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# Legal aspects of the use of medical cannabis in Poland compared to other countries: Comparative legal analysis

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## Abstract

The importance of this issue is that there is an increasing demand for the use of medical marijuana in treatment where methods based on traditional medicine have failed. The aim of the article is the analysis and evaluation of the legal regulation of treatment with preparations containing medical marijuana in Poland against the background of trends in other countries. The study employs a dogmatic and black-letter methods of analyzing the provisions of the law in force in Poland and also a comparative method. Studies have shown that the systems of countries in Europe and the world vary in this regard. When it comes to the medical use of marijuana, three solutions are possible: a liberal model, where the patient can grow the plant himself, a moderate model, which relies on the possibility of obtaining a drug based on medical marijuana with a prescription. The third model is based on the impossibility of medical use of marijuana. The Polish legal model is moderate and consists of the possibility of obtaining a medical marijuana-based drug by prescription. Independent cultivation under this model is not possible. A business entity that intends to cultivate cannabis for medical purposes must have the appropriate permit from the competent state authority. This solution (present in many other countries) is characterized by a balance between legalization of medical marijuana and drug prevention. Under the Polish legal model, cannabis cultivation remains under state supervision. Medical marijuana is available to the patient, but access to it is strictly regulated. This is not a liberal legalization model, as availability depends largely on the doctor. Practical results show a progression in the availability of medical marijuana medicines compared to previous years. The legislature is open to change, but out of caution against the proliferation of drug offenses, it has not decided on greater liberalization

## Keywords:

law; medical marijuana; legalization; treatment; the Polish legal system

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## Introduction

The Polish legal provisions allow to use of medical cannabis-based drugs for treatment, which coincides with European- and worldwide trends. Cannabis, being one of the oldest medicines, has a long, millennia-long history (Nutt, 2019). Medications based on cannabis have been used for therapeutic purposes in many cultures. There is now clear evidence that cannabinoids are useful for the treatment of various medical conditions (Grotenhermen & Müller-Vahl, 2012). Over 30 countries internationally have legalised medical cannabis. Medical use can also be found in Argentina, Colombia, Mexico, Chile, Peru, Jamaica, and Uruguay. Commercial drugs based on cannabis are available in the European countries: Netherlands, Great Britain, Germany, Czech Republic etc. International law, mainly from the perspective of human rights obligations, also allows for the legalization of cannabis. Research suggests that given these positive human rights obligations states may be required to introduce controlled legalization of cultivation and trade of recreational cannabis if such a regulation contributes to the protection of human rights more effectively than absolute prohibition of narcotic substances, as provided for in UN drug conventions (Van Kempen & Fedorova, 2019).

Meanwhile, in federal countries, individual states have their regulations on the use of medical marijuana. The leader in legalizing medical marijuana is undoubtedly the United States. A study in the United States shows that medicinal cannabis in some form is legal in 47 states, the District of Columbia, Guam, the United States Virgin Islands, and Puerto Rico (Ryan *et al.*, 2021). A wide-ranging context can be found in the study by F. Baratta *et al.* (2022). The authors analyse legislation in countries that permit the use of medical marijuana concerning the impact that this legislation has had on clinical trials. The study points to a variety of guidelines for the use of medical marijuana in the treatment of various diseases, including varieties, forms of administration and treatment methodologies.

Since this article deals with Polish law, it is worth pointing out the state of research studies in Poland. First of all, it should be noted that the literature on Polish law on this subject is not extensive. M. Kuna (2019) made several terminological remarks. The article extensively discusses the institution of so-called “target import”, which was the only method of procuring medical marijuana-based medicine in Poland before 2017. The current article broadens the perspective to the period from 2017 and includes legal comparative threads. A slightly earlier study A. Habib (2016) addressed the aforementioned terminological comments and noted the distinction between tetrahydrocannabinol (THC) and cannabidiol (CBD). The author’s study devotes

considerable devotion to non-legal issues regarding the legalization of medical marijuana in public opinion, including that of doctors and patients and the Helsinki Foundation for Human Rights. J.E. Król-Ćalkowska & J. Jaroszyński (2023) attempted to answer the question of whether the use of medical marijuana in terminally ill patients is akin to medical experimentation, or whether it represents the patient’s right to health services based on the latest medical knowledge and pain management.

