its favorable import rules, which is why it has built a strong infrastructure.



Michael Sassano,

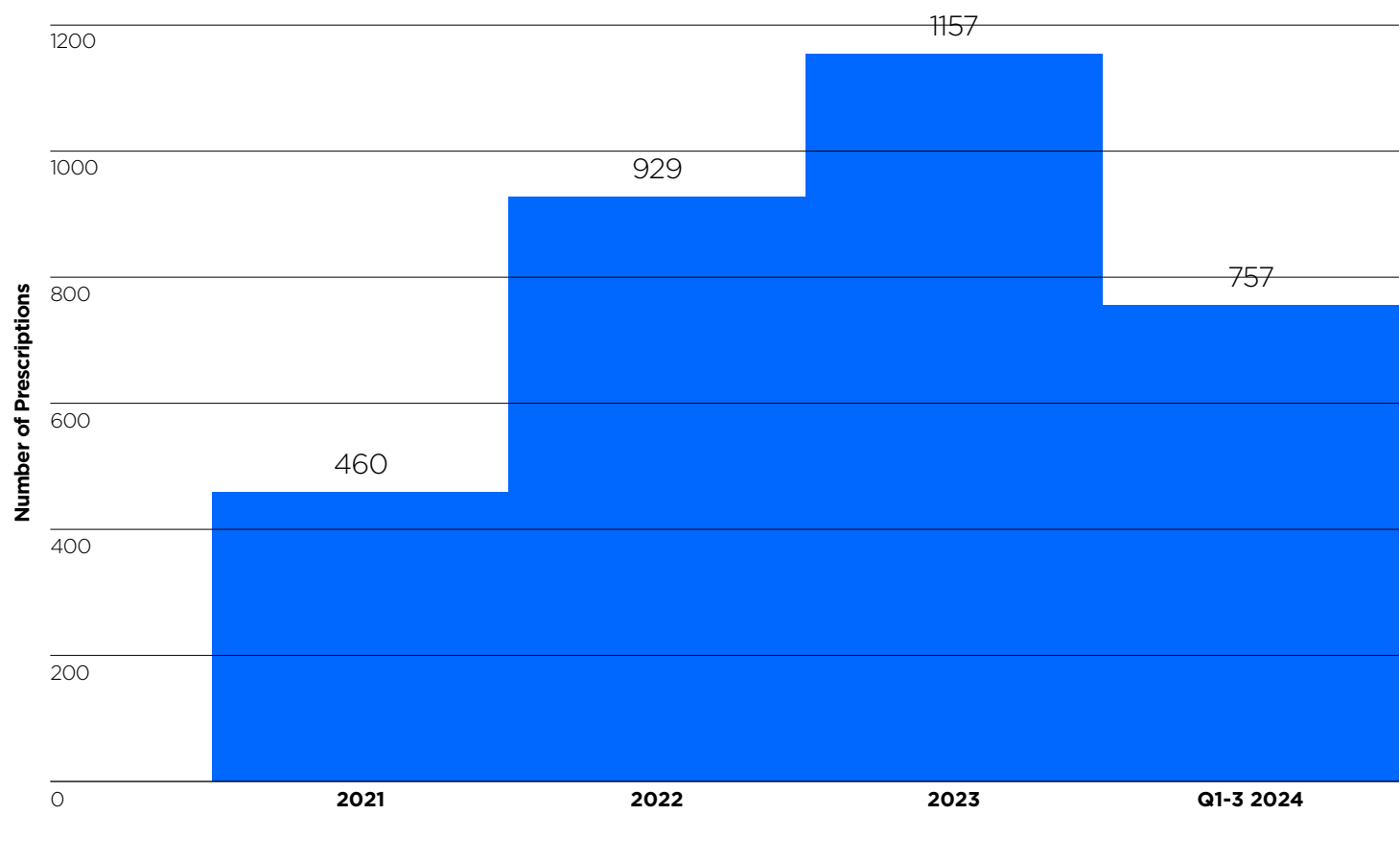
CEO and Founder, SOMA Pharmaceuticals
(See Appendix for full interview.)

Graph 08 **Portuguese Medical Cannabis Exports** (2017- Aug 2025)



Source: INFARMED, 2025

Graph 09 **Medical Cannabis Prescriptions** (2021 - Q3 2024)



Source: INFARMED, 2025

From 2021 to 2023, Portugal experienced a notable increase in annual medical cannabis prescriptions, rising from 460 to 1157. However, figures released by INFARMED

for Q3 2024 indicate a potential slowdown, with only 757 prescriptions issued, averaging 252 per quarter.

KEY CHALLENGES

SMALL NUMBER OF DOCTORS

The lack of cannabis education in the medical cannabis framework in Portugal, associated with the strict list of treatable conditions and the stigma of cannabis, has created a medical cannabis landscape whereby only a few physicians are willing to prescribe medical cannabis treatment to patients.

NO REIMBURSEMENT

Public health insurers do not provide medical cannabis reimbursement in Portugal, thus patients face a financial barrier when seeking treatment. In order to save money, many patients will resort to other reimbursable medications or illegal procurement that may be cheaper.

LONG LICENSING PROCEDURE

Obtaining a product approval in Portugal is a lengthy process, which hinders many from listing their products on the market. As the medical cannabis patient base is too small for companies to generate enough sales, many operators and domestic producers seek to sell products to other larger markets, including the UK and Germany.



MALTA



ADULT-USE FRAMEWORK:

Social Clubs and Home Cultivation



DATE OF FIRST SALES

(DISTRIBUTION TO MEMBERS):

January 2024



DATE OF FRAMEWORK:

December 2021



NUMBER OF LICENSED CULTIVATION CLUBS (2025):

22

Malta established a regulatory framework for medical cannabis in 2018, allowing for patient treatment and commercial cultivation/manufacture. Domestic production has been limited, and the market is supplied via imports, with most of the volume coming from Canada.

Despite restrictive patient access, Malta has a high number of medical cannabis patients relative to its population. Export regulations prioritize finished products, though intermediate products can be exported with additional approvals. Medical cannabis can be prescribed by any doctor in Malta if it is considered that there is no viable alternative after all other treatment options have been tried.

Malta decriminalized cannabis possession under 3.5 grams in 2015, by March 2021, the Maltese government were advocating for further decriminalization due to widespread cannabis use across social groups, citing harm reduction and criminality as key motivations. On December 14 2021, Malta became the first EU country to legalize cannabis. Currently, 19 cannabis associations hold operating permits issued by the Authority for the Responsible Use of Cannabis (ARUC).

PERSONAL CONSUMPTION AND HOME CULTIVATION REGULATIONS:

- It is legal for adults 18 and above to possess seven grams.
- Consumption of cannabis may only occur in private spaces; however, public consumption and consumption in front of a minor is subject to fines and penalties.
- Adults may also cultivate up to four plants in a residence and have no more than 50 grams in the residence. Cultivation may not be visible to the public.

CANNABIS ASSOCIATION REGULATIONS

Cannabis cultivation associations, officially known as Cannabis Harm Reduction Associations (CHRAs) operate under the oversight and licensing of the ARUC.

Key regulations governing CHRAs include:

- **Prohibition on Advertising:** CHRAs are strictly prohibited from engaging in advertising or promotional activities.
- **Compliance and Reporting:** Adherence to rigorous compliance and monitoring standards is required, along with the submission of annual financial reports.
- **Nonprofit Status:** CHRAs must function as nonprofit organizations.
- **Location Restrictions:** A minimum distance of 250 meters from schools, clubs, and youth centers must be maintained for CHRA premises.
- **Membership Requirements:** Membership is restricted to residents who are 18 years of age or older.
- **Product Distribution:** CHRAs are authorized to distribute cannabis flowers exclusively to their registered members at designated distribution sites.
- **Packaging and Labeling:** Distributed cannabis must be provided in tamper-evident, child-resistant packaging, and must bear ARUC-prescribed labeling and health warnings.
- **On-site Prohibitions:** The consumption of cannabis and alcohol is expressly forbidden on CHRA premises.
- **Licensing Fees and Membership Limits:** An annual license fee is assessed based on the number of members, with a maximum permissible membership of 500 individuals.
- **Distribution Limits:** Members are subject to a maximum daily distribution limit of seven grams of dried cannabis flowers (inflorescence) and a maximum monthly limit of 50 grams.
- **THC Limits for Younger Members:** Members under the age of 21 are restricted to purchasing cannabis with a THC content not exceeding 18%.

As of December 2025, there are 22 CHRAs with operating permits.

KEY CHALLENGES

NONPROFIT

Cannabis associations in Malta must be nonprofit making, thus limiting the potential commercial profitability and potential of the market.

REGULATORY RESTRICTIONS

Recent regulatory developments have placed further restrictions on Malta's adult-use framework, such as placing fines for public consumption of non-medical cannabis, potentially curbing future growth.

UNITED STATES

The United States is the world's largest cannabis market with sales (medical and adult-use) forecasted to reach \$33 billion in 2025 and \$42 billion by 2030. In December 2025, President Trump signed an executive order to reclassify cannabis from a Schedule I to a Schedule III drug under the Controlled Substances Act. This change shifts its federal status from a highly restricted drug with no accepted medical use to one that is recognized as having acceptable medical applications. This reclassification has the potential to significantly alter the nation's medical cannabis environment, particularly regarding tax relief and research. Specifically, medical cannabis businesses may no longer be subject to the 280E tax provision, which currently prohibits them from deducting business expenses from gross income due to their association with trafficking Schedule I and II substances.

However, the full implementation timeline and mechanism for this reclassification remain unclear. As of now, it remains a Schedule I substance; thus, medical cannabis distribution, production, and transportation continue to be illegal under federal law. This classification creates significant structural barriers to business growth, limiting operators' access to financial services, standard business tax deductions, and interstate trade.

These limitations have led to a state-by-state market model for cannabis, requiring operators who wish to expand into various legal states to duplicate their operations and infrastructure in each desired location also known as multistate operators (MSOs). Furthermore, this confines businesses to US-only operations, as international cannabis imports or exports are deemed illegal, preventing them from benefiting from the expanding global medical cannabis industry.

The absence of federal consistency and the variations in state models have resulted in a fragmented system, characterized by a patchwork of diverse regulations, while simultaneously subjecting operators to potential federal enforcement risks.

SNAPSHOT STATISTICS:

- **40** states have implemented a comprehensive medical cannabis framework
- **24** states have legalized adult-use cannabis
- **8** states implemented a CBD/low THC medical framework

As of November 2025, 40 states, Washington D.C., and four US territories (Guam, Commonwealth of the Northern Mariana Islands, Puerto Rico, and the US Virgin Islands) have established some form of cannabis framework (adult-use and/or medical programs). In states including Georgia, Texas, Wyoming, only CBD-only or low-THC/high-CBD products are permitted for specific patients, suffering from certain conditions including those with epilepsy.

Regarding adult-use cannabis, 24 states have legalized it to a certain extent, with Delaware being the most recent to commence sales in August 2025. This means that approximately 80% of states have legalized medical cannabis in some capacity, and nearly half have legalized adult-use cannabis. The trend toward further legalization is evident, with Kentucky, Mississippi, Indiana, Iowa, South Carolina, and Texas all having proposed medical cannabis bills in recent years. Hawaii, New Hampshire, Tennessee, and Indiana are also pursuing adult-use legalization.

The following section will examine the recent cannabis developments, trends, and challenges of the largest US markets in terms of adult-use and medical cannabis sales.



The biggest challenge is the lack of interstate transport. MSOs would prefer to centralize cultivation and processing, but laws require everything to be done within each state. This makes operations inefficient and costly. Security requirements surrounding transportation are also excessive, adding additional costs. Since cannabis remains federally illegal, insurance options are limited and expensive, leaving operators vulnerable. So, the combination of regulatory restrictions and financial exposure makes supply chain management particularly challenging.

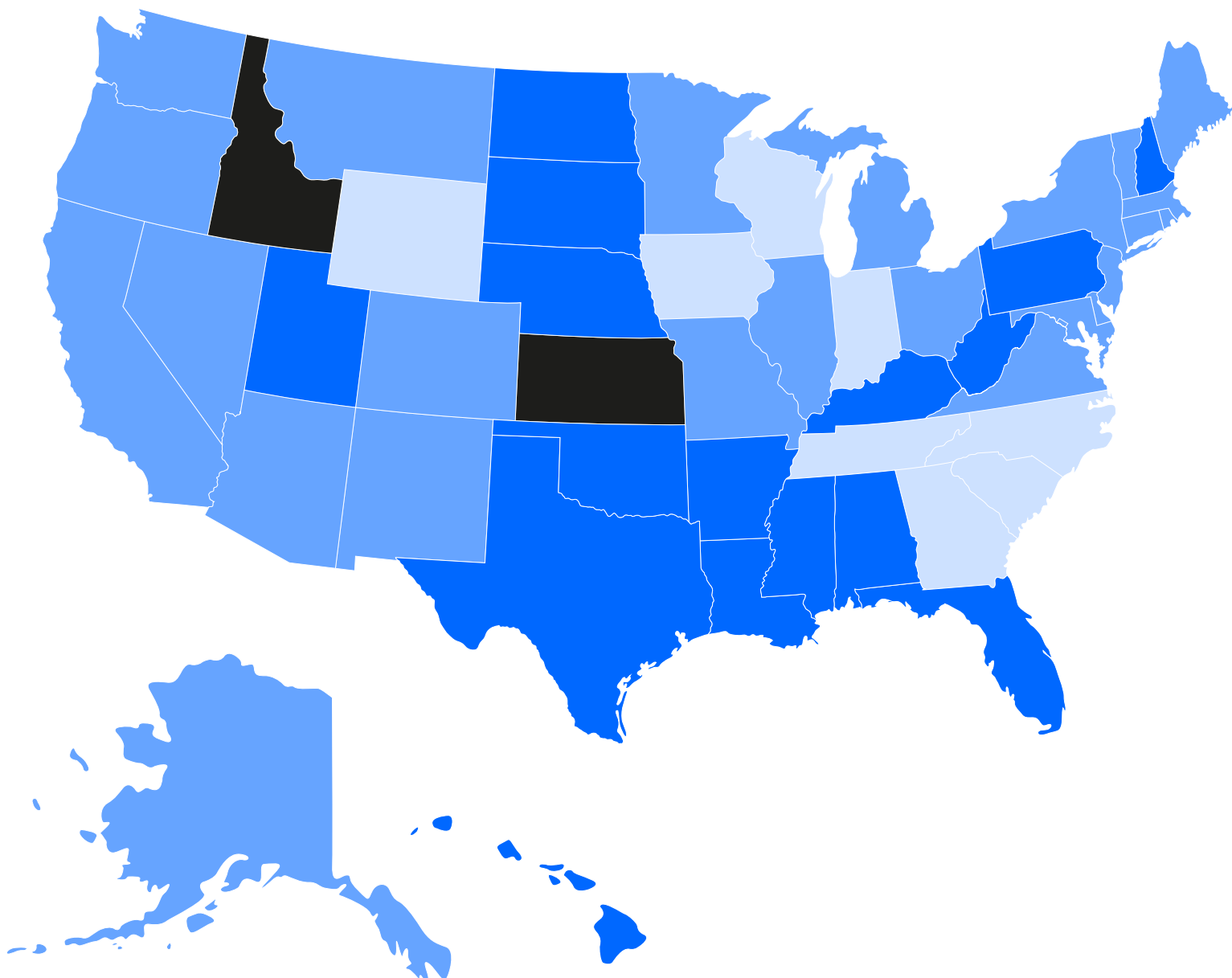


Eric Berlin,

Head of Cannabis Sector, Dentons
(See Appendix for full interview.)

Map 03 Cannabis Framework by US State

■ Medical Only
 ■ Medical and Adult-use
 ■ Medical CBD/Low THC Only
 ■ None



CALIFORNIA



NUMBER OF RETAILERS
(DECEMBER 2025):
1453 (Online and Storefront)



LEGAL STATUS:
Adult-Use and Medical



NUMBER OF CULTIVATORS:
4506



LEGALIZATION DATES:
1996 (Medical) and 2016 (Adult-Use)



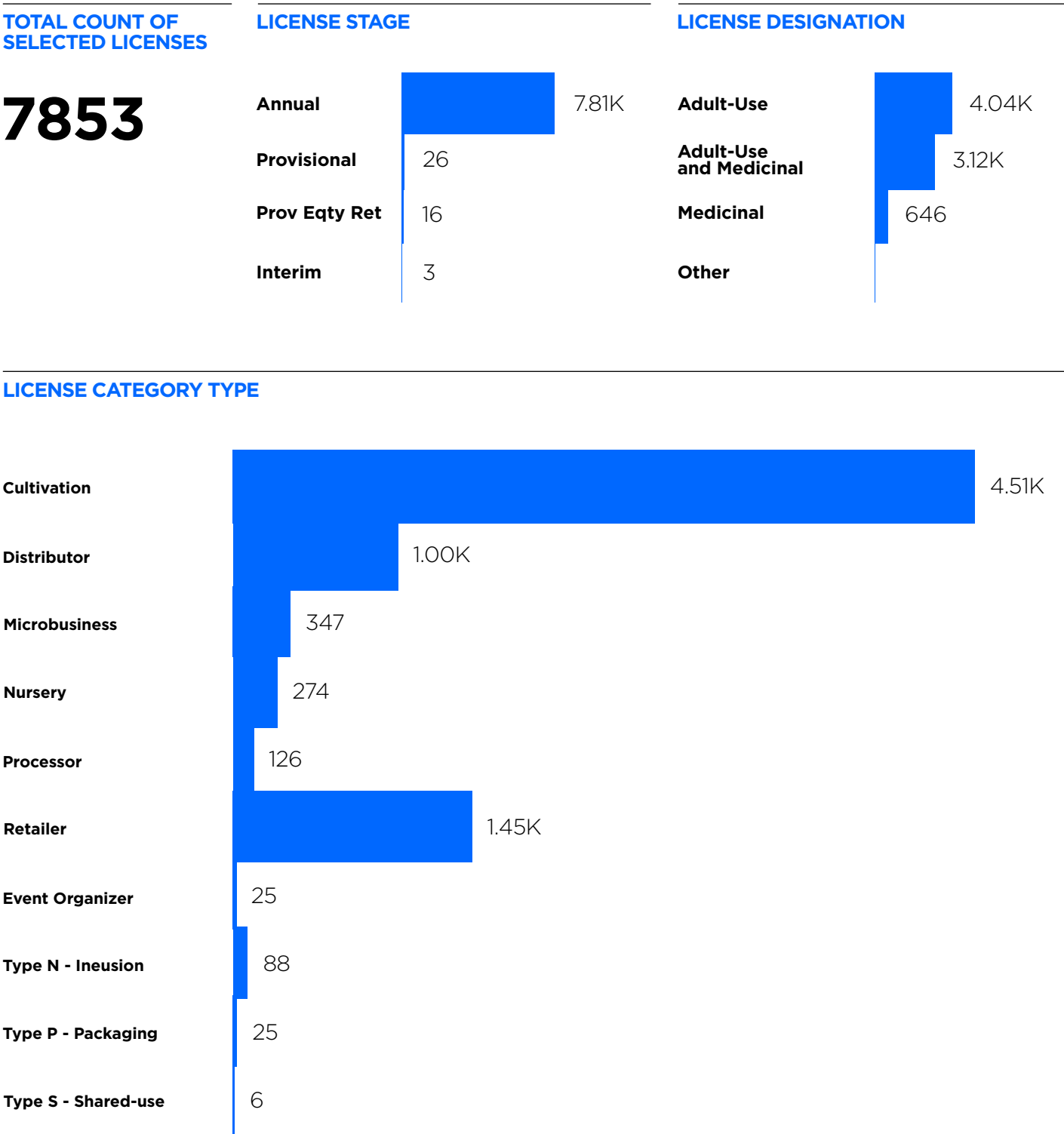
REGULATORY AUTHORITY:
Department of Cannabis Control, California

The state of California, the largest cannabis market in the world, has become synonymous with cannabis. The state was the first in the country to officially legalize medical cannabis in 1996, creating an infrastructure allowing doctors to recommend medical cannabis to patients. This initial step was a catalyst toward California’s market growth, providing initial growers, producers, and operators with a first-mover advantage that enabled them to create and develop brands, new products, and strains that have become highly demanded by cannabis consumers, locally and internationally.

Following the legalization of adult-use cannabis in California in 2016, the medical cannabis market eroded significantly as patient preferences moved toward adult-use products due to their ease of access and variety. By 2025, the medical market experienced significant shrinkage, with only 10% of active licenses focusing solely on the medical market in 2025, as shown in Graph 10.

Graph 10 also shows how the cannabis market in California is significantly focused on areas of cultivation – compared to later stages of the supply chain, such as retail, distribution, and manufacturing. This alludes to the oversupply of products in the California market and a lack of retailers due to high taxes and competition from the illicit market.

Graph 10 **California Cannabis Licensing Overview** (December 2025)



LICENSE CATEGORY TYPE

Cultivation		4.51K
Distributor	1.00K	
Microbusiness	347	
Nursery	274	
Processor	126	
Retailer	1.45K	
Event Organizer	25	
Type N - Ineusion	88	
Type P - Packaging	25	
Type S - Shared-use	6	

Source: Department of Cannabis Control California, 2025

The adult-use market saw an immense surge in sales throughout 2020 and the first half of 2021 during the COVID-19 lockdown period as consumers shifted toward cannabis consumption. This growth was also fueled by counties in the state deeming dispensaries as essential businesses to continue operations, and the ease of access made through online delivery and curbside pickup services.

Although, accessing cannabis has never been easier for Californians, cannabis companies are facing significant difficulties due to the surplus of product on the market leading to wholesale price compression, lack of banking and financial services, fraudulent testing certificates as well as the lingering illicit market which is undercutting legal prices as well as providing a large variety of product formats.

Following the pandemic and the return to regular work and social practices, sales of cannabis saw a notable decline. Economic conditions in the US also played a role in this decline, with plummeting consumer confidence, fueled by domestic inflation. Consumers are often purchasing the same amount of cannabis annually, yet opting for budget-friendly cannabis products. Additionally, consumers are increasingly favoring vape products over other formats.

KEY CHALLENGES

TAXES, FEES AND OTHER COMPLIANCE COSTS

Setting up, operating and maintaining an active cannabis license in California is expensive and time consuming. As traditional financial services are difficult to obtain it is difficult to find capital and loans. Additionally, taxes and other duty fees is pushing many players out of the market.

