Cressida de Witte

# Prescribed Ambiguity: Medical Cannabis in Europe

## BETWEEN MEDICINE AND MARKET

NARKOTIKA POLITISKT CENTER

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**The Swedish Drug Policy Centre (NPC)** is a network of non-profit organisations advocating for a restrictive and humane drug policy.

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# Foreword

Interest in and production of so-called “medical cannabis” have increased sharply in recent years and have become increasingly difficult to navigate. This development has gone hand in hand with the rapid growth of the broader market for cannabis- and CBD-related products. As several countries and states have legalized cannabis, a legal platform has emerged for the development and marketing of a wide range of products – from pharmaceuticals, edibles, and cosmetics to psychoactive products. **This has led to increased investment and growing commercial interest, while at the same time challenging existing legislation at both national and EU level.**

The confusion is further compounded by the frequent use of the term “medical cannabis” or ”medical marijuana” without a clear or shared definition. It can refer to anything from approved, evidence-based medicines to cannabis products that lack scientific support. This ambiguity blurs the line between medical treatment and commercial sales, complicating both regulatory oversight and the development of coherent legislation.

These developments do not occur in a vacuum. As the market for cannabis-based products has expanded, commercial interests have gained increasing influence. **The cannabis industry actively engages in marketing, opinion-building, and political lobbying to associate cannabis with health and well-being.** Experiences – particularly from North America – also show that loosely regulated systems for widespread prescribing of “medical cannabis” have functioned as a gateway to the legalization of cannabis for recreational use. At the same time, lessons from other policy areas, not least tobacco control, clearly demonstrate the risk that public health is sidelined when strong economic interests are allowed to influence how products are developed and regulated.

Against this background, it is striking that cannabis-based medicines are often treated differently from other medicines, including other narcotic-classified medicines. For these, requirements regarding evidence, clearly defined indications, regulatory approval, and physician prescribing are consistently strict and well established. When it comes to cannabis, however, these principles tend to be relaxed.

**This report takes its starting point in precisely this problem. By analysing how medical or medicinal cannabis is defined, regulated, and applied in different European countries, we highlight an unclear and inconsistent regulatory framework.** The report shows how rapid product development, vague definitions, and divergent national interpretations have created grey areas – where it is often unclear whether a product should be regarded as a medicine, a regular consumer product, or classified as a narcotic. This has made it difficult for authorities and supervisory bodies to enforce regulations, for companies to know what they are permitted to produce and sell, and for consumers to understand which products are legal and medically justified to use.

In a broader European context, developments in drug policy are far from uniform. Different countries are choosing different paths, with some allowing room for commercial and political interests, while others – Sweden among them – place public

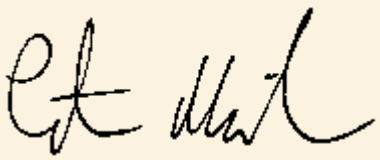
health at the centre of decision-making. There are also examples of countries that have experienced negative consequences from overly permissive regulatory frameworks and have subsequently chosen to tighten regulations again. It is therefore clear that drug policy is not predetermined, but shaped through active choices, reassessments, and priorities.

At the same time, several processes are currently underway at EU level aimed at clarifying and harmonising regulatory frameworks. These include, among other things, the use of CBD in cosmetics and beauty products, the handling of industrial hemp, and the delineation between pharmaceutical and narcotics legislation. These processes illustrate both the need for – and the difficulty of – creating legally robust and public health-oriented regulations in a field characterised by rapid market development and strong commercial interests.

**The purpose of this report is not to question that certain cannabinoid-based medicines may have medical benefits, but to emphasise the need for clear boundaries.** This requires, among other things:

- A shared definition and a clear distinction between cannabinoid-based medicines and non-medical cannabis, so that medical systems and the use of the term "medical cannabis" do not create legal grey zones or serve as shortcuts to open up for recreational use.
- The removal of profit motives from the management of so-called "medical cannabis", and ensuring that actors with commercial interests do not participate in shaping regulatory frameworks or medical guidelines.

With this report, we aim to contribute to a more balanced and evidence-based discussion, and to a development in which requirements for evidence and prescribing regulations apply equally to all substances. A development in which medical decisions are not shaped by the market or a profit-driven industry – but where public health remains at the centre.



Stockholm, March 2026
Peter Moilanen
Director of Narkotikapolitiskt Center

## ABBREVIATIONS

| | |
|---|---|
| **AEMPS** | Spanish Agency for Medicines and Health |
| **AIDS** | Acquired Immunodeficiency Syndrome |
| **ANSM** | French National Agency for Medicines and Health Products Safety |
| **BfArM** | Federal Institute for Drugs and Medical Devices (Germany) |
| **BMC** | Office for Medical Cannabis (Netherlands) |
| **BtMG** | German Narcotics Act |
| **CBD** | Cannabidiol |
| **CBG** | Cannabigerol |
| **CIBG** | Executive organisation of the Ministry of Health, Welfare, and Sport (Netherlands) |
| **CJEU** | Court of Justice of the European Union |
| **EMA** | European Medicines Agency |
| **EMCDDA** | European Monitoring Centre for Drugs and Drug Addiction (also known as the European Drug Agency – EUDA since 2024) |
| **EU** | European Union |
| **EU-GDP** | Good Distribution Practice |
| **EU-GMP** | Good Manufacturing Practice |
| **GACP** | Good Agricultural and Collection Practice |
| **HIV** | human immunodeficiency viruses |
| **IGJ** | Health and Youth Care Inspectorate (Netherlands INFAMRED – The National Authority of Medicines and Health Products (Portugal) |
| **INCB** | International Narcotics Control Board |
| **INFARMED** | National Authority of Medicines and Health Products (Portugal) |
| **MedCanG** | Medizinal Cannabisgesetz (German Medical Cannabis Law) |
| **MMA** | Malta Medicines Authority |
| **THC** | Tetrahydrocannabinol |
| **UK** | United Kingdom |
| **UN** | United Nations |
| **WHO** | World Health Organisation |

# Definition of Medical Cannabis

The term medical cannabis lacks a universally agreed-upon definition and is used variably across regulatory, scientific, and industrial contexts, often leading to confusion in public discourse and policy. According to sources such as Britannica Encyclopaedia (Ware, 2025) and the US National Institutes of Health (NIH) (NIH, 2018), medical cannabis broadly refers to the use of the whole, unprocessed cannabis plants or its extracts to treat specific medical symptoms or conditions, under medical supervision with an established diagnosis of the target symptom-disease complex.

It is important to note that a distinction is made between cannabinoid-based medicines and herbal medical cannabis. Cannabinoid-based medicines refer to the pharmaceutical-grade preparations that have undergone clinical testing, received regulatory approval, and are prescribed for specific indications (Šuica, et al., 2019). These include synthetic cannabinoids like dronabinol (synthetic THC) and nabilone (a THC analogue), as well as plant-derived and purified compounds like Epidiolex, a cannabidiol (CBD) extract approved by the European Medicines Agency (EMA) in 2019 for rare forms of childhood epilepsy (Lipnik-Štangelj & Razinger, 2020). Herbal cannabis is defined as *"harvested and dried female flowering tops, which contain the highest concentrations of cannabinoids, THC, CBD, CBG, etc."* while it simultaneously is a generic term *"used to denote cannabis products that are not pharmaceutical products with marketing authorisation"* (UNODC, 2023, p. 41). It seems that, besides in Canada and the Netherlands, there is *"no inherent difference between [non-medical] herbal cannabis and that used medically"* (Ware, 2025). In such cases, the term 'medical cannabis' may serve more as a legal or marketing category than a pharmacologically precise label.

Research on the benefit of medical cannabis is generally lacking. Certain conditions for which evidence supports a benefit include the epileptic syndromes Lennox–Gastaut and Dravet. (Silvinato, Floriano, & Bernardo, 2022), multiple sclerosis spasticity, and loss of appetite and weight loss associated with HIV/AIDS. Other, often commonly cited conditions, do lack evidence, such as Tourette, glaucoma, cancer-associated anorexia-cachexia syndrome, and other forms of epilepsy than the ones mentioned above (National Academies of Sciences, Engineering, and Medicine, 2017).

**"In the broader public and policy debate, the term 'medical use of cannabis and cannabinoids' is frequently used non-technically and inconsistently, encompassing a wide array of products, preparations, and delivery methods."**

In the broader public and policy debate, the term 'medical use of cannabis and cannabinoids' is frequently used non-technically and inconsistently, encompassing a wide array of products, preparations, and delivery methods. These can vary significantly in their active ingredients, purity, and routes of administration. While in practice these

terms are often used loosely, the distinctions between them carry important regulatory and clinical implications (see "Medicinal Cannabis Regulation and Regional Definitions).

## Distinction between medical cannabis and industrial hemp

There is a distinct difference between medical cannabis and industrial hemp. Medical cannabis plant varieties are cultivated indoors under controlled conditions and contain high levels of THC (over 0.3%). In contrast, hemp is cultivated outdoors for industrial uses (fibre, seeds, oil) and contains less than 0.3% THC. Hemp may be rich in CBD, which is used in, e.g., functional foods and wellness products, which has gained popularity in Europe (Malabadi, Kolkar, Chalannavar, & Baijnath, 2023).

## Definition by the Cannabis Industry

The cannabis industry defines medical cannabis as *"cannabinoid-based medicine not holding marketing authorisation and therefore sold as an unlicensed medicine that is supplied through health systems and prescribed by a doctor"* or *"Active Pharmaceutical ingredient to be manipulated and/or compounded by a magistral pharmacy in order to prepare a cannabinoid-based medicine without marketing authorisation (unlicensed)"*.

Medicinal cannabis, on the other hand, is referred to as *"all cannabinoid-based therapeutic products (medical and pharmaceutical)"*. Finally, they provide a further distinction of pharmaceutical cannabis, which is "*formulated, processed or synthetic cannabis sold as a finished product, which has undergone full medical trials, and holds a medical marketing authorisation*", such as Epidiolex, Sativex, etc. (Prohibition Partners, 2023) The latter distinction can cause confusion, as in other cases (such as by the European Union, see Medical Cannabis Regulation and Regional Definitions – European Union) these are all included under the umbrella term of medicinal cannabis.

This report will use *medicinal cannabis* as an umbrella term but further refer to *cannabinoid-based medicines* to clearly distinguish authorised medicinal cannabis from medical cannabis.

# Medicinal Cannabis Regulation and Regional Definitions

## Universal Regulations

From a regulatory perspective, cannabis was classified under Schedule IV of the 1961 Single Convention on Narcotic Drugs, placing it alongside other harmful addictive substances with little to no recognised therapeutic value. However, in 2020, following recommendations from the World Health Organisation (WHO), 27 out of 53 UN Member States voted in favour of reclassifying cannabis to Schedule I. This reclassification acknowledges the potential medical and scientific use of cannabis, while continuing to prohibit its use for non-medical and non-scientific purposes (United Nations, 2020).

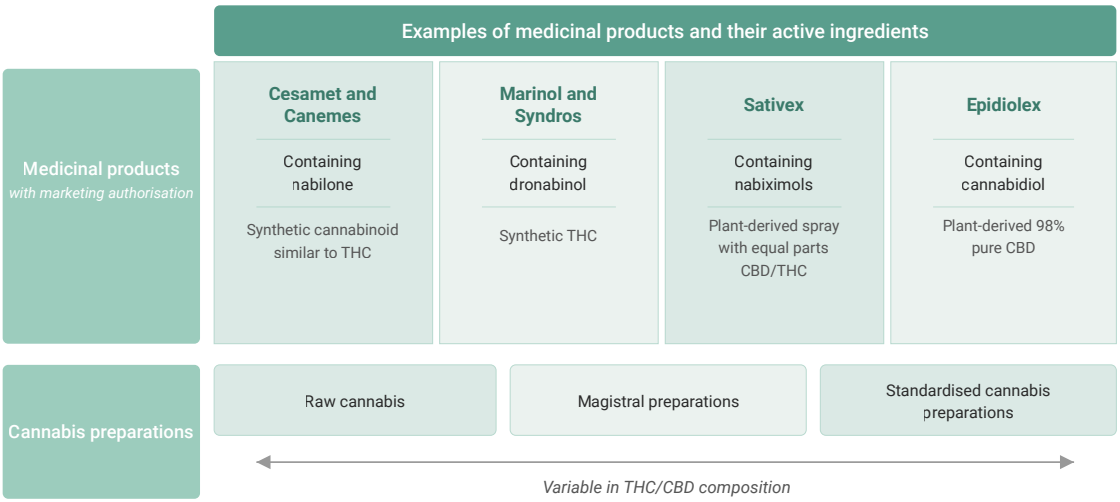



*Figure 1 - Cannabis and Cannabinoids used for medical purposes - a broad typology (EMCDDA)*

## European Union

The European Union is bound by the provisions of the 1961 UN Single Convention on Narcotic Drugs, which provides the overarching international legal framework for drug control (Lipnik-Štangelj & Razinger, 2020). Within the European Union, the overarching legal framework for authorised medicinal products is defined by Directive 2001/83/EC and its amendments, which establish standards for safety, efficacy, and quality.