At this point, it is necessary to establish that, in the light of Polish law, medical cannabis is understood as “non-fibrous hemp herb and pharmaceutical extracts, tinctures, as well as all other non-fibrous hemp extracts and non-fibrous hemp resin...”, referring to in Article 33a of the Act of 29 July 2005 on Counteracting Drug Addiction<sup>1</sup>. Thus, the issue of fibre hemp was not studied. Medical cannabis also includes cannabis in its subject scope (*Cannabis indica* Lam.) and wild hemp (*Cannabis ruderalis* Janisch). Generally, their cultivation in Poland is prohibited (Article 45(4) of the Counteracting Drug Addiction (CDA)<sup>2</sup>. However, it is clear from the wording of Article 33a(1) of the CDA that the legislator allows to use of cannabis herb other than fibre, as well as extracts, pharmaceutical tinctures and resin, as pharmaceutical raw material intended for the preparation of prescription drugs<sup>3</sup>. This is a giant step by the Polish legislators towards ensuring the possibility of treatment with medical marijuana-based drugs. Thus, it is a step which brings Poland closer to European and world trends in this respect.

The research aims to analyse and evaluate legal regulations regarding treatment with medical marijuana preparations in Poland against the background of solutions functioning in this regard in other countries. The research carried out in this article concerns Poland, a unitary state with uniform laws throughout the country. Dogmatic and black-letter methods, consisting of the analysis of the provisions of the law in force in Poland, including the Constitution of the Republic of Poland and laws, were used. An analysis of the current legal status of the use of medical marijuana in Poland was made with its help. The Constitution of the Republic of Poland was used as an information base, which was used to highlight the axiological justification of the issue under consideration. This has shown that the constitutional right to health can be realized by other than conventional methods of treatment. The article also uses a comparative method, which was used to show the Polish model in comparison with the models of other countries in Europe and the world. The use of the comparative method showed a broader perspective of the studied issue, seeing the advantages and disadvantages of the approaches adopted in Poland.

<sup>1</sup> Law of Poland No. 2005-VII “On Counteracting Drug Addiction”. (2023, January). Retrieved from <https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20051791485>.

<sup>2</sup> Ibidem, 2023.

<sup>3</sup> Ibidem, 2023.

## The axiological and systemic conditions and the two stages in the development of the legal regulation in Poland

The Polish legal system, in which the possibility of treatment with medical cannabis drugs exists, is characterised by openness, recognising the patient's right to seek treatment methods other than those generally recognised by the state. At the same time, the introduction of this possibility goes beyond the traditional model of the provision of medical care by the state, which depends solely on the market for medicines. It requires a value judgement between the guarantee of the right to health protection and to obtain health services by current medical knowledge and the corresponding rights and duties of the physician, and the necessity to carry out activities in the field of supervision of medical safety and counteracting drug addiction. For decades, the world has collectively prohibited or controlled access to some drugs including marijuana. Those kinds of issues occur in other countries, e.g., in Canada (Hoffman & Habibi, 2016).

The new status of medical cannabis in Poland is justified by the right to health protection proclaimed in Article 68 of the Constitution of the Republic of Poland<sup>1</sup> of 2 April 1997. This right is not declaratory in nature and is a "bipolar" right, which means that certain duties, incumbent on public authorities, correspond to it. One of them is the obligation to provide systemic guarantees for the search for and implementation of such methods that the patient would like to use and that, at the same time, are justified by the paradigm of modern medicine. The literature emphasises that medical knowledge is co-shaped by the preferences of patients (Jahnz-Różyk, 2010). The jurisprudence of the Supreme Court also pointed out that "even the criteria of medical expediency do not prejudge the choice of a method of diagnosis or treatment. This choice is determined by the patient's convictions, his or her individual sensitivity (...) other personal characteristics, which he or she gives expression to by expressing his or her opinion" (Judgment of the..., 2003).

