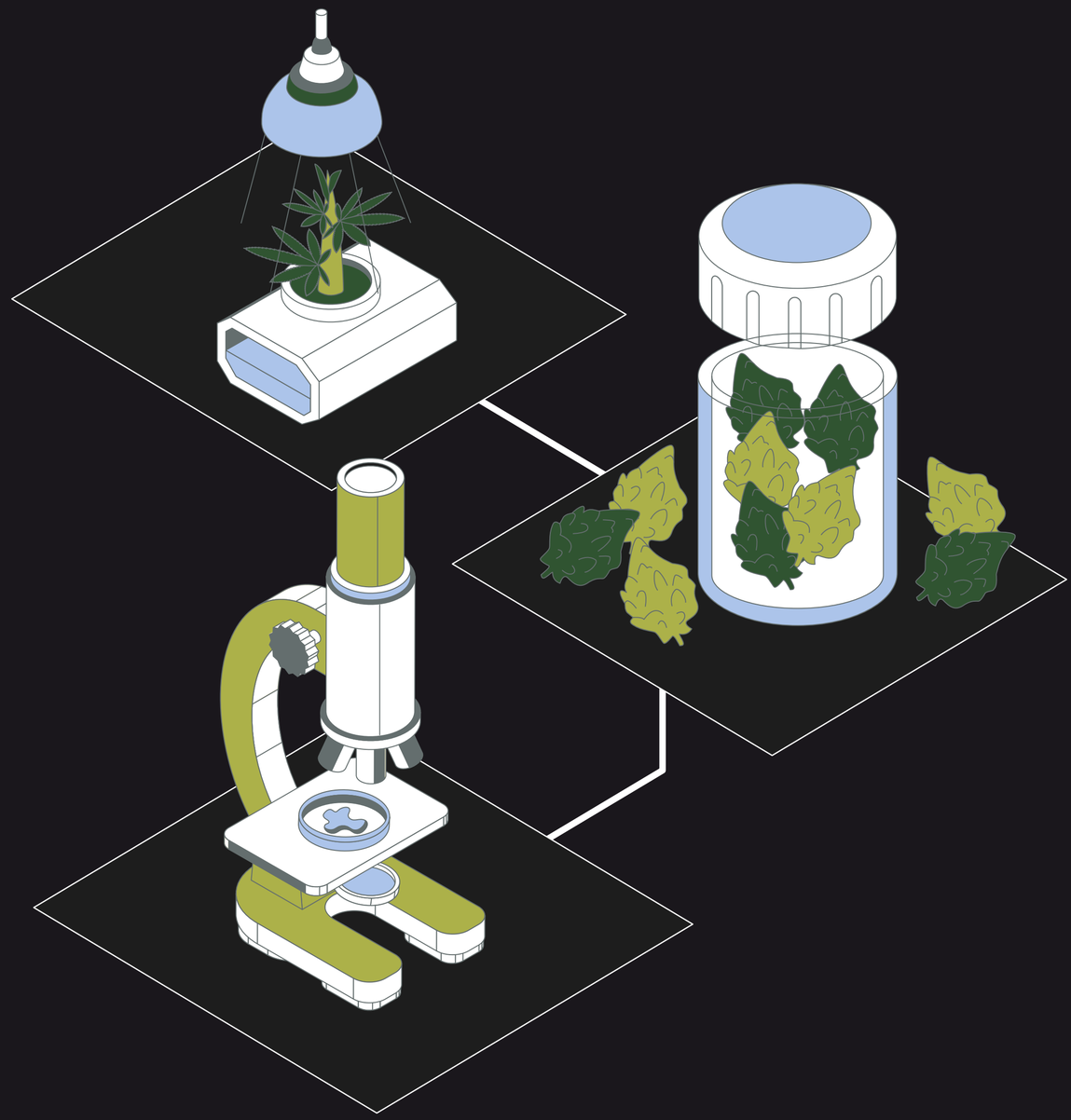
European Medical **Cannabis Ecosystem**

Published by the First Wednesdays network, with insights provided in collaboration with Hanway Associates and Invest In Denmark (part of The Danish Ministry of Foreign Affairs).

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
Invest in Denmark

HA
HANWAY ASSOCIATES



PUBLISHED OCTOBER 2020

Contents

Introduction

What is so special about the European medical cannabis ecosystem, is that it is uniquely *European*. It has developed its own regional outlook for how it wants to regulate cannabis and implement access programmes, and in this process has developed its own entrepreneurial flair.

A mix of socialised healthcare, a pharmaceutical heritage, and being later to the party than the US and Canada, has created a strict medical approach to cannabis medicines – one that is (mostly) *with the grain* of the medical establishment, not against it.

Compare two investor decks from both sides of the Atlantic, and you can quickly see the differences in how we talk about cannabis as a medicine, how it should be controlled, and the regional-specific concerns its proponents need to address.

The European medical cannabis ecosystem is maturing quickly as experienced founders and investors move into the sector and shape not only the discourse, but the value chain around them. It is in this context that we are very excited to bring the first European medical cannabis ecosystem map to our network.

Market projections and financial analysts point to the large population of Europe and talk about how demand will surpass all expectations in the years to come. But how does a nascent market struggling to find its footing become the behemoth it is expected to be one day? We decided to look under the hood of some of the most exciting companies, markets and trends to find out where the real potential lies.

The promise of foreign investment, job creation and economic growth is alluring, but the journey towards a sustainable and commercially profitable sector is a long one, and Europe is just at the beginning of this journey. Without companies that tackle regulators' concerns around black market diversion, the lack of patient data, or doctor's unfamiliarity and cautiousness in prescribing a medicine that has typically been consumed as a combustible, there will be no real long-term growth in the sector.

Companies solving these problems already exist, and their presence is promising. Patient data apps, medical devices, formulation technologies, and plant R&D are propelling the sector towards its ambitious goals. The sector is truly aspirational and full of problem solvers, giving us great faith in its chances of success.

We are already seeing signs that the sector is being taken more seriously by regulators and corporates alike. State supported cannabis startups and the appearance of more mainstream pharmaceutical companies on the scene are two indications that this is happening.

Two European states, Denmark and Greece, that have recently embraced the medical cannabis sector have already attracted proposed foreign investments of over €610 million according to recent reports.

From Copenhagen to Berlin, life science startups jostle for capital and new specialist cannabis investment funds in Stockholm and Paris stoke investor interest in the sector.

UK financial regulators have announced that British-based medical cannabis businesses have a compliant path to the public markets in London, while Scandinavian stock exchanges signal they are open for business.

Competition in crowded markets like Germany pushes competitors to innovate with their supply chains, breaking established monopolies, while Spain, a world leader in morphine production, dips its toes in the arena through traditional pharma routes.

Underpinning all this innovation is research. The Netherlands is home to approximately

30%

of Europe's active cannabis and cannabinoid clinical trials, with the UK following closely with

20%

and Germany home to another

15%

Source: www.clinicaltrialsregister.eu

Whatever your thoughts about the market, the right foundations are being laid for a very interesting journey over the coming years.

Alastair Moore
CO-FOUNDER, HANWAY ASSOCIATES
AND FIRST WEDNESDAYS

Mapping the Ecosystem

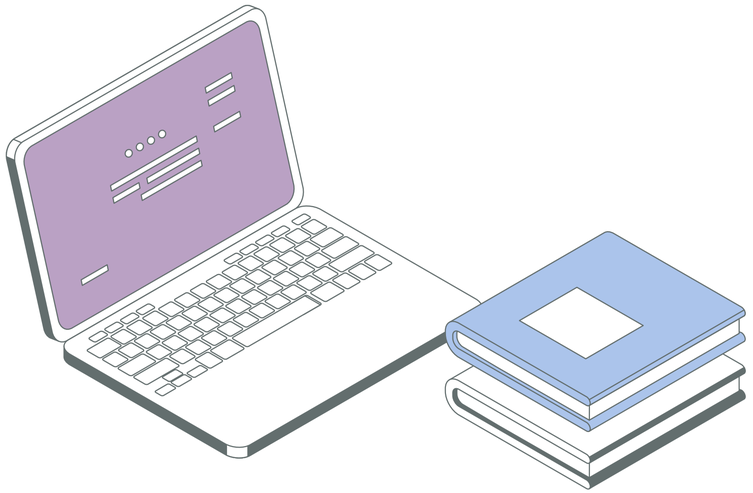
This section has been produced in collaboration with First Wednesdays.

First Wednesdays is a network of entrepreneurs and investors in the European cannabis sector. FW members benefit from news, insights, matchmaking and business support.

Inclusion Criteria – General

INCLUSION CRITERIA

- → This list has been compiled primarily from the First Wednesdays member database and publicly available information alongside targeted interviews with companies not already known to us.
- → The ecosystem features the top 150 companies which are currently active in the legal, European medical cannabis market based on the following criteria.
- → We have only featured companies who have headquarters or an important hub in Europe, or otherwise have a key role in supplying the market.
- → Vertically integrated companies active in multiple segments have been listed in the segment they are best known for.
- → In addition to these general requirements, companies must also adhere to the relevant value-chain specific requirements set out on page 6.
- → Dispensing has not been included on the ecosystem map as this role is typically undertaken by non-cannabis specific community pharmacies. Prescribing and dispensing in Europe is discussed on page 18.



Inclusion Criteria — Value Chain Step-Specific

01. **GENETICS / SEED BANKS**

- → Provided seeds or genetics to at least one company who is active in the European medical cannabis industry
- → Providing genetics as a service rather than an internal breeding program

02. **CULTIVATION**

- → Cultivating in Europe for medical purposes with required licenses
- → Already have seeds in the ground
- → Contract cultivation for production of licensed pharmaceuticals has not been included
- → We have not included facilities under construction

03. **TESTING**

- → Hold an EU-GMP certification
- → Must have ISO/IEC 17025
- → Must have all relevant licences to handle narcotics

04. **COMMERCIAL R&D**

- → Active R&D into agritech / growing conditions, new product development or medical efficacy
- → Not a genetics company

Research / Academic Groups

- → European institution championing or actively researching medical cannabis

05. **EXTRACTION / PURIFICATION**

- → Primarily focused on cannabinoid extraction for medical purposes

06. **FORMULATION / MANUFACTURE**

- → Hold the required licenses and EU-GMP certification
- → Ongoing manufacturing of medical cannabis products or APIs / active substances
- → Unlicensed cannabis companies that manufacture and distribute are listed as a manufacturer if they formulate their own medical cannabis products

07. **BRANDED MEDICINES**

- → Duplications from value chain segments permitted
- → Must have sold branded products to patients in Europe
- → We have included the company that is listed as owing the product (ie. not the company that white-labelled)
- → We have included the parent company or most relevant sub-division

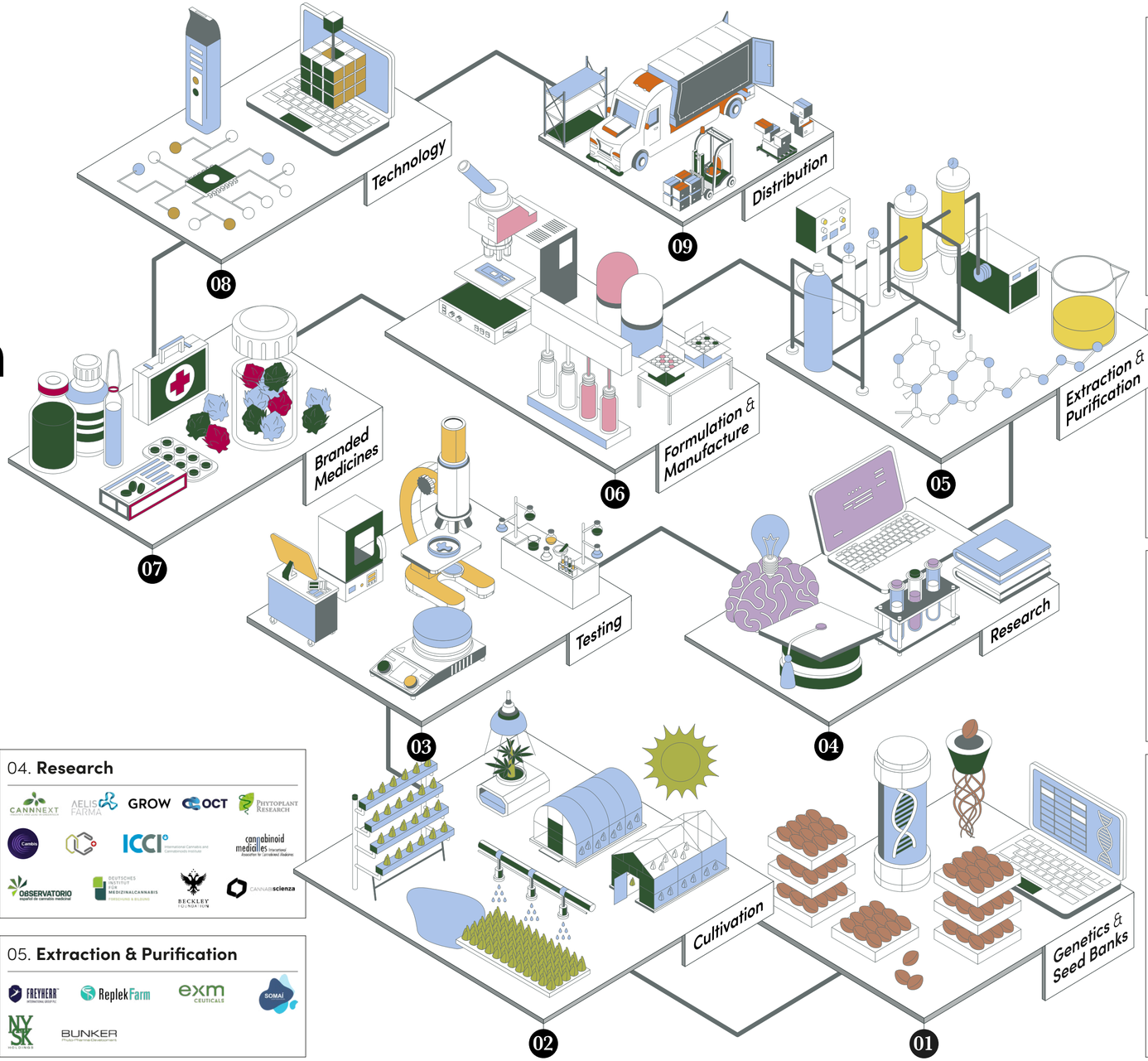
08. **TECHNOLOGY**

- → Developer of specialised equipment, software, or medical devices for the medical cannabis market
- → Hold required authorisations and certifications

