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# Key elements of legal environments for medical use of cannabis in different countries

## Introduction

Cannabis has always been a subject of public interest. Its use has a long tradition in different parts of the world. Particularly, different pharmacological effects have been observed, and because of narcotic effects, policies were developed to clarify its legal status. The general approach has been to classify cannabis as a narcotic drug and to prohibit any use or at least define restrictive conditions of use. Although some knowledge has been generated with respect to the natural constituents of cannabis and its biological effects, data are very limited on medicinal use in compliance with current standards and requirements for medicinal products. Specifically, some court cases in Member States of the European Union have attributed a high priority to the option of medical use of cannabis by individual patients, even where there is no marketing authorization in place for such a product. This article highlights recent developments to create regulatory strategies and environments for cannabis flowers and cannabis-derived products for medical use. Recreational use is not addressed.

The Netherlands was the first Member State of the European Union, to create a government agency to control growth and distribution of medical cannabis. The particular example of the Netherlands and further selected examples from the European Union and other countries are presented to highlight current approaches. The development is highly dynamic, and this article can present only a snapshot and identify key elements that must be taken into account when creating or optimizing legal frameworks on cannabis for medical use.

## Basic regulations on cannabis for medical use

There is a unique document that defines the international regulatory framework on narcotic drugs: the "Single Convention on Narcotic Drugs", which was released by the United Nations in 1961 and amended in 1972 [1]. The objective was to lay down the principles of control of narcotic drugs for medical and scientific use in a single convention, instead of having different bilateral or multinational treaties. The requirements of a system of control for cultivating the cannabis plant for the production of cannabis or cannabis resin are addressed in article 28, and those for the control system for the opium poppy are laid down in article 23 (**Infobox 1**). Misuse of the leaves of the cannabis plant and illicit traffic should be avoided. The Single Convention does not cover cultivation of the cannabis plant exclusively for industrial purpose (fiber and seed) or horticultural purposes. The core element of the control system is the establishment of a national agency, which is responsible for making contracts for cultivation within the country and which must purchase the material after its harvest. The Single Convention clearly sets a framework and defines the national responsibility for establishing a control system if cultivation is allowed. However, the framework is rather broad, and it is up to the countries to implement detailed and specific regulations at the national level. With respect to different cultures, national policies, and strategies, the developments in different countries have been quite diverse based on different interpretations of the wording of the Single Convention.

The International Narcotics Control Board (INCB) is the independent monitoring body for implementation of the United Nations international drug control conventions [2]. Established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961, the INCB is located at Vienna, Austria. It is an important platform for communication and information exchange about the results of monitoring the implementations of the requirements laid down in the Single Convention on Narcotic Drugs. The INCB can support national activities; however, options for enforcement are limited because details of the regulatory frameworks on cannabis are decided at national levels.

## Long-standing experience with regulation of cannabis for medical use in the Netherlands

What most people do not know is that besides recreational cannabis, medicinal cannabis has been available for patients via pharmacies in the Netherlands for over 15 years.

The Netherlands first developed a policy on medicinal cannabis in 1998, which had the objective of cultivating cannabis to meet pharmaceutical quality standards

**Infobox 1** Citations from the Single Convention on Narcotic Drugs [1] referring to cannabis

**Article 23**
National Opium Agencies:
*"(1) A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article. …"*

**Article 28**
Control of cannabis:

1. *"If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy."*
2. *This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.*
3. *The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant. …"*

and to make that cannabis available for research and product development as an authorized medical product. In 2001, the Netherlands changed its policy on medical cannabis to also make it available to patients with a prescription [3].

This change in policy resulted from political and social pressures. In particular, patients seeking cannabis for medical purposes were purchasing it from the so-called coffee shops. Although coffee shops are tolerated in the Netherlands for selling very limited amounts of cannabis for recreational use, they are prohibited from selling it as medicine. This is because the cannabis sold by coffee shops is not subject to any quality control. Moreover, patients who purchase cannabis from coffee shops for medicinal use have most likely not received any medical counseling about it. Therefore, the Netherlands believed that making a cannabis product available that met pharmaceutical quality requirements and standards and that could be obtained only by patients with a prescription would result in—at least to some degree, it was assumed—fewer risks to health.