The European Union differentiates between cannabinoid-based medicinal products with marketing authorisation and other cannabis preparations made available under alternative regulatory frameworks (see Figure 1). Medicinal products undergo central-

ised EMA evaluations and can be marketed and prescribed across all member states according to "their approved indication and posology" (Lipnik-Štangelj & Razinger, 2020). Cannabis preparations, on the other hand, are prepared by pharmacists according to national regulations for individual patients (EMCDDA, 2023).

Currently, the following cannabinoid-based medicinal products have been authorised by the European Medicines Agency (EMCDDA, 2018):

- **Marinol and Syndros** (active ingredient: dronabinol): oral capsules or an oral solution containing synthetic THC. Dronabinol is indicated for anorexia associated with weight loss in patients with acquired immune deficiency syndrome (AIDS) and nausea and vomiting associated with cancer chemotherapy, usually after previous treatments have failed.
- **Cesamet and Canemet** (active ingredient: nabilone): oral capsules containing a synthetic cannabinoid similar to THC. The main indication for their use is nausea and vomiting associated with chemotherapy, usually after previous treatments have failed.
- **Sativex** (active ingredient: nabiximols): a medicinal product containing approximately equal quantities of THC and CBD from two cannabis extracts. This product, which is sprayed inside the cheek or under the tongue, has been authorised for the treatment of spasticity resulting from multiple sclerosis.
- **Epidiolex** (active ingredient: CBD): a plant-derived CBD oral solution indicated for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age or older.

Nevertheless, additional medical cannabis or cannabinoid-based medicines can be approved through a decentralised procedure in single EU Member State countries. Furthermore, each Member State maintains autonomy over how cannabis-related policies are interpreted and implemented, resulting in a highly fragmented landscape across the Union with varying definitions, policies, and regulatory approaches (Kohut, 2021). This has led to a growing number of countries allowing limited access to medical cannabis under specific regulatory frameworks, including herbal cannabis (e.g. flowers). It is worth mentioning that, generally, cannabinoid-based medicines are prescribed in limited quantity, compared to flowers (see Available Users Data).

Recognising this fragmentation and the lack of a universally accepted legal definition, the European Parliament adopted a resolution on 13 February 2019 (2018/2775(RSP) on the use of cannabis for medicinal purposes. While it acknowledged that the UN Conventions and International Law do not prevent *"the medical use of cannabis or cannabis-derived products for the treatment of specific medical conditions"* (European Parliament, 2019, p. 1), it also suggested a terminological distinction.

Since medical cannabis lacks a universally accepted legal definition compared to the formal and clinically approved cannabinoid-based medicines, it recommended to separate both terms. The Resolution also called on the Commission and Member States to, among others, set research priorities related to medical cannabis, develop an EU-wide strategy with coordinated implementation of cannabinoid-based medicines,

guarantee quality and labelling, protect minors, provide legal certainty for patients, and safeguard vulnerable populations.

Considering that CBD-products have gained popularity, it is important to note that CBD, under the recommendation by the World Health Organisation Expert Committee on Drug Dependence (2019), is not placed under international drug control. Therefore, the European Court of Justice published a judgement stating that cannabidiol extracted from the cannabis plant should not be considered a drug under the 1961 United Nations Single Convention on Narcotic Drugs (EMCDDA, 2020), with a proposed limit of 0.2% THC in November 2020 (EUMCA, 2020).

## Cultivation

The 1961 UN Single Convention on Narcotic Drugs *"paved the way for cultivation for medical and scientific purposes"*. It is, however, required to comply with the *"provisions of the United Nations Conventions and WHO guidelines on good agricultural practices, harvesting, and handling of medical plants"* (Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023, p. 93). Nevertheless, each country is to establish a control system, including a designated agency that oversees production and purchases of the crop. Within the European Union, a number of countries have implemented state-regulated cultivation schemes, typically involving licensed producers operating under national oversight.

Yet, the cultivation frameworks in each country differ. These differences in cultivation practices and legal oversight further underscore that the definition of "medical cannabis" is not purely scientific, but shaped by national drug policy, regulatory classifications, and intended use (Lipnik-Štangelj & Razinger, 2020).

## Evolving National Approaches

Since 2018, more EU countries have moved toward regulating medical cannabis. As noted by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2018, the topic has gained momentum both within European and international policy frameworks (EMCDDA, 2018). The growing interest in the medicinal use of cannabis and phytocannabinoids has prompted many Member States to adopt domestic regulatory frameworks governing the production, distribution, and access to cannabis products (Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023).

**These products often fall outside the scope of narcotic legislation and are marketed as health supplements, vapes, cosmetics, or wellness products, depending on their formulation and use.**

In parallel the therapeutic use of cannabis, commercial interest in cannabis derivatives, especially cannabidiol (CBD) as well as Delta-8 and Hexahydrocannabinol (HHC), has increased significantly (EMCDDA, 2023). These products often fall outside the scope of narcotic legislation and are marketed as health supplements, vapes, cosmetics, or wellness products, depending on their formulation and use. While some products focus on health and well-being, others appear to target the adult market by producing products that closely resemble illicit cannabis products.

This evolving market has resulted in products containing cannabis extracts appearing across multiple commercial sectors, each governed by distinct regulatory frameworks,

including food safety, cosmetic regulations, and pharmaceutical laws. Often, this overlap has created legal grey zones and tensions with drug control regulations, particularly when products with trace levels of THC are sold outside of the regulated markets. As a result, concerns have emerged at the policy level regarding the legal status, marketing practices, and potential health risks of these widely available cannabis-derived products (EMCDDA, 2023).

Newer unregulated synthetic cannabinoids used non-medically have been linked to higher health risks due to unpredictable effects and insufficient safety data (Lipnik-Štangelj & Razinger, 2020). Nevertheless, countries regulate emerging products and their compounds inconsistently (Mikolášová, 2025), further exacerbating the already fragmented regulatory landscape.

It is argued that this regulatory evolution is also forcing EU Member States to choose between two competing governance models. On the one hand is the medicinal cannabis industry model, in which a single company controls the entire supply chain, from seed to shelf, including cultivation, processing, manufacturing, and distribution. On the other is the pharmaceutical industry model, where different specialised entities manage individual segments of the supply chain, from raw material production to the creation and marketing of finished pharmaceutical products (Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023).

# Medical Cannabis in European Member States

Over the years, many EU Member States have adopted diverse regulatory frameworks, varying from no official legal framework, to regulating cannabinoid-based medicines or medical cannabis, which includes herbal cannabis. To provide an overview, the chapter has been divided into three sections: "countries without an official legal framework" for cannabinoid-based medicines or medical cannabis, countries with "cannabinoid-based medicines regulations", and finally a timeline of countries that have regulated medical cannabis, including herbal cannabis.

## Countries without an Official Legal Framework

The following European countries do not have an official legal framework in place for cannabinoid-based medicines or medical cannabis.

| Country | Approved Medicines | Access Mechanism | Regulatory/Policy Developments | Notes/Exceptions |
|---|---|---|---|---|
| Bulgaria (Georgiev, 2021) (Bogdan, Zhelyazkova, & Petk, 2020) | None | Illegal | | Only CBD supplements are tolerated |
| Hungary (Petrányi, Kovács, & Kohl, 2024) | None | Special authorisation from the National Centre for Public Health and Pharmacy | | In exceptional cases, authorised cannabinoid-based medicines in other countries (e.g. Sativex) are permitted. |
| Serbia (Stepanović, 2023) (Dragojlo, 2021) | No cannabinoid-based medicines are currently registered (although technically allowed) | In practice, medical use of cannabis remains illegal. | 2015: a governmental working group was created to draft legislation on medical cannabis. | No significant progress has been made since 2015. |
| Slovakia (Matějovský & Gavalec, 2024) | Not permitted. | | | Cannabis cultivation is allowed for research purposes |

## Cannabinoid-based Medicines Regulation

The following countries approve authorised cannabinoid-based medicines for individual cases but prohibit medical cannabis, e.g. flowers/herbal cannabis.

| Country | Approved Medicines | Access Mechanism | Regulatory/Policy Developments | Notes/Exceptions |
|---|---|---|---|---|
| Austria (Keimpema, Di Marzo, & Harkany, 2021) (HigherYields Consulting, 2023) | Sativex, Nabilone, Dronabinol, and Epidiolex (since 2008) | Case-by-case review | | Reimbursement of the medicine is not guaranteed. |
| Belgium (FAMHP, 2025) (Fonteyn, 2021) | Sativex and Epidiolex (not yet commercialised) | Any doctor can prescribe | 2019: plan presented to establish a cannabis government agency with exclusive right to distribute medical cannabis cultivated by licensed producers | Plan is not yet operational |
| Estonia (The Cannigma Staff, 2022a) | Sativex | Case-by-case approval by the Ministry of Social Affairs (advised by doctor) | | only one patient was reported between 2005-2016. |
| France (FRANCE 24, 2014), (Lejczak, Rousselot, Di Patrizio, & Debouverie, 2019), (New Frontier, 2018), (Green, 2025), (Health Europe, 2019) (Bullens, 2024) (RFI, 2025) (Stevens, 2024a) | Sativex (since 2014), Dronabinol (since 2004), Nabilone, and Epidiolex (temporary authorisation, 2018), | Authorised neurologists or physicians (e.g. Sativex) or centres (e.g. dronabinol – CETD) could prescribe. | 2021: Introduced the pilot programme (extended until 2025).<br><br>March 2025: France formally notified the European Commission to regulate medical cannabis. | ANSM confirmed that the cannabis flower is not included in the proposed framework<br><br>Deep Dive for more information |
| Latvia (Mis & Rusjan, 2025a) (LSM+ & Fridrihsone, 2019) (LETA/TBT Staff, 2025) | Sativex | Strictly regulated | 2019: First discussions surrounding the regulation of medical cannabis were introduced.<br><br>2025: Social-Liberal Progresivie sends proposal to legalise medical cannabis. | The proposal is yet to be discussed (publicly). |
| Lithuania (The Cannigma Staff, 2022b) (Mis & Rusjan, 2025b) | Sativex (since 2018) | Prescription by licensed physician, and collection from authorised pharmacy. | May 2019: licensed companies are permitted to manufacture, import, export, and distribute the products: subject to strict regulatory controls | Whole-plant cannabis remains unavailable, and the programme is limited to approved cannabinoid-based medicines |
| Norway (NordAn, 2023a) | Sativex (since 2012), Dronabinol and Nabilone under special circumstances | Group A physicians, authorised to prescribe high-risk medicines, can prescribe. | | Prescriptions are carefully monitored. |
| Sweden (NordAn, 2023b) | Sativex (2012), Dronabinol and Epidiolex under special circumstances. | Case-by-case evaluation, requiring special approval. | | 2018: 395 patients had received Sativex, 11 patients received Marinol, and a small number of patients received Epidiolex |

# Medical Cannabis Regulation – A Timeline

Several European countries have legalised the medical use of cannabis, including dried/herbal cannabis, under diverse frameworks. Some countries introduced legal medical cannabis as early as 2003, while others have recently announced the legal permission of medical cannabis.