09. **DISTRIBUTION**

- → Distributing a medical cannabis product that requires a prescription to at least one European market
- → Hold an EU GDP certificate
- → Unlicensed cannabis companies that manufacture and distribute are listed as a distributor if they primarily distribute other companies' products

European Medical **Cannabis Ecosystem**



01. Genetics & Seeds Banks

Sensi Seeds · Barney's Farm · Dutch Passion Seed Company · Dinafem Seeds · seedsman · NIAB

02. Cultivation

bedrocan · Canopy Growth · limeco · emmac · GroVida · Tilray · Sabores Púrpura · Symtomax · RPK Biopharma · VF 1883 · Demecan · aphria · Aurora Europe · Ministero della Difesa · AGES · Elkoplast · Schirolí Medical · Aurora Nordic · SpectrumTherapeutics · 5 Letters

03. Testing

PhytoVista Laboratories · Ofichem Group · Tentamus · Medicinal Genomics · Fundación Canna · aquatest · eurofins · Tekniker · Tekniker Institute

04. Research

CannNext · Aelis Farma · GROW · OCT · Phytoplant Research · Canbio · ICCI · Cannabinoid Medicines · Observatorio · Deutsches Institut für Medizinalcannabis · Beckley Foundation · CannabisCienza

05. Extraction & Purification

Freyherr · ReplekFarm · exm Ceuticals · Somai · NYSK · Bunker

06. Formulation & Manufacture

HAPA pharm · THC Pharm · Vektor Pharma · adjupharm · Cannapharm AG · Vertanical · Fagron · limeco · ASG · TTS Pharma · echo pharmaceuticals · ODI Pharma · mgc pharma · Stenocare · Cellen Therapeutics · rokshaw laboratories · medalchemy · can tourage · C³ · octarine · Apocare Pharma · C² Pharma · Brains · Linnea · CBDepot.eu · Finext

07. Branded Medicines

Tilray · Spectrum Therapeutics · bedrocan · Cronos Group · Aurora · Grow · Cannamedical · emmac · Cellen Therapeutics · mgc pharma · Four20 Pharma · little green pharma · Althea · GW pharmaceuticals · Valeant · Unimed Pharma · bod australia · Khiron · Vertanical

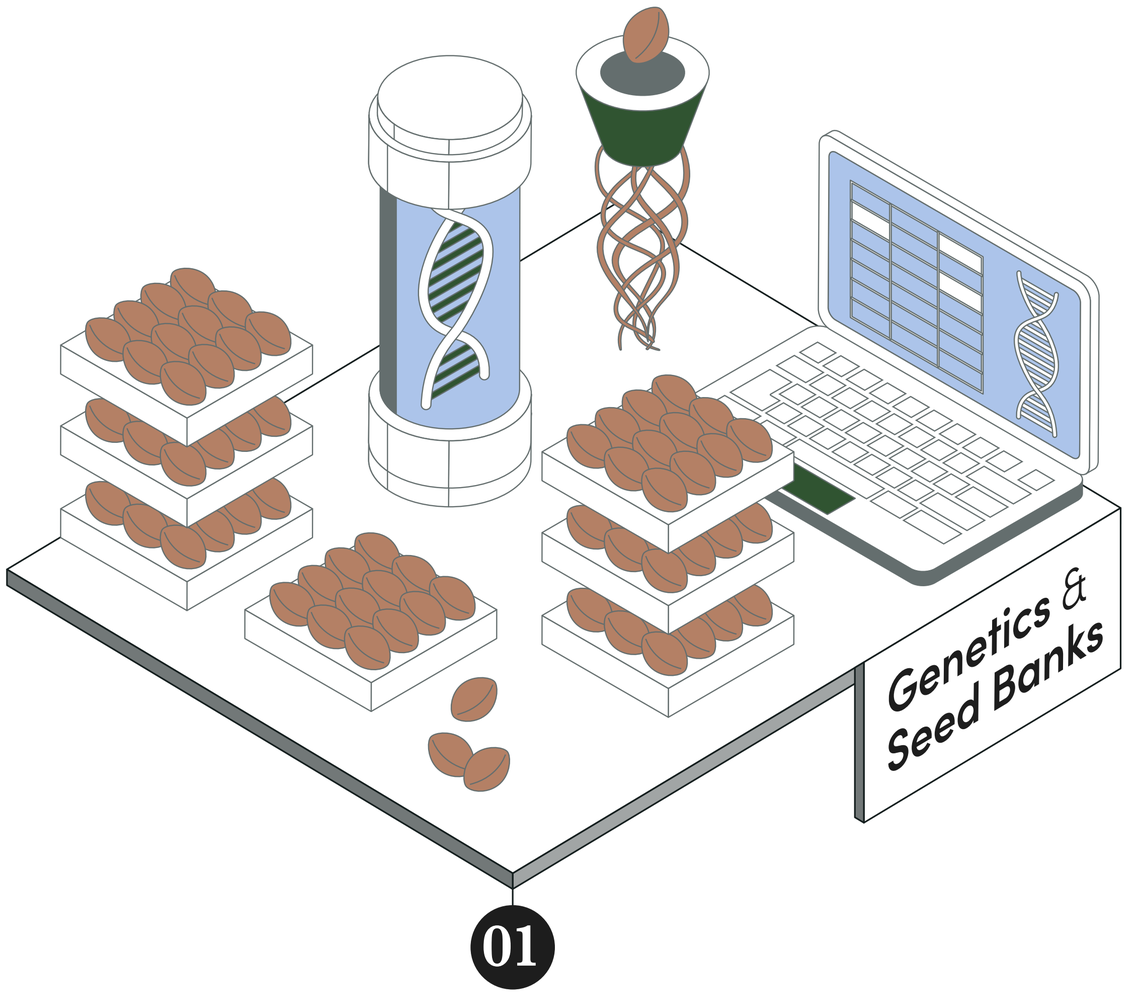
08. Technology

phytonext · Shimadzu · Herbolea · Vitalis · Devex · Rousselet Robatel · PerkinElmer · ThermoFisher Scientific · Alta Flora · releaf. · syqe medical · Senzer · Ryah · hapac · Merxin

09. Distribution

Cannamedical · cc pharma · cansativa · ilivo · Farmako · Materia · Pohl Boskamp · Nimbus Health · AMP · Vayamed · Noweda · Adrex pharma · paesel + lorei · ACA · Herbamedica · CanPharma · Acnos · GECA Pharma GmbH · STADA · IMP&C · delfarma · Canngros · sana life science · therismos · Astral Health · Grow Pharma · Health House · PCCA · Alliance Healthcare · Czech Medical Herbs · Pharma.MT

01. Genetics & Seed Banks

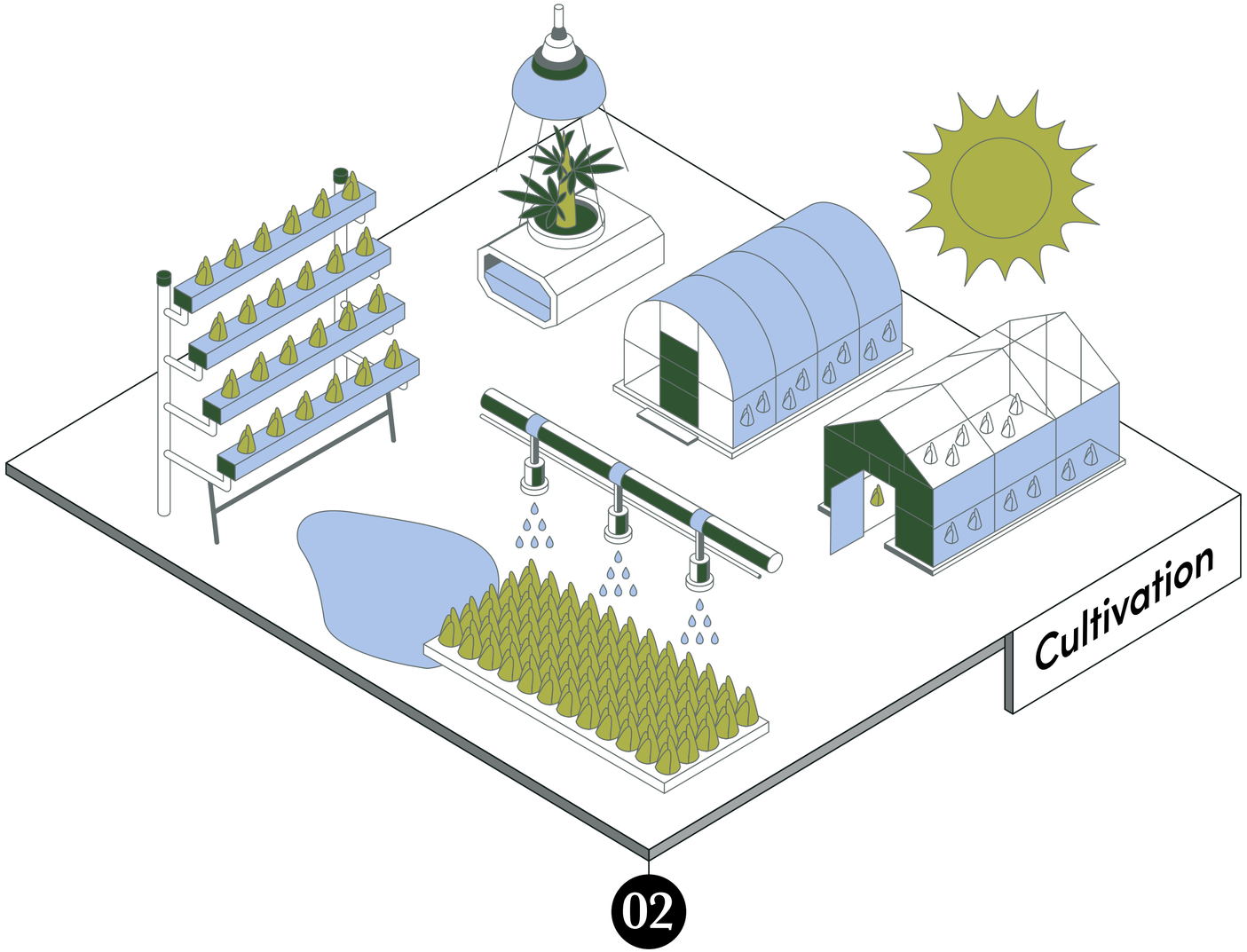


HANWAY INSIGHTS

- There are currently a limited number of European companies producing specialised seeds and genetics for the European medical cannabis market.
- The majority of seeds are supplied by companies geared towards grey and recreational markets.
- The need for reliable genetics and increasing R&D in this field will drive development of cultivar catalogues tailored for medical use.
- Specifically we expect to see improved stability become a key focus alongside bespoke cannabinoid and terpene profiles.
- Until this area of the market is fully developed, companies are likely to continue to source from grey market seed suppliers and licensed operators in Canada.

If you require support building your supply chain, contact us here.