To meet the requirement of the Single Convention, in 2000 the Netherlands created the governmental Office for Medicinal Cannabis (OMC), which is a part of the Dutch Ministry of Health, Welfare and Sport and has acted as the national office since January 2001. On September 1, 2003, the OMC started delivering medicinal-grade cannabis to patients for medical use through pharmacies.

The responsibilities of the OMC are set out as follows:

a. To ensure the production of a consistent quality of medicinal cannabis in the Netherlands, which meets pharmaceutical standards;
b. To establish an effective procedure for distribution of medicinal cannabis;
c. To prevent diversion to the criminal circuit, for example by implementing procedures for tracking and record keeping; and
d. To ensure the availability of medicinal cannabis.

In 2001, around the time the OMC became operational as a national agency, a guidance committee with internal and external members from different disciplines was established in the Netherlands. The purpose of this committee was to assist and advise the OMC on various issues, including making amendments to the Netherlands' Opium Act and contacting pharmaceutical and other companies as well as patient organizations. When the OMC first started making medicinal cannabis available to patients through pharmacies in 2003, patients and growers in the illegal circuit raised complaints and lobbied against the OMC's products. In the first few years, the image of the OMC and its products was very negative, and barely 600 patients enrolled in the program despite the OMC's research showing the number of potential patients to be about 10,000. However, this negative image changed over time as doctors gained more knowledge about medicinal cannabis and patients tried the product, which many were willing to do because it was available in the same way as other medications (i.e., by way of prescription from a doctor and dispensed by pharmacies).

Nonetheless, the fact that cannabis in the Netherlands is available in coffee shops (even though the quality of coffee-shop cannabis is incomparable to the quality of medicinal cannabis) means it is easier for some patients to buy cannabis there rather than through pharmacies. This is because patients buying coffee-shop cannabis do not need to speak with a doctor in order to obtain it. Also, if patients' medicinal cannabis is not covered by their health insurance, they can go to a coffee shop and obtain recreational cannabis on discount. However, at this time the cost of medicinal cannabis available by prescription in a Dutch pharmacy (€5.80 per gram) is significantly lower compared to the nonstandardized and uncontrolled recreational cannabis available in coffee shops (>€7.50 per gram).

Currently, it is permitted to prescribe medicinal cannabis only in the form of dried inflorescences (i.e., dried flowers), but Good Manufacturing Practice (GMP)-approved pharmacies are allowed to prepare an oil of it for the patient. Each doctor in the Netherlands is permitted to prescribe medicinal cannabis, and for any medical condition.

## Prescription of medicinal cannabis

In the Netherlands, physicians and general practitioners strongly adhere to general guidelines. These protocols are evidence based and developed by scientific societies after consultation and review of results obtained from clinical studies. Physicians prescribe only if the patient's regular pharmacotherapy is insufficient or is producing too many side effects. In the period 2006–2018, a steady increase in the number of patients using medicinal cannabis was observed [4]. Independent researchers thoroughly analyzed prescription data on medicinal cannabis used by Dutch patients, which was obtained from the Dutch Foundation for Pharmaceutical Statistics (in Dutch: SFK), an independent organization collecting detailed information from community pharmacies and covering over 90% of all prescriptions dispensed in the Netherlands. The results of this study showed that the individuals in the main patient group using prescribed medicinal

cannabis were aged 40–60 years and consumed an average daily dosage of 0.73 g, which did not change much over time.

The OMC is not involved in prescribing or dispensing medicinal cannabis to Dutch patients as such, and it does not maintain its own records concerning the therapeutic indications for which medicinal cannabis is prescribed. **Fig. 1** indicates how the OMC organizes the production and distribution process.