Across these legal systems, the most common indications for medical cannabis include spasticity due to multiple sclerosis, spinal cord trauma, chronic pain, palliative care, cancer-related complications, HIV/AIDS, hepatitis, nausea and vomiting from chemotherapy, neurological conditions, radiotherapy side effects, and glaucoma (Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023). However, the listed conditions for which medical cannabis is approved for are unique to each country.

| Year | Country | Description | Comments |
|---|---|---|---|
| 2003 | The Netherlands<br>(CIBG, n.d.a) (Zaami, Di Luca, & Montanari Vergallo, 2018) | Becomes the first European country, and second globally, to regulate medical cannabis. The chain is supervised by the Office of Medical Cannabis and prescribed by doctors. | Although legal, the majority accesses their medical cannabis through the tolerated non-medical channels.<br>Deep Dive (p.21) for more information. |
| 2006 | Italy<br>(Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023) | Allows medical cannabis prescriptions, initially requiring pharmacists to manipulate raw materials (dronabinol or natural cannabis extracts) under prescription. | |
| 2007 | Italy<br>(Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023) | The therapeutic use of THC, dronabinol, and nabilone have been recognised for therapeutic use. | |
| 2008 | Finland<br>(Sensi Seeds, 2021a) | Imported herbal cannabis from the Netherlands was permitted under strict regulations where patients must obtain a special permit – granted only when other treatments had failed. | At the moment, Sativex seems to be the only cannabis-medicine available. |
| 2013 | Italy<br>(Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023) (Zaami, Di Luca, & Montanari Vergallo, 2018) | Medical cannabis expanded to include imported extracts, such as Sativex and cannabis flowers from Canada and the Netherlands. | Full reimbursement by the national healthcare system is available. Yet, it stresses that cannabis is not considered a primary therapy, but a supportive treatment when conventional methods fail or cause non-tolerable secondary effects.<br>By 2019, approximately 13,000 patients were receiving prescriptions. |
| 2013 | Czech Republic<br>(Smith, 2025) (Kopac, n.d.) | Specialist physicians were allowed (approximately 250 doctors in total) to prescribe medical cannabis. | Since 2020, patients can receive up to 90% reimbursement for cannabinoid-based medication, capped at 30g/month. A maximum pricing scheme was introduced by the Ministry of Health. |
| 2013 | Romania<br>(Gates, 2013) (Marijuana Doctors, n.d.) (Popescu & Predescu, 2024) | Derivatives of the cannabis flower are allowed to be used for conditions like epilepsy, cancer, and multiple sclerosis – Cannabinoid-based medicines can be prescribed by doctors and are dispensed through pharmacies. | Medical cannabis cannot be consumed through smoking or edibles. The growth, import, and sale are allowed under strict government supervision. |
| 2014 | Italy<br>(Sensi Seeds, 2021b) | Italy permitted cannabis cultivation for medical purposes, which is conducted under military supervision, | Deep Dive (p.28) for more information. |

| Year | Country | Description | Comments |
|---|---|---|---|
| 2015 | Croatia<br>(Milekic, 2015)<br>(HempKing, 2023) | Medical cannabis, including cannabinoid-based medicines such as dronabinol and nabilone, as well as dried medical cannabis were permitted. There is a monthly limit of 0.75g of THC per patient. | Insurance reimbursement is not available. Import is regulated by the Croatian health authorities. |
| 2015 | Malta<br>(BDO, n.d.) | Regulated the possession and use of prescribed medical cannabis in 2015. | Prescriptions are limited to doctors approved by the Malta Medical Council. |
| 2017 | Germany<br>(Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023) | Regulated medical cannabis, introducing a framework that allows for the prescription of 14 varieties of cannabis flowers for any medical condition, provided that conventional treatments have proven ineffective or caused adverse effects. | This policy allows broad access to medical cannabis. Health insurance does cover treatment costs. However, each case is evaluated individually due to the absence of standardised protocols.<br>Deep Dive (p. 25) for more information. |
| 2017 | Greece<br>(Sinclair, Greece welcomes 'new era' of medical cannabis after seven-year wait, 2024) | Regulated medical cannabis following a public campaign led by mothers of children with severe epilepsy. | Despite the legal change, the domestic market was not yet established, and the imports were initially banned. |
| 2018 | Poland<br>(Los, 2025)<br>(Brezden, Zaliska, Stostko, & Zaliskyy, 2023) | Regulated medical cannabis, "in the form of dried female inflorescences of the Cannabis plant", enabling doctors to prescribe medicines that can be dispensed through pharmacies. | User feedback (both medical and non-medical – a market that has also profited since) suggests that medical cannabis prescriptions are relatively easy to obtain, particularly through cannabis clinics, which patients prefer over traditional general practitioners. Health insurance does not reimburse the costs. |
| 2018 | Malta<br>(BDO, n.d.)<br>(Farrugia, 2019) | Formally regulated medical cannabis, permitting entities to produce, cultivate, import, and process cannabis strictly for medical purposes in accordance with the Production of Cannabis for Medicinal and Research Purposes Act. | Branded themselves as the de facto medical cannabis capital of Europe. In 2019, Economy Minister Chris Cardona, proudly announced that Malta is one of the first countries to provide high-grade, genuine medical cannabis across Europe.<br>Deep Dive (p.32) for more information |
| 2018 | Luxembourg<br>(Halder, 2025) | Regulated medical cannabis, permitting the prescription, dispensing, and possession of it while integrating it into the national healthcare system. As a result, the Medical Cannabis Access Programme was launched in 2019. A range of cannabis-derived products are eligible for prescription for specific therapeutic purposes, including dried flowering tops, extracts, and oils. | Products are distributed with a scientific leaflet, but do not include full product characteristics or side-effect profiles, as would typically be found in conventional pharmaceutical labelling. The procurement of the product is managed by the Ministry of Health, which has been issuing annual public tenders for medical cannabis products since 2019. |
| 2018 | United Kingdom<br>(NHS, 2022)<br>(United Patients Alliance, n.d.)<br>(Sinclair, 2025)<br>(Turney, 2024) | Medical cannabis was regulated, including cannabinoid-based medicines, such as Epidiolex, Nabilone, Sativex, as well as herbal. It also regulated the cultivation of medical cannabis. Over the years, UK has become one of the largest medical cannabis producers in the world. | Advocacy groups push for broader access and recognition of medical cannabis. While the NHS does prescribe medical cannabis to patients, the number is limited. The majority is being prescribed by private pharmacies. |
| 2018 | Denmark<br>(Laegemiddel-styrelsen, 2022b)<br>(Egnell, Villman, & Obstbaum, 2019) | Introduced a pilot programme, allowing medical cannabis. Previously, only Sativex was available. The pilot allowed the import and promotion of various cannabis products. It did not officially authorise the products, placing full responsibility on doctors (e.g. prescribing and dosage). | While the Danish Medicines Agency had issued a guideline for doctors, informed by ongoing evaluations in the Netherlands, Canada, and Israel, the lack of formal approval, combined with limited clinical research, led to hesitation among many physicians to prescribe cannabinoid-based treatment.<br>Deep Dive (p.35) for more information. |

| Year | Country | Description | Comments |
|---|---|---|---|
| 2019 | Croatia<br>(Morris, 2023a) | Amended the Drug Abuse Prevention Act to permit the cultivation and production of hemp for medical purposes, officially designating hemp as an agricultural product. | Access to medical cannabis requires a specialist's (e.g. neurologist or radiologist) recommendation, after which the prescription can be continued by a general practitioner or family doctor. |
| 2019 | Portugal<br>(Advertiser, 2024)<br>(Elci, 2024)<br>(Cabral, 2024) | Regulated medical cannabis, permitting production, distribution, and consumption – which chain is controlled. Medicines can be prescribed by doctors and are dispensed in pharmacies. | Portugal is the second-largest producer of medical cannabis in the EU, reporting 34 tonnes of production in 2024. They authorised over 60 companies to cultivate, produce, or distribute cannabis, with an additional 170 applications under review.<br><br>Deep Dive (p.30) for more information |
| 2021 | Denmark<br>(World Law Group, 2023) | Based on the evaluation report by the Danish Ministry of Health, concluding that the pilot scheme provided a "proper and safe framework for the use of medical cannabis", the pilot was extended from 2021 until 2024 | All licenses under the pilot programme had to be reissued, and application procedures for both imported and domestically grown products were updated. Furthermore, companies were granted permission to "permanently grow and manufacture bulk cannabis and cannabis starting products for medicinal use", supposedly providing legal clarity and greater security for industry investors. |
| 2022 | Switzerland (ch.ch, n.d.)<br>(Bundesamt für Gesundheit BAG, n.d.) | Regulated medical cannabis, placing cultivation, processing, and trade under the regulation of Swissmedic while eliminating the requirement for doctors to obtain special exemptions from the Federal Office of Public Health to prescribe cannabis. | Physicians are now mandated to report treatment data to the Office during the first two years of each case. Medical cannabis is only reimbursed by health insurance in exceptional cases, due to limited clinical evidence on its efficacy and cost-effectiveness |
| 2024 | Greece<br>(Sinclair, 2024) | Cannabis can now be prescribed by a specialist doctor, including anaesthetists, neurologists, and oncologists, particularly for conditions like cancer, infections, and rheumatism. Prescriptions can be renewed every six months by a general practitioner, though the treatment must be re-evaluated by a specialist. | The medicine costs are not covered by the public health insurance. |
| 2024 | Germany<br>(Bundes-ministerium für Gesundheit, 2025a)<br>(BfArM, n.d.) | Coinciding with the semi-legalisation of non-medical cannabis, medical cannabis was removed from the Narcotics Act and placed under a standalone medical-cannabis law. | This has led to the emergence of online platforms, where with minimal self-reporting, anyone could get a prescription. |
| 2024 | Denmark<br>(Stenocare, 2025) | In November 2024, the Danish parliament decided in favour of permanently regulating medical cannabis. | Effective from January 1st, 2026 |
| 2024 | Poland<br>(Stevens, 2025b) | Due to the influx of cannabis patients, especially via private clinics through online consultations, new regulations were introduced to disable prescriptions via remote consultation. | Now, national health physicians are allowed to provide online consultations and prescriptions to patients that previously had an in-person consultation. |
| 2025 | Czech Republic<br>(Smith, 2025) | All general practitioners are now allowed to prescribe medical cannabis for chronic pain. | |
| 2025 | The Netherlands<br>(Picavet, 2025)<br>(Jansen, 2025) | Announced changes to the medical cannabis law in 2027. From 2026 onwards, production is no longer permitted in the Netherlands. | |

| Year | Country | Description | Comments |
|---|---|---|---|
| 2025 | Slovenia<br><br>(Sodja & Vrankar, 2024)<br>(Ferreira, 2025)<br>(SiBiz, 2025)<br>(The Slovenia Times, 2025) | Regulated medical cannabis beyond the cannabinoid-based medicines approved since 2016. It now permits cultivation, production, and distribution of cannabis for medical purposes. Personal cultivation is not permitted. | Medicines can now be prescribed for any condition, based on the doctor's judgement. Prescriptions are valid for one month and not renewable. Before their first prescription, patients must undergo a medical examination (then once a year).<br><br>The Medical Chamber expressed concern the law creates unrealistic patient expectations and training is inadequate, stressing that prescribing guidelines should be set by medical associations rather than imposed by law. |
| 2025 | Italy<br><br>(Mis M. V., 2025) | Light cannabis products are to be banned and cannabidiol is reclassified as a narcotic. The sale and possession of oral and lower-based CBD is no longer permitted, unless prescribed by a doctor. | |
| 2025 | Germany<br><br>(Suliak, 2025) | Trying to curb the influx of the number of prescriptions since the legal changes in 2024, the Health Minister introduced a legislative draft to adjust the procedure to retrieve the medicines. | The draft is yet to be approved and faces resistance from the coalition partner SPD |
| 2025 | Spain<br><br>(SMC Spain, 2024)<br>(Menendez-Roche, 2025)<br>(Mokrani, 2025) | Cannabinoid-based medicines have been approved since 2010 (Sativex and Dronabinol) while Epidiolex was introduced in 2021. Following an approval to explore medical cannabis programmes in 2022 and reports on potential approval early 2025, medical cannabis was officially approved in October 2025. | While the details are yet to be published, it seems that only hospitals are allowed to prescribe medical cannabis for particular conditions.<br><br>Deep Dive for more information. |

## Available User Data

Although several countries have regulated medical/medicinal cannabis, reliable patient data remains limited, and in some cases non-existent. This lack of robust evidence makes it difficult to assess the actual impact or "effectiveness" of medical/medicinal cannabis regulation.

When examining the use of cannabinoid-based medicines specifically, detailed data are particularly limited. The cases of Germany and the United Kingdom illustrate that these authorised medicines are prescribed far less frequently than cannabis flowers, whereas they have undergone official authorisation. In Germany, only 3.5% of patients used dronabinol and 0.4% Sativex exclusively, without cannabis flower (Figure 2) (Hundertmark , et al., 2025). In the UK, prescriptions increased only marginally, by an average of 0.34% per year between 2013 and 2022, reaching just 3,483 prescriptions in 2022 (Javid, et al., 2024).