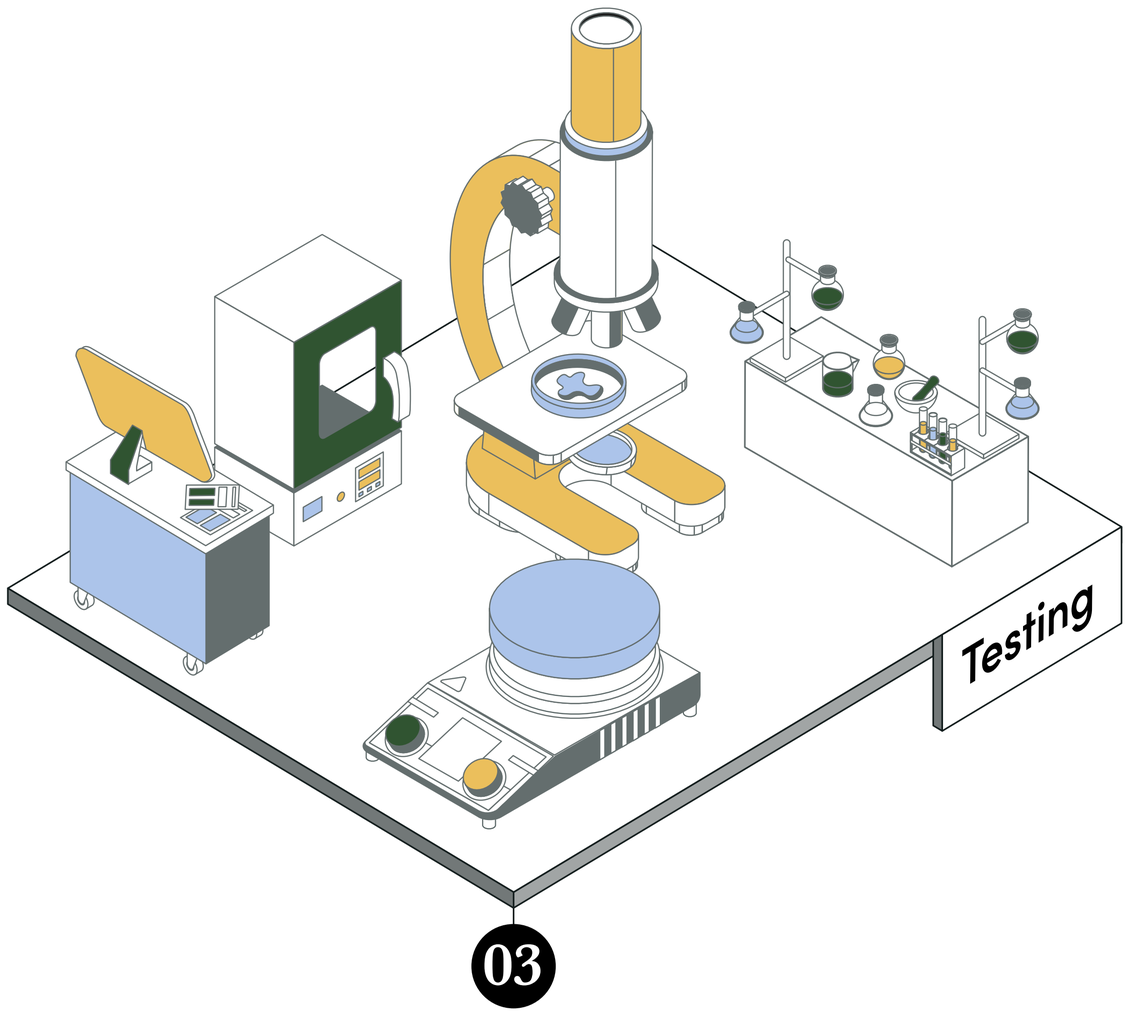
02. Cultivation



HANWAY INSIGHTS

- European medical cannabis cultivation is undertaken by a number of operators across several countries. While many active operators are based in Portugal due to favourable growing conditions and licensing processes, we expect other South European markets such as Macedonia and Greece to feature more prominently from 2021 onwards.
- Europe does not have a harmonised approach towards cultivation licensing. While each country's framework remains unique, several distinct models have emerged depending on the country's motivation for regulating production.
- Several European countries, such as Germany and Denmark, have licensed cultivation to reduce reliance on imports and ensure suitable supply for domestic patients.
- Other jurisdictions have formed medicinal cannabis frameworks focused towards commercial exports rather than domestic supply. Exports from Spain and Portugal indicate that a wider European cultivation market is developing, with viable supply no longer limited to Bedrocan from the Netherlands.
- The recent introduction of low cost GACP producers into the European market, such as Uruguayan producer Fotmer, indicates the start of a disruption in the market with the need to maintain top quality, differentiated offerings at a competitive price.

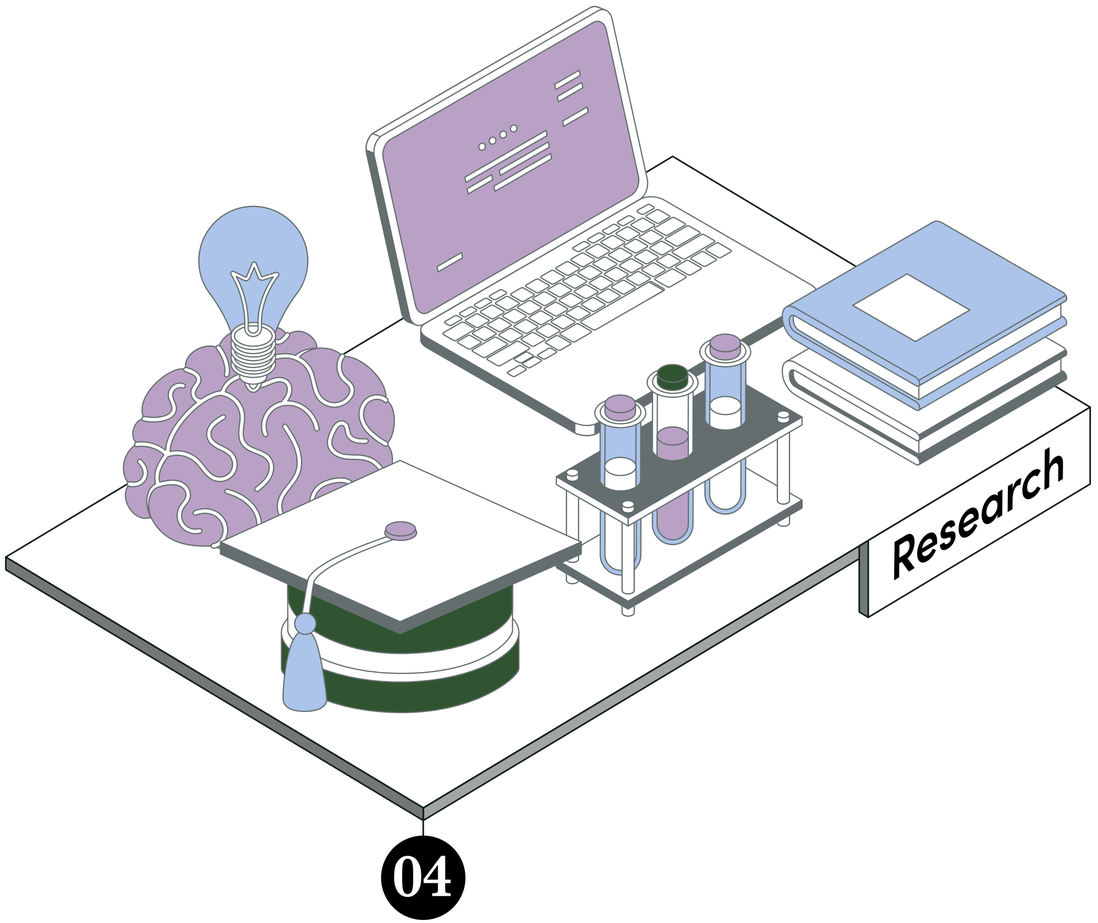
03. Testing



HANWAY INSIGHTS

- There is currently an undersupply of reliable, scalable testing companies across the region, evident by the limited number of companies presented on the ecosystem.
- Inconsistencies in quality standards can occur, where different methods for testing can result in confusion regarding results.
- Not all testing companies are accredited to an internationally recognised standard, such as ISO/IEC 17025.
- Speeds of analysis can vary across companies. In some instances delays have been reported with samples sent internationally for final testing.
- There is a clear space in the market for a reliable, accredited, fast and widely trusted testing company.

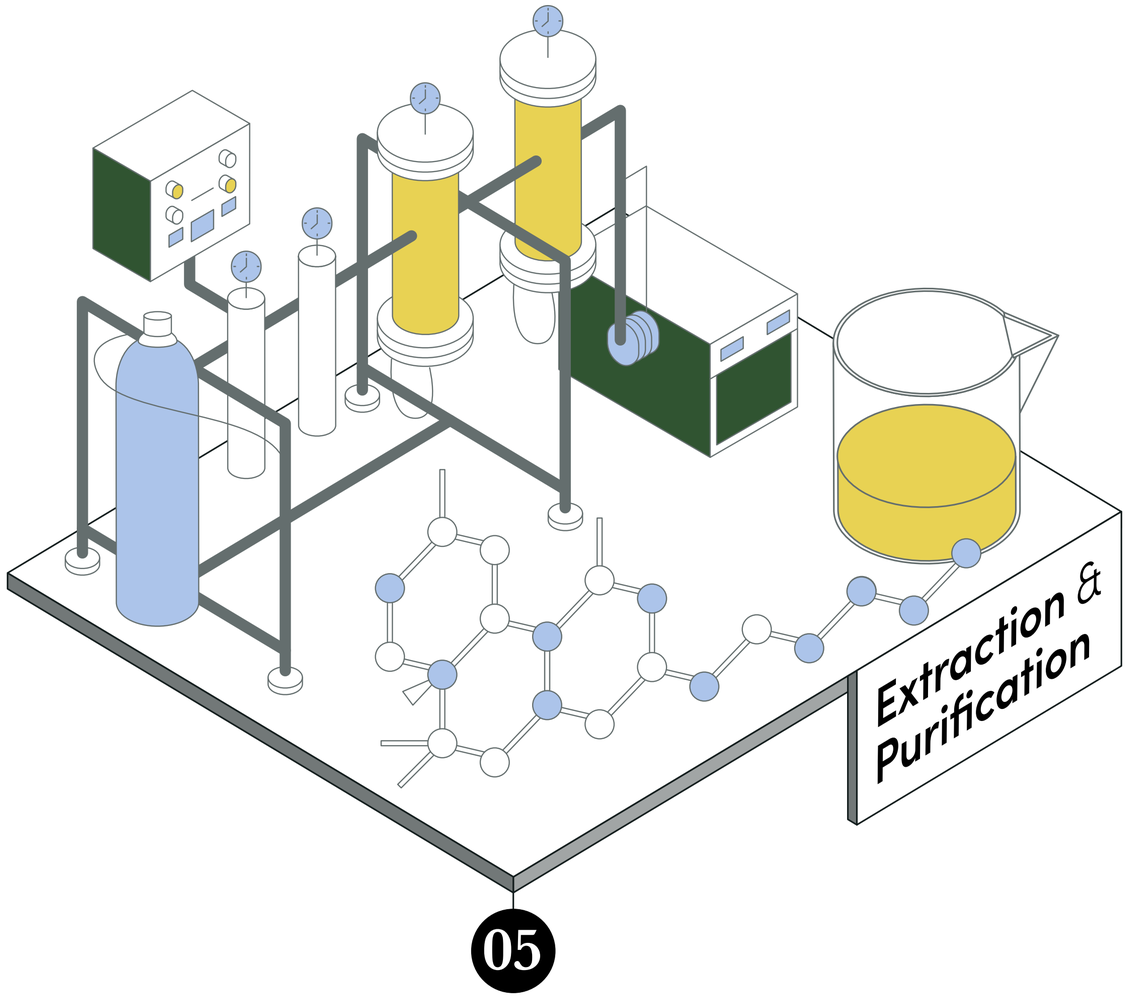
04. Commercial R&D



HANWAY INSIGHTS

- Despite Europe's leadership in biotech and agritech fields, companies in these sectors have been slow to engage with cannabis, both in terms of clinical research and process innovation.
- Regulatory barriers have inhibited commercial research, with the financial and time cost of high-THC licence applications often deterring companies from this space.
- Positive progress is underway however, as growing medical markets shine a light on research and IP opportunities within the sector.
- Growing numbers of cultivators looking to increase output and optimise revenue are helping to drive this momentum and are eager to collaborate and engage with research companies.
- Innovation grants and support from governments can be patchy and funding support varies across European countries. At times, cannabis falls between the cracks of medical and agro-food funding, and is sometimes explicitly excluded from funding opportunities.