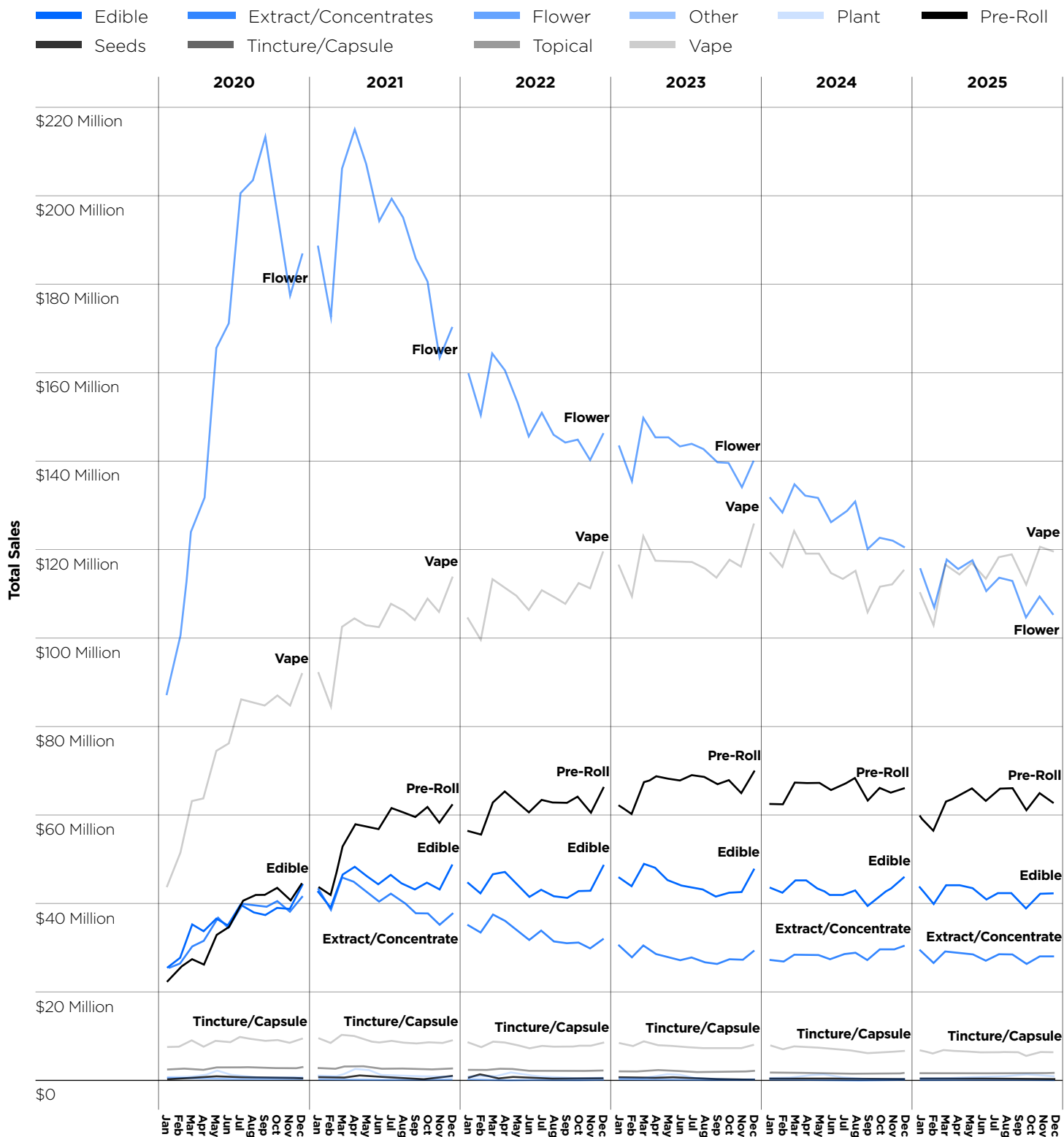
OVERSUPPLY, PRICE COMPRESSION AND DECLINE IN REVENUE

As production continues to increase, wholesale prices continue to fall in California. This has led to an oversaturated market with little room for margins for producers and wholesalers as well as a drop in revenue by retailers.

ILLICIT COMPETITION

A pervasive illicit market draws away consumers, patients, and capacity, undermining the legal supply chain, as illicit prices significantly undercut legal competition.

Graph 11 **California Cannabis Sales Annual Overview** (December 2025)



NEW YORK



LEGAL STATUS:

Adult-Use and Medical



NUMBER OF ADULT-USE RETAILERS (2025):

>500



LEGALIZATION DATES:

2016 (Medical) and
2021 (Adult-Use)



NUMBER OF CULTIVATORS

(DECEMBER 2025):

>450



NUMBER OF REGISTERED ORGANIZATIONS (2025):

19 (Medical)



REGULATORY AUTHORITY:

New York's Office of
Cannabis Management

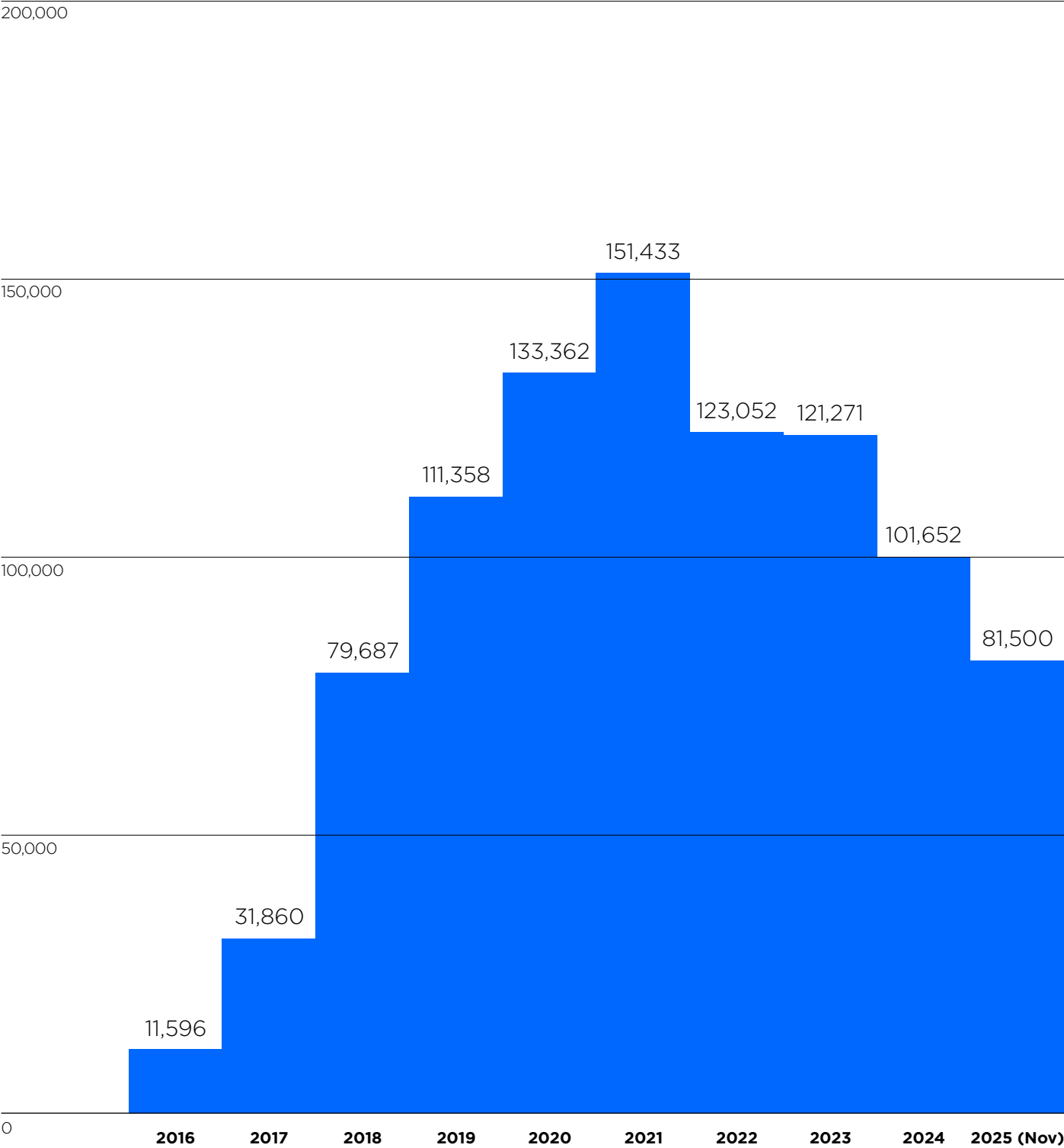
New York State's cannabis market is experiencing rapid expansion, driven by the full adult-use legalization in 2021, with initial sales commencing in December 2022. Despite sustained market growth, operators continue to face challenges, including unclear regulatory changes, costly licensing procedures, declining patient numbers, high taxes, and a widespread, well-organized illicit market.

New York State first legalized medical cannabis in 2016, but the state saw slow growth as the framework was one of the most restrictive medical cannabis programs in the country. At the launch of New York's medical cannabis program, only a few qualifying conditions (e.g., cancer, HIV/AIDS, epilepsy, Parkinson's) were eligible for medical cannabis treatment; chronic pain was only included in the list in 2017. There were further restrictions on available product formats - only non-smokable forms of medical cannabis were initially available.

The state also scarcely granted licenses to Registered Organizations (ROs), which are vertically integrated organizations that cultivate, process, manufacture, and distribute medical cannabis to patients, thereby limiting access and market growth.

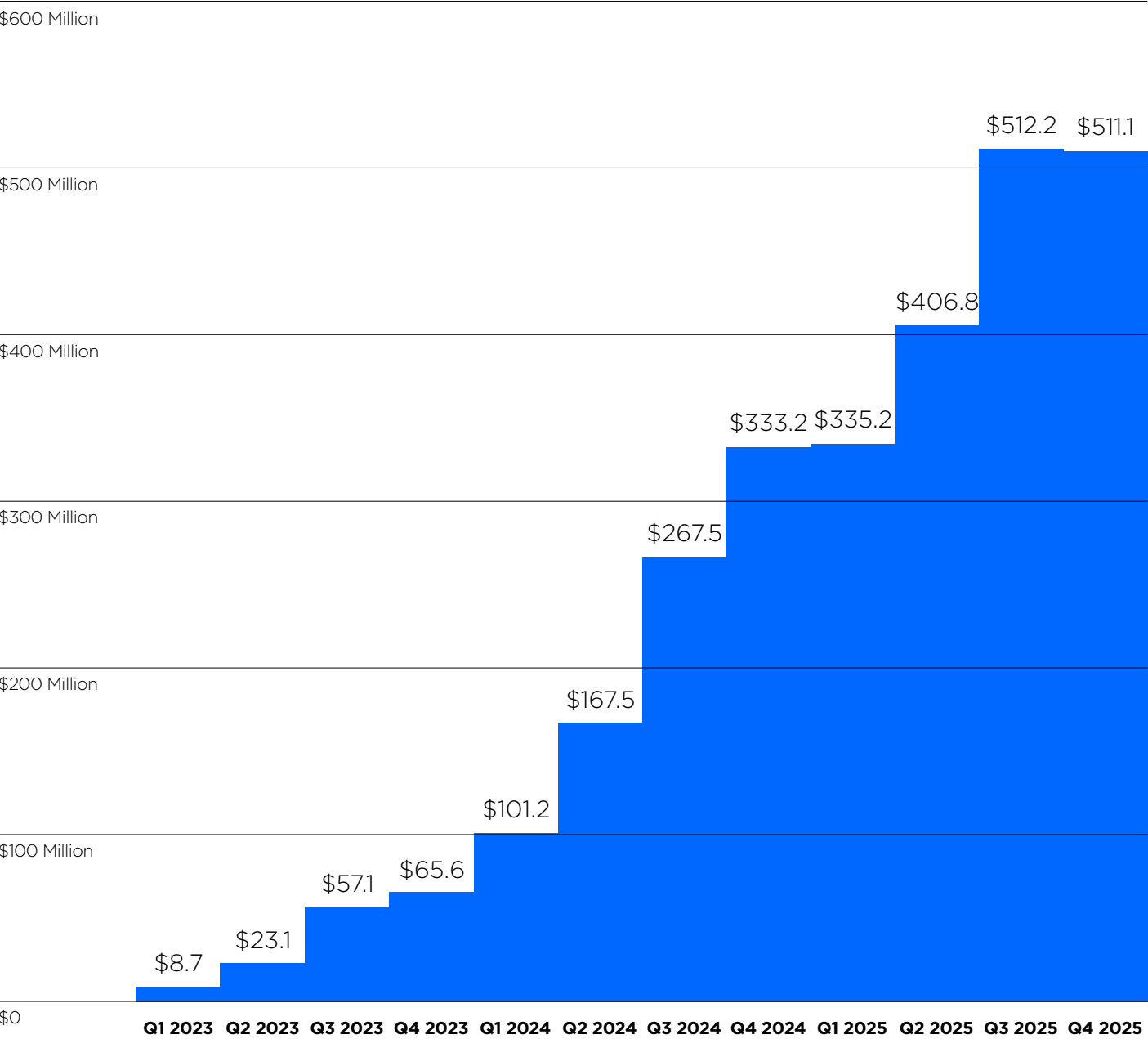
High product prices, lack of insurance, cheap illicit market products, and slow acceptance of the medical community all became significant factors for limiting New York State's medical cannabis market potential. After adult-use legalization, medical patients dropped 30-40%, and high transition costs posed a barrier to evolution for ROs, thereby creating an unsustainable market environment for medical use-only commerce market potential.

Graph 12 **Evolution Medical Cannabis Patients in New York**
(2016-November 2025)



Source: Office of Cannabis Management, New York State, 2025

Graph 13 **New York Cannabis Reported Retail Sales** By Quarter

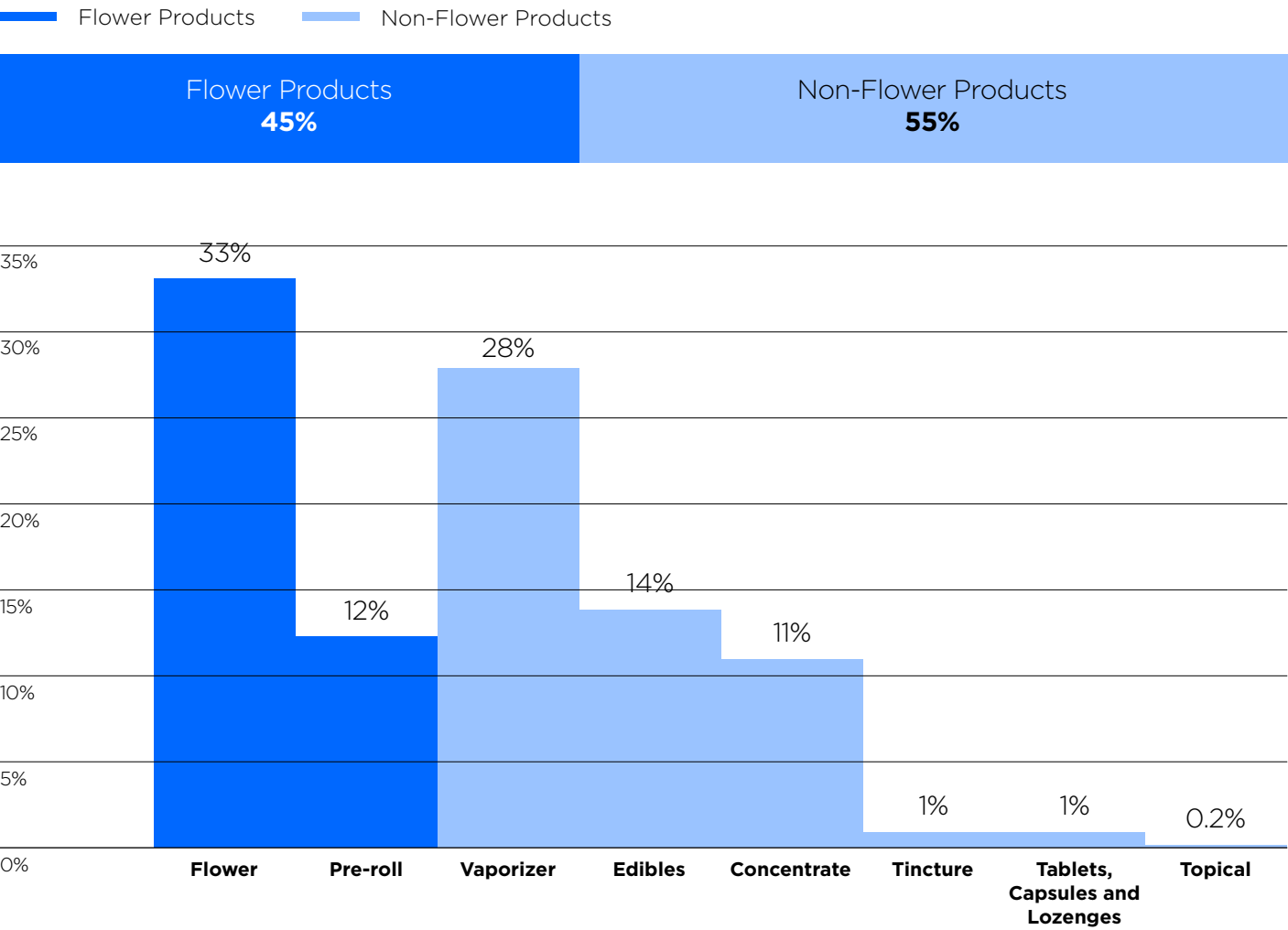


Source: Office of Cannabis Management, New York State, Prohibition Partners, 2025

In terms of New York’s adult-use cannabis market, the state is witnessing year-over-year growth. New York’s adult-use market reached over \$1.5 billion in 2025, driven by high usage rates by consumers and authorities placing pressure on illicit market providers.

However, smaller operators are being squeezed out by larger MSOs and operators with strong financial backing as they are able to spend high levels of capital on acquisitions, premium retail locations and large scale production facilities. These factors combined with high start-up costs and limited access to banking services make it difficult for small and medium-sized enterprises (SMEs) to compete.

Graph 14 **Product Share of Sales By Category**



Source: Office of Cannabis Management, New York State, 2025

The product formats in highest demand in New York are flowers, followed by vaporizers and edibles. Similar to other markets, there is a growing trend for non-combustible and safer product format options for consuming cannabis.

KEY CHALLENGES

MULTISTATE OPERATORS, HIGH COMPLIANCE AND START-UP COSTS

Entering the adult-use market as an SME can be difficult as there are high compliance and start-up costs combined with tough competition from MSOs.

STRONG ILLICIT MARKET

Although the state has implemented initiatives to combat the illicit cannabis trade in the state, there remains a strong underground market which is undercutting legal operators.

SHRINKING MEDICAL MARKET

Factors including decreasing patient numbers, a restrictive operational framework, and a lack of developmental initiatives contribute to New York’s shrinking medical cannabis market.

MICHIGAN



NUMBER OF ADULT-USE RETAILERS
(NOVEMBER 2025): >850



NUMBER OF ACTIVE CULTIVATOR LICENSES
(NOVEMBER 2025): >2,500



LEGAL STATUS:
Adult-Use and Medical



LEGALIZATION DATES:
2008 (Medical) and 2018 (Adult-Use)



REGULATORY AUTHORITY:
Cannabis Regulatory Agency, Michigan

Michigan's cannabis market stands out as one of the most robust in the US, with adult-use sales surpassing \$3 billion in 2024. This growth is fueled by strong consumer demand, high per capita consumption, and widespread retail access. The state fosters a highly competitive environment, boasting over 2200 active adult-use licenses that support rapid retail and product expansion.

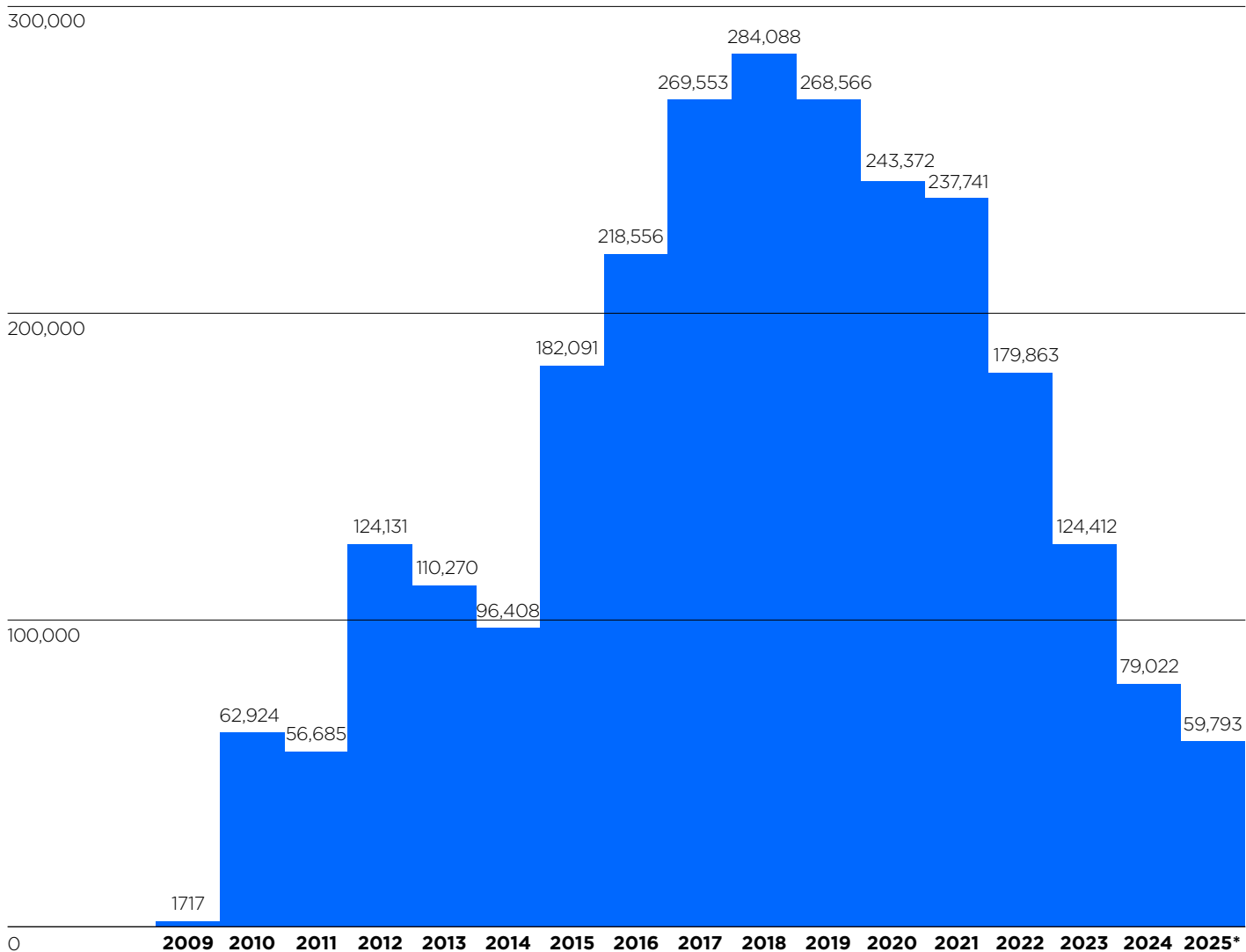
This aggressive growth has led to a collapse in wholesale flower prices, dropping below \$70 per ounce due to oversupply, which in turn pressures cultivator margins and accelerates consolidation across the supply chain. Many cities in the state have prohibited cannabis businesses, thereby limiting commercial potential in the state.