## Growers

In the Netherlands, medicinal cannabis is grown by a professional company according to the current European directives for herbal medicines. This is a requirement in order to obtain a standardized product that meets the stringent pharmaceutical quality requirements; a standardized product can be achieved only if the whole process of cultivation is fully controlled. Therefore, the production process has to comply with GMP pharmaceutical standards. All of the different steps within the production process, including harvesting, drying, processing, and packaging, need to adhere to the protocol. After harvesting, the plants are dried for several days in a separate room before further processing takes place. The small leaves are picked from the flower tips in a special clean room. Next, the flower tips are cut to a specific size or are granulated (finely grinded). This varies with the type of medicinal cannabis.

Bags of 400 g are filled before transportation to the packaging company. After each harvest, an OMC employee visits the grower for sampling and collection. He or she weighs the harvest, checks its appearance, and prepares a sample for inspection by the laboratory.

The grower is contracted via a European tender.

## Laboratory

To ensure that all current quality requirements have been met, the medicinal cannabis is tested by an independent laboratory contracted by the OMC. This is done for two reasons.

1. The medicinal cannabis is tested for levels of active ingredients and for the presence of unwanted substances such as heavy metals, pesticides, and microorganisms.
2. The cannabis is tested for moisture content.

Under the authority of the OMC, the contracted laboratory formulates an analytical monograph. This demonstrates that all analytical methods were validated and tests were performed in compliance with the "Good Control Laboratory Practice" as defined in the GMP guide to "Good Manufacturing Practice for Medicinal Products" in the European Union. In this way, the stringent quality checks of medicinal cannabis are comparable to requirements for other (herbal) products used as pharmaceutical products. Each batch of cannabis produced is analyzed, and the results are incorporated in a release certificate composed by the OMC pharmacist. This certificate is placed on the OMC's website and is

## Abstract · Zusammenfassung

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### Key elements of legal environments for medical use of cannabis in different countries

**Abstract**

Worldwide, a highly dynamic development of regulatory strategies for cannabis flowers and cannabis-derived products for medical use can be observed. Conditions laid down in the Single Convention on Narcotic Drugs are basic, and implementation in countries is diverse.

As early as 1998, the Netherlands was the first Member State of the European Union (EU) to establish a strategy to provide patient access to cannabis for medical use. Since then, more and more Member States of the European Union have facilitated access to cannabis for medical use. A comparable development has taken place outside Europe. This article describes the current situation in the Netherlands and presents selected highlights of developments within and outside Europe to demonstrate the broad spectrum of strategies. Key parameters are identified that should be considered when changing or amending regulatory frameworks on cannabis for medical use. In addition to the establishment of adequate regulatory frameworks, there is a substantial need to generate adequate scientific data.

**Keywords**

Cannabis flowers · Single Convention · Regulatory framework · Data monitoring · INCB

### Schlüsselelemente der rechtlichen Rahmenbedingungen für die medizinische Nutzung von Cannabis in verschiedenen Ländern

**Zusammenfassung**

Weltweit gibt es eine sehr dynamische Entwicklung hinsichtlich der gesetzlichen Regelungen zu Cannabisblüten zur medizinischen Verwendung und zu weiteren Cannabis-basierten Arzneimitteln. Die Festlegungen im Einheitsübereinkommen für Betäubungsmittel sind vergleichsweise allgemein und die Umsetzung in nationale Gesetze wird unterschiedlich gehandhabt. Die Niederlande waren der erste Mitgliedsstaat der Europäischen Union, in dem bereits 1998 eine Strategie entwickelt wurde, um Patienten einen vereinfachten Zugang zu Cannabis zur medizinischen Verwendung zu ermöglichen. Seitdem fanden in anderen Mitgliedstaaten zunehmend ähnliche Entwicklungen statt. Dieser Artikel beschreibt die gegenwärtige Situation in den Niederlanden. Ausgewählte Aspekte der Entwicklungen innerhalb und außerhalb Europas werden vorgestellt, um die unterschiedlichen strategischen Ansätze darzustellen. Wichtige Schlüsselelemente werden identifiziert, die berücksichtigt werden sollten, wenn Änderungen oder Ergänzungen gesetzlicher Regelungen zu Cannabis zur medizinischen Verwendung vorgenommen werden. Darüber hinaus besteht die dringende Notwendigkeit angemessene wissenschaftliche Daten zu generieren.