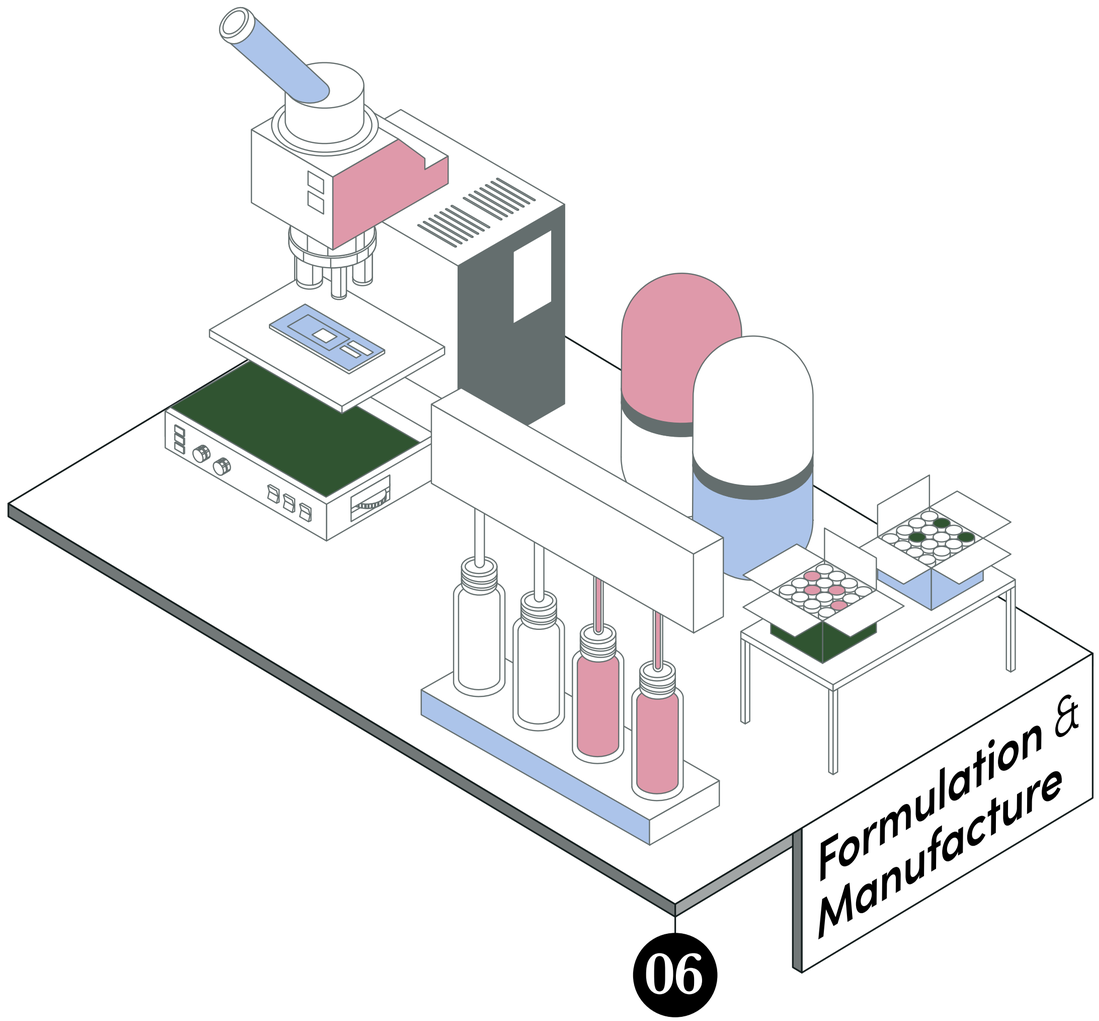
05. Extraction & Purification



HANWAY INSIGHTS

- Despite a growing number of sites capable of conducting EU-GMP standard extraction and purification, there is a shortage of contract extraction facilities in Europe with most facilities being built to meet internal capacity requirements.
- To date, many producers have established or acquired their own extraction facilities in a move towards vertical integration.
- There is a growing preference for oils and extracts in Europe due to the need for precise dosing and targeted formulations rather than the vaporising of cannabis flower.
- In North Macedonia only oils and extracts are permitted for export, positioning extraction facilities as an essential part of the supply chain. Yet without viable third party facilities in place, Macedonian cultivators are resorting to freezing harvests of flower.

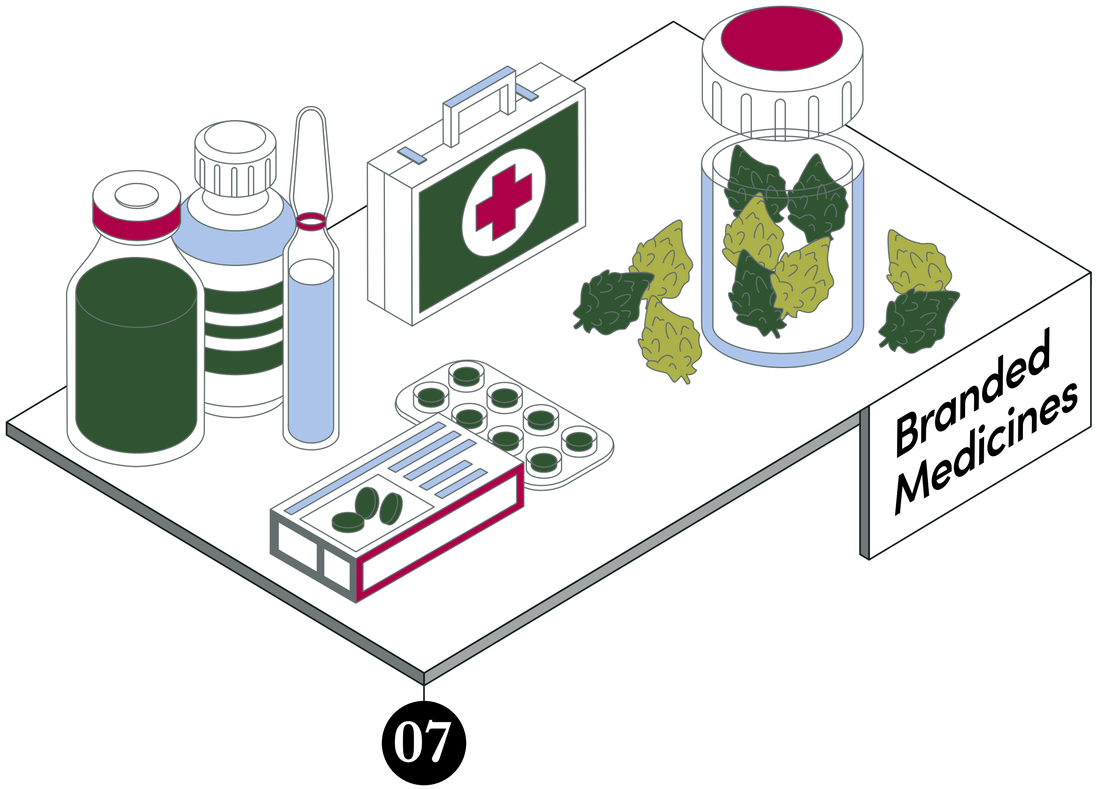
06. Formulation & Manufacturing



HANWAY INSIGHTS

- In contrast to North American markets, manufacturing and formulation activities have grown in significance in Europe due to demand for dosable, pharmaceutical-style products. This has resulted in a growing market segment with a substantial number of companies focusing on such operations.
- Developments in manufacturing techniques further enable targeting of specific conditions, in line with growing research into the conditions medical cannabis can be prescribed for.
- Europe is expected to drive the next stage of product development. Specialised manufacturers are producing sophisticated product formats that lend to use in clinical trials, and will arguably allow medical cannabis markets to develop in countries that are skeptical of flower.

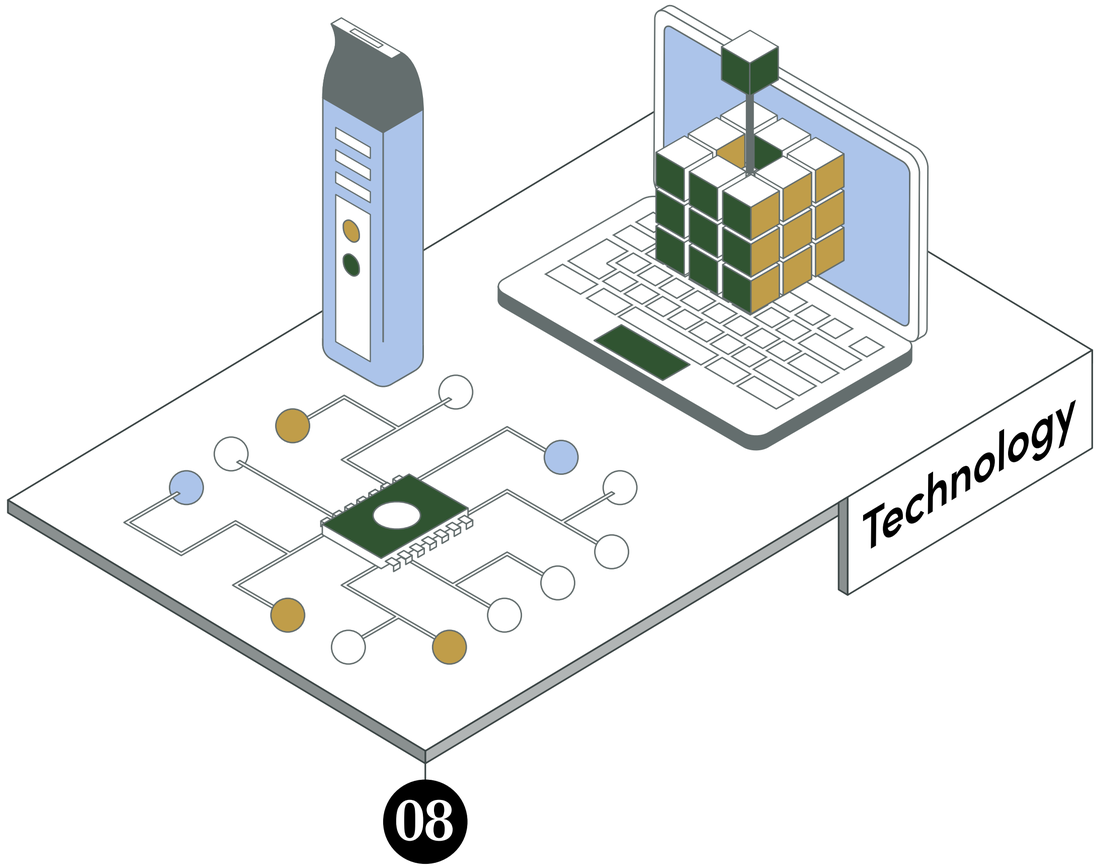
07. Branded Medicines



HANWAY INSIGHTS

- The past year has seen a surge in the number of branded cannabis products available to patients across Europe.
- This increase has predominantly come from European innovators challenging the dominance of Canadian LPs and Bedrocan, who until 2020 held almost 100% of European medical cannabis sales (excluding GW Pharmaceuticals' products with marketing authorisation).
- White labelling has increased in prevalence with local companies processing and packaging flower and extracted products originating from Canada and countries with low cultivation overheads.
- As the number of products available continues to increase, companies will need to establish novel ways to differentiate themselves, whether through clever branding (see Spectrum's colour coded products), enhanced healthcare practitioner education or, ideally, thorough generation of valid clinical evidence.
- Understanding country specific regulations and healthcare practitioner perceptions is vital to succeed in bringing a new product to market in Europe. If this is something you require support with get in touch.

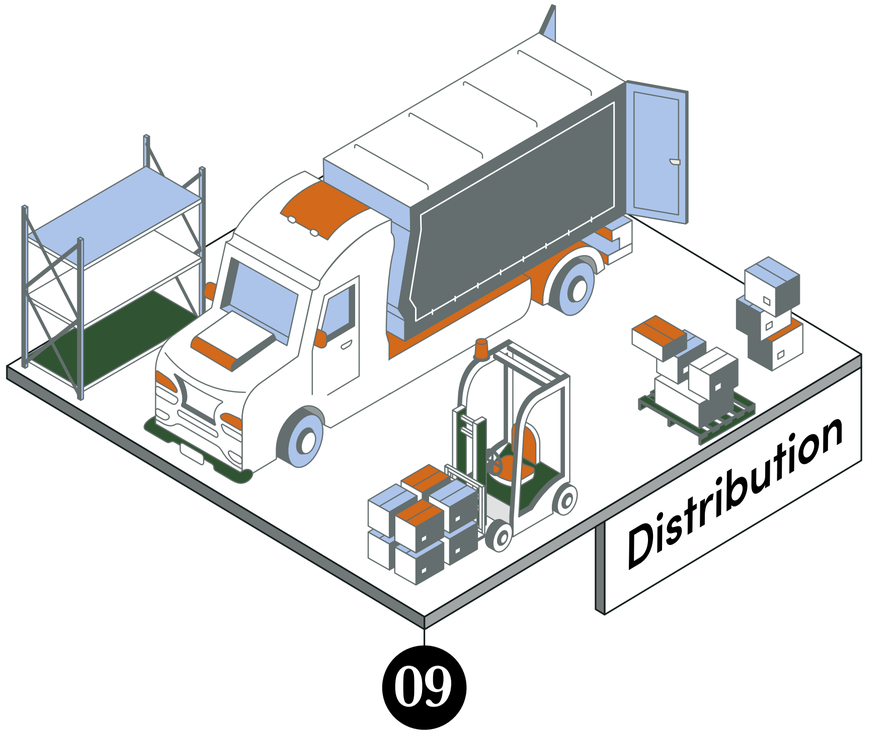
08. Technology



HANWAY INSIGHTS

- To date, technological innovation within the European cannabis sector has been limited outside of a few key areas such as extraction and product formulations.
- This is, in part, due to the relatively low patient numbers that make costly R&D activities less attractive than in more mature markets, such as the US and Israel who also benefit from a rich health tech ecosystem. In addition, technological innovation is likely to be limited by the need to develop products specifically for the medical market and the regulations associated with this.
- Specific areas with strong promise for innovation in the coming years include:
  - Big data analytics to accelerate the drug development pipeline
  - Patient facing apps and wearables to maximise adherence and generate real world evidence
  - Intelligent agritech solutions to maximise the efficiency of European cultivation facilities
- There is a clear opportunity to excel in this space as many non-European companies will focus on the local opportunity for the foreseeable future and commonly struggle to meet the stringent European requirements for medical technologies.