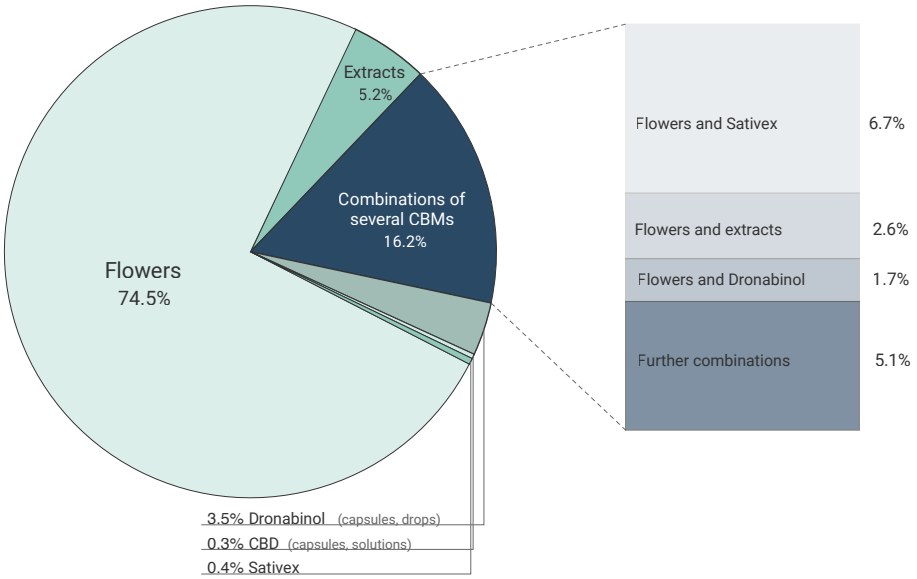



*Figure 2 - Classification of the surveyed patient collective according to the type of CBM prescribed and subdivision of the collective depending on whether costs are covered by health insurances. Hundertmark, et al., 2025*

Where data are available, they often reveal blurred boundaries between medical/medicinal and non-medical markets, suggesting that the two are more interlinked than might be assumed. Over the past decade, only a handful of countries have published meaningful figures. It is important to note, however, that part of this data originates from within the cannabis industry itself, raising questions about its accuracy and representativeness. Yet, they have been included in the report to provide an impression.

| Country | Data Available |
|---|---|
| Germany<br><br>(Ferreira de Oliveira e Silva & Nabas Figueiredo, 2023)<br><br>(BfArM, 2022)<br><br>(rbb24, 2025) | Prior to the regulation of medical cannabis in 2018, about 1,000 patients had special permission to use cannabinoid-based medicines. After the change, this number grew rapidly. By 2018, approximately 80,000 patients had received prescriptions, making Germany the country with the highest number of medical cannabis users in Europe.<br><br>This number significantly increased after the legal changes in 2024. While Germany used to import around 20.6 tonnes of medical cannabis a year, this rose sharply to 8.1 tonnes in the first quarter, 11.6 tonnes in the second, 20.7 tonnes in the third, and 31.7 tonnes in the fourth. |
| Italy<br><br>(Prohibition Partners, 2021) | In 2020, Italy was considered the second largest distributor of medical cannabis, with 1.2 tonnes distributed among 20 000 patients. Most of the medical cannabis was sold via private wholesale (59%), followed by Stabilimento Chimico Famaceutico Militare (21%) and hospital pharmacies (19%). |
| The Netherlands<br><br>(Zaami, Di Luca, & Montanari Vergallo, 2018) | Despite medical cannabis being legal, the majority of patients (estimated 0.5 million) still access cannabis through non-medical channels due to the low barriers and general tolerance. By 2016, the number of prescriptions rose from 6.4 to 24.6 per 100,000 inhabitants, but it has seen a decline since 2017. Yet, it is still the third largest market in Europe. |
| United Kingdom<br><br>(Sinclair, 2025)<br><br>(Turney, 2024) | Data on medical cannabis prescriptions is inconsistent. Some reports estimate that in 2023 around 50,000 patients received prescriptions through 33 private pharmacies. By contrast, figures from the NHS Business Services Authority, indicated that over 300,000 cannabis items were prescribed between April 2023 and April 2024, which is more than double the number in the previous year. According to Cannamonitor, approximately 79% of these prescriptions were for cannabis flowers, many of which contained high levels of THC and were almost entirely imported. |
| Finland<br><br>(Hupli, Unlu, Jylkkä, & Oksanen, 2024) | As of 2015, only a few hundred patients held permits. A 2014 survey estimated that 2,000-5,000 individuals were using cannabis for medical purposes without prescription, a number believed to have increased over time, considering the general increase in cannabis use, while official prescriptions have declined. |
| Czech Republic<br><br>(Smith, 2025) | While in 2013, less than 1kg of medical was dispensed by pharmacists, the number had risen to 100kg in 2021, and 320kg in 2023 – keeping in mind that medical cannabis became available in the pharmacies in 2018. Official numbers estimate that around 8,000 individuals use medical cannabis, while experts suggest a much higher actual number. |
| Poland<br><br>(Stevens, 2024a)<br><br>(Stevens, 2025b) | Medical cannabis sales increased from 26,164 grams in 2019 to 2,578,777 grams in 2023. Patient numbers rose from 1,698 to 90,297 during the same period, representing a compound annual growth rate of 189.2% for patients and 214.6% for volume sold. Since the legislative change in November 2024, prescriptions have decreased from 68,000 in October 2024 to 28,000 in December 2024. |
| Luxembourg<br><br>(Halder, 2025) | By 2024, over 1,100 registered patients had received prescriptions for medical cannabis, an increase of 712 patients since the programme's inception. The average quantity prescribed per patient also rose significantly, from 36.4 grams to 66.7 grams. |
| Denmark<br><br>(Stenocare, 2025) | Since the pilot's launch, the number of registered medical cannabis users have grown from 712 in 2018 to 8,848 in 2023. |
| Malta<br><br>(Buhagiar, Vella, Serracino Inglott, & Gauci, n.d.)<br><br>(Balzan, 2021) | Data shows that between July 2018 and October 2019 (the first year since its regulation), 34 prescribers issued medical cannabis treatment to 449 patients. The latest data in 2021 showed that around 1,900 patients had been prescribed medical cannabis. However, no new data has been published since the non-medical cannabis was legalised. |
| France<br><br>(Valdovinos, 2025) | The trial included 3,200 patients, with defined conditions, out of which 1,842 had continued their treatment in 2024 and was implemented across 275 health facilities |

# A Deep Dive

To provide an insight into the diversity among the national legislative frameworks, as well as their outcomes, a number of countries have been selected for a deeper examination. These countries were chosen based on either their liberal stance toward medical cannabis, their reputation for cannabis cultivation, or recent policy developments indicating a shift toward further regulating medical cannabis, not to be confused with cannabinoid-based medicines.

*Pharmacy dispensations have steadily declined since 2016, with patients turning to cheaper non-medical channels instead. Photo: Adobe Stock*

## The Netherlands

The Netherlands was the first European country to regulate medical cannabis in 2003. According to Wallage & Bertens (2023), they clearly distinguished medical cannabis from the tolerated non-medical market, unlike many other countries. To oversee this separation, the Ministry of Health, Welfare, and Sports (VWS) established the Office for Medical Cannabis (BMC), which operates within the executive organisation CIBG. The BMC was tasked with managing the entire supply chain for medical cannabis, from cultivation to pharmacy distribution, while maintaining exclusive control over import, export, and possession (Bureau voor Medicinale Cannabis, n.d.).

### Legal and Institutional Framework

Medical cannabis is not registered as a medicine in the Netherlands but is governed by the Opium Act. Specific exemptions in Articles 8(2), 8h, and 8i provide the legal basis for production and distribution. The law distinguishes between cannabis preparations

(liquid or solid mixtures), cannabis flos (dried flower), and cannabis plants. Exemptions are provided based on public European tender procedures, and Bedrocan has been the only producer awarded the cultivation contract since 2003. The exemption in the Opium Act allows them to grow medical cannabis under defined requirements, with a cap on cultivation volumes based on government orders.

In 2024, the framework was updated to introduce two operational regimes. Under regime 1, BMC contracts cultivators, purchases the harvest within four months, and oversees further sales and transfers, including import and export. Under Regime 2, BMC facilitates cannabis trade for research or small-scale purposes without contracting directly. These changes were intended to accommodate evolving external research and the production of cannabinoid-based medicines. Additionally, opportunities for the trade of medicinal cannabis, including the necessary preconditions, were being investigated, creating additional opportunities for export (Ministerie van Volksgezondheid, Welzijn en Sport, 2024).

Generally, medical cannabis is not covered by the national health insurance, due to insufficient scientific evidence according to the National Health Care Institute (Zorginstituut Nederland, 2017). Since 2022, an exception was introduced for patients with Lennox-Gastaut or Dravet syndromes that otherwise do not respond to alternative treatment options. For these patients, a cannabidiol-clobazam combination is reimbursed (Zorginstituut Nederland, 2022).

## Distinction between medical and non-medical market

The separation of medical cannabis from the tolerated non-medical market is reiterated by the sole-producer Bedrocan. They have been vocal about this division, publicly distancing themselves from the ongoing non-medical cannabis cultivation pilot project in the Netherlands. As the company stated:

> *"In other countries, we've (unfortunately) seen patients using medicinal cannabis suffer from the legalisation of [non-medical] use. Not so much from the legalisation itself, but rather from the fact that producers were tempted to enter this market. Quality standards are lower, regulations are more lenient, inspections are less strict, and yields (they hoped) are higher. The result: medicinal cannabis received less (or no) attention, and patients were left without a product. We want to prevent that at all costs."*

Their statement stresses that cannabis can pose risks and should remain under prescription and pharmacy supervision (Bedrocan, 2020).

## Supply Chain and Oversight

Not only the producer, but also all processes in the supply chain are contracted via the European tender procedure. Once cultivated, cannabis is irradiated (currently by Steris), laboratory tested (by Lab Ofichem) and packaged by pharmaceutical contractors (currently Fagron). Pharmacies place orders with Fagron, which must ensure delivery within 24 hours and is responsible for invoicing. CIBG, BMC, and IGJ (Health and Youth Care Inspectorate) regulate the various stages, while pharmacies

themselves are also subject to IGJ controls. A total of five medical cannabis products are available, all produced by Bedrocan (Bedrocan, 2021). Overall, BMC is responsible for providing information about medical cannabis to patients and professionals upon request (Bureau voor Medicinale Cannabis, n.d.).

## Domestic Market and Patient Use

Despite being legally available since 2003, the majority of patients seem to obtain cannabis without a prescription from tolerated non-medical markets or through home growing. The latter, however, is only tolerated for non-medical purposes and remains illegal for medical use as the quality and dosage cannot be guaranteed (Trimbos Instituut, 2025).

Data from 2022 confirm this. 17.6% of cannabis users reported medicinal use, yet 94.3% obtained their cannabis without a prescription. 2.8% received their cannabis with a prescription only and 2.9% received their cannabis both with and without prescription. Among medical users, the flower remained the dominant product (83%), followed by CBD oil (16.3%) and THC oil (8.1%). A reason for this mentioned by the participants is the high costs and inability to get the products reimbursed.

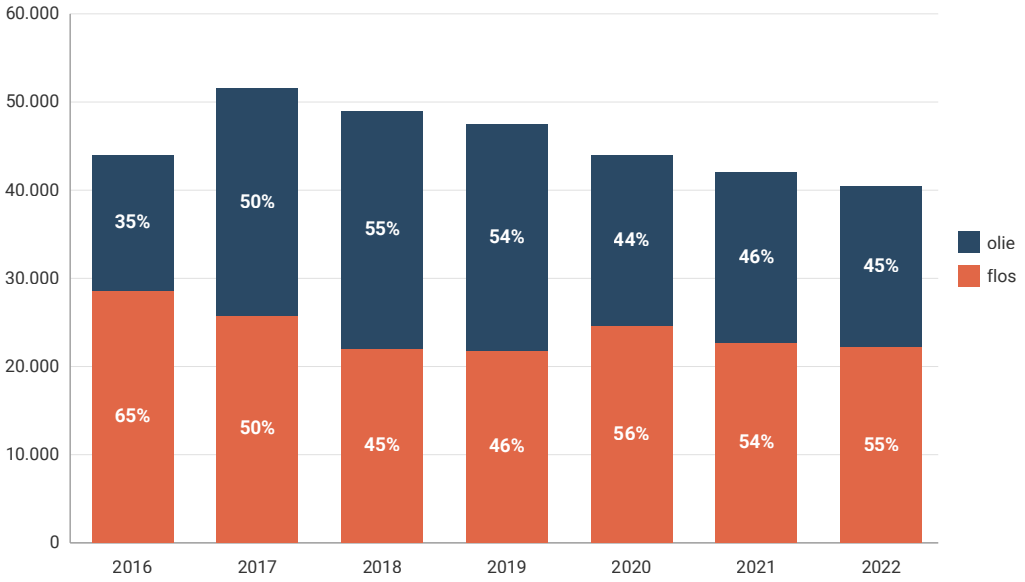



*Figure 3 - Number of Prescriptions by pharmacies 2016-2022 (SFK)*

Simultaneously, dispensation data shows a decline over the years (see figure 3). After peaking in 2016 with the introduction of cannabis oil, pharmacy dispensations have steadily decreased. In 2022, 41,000 total dispensations were recorded, down 2.2% compared to the previous year. Most prescriptions came from general practitioners (65%), while specialists prescriptions fell by 7.5% (SFK, 2023).