As such, the thesis is drawn that the protection of public health is the responsibility of the state authorities, which should create a status of protection for patients considering the highest medical standards, following the current level of knowledge, and considering treatment methods that extend beyond traditional academic knowledge. From an axiological point of view, the use of medical cannabis in Poland for medicinal purposes is supported by the interpretative directive

according to which all possible doubts concerning the protection of human life should be resolved in favour of this protection (*in dubio pro vita humana*). According to the Judgment of the Supreme Administrative Court in Warsaw No. 2404282 (2017), the right to health protection is primarily the right to preserve life and protect it when it is endangered. The Supreme Administrative Court recommends the application of the *in dubio pro vita humana* directive concerning the reimbursement of medicines, in exceptional situations, including in cases where human life or health is at risk. The application of this directive can be extended to legal and factual situations involving the use of medical marijuana.

The legal regulation of the use of medical marijuana in the Polish legal order can be divided into two stages, which are separated on 1 November 2017. On this date, regulations allowing its use for medical purposes entered into force<sup>2</sup>. Initially, the benefits of the introduction of these provisions were illusory, as pointed out by the Ombudsman (RPO: medical marijuana..., 2018), but with them, a sense of security for patients interested in this method of treatment appeared. The undoubted advantage of the legislation allowing the use of medical marijuana is the ability to distinguish its legal possession for medical purposes from common drug offences. Overall, this was a revolutionary change, but if one were to analyse its key aspects in detail, it could hardly be called the 'legalisation of medical marijuana' in the sense that it occurs in other states.

Before 1 November 2017, Polish law did not have much to offer to patients wishing to use medical marijuana preparations. The only way to obtain these drugs was to use the target import procedure, which was provided for in Article 4 of the Act of 6 September 2001 - Pharmaceutical Law<sup>3</sup>. Worth noting that the institution of target import corresponds to Article 5 of Directive 2001/83/EC of 6 November 2001<sup>4</sup> on the Community code relating to medicinal products for human use. According to the document, a Member State may, to meet special needs, exclude medicinal products supplied in response to a bona fide order from the provisions of the Directive. This is done compliant with the specifications of an authorised specialist doctor and under his or her direct personal responsibility.

According to the aforementioned provision, a medicine could be imported from abroad without the need for a marketing authorisation if the use of the medicine was necessary to save the life or health of the patient, provided that the medicine in question was authorised

<sup>1</sup> The Constitution of the Republic of Poland. (2009, October). Retrieved from <https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu19970780483>.

<sup>2</sup> Law of Poland No. 2017-VII "On Counteracting Drug Addiction and the Act on Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices". (2017, June). Retrieved from <https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20170001458>.

<sup>3</sup> Law of Poland No. 2001-IX "Pharmaceutical Law". (2002, November). Retrieved from <https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20011261381>.

<sup>4</sup> Directive of the European Parliament and the Council No. 2001/83/EC "On the Community Code Relating to Medicinal Products for Human Use". (2001, November). Retrieved from <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32001L0083>.

in the country from which it was imported and had a current marketing authorisation in that country. The condition for importing medicinal products necessary to save the patient's life or health from abroad was that the hospital or the treating physician outside the hospital submitted a requisition confirmed by a provincial consultant or a national consultant in the relevant field of medicine. The Minister of Health, according to Article 4(9) p.f. (Masełbas *et al.*, 2016), decided whether or not to grant permission to import a medicinal product from abroad. At that time, this was the only possibility to obtain a medical marijuana-based medicine in Poland. This was very uncomfortable for patients and often prevented them from obtaining the medicine in time, as the need for confirmation by a consultant significantly prolonged the acquisition of the medicine.