09. Distribution



HANWAY INSIGHTS

- Medical cannabis distribution is currently one of the most competitive segments of the European market.
- Medical cannabis is typically distributed by cannabis-specific or speciality unlicensed medicine distributors. However, Europe has started to see traditional pharma companies such as STADA also begin to enter the sector.
- Distributors tend to only operate within one country in Europe, despite the same products being supplied across multiple jurisdictions. However, some distributors are emerging as multi-country operators and we expect this trend to continue as sales increase across Europe.
- Licensed distributors may only supply licensed pharmacies, which in turn are able to fulfil patients' prescriptions.
- Many licensed producers have acquired national or regional distributors to secure a vertically integrated supply chain, in some cases providing exclusive access to the distributor's established network.

Trends & Insights

1. Prescribing and Dispensing
2. Isolated Cannabinoids
3. Catalysts for Change
4. Domestic Cultivation
5. Research and Clinical Trials
6. Opinion Leaders

This section has been produced in collaboration with Hanway Associates.

HANWAY ASSOCIATES

Hanway Associates is a strategic consultancy specialising in cannabis research, new market entry, commercial diligence and M&A strategy. Hanway Associates provide services to help open and enter markets, build brands and grow clients' networks, as well as producing ready-to-buy reports to help companies navigate a complex and rapidly changing industry.

1. Prescribing and Dispensing — The Landscape

The prescribing and dispensing landscape varies between countries in Europe. We have outlined some of the key differences including uptake of magistral preparations and the compounding route, as well as the importance of private and specialist clinics in driving patient demand and access to medical cannabis in several European countries.

COMPOUNDING PHARMACIES

In European countries such as Germany and Italy, pharmacists play a large role in preparing formulations. This allows for the provision of personalised medicines to patients. The focus is therefore less on off-the-shelf cannabis products, and more on targeting a patient's specific need. The Italian pharmacist Dr Marco Ternelli reports that in Italy,

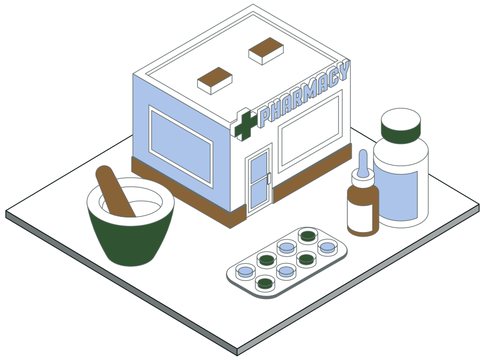
> **"The most prescribed and preferred forms are oral oils and capsules, followed by sachets for vaporising.**

A recent interpretation issued by the Ministry of Health in Italy is believed to have a negative effect on patients accessing medical cannabis preparations.

Under the new interpretation, pharmacies will no longer be permitted to ship prescriptions to patients or produce oil in bulk, and will be limited in the product formats they are able to process. Dr Ternelli explains,

> **"Although there is no new law or decree, the Ministry of Health has issued an absurd interpretation, denying pharmacies the ability to produce cannabis extracts for non oral use (eg. eye drops, creams, suppositories) and shipping directly to patients (home delivery) though courier. An appeal to court is currently being issued by some pharmacists.**

In Germany, cannabis supplied to pharmacies must be as a 'bulk intermediate product' rather than a finished product, and compounding is a compulsory step. A national monograph states the types of cannabis medicines pharmacists can formulate, including oils and capsules prepared using dried flower or dronabinol. Flower may also be prescribed, and weighing and re-packaging by pharmacists constitutes the required processing step.



1. Prescribing and Dispensing — New Routes to Access

TRIALS

- → A lack of evidence is often cited by regulatory bodies as a key barrier to wider medical cannabis adoption and access.
- → There are currently several medical cannabis trials taking place or due to start in the near-future in Europe. It is hoped these, alongside the launch of patient registries such as Project Twenty21 and the Sapphire Registry, will contribute to evidence on the effectiveness and safety of medical cannabis.
- → Combined, specialist clinics, trials and registries are helping to overcome the barriers remaining in the European medical cannabis industry.

PRIVATE & SPECIALIST CLINICS

- → Private prescribers and specialist clinics have been a key driver of industry growth in some countries where physician cannabis awareness is low or national health insurance coverage is limited.
- → Specialist clinics have enabled patient access to medical cannabis in countries with restrictive prescribing frameworks such as the UK and Poland. In the UK, specialist clinics have allowed those with conditions and symptoms currently not advised to be prescribed medical cannabis under NICE guidelines such as chronic pain, cancer and psychiatric conditions, to access medical cannabis.
- → By contrast in Germany, cannabis-specific clinics are not permitted under healthcare regulations. Centres of knowledge for the treatment of a specific disease are permitted, however this is not the case for a specific medication such as cannabis.

The UK has a unique clinic-focused ecosystem.

Some of the operators include:

INTEGRO

cannabis access clinics

THE MEDICAL CANNABIS CLINICS

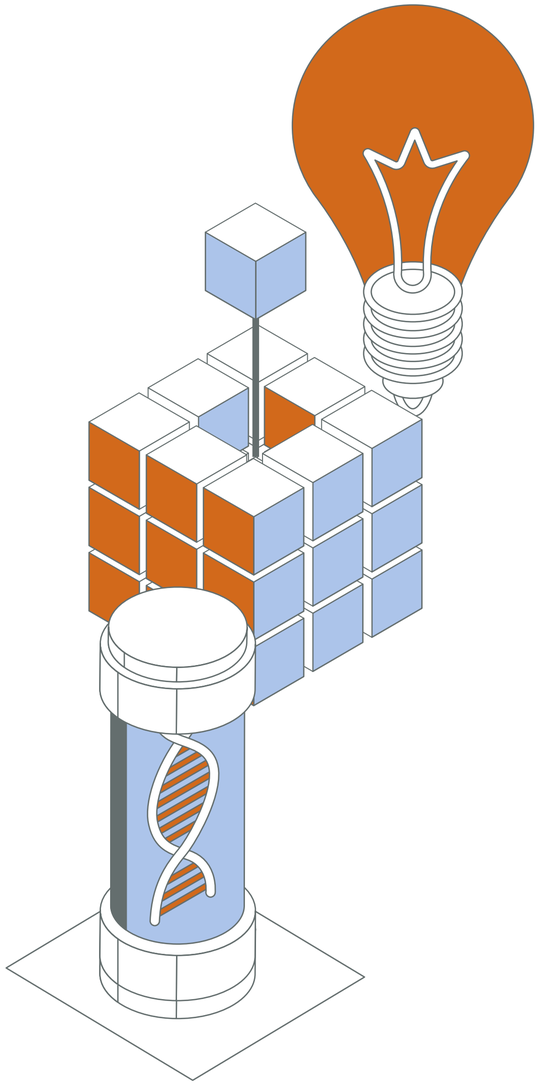
SapphireMedical

myaccess clinics

2. Isolated Cannabinoids — Synthetic and Plant Derived

Despite representing a significant percentage of medical cannabis prescriptions in Europe, isolated cannabinoids are often an overlooked product category compared to flower and whole plant extracts. However, there has been an increase in European demand for isolated cannabinoids (both synthetic and plant-derived), with dronabinol (isolated THC) playing a central role in Germany, Denmark, Austria and Switzerland. Synthetic cannabinoids can be more palatable to regulators and have enabled significant medical cannabis markets to develop in countries such as Austria, which currently prohibits prescriptions of flower and full spectrum extracts.

Isolated cannabinoids present a strong investment opportunity through the ability to develop IP and patent bespoke, targeted formulations. In line with Europe's status as a pharmaceutical hub, European producers have been a major driving force behind innovations to synthesize and isolate rare and novel cannabinoids, in addition to those typically required as an active pharmaceutical ingredient (API) for magistral preparations.

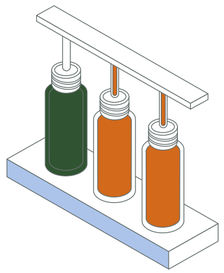


2. Isolated Cannabinoids — Definitions

KEY INFORMATION			
DEFINITION	**Synthetic** Synthetic cannabinoids are the result of chemical or biochemical synthesis methods to reproduce compounds found in the cannabis plant, or artificial derivatives. This laboratory process produces a pure isolated compound, once the byproducts of synthesis have been removed.	**Isolate** Individual cannabinoids can be purified to reach beyond 99.5% purity and can be either crystalline or oil form at room temperature.	**Full-Spectrum** Full-spectrum refers to a form of plant-derived cannabis containing all naturally occurring cannabinoids, terpenes and other compounds. The cannabinoid profile may vary due to difficulties standardising composition.
SOURCE	**Laboratory**	**Laboratory or plant**	**Plant**
NUMBER OF COMPOUNDS	**Single**	**Single**	**Multiple**

2. Isolated Cannabinoids — Advantages

ADVANTAGES OF SYNTHETIC CANNABINOIDS



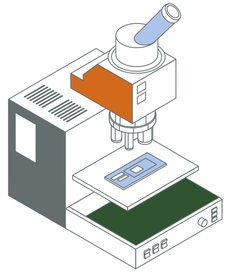
SUPPLY CHAIN

Synthesis avoids supply disruptions arising from failed harvests and difficulties transporting the controlled plant matter. It enables manufacturers to scale production depending on market demand and changing national requirements and regulations.

COST

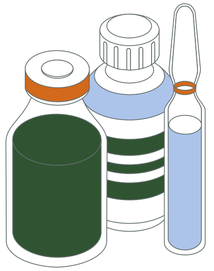
The movement towards synthetic compounds has already been experienced with the likes of aspirin, caffeine and multivitamins due to their lower production costs and the capacity for large-scale production. While the cost of synthetic cannabinoids is currently high relative to plant-based production, prices are falling with new market entrants and increasing R&D.

ADVANTAGES OF ISOLATED CANNABINOIDS



RESEARCH POTENTIAL

Single compounds are better-suited for use in trials to identify the effects of specific cannabinoids. Synthetic cannabinoids are typically easier to obtain for research purposes and are sometimes viewed more favourably from a regulatory standpoint, driving progress towards the body of evidence needed for wider adoption of medical cannabinoids.



TARGETED THERAPEUTIC PROPERTIES

Unlike whole plant products, isolated cannabinoids make it possible to utilise minor cannabinoids with high therapeutic potential to target specific medical conditions, and to avoid unwanted side effects caused by the presence of THC for patients that express sensitivity.

2. Isolated Cannabinoids — Regional Popularity

WHY ARE ISOLATED CANNABINOIDS MORE SIGNIFICANT IN THE EUROPEAN MARKET THAN AT A GLOBAL LEVEL?

Several European countries introduced access to synthetic cannabinoid products (e.g. Nabilone and Marinol) at an early stage, before implementing a broader medical cannabis program or pilot. Dronabinol was the first cannabinoid product in Germany that could be prescribed by the country's doctors and accessed through the traditional medicines system.

European medical cannabis access is largely through conventional medical and pharmaceutical frameworks. As such there are greater requirements for product standardisation, quality and evidence than North American markets, where conventional pharmaceutical standards do not apply to medical cannabis. Isolated cannabinoids are highly standardised and optimised to ensure consistency in trials, R&D and patient-specific formulations.

Isolated cannabinoids have gained significance in Europe partly due to widespread adoption of the pharmacy compounding model, particularly in Germany and Italy. Several key European markets allow pharmacists to prepare patient-specific magistral preparations in accordance with national monographs, offering doctors and patients a greater choice of formats and strengths. Magistral preparations are more easily and consistently prepared using active pharmaceutical ingredients (e.g. isolated THC and CBD) rather than the alternative method of performing in-house extraction using plant material.

2. Isolated Cannabinoids — European players driving the rise of isolated cannabinoids

- → C3, formerly Bionorica SE, is the leading manufacturer and distributor of dronabinol, founded in 2014 and acquired by Canopy Growth in May 2019.
- → Until recently, C3 held a monopoly in supplying the German market with dronabinol, used by pharmacies to produce patient-specific formulations. The introduction of Cantourage to the market has since created a duopoly.
- → The Austrian Agency for Health and Food Safety (AGES) has a contractual partnership with C3, with C3 performing extraction and manufacturing dronabinol from cannabis produced domestically by AGES.
- → C3 has a total of five medicines in the market, and has clinical research programmes in progress.

can tourage

- → Cantourage is a new entrant to the German medical cannabis market, founded in 2019 by Dr. Florian Holzapfel and Patrick Hoffmann, who previously sold Pedanios to Aurora.
- → Cantourage is the first firm to challenge the established C3 in the European market through its imports of dronabinol from exclusive Israeli partner BOL Pharma, and has been supplying THC as an API to German pharmacies since April 2020.
- → Cantourage aims to increase product variety, drive innovation and ensure reliable supply of product.

2. Isolated Cannabinoids — European players driving the rise of isolated cannabinoids

CBDepot.eu
Upmarket Cannabinoid Solutions

→ CBDepot is a pioneer in the production of cannabinoid ingredients. Its Novel Food application for synthetic CBD was the first cannabinoid novel food application to be validated by the European Commission, and is one of only three CBD applications under review by the European Food Safety Authority (EFSA).

→ CBDepot's sister company CB21 Pharma received EU-GMP certification in June 2020 for its manufacturing of Cannabidiol API.

CBD is gaining attention in the pharmaceutical and cosmetic industries. It can be extracted from the plant or chemically synthesized. Evidence of CBD's potential health benefits in scientific literature are from studies analysing pharmaceutical-grade CBD, which is different from isolated CBD. We deal with synthetic CBD to be in line with clinical data and ensure the quality needed by regulatory bodies.

