



Planting the seeds of growth in European soil

**A prescription for medical
cannabis companies**

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Growing into the European market

A tidal wave of regulatory change is sweeping the European medical cannabis market. Pioneering US and Canadian companies are boldly navigating evolving regulations and readying themselves to reap the rewards of the opening markets.

Are you ready to grow roots and expand on foreign soil? Can you fend off rising competition in an uncertain and still changing regulatory environment? Here's a look at what you need to know and how we can help you.

First medical cannabis drugs go on scale

The number of patients reporting symptomatic benefit from medical cannabis (cannabinoids THC and CBD) has increased over the last 10 years. Diagnosed ailments such as multiple sclerosis (MS), epilepsy or chronic pain have shown varying degrees of response, and many still require being confirmed by good clinical studies, but the market is open to novel approaches for treating so-called incurable diseases like never before.

5800%

The percentage by which the €1 billion EU medicinal cannabis market is projected to grow in the next decade.

Medicinal cannabis is a novel class of medicine. In the early 2000s, Israel (2001) and the Netherlands (2003), and later other countries, such as Switzerland (2011), Czech Republic (2013), Australia (2016) and Germany (2017), legislated the medical use of cannabis to be allowed under specified conditions.

At the same time, one medical cannabis product has earned through clinical trials the required authorization to be marketed in many EU member states. The product, which is based on cannabis extracts, has proven effective in the treatment of muscle spasticity due to MS. It has changed the perception of cannabis-based medical products and paved the way for the use of cannabis and cannabinoids. Still, different EU member states are taking on varying approaches towards allowing the products or the regulatory frameworks governing their provision.

Commercializing medical cannabis in Europe

Where medical cannabis is legal, finished medicinal products containing cannabis derivatives as an active substance can receive a positive marketing authorization and thus free marketability as a controlled drug for medical purposes.

In Germany, for example, these medicinal products require a special type of prescription and are subject to an additional monitoring system to ensure that no products leave the approved supply chain and are not misused for non-medical purposes, in particular illicit trade.

Cannabis, on the other hand, both as an active pharmaceutical ingredient (API) or as a substance for consumption, is subject to severe restrictions. The intra-EU trade is possible if the Cannabis is grown within the EU according to specific requirements from certified seeds and the THC level is below 0.2 percent.

Scout the field before making your first move

Europe is the place to be for medical cannabis companies with high growth ambitions, and a bunch of European markets are competing to take the lead:

- The leader: Germany – Is the country with the highest demand and has developed a progressive legal framework
- Fast followers: Italy, Netherlands and Spain – These countries have high internal demand and are increasingly developing progressive regulations to facilitate the use of medical cannabis
- Long-term: France and UK – Conservative and still countries with a moderate internal demand, but with high growth projections in the next 5 to 10 years.

90%

Did you know? Germany, the third medical cannabis market globally, has legalized medical cannabis. Health insurance covers the costs of medical cannabis for 90 percent of its population.

What to know before you go

Similar to North America, the climate may be favorable and the soil might be fertile, but planting and growing your medical cannabis business in Europe will still have its differences.

For starters, there is no EU-wide, harmonized regulation on medicinal cannabis. From complying with strict and dynamic regulations and keeping pace with local competitors, to establishing and growing a solid reputation, there are a few considerations you need to explore before your plans to grow in Europe take root.

1

Understand your expansion options and requirements

In locating your European point of entry, think about how your product will flow. Obtaining licenses and setting up the supply chain are critical factors. What local regulation does your product need to adhere to? Are there partners in the region? Who will be your main customers? Of course, remember that exports/imports in EU member states require case-by-case consideration.

2

Apply for licenses early and quickly

Timing is everything. Once you have decided on your location, you'll want to move fast, meet compliance requirements and secure licenses such as:

- Good manufacturing practice (GMP),
- Good distribution practice (GDP),
- Pharmacovigilance inspections,
- Import licenses (country-by-country),
- Manufacturing and import authorization (MIA), or
- Wholesale distribution authorization (WDL)

3

Build an agile value chain

Your value chain must be ready to respond to a changing market and regulatory environment. You will want to build up a partner network that can seize opportunities and fend off challenges just as quickly – if not, faster – than your competitors.

4

Start thinking about your global brand

In each market where you establish commercial operations you will be expanding your brand. Establishing a good reputation, locally and internationally, is key for positioning yourself well before the medical and patient communities. By engaging key opinion leaders and communities, your company will be at the forefront of shifting cultural, social and political attitudes about cannabis.

5

Grow market intelligence for sustainable growth and future success

Top cannabis companies in the EU are keeping a watchful eye on the political and regulatory climate in Europe to be ready for market changes. Gain insight into those countries most likely to change or relax their regulations and position your company for optimal agility. Market intelligence is critical to ensure that your sales meet expectations, and your strategic growth decisions are sound.