**Schlüsselwörter**

Cannabisblüten · Einheitsübereinkommen · Gesetzgebung · Begleiterhebung · INCB

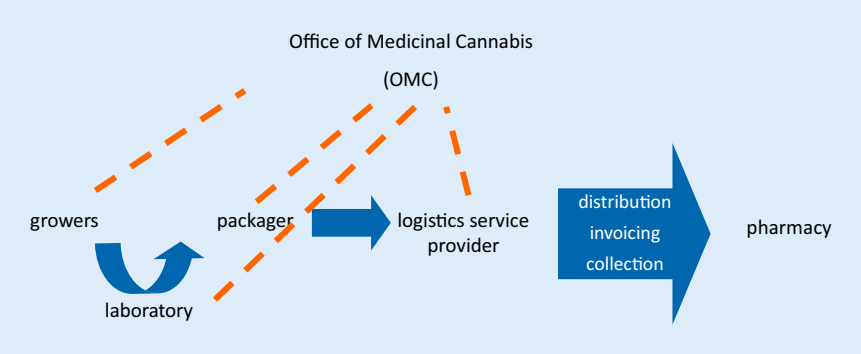


**Fig. 1** ▲ Production and distribution process for medicinal cannabis in the Netherlands, regulated by the Office for Medicinal Cannabis (*OMC*). *Blue arrows* demonstrate the flow, and *dashed lines in orange* indicate the OMC's different contract partners

available on request to doctors and pharmacists. If a batch does not comply, it will not be released for patient use.

Currently, a working group of the European Directorate for the Quality of Medicines and HealthCare is writing a cannabis monograph for the European Pharmacopoeia, for which the Dutch monograph is one of the documents being consulted.

### Packager/logistic service provider

Once the laboratory has approved the medicinal cannabis, the batch is sent to the irradiation company. The product is then irradiated with gamma radiation in the same way that fruits and vegetables are irradiated. The batch of 400-g bags is then sent to the packaging and distribution company, where the product is packed manually in portions of 5 g by specialized employees in rooms that have been made suitable for the process. The 400-g bags are also stored there. Every few weeks an OMC employee visits the packager; he or she weighs the 5-g containers and checks the labels and total amount. The company receives the orders from the pharmacies and takes care of the delivery and invoicing.

### Information for healthcare providers

For a long time, the therapeutic use of medicinal cannabis was controversial in the Netherlands. Even now prescription of medicinal cannabis by physicians and general practitioners is rather uncommon, and many are not familiar with it. In addition, it is not part of their academic education. Therefore, the OMC together with the Dutch organization IVM have developed learning modules focused on healthcare providers to increase their knowledge about the position of medicinal cannabis within pharmacotherapy and how to advise patients in its use. A special module on medicinal cannabis is available, as well as a pharmacotherapeutic module with background and practical advice. These tools can be used for mutual consultations to formulate agreements about how to counsel patients. A leaflet for healthcare providers as well as for patients is available, which provides the most important information concerning the different varieties, routes of administration, and main side effects. More specific information and answers to questions can be obtained by phone or e-mail.

### Reimbursement

Up to now, medicinal cannabis has not been part of the standard package of medical insurance in the Netherlands, meaning that it is not automatically reimbursed. Over the years several health insurers have offered the possibility of additional insurance, or they reimbursed via a leniency arrangement. In 2017 the National Health Care Institute did a literature survey on the therapeutic effect and efficacy of preparations containing cannabinoids and reported many methodological shortcomings of the clinical studies reviewed. For instance, the studies were too small, were not placebo-controlled, or included follow-up that was too short (although treatment with medicinal cannabis is often chronic). Furthermore, only a few clinical studies were designed in conformity with modern standards of clinical research. The Institute concluded that there is insufficient clinical evidence for therapeutic effectiveness of medicinal cannabis at this time. With this in mind, the OMC concentrates more on facilitation of clinical studies with medicinal cannabis in the Netherlands. In that respect, it is important to mention that placebo–cannabis is available to perform placebo-controlled clinical trials. Placebo–cannabis contains the original constituents (e.g., terpenes) with the exception of the cannabinoids, which have been extracted.