Producers getting CBD from the plant must contend with impurities exceeding levels that are standard in pharmaceutical practice. Synthetically produced CBD is well characterised with no minor cannabinoids and other impurities.

BORIS BAŇAS- CSO AT CBDEPOT

octarine

→ Octarine is a synthetic biology company developing cannabinoid and psilocybin derivatives through microbial fermentation.

→ Octarine was awarded the TWB (Toulouse White Biotechnology) award in 2020, granting access to TWB's technical platforms with a high level of scientific support.

→ Received funding from Bruce Linton in January 2020, the former CEO and founder of Canopy Growth, to fund R&D and strengthen existing IP.

We saw an opportunity to harness synthetic biology to deliver new health care solutions. Many neurological and psychological conditions are poorly served by current drugs, leaving physicians and patients desperately seeking alternatives. Cannabinoids are poised to offer breakthrough therapies for these conditions, but to realise the full potential of these molecules, issues with their production and undesirable properties must first be solved.

Our platform is focusing on improving cannabinoids molecules through enzymatic modifications and developing NCE's targeting selective therapeutic indications.

NETHAJI GALLAGE - FOUNDER AND CEO OF OCTARINE

3. Catalysts for Change – Gradual Acceptance

The past decade has seen the emergence of medical cannabis programmes across the globe, with a growing number of European nations expanding their conventional medical frameworks to provide access. European reform has progressed through different legal frameworks to those established in in North America, where ballot initiatives and political manifestos provided the catalyst for reform. Patient advocacy groups have played a substantial role in shifting public opinion in favour of medical cannabis through high-profile cases, and political barriers to reform are steadily being dismantled.

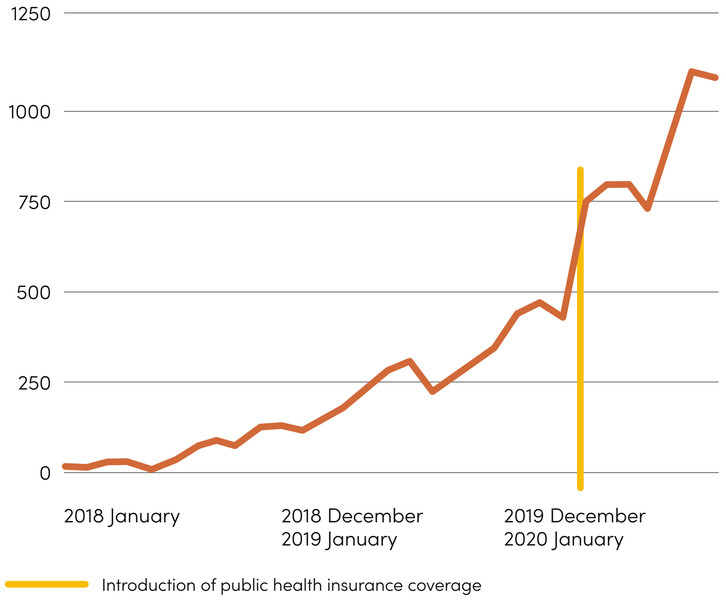
Several countries (e.g. France & Denmark) have opted to introduce medical cannabis through time-limited 'pilots' rather than permanent regulatory frameworks, with their success partly reliant on the budget and resources allocated to the scheme. However, cost remains a hurdle for patients in Europe.

The Netherlands was the first European nation to introduce access to medical cannabis, yet patient adoption rates and market growth have been hindered by limited insurance coverage. Robust reimbursement policies and favourable prescribing criteria solidified Germany's position as Europe's largest medical market, and the number of patients in the Czech Republic has risen significantly since public health insurance coverage was mandated early this year.

We expect to see increased acceptance and adoption of medical cannabis programmes as the clinical evidence base continues to develop, allowing prosperous domestic industries to develop and the number of eligible conditions and patients receiving treatment to increase throughout Europe.

> **Many patients are now able to access cannabis medicines legally, and advocacy groups have been instrumental in engineering this change. There is still work to be done and we believe that cross-jurisdiction communication and collaboration will continue to improve the lives of patients.**
>
> PAUL NORTH, DIRECTOR OF VOLTEFACE

NUMBER OF MEDICAL CANNABIS PATIENTS IN THE CZECH REPUBLIC, 2018 - JULY 2020

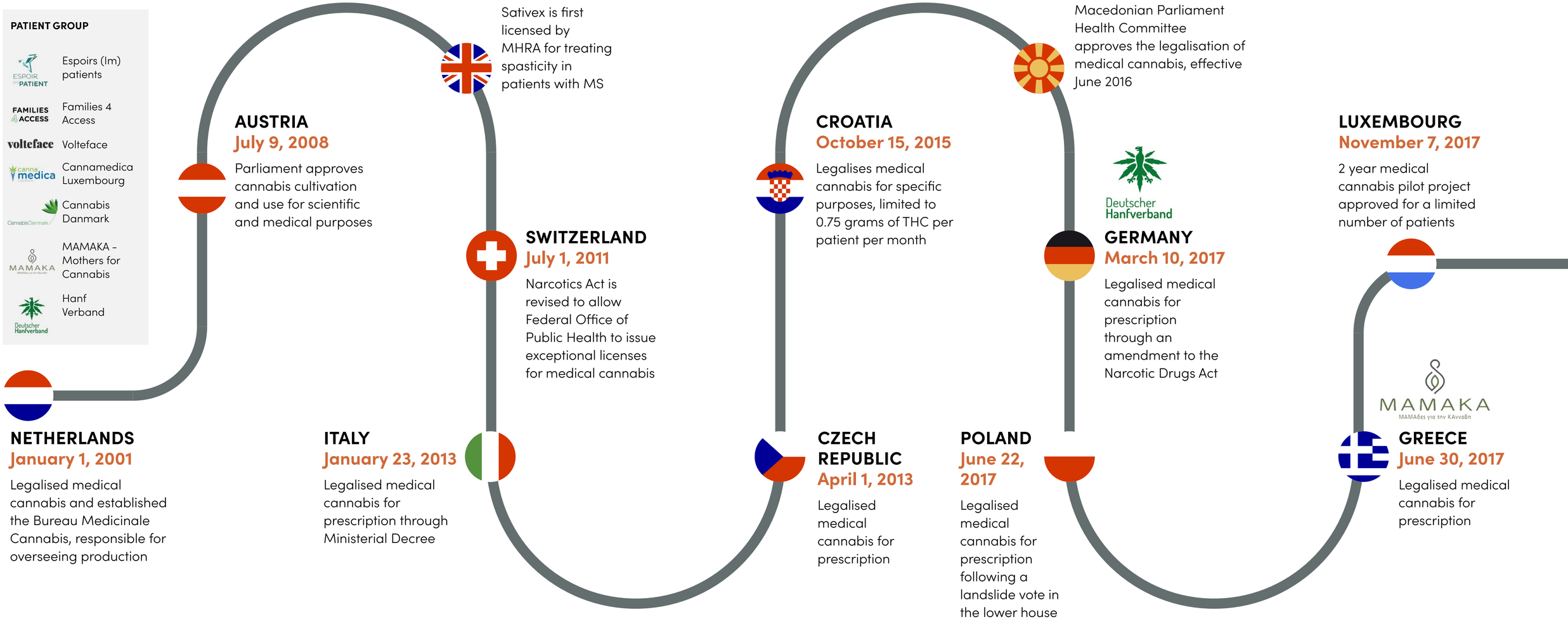


Source: SAKL

3. Catalysts for Change – Key Moments

PATIENT GROUP

- Espoirs (Im) patients
- Families 4 Access
- Volteface
- Cannamedica Luxembourg
- Cannabis Danmark
- MAMAKA – Mothers for Cannabis
- Hanf Verband



NETHERLANDS
January 1, 2001
Legalised medical cannabis and established the Bureau Medicinale Cannabis, responsible for overseeing production

AUSTRIA
July 9, 2008
Parliament approves cannabis cultivation and use for scientific and medical purposes

UK
June 16, 2010
Sativex is first licensed by MHRA for treating spasticity in patients with MS

SWITZERLAND
July 1, 2011
Narcotics Act is revised to allow Federal Office of Public Health to issue exceptional licenses for medical cannabis

ITALY
January 23, 2013
Legalised medical cannabis for prescription through Ministerial Decree

CZECH REPUBLIC
April 1, 2013
Legalised medical cannabis for prescription

CROATIA
October 15, 2015
Legalises medical cannabis for specific purposes, limited to 0.75 grams of THC per patient per month

NORTH MACEDONIA
February 9, 2016
Macedonian Parliament Health Committee approves the legalisation of medical cannabis, effective June 2016

POLAND
June 22, 2017
Legalised medical cannabis for prescription following a landslide vote in the lower house of parliament

GERMANY
March 10, 2017
Legalised medical cannabis for prescription through an amendment to the Narcotic Drugs Act

LUXEMBOURG
November 7, 2017
2 year medical cannabis pilot project approved for a limited number of patients

GREECE
June 30, 2017
Legalised medical cannabis for prescription

3. Catalysts for Change – Key Moments

Cannabis Danmark

DENMARK
January 1, 2018
Four year medical cannabis pilot project commences

MALTA
March 23, 2018
Legalised medical cannabis for prescription through an amendment to the Drug Dependence Act

canna medica LUXEMBOURG

LUXEMBOURG
June 28, 2018
Legalised medical cannabis for prescription by any GP

PORTUGAL
July 18, 2018
Legalised medical cannabis for prescription

volteface
FAMILIES 4 ACCESS

UK
October 11, 2018
Regulatory amendment enables the prescription of medicinal cannabis

LITHUANIA
October 11, 2018
Parliament approves a law allowing for medical use of cannabis, with an effective date of 1 May 2019

CYPRUS
February 15, 2019
Legalised cultivation and medical use of cannabis through amendments to the Drugs and Psychotropic Substances law

IRELAND
June 26, 2019
Minister for Health signs legislation enabling the Medical Cannabis Access Programme as a 5 year pilot project

EUROPEAN UNION
September 23, 2019
Epidyolex receives EMA approval for the treatment of seizures in childhood-onset epilepsy

CZECH REPUBLIC
January 1, 2020
Law mandates public health insurance to reimburse 90% of the prescription price up to 30 grams per month, significantly expanding patient access

ESPOIR (IM)PATIENT

FRANCE
October 25, 2019
National Assembly of France authorises plans for a two-year medical cannabis trial, due to commence in 2021

4. Domestic Cultivation — Exploring the Models

Alongside medical cannabis treatment programmes, a significant number of European countries have introduced domestic cannabis cultivation for medical and scientific purposes.

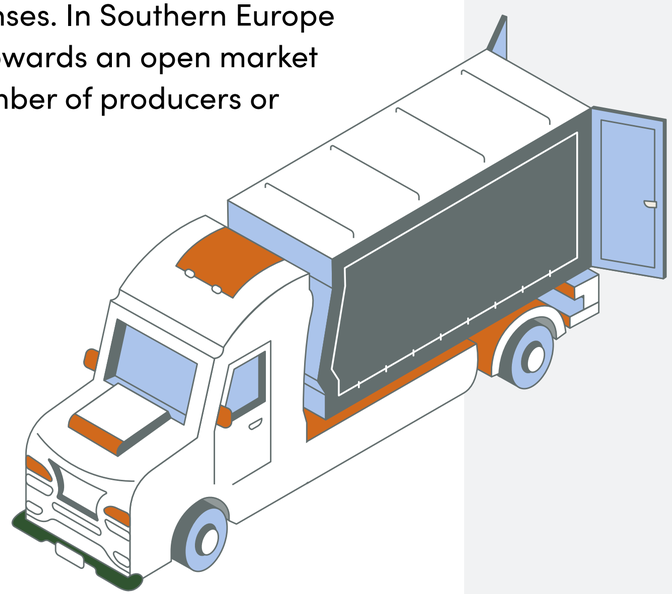
European cannabis markets have often faced shortages of readily available flower or formulated products. To date, a limited number of licensed producers have been able to meet EU-GMP standards required for prescription to patients through the conventional medicines framework. There is no harmonised supply chain model ensuring patient access to products in Europe, despite the same products being nominally available in many jurisdictions across the continent.

The number of countries with significant cultivation capacity is expected to increase sharply in the next five years. The global flow of medical cannabis is likely to shift as facilities in Europe and the global south become operational, providing viable alternatives to supply from the Netherlands and Canada.

European countries are moving away from a state-issued monopoly approach to cultivation towards public tenders for a designated capacity or issuing open-ended commercial licenses. In Southern Europe there is an increasing trend towards an open market model with no cap on the number of producers or total cannabis output.

FOUR OVERLAPPING APPROACHES TOWARDS LICENSING CULTIVATION ARE EMERGING IN EUROPE:

1. Production solely for domestic patients
2. Export-focused production
3. Production exclusively for pharmaceuticals
4. Hybrid production model



4. Domestic Cultivation — Production Solely for Domestic Patients

Through this model, production is licensed for the purpose of ensuring stable supply for domestic patient requirements. Cultivation may be overseen by a state body, or contracted to commercial companies through state issued tenders. The contracted quantities have tended to be lower than the volume of medical cannabis required by domestic patients, maintaining a need to supplement production with imports.