### Medical cannabis – current legal aspects compared to models in other countries

A contribution to the change of legislation in Poland was the signalling decision of the Constitutional Tribunal (CT) of 17 March 2015<sup>1</sup>. Which indicated that: “in the light of current scientific research, cannabis can be used for medical purposes (...) from the point of view of a specific group of citizens using health care services, the authorisation of the medical use of cannabis needs to be considered given the therapeutic usefulness of cannabis in certain medical conditions (...)”. The CT noted an inconsistency in the provisions and an unregulated relationship between the fight against addiction and the possibility of medical use of marijuana between “On Counteracting Drug Addiction” and “Pharmaceutical Law”. Balancing these two objectives requires urgent legislative intervention, as CT assessed. In other countries, the medical use of cannabis also remains in an inappropriate proportion to negative phenomena, such as addiction among young people or an increase in the number of road accident victims, as indicated by a study conducted by M. Leyton (2019) on the example of Canada.

In the second and current stage of Polish legal development, the issue of medical use of cannabis remains under special state supervision. Medical cannabis may constitute, based on Article 33a(1) of the CDA, a pharmaceutical raw material intended for the preparation of prescription drugs. This is subject to a special administrative procedure and requires obtaining a permit from the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products issued for a period of 5 years for marketing authorisation. An application for permission to use hemp as a pharmaceutical raw material is submitted to this authority by an entrepreneur or an entity conducting

business in a European Union Member State, the so-called responsible entity. A hemp-based medicine thus acquires the status of a “prescription medicine”. Concerning the form or, more broadly, the technical side of “use”, the manufacture of the pharmaceutical raw material from hemp may be in the form of extracts, or tinctures, but also includes the crushing of dried plant parts and the performance of any physico-chemical operations leading to the substance.

Although Polish statutory regulations in 2017<sup>2</sup> opened the way for the provision of medicines based on medical marijuana, it wasn't possible to acquire them until early 2019, when one company (Spectrum Cannabis) obtained permission to sell the prescription drug, initially in the form of dried cannabis, which came from Canada. The nearly two-year lack of availability of the drug was due to a lack of regulatory provisions. In addition, a weakness of the above-mentioned regulation was the dependence of the possibility of treatment on the price of medicines containing medicinal marijuana. The reimbursement of medicines containing medical marijuana has since faced administrative barriers, as a specialized state body, the Agency for Health Technology Assessment and Tariffication has concluded that in conditions related to chronic pain, reimbursement is not justified due to a lack of sufficient scientific evidence (Recommendation of the..., 2018).

In the Polish legal model, the patient is not allowed to personally cultivate the plant and produce medicine from the harvested raw material for therapy, as is the case, for example, in the Czech Republic, the Netherlands and Belgium. The model for the legalisation of medical cannabis adopted in Poland, as in most European countries e.g., France, Greece, Finland and, from 2018, Portugal, consists of the possibility to purchase the prescription drug. Since 2017, medical cannabis has been allowed in Germany for critically ill patients in whom other therapies have failed. The cost of treatment with this drug is reimbursed by the health insurance funds and the patient does not need to obtain any special authorisation. In Croatia, on the other hand, doctors can prescribe medicines, teas and ointments containing THC – the active ingredient of cannabis – to their patients (Witt *et al.*, 2023).

Lately, legislation reforming the laws regulating the supply of marijuana has already been implemented in some European countries (Hughes *et al.*, 2017). As such, there are states which present an open approach to the question, with the Netherlands, Czechia, Germany, or Italy in the lead. For instance, a more liberal policy including recreational use, prevails in the Netherlands, where cannabis for medical purposes is used by about half a million people, only some of whom have

<sup>1</sup> Judgment of the Constitutional Tribunal No. S 3/15. (2015, March). Retrieved from [https://www.senat.gov.pl/gfx/senat/userfiles/\\_public/k8/komisje/2015/ku/wyroki\\_tk/s\\_03\\_15.pdf](https://www.senat.gov.pl/gfx/senat/userfiles/_public/k8/komisje/2015/ku/wyroki_tk/s_03_15.pdf).