## International Supply Chain

The BMC also manages exports of medical cannabis to countries such as Italy, Germany, and Finland, subject to import authorisation (CIBG, n.d.b). To reduce dependence

on a single supplier, the government announced a new European tender in 2019 with the intention of contracting two producers. The plan was meant to diversify product variations and improve supply security but has since been delayed and eventually suspended (Trimbos Instituut, 2025).

## Recent Developments

In 2024, a policy shift was announced by the Dutch Ministry of Health. While officially a second contractor was to be welcomed in 2023/2024, the process was put on hold in 2024 and eventually stopped completely by the Health Minister Mrs Agema in 2025. In an open letter on February 21st, 2025, she announced that the BMC would stop contracting cultivators altogether, including the longstanding supplier Bedrocan, from January 1st 2026 (Picavet, 2025). It was also announced that the BMC will no longer export medical cannabis from 2025 onwards and once the contract with Bedrocan ends, cannabis will be supplied to Dutch patients from the existing stock. If necessary, imported finished products will be procured via public tenders. Furthermore, a predicted change in legalisation in 2027 was mentioned, following parliamentary questions on June 3rd (Jansen, 2025).


*Online platforms now offer cannabis prescriptions within minutes, with minimal medical assessment. Photo: Adobe Stock*

# Germany

## Legal Foundation (2017-2022)

Germany regulated medical cannabis in March 2017, introducing one of the most liberal frameworks in Europe. The Federal Institute for Drugs and Medical Devices (BfArM) became the designated regulatory body responsible for overseeing cultivation and distribution of medical cannabis. The law allowed any physician to prescribe cannabinoid-based medicines, including dried flowers, standardised extracts, and synthetic cannabinoids such as Dronabinol and Nabilone, without requiring a special licence.

Prescriptions could be filed at pharmacies, with reimbursement possible under public health insurance if three criteria were met: the illness was considered "serious", standard treatments had failed or were unavailable, and there was a realistic prospect of symptom improvement and disease progression (Bundesministerium für Gesundheit, 2025a).

These conditions were intended to restrict use to medically justified cases, but their enforcement was ambiguous. Terms such as *"serious illness"* or *"treatment failure"* were only vaguely defined, leaving much to physicians' discretion. Criticism has been raised by the cannabis industry regarding the high rejection rate of health insurance coverage (estimated at 30-40%) (BvCW, 2024), limited training for physicians (Kowollik, 2025), and their reluctance to prescribe medical cannabis (Sinclair, 2023). Nevertheless, patient numbers grew steadily: from around 40,000 in 2018 to 60,000 in 2019, 170,000 in 2022, and an estimated 250,000 by April 2024 (cannabusinessplans.eu, 2025b).

The Federal Institute for Drugs and Medical Devices (BfArM) conducted a five-year observational study, published in 2022, covering 16,809 patients. It found that 76.4% of prescriptions were for chronic pain, while smaller shares were for spasticity (9.6%), anorexia (5.1%), and nausea (2.2%). Cancer patients accounted for 14.5% of cases, and multiple sclerosis for 5.6%. Notably, one-third of patients discontinued treatment within a year due to lack of efficacy (Haug, 2025), raising questions about its long-term therapeutic value.

## Regulatory Changes and Blurred Boundaries (2024)

In April 2024, Germany introduced a new legal framework that removed medical cannabis from the Narcotics Act (BtMG) and placed it under the standalone Medizinal-Cannabisgesetz (MedCanG). This shift coincided with the semi-legalisation of non-medical cannabis and was intended to separate the two domains.

However, instead of clarifying boundaries, the changes blurred them further. Under the new framework, cultivation moved from tendering to a licensing scheme intended to boost competition and domestic supply (Bundesministerium für Gesundheit, 2025a). Simultaneously, the removal of cannabis from the Narcotics Act meant that oversight was relaxed. This opened the door for new actors, particularly online platforms, to exploit regulatory gaps. These actors now offer cannabis prescriptions through minimal self-reporting, often without any live interaction (either in-person or virtual) with a physician (BfArM, n.d.).

Telemedicine providers emerged, offering prescriptions within minutes based on online questionnaires. Under EU telemedicine rules, even foreign doctors can issue valid prescriptions for German patients. These services often advertise with slogans such as *"Become a cannabis patient in 3 minutes"*. Patients can complete short forms with multiple-choice questions about symptoms, prior treatments, and medical history, before uploading ID for age-verification (CanDoc, n.d.). Prescriptions are then approved remotely and dispatched within hours or days, and delivered to the door.

Prices typically range between €8.50 to €12.70 per gram, including delivery costs, making the pathway fast and relatively cheap. Individuals can also retrieve their prescriptions from the pharmacies, which are legally obliged to dispense them. They have limited authority to question their validity or its medical indication unless clear misuse is suspected.

It is estimated that over 50,000 people have already used such services up to June 2025 (Kowollik, 2025). While technically compliant with telemedicine requirements, this system raises serious concerns about the depth of medical assessment involved. Critics argue that the ease and speed of this system undermine the credibility of medical cannabis prescribing, effectively creating a backdoor to non-medical access.

## Impact and Pushback

Medical cannabis consumption increased dramatically after the 2024 legal changes, as reflected in import data. In 2021, before the semi-legalisation, Germany imported around 20.6 tonnes of medical cannabis (BfArM, 2022). After the 2024 changes,

imports rose sharply: 8.1 tonnes in the first quarter, 11.6 tonnes in the second, 20.7 tonnes in the third, and 31.7 tonnes in the fourth (rbb24, 2025).

The new framework faces broad criticism. Physicians point out that cannabis flowers, mostly sold on online platforms, are "*rarely medically necessary, perhaps in palliative care*" (Haug, 2025). Despite surge in the import of medical cannabis, patients with severe or chronic illnesses reported that their access to medically necessary cannabis has actually worsened, due to supply shortages (Die Spur, 2025). Meanwhile, the medical cannabis industry itself also voiced alarm. In December 2024, an open letter undersigned by organisations including the Bund Deutscher Cannabis-Patienten (BDCan), Deutsche Cannabis-Akademie (DCA), Verband der Cannabis versorgenden Apotheken, Fette Pharma, and Bedrocan, called for prohibiting online prescriptions without in-person consultations. The signatories warned of "*widespread abuse of medical cannabis*" for non-medical purposes (Bedrocan, 2024).

## Political Response and Legislative Revision (2025)

In response to these developments and criticism, Health Minister Nina Warken (representing the Christian Democrats – CDU), appointed in 2025, introduced a legislative draft in June 2025 aimed at curbing what she describes as an, "inflationary increase in prescriptions" (Suliak, 2025). Following the announcement, the Bavarian government called for even stricter measures. Officials argue that any prescription should require clear documentation of medical necessity, an explicit clause still missing from the draft presented by Ms Warken (Heim, 2025a).

While in August, the Social Democrats, part of the Federal Cabinet and responsible for the original semi-legalisation, had announced that they will not accept the presented draft and that changes will most likely require time before it is discussed in the parliament (Schulze, 2025), the Federal Cabinet approved the draft bill amending the Medical Cannabis Act. This Bill proposes the following changes (Bundesministerium für Gesundheit, 2025b):

- Prescriptions can only be obtained after in-person consultation, including assessment on the patient's physical health, medical history and risk of addiction/psychological consequences.
- Quarterly follow-up in-person consultation meetings with the same prescriber are required to extend the prescription.
- Mail-order sales will be banned, with an exception on pharmacy delivery services.

Nevertheless, the draft still needs to be approved by the German Parliament, where the CDU and SPD enjoy a majority. However, the SPD is divided and could cause a delay in the adoption of the amendment. The date of the vote is not yet announced (Heim, 2025b).

*Italy's domestic cannabis cultivation is uniquely conducted under military supervision. Photo: iStock*

# Italy

## Legal Framework

Italy regulated medical cannabis by recognising THC and derivatives for therapeutic use in 2007 (Decree No. 98). The framework was refined through subsequent decrees, notably the 2015 Ministerial Decree, which formally defined the conditions for the cultivation, production, possession, and use of cannabis for medical purposes (Cannabiscientia, 2023) and Law 242/2016, which distinguished between industrial hemp and cannabis intended for therapeutic use (MOCA, n.d.).

There are two main pathways for prescription (Stevens, 2022; MOCA, n.d.):

1. **Private prescriptions**: Any doctor can prescribe cannabis privately for conditions supported by minimal scientific evidence (at least one available study), fitting within the national framework. Patients do not receive reimbursement from the national health systems.

2. **Public Prescriptions**: General practitioners within the public health care system may prescribe cannabis for a limited list of conditions, such as chronic pain, spasticity, and chemotherapy-related nausea. The prescriptions must be sent to the Italian Medicines Agency (AIFA) and may be eligible for reimbursement.

Prescriptions are valid for 30 days and doctors must assume medical responsibility and obtain informed consent from the patient (Brightfield Group, n.d.). Distribution is conducted via licensed pharmacies. While the framework is national, implementation and reimbursement policies are decentralised, delegated to Italy's Regional National Health Systems. This leads, according to critics from the cannabis industry, to "regulatory variations across regions" (Cannabiscientia, 2023).

## Cultivation and Production

Unlike the Netherlands or Germany, Italy has designed a centralised model of domestic cultivation, unique in Europe. The Stabilimento Chimico Farmaceutico Militare (SCFM) in Florence, operated by the Ministry of Defence, is the sole domestic cultivator (Opilio & Patania, 2024). They produce around 102 kg (2021) and are responsible for one-third of the total annual demand (Stevens, 2022). The remaining demand is supplied through imports, primarily from Bedrocan (Netherlands) and Aurora (Canada), with Tilray (Portugal/Italy) only recently authorised to enter the market. Licensed companies must adhere to Good Agricultural and Collection Practices (GACP) (MOCA, n.d.).

## Products and Pricing

Italy recognises both authorised cannabinoid-based medicines (such as Sativex) and unlicensed magistral preparations from cannabis flowers. If a medicine is not authorised in Italy but approved abroad, physicians must apply to the Ministry of Health and customs for special import permission, justifying the medical need. The prices of the military-grown cannabis are regulated (Brightfield Group, n.d.).

## Recent Developments

Recently, Italy tightened its stance on cannabidiol (CBD) and low-THC "cannabis-light" products, which include products with <0.2% THC. Permitted since 2016 by Law 242, the market with CBD-rich flowers and derivatives became established. The products were often sold as "collectors' items" to bypass consumption laws yet were widely used for therapeutic and non-medical purposes (Piscioneri & Balmer, 2024). However, due to concerns about the potential interaction between CBD and THC, the contamination risks during extraction, and insufficient consumer protections around the composition and labelling of over-the-counter CBD products, the Italian court ruled that the Italian government could apply the EU's precautionary principle (Stevens, 2025a).

As a result, in June 2025 Italy banned most CBD and cannabis-light products by reclassifying them as narcotics unless prescribed by a physician. This followed TAR Lazio's ruling upholding the Ministry of Health's decree, supported by advisory bodies citing concerns about insufficient scientific evidence and consumer protection. Since the products are permitted within Europe, the European Commission has already formally requested clarification from Italy, "triggering a 90-day evaluation period to assess whether the ban violates the EU's internal market rules" (Mis M. V., 2025).