	GERMANY	ITALY	CZECH REPUBLIC
FRAMEWORK	→ State-issued commercial tender	→ State-controlled monopoly	→ State-issued commercial tender
CULTIVATORS	→ Aphria, Aurora, Demecan	→ The armed forces, Military Chemical and Pharmaceutical Plant (SCFM)	→ Elkoplast Slušovice
QUANTITY CONTRACTED	→ 10,400kg over a four-year period → 13 lots of 200kg were issued, totalling 2,600kg per year	→ 200kg estimated current capacity → Health Ministry authorised expansion up to 500kg in 2020	→ 40kg over a four-year period
QUANTITY SUPPLIED IN 2019	→ N/A → First harvest expected Q1 2021	→ 157kg supplied to pharmacies	→ 25kg supplied to the government → 17kg sold by pharmacies
PRICE PAID TO CULTIVATOR PER GRAM	→ Estimated average of €2.30	→ €6.88	→ CZK 139 plus VAT (~€5.11)
INSIGHTS	→ An estimated 6,500kg was imported for dispensing to domestic patients in 2019. Imports will still be required to supplement domestic supply. → The government may purchase a larger quantity depending on the size of the harvests, at a potentially lower cost than the previous government estimate of an average €2.3 per gram. → The total amount of the tender has already been increased from 6,600kg to adjust for rising demand.	→ Domestic production remains insufficient compared to patient demand. Just 11% of cannabis sold in 2019 was produced by SCFM. → Production is supplemented by imports from Bedrocan and a state-issued tender of which Aurora was the sole winner. → SCFM has signed a three-year joint venture with the Italian region of Tuscany, in part exploring production of flower and standardisation of oil extracts.	→ Elkoplast Slušovice was the only bidder in the most recent tender in 2017, and previous tenders were reportedly cancelled due to no applications being made. → In 2019, imports from Bedrocan and Canadian producers still occurred despite production volumes being greater than demand. This is thought to be the result of both quality and logistical challenges.

4. Domestic Cultivation – Export-Focused Production

Several countries have legalised cannabis cultivation with an eye to capture the export market, driven by opportunities for foreign direct investment and economic growth. Most of these countries have limited domestic markets and in some instances no framework for medical access. In order for an export-driven market to succeed, originating countries must implement a framework requiring quality standards to at least the level of the destination country. However, not all jurisdictions with an international focus have the requisite frameworks fully in place, and it remains to be seen which countries will succeed in capturing market share.

	PORTUGAL	SPAIN	MALTA	NORTH MACEDONIA	GREECE
INSIGHTS	→ Emerging as a European cultivation hotspot due to a favourable climate, low production costs and an efficient licensing framework. → A framework for domestic patient access is in place, although no products have yet been approved.	→ Developing as a cultivation, research and manufacturing hub for export. → No licensed medical cannabis scheme – patients access cannabis through a non-commercial, quasi adult-use model.	→ Viewed as a strategic entrypoint into Europe and hub for manufacturing due to accommodating regulations. → Many companies based outside of Europe plan to export to Malta for processing prior to for EU distribution.	→ Likely to become an export hub if regulations are amended, due to climate, low costs of production and intention to join the EU. → Currently restricted by regulatory barriers and inability to export dried flower.	→ Significant number of licenses have been issued for production. → Many sites are still under development or awaiting regulatory approval.

4. Domestic Cultivation — Production Exclusively for Pharmaceuticals

In these markets, no dried flower is currently produced as an end product for either domestic patients or exports. Aside from research, cultivation is currently licensed solely for the purpose of producing APIs and licensed pharmaceuticals. We expect this model to shift towards a hybrid one over the next year as local demand for medical cannabis increases and reputable businesses apply for licenses.

	UNITED KINGDOM	AUSTRIA
PURPOSE	→ Production of Sativex and Epydiolex	→ Production of Dronabinol (isolated THC)
MANUFACTURER	→ GW Pharmaceuticals	→ Bionorica Ethics (C3)
CULTIVATORS	→ Contract growers	→ AGES - Institute for Sustainable Plant Production
INSIGHTS	→ World's largest exporter of cannabis pharmaceuticals supplying global markets. → Domestic market is limited by restrictive prescribing guidelines through the National Health Service (NHS), but private clinics are driving increased patient uptake. → In July 2020, the NHS announced plans to manufacture medical cannabis oil for a clinical trial for children with severe epilepsy, although no further detail has been provided.	→ Dried flower cannot be prescribed to patients in Austria. → Dronabinol is supplied to domestic patients in addition to export markets including Denmark, Germany and Switzerland. → Production has significantly scaled up in recent years, from 59.19 kg in 2015 to 361.78kg in 2018 according to a response to a parliamentary inquiry in 2019.

4. Domestic Cultivation — Hybrid Production Model

In these markets, production is authorised for a dual-purpose of supplying domestic patients and driving economic growth through commercial exports of EU-GMP medical cannabis.

	THE NETHERLANDS	DENMARK
FRAMEWORK	→ State-controlled monopoly	→ Four-year development scheme to supply domestic patients and export markets
CULTIVATORS	→ Bedrocan bedrocan®	→ Uncapped
INSIGHTS	→ The Office of Medicinal Cannabis (OMC) purchases all cannabis produced by Bedrocan at a mandated price and facilitates distribution and exports. → The OMC has an ongoing tender application process for a maximum of two new suppliers. → The Netherlands now exports significantly more cannabis than is sold domestically. 2,150kg was exported to Germany alone in 2019, in comparison to 580kg supplied to domestic patients.	→ The domestic production pilot runs in parallel with the four-year medical cannabis pilot programme. → No cap on production volumes or limit to the number of licensed producers. → Producers must follow strict requirements including additional restrictions on pesticide use and required levels of product consistency. → A number of international cannabis companies have established facilities in Denmark with a view to develop an export hub to the wider EU.

5. Research and Clinical Trials — A Demand for Data

A lack of clinical data has been widely cited as the main factor limiting widespread medical cannabis adoption by most European national regulators. Despite this being a well-known issue, the industry has been slow to rise to the challenge of providing clinical data. This is most likely due to the perceived issues with IP, high investment costs, a lack of clinical research experience, the long lead times of developing clinical data, and because cannabis continues to remain strictly controlled and subject to various rulings in the majority of countries. Franjo Grotenhermen of the International Association for Cannabinoid Medicines explains

> **In Europe and especially in Germany there is a growing interest in the medical use of cannabis and cannabinoids. In addition, large pharmaceutical companies are conducting research on synthetic modulators of the endocannabinoid system, in particular inhibitors of the degradation of endocannabinoids.**

Additionally, regulators' preference for evidence derived from randomised controlled trials (RCTs) has also limited uptake by researchers due to complexities standardising cannabis plant products. As UK medical cannabis expert Dr. Steve Hajio stated

> **One of the key barriers to research into cannabis- derived medicines in Europe is the lack of standardisation within proposed studies. We need a clear target group of patients, a trial using a single product with a single delivery mechanism and a xed dose. With this sort of standardisation, researchers will be much more keen to do further studies.**

Despite these barriers, there is evidence of a shift towards companies and research institutes actively engaging in and supporting the development of clinical data, with over 27 trials ongoing in Europe. Such trials will contribute to a wider clinical understanding of medical cannabis. This, combined with attempts to reduce costs should enable a larger number of patients to access much needed medical cannabis products in Europe. Dr Saoirse O'Sullivan said,

> **'Phase 3 research which leads to regulatory approval, changes in clinical guidance and increased clinical con dence in novel products is very expensive and generally only carried out by pharmaceutical companies looking to develop licensed products, and unfortunately we do not have enough companies like GW carrying out phase 3 research, although this is one of the fastest growing sectors in biotech at the moment.**

5. Research and Clinical Trials – The Statistics

27

ongoing clinical trials across Europe for a wide range of medical conditions such as:

- → Multiple sclerosis (MS)
- → Neuropathic pain
- → Tic disorders and Tourette Syndrome
- → Cancer pain
- → Chemotherapy induced nausea and vomiting

There is a clear growing interest in research into cannabis and psychiatric disorders such as schizophrenia, PTSD, fear and phobias.

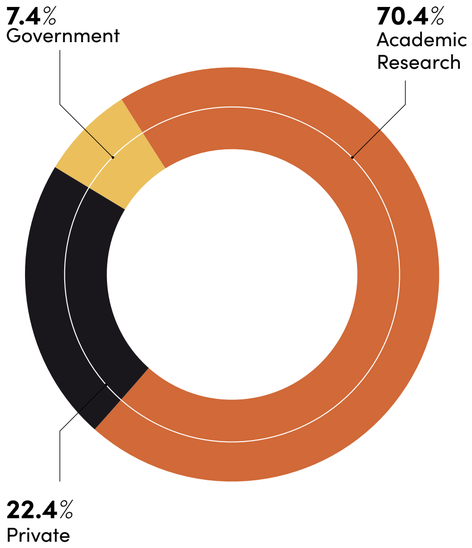
Over

70%

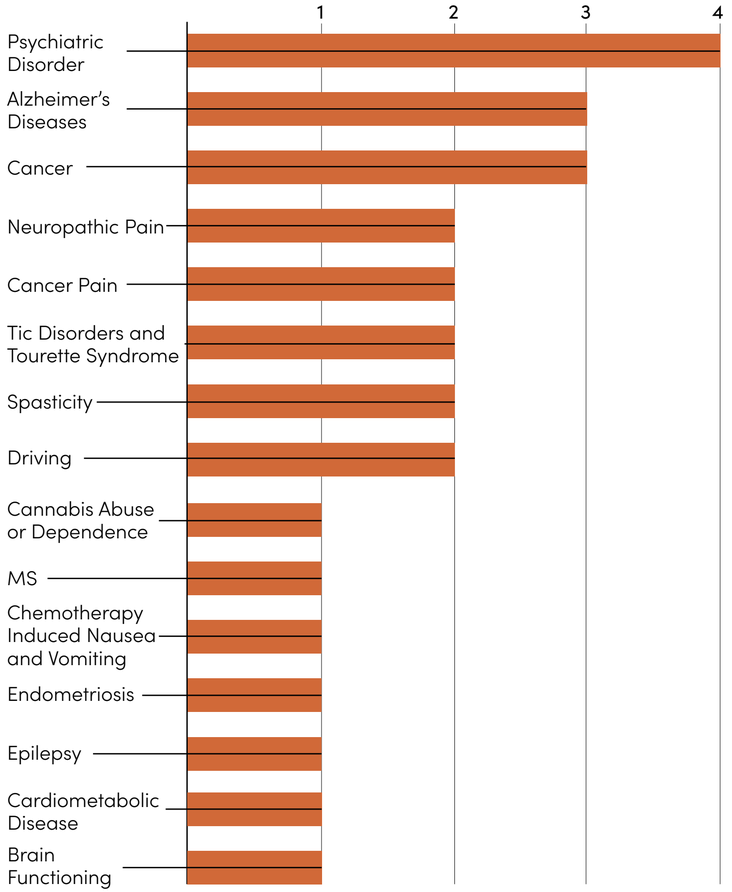
of these trials are sponsored by academic or research institutions such as King's College London, Universiteit Utrecht and Maastricht University.

Source: www.clinicaltrialsregister.eu

SPONSORS OF ONGOING CANNABIS & CANNABINOID CLINICAL TRIALS IN EUROPE



NUMBER OF CLINICAL TRIALS RESEARCHING MEDICAL CONDITIONS



6. Opinion Leaders — What Lies Ahead

HEAD OF THE MEDICAL CANNABIS CLUSTER

Marion Zammit

Malta Enterprise

Malta continues to attract and approve projects with the intent of setting up operations in this sector. The first manufacturing licenses have been awarded, both in third countries, as in Israel, as well as in Malta. Soon the country shall see its first medical cannabis products being exported from our shores. It is our imperative to continue adding layers and depth to this European ecosystem we are a part of, in order to ensure its long term viability, competitiveness and success.

CEO

José Antonio de la Puente

Linneo Health

The EU medical cannabis industry is ready to jump to the next stage. The pharmaceutical industry needs more sophisticated products under pharmaceutical standards. It is time to move from a production focus to a focus on product development. The cannabis industry should evolve with that vision, from cannabis growers to pharmaceuticals companies, but without losing their agility and flexibility to navigate in a new world. A robust business model, full range of products, scale up capabilities and competitiveness will be the key assets for suppliers to be on the ground.

6. Opinion Leaders — What Lies Ahead

GENERAL COUNSEL AND CO-FOUNDER

Jakob Sons

Cansativa GMBH

We observe that the European market is not depending on overseas anymore. Pharmaceutical cannabis products cultivated and processed in the European Union already were launched successfully in Germany and in 2021 the German domestic cultivation will be available for German pharmacies. Local production facilitates many steps on the pharmaceutical supply chains and is challenging existing pathways especially from Canada. However we assume that the next game change is already in sight once low-cost production (e.g. LatAm) can be tapped.

MANAGER OF CULTIVATION AND BREEDING

Dr Verónica Codesido Sampedro

Phytoplant Research S.L.

The medical cannabis market is still in its early stage due to a lack of regulatory consensus in the EU. However, the effort of scientists, researchers, breeders, lawyers and patients are getting heard. When it comes to researching cannabinoids and how to produce them, fantastic work is being done in Europe on the manufacturing of synthetic cannabinoids and the breeding of phytocannabinoids, both key to increasing the quality and safety of cannabinoids to be able to develop cannabis medicines.