The Cannabis Regulatory Agency (CRA) oversees the state's medical licensing system, issuing licenses for the entire supply chain: growers, processors, secure transporters, safety compliance (testing) facilities, and provisioning centers (medical dispensaries). Similar to the adult-use market, medical businesses must obtain state licenses, adhere to stringent testing and security regulations, and report all sales and transfers via the Metrc seed-to-sale tracking system. While caregivers were once

crucial to the program, their importance has significantly declined due to regulatory restrictions and the growth of the commercial market.

Following adult-use cannabis legalization in 2018, Michigan's medical cannabis market has largely diminished, making up less than 1% of total cannabis sales in 2024. The number of registered medical patients has halved in recent years, as the accessibility, lower prices, and fewer restrictions of the adult-use market have rendered medical registration increasingly unnecessary for most consumers. The industry continues to face challenges such as: overregulation, lab testing backlogs, and since the start of January 2026 a 24% wholesale tax on cannabis sales came to effect, which many fear will further strain the market. Despite these obstacles, Michigan's cannabis sector continues to mature, with ongoing discussions centered on sustainability, equity, and balancing growth with long-term viability.

Graph 15 **Evolution Medical Cannabis Patients in Michigan** (2009-2025*)



Source: Cannabis Regulatory Agency, November 2025

*As of November 2025

KEY CHALLENGES

OVERSUPPLY AND PRICE DROPS

Excess production has led to a saturated market, causing wholesale flower prices to plummet. This has left small margins for cultivators and producers.

MARKET SATURATION AND STRONG COMPETITION

With over 2000 active adult-use cannabis licenses, competition is steep, especially in the retail sector.

SHRINKING MEDICAL MARKET

Decreasing number of patients, restrictive operational framework and lack of development on a regulatory level are all contributing factors to the state's shrinking medical cannabis market.

MASSACHUSETTS



LEGAL STATUS:
Adult-Use and Medical



**NUMBER OF FINAL LICENSED
ADULT-USE CULTIVATORS (DECEMBER 2025):**
>160



LEGALIZATION DATES:
2012 (Medical) and
2016 (Adult-Use)



**NUMBER OF MARIJUANA TREATMENT
CENTERS (OCTOBER 2025):**
93



**NUMBER OF FINAL LICENSED
ADULT-USE RETAILERS (DECEMBER 2025):**
>420

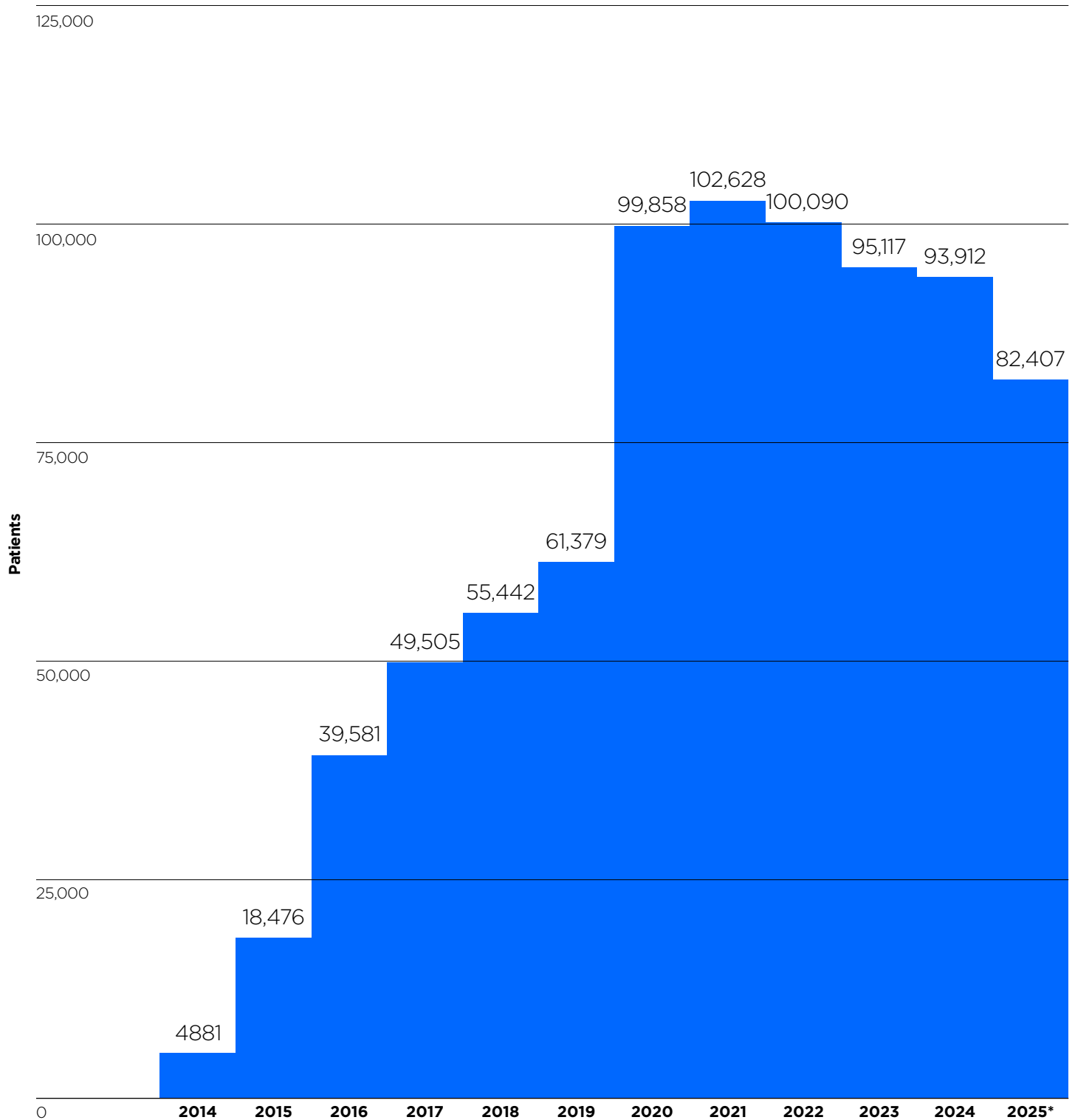


REGULATORY AUTHORITY:
Massachusetts's Cannabis
Control Commission

Since adult-use sales launched in 2018, Massachusetts's cannabis economy has evolved into a multibillion-dollar industry. In 2025, the state generated over \$1 billion in annual sales, driven by consistent consumer demand, tourism, and regional supply shortages resulting from delayed legalization in neighboring states. While growth has been strong, it has recently leveled off, indicating a shift from an emerging market to a more saturated and competitive environment.

However, Massachusetts's operators are encountering increasing difficulties. Retail prices have dropped due to heightened competition and market saturation, while the expenses associated with compliance, testing, and taxation—particularly the 17-20% effective tax rate—continue to squeeze margins. Additionally, municipal control over licensing has led to unequal access, with some towns restricting or prohibiting cannabis businesses entirely. Social equity implementation remains a contentious issue, as many advocates argue that despite the program's objectives, barriers to entry persist. These challenges, combined with complex local permitting, escalating real estate costs, and the ongoing presence of illicit market competition, necessitate that Massachusetts' operators navigate a maturing market by prioritizing efficiency, strong branding, and sustainable scaling.

Graph 16 **Evolution Medical Cannabis Patients in Massachusetts** (2014-2025*)



Source: Massachusetts's Cannabis Control Commission, 2025

*As of October 2025

Contrary to typical post-legalization trends, the medical cannabis market in Massachusetts experienced significant growth between 2016 and 2021. This unexpected increase defied expert predictions, suggesting that patients valued the advantages offered by the medical program, such as tax exemptions, access to higher-potency products, and professional medical guidance.

However, since 2021, patient numbers have gradually declined and sales have plateaued. Several factors have contributed to this waning engagement, including: a drop in adult-use cannabis prices, the widespread accessibility of adult-use products, and a lack of regulatory progress in expanding the medical cannabis framework.

Further hindering the medical market are restrictive regulations imposed on Marijuana Treatment Centers (MTCs), which burden both patients and businesses. MTCs are currently mandated to be vertically integrated, requiring

licenses for cultivation, processing, and dispensing. This leads to substantial start-up, operational, and compliance costs. Faced with a thriving adult-use market offering lower prices, many medical operators have been forced to close dispensaries as they struggle to compete.

In a recent development, the Massachusetts House of Representatives and Senate passed bills which aim to eliminate the vertical integration requirement for medical cannabis businesses. A conference committee has been assigned to negotiate the differences of the bill to create a final consensus in 2026.

KEY CHALLENGES

HIGH COMPLIANCE AND START-UP COSTS

Operating within the cannabis industry is challenging due to stringent regulations imposed by the Cannabis Control Commission (CCC). Businesses face complexities and high costs associated with frequent rule changes, lengthy approval procedures, and strict adherence to compliance standards for security, testing, packaging, and labeling. Additionally limited access to banking services makes it difficult to access loans and credit.

MARKET SATURATION AND STRONG COMPETITION

Market saturation in some high-density regions, due to the expansion of retailers, has resulted in intense competition. This has led to competitive pricing and business closures. The resulting price compression has eroded profit margins, particularly for smaller operators and craft growers who lack economies of scale.

SHRINKING MEDICAL MARKET

Decreasing number of patients and lack of development on a regulatory level are all contributing factors to the state's shrinking medical cannabis market.



MISSOURI



NUMBER OF DISPENSARIES

(DECEMBER 2025):

>220



LEGAL STATUS:

Adult-Use and Medical



NUMBER OF ADULT-USE CULTIVATORS

(DECEMBER 2025):

~60



LEGALIZATION DATES:

2018 (Medical) and
2022 (Adult-Use)



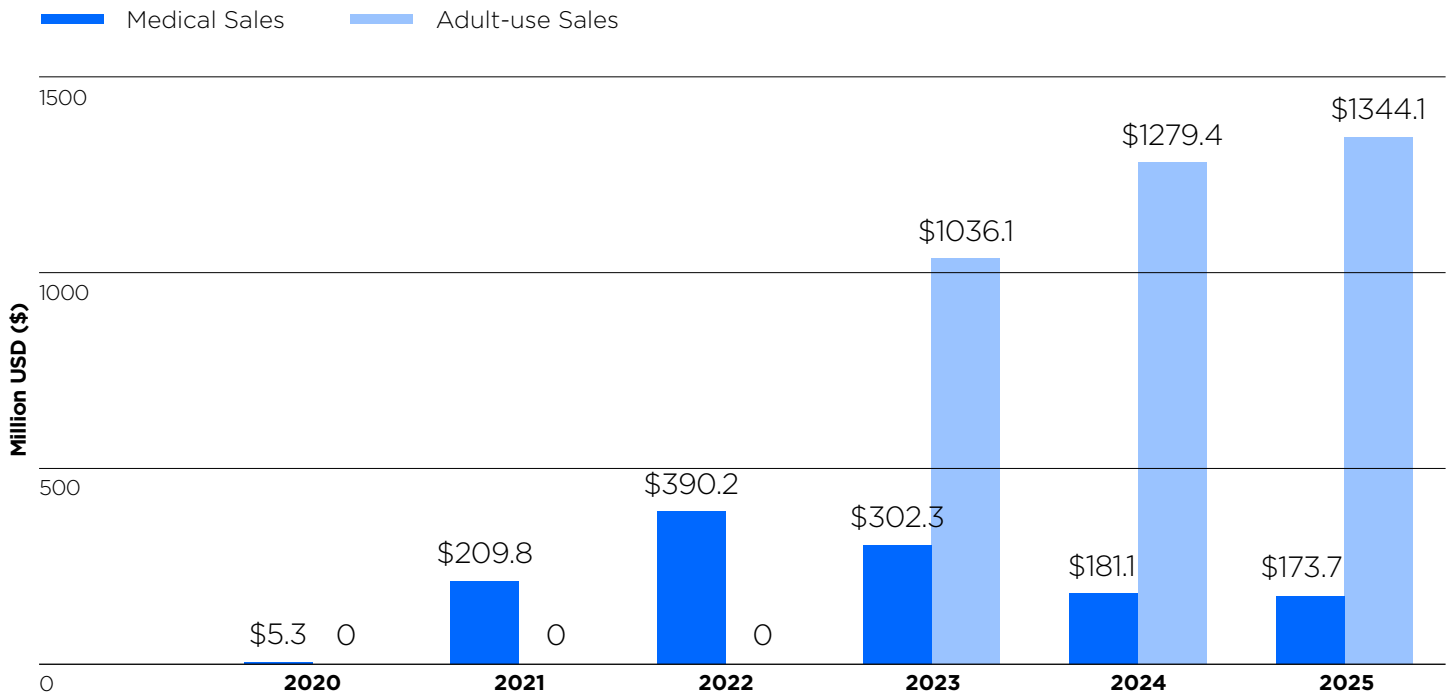
REGULATORY AUTHORITY:

Missouri Department of Health and
Senior Services' Division of Cannabis Regulation

Missouri's cannabis market has rapidly expanded, becoming one of the most successful in the US. This growth follows the legalization of medical cannabis in 2018 and the launch of adult-use sales in February 2023. The state's quick scaling is attributed to a robust regulatory framework, a deliberate and limited licensing strategy, and favorable tax policies. By the end of 2025, annual cannabis sales in Missouri exceeded \$1.5 billion, predominantly from the adult-use market. Its strategic location, bordering states where cannabis is prohibited, has also boosted demand by attracting out-of-state consumers.

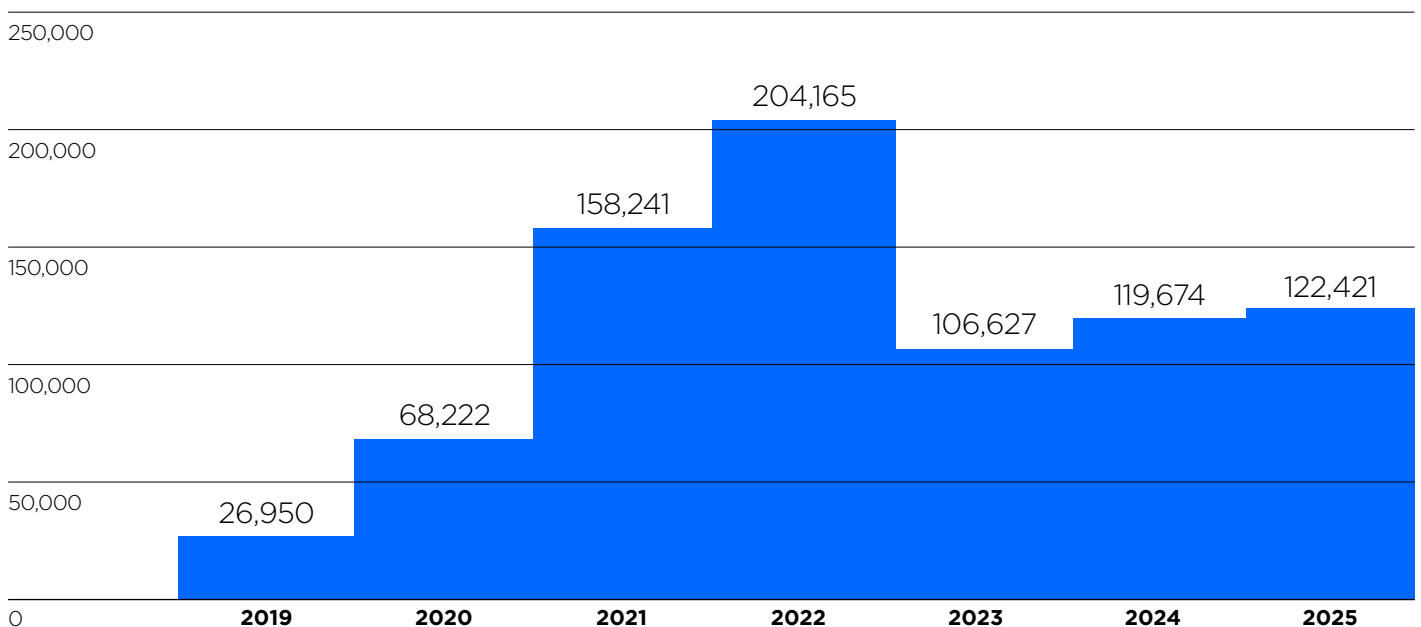
A distinctive aspect of Missouri's cannabis sector is its vertically integrated licensing, which allows many businesses to manage cultivation, manufacturing, and retail under a single license. The existing medical cannabis infrastructure facilitated a smooth shift to adult-use, as dispensaries and supply chains transitioned to dual operations. Furthermore, the state introduced a microbusiness program to advance social equity, though it has faced obstacles like ownership compliance and funding shortages. Despite these challenges, Missouri's controlled license issuance and consistent monthly sales have established it as an effective model for market implementation.

Graph 17 **Medical and Adult-Use Cannabis Sales in Missouri** (2019-2025)



Source: Missouri Department of Health and Senior Services, 2025

Graph 18 **Evolution Medical Cannabis Patients in Missouri** (2019-2025)



Source: Missouri Department of Health and Senior Services, 2025

The legalization of adult-use cannabis in Missouri significantly impacted the medical cannabis sector. Following the launch of recreational sales, medical cannabis sales declined by approximately 37% between early 2023 and the end of 2024, stabilizing at \$14-15 million monthly from a previous average of over \$24 million. This trend is consistent with other legal states, where patients often transition to the adult-use market due to enhanced accessibility, fewer bureaucratic hurdles, and a wider variety of products, even if it means sacrificing certain tax exemptions or dosage benefits. Despite this shift, the medical market continues to serve

a dedicated, and somewhat growing, patient base reliant on the program for specific therapeutic needs, higher-potency products, and tax advantages. However, the sharp reduction in patient numbers from highs of 2022, and lower margins, have prompted some operators to scale back or consolidate their medical operations.

While the success of the adult-use market has undeniably overshadowed the medical market, thoughtful adjustments or reforms to cannabis medical programs could ensure medical cannabis remains a crucial component of Missouri's broader cannabis ecosystem.

KEY CHALLENGES

STRICT REGULATIONS AND OVERSIGHT

Missouri Department of Health and Senior Services' Division of Cannabis Regulation has implemented many strict controls on cannabis operators. This has led to several license revocations, especially among microbusinesses, due to noncompliance. Additionally, the state has recently imposed new guidelines and requirements in regard to packaging and advertising which has led to operators reinvesting their capital and time to meet the new standards.

MARKET SATURATION AND PRICE COMPRESSION

Localized saturation is a growing concern for operators, particularly in urban areas where numerous dispensaries vie for the same customer base. The rapid increase in supply following adult-use legalization has led to declining wholesale prices. This trend is putting pressure on cultivators and manufacturers, forcing them to either reduce costs or consolidate operations.

SOCIAL EQUITY LICENSING ISSUES

Missouri's microbusiness licensing program, designed to promote social equity and economic inclusion, has faced significant challenges. A considerable number of licenses have been revoked due to fraudulent or non-compliant ownership structures, often seen as predatory practices by individuals seeking to profit from, and control, social equity license holders. Furthermore, many equity applicants struggle to compete effectively due to a lack of access to startup capital and technical support.



