SILESIAN UNIVERSITY OF TECHNOLOGY PUBLISHING HOUSE

SCIENTIFIC PAPERS OF SILESIAN UNIVERSITY OF TECHNOLOGY 2019
ORGANIZATION AND MANAGEMENT SERIES NO. 140

JURIDICAL AND SOCIAL ASPECTS OF THE LEGALIZATION OF CANNABIS FOR MEDICAL USE

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Abstract: Media coverage of everyday life problems of suffering people is increasing. Cannabis for medical use is a subject of various disputes around which numerous understatements are formed. Proponents of legalization emphasize the healing properties of cannabis, while opponents fear the harmful effects of this substance, arguing that its use leads to addiction. The aim of the paper is to present juridical and social aspects related to the legalization of cannabis for medical use in Poland. On the basis of the new regulations, cannabis has been admitted in some forms to legal trading. The therapeutic properties of cannabis are confirmed by scientific research. Conducting further research will enable a better understanding of the therapeutic properties and a wider use of this substance in medicine to cure various diseases. In view of the fact that the basic thematic assumptions of the present study concern the problems that emerged after the amendment of the anti-drug legislation, the research findings in this area are far from exhaustive.

Keywords: cannabis, hemp, legalization, treatment, import.

1. Introduction

The present paper aims at assessing the institutions introduced by the amendment of 7 July 2017, which took effect on 1 November 2017, amending the Act on Prevention of Drug Abuse and the Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use and Medical Devices, hereinafter referred to as the amendment. A key change was the addition to the Act of Article 33a, pursuant to which hemp plant matter other than fibrous, and extracts, pharmaceutical tinctures and all other extracts of hemp other than fibrous, and hemp resin other than fibrous may constitute a pharmaceutical raw material intended for the preparation of prescription drugs after obtaining a marketing authorization issued by the

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, hereinafter referred to as the President of the Office.

Although the legalization of cannabis for medical use has been restricted by a number of administrative and medical procedures, it has ended the current ban on the marketing of hemp derivatives other than fibrous. Undoubtedly, the changes in Polish law are in line with global trends in this area.

The bibliographic resources which closely correspond to the subject of the study are not extensive. The list of sources used for the purposes of the study is to be found at the end of the paper.

2. Historical background and basic issues

Cannabis is native to Central Asia, and more specifically to what is now Mongolia and South Siberia. One of the oldest records of cannabis is a Chinese medical book dating back to 2700 BC, documenting over 100 medicinal uses of cannabis (Wolf, L., and Wolf, M., 2019). Also other ancient civilizations such as Egyptians, Indians, Greeks and Romans used marijuana to treat various types of pain (Taccket, 2018). In addition, cannabis was intensively used in the Islamic culture, where alcohol was prohibited. Soon their use spread beyond the therapeutic effect since it had a positive influence on the mood, usually causing cheerfulness. Hence, cannabis resin, a cannabis derivative, aroused a lot of interest, especially among French romantics. The wave of resentment towards the use cannabis began to increase in the early 20th century in the USA as a result of an influx of refugees from Mexico, which was engulfed in a long-lasting revolution. Soon, the use of marijuana began to be associated with criminal offences committed by immigrant populations, which resulted in its criminalization in the United States (Januszaniec, 2019). Consequently, marijuana was banned not only as a recreational substance, but also as a drug (Vetulani, 2014).

Hemp (also called fibrous hemp) and marijuana (Indian hemp) are derived from the same plant species, Cannabis sativa L. This species includes many varieties and strains containing a wide range of CBD, THC and their derivatives. Fibrous hemp alone does not contain more than 0,2 % THC in its composition and is therefore not psychoactive. Marijuana, on the other hand, is a selected species of cannabis with a higher THC and CBD content. Cannabidiol (CBD) is one of more than 100 organic compounds naturally occurring in cannabis that belong to the group of cannabinoids. CBD is the most common cannabinoid in fibrous hemp and, unlike THC (tetrahydrocannabinol), it has no psychoactive effect and is not classified as a narcotic substance.

For hemp, whole plants are used, not just leaves and feather crown, as in cannabis. Therefore, marijuana is grown all year round mainly in monitored premises in order to obtain the best possible flower quality. Although cannabis is the most popular variety used for narcotic purposes, it also contains substances with analgesic and anti-inflammatory effects (Motyka, and Marcinkowski, 2014).