6

Understanding the value chain is a must

One hundred percent of the top five European cannabis companies are vertically integrated, boasting EU-based capabilities along the value chain (see pages 4 and 5). During your first move to Europe, it is unrealistic to expect coverage of all six value chain layers. Focus on value chain layers where your core competencies lie while at the same time leveraging from partners to become an integrated player.

Plant the seeds to grow your competitive advantage

From seed production technologies to drug development, KPMG helps you develop each layer of your operation's value chain to shape your optimal European market entry strategy.



1

Cultivation - find the optimal sourcing strategy for your product

Depending on your expansion goals and product, you want to find the right location, raw materials and best partner for growing, harvesting, drying and processing raw materials that include THC or CBD. KPMG helps you identify the optimal location and partners, to support your activities in this critical step in the value chain.



To manufacture or to source API?

Extraction and crystallization are two key processes to create active pharmaceutical ingredients (API) from the manufacture and development of cannabis-based drugs. KPMG helps you find the right balance between manufacturing APIs on your own and sourcing relevant APIs, such as CBD, THC, and other ingredients needed to succeed, while providing guidance on EU-GMP compliance requirements.



2



3

Build partnerships for swift and effective product development

Drug development is predominantly performed through partnerships. Each product needs to pass clinical studies that vary depending on the targeted disease. KPMG helps you develop effective partnering strategies and supports you in facilitating clinical studies.

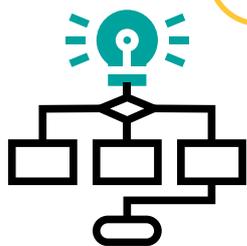
Cultivate a reputation of quality and global market presence

To gain a global reputation as a leading medical cannabis company, you need a supply chain that consistently and dependably delivers your products to the European market, while ensuring full compliance with EU-wide and country-specific regulations.

We help you build a world-class supply chain so you can:

- cover as many markets as possible,
- be agile to sustain growth in a fast-moving European market and regulatory landscape,
- turn a profit as quickly as possible to cover your investment.

4



Set up EU-GMP compliant operations

Operations include manufacturing medical cannabis products as well as all the supply chain activities that follow. A medical cannabis company will need either in-house or partner facilities with a EU-GMP certificate. Our approach helps you find the ideal operations setup, either by establishing GMP-certified facilities, or partnering with EU-GMP certified companies aligned with your supply chain strategy.

Commercialize – cultivate a fertile environment for growth

We help you identify and compare pricing, reimbursement and market access conditions across EU countries, and develop an expansion roadmap across work streams to achieve your commercial ambitions. We also analyze your main competitors and adjust the roadmap to mitigate any risks that they might pose to your successful growth.