CANADA



NUMBER OF DISPENSARIES (2025):
>3600



LEGAL STATUS:
Adult-Use and Medical



NUMBER OF ACTIVE CANNABIS LICENSES (2025):
>900



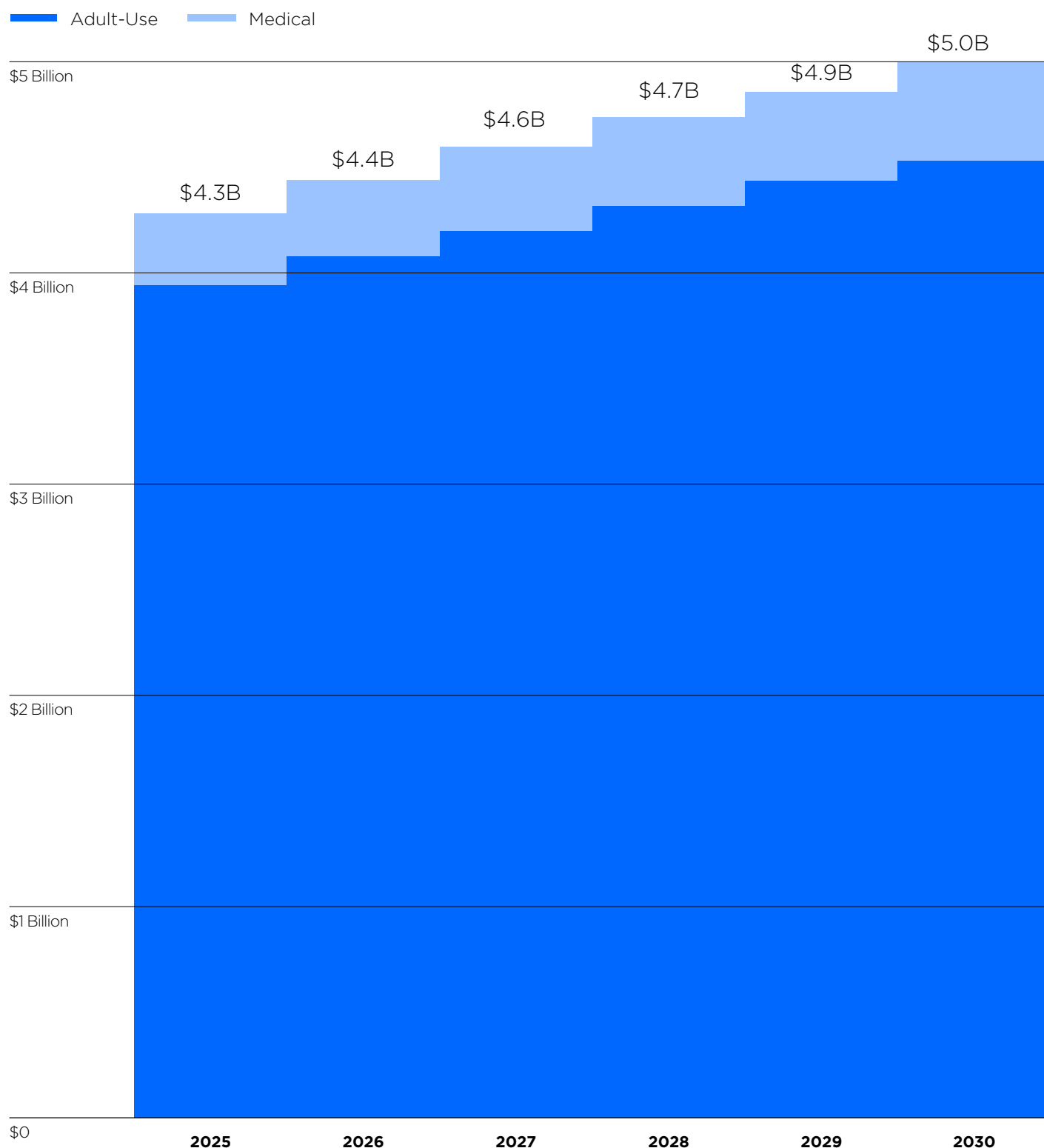
LEGALIZATION DATES:
2001 (Medical) and 2018 (Adult-Use)



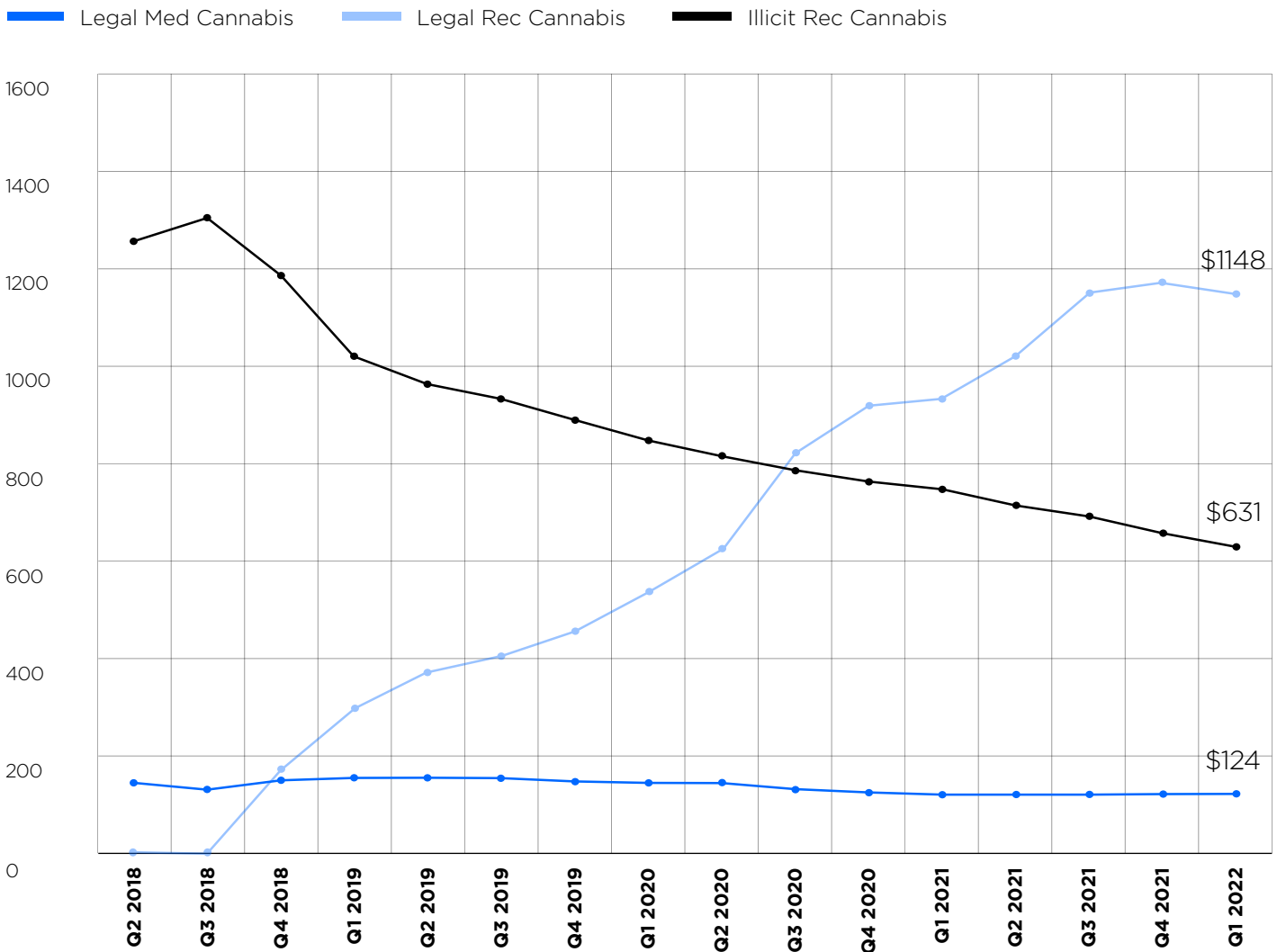
REGULATORY AUTHORITY:
Provinces and Territories Cannabis Authorities

Canada’s regulated cannabis market has matured significantly since the legalization of adult-use cannabis in October 2018. Evolving from a medical program established in 2001, it has grown into a multibillion-dollar national industry. This growth has been influenced by the federal Cannabis Act, which set national production and quality standards, and by provincial control over retail distribution, leading to diverse store models and accessibility across regions.

Graph 19 **Total Cannabis Sales Forecast Canada** (2025-2030)



Graph 20 **Legal vs Illegal Recreational Cannabis Household Expenditure**
(CAD\$ millions per Quarter)

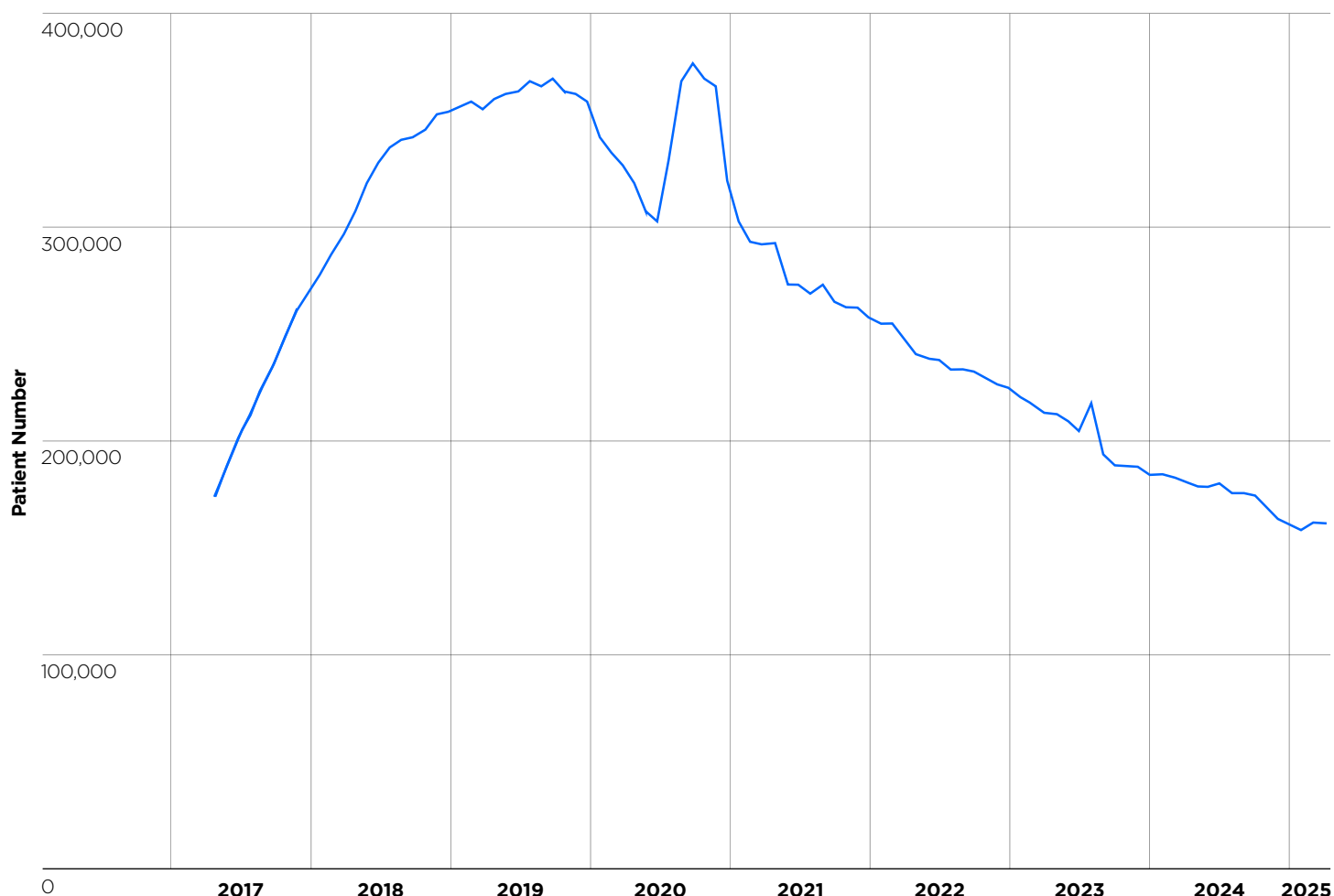


Source: New Leaf Data Services, LLC. 2022

Early on, rapid expansion by licensed producers (LPs) in anticipation of high demand led to oversupply, price compression, and strong competition from the illicit market. However, the legal market share has steadily increased over time, driven by falling retail prices, broader product availability including vapes, edibles, and concentrates introduced in late 2019 and the expansion of bricks-and-mortar retail networks, especially in Ontario and Alberta.

Currently, the Canadian cannabis market is marked by producer consolidation, a strong emphasis on operational efficiency, and ongoing regulatory adjustments aimed at reducing administrative burdens while upholding strict public health protections. Operators navigate a challenging environment characterized by thin margins, stringent compliance requirements, and fragmented provincial regulations. Despite these hurdles, the industry continues to adapt through product innovation, brand differentiation, and strategic international expansion. While recreational sales dominate, the medical segment remains a crucial channel, particularly for patients requiring standardized dosages and clinical oversight.

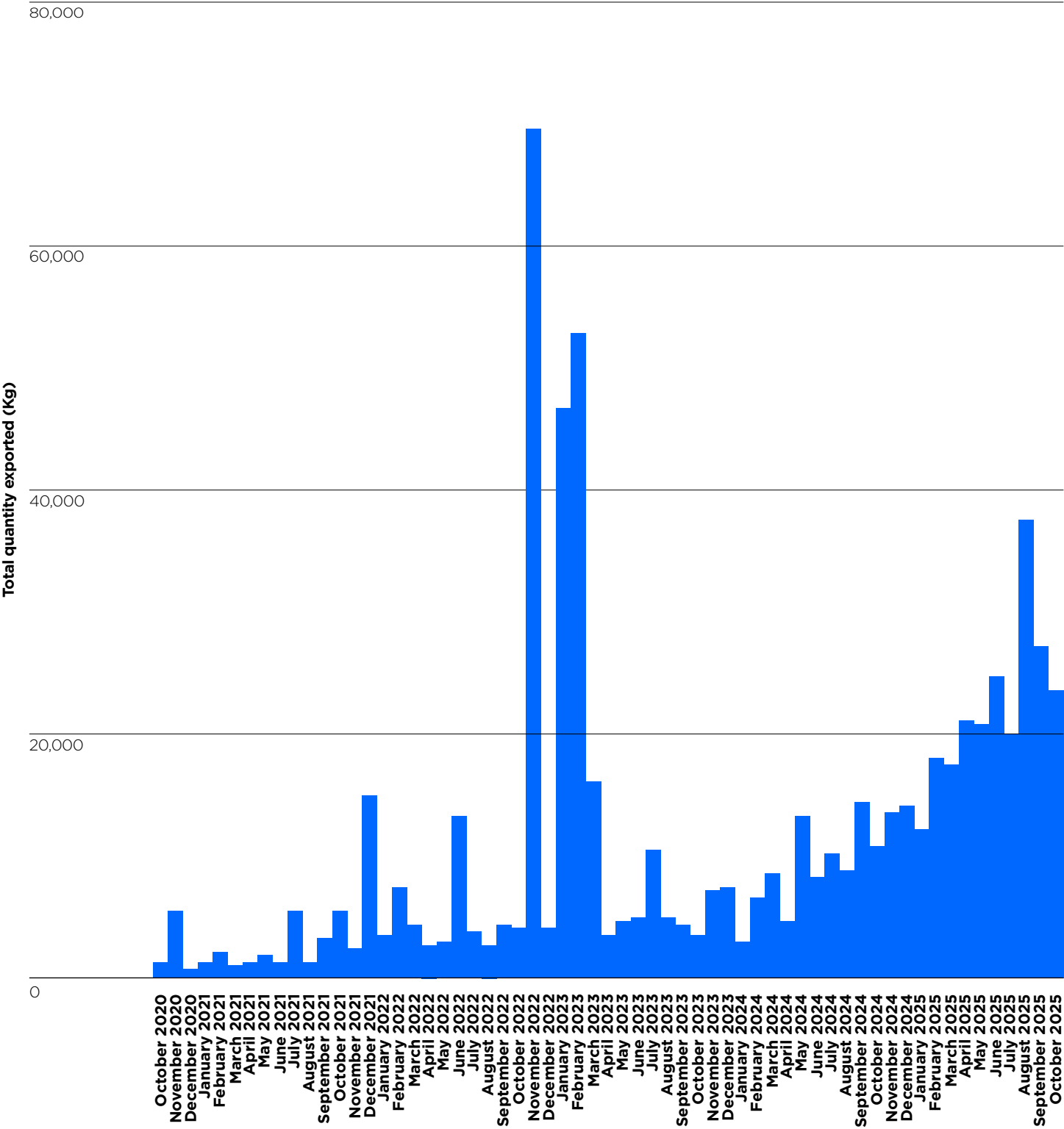
Graph 21 **Active Medical Cannabis Client Registrations**
(2019 - 2024)



Source: Health Canada, 2025

Once the global leader in medical cannabis, Canada had 350,000 registered patients with licensed producers in 2019. However, the subsequent legalization of adult-use cannabis and the launch of recreational sales led to a rapid decline in patient numbers. Many users migrated to the recreational market, drawn by factors such as: convenience, lower prices, and wider product variety. Furthermore, limited access to reimbursement and physician expertise, coupled with the requirement for patients to register with individual licensed producers, has restricted both product choice and general accessibility within the medical cannabis sector.

Graph 22 **Canadian Exports of Dried Cannabis** (2018-2025*)



Source: Statistics Canada, 2025
*As of October 2025

Following the legalization of adult-use cannabis, most licensed producers in the medical market expanded their activities to meet recreational demand. However, with increased competition and shrinking profit margins, many shifted focus to the growing international medical markets for profitability.

Canada currently stands as the world's largest medical cannabis exporter, supplying markets including: Germany, the UK, Australia, Israel, the Czech Republic, and Poland. Canadian medical cannabis exports have consistently risen; in the first three quarters of 2025, Canada exported over 66 tons of medical cannabis to Germany alone, accounting for nearly half of Germany's total medical cannabis imports. With the upcoming opening of additional international markets, such as France, Canadian LPs are well-positioned due to the lack of robust domestic supply in many countries. Furthermore, cannabis cultivators can focus on export benefits as they do not need to pay an excise tax for the exported products.

A significant opportunity exists for companies to expand international sales, but they face stringent medical and pharmaceutical regulations. For instance, selling

products within the EU requires European Union - Good Manufacturing Practice (EU-GMP) certification, which only about 2% of 900 producers currently possess. Obtaining this certification is a lengthy and expensive process, unaffordable for many smaller companies. Consequently, many smaller companies ship their products to EU-GMP tolling facilities for processing and transformation into EU-GMP compliant products. This practice, known as EU-GMP washing, has become controversial due to concerns about converted products being exposed to mold and other contaminants, posing risks to cannabis patients.

While Canadian LPs benefit from international sales, they are facing backlash from cannabis stakeholders in Australia and Israel, who accuse Canada of unfair competition and dumping, harming domestic businesses. In April 2025, Israeli officials proposed tariffs of up to 165% on Canadian medical cannabis imports. If import tariffs are imposed on Canadian imports, it could negatively impact the revenue streams and margins of Canadian LPs, who have heavily focused on the international market.

KEY CHALLENGES

ILLICIT MARKET, MARKET SATURATION AND PRICE COMPRESSION

The legal market faces intense competition from a deeply entrenched illicit sector. This competition is driven by the illicit sector's lower prices and, in some areas, more convenient access. The increased legal supply has led to a drop in legal prices to remain competitive, which has subsequently squeezed profit margins and put pressure on overall profitability.

EXPORT UNCERTAINTY AND SHRINKING MEDICAL MARKET

Canada's domestic medical cannabis market has been shrinking throughout the years driving operators to export their product to international markets. As medical cannabis frameworks develop in countries, they will be seeking to grow and protect their domestic production. Imposing tariffs on Canadian imports is a possibility and could severely limit LP's international expansion plans.

STRICT REGULATIONS AND PROVINCIAL FRAGMENTATION

Federal regulations and provincial variations create a complex landscape for cannabis businesses in Canada. High compliance costs stem from strict rules on cultivation, processing, packaging, comprehensive product testing, monthly reporting, and stringent marketing. Additionally, provinces manage distribution and retail, leading to unique store limits, product listings, and wholesale markups, forcing national brands to adapt to diverse procurement systems and competitive environments.

SECTION 2: RISK MANAGEMENT IN THE CANNABIS SECTOR

The market overviews discussed in Section 1 highlight the various business conditions and regulatory landscapes that cannabis businesses encounter in the sector. Effective management of the risks associated with these conditions and regulations is essential for ensuring the safety, reliability, and consistent availability of products intended for human consumption. This is especially important in the cannabis industry, where products are meant to enhance the well-being of patients and consumers.

One way to reduce the impact of risk is by transferring it to an insurer through the purchase of insurance coverage. However, securing comprehensive insurance for the cannabis industry is inherently complex. Due to the unique nature of this sector, operators face higher legal and operational risks that are specific to the industry. As the cannabis industry continues to evolve, it operates under a patchwork of global regulations, and there is limited data available on the associated risks and

their potential costs. This makes it extremely challenging for insurers to accurately assess and underwrite premiums, as well as to establish suitable terms and conditions for coverage.

Nevertheless, specialized insurance is a critical tool for cannabis businesses to actively mitigate their risk exposure. It is important for insurers to understand the unique challenges that business owners and practitioners in this sector face when seeking coverage to protect their operations and services.

To better understand the risks cannabis operators encounter and the strategies they implement to mitigate them, we conducted interviews with various businesses across different points in the supply chain. Their insights regarding the most critical risks to their operations are explored in this section, along with potential risk mitigation strategies that should be considered.

UPSTREAM SUPPLY CHAIN RISKS

The upstream operations of the cannabis supply chain encompass every step of the procurement and production process, leading up to the distribution of finished goods to consumers. These steps include: cultivation, manufacturing, testing, packaging, and labeling. Drawing on interviews with leading cannabis operators, including: Glass Pharms, Linnea, SOMAí Pharmaceuticals, and PHCANN International, we've identified some of the common threads that appear throughout these conversations with regard to the risks faced at this stage of the supply chain and the mitigation strategies they and other companies implement.

CULTIVATION

Cultivation of cannabis means the propagation, planting, growing, tending, pruning, harvesting, drying, curing, or processing of cannabis plants or their parts. It encompasses all activities involved in producing cannabis, whether done outdoors, indoors, or in greenhouses.

Effective oversight of the cannabis cultivation process is crucial within the supply chain. This is because cultivation forms the basis of the final product, which is intended for human consumption. The quality and safety of an operator's cultivation directly translates to patient/consumer outcomes and directly affects a company's reputation.

Agricultural Risks

As an agricultural product, cannabis is highly sensitive to its environment, as changes to any external input, such as temperature, light, soil, and water, can significantly impact the quality of the plant, leading to smaller yields and possible crop failure. As many cultivators operate in outdoor

environments lacking controls, companies have faced specific challenges, including lower yields and crop damage in places like Colorado due to early winter freezes and crop damage in California due to wildfires. It is thus essential for growers to be aware of their level of agricultural risk exposure when establishing a cultivation operation.

Additionally, as a biological product, cannabis is susceptible to pests, mold, mildew, and diseases, which, if not maintained responsibly, can be highly damaging. Contamination through soil and water is another factor to consider, as these inputs can carry pesticides and heavy metals, which are particularly damaging in terms of harmful effects to consumers and patients.

CASE STUDY



One example of a cannabis operator experiencing crop failure due to pesticide contamination occurred in Massachusetts in 2022, when a licensed cannabis cultivator, River Valley Growers (RVG), lost its entire 2022 harvest valued at \$7 million, as a result of an off-site pesticide drift from a neighboring farm that contaminated their crop. This contamination led to RVG going out of business as they were unable to meet their production contracts, and they have since filed a lawsuit against the neighboring farm, as they haven't been able to cultivate since the incident. Incidents such as contamination from neighboring farms and the lack of checks regarding mold and disease are common, especially in adult-use markets, where the lack of testing and oversight, combined with uncontrolled environments, can lead to significant damage to an operator as well as serious health risks if consumed.

protocols, sterilized equipment, and the use of pest-free propagation material. Vigilant monitoring through visual and digital inspections, alongside environmental sensors, is also crucial. By implementing best practices like crop rotation and efficient irrigation and sanitation systems, operators can minimize pesticide use while also mitigating pest risks.