## Selected highlights of recent developments in Europe

The option of giving access to cannabis for medical use has been increasingly discussed in Member States of the European Unionover the past two decades [5]. In addition to the development in the Netherlands, which is described in detail in the section above, other Member States have modified or are discussing modification of their national provisions defining the framework on cannabis for medical use. An important incentive to this development has been court decisions that emphasized individual rights of patients. Accordingly, there is an overall tendency to move from full prohibition of cannabis for medical use to exceptional-access programs or programs offering facilitated access. This process is highly dynamic.

In most Member States of the European Union marketing authorization has been granted for an herbal medicinal product having a standardized herbal preparation from *Cannabis sativa* L., called nabiximols. In addition, marketing authorizations may be available for medicinal products with chemical ingredients.

In *Austria* the national agency, in accordance with the Single Convention on Narcotic Drugs, has been established at

the Austrian Agency for Health and Food Safety (AGES) [6]. Since 2008 AGES has been cultivating cannabis, which is sold to pharmaceutical companies for production of purified constituents, particularly dronabinol. Prescription of cannabis for medical use is not allowed. Interestingly, in contrast to other countries, seeds or plantlets of cannabis with or without very low amounts of tetrahydrocannabinol (THC) can be purchased and grown at home without major restrictions.

An important change in the regulatory framework on cannabis for medical use was implemented in *Germany* in 2017 [7]. Until then, a court decision had allowed exceptional licenses to be granted to individual patients. The new legislation allows prescription of cannabis and cannabis-derived medicines in cases of severe illnesses under specific conditions. The prescribing physician is responsible for determining appropriate indications and dosages. The costs are reimbursed by the public healthcare insurance system. Noninterventional data monitoring was set up for a period of five years, and a national cannabis agency was established at the Federal Institute for Drugs and Medical Devices, which is obliged to control cultivation, production, and distribution of cannabis for medical use under the rules of laws of procurement. Currently, there is an ongoing tender to identify contract partners for cultivation and production of cannabis flowers of pharmaceutical quality.

In *Denmark* and *Poland*, legal changes were adopted in 2018 that define exceptional-use programs for medicinal cannabis [5, 8]. *Portugal* decided to strive for an expanded-access program. In Denmark and Portugal, the cultivation of cannabis for medical use has been initiated as a pilot project [5]. The public pressure for changes and the intense dynamic of the development can also be demonstrated by looking at the very recent developments in the *United Kingdom* and *France* [9, 10]. In the past, laws in both countries were rather restrictive, and no prescription of cannabis was allowed. Now, as of November 2018, physicians in the United Kingdom have been permitted to prescribe it for distinct medical conditions. In France, the government has asked an expert group for an opinion about the future regulatory framework on cannabis for medical use.

There is no formal harmonization on a detailed regulatory framework for medical cannabis in the European Union. However, there is obviously co-evolution, which is resulting in modifications of existing legislation and improved access for patients to cannabis for medical use. Within the European Union network on medicinal products, there is increasing dialogue about the ongoing developments.

In *Switzerland* authorities intend to implement new legislation on cannabis for medical use in 2019 [5, 11]. Currently, prescription is permitted for authorized medicinal products or magistral preparations on a named-patient basis with an individual license. A regular reimbursement system has not been installed, but a national agency has been established at the Swiss Federal Office of Public Health. It is worth mentioning that in Switzerland, products are covered by the legislation on narcotics only if the THC content is > 1.0% (in the majority of Member States of the European Union the limit is 0.2%). Therefore, in Switzerland an extended portfolio of cannabis-derived food products is on the market.

## Selected highlights of developments outside Europe

In the *United States of America* discussions to reconsider complete prohibition of cannabis and initiatives to modify legislation started as early as the mid-1990s. Since then, rather liberal approaches to the regulation of cannabis, including recreational use, have been implemented in some states. However, the federal laws have not followed this development. Because federal laws take precedence over state laws, the situation is complex, and a general description cannot be given [12]. The status of cannabis may be different at state level, and it must be taken into account to what extent any deviations from or violations of federal law are tolerated.