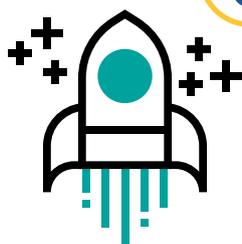
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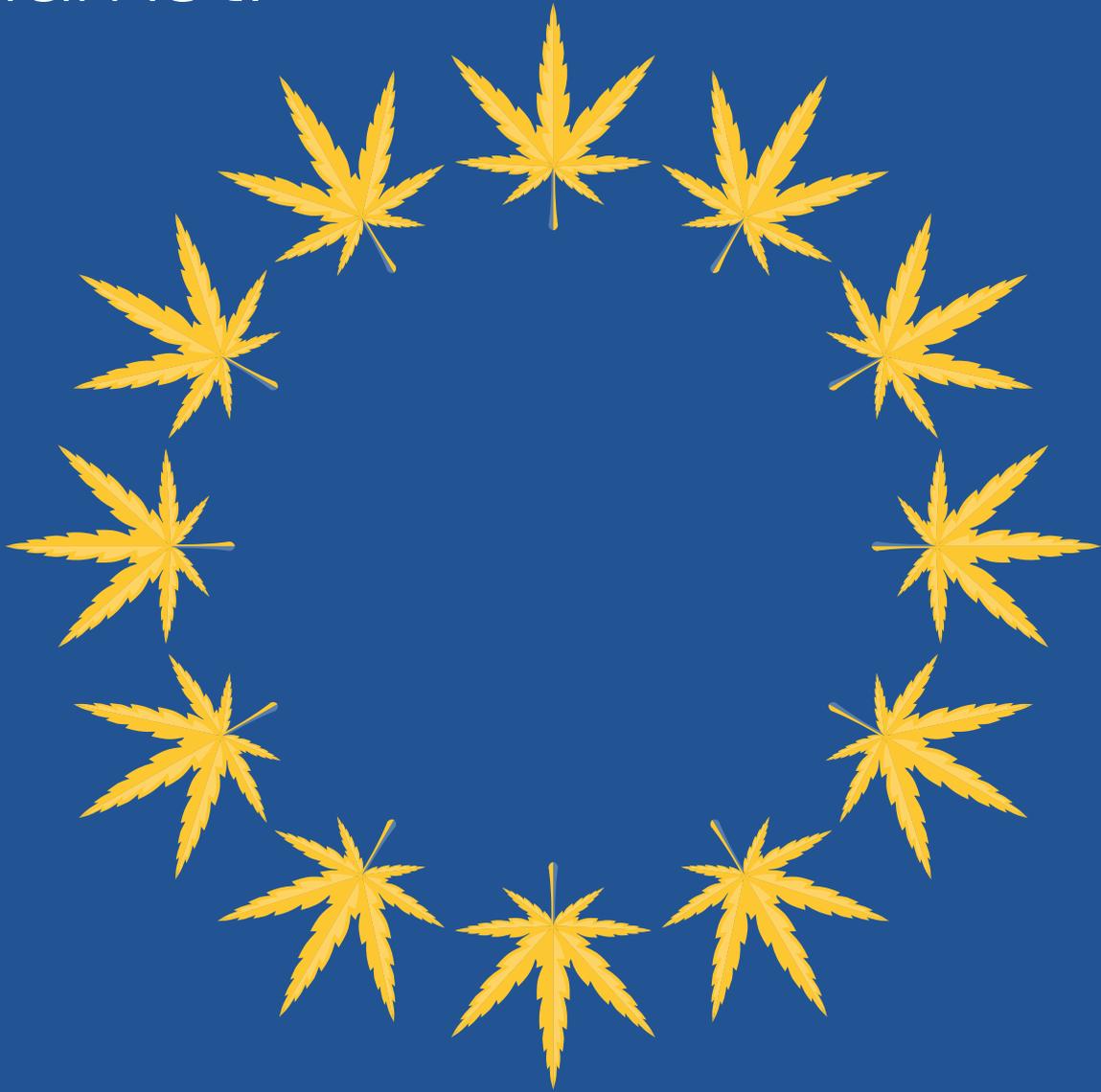
Distribute – without hitting the streets

Getting your medical cannabis product to your clients (e.g. retailer, wholesaler, hospitals) is the last step in the value chain. An EU-GMP or WDL is required for this step and MIA for non-EU countries. We assist you in developing an optimal distribution strategy, as well as ensuring EU regulatory compliance.

6



Europe is expected to become the world's largest medical cannabis market.



Investors seeking marijuana stocks that are most likely to succeed in the long run are looking at companies with a head start in Europe.



Client success story

European experience, fit for your needs

Client Challenge

A vertically-integrated cannabis holding group decided to launch its first medical cannabis product in Europe. The client asked KPMG to define an optimal market entry strategy and develop a European regulatory-compliant and tax-efficient business model.

KPMG Approach

Ensuring market, product and supply chain readiness while also addressing key interdependencies across functional areas made up the three pillars of our approach, which included:

- **A market-entry analysis** recommended a direct launch as the preferred approach for this client and product.
- **A detailed regulatory assessments** to identify the regulatory and licensing requirements to ensure the timely delivery to patients in new markets.
- **A detailed pricing analysis** secured the highest price possible for launch in each of the countries in scope.

Additionally, KPMG's multidisciplinary team provided expertise in the areas of commercial, supply chain and tax, ensuring successful and timely product launches across several European countries.

Client benefit

- The client successfully introduced into Europe its first medical cannabis product, effectively expanding the client's industry footprint.
- Increased value for the client's patients and shareholders.
- Simplified complexities ensured a smooth geographical expansion.
- Contributed to building product awareness thus resulting in a reputable brand identity.

Medical cannabis companies have a unique set of needs for which we can develop, tailor and package the full range of market-leading methodologies, tools and services. Areas where we can assist include

- **Corporate strategy:** we help medical cannabis clients to design and implement their European expansion strategies, including portfolio optimization.
 - **Commercial excellence:** we support you in growing your trusted medical cannabis brand in Europe. We help define your commercial and market-entry strategies, pricing and reimbursement and your product launch strategy.
 - **Business model design:** we define a tax-efficient business model for you that is fully compliant with medical cannabis laws and regulations at both European and local levels.
 - **Value chain agility:** we help you build a flexible and agile value chain network, future proofing your business to the shifting European medical cannabis market.
 - **Value creation:** we assist you in turning a profit to cover your investment as quickly as possible and ensuring long-term growth. We help optimize your distribution network, refine your product strategy and increase your salesforce effectiveness.
- Reaping the benefits of the European medical cannabis market requires a strong and sustainable business strategy sustained by robust and trusted support. At KPMG, we bring those qualities and more. We help you along your journey: from defining your expansion roadmap, to setting up your compliant business model, and commercializing your products in Europe.

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