- **Crop Insurance Coverage:** Although it may be difficult to obtain, crop insurance cover that spans the various stages of the cannabis cultivation process is essential for mitigating the financial impact of crop failure caused by environmental factors. Crop insurance protects farmers from financial losses resulting from unexpected natural, environmental, or operational events that can damage or destroy crops before they are harvested. Given the high value of cannabis, any loss can significantly impact the financial stability of a cannabis cultivator.

Quality and Consistency Risks

The cannabis market requires consistency of products. However, cultivators often face variability in cannabinoid and terpene profiles due to unstable genetics, improper propagation, or changes in cultivation practices, leading to significant deviations between batches. Post-harvest handling is another critical phase where inadequate drying, curing, or storage can result in mold, potency loss, or regulatory test failures. Furthermore, scaling production while maintaining quality remains a persistent challenge, especially in nascent markets. Therefore, to meet the quality requirements, cultivators must implement solutions that minimize the chances of inconsistent batches.

Risk Mitigation Strategies

- **Controlled Environments and Stringent Protocols:** Controlling environmental factors is crucial for cannabis plant health and yield. Indoor or hybrid cultivation rooms offer a controlled environment, significantly reducing exposure to external risks. High-tech indoor facilities or greenhouses equipped with controls for temperature, humidity, lighting, air quality, soil, and nutrients enable operators to better manage plant yield and health. However, the effectiveness of these controls depends entirely on the operator's adherence to stringent protocols concerning microbial contamination, disease, pests, pesticides, and heavy metals.
- **Integrated Pest Management:** For cannabis cultivators, particularly in the medical and pharmaceutical sectors, a proactive and integrated pest management (IPM) strategy is vital. This approach emphasizes preventative measures, such as clean room



We strictly follow European Pharmacopoeia guidelines, with SOPs covering every stage. All incoming materials are tested in our in-house EU-GMP laboratory before entering production areas. Water and air are routinely monitored, and cleanroom procedures are mandatory.



Vladimir Kofcegariski,

CSO, PHCANN

(See Appendix for full interview.)

Risk Mitigation Strategies

- **Tissue Culture:** Tissue culture is seen as an efficient method to ensure quality when compared to seed-based cannabis cultivation, especially for medical markets; seeds lead to inconsistent cannabinoid/terpene profiles and yields. Tissue culture propagates genetically identical, sterile, and stable clones, ensuring uniform plants and consistent cannabinoid profiles. It also preserves genetics long-term, mitigating genetic drift and viral infection risks from traditional cloning. For cannabis operators, tissue culture reduces crop loss, ensures regulatory compliance, and meets patient and regulator demands for consistency.
- **In-house Testing and Monitoring:** To guarantee product consistency and health, and to meet client demand, in-house testing and quality monitoring are essential. Integrating microbiological, chemical, and cannabinoid profiling directly into facilities allows operators to identify contamination, potency deviations, or heavy metal residues before products move downstream. This proactive approach prevents costly recalls and regulatory failures while enabling real-time adjustments to cultivation or processing, thereby minimizing crop loss. In-house laboratories offer superior control and faster turnaround times compared to relying solely on third-party testing; however, it is more expensive. Alternatively, there are less costly portable options; however, the granularity of detail is a lot smaller. Crucially, continuous monitoring by experienced headgrowers and quality control officers ensures each batch meets pharmaceutical-grade standards, delivering consistent cannabinoid profiles that patients and manufacturing partners can trust.

Regulatory and Compliance Risks

As explored in Part 1 of this report, cannabis cultivators are subject to strict regulatory requirements, and failing to comply can lead to serious legal and financial consequences; not only do cannabis cultivators need to hold all the necessary licenses and permits to cultivate, but in certain jurisdictions they also need to meet specific track-and-trace and health and safety standards. When producing for the medical and pharmaceutical industry, cultivators have to meet more rigorous control standards and licensing procedures.

Cultivation companies within the cannabis industry have frequently encountered legal and financial penalties due to insufficient adherence to regulatory and compliance standards. This disregard may stem from either a lack of awareness or a deliberate pursuit of profits over compliance.

CASE STUDY



In the last quarter of 2024, the New Mexico-based cannabis company, NNK Equity LLC, faced serious legal repercussions as it failed to meet compliance requirements. The New Mexico Cannabis Control Division filed non-compliance orders, following significant regulatory violations, including: failed on-site security, failure to obtain water rights, failure to post its license on site, operating under unsanitary standards, failure to tag plants under the state's track-and-trace system, and commercially cultivating at unlicensed premises. This led to state authorities seizing and destroying tens of thousands of cannabis plants, allegedly worth hundreds of thousands of dollars, from NNK Equity LLC.

This example highlights that regulatory compliance must be taken very seriously by cultivators, as authorities often conduct unannounced inspections to ensure premises and operations meet the necessary codes and standards. Failure to comply can result in financial and legal consequences.



Seeds proved too variable, so we use only tissue culture genetics for consistency.



The MHRA, GPhC, and CQC have a clear set of rules to follow, but the Home Office remains the most challenging, often stricter on cannabis than on far more dangerous substances like diamorphine (heroin). This creates uncertainty, so we maintain rigorous protocols and comprehensive documentation to ensure we're inspection-ready at all times.



James Duckenfield,

CEO, Glass Pharms

(See Appendix for full interview.)



Risk Mitigation Strategies

- **Robust Compliance Protocols:** To prevent penalties and license revocations, operators are required to implement strong compliance management systems. These systems should feature clear oversight, comprehensive staff training, and meticulous documentation. Key components include: maintaining current licenses, adhering to health and safety standards, implementing robust security protocols, and utilizing track-and-trace systems. Consequently, operators must have internal compliance officers who conduct regular site checks and provide ongoing training. This proactive approach helps avoid issues during authority audits that could lead to license revocation.
- **Third Party Audits and Good Agricultural and Collection Practices (GACP):** External audits conducted by compliance professionals enhance verification, identifying compliance gaps and mitigating risks before regulatory inspections. These regular audits also build trust with partners and regulators regarding operational integrity. Furthermore, obtaining GACP certification is highly advantageous and necessary for the medical and pharmaceutical sectors and in many jurisdictions. GACP certification not only lends credibility to a cultivator's operations but also ensures adherence to quality assurance standards, encompassing controlled environments and thorough documentation for aspects such as substrate management, pest control, harvesting and handling, and environmental monitoring.
- **Communication with Regulators:** To mitigate legal risks, cultivators should initiate early discussions with licensing and permitting authorities. A proactive approach from the outset of establishing a cultivation operation is advisable. This not only demonstrates a commitment to compliance but is also crucial for anticipating regulatory changes and securing any necessary permits.

Physical Security Risks

As cannabis is a controlled substance internationally, a high-value crop on the illicit market, and in many states in the US, a cash-only operation, cultivators are exposed to a large number of physical security threats, especially theft. This can occur through theft and robbery by a third party or contractors, theft while in transit, or by employees. Without a robust security program, cultivators risk losing significant amounts of cash, produce, and equipment, as well as suffering property damage and employee injuries.

CASE STUDY



There have been several occurrences in which cannabis cultivation facilities have been burgled, with an example occurring in 2024 in Oregon's Jackson County, where it was alleged that a crime gang stole cannabis and equipment from at least 16 licensed cannabis farms, which were based in rural areas of the county and had weak security controls. Occurrences like these could have been mitigated through stronger security measures.



Our Macedonian site is highly secure, with 5-meter walls, licensed guards to carry or use a firearm if needed, well over 200 cameras, and annual attack-response drills. The facility is near Skopje International Airport, which is basically inside a military zone, ensuring that special forces can respond to any possible threat within a minute. With a 20,000 m² factory and secure vaults, breaking in and escaping with any product would be nearly impossible.



Vladimir Kofcegariski,

CSO, PHCANN

(See Appendix for full interview.)

Risk Mitigation Strategies

- **Robust Physical and Technological Infrastructure:** To minimise burglaries, cultivation facilities should have strong security perimeter defenses, including high fencing, reinforced gates, and anti-climbing barriers. For storage purposes, such as finished goods and cash, it is also beneficial to place them in secure vaults. The installation of 24/7 integrated alarm and surveillance systems with remote monitoring by security teams and law enforcement, along with motion sensors and thermal imaging for night security, is essential.
- **Access Control and Security Personnel:** Implementing restrictive access controls, such as key cards, biometrics, and coded gates, for specific personnel in designated facility areas can significantly

mitigate internal and external theft risks. Moreover, the presence of on-site security personnel serves as both a deterrent and a direct line of defense against potential theft.

- **Theft Insurance:** Crime insurance provides a financial backstop to cover losses of money or property stolen from business premises or in transit, whether by a malicious insider or a third party. However, many insurers want to see that there are controls in place to mitigate the likelihood of a loss under the policy.

Market Volatility Risk

Oversupply and wholesale price drops of cannabis are two of the leading challenges in many North American markets, which have led to businesses dissolving their operations or exiting cultivation and focusing their strategy on the downstream supply chain, including packaging, white labeling, and retail. Oregon is one market currently facing oversupply, leading to a significant drop in wholesale prices and thereby leaving little room for margins. According to estimates by Oregon's Liquor and Cannabis Commission(OLCC), supply met demand at 57% in 2024, a significant drop from 71% in 2023, highlighting that almost half of what is produced is not sold. Although beneficial for consumers, this is detrimental for operators as they have to survive on razor-thin margins.

Risk Mitigation Strategies

- **Establish Long-term Partnerships and Contracts:** Securing long-term contracts with trusted partners is beneficial, as it provides a guarantee of minimum purchase volumes and can include forward pricing models, which can reduce exposure to wholesale price drops.
- **Export Strategy:** Market volatility and oversupply of cannabis are very regional and are usually based on the maturity of the market; thus, operators with the ability to export into emerging and growing markets have the ability to generate new and additional revenue streams while avoiding being reliant on a single market.
- **Diversification of Business Model:** Many in the industry have expanded their services to include downstream supply channels, including the retail market, where higher margins are often found. By strategically implementing these expansions throughout the supply chain, businesses can increase their profitability.

Environmental, Social, and Governance (ESG) and Sustainability Risks

Sustainability and ESG standards are gaining importance in the cannabis industry. This is driven by increasing social concerns from stakeholders and governments regarding environmental impact. Cannabis cultivation and manufacturing, particularly indoor growing and extraction, are resource-intensive, requiring significant electricity and water. This heavily contributes to an operator's carbon footprint. Furthermore, regulators are implementing stricter sustainability measures for permit and license holders, especially concerning water usage and waste. Therefore, a robust sustainability strategy is also beneficial from a legal standpoint.



We are co-located with an anaerobic digester and solar array, which provides us with secure, renewable energy. This reduces one of the biggest risks growers face; underestimating electricity and water needs, while ensuring everything we produce is powered by green energy.



James Duckenfield,

CEO, Glass Pharms

(See Appendix for full interview.)



Sustainability is a core part of our operations. We monitor greenhouse gas emissions and recycle extraction waste into renewable energy via a local biogas plant. Linnea currently holds an EcoVadis silver medal, which places us among the top 15% of assessed companies worldwide, reflecting strong performance across environmental, social, and governance criteria.



Susanne Caspar,

CEO, Linnea

(See Appendix for full interview.)

Risk Mitigation Strategies

- **Water Management and Waste Circularity:** Investing in precise technology for irrigation solutions that reuse water and use rainwater for cultivation not only increases the sustainability of the operation, but also reduces water consumption and is cost-effective. Additionally, waste in the form of biomass from cultivation operations can be used to make nutrient-rich compost.
- **Renewable Energy:** As the environmental damage of fossil fuels and oil generators becomes more detrimental, many companies are implementing renewable energy sources to fuel their cultivation sites. This can be achieved by utilizing solar panels and energy storage units to create more efficient and sustainable microgrids. Additionally, there are several governmental programs and environmental funds that support the shift toward renewable energy, making the transition and implementation of renewable energy sources economically feasible.

PROCESSING AND MANUFACTURING

The post-harvest processing and manufacturing point of the cannabis supply chain is where raw cannabis is dried, trimmed, and cured, and is either packaged or refined/extracted to produce a finished product in the form of Fast-Moving Consumer Goods (FMCG) such as edibles, vapes, creams, oils, and lotions. This can involve manufacturing equipment and assembly lines that are exposed to human injury, mistakes, and technical failures. During these operations, the aim is for consistency, purity, and market compliance. Again this translates directly into customer and patient outcomes.

Contamination Risk

Cannabis products are highly susceptible to contamination in the post-harvesting and manufacturing process, as raw material is transported, handled, and stored at various stages of the operation. As the raw material of cannabis needs to be dried, trimmed, and sorted either through machinery or manual labor, operators face a risk of unwanted contaminants, as unclean machinery and unsanitary staff conditions can lead to the transmission of foreign chemicals and microbes. Additionally, if post-harvesting processes are improperly managed, such as storing wet cannabis in humid conditions, the cannabis being processed is highly susceptible to microbial, fungal, and insect infections. Heavy metal and microbial contamination may also occur through contamination between batches during the drying process.

These risks of contamination can cause serious consequences for unvigilant operators, including product recalls, batch destruction, and, in the worst-case scenario, severe injury to consumers or patients. It is therefore essential to ensure material and product integrity throughout the process to avoid any reputational, legal, or financial ramifications.

CASE STUDY



There have been several incidents of cannabis contamination that have resulted in product recalls across the United States. In June 2023, the OLCC issued a recall for multiple batches of cannabis flower that tested positive for mold and heavy metals. These issues are believed to have arisen during the drying and packaging phases of production. Sales of the contaminated products from three producers—Greenworks Farms, Nectar Markets LLC, and Rebel Spirit—were halted at the retail level, and consumers were advised to either destroy or return the affected products. In September 2024, Maine's Office of Cannabis Policy also issued a mandatory recall, as adult-use flowers and pre-rolls produced by Cannabis Cured were found to have levels of yeast and mold above the approved limit.

These product recalls are not only financially costly as they lead to a reduction of sales, potential fines, and interruptions of day-to-day activities, but are also legally and reputationally damaging.



Our long history in pharma ensures we operate to the highest standards. We follow strict SOPs, are audited by Swissmedic, FDA, Anvisa, and other regulatory bodies, and have in-house testing laboratories, including microbiology laboratories. We only accept raw material that meets strict requirements for purity, heavy metals, and microbial levels. This process minimizes risks and allows us to consistently produce large volumes of compliant extracts and isolates.



Susanne Caspar,

CEO, Linnea

(See Appendix for full interview.)

Risk Mitigation Strategies

- **In-house Testing:** To understand the quality and health of the product, it is essential to perform several testing checks on the material before, during, and after the manufacturing process. By implementing a rigid in-house testing protocol throughout these processes, operators can mitigate contamination issues as soon as they occur. Having an in-house testing laboratory, preferably with GMP certification, may be an expensive yet crucial step to ensure product stability throughout the manufacturing process. As manufacturers may procure cannabis materials for processing from third-party cultivators, performing in-house analytical tests can ensure that the product they receive is transported safely and that it is of the required quality. This process serves as a crucial initial check on the reliability of logistics and cultivation partners before the cannabis can undergo processing. Additionally, conducting an in-house laboratory assessment of finished products before they are sent for third-party laboratory testing ensures that the operator's products meet requirements before going to market.
- **Controlled Rooms:** To mitigate the risk of contamination throughout the production process, operators should build facilities with various rooms specific to the activity (drying, curing, trimming, extraction, packaging, and testing). By separating these operations in a controlled environment with temperature and humidity controls, as well as high-efficiency particulate air (HEPA) filters, operators can mitigate quality risks as well as quarantine batches that have been exposed to contamination.

- **European Union Good Manufacturing Practice (EU-GMP) and Standard Operating Procedures (SOPs):** Implementing GMP and its standard operating procedures is a necessity for the industry, as it ensures product safety from contamination. As with GMP standards for the pharmaceutical industry, cannabis manufacturers need to meet GMP-compliant clean room standards, sanitation guidelines, hygiene programs, batch testing, filtration systems, and strong documentation procedures. If these standards are maintained and rigorously enforced, operating manufacturers can significantly mitigate the risk of product contamination throughout the processes.
- **Product Liability Insurance Coverage:** Purchasing this coverage, if possible, provides customers and supply chain partners with confidence that the manufacturer of cannabis products is backed by regulated capital in the event of a consumer claim. It would respond to third party claims alleging harm as a result of consuming, or exposure to, the insured's products.

Equipment and Operational Risk

The manufacturing process for many cannabis products involves expensive equipment and potentially hazardous/flammable extraction procedures. Operators are prone to risks that can damage facilities and equipment as well as cause workplace injuries. Significant workforce and equipment risks tend to be found in the extraction process, which may use solvent-based systems using high-pressure CO₂ or ethanol and hydrocarbon, which, when not operated or maintained correctly, can cause unsafe working conditions.

CASE STUDY



In January 2025, the PharmaCann extraction facility in Maryland witnessed an explosion and fire in an extraction booth where butane and propane were being used to extract cannabis. The explosion and fire, although controlled by emergency fire sprinklers, injured two employees, with one being severely injured. The Office of the Fire Marshal estimated that the damages exceeded \$250,000. Although the cause of the explosion and fire is being investigated, it is assumed that the flammable solvents in the extraction booth were the likely sources. In another case in 2023, a 23-year-old employee at the cannabis production facility of Minerva Canna in New Mexico suffered moderate chemical burns due to a fire and explosion caused by ethanol being used in the extraction process.

These incidents of workplace injury and facility/equipment damage in the production process are more common than they should be in the cannabis industry.

Risk Mitigation Strategies

- Safety Management Protocols and Training:** Inadequate safety protocols and staff training are significant drivers of workplace injuries and property/equipment damage. To operate safely, cannabis producers must implement strict safety protocols and operating procedures for handling equipment and solvents for production. Companies need to provide the workforce with continuous training regarding safety measures when handling specific materials and equipment, as well as for emergency responses. Under the safety protocols, only those qualified must be able to handle the particular equipment and hazardous materials. Additionally, safety protocols should outline that personal protective equipment, including fire-resistant clothing, gloves, and eye protection, should be required when working in such environments.
- Facility Safety Controls:** Facilities that undergo cannabis production should be safeguarded to mitigate any workforce injuries or operational risks throughout the manufacturing process. All rooms should have emergency sprinkler and ventilation systems to address any issues directly. In rooms where extraction operations are performed, explosion and fire-proof materials and equipment should be used.
- Equipment Maintenance:** The lack of equipment maintenance has the potential to damage, not only the equipment itself, but also cause damage to facilities and injuries to the workforce. It is therefore a necessity that routine inspections and maintenance on production equipment are scheduled. To mitigate equipment failure interruptions, producers would also benefit from purchasing spare equipment parts and having a mechanical expert on site. Additionally, if equipment is damaged, it would be wise to have backup production lines in case of interruptions.
- Insurance Coverage:** Workers Compensation or Employers' Liability coverage provides a financial backstop for claims made against the business as a direct result of an injury that happened in the workplace. Having insurance does not replace the need for following health and safety best practices, but can protect the balance sheet when the most unfortunate of accidents happen. In addition, General Liability provides similar coverage but for when third parties suffer injuries or property damage as a result

of the insured's business operations. Both coverages would be advisable for cannabis manufacturers.

Regulatory and Compliance Risks

Cannabis manufacturers are bound by strict certificate, permit, and operation requirements, where failure to meet such standards can result in product rejections/recalls, license rejections/suspensions, and criminal liability. To operate legally and avoid product rejections and fines, companies must ensure they hold the necessary documents and certificates for their operations and products. The main regulatory requirement is to ensure that all the required health and safety measures are implemented during operations, as well as to produce safe, consumable products. Unfortunately, there is a chequered track record of cannabis manufacturers failing to meet regulatory requirements.

CASE STUDY



In July 2025, C&C Manufacturing LLC, a cannabis manufacturer in Missouri, had its license revoked by regulators as the company created distillate with unregulated tetrahydrocannabinol (THC) and sold it to various other manufacturers, leading to a statewide recall of 135,000 products in 2024. After C&C Manufacturing LLC received a notice of pending revocation, the company removed and destroyed all cannabis products in its facility as well as deleted any video recordings. These actions of the company, as well as failing to maintain track-and-trace compliance, led to the authorities revoking its license. In another case in Missouri, Delta Extraction LLC lost its license when regulators determined that the company was sourcing tetrahydrocannabinolic acid (THC-A) from outside the regulated cannabis program to manufacture cannabis products, where it was converting THC-A from the hemp industry and converting it to THC for its regulated products. This violation led to a product recall and a revocation of its license.

Evidently, there are substantial consequences if cannabis manufacturers do not follow the strict regulations and requirements outlined for their market.

Risk Mitigation Strategies

- Quality Management Systems and Qualified Person Oversight:** It is of the utmost importance for cannabis companies that they maintain rigid quality management systems and ensure there is oversight by qualified assessors and controllers. A qualified person should ensure that batches meet quality and safety requirements and are released with the required documentation. In most cases, companies are required to implement quality management systems due to their certifications and permits, including EU-GMP; thus, it is essential to maintain such systems and implement new controls once gaps in operations are identified. Authorities tend to conduct unannounced inspections, so it is imperative that companies undergo mock inspections and internal audits.
- Track-and-Trace Integration:** New software solutions that track and trace products throughout the supply chain are available for cannabis companies to introduce. Through these track-and-trace solutions, companies can operate more efficiently in terms of record-keeping requirements placed by authorities, because production information is automatically saved onto real-time databases.
- Compliance and Regulatory Officer:** Navigating the cannabis industry is a difficult task for many operators seeking to enter or expand into markets. Each market holds its own set of specific regulations, and companies must stay up-to-date with current and upcoming regulations. By introducing regulatory and compliance officers, these individuals can focus solely on ensuring that the organization complies with domestic laws, internal policies, and standards. Additionally, it serves as a valuable resource for an expansion strategy when entering new markets, given that cannabis rules and regulations vary significantly across jurisdictions.

Supply Risk

Cannabis manufacturers, especially those that are not vertically integrated, are exposed to the risk of disruption to their production as a result of inadequate supplies (by volume or quality) of raw materials, such as raw cannabis biomass, FMCG ingredients, solvents for extraction, equipment, and utilities. Particularly for raw cannabis biomass, the manufacturer may receive its order but it may not meet quality standards. Interruptions cost time and capital, leading to unrealized revenue and potential contractual liability if obligations are not met.