Medical Cannabis in Denmark

The Danish market has become a uniquely European model for the regulation of medical cannabis. In 2018, Denmark announced a 4-year program to assess the effectiveness of cannabis based medicines, and build the base of what could be a supply of pharmaceutical-grade cannabis grown domestically.

In order to accelerate the development of the infrastructure and facilitate the development of cannabis medicines for patients in the country, the Ministry of Foreign Affairs engages with the private sector to inform investors of the framework in which Denmark operates in the context of its medical cannabis access programme and the development of its industry. The Danish model echoes life science and biotechnology European ecosystems, with university spin outs, state funding for innovation, and a high concentration of pharmaceutical R&D campuses.

In collaboration with Invest in Denmark, part of the Ministry of Foreign Affairs of Denmark and the First Wednesdays network, Hanway has produced this deep dive into the Danish market.

This section has been produced in collaboration with Invest in Denmark.
www.investindk.com

MINISTRY OF FOREIGN AFFAIRS
OF DENMARK
Invest in Denmark

Invest in Denmark is part of the Danish Ministry of Foreign Affairs. They provide tailor-made solutions for foreign companies looking to set up or expand business or research activities in Denmark.

An Introduction to the Routes to Access Medical Cannabis in Denmark

MINISTRY OF FOREIGN AFFAIRS
OF DENMARK
Invest in Denmark

The Danish medical cannabis program is actually two parallel four-year trials – one for domestic medical use and another for domestic cultivation. Although there is no guarantee that either program will be extended once concluded, both trials have been backed by 100% of the country's parliamentarians. 2020 marks the halfway point of the programs, and an evaluation is pending. An extension or a permanent program looks promising, but it is a political process that remains to play out.

The Danish framework was developed on a hybrid model, bringing together the "patient-driven model" based on the needs of patients and their doctors, and the "cultivation for export model". This is where the Danish hybrid model is especially interesting. In Denmark, cultivation is structured in an open-ended system with no cap on production volumes and no limit to the number of licenced producers.

It is based on a pharma paradigm that requires serious planning to achieve minimum standards, but the transparent requirements offer significant scope to explore business models, breeding approaches, and improving cultivation techniques.

A clear framework has been set but many opportunities remain to be explored. This means that cultivators need to engage with the local ecosystem of plant scientists, breeders, AgTech, and pharma engineering firms to bring the standards up to higher levels of medical grade cultivation. It is not a quick copy-paste process. Some of the know-how from North America and elsewhere in Europe has been really valuable to the development of a Danish model, but it has required a process of incorporating and also developing Danish expertise to help the industry.

Michael Prytz
INVESTMENT MANAGER,
MINISTRY OF FOREIGN
AFFAIRS OF DENMARK

Derek Light
SPECIAL ADVISOR,
LIFE SCIENCES,
MINISTRY OF FOREIGN
AFFAIRS OF DENMARK

The **Danish Ecosystem**

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
Invest in Denmark

This map has been compiled by Invest in Denmark to highlight diverse activity across the value chain.

Company information has been gathered from government lists of license holders and publicly available information. Invest in Denmark has focused on companies that have made clear progress, although there are a number of other license holders at varying stages of development.

An interesting medical cannabis ecosystem is developing in Denmark, centred around establishing a viable domestic supply chain. Collaboration between licensed cannabis operators and leading non-cannabis companies has been necessary to achieve the required high standards of production, which is evident through the engagement of leading equipment suppliers, logistics and professional services companies.

Denmark's pharmaceutical industry is based in the Copenhagen region, while key cultivation sites are clustered around the Odense region.

Cultivation

Valeos Pharma · STENOCARE · SCHRÖLL MEDICAL · SpectrumTherapeutics · Medican · AURORA NORDIC · ATLAS · VERTANICAL

Extraction & Purification

Aureum

Formulation & Manufacturing

Silease cannabis patches · TETRA PHARM TECHNOLOGIES · DanCann Pharma · octarine

Testing & Quality Assurance

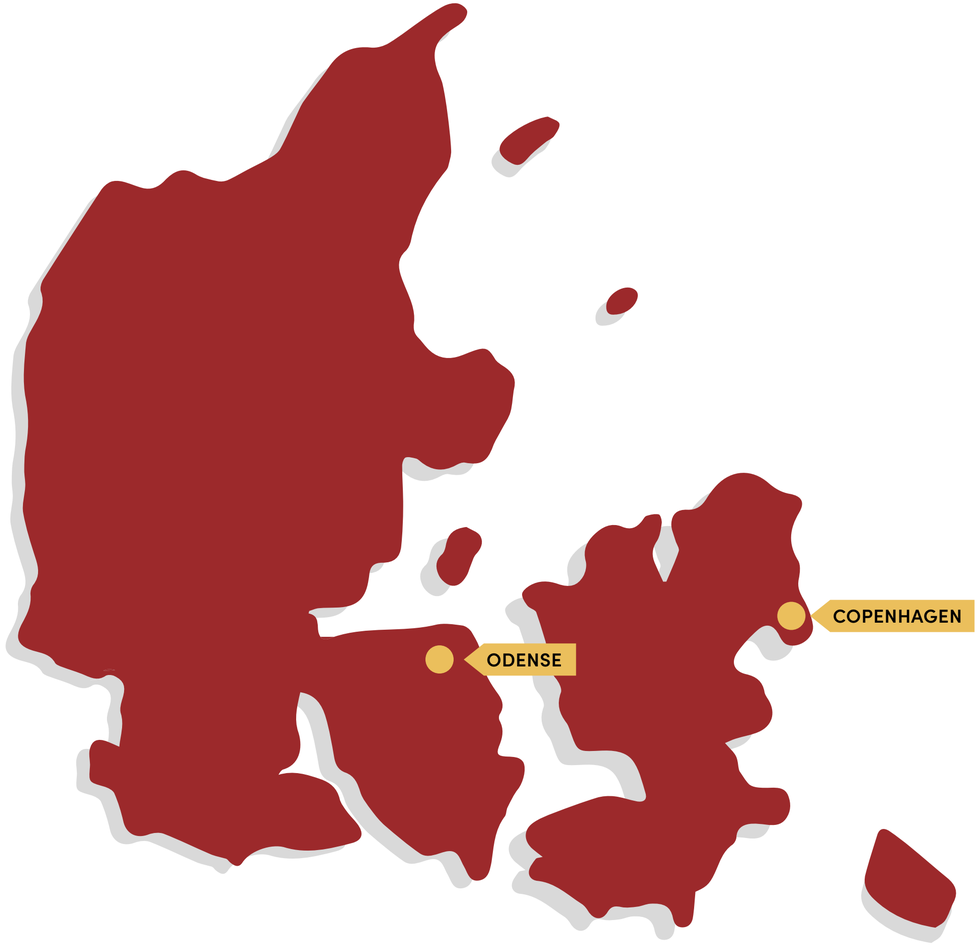
Sterigenics · QNTM · BBS · eurofins

Distribution & Logistics

movianto · CANNGROS

Industry Associations

Dansk Gartneri · MEDICAL CANNABIS FYN · Cannabis Denmark · MEDICINSKE PRODUCENTER · KCF



Private Specialist Clinics

Lægernes Cannabis Ordning · Rigshospitalet · CLINIC HORSTED · OUH Odense Universitetshospital

Public Agencies

INVEST IN ODENSE · MINISTRY OF FOREIGN AFFAIRS OF DENMARK · LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY

Research

TEKNOLOGISK INSTITUT · DTU Technical University of Denmark · SDU Syddansk Universitet

Ancillary Equipment Suppliers

Grodan · MedicoPack · DGS · senmatic

Investment

Innovation Fund Denmark · GEMSTONE CAPITAL · KEYSTONES

Professional Services

DLA PIPER · NJORD LAW FIRM · AlfaNordic · nne · NIRAS

Deep Dive: **Denmark**

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
Invest in Denmark

HANWAY INSIGHTS

A UNIQUELY EUROPEAN HYBRID MODEL

To date, timelines for facilities to become licensed and active have been longer in Denmark than in other jurisdictions. The Danish cultivation trial has been purposefully designed to the benefit of domestic patients. Cultivation is not licensed simply for the purpose of producing a valuable export product for international markets, but as a vital, highly-regulated stage of the pharmaceutical supply chain. A prerequisite to being able to export bulk product is that the company must have delivered products to the Danish market, which is currently subject to some of the strictest standards in the world. Producers are unable to profit from their investments into facilities in Denmark without also ensuring patients are supplied with high-quality products.

Producers must follow strict quality standards to operate in the Danish market; cultivators must comply with Good Agricultural Collection Practices (GACP) and post-harvest manufacturers must abide by Good Manufacturing Practices (GMP). Strict planning and Quality Assurance is required to achieve the required product standards, which include a permitted standard deviation of ±10% from the THC and CBD content stated before harvest. Pesticide use during cultivation of cannabis primary products was initially prohibited, but was amended in January 2019 due to the limited number of products approved for patient use under the pilot program. Selected use of plant protection methods is now permitted for imported oral-use products.

Access to medical cannabis in Denmark is not limited to the pilot scheme, and finished pharmaceutical products (Sativex, Nabilone and Marinol) can be prescribed outside of the pilot. Magistral preparations of oils and capsules (using isolated THC and CBD) remain the leading route by which patients access medical cannabis. After CannTrust's supply of the only full-spectrum oil available through the pilot was suspended, the Danish preference for formulated products over flower became clear from the sharp increase in prescriptions for isolated THC oil preparations through the compounding route.

Deep Dive: **Denmark**

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
Invest in Denmark

HANWAY INSIGHTS

STRUCTURAL ADVANTAGES

Denmark's strong business ecosystem offers investors a plug-and-play model for establishing and rapidly scaling operations in the pharma-oriented European market. Denmark has been quick to attract investment as a result, with Canadian producers driving a large proportion of direct expenditure. Initially announced foreign direct investment into the sector totalled over CAD$407 million, according to estimates by Denmark's Horticultural Association and Invest in Denmark, although some facilities have subsequently ceased activities.

Investors can draw on expertise from both pharmaceutical and horticultural industries, with strong Danish heritage in agriculture and greenhouse production and 2.6% of national GDP originating from pharmaceutical manufacturing. Denmark benefits from a highly-trained talent pool, readily-available land and deep expertise in product development and Quality Assurance.

Producers also benefit from sustainable access to low-cost renewable energy, which is highly advantageous for indoor production to ensure the required consistency levels for EU-GMP certification.

Denmark's proximity to major markets, particularly the UK, Germany and France, alongside excellent infrastructure for transport and shipping is advantageous from an export-focused perspective. Cannabis producers can leverage Denmark's optimal location as has historically benefitted pharmaceutical manufacturers, combatting Europe's historical reliance on Canadian and Dutch imports.

Deep Dive: **Denmark**

MINISTRY OF FOREIGN AFFAIRS OF DENMARK
Invest in Denmark

HANWAY INSIGHTS

PHARMACEUTICAL APPROACH AND DATA COLLECTION

Alongside offering a favourable environment for production, Denmark's domestic trial program encourages patient feedback, product development, and research. The country has also ensured financial support is available to support patient enrollment. As of January 2019 terminally ill patients have had their prescriptions fully reimbursed, with the financial supplement program covering 50% of medical cannabis spending for all other patients up to an annual reimbursement of DKK 10,000 (~EUR 1,350).

Denmark has consolidated access to medical cannabis within its well-reputed pharmaceutical industry, placing high emphasis on data collection from patients and doctors to demonstrate efficacy and build upon anecdotal evidence.

Denmark has ongoing active research projects in every national university hospital, with six ongoing randomized controlled trial (RCT) studies into indications including arthritis, multiple sclerosis and pain induced by chemotherapy. Additional research projects, including a number of observational and RCT studies, are planned to commence throughout the domestic trial program.

Close monitoring and relationships between patients and doctors facilitate deeper analysis of patient preferences, when considering product types, formulations and delivery systems. Engaging physicians has been a key focus in Denmark, with a dedicated national Klinisk Cannabis Forum (KCF) composed of prescribing doctors and around 60 scientific researchers planning to launch courses for doctors this year.

Healthcare professionals in Denmark emphasise European doctors' demand for doseable, pharma-style products. Aurora Nordic's 'Sedamen' softgel capsules are viewed favourably by prescribing physicians and are the only product format aside from flower currently authorised through the pilot program, containing 5mg THC per capsule for simple dosage. As contract extractors, manufacturers and research laboratories become fully licensed and operational, Denmark is expected to drive product development towards sophisticated, pharmaceutical products with proven efficacy for specific conditions and therapeutic areas of treatment.

First Wednesdays is a network of entrepreneurs and investors in the European cannabis sector.
FW members benefit from news, insights, matchmaking and business support.

Firstwednesdays.eu

Hanway Associates is the leading European strategic consultancy, specialising in cannabis research, new market entry, commercial diligence and M&A strategy.

Whether you are looking to understand the market, pivot your existing business, expand to new markets, apply for licences, protect your reputation, find the right partners, or start a business from scratch, our multidisciplinary teams can help. Our clients include listed-pharmaceutical companies, global FMCG consumer brands, top tier cannabis companies, investors, and innovative biotech / R&D startups.

If there are any companies in the report you want to speak to please drop us a line.

hanwayassociates.com