<sup>2</sup> Law of Poland No. 2005-VII “On Counteracting Drug Addiction”. (2023, January). Retrieved from <https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20051791485>.

medical indications (Nationale drug monitor, 2017). Second only to the Netherlands and one of the most liberal countries in this respect is Czechia, which, like the former, has opted for home cultivation of cannabis and marijuana. The Czech Republic's medical cannabis program is one of the oldest in Europe and was the second on the continent (following the Netherlands') to allow home cultivation of cannabis, even though medical marijuana has not been covered by health insurance there to date. Studies indicate that in the Czech Republic, medical marijuana is prescribed by doctors and available in pharmacies (Kilmer, 2017).

Another country offering a relatively liberal approach to legalizing marijuana is Germany, where the official legalization of medical marijuana was done in March 2017. Since then, the country has been the leading producer of medical marijuana in Europe. As was the case in Poland before 2017, medical marijuana used to be a niche in Germany, with only about 1,000 critically ill patients receiving special permission to use it (The European Cannabis..., 2019). German regulations have been shaped over many years following lawsuits against the state. The result is a strategy that provides universal access to marijuana for medical purposes. As is the case in Poland, cannabis-infused medicinal products in Germany are available by prescription, but a substantial difference is the possibility of reimbursement by national health or social insurance companies (Medical use of..., 2018).

The pioneer in prescribing medical marijuana in the EU, after Germany, is Italy. In this country, the proper genetic variety of the type and amount of marijuana is selected individually for each patient. Apart from that, medical marijuana is reimbursed (Da Cas *et al.*, 2019). A study in the United Kingdom, where medical marijuana is legal but still very difficult to obtain, shows that restrictions on treatment with medical marijuana preparations are much stricter. Although, as a result of public pressure, medical marijuana was legalized there in November 2018 and made available under a special license issued by the Medicines and Healthcare Products Regulatory Agency, it is still not available to most patients (Schlag, 2020).

It is worth noting at this point that there are significant differences between Europe and the United States when it comes to medical marijuana. What differentiates the American model from the European one is the possibility of promoting cannabis to doctors and patients, while in Europe direct advertising of these products to consumers is prohibited. The literature reports that in the United States, medical officials cannot legally prescribe cannabis due to federal prohibition but can recommend patients "dispensaries" that sell only cannabis products (Pacula *et al.*, 2002). Depending on the state, getting a recommendation can be very easy (D'Amico *et al.*, 2015). Recently, there has been a dynamic shift in many states' attitudes toward the use of medical

marijuana. Studies report that some form of medical marijuana has now been legalized by thirty-nine states, the District of Columbia and Guam (Titus, 2016).

However, regarding both its clinical use in official medical institutions and the status in health care policy of the United States, medical marijuana (cannabis), obtained from the plant *Cannabis sativa*, has provoked constant controversy in the country for many years now (Marcoux *et al.*, 2013). On the other hand, Canada is the country which introduced a national program for legalizing the medical use of cannabis (Freckelton, 2015). The year 1999 saw the first permits for legal access to dried cannabis granted through special exemptions for medical, scientific, or public purposes, issued by the Minister of Health, while the full legalization of medical cannabis production took place in April 2014 (Market data under..., 2019). The country provides an example of how patient pressure and implementation of special access programs can gradually change an initial negative approach and result in court decisions in favour of access to medical cannabis (Medical use of..., 2018). Innovative policy decisions concerning the medical use of cannabis in the United States and Canada have served as an incentive for other countries, including some European ones such as Poland, to loosen the controls and allow patients to use cannabis for medical purposes. Some European Union countries allow patients access to cannabis preparations, both imported and domestically grown, according to the study. Other countries provide patients with access to cannabis for medicinal purposes in the form of magisterial preparations. In this situation, raw cannabis is transformed by the pharmacist into a final consumption format (Medical use of..., 2018).