Disruptions to supply can have multiple causes which are difficult to control, including geopolitical environment, physical perils, and failures of contracting partners. Yet for manufacturers, this supply risk and interruptions to production costs time and capital, leading to unrealized revenue and potential contractual liability if obligations are not met.



[Relationships with regulatory authorities] is vital. For example, when we built our new THC production facility, we consulted Swissmedic early to ensure compliance. We also maintain dialogue with authorities in Brazil and other countries to stay conversant with evolving laws. This proactive approach ensures our products always meet new requirements.



Susanne Caspar,

CEO, Linnea

(See Appendix for full interview.)



[When evaluating supply partners], we visit all growers personally—if you haven't visited them, you shouldn't be doing business with them. Second, financial stability is crucial. Companies in financial trouble often cut corners, even unintentionally. We're always transparent about our own financials with partners. Third, suppliers must have a competent QA team that can service global pharmaceutical markets. Without it, one small issue can cause months of delays due to regulatory paperwork.



Michael Sassano,

CEO and Founder, SOMA Pharmaceuticals

(See Appendix for full interview.)

Risk Mitigation Strategies

- **Robust Supply Partner Contracts:** It is vital for cannabis manufacturers to have consistent supply chain partners and establish strong, reliable partnerships whereby product quality and service is guaranteed. Cannabis manufacturers need to examine the financial health, management, and compliance of the companies they establish partnerships with to ensure the legality and stability of their supply. With legally binding contracts, manufacturers can mitigate the exposure of price fluctuations as well as mandate quality requirements.
- **Diversified Sourcing:** Companies may need to establish multiple supply partners to mitigate supply disruptions. By having several back-up suppliers, manufacturers can operate more efficiently if one supplier fails to meet their requirements. As uniformity is key for many cannabis producers, manufacturers should introduce strict product and quality specifications into contracts to mitigate any deviations that could alter the final product.
- **Business Interruption Insurance:** This coverage provides vital financial protection by covering lost income and ongoing expenses when operations are disrupted — whether by a physical event such as a fire, flood, or equipment breakdown, or a cyber event like a ransomware attack that halts production systems. For physical losses, it helps replace income that would have been earned during downtime, covers fixed costs such as payroll and rent, and funds temporary relocation or expedited repairs to resume operations quickly. For cyber incidents, it compensates for revenue lost due to system outages, supply chain disruption, or data recovery efforts. In both cases, business interruption coverage helps manufacturers maintain financial stability, meet obligations to employees and customers, and recover more smoothly from events that could otherwise jeopardize long-term viability.

TESTING

Cannabis testing is essential for the industry; to validate that products meet the quality standards and are safe for patients and users to consume. In most jurisdictions, particularly in the medical and pharmaceutical markets, accredited testing results are required before a product can be sold or released to the market. However, the testing environment in the cannabis industry has its own set of risks and challenges due to the lack of standardization between testing protocols and the possibility of lab-shopping.

It is often the case that testing results for cannabis vary from one testing lab to another. This is primarily due to the fact that testing labs use different equipment, analytical instruments, and sample preparation techniques, leading to inconsistent results. Thus, if a batch of cannabis is tested as 22% in one lab and 19% in another, it can be unclear for operators on which result they should rely on. Additionally, based on the jurisdiction of the laboratory and cannabis testing protocols, requirements for certificates of analysis (COA) may differ, which may cause problems when exporting to various markets and the COA requirements of the importing country are not fulfilled. Failing to meet testing requirements for laboratories as well as for operators can cause irreparable damage to the business.



If you're only producing a handful of products for a few markets, it might not be worth it—the setup is over a million euros plus staffing costs. But for multiproduct, multicountry operations like ours, it's essential. Having our own lab means we can test immediately, keep costs down, and deliver products directly with our own certificates of analysis (COAs). This avoids delays, disputes with third-party labs, and ensures patients receive consistent, compliant medicine.



Michael Sassano,

CEO and Founder, SOMAí Pharmaceuticals
(See Appendix for full interview.)

Risk Mitigation Strategies

- Method Harmonization:** To ensure stable lab results, operators should validate their analytical methods against recognized pharmacopoeial standards tailored to their target markets. For instance, a Canadian manufacturer exporting to Germany must adhere to the standards set by the European Pharmacopoeia. Additionally, in-house and third-party labs should participate in inter-laboratory proficiency testing programs to benchmark performance and reduce result variability. It would also be beneficial for operators to work with ISO 17025-accredited laboratories, which are laboratories that hold an international standard for the competence of testing and calibration. Working with accredited labs ensures operators that methods are standardized, audited, and improved.
- Uniform Sampling Procedures:** Lab operators should implement statistically sound sampling protocols and follow standardized operating procedures to ensure consistency in how samples are procured, stored, handled, and transported. These procedures should also provide training to lab operators on sampling procedures to prevent contamination or testing errors.
- Dual Testing Approach:** Manufacturers should implement in-house testing as well as undergo testing with accredited third-party laboratories to minimize regulatory risk. By having an in-house laboratory, operators can implement testing strategies throughout the manufacturing process to remove products that do not meet requirements early. Additionally, testing with third-party accredited laboratories allows companies to identify discrepancies early and provides reliability toward meeting regulatory requirements.
- Recall Preparation:** There is always a possibility that cannabis operators may face a product recall, as several points throughout the cultivation and manufacturing process can expose the product to external factors that compromise its quality and safety. As a recall is a stressful experience, which is costly and time-consuming, operators should implement a robust recall management plan for such occurrences. Under the plan, operators should establish a recall team assigning qualified personnel to emergency responsibilities, establish recall guidelines which cover issue identification, recall monitoring and documentation, as well as stakeholder communication. Each plan should also include sessions for corrective actions and improvement.
- Alignment of Testing Panels:** It is vital for operators trading cannabis in multiple jurisdictions to be aware of the required testing panels for each market. In many cases, domestic regulations on required testing differ from those found in other import/export markets. Failing to meet such requirements can result in customs seizing/rejecting products, which leads to financial losses in revenue. It is therefore integral for operators to understand and perform the exact testing panel requirements before they enter each market to mitigate any potential customs rejections.

PACKAGING AND LABELING

Packaging and labeling are the final essential steps in the production process of the finished cannabis product. Packaging in the cannabis industry is essential, as not only does it protect the product, but it is also heavily regulated. Labeling is of utmost importance in providing transparency regarding the product, ensuring patients and customers receive the required information for its safe use.

Each jurisdiction has its own set of required standards. In almost all cases, products must provide warning labels, cannabinoid ratios, batch numbers, expiry dates, dosage instructions, and additional jurisdictional requirements (such as languages and warnings). Some markets also restrict the use of colors and imagery to reduce the products' appeal to children.

CASE STUDY



Failing to comply with standards or having errors in the labeling can lead to expensive product recalls. For example, in September 2025, California cannabis regulators issued a recall on four THC-infused beverages as product labeling did not identify the serving size, nor that the product was produced under GMP practices. Mistakes in this regard are costly, as recalled products result in lost revenue, and companies must waste inventory due to mislabeled packaging. Additionally, they must invest capital in rectifying the labeling issues.



We've designed packaging to protect quality. For white-label vials, we have validated bottles and droppers with stability data of more than 5 years. For bulk extracts, we use containers tested under varying conditions.



Susanne Caspar,

CEO, Linnea

(See Appendix for full interview.)



Products are packaged in sterile, sealed environments with minimal staff presence. They are then boxed, palletized, and wrapped with temperature blankets.



Vladimir Kofcegariski,

CSO, PHCANN International

(See Appendix for full interview.)

Any errors or weaknesses in this stage can be detrimental for operators; therefore, companies should ensure they are aware of the risks and meet the standards for each jurisdiction in which they operate.

Risk Mitigation Strategies

- **Regulatory Oversight:** Operators should implement and work closely with compliance officers who are aware of the specific packaging and labeling requirements for each market. As regulations in the cannabis industry differ and rapidly evolve, operators must communicate effectively with regulators to ensure they do not overlook any changes that may lead to product recalls and other negative implications. Companies should pre-clear labels with authorities before placing their product on the market, as any issues caught early can significantly reduce the chance of further problems.
- **Verification Protocols:** To ensure that labels and packaging align with the intended product, operators should conduct several verification protocols on cannabinoid content, batch data, and testing results before printing product labels. Companies should also perform several random audits of products to ensure that labeling accuracy and packaging integrity are aligned and meet standards.
- **Product Recall Insurance:** This coverage can help to mitigate the financial impact of recalling products — covering the direct financial costs associated with:
 - Product withdrawal, shipping and disposal.
 - Replacement and redistribution of corrected stock.
 - Customer notification and public relations expenses.
 - Business interruption and loss of profit.

DOWNSTREAM SUPPLY CHAIN RISKS

As cannabis products move downstream from cultivation and manufacturing to logistics, distribution, and retail or pharmacy channels, the risks operators face become increasingly complex. These stages are where regulatory oversight is most stringent, consumer expectations are highest, and reputational exposure is most acute.

Drawing on interviews with Cannabilog, Enuu, PHCANN International and SOMA Pharmaceuticals, we've identified some of the common threads that appear throughout these conversations with regard to the downstream supply chain risks operators face and what mitigation strategies they can implement.

LOGISTICS AND DISTRIBUTION

Logistics and distribution firms are tasked with ensuring that cannabis products reach their next destination, either nationally or internationally. Cannabis products' high value, strict regulatory requirements, and sensitivity to environmental conditions means that distribution of these products carries heightened risks.

The loss of products during this phase of the supply chain has an instant impact on revenue — either the products do not meet their intended destination or they are rendered unusable in the journey, which has a knock-on impact to the rest of the supply chain.

Security Risk

Cannabis shipments are high-value and desirable, making them vulnerable to theft by either insiders or third parties. This necessitates robust protection measures.

Robberies involving cannabis delivery trucks and warehouses are not uncommon in the industry. For instance, Aleafia Health, a Canadian licensed producer, announced that one of their delivery vehicles, containing finished cannabis products intended for the adult-use market, was stolen in 2019. Furthermore, between 2018 and 2022, licensed producers in Canada reported over 2200 kg of cannabis as missing or stolen, with the majority of these incidents occurring during transportation and shipping stages.

As instances of robberies and theft are fairly frequent in the industry, it is important for operators to implement robust security measures when transporting and storing cannabis.



Security risks are significant; in some countries, we use armed escorts even when not legally required..... We can offer marine or transportation insurance that specifically covers cannabis shipments, including temperature excursions, theft, and damage. We always advise clients to have door-to-door coverage, regardless of Incoterms, to avoid disputes between buyers and sellers.



Susanne Caspar,

CEO, Linnea

(See Appendix for full interview.)

Risk Mitigation Strategies

- **Security Protocols:** It is essential for cannabis operators to partner with licensed and vetted logistics providers that have robust security protocols in place. These include: GPS trackers on vehicles, route variability, and restrictive access to delivery information. Armoured transport may also be advisable for high-value shipments, especially in markets with high rates of theft and burglary.
- **Cargo Insurance:** Those responsible for sending the products should only partner with logistics providers that offer cargo insurance or crime coverage, which covers theft and loss. In most cases, especially on the international medical cannabis market, cargo insurance is the norm, where insurance typically covers 110-120% of the cargo value.

Product Quality Risk

Maintaining adequate transportation and storage protocols of cannabis, especially in its raw form (flowers and pre-rolls), is crucial before it reaches consumers. At this point in the supply chain, cannabis may be exposed to environmental conditions such as heat, humidity, or light, which can degrade terpenes, cannabinoid ratios, and the shelf life of the product. Inefficiencies and a lack of oversight during the transport and storage phase may lead to the cannabis being unsuitable or unsafe for consumption. Therefore, companies must ensure that products are handled in safe and controlled environments with sufficient oversight to maintain product quality and safety.



Quality risks are also unique in cannabis because it's both a pharmaceutical and an agricultural product. This means issues such as temperature control, mold, and contamination are constant concerns....At Cannabilog, we always use pharmaceutical-grade services, air freight, and land transportation alike. As a standard, throughout the logistics chain, we utilize temperature-controlled vehicles, validated packages, implement required GDP procedures, and ensure proper insurance. It's more expensive, but protecting the integrity of the medicine is non-negotiable.



Yoram Eshel,

CEO, Cannabilog

(See Appendix for full interview.)



Every shipment is closely monitored by our logistics department. To make sure they follow GDP guidelines, we place our own data loggers in each shipment to track temperature and location independently.



Vladimir KofcegarSKI,

CSO, PHCANN International

(See Appendix for full interview.)



Every batch undergoes quality and quantity checks, documentation review, and temperature control validation. We also use independent certified laboratories in Germany for mandatory testing before releasing any product to the market. The transportation temperature must remain between 8–25°C, verified by data loggers on each pallet.



Justin Stenchly,

Supply Chain Manager, Enuu
(See Appendix for full interview.)



Regulatory risks are the most critical. Every exporting and importing country has different rules, and they change frequently. If you don't stay current, a shipment could be destroyed.... Delays often come from licensing; import and export permits can take weeks in some countries.



Yoram Eshel,

CEO, Cannabilog
(See Appendix for full interview.)



Having watertight paperwork and enterprise resource planning (ERP) systems is vital. Regulators now cross-check import and export licenses with source countries. If you can't produce the correct documents immediately, you'll be flagged and potentially inspected. Many companies tried to 'chase paperwork later'—that doesn't work anymore.



Michael Sassano,

CEO and Founder, SOMA Pharmaceuticals
(See Appendix for full interview.)

Risk Mitigation Strategies

- **Data Loggers:** Cannabis operators transporting cannabis may implement data loggers on their shipments as they provide continuous monitoring of environmental conditions. With data loggers, companies can track whether their products have been exposed to unstable environments and identify potential causes. Additionally, data loggers keep a record that assures operators that they are maintaining regulatory compliance and can determine whether their logistics partners are transporting their cargo in stable environments.
- **Cold Chain Logistics:** Cannabis operators should work with logistics providers who provide temperature-controlled cargo vehicles and warehouses. Similar to the food and pharmaceutical industry, implementing cold chain logistics is necessary to ensure that product quality and integrity is maintained.

Regulatory Risk

Regulations on the transportation and handling of cannabis, especially in regard to import and export, are complex; every market has its own regulations, requirements, and licensing procedures. The complexity and fragmentation of regulations often exposes companies who are internationally trading cannabis to costly custom delays, seizures, and regulatory fines.

Risk Mitigation Strategies

- Digital Documentation and Record Keeping:** Cannabis companies are required to maintain detailed records regarding the transportation of cannabis products. In many cases, especially in the US, records are integrated with digital state track-and-trace systems; however, companies can also integrate them into their own tracking systems. Additionally, companies should have detailed chain of custody documentation providing a comprehensive record of the collection, storage, and transportation of cargo. During the logistics and distribution process, companies should implement tamper-proof barcoding or scanning of cargo at every transfer point to maintain a fully auditable chain of custody. By implementing a sound record-keeping protocol, companies are able to mitigate any potential fines, shipment seizures, or regulatory audits.
- Regulatory Affairs Officer:** Keeping up with regulations in the cannabis industry is already an exhaustive undertaking domestically; this is further exacerbated once a company seeks to trade cannabis products on international markets. As regulations in terms of product specifications, permit and licensing procedures, and documentation requirements vary significantly, having a lack of oversight at this stage can lead to customs seizures and financial losses. Thus, companies should have regulatory affairs officers or consultants who are specialized in certain markets and are up to date with any regulatory changes. They can provide companies with information on the required testing panels, packaging, and documentation needed, as well as pre-clear shipments with authorities, which helps to mitigate any disruptions.

Supply Disruption Risk

Transporting and distributing cannabis domestically and internationally exposes cannabis operators to a range of disruption risks that can lead to costly supply chain interruptions, such as natural disasters, logistic provider failures, and global supply chain shocks. To mitigate supply chain interruptions, operators should implement robust mitigation strategies to prevent any financial consequences in terms of lost revenue or wasted product.



Regulatory changes, customs delays, and transport disruptions are major risks. We mitigate them by working with multiple suppliers, partnering with specialized logistics providers, and closely monitoring regulatory frameworks to adjust our planning early.



Justin Stenchly,

Supply Chain Manager, Enea

(See Appendix for full interview.)

Risk Mitigation Strategies

- Logistic Provider Diversification:** To mitigate any potential failures of logistics providers, cannabis companies should partner with several vetted and certified logistics providers to minimise dependence on a single entity. This allows flexibility for operators when one provider is currently out of service. Additionally, companies should maintain service level agreements with logistics providers, which include penalties for non-performance, thereby mitigating any financial losses that could occur.
- Business continuity planning:** Operators should conduct risk mapping for their logistics and distribution activities to identify potential supply chain disruptions, which may be caused by political, cyber, or environmental factors. Implementing business continuity plans should include pre-arranged emergency logistics routes and manual work-arounds.

RETAIL/PHARMACY

Retail and pharmacy operations are consumer and patient facing. Risks at this stage of the supply chain can lead to failures that are often immediately apparent and have heightened visibility. Although adult-use retailers and pharmacies have varying levels of requirements, both require high levels of vigilance and management to ensure that products being sold meet the regulatory requirements, the inventory of products and cash is safeguarded, and products can be safely distributed to patients/consumers.

Theft Risk

Due to cannabis being a high-value crop and many retailers operating as cash-only businesses (a consequence of limited financial services within the industry), retail stores have become appealing targets for criminals. The absence of robust security measures further facilitates these criminal activities, allowing perpetrators to identify vulnerable entry points easily.

- **Crime Insurance:** Insurance is available to reimburse retailers in the event of theft, either by an employee or a third party. Some companies provide insurance for retailers regarding theft; however, many of these policies often require operators to meet high security standards, such as implementing strict security infrastructure and protocols.
- **Inventory and Cash Management:** It is beneficial for retailers to have digitized records of their inventory, which is continuously checked and updated providing retailers with an overview of any missing/stolen inventory. As many retailers are cash-only businesses implementing cash management protocols including frequent cash transfers, reduced on-site cash inventory and the usage of a safe can minimise the amount of losses in the occurrence of theft.

CASE STUDY



Theft on retailers has become a significant issue in the US, as for example in California in 2024, there were over 15 retail burglaries in nine Californian counties conducted by one organized crime syndicate, in which dispensaries experienced a total loss of \$1 million and 975 pounds of cannabis. Cases like these are fairly common as in adult-use states, dispensaries continue to face smash and grab and vehicle break-ins leading to property damage, inventory, and financial losses.

Regulatory Risk

Retailers and pharmacies in the cannabis industry face various regulatory challenges. They must obtain specific licenses and permits through rigorous application processes and ongoing compliance checks. After obtaining licenses, they must follow strict operational requirements, including accurate record-keeping of cannabis products, implementing age verification protocols, and establishing systems for patient and prescription verification for medical cannabis. For pharmacies handling cannabis as a magistral product, quality control is crucial, requiring adherence to proper storage, handling, and dispensing procedures. Qualified personnel, often with specific training and certifications, are necessary to ensure the safe handling of cannabis products. Additionally, purchasing limits are often set to prevent diversion and overconsumption. Failure to comply with these regulations can lead to severe consequences, including financial penalties, license suspension or revocation, and potential business closure.

Risk Mitigation Strategies

- **Security Enforcement:** As retailers are prime targets for theft and burglaries, implementing security measures, including 24/7 surveillance, reinforced doors, bollards, safes, and alarms, is very important. Depending on the level of criminal activity in an area, retailers may want to partner with security providers and local law enforcement to ensure rapid response rates in the event of burglaries.
- **Staff Training and Due Diligence:** In many cases, theft in dispensaries happens at the hands of employees; thus it is vital for companies to undergo background checks before hiring employees to mitigate any potential theft. Additionally, employees and staff members should undergo training regarding robbery response and emergency protocols.



Pharmacies are required to open shipments, check quality, and ensure compliance. Due to the growth of the market in Germany, many pharmacies have specialized in medical cannabis and are well prepared. Ultimately, responsibility shifts to them once they receive the product.



Justin Stenchly,

Supply Chain Manager, Enea
(See Appendix for full interview.)

Risk Mitigation Strategies

- **Verification and Limit Controls:** Failing to comply with age and purchasing restrictions can have severe legal and financial consequences for retailers. Additionally, for pharmacies, prescription and patient verification are a must. It is therefore advised that retailers and pharmacies implement automated point-of-sale systems that are integrated with state-wide track-and-trace systems or patient registries to ensure consistent controls are in place before a product is sold.
- **Quality Control Protocols:** To mitigate any product recalls and to ensure consumer/patient safety, retailers, and especially pharmacies, should implement quality control protocols of products before they are shelved. These protocols should include COA checks, visual and olfactory assessments of products, labeling and packaging checks, retention samples, and environmental controls for storage. Updating these protocols, combined with continuous staff training and record keeping, should aid in mitigating regulatory risks.
- **Recall Management:** In the case of product recalls, retailers and pharmacies should implement SOPs that aim to withdraw products from shelves as soon as possible. The SOPs should also include a solid communication strategy toward authorities, suppliers, and consumers/patients. Additionally, having batch traceability systems and seed-to-sale software can provide useful details on how much of the recalled product was sold and to whom. Retailers should also establish a record-keeping system that covers reports on damaged products and quality complaints, as it provides insight into potential quality control failures.
- **Comprehensive Training:** Pharmacies dispensing medical cannabis are the last line of patient safety before it is consumed. Therefore, pharmacies face a liability risk if products negatively interact with patients due to ill-informed advice on dosage requirements and interactions with other medications. It is crucial that pharmacies provide comprehensive staff training regarding medical cannabis safety, including effects, contraindications, dosing guidelines, and its effect on different medicines.

EXECUTIVE RISK

Management teams in the cannabis industry can face intense scrutiny from regulators, investors, and customers. The complex legal and regulatory environment exposes directors and officers to heightened risks that extend beyond typical corporate governance challenges. Failures in decision-making, compliance oversight, or financial management can result in litigation, reputational harm, regulatory fines, M&A failures, and corporate and personal liability. Given the high-risk nature of this sector, cannabis companies and their management must adopt risk management strategies and solutions that transfer risk.

Regulatory Oversight

Executives hold a crucial governance responsibility in ensuring that their organizations comply with the various laws and regulations pertaining to cannabis cultivation, manufacturing, distribution, and retail. Actual or alleged violations of regulations, such as product mislabeling, diversion of products to unregulated markets, and failures to adhere to Good Manufacturing Practices (GMPs), can lead to serious legal consequences, claims of negligence or misstatements. Competency in regulatory governance is essential, not only for the financial integrity and stability of the business, but also for the safety and well-being of consumers and patients.