The legal definition of cannabis is contained in the Single Convention on Narcotic Drugs of 1961, which states that cannabis means the floral or fruiting tops of hemp plants (excluding seeds and leaves if they are not present together with the tops) from which no resin has been extracted, irrespective of the name given to them (Journal of Laws, 1966, No. 45, item 277).

Pursuant to the Act of 29 July 2005 on Prevention of Drug Abuse, hereinafter referred to as PDA (Journal of Laws 2019, item 852), other than fibrous hemp means any above-ground part of a hemp plant (single or in a mixture), excluding seeds, containing more than 0.20% of the sum of delta-9-tetrahydrocannabinol and tetrahydrocannabinolenic acid (delta-9-THC-2-carboxylic acid). In contrast, cannabis resin is a resin and other cannabis products containing delta-9-tetrahydrocannabinol or other biologically active cannabinoids, i.e. substances contained in hemp and cannabis that do not have addictive effects and can increase the effectiveness of addiction treatment, relieve pain or alleviate certain effects of chemotherapy (PWN, 2019).

Narcotic drugs are divided into groups I-N, II-N, III-N and IV-N depending on the risk of addiction in the case of using them for purposes other than medical ones and the scope of their use for medical purposes (Journal of Laws 2019, item 852). Plant matter and resin of hemp other than fibrous, as well as extracts, pharmaceutical tinctures and all other extracts of hemp other than fibrous are included in group I-N: substances of high addictive potential that may be used for medical, scientific and industrial purposes, and in group IV-N: substances for which stricter control is applied and which may be used only for research purposes and in animal medicine (Journal of Laws 2018, item 1591).

3. Patients' rights

In the light of the binding regulations, the patient has the right to treat pain, and the entity providing health services is obliged to undertake actions consisting in determining the degree of pain intensity, treating pain and monitoring the effectiveness of this treatment (Journal of Laws 2019, item 1127).

Treatment of a person suffering pain in a manner that makes it impossible to cure pain effectively is an act that grossly violates the sense of dignity resulting from Article 30 of the Constitution of the Republic of Poland, according to which natural and inalienable human dignity is a source of freedom and human as well as civil rights. Human dignity is inviolable

and respecting as well as protecting the dignity is the duty of public authorities. In the justification of the judgment of 1 September 2006, the Constitutional Tribunal indicated that the reference to Article 30 of the Constitution is always valid when the subject of the assessment is legal protection connected with respect for the most vital interests of each individual, i.e. those relating to life, health and physical integrity (Journal of Laws of 2006, No. 164, item 1166).

Cannabinoid preparations are used in many illnesses and civilization diseases. The difference in cannabinoid content means that different hemp species act on different diseases, and the therapeutic effectiveness of the plant varies for different people with the same disease (Januszaniec, 2019).

The National Academies of Sciences, Engineering and Medicine (NASEM) report updated in 2016 indicates, among other things, that there is strong evidence for cannabinoids being effective in treating chronic pain, alleviating nausea and chemotherapy-related vomiting (Abrams, 2018). Thus, the use of cannabis to cure pain in the terminal stages of cancer seems to be particularly beneficial, especially when the morphine effect decreases as a result of developing tolerance (Vetulani, 2014). Furthermore, the Constitutional Tribunal in its decision of 17 March 2015 indicated that in the light of current scientific research, cannabis can be used for medical purposes, especially in the case of alleviating the negative symptoms of chemotherapy used in cancer treatment, and drew attention to the need to regulate the medical use of cannabis (S 3/15). On 1 November 2017, the Act of 7 July 2017 amending the Act on Prevention of Drug Abuse and the Act on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use and Medical Devices (Journal of Laws 2017, item 1458) took effect, legalizing the use of cannabis for medical purposes in Poland and enabling the purchase of medicinal products based on dried hemp. In accordance with Act 1 Article 68 of the Constitution, everyone has the right to health protection. Moreover, in the light of the Act on Patients' Rights and the Commissioner for Patients' Rights, hereinafter referred to as PR and CPR, each patient has the right to health services that meet the requirements of current medical knowledge (Journal of Laws 2019, item 1127). The very concept of "current medical knowledge" is an ambiguous term associated with the rapid development of medicine (Karkowska, 2016).