The decision has provoked strong opposition from industry groups and political critics alike. Sector stakeholders, including Canapa Sativa Italia and several companies affected by the decree, see it as an economic threat. They have also argued that the measure contradicts EU-level norms regarding hemp cultivation and the free movement of goods. The decision might be challenged before the Court of Justice of the European Union (CJEU) (Ibid).

*Portugal has become the EU's second-largest cannabis producer, with most output destined for export. Photo: Pierre Andersson*

# Portugal

Portugal regulated medical cannabis in 2018 with Law No. 33/2018, followed by implementing regulations in 2019. These established the framework for the cultivation, manufacturing, distribution, and prescriptions of cannabinoid-based medicines, including oils, tinctures, and dried flowers, under the oversight of INFARMED (National Authority of Medicines and Health Products) (Santos, 2025a). Over the years, Portugal has positioned itself as one of the largest exporters of medical cannabis in Europe, illustrating the economic incentives behind the ambition of regulating medical cannabis.

## Domestic Use and Regulation

Under Portugal's medical cannabis law, doctors can prescribe cannabinoid-based products only after conventional therapies have proven ineffective. These prescriptions are permitted for a limited number of conditions, similar to other European countries, as well as glaucoma, Gilles de la Tourette syndrome, and palliative care (cannabusinessplans.eu, 2025a).

At present, only a limited number of cannabinoid-based medicines are available, most notably Sativex (Cave, 2024). The number of prescriptions shows consistent growth, from 460 prescriptions in 2021 to 929 in 2022, 1,157 in 2023, and 757 in the first six months of 2024. Public hospital usage has also risen, from 524 units in 2022 to 950 units between January and November 2024 (cannabusinessplans.eu, 2025a).

## Licensing and Oversight

INFARMED serves as the central regulatory body, responsible for issuing licenses and supervising all activities related to medical cannabis. Its quality control procedures include stringent testing for contaminants (e.g. mould, pesticides) and traceability requirements to ensure patient safety (Santos, 2025b).

INFARMED states that its licensing and supervisory approach is based on five core pillars (cannabusinessplans.eu, 2025a):

1. Product Quality (GACP and GMP compliance)
2. Adherence to UN Conventions on Narcotics (1961 and 1971)
3. Security measures, product registration, and traceability
4. Economic and health value of the project
5. Multidisciplinary evaluation involving health, agriculture, justice, economy, and local government.

Ordinance No. 83/2021 formalised the licensing requirements and procedures for all cannabis-related activities, introducing entry fees for cultivation, manufacturing, and wholesale trade (each $150,000) and import/export ($200,000). Licenses must be renewed annually (groweriq, n.d.). The number of licenses has also shown a steady increase. As of May 2025, Portugal had authorised 39 companies for cultivation, 25 for manufacturing, 49 for import, 50 for export, and 16 for wholesale trade (cannabusinessplans.eu, 2025a).

## Market Growth and Export

Portugal's regulatory framework and favourable conditions, such as its climate, low production costs, and strategic location, have led to it being the second largest producer of medical cannabis, after Spain, as per data provided by the International Narcotics Control Board (INCB). Industry professionals have estimated that Portugal might be producing twice as much (Ibid), nevertheless, export increased from less than 5000 kg in 2020 to over 32000 in 2024.

As shown in Figure 4, Germany remains the primary destination (38% of 2023 exports), followed by Spain (19%), Poland, the UK, and Australia (see figure 3). Interestingly, while Poland, UK, and Australia do have a medical cannabis framework, Spain does not (until 2026). Portugal's projected domestic requirement for medical cannabis also surged, rising from 6.5 tonnes in 2023 to 32 tonnes in 2024, as reported by the INCB (cannabusinessplans.eu, 2025a). While domestic demand is growing, the majority are still meant for export, which suggests that the framework is geared toward economic opportunity.

**Export Destination Countries – in kg**
(plant, preparations and substances)

| | 2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 Q3 |
|---|---|---|---|---|---|---|---|---|
| Germany | | 460 | | 1063 | 1917 | 3685 | 4402 | 8540 |
| Poland | | | | | | | 2469 | 2998 |
| Spain | | | 3 | 202 | 787 | 2812 | 2181 | 3830 |
| Australia | | | | | | | 1659 | 945 |
| Malta | | | | 247 | 150 | 0 | 236 | 10 |
| United Kingdom | 204 | | | 31 | 38 | 155 | 363 | 1822 |
| Others (GW, NZL, FR, LU, COL, DK, IL) | | | | | 113 | 1054 | 663 | 370 |

*Figure 4 - Export destination countries - in kg (plant, preparation and substances (INFARMED)*

*No patient data has been published since non-medical cannabis was legalised in 2021. Photo: Adobe Stock*

# Malta

## Legal and Regulatory Framework

Malta established its medical cannabis framework in 2018 through the "Production of Medicinal and Research Purposes Act", complemented by the amendments to the "Drug Dependence (Treatment not Imprisonment) Act". Together, these measures created the statutory basis for controlling the cultivation, processing, production, and distribution of cannabis for both medical and research uses. The regulatory authority responsible for enforcement is the Malta Medicines Authority (MMA).

The law permits the production of cannabis derivatives including dried flower, oils, plants, seeds, and extracts (excluding synthetics). Smoking as a mode of administration is not allowed and dispensing is conducted only by pharmacies based on a valid prescription issued under the Medicines and Dangerous Drugs Ordinance (Farrugia, 2019).

## Licensing and Oversight

Malta's licensing framework is rather open, with both domestic and foreign firms eligible to apply under Chapter 578 of the Laws of Malta (Ibid). However, those applying for a license must comply with the regulatory standards set by the MMA (Buhagiar, Vella, Serracino Inglott, & Gauci, n.d.). The application process includes:

1. **Letter of Intent (LOI)**: Issued by Malta Enterprise, confirming that the proposed action carries strategic economic value (BDO, n.d.).
2. **Approval to Trade**: Granted by the Superintendent of Public Health, followed by a formal licensing request through the MMA (Medicines Authority, n.d.).

Licences are granted only to companies that adhere to EU-GMP (Good Manufacturing Practice) and EU-GDP (Good Distribution Practice) standards (BDO, n.d.). Each

facility must appoint a Responsible Person (RP), typically a pharmacist, to monitor, oversee adherence to conditions and record-keeping (Cannabis for Medicinal and Research Purposes Unit, 2025).

Applicants are subjected to application and renewal fees: €25,000 annually for manufacturing licences, €10,000-€15,000 for research or GMP certification, with additional renewal and inspection costs (Malta, 2018a).

## Medical Cannabis Access and Products

Malta's medical cannabis programme allows patients with specific conditions to access treatment upon obtaining approval from the Superintendent of Public Health, following specialist assessment and evidence of treatment failure with conventional therapies. Patients are issued a Drug control card, valid for six to twelve months, enabling prescriptions that are renewable (the PainClinic, n.d.).

Patients may be prescribed up to 90 grams per month. Available medical cannabis includes fresh or dried cannabis, cannabis oil, cannabis plant or seeds, derivatives of cannabis (no synthetics), or any substance and/or product set out in the guidelines by the regulatory authority (Malta, 2018b).

Data show that primarily products in the form of dried flower (for vaporisation) and cannabis oils have been prescribed (Grima, 2025). Between July 2018 and October 2019, the MMA received 17 applications for cannabis products intended for the local market. Four products (dried flower) were approved. In 2025, a total of 33 varieties of medical cannabis had been approved (Medicines Authority, 2025).

Data on actual patient usage is both outdated and sparse. The only comprehensive figures show that between July 2018 and October 2019, 34 doctors prescribed medical cannabis to 449 patients for a wide range of medical conditions, including "anxiety, insomnia, depression, fibromyalgia, pain, migraine, cancer, post-traumatic stress disorder and multiple sclerosis" (Buhagiar, Vella, Serracino Inglott, & Gauci, n.d.).

The most recent available data, from 2021, suggests 1,900 patients (Balzan, 2021). Since then, no official figures have been released, making it difficult to understand whether the legalisation of non-medical cannabis in 2021 has impacted the medical market and led to an increase in use, similarly to Germany.

## Investments and Industrial Activity

From the outset, Malta framed medical cannabis as an economic opportunity, framing itself as an investment destination. At the first World Forum for Medical Cannabis in 2018, Parliamentary Secretary Deo Debattista stated that "*in this sector I dream that we will be leaders*" (Vassallo, 2018). Furthermore, Minister for Energy, Enterprise and Sustainable Development Miriam Dalli considered the first approved license for Zenabis "another milestone in the establishment of Malta's Medical Cannabis Industry", sharing the government's vision to *"establish this emerging vertical as a new economic niche for Malta"* (Ibid). In 2018, Malta Enterprise had approved five initial projects valued at 30 million EUR, with investors from Canada, Israel and Australia (Pace, 2018).

However, implementation has fallen short of expectations. By 2022, only 7 out of 26 licensed companies had commenced operations, employing 79 people and generating €20 million in direct investment, which is significantly lower than earlier estimates of €153 million in capital inflows (Camilleri, 2022).

Despite the 'slow start', international firms such as Aphria, Zenabis (later acquired by HEXO corp), and Israeli-backed Techfor CannEU have entered the Maltese market (The Malta Business Weekly, 2021). Malta's logistical advantages, such as the EU membership, stable regulatory environment, and geographic accessibility, make it a potentially attractive location for production (Farrugia, 2019).

## Market Overlap with Non-medical Cannabis

The legalisation of non-medical cannabis in 2021 has created a parallel route to the medical cannabis framework. While the two systems are legally distinct, in practice they overlap and compete. Residents can now join [non-medical] Cannabis Associations and access cannabis products outside the medical model (Morris, 2023b) (Grima, 2025). For many, this would be considered more attractive since it would be faster and less strict, particularly considering that some would want smokeable products which are not prescribed by pharmacies (Morris, 2023b). This undermines the medical framework.

*Denmark made medical cannabis permanent despite evaluation reports finding no new evidence on efficacy. Photo: Adobe Stock*

# Denmark

Before the formal introduction of a medical cannabis framework in 2018, two cannabinoid-based medicines were authorised for the treatment of specific conditions. Sativex was authorised for adult patients with moderate to severe spasticity caused by multiple sclerosis for whom conventional medication had proven unsuccessful, and Epidiolex for rare forms of epilepsy such as Dravet and Lennox-Gastaut syndromes. Only specialists in neurology and paediatrics could provide prescriptions. Other synthetic cannabinoids, such as Marinol and Nabilone, were not authorised, though doctors could request case-by-case imports under special approval from the Danish Medicines Agency (Laegemiddelstyrelsen, 2022a).

## The 2018–2025 Pilot Programme

On January 1st, 2018, Denmark launched a four-year pilot programme, which was later extended until the end of 2025. The programme allowed doctors to prescribe certain cannabis products that do not meet the conventional standards of authorisation or magistral preparations. These included dried cannabis flowers, cannabis oils, tablets and capsules.

The products included in the programme had to meet minimum quality standards regarding cultivation, standardisation and documentation. However, the products under the pilot programme did not undergo the same level of clinical testing or safety evaluations as conventional medicines and were not officially authorised. This places full responsibility on doctors to prescribe the correct dosage. Although they received

guidance documents, informed by ongoing evaluations in the Netherlands, Canada and Israel (Ibid), the lack of formal approval, combined with limited clinical research, led to hesitation among many physicians to prescribe cannabinoid-based treatment (Egnell, Villman, & Obstbaum, 2019). By 2024, approximately 20,000 prescriptions had been issued to around 1,800 patients through the last three years of the pilot (Business of Cannabis, 2025).

The Danish medical cannabis trial has undergone two official evaluations, first in 2020 and again in 2024. In the most recent report, it was concluded that no new evidence had emerged since the first assessment that would justify changes to the existing medical indications outlined in the guidance for physicians. The evaluation further noted that it remains uncertain to what extent new knowledge had been generated using products comparable to those included in the Danish trial scheme. Reaffirming the limitation already identified in the 2020 evaluation, the report highlights the inability to "carry out scientific research on the effect in relation to treatment with the cannabis products in the trial scheme" (Indenrigs- og - Sundhedsministeriet, 2024).

## Permanent Regulation

Nevertheless, the Danish Parliament passed Act 2024/1 LSF 135 in 2025, establishing a permanent regulatory framework that will take effect from January 1st, 2026. The legislation allows the cultivation, manufacturing, import, export, distribution, and dispensing of cannabis products for medical use. The legislation is designed to align with Denmark's obligations under international drug control treaties, including the 1961 UN Single Convention on Narcotic Drugs.