Risk Mitigation Strategies

- **Regulatory Education:** Directors and managers should receive ongoing education regarding regulatory developments within the markets in which they operate or seek to enter. As regulations in the cannabis industry change rapidly, constant board education sessions on regulatory updates provide leadership teams with insight into the legal requirements and best practices for operations.
- **Chief Compliance Officer (CCO):** Companies should establish robust governance frameworks that include a compliance committee navigated by the company's CCO. It will be the CCO's responsibility to ensure that the organization is in the best position to navigate the relevant regulatory requirements, drawing on specialist and local expertise when needed.
- **Third-Party Audits:** To establish an organization's compliance position and maintain a position of continuous improvement, companies should engage with third party auditors that have the necessary certifications and experience. Auditors will be able to provide information on whether the company is complying with regulations and identify any potential areas of concern, enabling the company to manage issues before they arise with regulators.

Investor Litigation

Directors and officers expose themselves to investor litigation if they misrepresent their financials, fail to disclose critical information and risks, engage in fraudulent accounting behavior, or make false/misleading statements in their disclosures.

CASE STUDY



Investor litigation is a common occurrence in the industry, with Canopy Growth Corp., one of the largest publicly traded companies, currently facing a class action lawsuit by its investors. In April 2025, investors sued the company, claiming that Canopy Growth had misled investors by making misleading and false statements that downplayed the costs associated with producing a line of pre-rolled joints, and the expenses incurred in the 2018 acquisition of Storz & Bickel. Weak financial results contradicted management's representations of expected performance. The lawsuit remains active at the time of writing, with investors alleging that the false and misleading statements made by Canopy Growth violate the US Securities Exchange Act, and could result in a significant penalty for the company.

To mitigate investor litigation, directors and officers of companies should implement strategies that are continuously transparent and realistic.

Risk Mitigation Strategies

- **Transparent Communication:** Companies can increase transparency and more effectively manage expectations through hosting an investor relations website page that is easy to use and that consistently discloses company activity and financial performance. Additionally, financial reports, press releases, and presentations should provide enough detail to allow investors to make informed decisions. Companies may use various media channels, including social media platforms, podcasts, and webinars, to provide information to their shareholders. Caution is recommended here, particularly when individual directors' and officers' posts could be construed as speaking on behalf of the company.

- **Manage Expectations:** For companies that are eager to grow and attract investment, there can be the temptation to downplay business risks or inflate future performance. These misstatements can lead to litigation and regulatory investigations. It is therefore essential for companies to adopt a reasonable and realistic approach when making representations about the business. Media training for executives can assist with this discipline.
- **Independent board members:** The inclusion of reputable and experienced independent board members can bring objective oversight, challenge, and guidance to help avoid missteps and misrepresentations. They can also balance the C-suite in terms of skills, backgrounds, and experiences. This robustness at the top reduces the chances of investor litigation.

Mergers and Acquisitions Failure

The last twelve months has seen significant M&A activity within the cannabis industry. High supply, falling product prices, and high barriers to licensing, has prompted vertical and horizontal consolidation. Engaging in M&A discussions, let alone closing transactions, exposes directors and officers to considerable risk if it is found that the company is overvaluing, undervaluing, misrepresenting, or lacking due diligence in a transaction. Confidentiality of these deals is paramount for good reason; the fall out can lead to significant reputational harm if parties choose not to proceed. Leadership teams are held responsible by investors, and may look to litigate as a result.

Risk Mitigation Strategies

- **Third-Party Valuations:** To ensure the values of a transaction are appropriate, cannabis companies engaging in a merger or acquisition should hire third-party auditors/financial advisors to undergo a comprehensive assessment of the target company's assets, liabilities, financial position, performance, and market dynamics. These assessments should provide conservative and realistic valuations, financials and projections, allowing companies to maintain a realistic approach that can be conveyed through transparent investor communications.
- **Due Diligence:** With any M&A transaction, especially in the cannabis industry, it is crucial for companies to implement stringent due diligence and compliance checks on targets. This includes examining: the status of licenses and permits, past regulatory penalties, and operational standards. By assessing the compliance and risk of targets, cannabis companies can make a more decisive judgment on whether an acquisition is suitable.
- **M&A Warranties:** To mitigate any risks associated with the target company's compliance, buyers should include regulatory representations and warranty clauses within the transaction documents. These warranties can consist of clauses that affirm that the target company meets all standards in terms of cannabis compliance, such as valid certifications and permits regarding the law and GMP activities, as well as affirming that the target company is not facing any lawsuits, enforcement actions, or investigations by any governmental authorities or other third parties. Through the implementation of such warranties, buyers can ensure that the target company is operating in compliance, which mitigates exposure to adverse consequences post-transaction. It allocates the risk onto the seller regarding the target's compliance. If statements and details provided by the seller are deemed false in relation to the warranties, buyers will be able to seek indemnification, price adjustments, or terminate the deal.

CASE STUDY



In one case, the Canadian cannabis company Aphria (acquired by Tilray) faced a class action lawsuit by investors alleging the company overvalued and misrepresented its acquisition of Nuuvera Inc. and LATAM Holdings Inc. in their prospectus filing. In March 2025, Aphria agreed to a CAD \$30 million settlement.

Reputational Risk

The media is a double-edged sword for the cannabis industry and its leadership; positive headlines on the industry and companies can attract investment, customers, and build the profile of a brand. Yet cannabis remains a controversial and highly sensationalized topic; negative media coverage can rapidly lead to regulatory investigations, reputational damage, and litigation from customers who feel that they have been misold a product. For directors and officers already operating in a stringent, highly regulated, and scrutinized industry, media risk remains a central challenge.

CASE STUDY



One of the most notable cases of media scrutiny affecting a cannabis company is MedMen, based in the United States. Between 2018 and 2020, MedMen faced multiple lawsuits for violations of labor laws, significant debt issues, and breaches of fiduciary duty, all of which received extensive media coverage by publishers including the Rolling Stones, Forbes, and Business Insider. The press also focused on the actions of the company's CEO and executives, alleging that they misused company funds for unnecessary expenses and contributed to a toxic workplace culture. This intense scrutiny took a toll on MedMen, causing its share price to drop significantly and resulting in lawsuits from investors. Ultimately, these issues led to the resignation of the CEO and other executives.

Risk Mitigation Strategies

- Strong Media Strategy:** Companies can reduce their media risk by implementing a strong media strategy that emphasizes positive narratives about their performance in areas such as ESG criteria, workplace satisfaction, and the successful acquisition of licenses and permits. By conducting transparent and encouraging campaigns about the company and its leadership through social media, interviews, webinars, press releases, and news publications, organizations can foster trust among stakeholders and the media.
- Crisis Communication Protocols:** During any crisis event, such as product recalls, workforce injuries, or executive misconduct, news organizations and the media can often sensationalize the situation. Therefore, companies should have a crisis communication protocol in place to minimize further negative impact. These protocols should include clear guidelines for messaging and focus on protecting the brand and its leadership. It is crucial that leadership teams are informed as soon as a crisis arises, enabling them to issue an initial holding statement within the first few hours of the event. Additionally, employees should receive timely updates regarding the crisis. Since the media frequently exaggerates or makes misleading claims, it is vital for a company to establish a rapid response team that will address any inaccuracies across various platforms and channels effectively.
- Media Training:** The leadership of cannabis organizations bears significant financial responsibility for business activities and performance, and also serves as the public face of the company and the broader cannabis industry. Consequently, it is paramount that company leaders receive appropriate media training. A single misstep in language, tone, or messaging during an interview or public forum can significantly harm both the leadership's reputation and the brand, potentially eroding investor trust and attracting undesirable scrutiny from regulators. Media training provides leaders with the ability to anticipate questions and effectively manage challenging conversations. Furthermore, this training equips them to articulate themselves in a credible manner, fostering confidence among investors and partners, and preparing them to navigate crisis situations.
- Directors' and Officers' Insurance:** Directors' and Officers' insurance protects the personal assets of company leaders, including their homes, savings and investments by covering legal defense costs, settlements, and investigation and regulatory inquiry costs. It also protects the balance sheet of the company who may need to indemnify or reimburse the directors, or face its own liability claims as a result of decisions taken. This coverage seeks to preserve corporate capital for operations and reduces the impact of a crisis on the balance sheet. Furthermore, such coverage gives experienced and reputable executives the confidence to join a management team or board in the industry, knowing that there is a protection mechanism in place.

I CONCLUSION

The cannabis industry operates under patchy oversight and rising expectations. Risks extend across every stage of production and distribution, from cultivation and manufacturing to logistics, retail, and business management. Environmental pressures, inconsistent regulations, and continued scrutiny challenge operational stability, financial performance, and public trust.

To strengthen their position, operators need to move from reactive risk handling to deliberate, documented management. This means building systems and standards that prevent loss while demonstrating control to regulators, investors, and insurers. Key priorities include:

- **Governance and compliance:** Clear accountability structures and adherence to GMP and GACP standards.
- **Quality and testing:** Consistent in-house and third-party testing programs supported by reliable documentation.
- **Security:** Safeguards against physical theft, data breaches, and supply chain diversification.
- **Transparency:** Accessible, verifiable data on operations and financial performance.
- **Preparedness:** Tested crisis response plans that protect continuity and reputation.

Insurance converts these controls into financial protection. As data quality and regulatory clarity improve, insurers are expanding capacity across product liability, crop loss, logistics, and directors' and officers' coverage. The growing sophistication of underwriting reflects a broader shift in how cannabis risk is evaluated. The sector is beginning to be assessed like any other complex industry where risk can be quantified, priced, and transferred responsibly.

Relm remains committed to advancing that progress. Through data-driven underwriting, tailored coverage, and collaboration with regulators and industry leaders, we help cannabis enterprises manage uncertainty, protect their balance sheets, and build the confidence needed for sustainable growth.

I APPENDIX

CANNABILOG INTERVIEW



Yoram Eshel,
CEO, Cannabilog

To start, could you give us an overview of Cannabilog—what you do and where you operate?

I founded Cannabilog about 6 years ago after serving as Global Head of Supply Chain and Logistics at Teva Pharmaceuticals for 14 years. At that time, most of the cannabis industry was focused on licensing, cultivation, and manufacturing, while very few were thinking about international logistics. Today, Cannabilog manages global logistics for cannabis companies across many regions, including Canada, the US, South America, Europe, Africa, Australia, and Thailand. We've already shipped over 200 tons of cannabis products worldwide. Our role is to act as a control tower, coordinating local partners and ensuring compliance across jurisdictions.

Are there specific risks associated with cannabis logistics that create additional challenges?

Yes. First, it's essential to categorize risks into four primary categories: regulatory, quality, security, and operational.

Regulatory risks are the most critical. Every exporting and importing country has different rules, and they change frequently. If you don't stay current, a shipment could be destroyed. Quality risks are also unique in cannabis because it's both a pharmaceutical and an agricultural product. This means issues such as temperature control, mold, and contamination are constant concerns. Security risks are also significant; in some countries, we use armed escorts even when not legally required. Finally, there are operational risks, from poor packaging to routing mistakes. We've seen entire shipments rejected for something as simple as improper vacuum sealing or detectable odor at the airport.

Which countries are the most challenging when it comes to customs and regulations?

The hardest situations arise when regulations are unclear. For example, Thailand's framework remains a gray area, making compliance difficult. In contrast, strict but clear rules are manageable. Delays often come from licensing; import and export permits can take weeks in some countries. Recent changes in Portugal have slowed processes there, but generally, if documents and licenses

are in order, shipments clear without major issues. We've even passed surprise police inspections in Europe, which show that preparation pays off.

What mistakes do operators make when they don't use a logistics provider like Cannabilog?

Many companies cut corners. For instance, they skip temperature-controlled trucks to save money or misdeclare their shipments as cannabis products to airlines to reduce costs. That creates two risks: insurance won't cover them, and airlines won't treat the cargo as sensitive. At Cannabilog, we always use pharma-grade services, air freight, and land transportation alike. As a standard, throughout the logistics chain, we utilize temperature-controlled vehicles, validated packages, implement required GDP procedures, and ensure proper insurance. It's more expensive, but protecting the integrity of the medicine is non-negotiable.

Speaking of insurance, what coverage do you recommend?

We can offer marine or transportation insurance that specifically covers cannabis shipments, including temperature excursions, theft, and damage. We always advise clients to have door-to-door coverage, regardless of Incoterms, to avoid disputes between buyers and sellers. We also recommend insuring at 110% of the invoice value to cover both the product and additional costs if something goes wrong.

What makes for a good client partnership, and what are the 'red flags'?

Good partners are transparent, provide complete information, and involve us early in the process so we can help structure shipments properly. Problems usually arise when clients ignore logistics until the last minute. We quote for every shipment individually, considering weight, dimensions, temperature requirements, and flight availability. We also use the waiting time during permit applications to align with shippers and consignees on packaging, routing, and compliance.

Looking ahead, what are the main challenges you see for cannabis logistics in the next two to three years?

Currently, Thailand is the biggest challenge. Many producers there want to export, but most lack pharmaceutical-grade certification, and it's unclear whether European authorities, especially in Germany, will accept Thai products. Beyond that, Europe is the key growth region, with France expected to open its market by 2026. South America and Africa may also become important markets, but their less developed infrastructure may create significant logistical hurdles. In parallel, we MUST take into consideration that regulations are constantly changing, even in the more 'organized' countries. The overall challenge is ensuring regulatory clarity and building resilient supply chains as the industry globalizes.

DENTONS INTERVIEW



Eric Berlin,

Head of Cannabis Sector, Dentons

Could you give us an overview of Dentons and the services you provide, as well as a bit about your own background?

The Dentons Cannabis Group is a sector group within Dentons, both in the US and globally. We provide full legal services for companies in or impacted by cannabis and hemp, across North America and internationally.

I've been an attorney for 32 years, and 17 of those years have been in the cannabis space—which makes me somewhat of a veteran in this industry. Early in my career, I worked 'pro bono' to help draft and pass the Illinois Medical Cannabis Law. Later, I helped redraft and pass the Ohio Medical Cannabis Law. Since then, I've dedicated my career to helping to ensure safe, legal, and affordable access to cannabis in all its forms.

In the US, our team has over 50 lawyers, with 11 of us working full-time on cannabis or hemp-related matters. Globally, Dentons has lawyers wherever cannabis is legalized. Our group tends to focus on high-level work, but we also handle transactions like dispensary mergers and acquisitions (M&As). Our work includes: public policy, government relations, regulatory compliance, corporate transactions, restructuring, intellectual property (IP), litigation, and employment issues. Ultimately, our role is to anticipate legal challenges and help clients navigate them, particularly when dealing with complex global supply chains.

Let's turn to North America. Given that cannabis is not federally legalized in the US, what kind of regulatory and financial risks are operators exposed to? How has this affected consolidation in the market?

The US is unique because cannabis cannot legally move across state lines. Unlike other industries that benefit from interstate commerce, cannabis operators must operate state by state. This forces multistate operators (MSOs) to establish separate operations in each state. Access to capital is also limited because of federal restrictions, which further complicates consolidation.

Another layer of risk arises from adjacent products, such as vape cartridges, which are often imported from China.

Import regulations, tariffs, and customs decisions add uncertainty. Even after products enter the country, risks remain throughout the supply chain, from filling cartridges to potential liability years later. While some risks can be insured, the insurance market for cannabis is still developing and often more expensive than in other industries.

Where do you see the biggest pain points in operators' supply chains - cultivation, distribution, transport, or retail?

The biggest challenge is the lack of interstate transport. MSOs would prefer to centralize cultivation and processing, but laws require everything to be done within each state. This makes operations inefficient and costly. Security requirements surrounding transportation are also excessive, adding additional costs. Since cannabis remains federally illegal, insurance options are limited and expensive, leaving operators vulnerable. So, the combination of regulatory restrictions and financial exposure makes supply chain management particularly challenging.

On the insurance point, how do operators protect themselves if insurance is limited or unavailable?

Most operators do obtain some insurance, but coverage is far less robust than in other industries. Some insurers entered the space expecting quick legalization, only to withdraw when that didn't happen. Others are slowly building cannabis expertise. The challenge is that insurance relies on historical data, and cannabis is a relatively new industry. For example, when social-use venues appeared, there wasn't a clear precedent for insurers to rely on. As a result, coverage is limited and expensive, with many exclusions. It's improving, but the market is still immature.

Looking at the medical versus adult-use markets in the US, it often seems that medical operators lose out after adult-use legalization. What's your perspective?

Almost every state provides a pathway for medical operators to add/transition into adult use. In reality, medical patients often lose out more than the operators, since the recreational market drives product development and availability. Medical products may become less available, but operators benefit from larger customer

bases and expanded opportunities. For example, medical patients might still keep tax breaks or priority in dispensaries, but many simply shift to the adult-use market, or they grow at home, where allowed.

That said, certain markets such as New York and Michigan are particularly messy — not because of the medical-to-adult-use transition itself — but because of how regulations were drafted or implemented. In New York, for instance, early vertical integration was intended to prevent diversion, but it became a barrier to smaller, social equity applicants. Over time, states are moving toward more inclusive licensing structures.

Are medical markets neglected once adult use is legalized?

Yes, to some extent. The hemp market also complicates things. Take the example of gummies with cannabidiol (CBD) for sleep: it's often cheaper to extract CBD from hemp, even if the product is sold in a regulated cannabis dispensary. So you might have a 'medical' product that actually comes from hemp. This blurs the lines between medical, adult-use, and hemp products. Patients may use cannabis medically but purchase it for adult use. Insurance reimbursement is further complicated by these blurred definitions.

Ultimately, though, cannabis works, and insurers will eventually recognize that covering it can save them money, compared to covering more expensive pharmaceuticals. But the current lack of federal legalization and reliable data slows that progress.

Interesting. Switching to Europe, how do you view developments there compared to the US?

Europe is fascinating but volatile. We might expect steady, linear progress — Germany, for instance, moving forward in a structured way. But then we see setbacks, such as in the Netherlands, where pilot programs face uncertainty. Switzerland is moving toward full legalization, but volatility makes business planning difficult. That uncertainty often drives a 'race to the bottom', where operators cut corners just to survive, which can harm the industry's credibility.

In your view, where are we in the broader trajectory toward full legalization and normalization of cannabis?

I see it as a 50-year process. If we start with California's legalization in 1996, we're a little over halfway there. The progress has been incredible - moving from complete prohibition to mainstream acceptance. Cannabis is increasingly normalized, whether it's tetrahydrocannabinol (THC) drinks at concerts or adult-use dispensaries in major cities. Still, challenges around regulation, insurance, and supply chains will take time to resolve. It's not ideal for someone like me who hoped to see full legalization in my career, but the direction is clear.

GLASS PHARMS INTERVIEW



James Duckenfield,
CEO, Glass Pharms

To start, could you give us an overview of Glass Pharms' operations and how you approach supply chain management?

We founded Glass Pharms to provide a de-risked supply chain for the UK medical cannabis market. Importing cannabis has always been problematic, as quality and availability are inconsistent, which leaves patients frustrated and often drives them back to the 'illicit market'. Our goal is to deliver a stable, reliable, high-quality supply at a fair price, helping patients stay within the medical system.

To achieve this, we built a world-class 2.4-hectare cultivation facility in Wiltshire, designed from day one to meet pharmaceutical standards and compete internationally. We are co-located with an anaerobic digester and solar array, which provides us with secure, renewable energy. This reduces one of the biggest risks growers face; underestimating electricity and water needs, while ensuring everything we produce is powered by green energy.

That sounds like a significant investment. Was securing financial backing a challenge, given the restrictions on cannabis businesses?

Yes, funding was a hurdle. We were fortunate to secure investment from Foresight Group, a £13 billion fund, via its environmental assets fund FGEN. They required us to demonstrate strong environmental, social and governance (ESG) credentials and to be completely compliant with the Proceeds of Crime Act, since they represent institutional investors. We went through nine months of rigorous due diligence, supported by strong legal, accounting, and management teams. My background in regulated industries and government work also helped establish credibility.

How do you handle contamination and microbial risks like mold, which are common in cannabis supply chains?

We designed the facility to pharmaceutical standards, obsessing over contamination control. Total yeast and mold management is a key focus. Unlike many products grown recreationally and later irradiated for medical use, our approach ensures standards are met without needing irradiation. We tested cultivation methods extensively and

eliminated plants that were not disease-resistant. Seeds proved too variable, so we use only tissue culture genetics for consistency.

Inside the facility, hygiene is paramount: staff change into scrubs, pass through hygiene stations, and plants are handled only in controlled work areas before reentering the greenhouse via a decontamination tunnel. Climate is tightly managed, and disease-susceptible genetics are deselected early. We have a proprietary drying process which minimizes microbial proliferation while preserving terpenes. This multilayered process minimizes microbial risk at every stage.

How do you ensure distribution risks are minimized once the product leaves your site?

We only distribute domestically within the UK, which avoids international transit risks. Before anything leaves, it's tested by third-party labs for microbial levels and cannabinoid content, then delivered to good manufacturing practice (GMP) certified special manufacturers. These partners have been carefully vetted, so we know that the handling process is secure. Because distribution is just a short domestic journey, risks like temperature fluctuations are far lower than with imports.

Have you experienced failed tests, and if so, how do you manage them?

Yes, failed tests happen; it's part of cultivation. In some cases, reprocessing is possible, but often we destroy the batch to maintain standards. Our conveyor-belt cultivation system, similar to a modern bakery, ensures continuous planting, pruning, and harvesting. This means we always have supply in motion, so destroying a failed batch doesn't compromise long-term continuity.

What about quality assurance (QA) staff? Did you bring them from the cannabis sector?

No, we deliberately recruited QA and QP staff from outside cannabis, choosing professionals with strong pharmaceutical experience but no industry 'bad habits'. They were trained on cannabis specifics internally. For final release decisions, we combine formal assays with a 'holistic organoleptic

assessment', evaluating smell, look, and feel. Patients on staff are sometimes a part of these assessments, ensuring quality beyond just hitting technical standards.

How do you manage regulatory risk in the UK?