It is worth noting at this point that over the last two years, interest in medical marijuana preparations has also increased in Ukraine. Russia's war against Ukraine has resulted in many patients needing medical cannabis to alleviate the suffering caused by post-traumatic stress syndrome and multiple injuries. This prompted the legislature in Ukraine to draft a law to regulate cannabis. Following the example of most countries, in Ukraine, medicines based on medical cannabis require state registration and medical cannabis can only exist as a registered medicinal product (Ocheretko, 2022). Undoubtedly, the prepared project is a response to the dire demand in this country that has emerged recently. Different countries have adopted various models based on their cultural, social, and political landscapes. The decision on which model to adopt is influenced by numerous factors including the country's stance on drugs, its existing medical infrastructure, public opinion, and experiences of other nations.

## Conclusions

In Poland, until 2017, regulation of the medical use of marijuana in Poland faced administrative barriers. For a long time, this regulation was under the "umbrella"

of the pharmaceutical law regime, and after the official legalization of medical marijuana in 2017, there were problems with the actual supply of cannabis preparations. The reason for this was the state's fear of blurring the lines between recreational and drug use of marijuana and its use for medical purposes. Over time, as a result of the intervention of the Ombudsman and the jurisprudence of the Constitutional Court and the Supreme Administrative Court, public authorities opened up to this type of therapy.

The study reviewed individual jurisdictions and found a wide range of approaches to the use of medical marijuana. It is due to cultural differences and the readiness of state systems to accept unconventional methods of treatment. It is argued that the very emergence of the possibility of treatment with cannabis preparations in Poland is part of a trend observed in many countries of Europe and the world. It was concluded that the Polish legal model favours a moderate approach, i.e., the possibility of purchasing the drug by

prescription, while the production of marijuana itself is subject to administrative regulation (permit). This guarantees that the purchasing of raw material and processed medicinal products based on medical marijuana is carried out under the state of world knowledge, to the extent required for the safety of patients and in a manner that allows availability.

This paper focuses on the doctrinal analysis of existing models of regulating the use of medical marijuana. Further research should be an empirical analysis of the effects of these rules on the practice of use of medical marijuana and a "fit-for-purpose" analysis. This particular research will however be more of a medical than legal nature.

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### Conflict of Interest

None.

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# Юридичні аспекти використання медичного канабісу в Польщі: порівняльно-правовий аналіз

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## Анотація

Актуальність досліджуваного питання полягає в тому, що зростає попит на використання в лікуванні медичного канабісу в тих випадках, де методи традиційної медицини не дали результатів. Метою статті є аналіз та оцінювання правового регулювання лікування препаратами, що містять медичний канабіс, у Польщі на тлі тенденцій в інших країнах. У дослідженні застосовано догматичний та чорновий методи аналізу положень чинного в Польщі законодавства, а також порівняльний метод. З'ясовано, що правові підходи країн Європи та світу до вирішення цього питання різняться. Коли йдеться про медичне використання марихуани, можливі три моделі: ліберальна модель, коли пацієнт може самостійно вирощувати рослину; поміркована модель, яка передбачає можливість отримання препарату на основі медичного канабісу за рецептом; третя модель ґрунтується на неможливості медичного використання марихуани. Польська правова модель є поміркованою та полягає в можливості отримання медичного препарату на основі марихуани за рецептом. Самостійне вирощування рослини за цією моделлю неможливе. Суб'єкт господарювання, який має намір культивувати коноплі для медичних потреб, повинен мати відповідний дозвіл уповноваженого державного органу. Такий підхід (притаманний іншим країнам) пропонує баланс між легалізацією медичного канабісу та профілактикою наркоманії. За польською правовою моделлю вирощування коноплі залишається під державним наглядом. Медичний канабіс доступний пацієнту, але доступ до нього суворо регламентований. Це не ліберальна модель легалізації, оскільки доступність безпосередньо залежить від лікаря. Практичні результати засвідчують прогрес у доступності медичних ліків на основі марихуани, порівняно з попередніми роками. Законодавча влада відкрита для змін, проте з міркувань запобігання поширенню злочинів, пов'язаних із незаконним обігом наркотиків, рішення про лібералізацію не було прийнято

## Ключові слова:

право; марихуана медична; легалізація; лікування; польська правова система