The framework requires authorisation from the Danish Medicines Agency for all activities, including cultivation, manufacturing, import, export, distribution, and dispensing. Applications must demonstrate compliance with requirements on staff qualifications, safety, quality assurance, and traceability, and fall under the responsibility of the Minister of Interior and Health.

Manufacturers and importers are subject to detailed technical requirements. For example, importers may only bring in cannabis source products that are legally authorised for medical use in the country of origin and must verify that such products meet that country's packaging, labelling, and quality standards. Imports of raw or bulk cannabis are not permitted unless the product is already packaged and ready for dispensing, ensuring that all imported cannabis products meet consistent safety and quality standards.

The act further outlines procedures for pharmacies that dispense cannabis products. Pharmacies must label compounded cannabis products with specific patient information, safety warnings and product details. The Danish Medicines Agency is authorised to issue additional rules governing pharmacy preparation, labelling, and pricing (Løhde, 2025).

## Reimbursement

Since the start of the pilot programme, participating patients have been eligible for partial reimbursement of the treatment costs. The standard arrangement covers 50% of treatment costs up to DKK 20,000 per year. Beyond this threshold, patients must cover the expenses themselves. For terminally ill patients, however, treatment is fully reimbursed with no upper limit (Laegemiddelstyrelsen, 2019).

As the country transitions to a permanent medicinal cannabis scheme, this reimbursement framework will remain in place. The Danish Medicines Agency has announced that updated prescribing guidelines and a simplified patient summary will be introduced to support better informed clinical decisions (Cision Sverige AB, 2024).

*Of over 3,000 pilot participants, only 1,850 remained in treatment by end of 2024. Photo: Adobe Stock*

# France

## Legal Classification

Cannabis in France remains classified as a narcotic under the 1961 Single Convention on Narcotic Drugs, to which France is a signatory. Consequently, its production, possession, distribution, and use are prohibited by law. However, recent legislative developments have introduced a defined exception for the controlled use of cannabis for medical purposes under a state-led experimental framework. The 2020 Social Security Financing Act (Act No. 2019-1446), amended by Act No. 2022-1616, and Decree 2020-1230 and Decree No. 2023-202, authorised a temporary pilot programme.

Products containing more than 0.3% THC were classified as narcotics for the purpose of experimentation, while CBD products below that threshold were treated as List I prescription medicines. In February 2022, Decree No. 2022-194 authorised the cultivation of cannabis for medical use for the first time, though subject to strict authorisation from the Ministry of Health and proposals issued by the ANSM (French National Agency for Medicines and Health Products Safety) (ANSM, 2021).

## Pilot Programme (2021-2026)

The pilot programme officially began on March 26th, 2021, with an initial duration of four years. It was subsequently extended twice, most recently until March 31st, 2026, to provide a longer runway for evaluation and bridge the gap until an official programme could be announced (Directorate for Legal and Administrative Information, 2025). The primary objective of the pilot was to evaluate the feasibility of prescribing and dispensing medical cannabis within the French healthcare system, including the necessary logistical infrastructure and patient follow-up mechanisms. It also aimed to

generate national data on the efficacy, safety, and clinical implementation of cannabinoid-based treatments (ANSM, 2020).

Participation is restricted to patients with serious treatment-resistant conditions, including neuropathic pain, drug-resistant epilepsy, cancer-related symptoms, palliative care needs, and multiple sclerosis-related spasticity (Directorate for Legal and Administrative Information, 2025). Throughout the pilot, over 3,200 patients had participated. However, by the end of 2024, 'only' 1,850 remained under treatment, largely due to perceived lack of efficacy, adverse effects, or other reasons (see Figure 5) (Valdovinos, 2025).

The programme was implemented across 275 health facilities. Authorised physicians and doctors, primarily in hospital settings (sante.gouv.fr, 2025), had to complete a mandatory 15-day training, including ongoing access to an e-learning platform offered by ANSM. They must log patient data in the RECANN monitoring system, with monthly reporting and follow-up requirements (ANSM, 2021).

Products provided, such as oils, capsules, and dried flower for vaporisation, were donated by four international suppliers: Aurora, Tilray, Panaxia, and Little Green Pharma (Gastautor, 2025). Since March 2024, the trial has been closed to new patients, only those already enrolled were able to continue treatment until the end of the pilot programme. All products remain reimbursed under the national healthcare system (Directorate for Legal and Administrative Information, 2025).

## EU Notification and Planned Transition

On March 20, 2025, the French government submitted a formal notification to the European Commission outlining its intention to move from a temporary pilot programme to a permanent regulatory framework. The intended framework includes the organisational structure, quality and safety standards, and domestic cultivation rules.

In accordance with EU procedures, other Member States have a three-month window to comment or raise objections. This means that the final adoption of the regulations is unlikely to happen before late 2025. If approved, the new framework would authorise ANSM to issue renewable five-year licences for the production, distribution, and use of medical cannabis. However, the medical cannabis programme would only be eligible for patients for whom conventional therapies fail and only for specific medical conditions. Prescriptions will continue to be provided only in hospital settings (France, 2025).

The plans to transition the pilot into a permanent regulation have been received with hesitation. Politicians and public health officials expressed concerns over the potential costs of scaling medical cannabis access as well as the inevitability of legalisation of non-medical cannabis, following the regulation of medical cannabis (Bullens, 2024).

## Assessment by the Cannabis Industry

The programme has been assessed by the cannabis industry and received positive, expected feedback citing high satisfaction, "robust safety profile", and operational viability within the healthcare system. At the same time, they highlighted various lim-

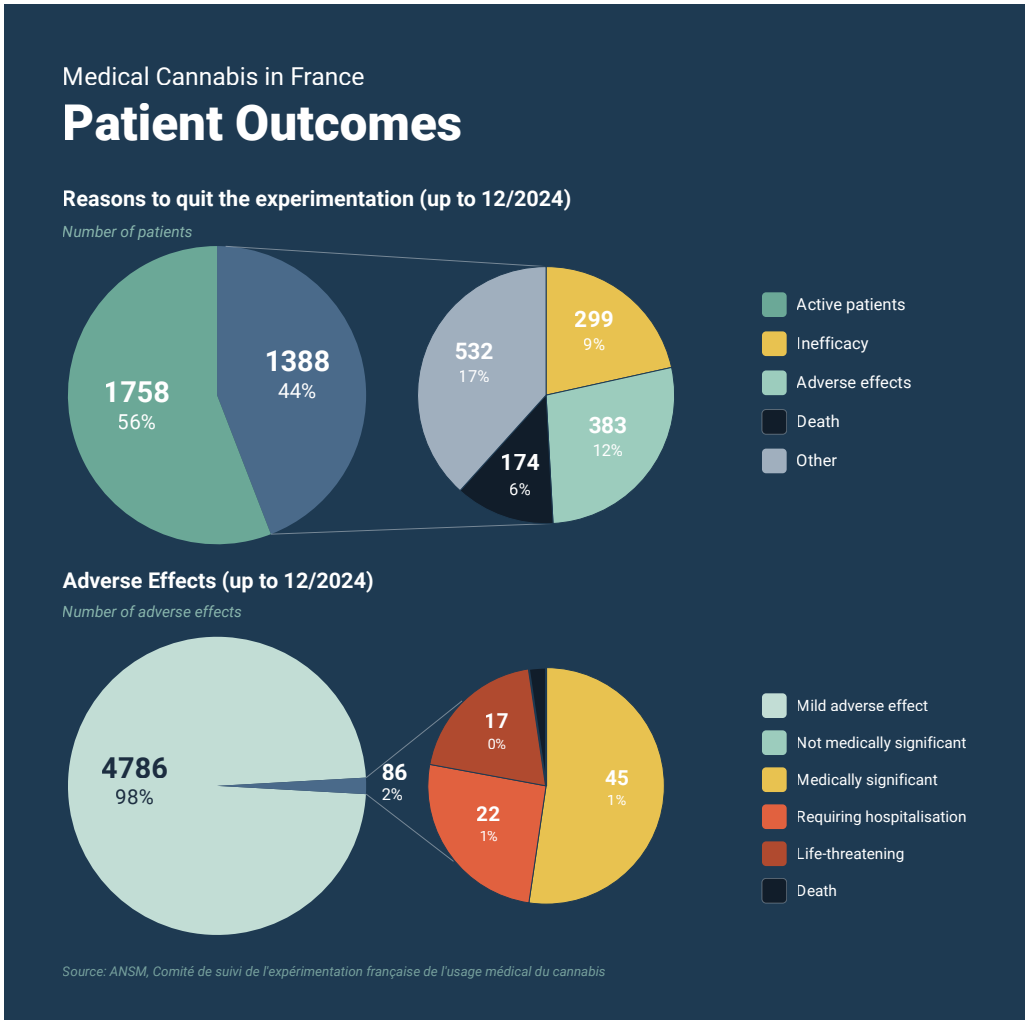



*Figure 5. Medical Cannabis in France (ANSM)*

itations, including high patient dropout rates, supply chain fragility, and unresolved regulatory and reimbursement uncertainties (Gastautor, 2025).

Professional engagement has also fallen short of expectations, especially among general practitioners. By 2025, around 2,300 healthcare professionals had completed the required training, comprising 531 hospital doctors and 999 pharmacists. Yet only 213 general practitioners, who typically serve as first-line providers, had become involved. The limited uptake received criticism and concerns about insufficient training, lack of clinical guidelines, and limited reimbursement structures (Valdovinos, 2025).

A 2024 report by Prohibition Partners projected that France's medical cannabis sector has the potential to reach an annual market value of €806 million by 2035, serving over 450,000 patients. However, this is an overly positive estimate. Even the report itself mentions that such growth would only be achievable if significant policy changes "unlock the sector" (Gastautor, 2025).

*Europe's largest cannabis exporter only approved domestic medical use in October 2025. Photo: Adobe Stock*

# Spain

## Legal framework

Cannabis in Spain is regulated under Law 17 of 8 April 1967, which incorporated the provisions of the 1961 United Nations Conventions. The law classifies cannabis as a narcotic, prohibiting cultivation for domestic consumption and granting the Spanish state exclusive authority over its cultivation, processing, marketing, and transportation. This authority is strictly for export purposes (AgroPharm, n.d.).

The Spanish Agency for Medicines and Health (AEMPS) oversees cultivation licensing, which falls into three categories:

1. **Research**: development of therapeutic varieties or studies of cannabis properties.
2. **Medical and scientific purposes**: production of cannabinoid-based medicines primarily for international markets.
3. **Manufacturing validation**: cultivation to generate batches for pharmaceutical process testing.

All licences are strictly regulated, periodically renewed, and published on the AEMPS website (Bautista & Espinosa, 2024). Synthetic cannabinoids (e.g. nabilone and dronabinol) and authorised products like Sativex and Epidiolex are available under existing pharmaceutical channels for specific conditions (Science Media Centre, 2024).

## Draft Royal Decree on Medicinal Cannabis

To date, Spain does not have a domestic medical cannabis use framework. However, in September 2024, a draft Royal Decree was submitted to the European Commission,

which would, if approved, establish a medicinal cannabis framework. The proposal allows compounded medications dispensed through hospital pharmacies, specifically prepared for each individual (Science Media Centre, 2024). A limited set of conditions is specified for the medicine, including severe refractory epilepsy, multiple sclerosis-related spasticity, chemotherapy-induced nausea, and chronic pain unresponsive to conventional treatment (Cannabis Trades Association, 2025).

The proposed framework excludes cannabis flower and other plant-based forms. The government's position is that any therapeutic use must comply with pharmaceutical norms, including clinical trial evidence of quality, efficacy, and safety. If the EU does not object and Spain's Council of State raises no significant concerns, the framework was expected to be enacted by mid-2025. However, as per mid-2025, no news reports have been published on the outcomes of the proposed framework. Even if it would be finalised this year, the current export-tailored infrastructure may delay domestic availability due to the need for importation, formulation development, and professional training (Stevens, 2025c).

## Market Structure and Investment Trends

Spain has emerged as Europe's leading medical cannabis exporter, largely due to its climate, relatively low production costs, and regulatory clarity for export-oriented activities. Reported production reached 51.3 tonnes in 2024, a 42.5% increase from earlier in the year and more than double the estimated 2023 output of 23.4 tonnes. This scale places Spain among the world's top seven producers.