An interesting example is the evolution of the regulatory framework on cannabis in *Canada* [13]. A new national approach was created in 1999, when court decisions demanded individual patient access to cannabis for medical use. At that time a rather restrictive individual exceptional-access scheme was implemented. This system was changed to a facilitated-access program when patient numbers were substantially increasing. Health Canada, which hosts the national agency in compliance with the Single Convention on Narcotic Drugs, granted licenses for the cultivation, production, and distribution of cannabis for medical use. This legislation allowed patients to purchase cannabis for medical use directly from licensed producers. It was reported that in 2018 more than 140,000 people were making use of this scheme. In October 2018, legislation came into force that also defined a liberal approach for recreational use. This step also took into account the general policy and strategy on narcotics such as cannabis and the attempt to seek alternative schemes for control.

*Israel* is also among those countries that put a special focus on cannabis for medical use and has supported, for example, research programs related to cannabis [14]. The current regulatory framework on cannabis for medical use was mainly implemented in 2016. This regulatory framework tries to define clear regulation, including rules for prescription, clinical practice, indications, contraindications, growers, and pharmacies. The responsibility for control was given to the Israel Medical Cannabis Agency, which is installed at the Ministry of Health. Despite existing technology for vaporization of cannabis for medical use, the option of smoking by patients is still accepted.

Special access to cannabis for medical use was legalized under the provisions of the Therapeutic Goods Act in *Australia* in 2016 [15]. Australia is promoting clinical research on cannabis for medical use in order to generate adequate scientific data. At state level, the federal law has been amended to set particular rules, such as those concerning cultivation, thereby contributing to a diverse and complex framework.

## Key elements of legal environments on cannabis for medical use

Based on the Single Convention for Narcotic Drugs, countries have established regulatory frameworks at the national level. The variety of existing strategies is a result of different historical, social, political, and strategic approaches. The value of scientific knowledge may be a part of decision making, but it usually does not represent a major driving force. Because of the different perspectives at the national level, there is no common view on a best practice. Nevertheless, a set of important key elements can be identified that transfer legal provisions concerning cannabis into a real environment. The following list results from the analysis of developments from the past decade:

- Implementation of the Single Convention on Narcotic Drugs
- Regulations for medicinal products
- Regulations for narcotic drugs
- Provisions defining borderlines between narcotic drugs, medicinal products, and food
- Rules for prescription
- Responsibility for clinical practice
- Routes of administration
- Quality standards
- Cultivation and supply
- Monitoring programs
- Public communication and information
- Reimbursement
- Incentives to generate scientific data

Each of these key elements may include a set of subelements. For example, rules of prescription may define who will be permitted to prescribe cannabis for medical use (either all physicians or only those with specific education), how much cannabis is allowed per patient, whether general recommendations are given on posology and possible indications, and what the limitations are of prescriptions. Reimbursement may be excluded, optional, or regular. In each setting, provisions must be defined and implemented into the national healthcare system. It is beyond the scope of this article to discuss all key elements, subelements, and their relevance in detail. Obviously, all the key elements are not stand-alone parameters. They are mutually dependent and make up a complex and integrative framework.

## Outlook

The dynamic development of regulatory frameworks on cannabis for medical use will continue all over the world during the coming years. Details of implementation of the Single Convention on Narcotic Drugs are designed at the national level. Nevertheless, countries should strive to increase the exchange of information and experiences about their establishment and modifications of a regulatory framework. The analysis of information available will support legislation implementation and optimization according to national policies. Irrespective of any national approach, an important task for the scientific community is to provide more data, which will contribute to appropriate use of medicinal cannabis and a broader portfolio of cannabis-derived medicinal products with marketing authorization in accordance with the European pharmaceutical legislation.


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## Compliance with ethical guidelines

**Conflict of interest** W. Knöss, M. van de Velde, C. Sandvos, and P. Cremer-Schaeffer declare that they have no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies performed were in accordance with the ethical standards indicated in each case.

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