The industry is under the control of four regulators: the Home Office, the Medicines and Healthcare Products Regulatory Agency (MHRA), the General Pharmaceutical Council (GPhC), and the Care Quality Commission (CQC). They cover overlapping areas from cultivation to pharmacies. Recently, coordination between them has improved. As a cultivator, we come under the purview of the Home Office and MHRA. The MHRA, GPhC, and CQC have a clear set of rules to follow, but the Home Office remains the most challenging, often stricter on cannabis than on far more dangerous substances like diamorphine (heroin). This creates uncertainty, so we maintain rigorous protocols and comprehensive documentation to ensure we're inspection-ready at all times.

Do you use insurance to mitigate financial and operational risks?

Yes, though insurance is notoriously difficult to obtain for cannabis. We're insured through the National Farmers Union, which covers business interruption and other risks. Building a strong relationship with them and demonstrating our professionalism through annual audits, strict health and safety protocols, and robust security was essential to gaining coverage. By contrast, importers face far greater risks: delays, spoilage, tariffs, and license issues. Domestic production avoids these complications.

Finally, what do you see as the biggest 'pain point' in the UK and European cannabis supply chains?

Importation. The inconsistency, regulatory risk, and opportunism, where operators chase cheap batches from abroad, ultimately undermine patient trust. Patients find a strain that works for them, only for it to disappear from the market. Our model avoids this by ensuring a continuous, standardized domestic supply. For example, with our partners at Releaf, we've maintained the same formulary from day one, giving doctors and patients consistency they can rely on.

SOMAI INTERVIEW



Michael Sassano,
CEO and Founder,
SOMAI Pharmaceuticals

To start, could you give us a brief overview of Somai - where your production and activities are currently located internationally?

Our main manufacturing and cultivation facilities are just outside Lisbon, Portugal. These also serve as import hubs. We import flower and raw goods from Canada, Colombia, South Africa, and Thailand. From there, we distribute to seven countries with five additional countries in registration for 2025 and four countries in registration for a 2026 launch, with a focus on extracts. The biggest markets are Germany, Australia, and the UK. Each of these has dedicated in-country teams. For example, Australia has 12 staff, Germany 14 with shared staffing with partners, and the UK has a smaller team of 3. We also have a sales team covering emerging markets like Italy, Poland, Ireland, and Switzerland.

Let's talk about importation risks. Are there particular challenges when bringing cannabis products in from different countries?

Absolutely. Each country has its own nuances. Portugal is the second-largest exporter to Europe after Canada because of its favorable import rules, which is why it has built a strong infrastructure. But when importing, you face risks such as contamination. We mitigate this with strict pharmaceutical protocols. For example, we have 11 quality assurance managers, three qualified persons (QPs), three regulatory affairs and a full GMP lab in-house. If a batch comes in, we immediately test it ourselves in a cleanroom environment for microbials as a first quarantine step. The QPs make the final call, and their word is binding—they answer directly to regulators.

If the product fails microbials, we can send it to Spain for irradiation, but that costs months in delays and cash flow, so choosing the right suppliers and training them well is critical.

How do you evaluate and select suppliers to reduce these risks?

First, we visit all growers personally—if you haven't visited them, you shouldn't be doing business with them. Second, financial stability is crucial. Companies in financial trouble often cut corners, even unintentionally. We're always transparent about our own financials with partners.

Third, suppliers must have a competent QA team that can service global pharmaceutical markets. Without it, one small issue can cause months of delays due to regulatory paperwork.

On the cultivation side, risks like theft or crop damage are common. Do you use insurance products to mitigate this?

Yes, we operate under an umbrella pharmaceutical insurance policy, even covering directors' liability. In Europe, few insurers cover cannabis, but those that do are often backed by groups like Lloyd's. Insurance is critical. For example, if a stability chamber fails due to a power outage, you could lose millions in product launches. We have redundancy generators, but still, insurance provides a safety net.

Transport is another story. Cannabis logistics are complicated. Bags can burst during pressurization on flights, and growers often dispute responsibility. Insurance companies aren't well-equipped for these 'gray areas' in cannabis logistics.

Would you say logistics is the highest-risk area of the supply chain?

Distribution across multiple countries is by far the most challenging. With suppliers, the quality is usually clear from the start—good suppliers remain consistent, bad ones reveal themselves quickly. But, every new supplier tends to make mistakes on the first orders because they're not familiar with global pharma standards. Strong QA processes can help them improve, but some are simply not trustworthy.

You mentioned having your own GMP lab. How important is this for mitigating risk?

If you're only producing a handful of products for a few markets, it might not be worth it—the setup is over a million euros plus staffing costs. But, for multiproduct, multicountry operations like ours, it's essential. Having our own lab means we can test immediately, keep costs down, and deliver products directly with our own certificates of analysis (COAs). This avoids delays, disputes with third-party labs, and ensures patients receive consistent, compliant medicine.

Accessing capital has been a challenge for cannabis operators in the US. Do you face similar issues in Europe?

Yes, to a degree. Many banks, insurers, or even accounting firms reject cannabis companies. That said, Portugal's supportive framework allows us to have banking and even a loan on one of our buildings. Still, large institutional investors like BlackRock aren't in the space here. Most funding comes from private equity, family offices, or cannabis-focused funds.

How do you approach risk when entering new markets, given that each has unique regulations?

We map out all potential markets in advance—size, growth potential, product types allowed, sales infrastructure, and regulatory hurdles. This is integrated into our board reports. For major markets such as Germany, Australia, and the UK, we handle distribution ourselves and sell directly to pharmacies, not through third-party distributors.

From your perspective, what are the key risks international operators should be most aware of right now?

Beware of inflated claims. Nobody, but the biggest names, is moving over 1000–2000 kilograms a month consistently and legally. Those saying otherwise are often tied to illicit activity. The illicit market is highly sophisticated, and regulators are tightening controls. The only real protection is robust QA and QP systems.

Having watertight paperwork and enterprise resource planning (ERP) systems is vital. Regulators now cross-check import and export licenses with source countries. If you can't produce the correct documents immediately, you'll be flagged and potentially inspected. Many companies tried to 'chase paperwork later'—that doesn't work anymore.

Given recent raids in Portugal, do you think growers face stricter regulations ahead?

What's happening is heightened scrutiny of paperwork. Authorities discovered forged import permits, so they're clamping down hard. If you can prove your paperwork is accurate and presented on time, there's no issue. Portugal actually wants to support cannabis as a key part of its economy, alongside tourism. But you must follow the rules strictly—there's no room for shortcuts.

Finally, where do you see the biggest opportunities ahead for the industry?

Europe is opening up, with Germany and France leading the way. Portugal has also positioned itself as a key export hub. Beyond that, other EU countries are up-and-coming, but again, it depends on clear and stable regulations. The companies that win will be those who deliver consistent, pharmaceutical-quality cannabis medicines at scale.

ENUA INTERVIEW



Justin Stenchly,
Supply Chain Manager, Enuu

To begin, could you give us some background on Enuu's operations and your role in the supply chain?

I'm Justin Stenchly, and I am the Supply Chain Manager at Enuu. I've been with Enuu for over a year, but I've worked in the German medical cannabis industry for nearly seven years. At Enuu we focus on the import and distribution of high-quality medical cannabis. Most of our suppliers are based in Canada; however, we also have suppliers from other countries. Our infrastructure in Germany is based on a GDP-certified warehouse with strict security and rigid protocols to ensure product integrity.

Operating under GDP requirements must involve strict compliance. What does that look like in practice?

Yes, Germany is very strict. We must validate all partners by ensuring they hold GDP and GMP certifications. Documentation is critical, and we regularly review licenses and compliance records. Partner qualification is one of our biggest responsibilities.

How has cannabis distribution in Germany evolved over the past few years?

We've expanded partnerships with international producers, mainly in Canada, strengthened our quality management systems, and introduced digital tools for compliance tracking. While some systems are still Excel-based, we're moving toward more advanced digital integration for better transparency across the supply chain.

What are the biggest risks you face when importing cannabis?

Regulatory changes, customs delays, and transport disruptions are major risks. We mitigate them by working with multiple suppliers, partnering with specialized logistics providers, and closely monitoring regulatory frameworks to adjust our planning early.

How do you select and evaluate your supply partners?

The product team handles the first stage—identifying potential suppliers in Canada, South Africa, and Europe. They visit sites, review products, and make initial agreements. Once that's done, the supply chain and quality teams audit the facilities, check documentation,

and conduct trial shipments. Only after this process, which can take up to six months, do we begin regular imports. Key factors are certifications, audit results, product quality, and pricing.

Have you experienced problems with suppliers in the past?

Yes, though nothing major. We've had delays in transport, packaging issues, or incomplete documentation. We addressed these by strengthening agreements, increasing communication, and ensuring backup sourcing to protect supply stability.

Once products arrive in Germany, what protocols do you follow?

Every batch undergoes quality and quantity checks, documentation review, and temperature control validation. We also use independent certified laboratories in Germany for mandatory testing before releasing any product to the market. The transportation temperature must remain between 8–25°C, verified by data loggers on each pallet.

What challenges do you face in bringing a new product to market in Germany?

First, we must register each new product name with the authorities, which can take up to three months. Other challenges include the limited availability of qualified logistics partners and rapidly evolving market expectations. Success depends on close teamwork between our supply chain, product, and quality teams to ensure compliance and smooth market entry.

How do you manage transport risks and insurance?

We always use cargo insurance arranged by our logistics providers to mitigate financial exposure. We diversify both suppliers and shipping methods to reduce dependency. We also use temperature data loggers, usually two per pallet, to monitor transport conditions end to end.

What about risks after products leave your warehouse, for example, when supplying pharmacies?

That's managed by our sales department. Once the quality department has released the product, Enuu remains responsible for ensuring compliant delivery to pharmacies.

Pharmacies are required to open shipments, check quality, and ensure compliance. Due to the growth of the market in Germany, many pharmacies have specialized in medical cannabis and are well prepared. Ultimately, responsibility shifts to them once they receive the product.

Looking ahead, what regulatory or market risks do you anticipate in Germany?

We don't expect major political changes in 2025, but risks could come from shifting international regulations, competition for logistics capacity, stricter quality requirements, or even climate change affecting cultivation regions abroad. Any of these could impact supply availability and patient prices.

What are your biggest lessons learned in managing supply chain risks?

Transparency and strong partnerships are key. This industry is highly regulated, fast-changing, and sensitive. Having multiple reliable partners and maintaining close, honest communication helps us anticipate challenges and reduce risk across the supply chain.

LINNEA INTERVIEW



Susanne Caspar,
CEO, Linnea

To begin, could you give us an overview of Linnea, your supply chain operations, and the markets where you're active?

Linnea is a Swiss-based Active Pharmaceutical Ingredient (API) producer with more than 40 years of experience in pharmaceuticals. We produce cannabinoid extracts and isolates, including CBD, CBG, THC, and combinations, all under GMP and regulated by Swissmedic. We source raw materials from audited European GACP suppliers, always maintaining at least two suppliers in different regions to reduce climate or crop risks. Our customers are pharmaceutical companies and pharmacies globally, and we also offer white-label cannabinoid products prepared for clients.

How do you ensure stability and consistency with your suppliers over the long term?

Consistency is critical for medical cannabinoids. Patients must receive the same variety every time. That means we build long-term relationships with cultivators and do not allow changes in varieties. Recreational growers often chase trends, but in medical markets, stability and uniformity are essential. Suppliers are audited, and once a product is registered in a country, regulations usually prevent us from changing suppliers. That's why, long-term, we only work with growers we can rely on.

Manufacturing APIs carries risks like contamination. How do you mitigate these risks and maintain pharmaceutical standards?

Our long history in pharma ensures we operate to the highest standards. We follow strict SOPs, are audited by Swissmedic, FDA, Anvisa, and other regulatory bodies, and have in-house testing laboratories, including microbiology laboratories. We only accept raw material that meets strict requirements for purity, heavy metals, and microbial levels. This process minimizes risks and allows us to consistently produce large volumes of compliant extracts and isolates.

Beyond compliance, Linnea contributes to shaping industry standards. We helped develop the European Pharmacopoeia monograph for cannabis flowers and cannabinoids and are currently contributing to the monograph for extracts, highlighting our role in setting global quality benchmarks.

How important are relationships with regulators in mitigating risk?

They're vital. For example, when we built our new THC production facility, we consulted Swissmedic early to ensure compliance. We also maintain dialogue with authorities in Brazil and other countries to stay conversant with evolving laws. This proactive approach ensures our products always meet new requirements.

Do you carry out risk assessments when entering new markets?

Yes, we perform internal assessments and, in some cases, we test with small samples to understand customs and regulatory processes before scaling shipments. Each country has its own requirements, especially for THC, where import and export licenses are needed. We collaborate closely with clients to evaluate risks and ensure smooth entry into new markets.

In terms of white-label products, do you provide guidance to clients on compliance and market entry?

Yes. We support clients, especially startups, who may lack pharmaceutical expertise. We provide dossiers for APIs, ensuring they can register finished products more easily in their markets. Initially, we offered more consultancy, but today most of our partners are experienced in the field.

Do you see ongoing mistakes or questionable practices in the industry?

Yes, particularly outside the strict medical space. Some claim GMP certification, but only mean they're 'in process' of obtaining certification. Others mislabel products, for instance, CBD with inaccurate cannabinoid content or THC levels above the limit. These undermine industry credibility.

What risks do products face after leaving your facility, such as during transport?

We've designed packaging to protect quality. For white-label vials, we have validated bottles and droppers with stability data of more than five years. For bulk extracts, we use containers tested under varying conditions. Some shipments require temperature control, but if bottles remain sealed and standards are maintained, risks are minimal.

Regarding transport, do you manage logistics directly?

We have an internal logistics department, but we work with specialist partners experienced in cannabinoids. Early on, some companies refused to transport cannabis, but now we collaborate with providers who know how to manage border and regulatory processes.

What about facility security—how stringent is it, especially for THC production?

Security is very strict. Facilities are fenced, monitored by cameras, and require codes for entry. THC areas are restricted to trained staff only, and two people must be at the facility to handle material at all times.

How do you manage intellectual property in formulations?

We operate an R&D laboratory that develops processes; we do have an IP policy, and we hold patents for certain products and formulations.

Are there particular countries that pose more challenges when exporting products?

Yes. For example, Germany requires CBD raw material that is produced under GMP and not only under GACP, which is not always required elsewhere. We adapt operations to meet these specific national requirements.

How do you give customers confidence in your products and reliability?

We provide certificates of analysis with every order, welcome audits, and share registration details from our drug master file. We're also working on certification of suitability for further streamlined approvals. Our structure allows us to adapt to diverse regulations. With registrations in more than 50 countries for other APIs, we're well-equipped to support clients across geographies.

Do you use traceability software to monitor your supply chain?

Yes, we use an ERP system to track all incoming and outgoing material. Traceability is mandatory in pharma, and our system ensures complete oversight.

What challenges exist in Switzerland's medical cannabis market?

Stronger patient access to cannabinoids is hindered by a lack of trained doctors and pharmacists. Although reimbursement is technically available, obtaining it is challenging for patients. Implementing clearer reimbursement policies, similar to those in Germany, would significantly improve access.

How easily did you translate Linnea's pharmaceutical expertise into cannabis APIs?

Our extensive experience with botanical raw materials provided a strong foundation. However, each plant necessitates distinct extraction processes, requiring years of dedicated research and development. A key example is our development of droppers designed to deliver an exact and consistent CBD or THC content per drop; a level of precision crucial for medicinal applications.

Do you integrate ESG into your operations?

Yes, sustainability is a core part of our operations. We monitor greenhouse gas emissions and recycle extraction waste into renewable energy via a local biogas plant. Linnea currently holds an EcoVadis silver medal, which places us among the top 15% of assessed companies worldwide, reflecting strong performance across environmental, social, and governance criteria.

Finally, how important is long-term reliability in this industry?

It's critical. We've seen growers and companies exit the market due to oversupply or regulatory changes. For clients planning clinical studies, supplier reliability is vital. With more than 40 years in pharma, Linnea is a stable partner that clients can count on for the long term.

PHCANN INTERVIEW



Vladimir Kofcegarski,

Chief Sales Officer at PHCANN International

To start, could you give us an overview of PHCANN and NYSK Holdings and the operations you're involved in?

PHCANN International is a holding headquartered in Amsterdam, with a major indoor production facility, NYSK Holdings in Macedonia, as well as operational offices in Poland and Germany. We are one of the largest indoor cannabis producers in Europe, with an annual capacity of 15 tons. We export globally to markets where medical cannabis is legal, including: the UK, Germany, Poland, the Czech Republic, Brazil, Uruguay, Australia, and New Zealand. In 2026, we will enter the Ukrainian market. I serve as Chief Sales Officer, overseeing global business development, while also holding the role of Chief Executive Officer (CEO) for our German entity.

So your operations cover cultivation, production, distribution, and wholesale?

Exactly. Everything is integrated under one roof at our fully EU-GMP certified facility, approved by the Polish authorities, among the strictest in Europe. We manage everything from cloning to final product, including the extraction of oils and white-label production for some clients. Apart from this, we have our own brand PHCANN Exotics and we also hold the Tyson 2.0 brand in our portfolio, for which we have exclusive European and Australian rights.

Let's focus on cultivation. What risks do you face, and how do you mitigate them?

We strictly follow European Pharmacopoeia guidelines, with SOPs covering every stage. All incoming materials are tested in our in-house EU-GMP laboratory before entering production areas. Water and air are routinely monitored, and cleanroom procedures are mandatory. Staff wear protective equipment to prevent contamination. We've completed over 250 harvests using these protocols. Our flowers consistently reach microbiology levels 5.1.8.cat B — the highest before irradiation. This enabled us to be the first to introduce non-irradiated flowers to the UK market back in 2022.

How do you prevent contamination during packaging and transport?

Products are packaged in sterile, sealed environments with minimal staff presence. They are then boxed, palletized, and wrapped with temperature blankets. All transport partners must be GDP-validated, maintaining a temperature of 15–25°C. Air and ground transport are temperature-controlled.

How do you evaluate and monitor logistics partners?

Every shipment is closely monitored by our logistics department. There are certain rules and obligations that every GDP transport company must follow. To make sure they follow the GDP guidelines, we place our own data loggers in each shipment to track temperature and location independently. This is monitored from the moment our products exit our warehouse until they reach the warehouse of our client.

Do you insure all shipments?

Yes, every shipment is insured, to cover both product and costs. For high-value shipments, insurers sometimes spread the risk across multiple providers. In Macedonia, according to the state law, medicinal cannabis products, from our facility to the airport, must be escorted by armed special forces. This ensures safe passage to the airport customs house. Insurance is a small cost compared to the risk of losing millions in products.

What security measures do you have in place at your facilities?

Our Macedonian site is highly secure, with 5-meter walls, licensed guards to carry or use a firearm if needed, well over 200 cameras, and annual attack-response drills. The facility is near Skopje International Airport, which is basically inside a military zone, ensuring that special forces can respond to any possible threat within a minute. With a 20,000 m² factory and secure vaults, breaking in and escaping with any product would be nearly impossible.

How do you manage regulatory risks when entering new markets?

We rely on our experienced internal regulatory team, not outsourcing. For each market, we work with local partners and sign technical quality agreements to ensure compliance is met at both ends. Registration timelines vary — a few weeks in Germany or the UK, and up to a year in Brazil. Our team's expertise allows us to guide local partners through processes and adapt quickly to any potential regulatory changes.

What are the biggest risks currently facing cannabis operators in Europe?

In general, I don't see them as risks, more like challenges. At this moment, three stand out: logistics, GACP to GMP conversion, and regulatory changes.

Transport reliability: Many companies rely on commercial airlines, which face payload limits, customs clearance delays, and scheduling issues. We switched to charter flights, ensuring faster and more reliable deliveries. This way, we control the delivery; it may be more expensive, but at least we don't rely on anyone; we are fully independent in this regard. Also, we created independent logistics hubs in Macedonia, Poland, and Germany for Europe, Australia for Oceania, and Brazil for South America. This spreads risk and ensures continuity of supply from any part of the world.

GACP to GMP conversion: The companies or operators that are using this model are facing massive delays, as one valid police intervention in Portugal showed us. The model is fragile, especially if you rely purely on one country to convert your product. Tons of flowers are still stuck and waiting to be processed. Some companies paid months in advance for the product and are still waiting for the product to be delivered.

Regulatory changes: This is a very agile and dynamic industry; governments are still adapting to the pace at which medicinal cannabis is moving. Regulatory changes may occur in some countries where you need to adapt quickly. For example, the police intervention in Portugal triggered an investigation for some operators, but in general, the whole industry suffered. It has led to new guidelines for export permits, new timelines, and so on. This will affect any operator in terms of planning and forecasting. Another example is that Germany reached the yearly quota for 2025 imports well before the start of Q4, so basically, there are no more exports to Germany this year; this is something that not many operators can foresee.

GLOSSARY

ABBREVIATIONS AND ACRONYMS

ACM	Market Placing Authorization (Portugal)	GPs	General Practitioners
ARUC	Authority for the Responsible Use of Cannabis (Malta)	HEPA	High Efficiency Particulate Air
BfArM	Federal Institute for Drugs and Medical Devices	INFARMED	National Medicines Authority, Portugal
CanG	German Cannabis Control Act	IP	Intellectual Property
CBN	Cannabinol	IPM	Integrated Pest Management
CCC	Cannabis Control Commission (Massachusetts)	KCanG	Germany's Consumer Cannabis Act
CCO	Chief Compliance Officer	LPs	Licensed Producers (Canada)
CHRA's	Cannabis Harm Reduction Associations	M&A	Mergers and Acquisitions
COA	Certificates of Analysis	MedCanG	Medical Cannabis Act
CQC	Care Quality Commission	MHRA	Medicines and Healthcare Regulatory Agency
CRA	Cannabis Regulatory Agency (Michigan)	MSOs	Multistate Operators
D&O	Directors and officers	MTCs	Marijuana Treatment Centers
DEA	Drug Enforcement Administration (USA)	OLCC	Oregon's Liquor and Cannabis Commission
ERP	Enterprise Resource Planning	QA	Quality Assurance
ESG	Environmental, Social, and Governance	QP	Qualified Person
EU-GMP	European Union - Good Manufacturing Practice	ROs	Registered Organizations (New York State)
FMCG	Fast-Moving Consumer Goods	SME	Small and Medium-sized Enterprises
GACP	Good Agricultural and Collection Practices	SOPs	Standard Operating Procedures
GL	General Liability	THC	Tetrahydrocannabinol
GMC	General Medical Council	THC-A	Tetrahydrocannabinolic Acid
GPhC	General Pharmaceutical Council		

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