Investment has followed and more than €115 million has been channelled into infrastructure, especially in the southern regions, with foreign companies (primarily Canadian and American) partnering with or acquiring Spanish licence holders (AgroPharm, n.d.). The strategic intent appears to be future-proofing their presence should domestic regulations evolve (Cannabis Trades Association, 2025).

The market is moderately concentrated. Notable licence holders include Linneo Health, with a capacity of up to 25 tonnes annually, alongside Medalchemy, Canamedics, and others such as Cáñamo y Fibras Naturales, Medical Plants, and Oils4cure (Pascual, 2020). In total, around seven medical producers and over a dozen research-focused entities are active. In 2023, over 4,300 kg of cannabis was cultivated for research (Stevens, 2024c).

## Non-medical Cannabis and Grey Zones

Compared to a strictly regulated medical cannabis framework, Spain has tolerated non-medical cannabis since its decriminalisation in 1982, removing criminal penalties for private consumption and personal cultivation (Gamella & Rodrigo, 2004). This interpretation extended to "shared consumption", enabling the rise of Cannabis Social Clubs (CSCs) in the early 2000s. These associations, mainly concentrated in Catalonia and the Basque Country, now number around 500 in Catalonia alone, with 200 in Barcelona. Attempts by the Barcelona City Council to regulate CSCs were struck down by Catalonia's High Court, which ruled that only criminal authorities and police had jurisdiction (Murkin, 2015) (Folch, 2022).

A study of Barcelona associations, published in the Journal of Drug Issues, showcases that CSC membership often overlaps with informal medical use. It found that 10% of male members (accounting for 70% of overall users) cited therapeutic purposes, while around 50% of female users reported cannabis use for menstrual pain (Burgen, 2020). These data illustrate the wide range of self-medication practices that occur outside medical oversight.

These tolerated grey zones coexist with large-scale illicit production. Spain accounted for 68% of EU cannabis resin seizures, 73% of cannabis plant seizures, and nearly a third of herbal cannabis seizures in 2023 (EUDA, 2025). Data from the High Court of Justice in Andalucia suggests that production is increasingly tied to organised crime, which exploits undocumented labour and launders money through cannabis operations (Finch, n.d.).

## Recent Developments

In early 2025, media reported that medical cannabis might be regulated by the summer. On 7 October 2025, the official green light was announced with the approval by the Council of Ministers of the "Royal Decree regulating the use of magisterial formulas made from standardised preparations of cannabis for medicinal use".

The Decree allows physicians working in hospitals to prescribe individualised cannabis preparations. Prescriptions containing more than 0.2% THC are subject to additional inspection, and all standardised preparations are to be recorded in a public registry managed by AEMPS. The Decree, however, does not establish a defined list of medical conditions for which cannabis may be prescribed. Instead, AEMPS is expected to issue and update monographs in the National Formulary within three months, outlining approved clinical uses, dosage parameters, and prescribing conditions. This structure could lead to uncertainty regarding the scope of authorised use and the criteria for medical justification (Ministerio De Sanidad, 2025).

The health authorities underlined that this measure should not be interpreted as a step towards non-medical legalisation, insisting that patient safety and medical integrity remain priorities (Mokrani, 2025). However, given Spain's longstanding tolerance of informal consumption through cannabis social clubs, its role as a major producer and exporter, and the missing defined list of medical conditions, only time will tell whether a clear separation between medical cannabis and non-medical cannabis will be established.

# Cannabis Industries and their Perspectives on Medical Cannabis in Europe

While various international cannabis companies are currently active in the European medical cannabis market, their strategies vary. To understand their scope of activities, perspectives, business models, and future investments in Europe, the major companies mentioned earlier in the report are discussed in more detail. Three broad approaches can be identified: pharmaceutical-aligned firms, export-oriented producers, and dual-market operators.

## Pharmaceutical-aligned firms

Some companies explicitly distance themselves from the non-medical cannabis industry, framing their operations strictly within pharmaceutical and medical parameters.

- **Bedrocan** (Netherlands) positions itself as a pharmaceutical supplier, producing raw materials and active ingredients to GMP standards. It has consistently rejected involvement in the non-medical cannabis debates, arguing that the two markets are fundamentally incompatible (Bedrocan, n.d.).
- **Panaxia** (Israel) markets itself as a 'medical innovator', focusing on pharmaceutical development and maintaining a product-focused rather than policy-focused profile (Panaxia, n.d.).
- **Stenocare** (Denmark) supplies prescription-based cannabis oils within Denmark's pilot programme and other Northern European markets. Its product portfolio emphasises controlled formulations rather than plant-based forms (Stenocare, n.d.).

## Export-Oriented Producers

A second group sees Europe primarily as an export hub or growth market, taking advantage of favourable production climates and regulatory openings.

- **Linneo Health** (Spain) supplies medical cannabis to, e.g., Germany, the UK, Israel, and Italy. It emphasises the "untapped potential" of the European market, noting that even Germany has low patient penetration compared to North America. The company does not take a position on non-medical legalisation but expresses concerns that patient rights may be undermined in policy shifts (Linneo Health, 2023).
- **Little Green Pharma** (Australia) exports to European markets, presenting Europe as a strategic growth area due to emerging legal frameworks and increasing

demand. Like Linneo, it highlights opportunities but has not engaged [publicly] in conversations about non-medical cannabis (Little Green Pharma, n.d.).

These companies seem to be largely motivated by future-proofing, establishing presence now in anticipation of broader reform.

## Dual-Market Operators

The third group comprises companies active in both medical and non-medical cannabis globally, but which adapt their European presence to the medical framework.

- **Aurora** (Canada) initially focused heavily on non-medical markets (Aurora Cannabis Inc., 2024), but shifted strategy after steep decline in Canadian sales (-45%). Its CEO described the medical business as "the most exciting and potentially profitable piece" of the industry, with Europe central to this pivot (BOFC, 2021). In 2025, they announced a 37% increase in net revenue, especially "driven by strong medical cannabis sales in Europe, Australia, Poland, and the UK" (Polczer, 2025).
- **HEXO** (Canada), which acquired Zenabis in 2021, remains primarily focused on non-medical sales in Canada. However, it has started to position itself in the European medical cannabis market (Leafly, n.d.).
- **Tilray** (Portugal, Germany, Canada) has established GMP-certified facilities in Portugal and distributes across Europe. In Italy, it works through FL Group, a pharmaceutical distributor (Tilray Medical, n.d.). While it operates in the non-medical market in Canada, its European strategy is framed as strictly medical. The company has not issued public criticism or support for non-medical legalisation in Europe (Tilray Brands, 2024). Nevertheless, their economic interest cannot be denied as they faced a direct drop in stocks after the German elections in February 2025 since the CDU-chancellor opposed non-medical cannabis (Moreno, 2025).

Dual-market operators highlight the possible overlap of medical and non-medical cannabis. While they publicly frame their European presence as medical, their broader corporate structures depend on non-medical markets abroad, which could influence their positioning and advocacy in Europe.

# Concluding Remarks

**It is safe to say that the current landscape of medical cannabis regulation in Europe is fragmented, shaped by divergent national approaches in the absence of a coherent EU-level framework.**

A core challenge lies in the lack of a consistent definition and distinction between cannabinoid-based medicines and medical cannabis. In this report, a distinction has been made between **cannabinoid-based medicines**, which undergo formal clinical trials and often receive EMA approval (such as Sativex, Dronabinol, Epidiolex, and Nabilone), and **medical cannabis**, which more broadly includes unlicensed preparations such as dried cannabis flowers. The absence of a harmonised definition contributes to inconsistent national policies, uneven implementation, and confusion across the healthcare landscape. Notably, the European Parliament's 2018 resolution (2018-2775 RSP) calling for such a definition has not been acted upon.

Over the past decade, more Member States have moved to regulate medical cannabis. In some cases, pilot programmes were introduced, with varying outcomes. Denmark, for example, saw an increase in medical cannabis patients and announced the introduction of a permanent framework in 2026, while evaluation reports had highlighted that no new knowledge was obtained during the trial phase on the efficacy or safety of the cannabis products used in the scheme. France, by contrast, has faced declining participation due to adverse effects, lack of efficacy, and patient dropouts. Yet, it is preparing to transition to permanent regulation.

Similar results emerged from studies in Germany, where one-third of patients discontinued treatment within a year due to poor outcomes. Despite these concerns, most countries are moving towards broader regulation. This raises the question of whether evidence is truly the primary driver. For example, cannabis flowers, criticised by physicians as medically unnecessary outside palliative care, remain dominant in countries such as Germany, the Netherlands, the UK, and Malta – while France has already announced their exclusion from its future framework. This uneven reliance on cannabis flowers reflects not medical consensus but differing national choices and, in some cases, economic motivations.

**Physician involvement has been a recurring point of contention. In several countries, doctors have criticised inadequate guidelines, insufficient training, or open-ended prescribing frameworks that leave them vulnerable to patient expectations.**

In Germany, broad definitions of eligible conditions have created one of Europe's most liberal markets, while in Slovenia, medical cannabis can now be prescribed by any doctor, raising concerns about oversight. By contrast, countries such as France, and also Spain, have restricted prescribing to trained hospital physicians yet face criticism by the cannabis industry that this model limits access.

Simultaneously, physicians express their fears regarding the risk of medical cannabis being a precursor to non-medical legalisation. Indeed, in Malta, Germany, and possibly, Slovenia, the introduction of medical cannabis has been followed by non-medical legalisation.

Where medical and non-medical frameworks overlap, legal grey zones have emerged. In Spain, for example, cannabis social clubs and tolerated home cultivation blur the lines between non-medical and self-medication, even as the country remains a major exporter without a domestic medical framework. Although a change was introduced in October 2025, its effect is unknown. In the Netherlands, many patients reportedly turn to non-medical cannabis instead of navigating the medical channel, largely to avoid costs.

**Germany's recent legalisation of non-medical cannabis has triggered its own set of complications: new digital platforms now offer fast-track prescriptions in ways that critics, including voices within the medical cannabis sector, see as exploiting regulatory loopholes.** Although for different reasons, the latter two countries seem to be reshaping aspects of their frameworks, whether in cultivation, distribution, or prescription protocols. The Netherlands has announced that it will change its medical cannabis framework in 2027 while cancelling its contract with their producer in 2026. In Germany, on the other hand, the Federal Cabinet has very recently approved the amendment to ban cannabis-flower prescriptions without an in-person consultation, to stop the influx of 'medical' cannabis users, which still awaits approval from the Parliament, a step that Poland has already undertaken.

It is to be noted that economic incentives play a strong role in shaping national strategies. Spain, Portugal, and the UK have become major exporters, with Spain and the UK doing so despite not regulating domestic medical cannabis. Very recently, Spain announced that it had given the green light to medical cannabis, but the details have yet to be defined. Malta has openly positioned itself as a hub for cultivation and export, but transparency around patient access or public health impact remains limited. Such dynamics invite broader concern that commercial ambitions, rather than patient-centred care, are driving regulation.

These tensions are mirrored within the industry itself. Some companies, such as Bedrocan and Linneo Health, restrict themselves to pharmaceutical-grade medical products and argue for stricter standards. Others, notably Canadian multinationals like Aurora, HEXO, and Tilray, operate across both medical and non-medical markets, raising questions about conflicts of interest and the influence of dual business models on European regulatory debates.

**To conclude, a coherent definition and harmonised framework distinguishing cannabinoid-based medicines from medical cannabis is required in Europe.** Without such clarity, fragmented policies will continue to blur boundaries between medical and non-medical, undermining medical integrity. A stronger emphasis on evidence-based evaluation, rather than economic or political considerations, is essential to ensure that medical cannabis regulation serves public health rather than commercial or ideological interests.

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The term ”medical cannabis” is used widely – but rarely with a shared definition. This ambiguity has allowed commercial interests to shape how cannabis products are developed, marketed, and regulated, often at the expense of public health.

This report examines how medical cannabis is defined, regulated, and applied across Europe. It maps a fragmented landscape in which vague definitions, inconsistent national frameworks, and strong economic incentives have created legal grey zones – blurring the line between medicine and market.

Drawing on case studies from the Netherlands, Germany, Italy, Portugal, Malta, Denmark, France and Spain, the report shows how loosely regulated medical cannabis frameworks can serve as pathways to broader commercialisation, while patients and public health priorities are sidelined.

The conclusion is clear: evidence-based standards for safety, efficacy, and prescribing must apply equally to all medicines – including those derived from cannabis. Medical decisions should not be shaped by a profit-driven industry.

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