On 13 February 2019 the European Parliament adopted a resolution on the use of cannabis for medicinal purposes (2018/2775(RSP)) calling on the Commission and national authorities to work together to develop a legal definition of medical cannabis and to remove regulatory, financial and cultural barriers that hamper research into cannabis for medicinal purposes and cannabis research in general. Additionally, the resolution calls on the Member States to ensure adequate medical training for health professionals and to promote medical cannabis knowledge based on independent and extensive scientific research. It should be noted that it is a very important postulate, because, as doctors themselves point out, there is an insufficient number of conferences and training courses organized by the Ministry of Health, such as those in Israel,

where the so-called green booklet has been published containing guidelines for doctors as to the circumstances in which cannabis can be used for medical purposes. Moreover, some of the aforementioned doctors are afraid to prescribe cannabis for medical purposes, claiming that although there are many laboratory and scientific studies confirming its effectiveness in various areas of medicine, there are not enough studies involving humans (Glanc, 2019). That is why it is so important for the European Parliament to call on the Commission to develop a comprehensive strategy to ensure the highest standards of independent scientific research, development, and authorization procedures, monitoring the safety of medicines and avoiding abuses of cannabis products.

The discrepancies between the representatives of different fields of medical knowledge indicated in the doctrine concern not only specific methods or medicines, but also cardinal principles. Therefore, it is difficult to clearly determine what is and what is not covered by the rules of the art in a specific case, especially when it comes to new methods, on which there are still disputes and not only discrepant, but also contradictory views (Kędziora, 2009, p. 113). Accordingly, it may be argued that, as a matter of principle, there is no prevalence of any particular trend represented in science and the patient should be free to choose one, after a thorough discussion of alternative methods and their consequences (Karkowska, 2016).

4. Indian hemp cultivation

In Poland, the cultivation of hemp other than fibrous hemp is illegal, whereas fibrous hemp is subject to restrictions under PDA. While working on that Act, the creation of a national cannabis cultivation system to be implemented by the Institute of Natural Fibres and Herbal Plants (Polish: Instytut Włókien Naturalnych i Roślin Zielarskich) was considered. It was established in 2009 by merging the Institute of Natural Fibres with the Institute of Plants and Herbal Preserves as a research institute with scientific, implementation, patenting and standardization activities in the field of acquisition, processing and application of textile and herbal plants. The Institute has a history of hemp cultivation dating back more than 90 years. In addition, the unit has one of the world's largest genotype banks with the best quality seeds. There are several experiment stations at the Institute where medical cannabis could be grown indoors or in greenhouses. Therefore, we should consider whether importing cannabis from abroad is the right solution, all the more so because the Institute has adequate intellectual capacity and technical facilities (Purgol, and Barcik, 2018).

In accordance with the Single Convention, if a Party authorizes the cultivation of hemp plants for cannabis harvesting or cannabis resin, it will apply an appropriate control system to them. The State organization shall designate the areas and parcels of land on which cultivation is permitted. Only persons to whom the organization grants an authorization shall be entitled to

engage in such cultivation. Each authorization shall specify the area of land on which such cultivation is permitted. All growers shall be obliged to provide the organization with the entire harvest. The organization shall purchase and physically acquire this harvest as soon as possible, but no later than within four months after the end of the harvest period. The organization shall have exclusive rights to import, export, wholesale trade and stock-holding, except as provided for in the Single Convention. In addition, the parties are obliged to take such steps as may prove necessary to prevent abuse of the leaves of the hemp plant or illegal trade in such leaves (Journal of Laws 1966, No. 45, item 277).

5. Marketing authorization

As a result of approving the Act amending the Act on Prevention of Drug Abuse and the Act on Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Use and Medical Devices, hemp plant matter other than fibrous and extracts, pharmaceutical tinctures and all other extracts from hemp other than fibrous and hemp resin other than fibrous may constitute a pharmaceutical raw material in accordance with the Act on Pharmaceutical Law, hereinafter referred to as PL (Journal of Laws of 2019, item 852), defined as a substance or mixture of substances used in the preparation or manufacture of medicinal products. A medicinal product is a substance or a mixture of substances presented as having properties of preventing or treating diseases occurring in humans or animals, or administered in order to make a diagnosis or to restore, correct or modify physiological functions of an organism through pharmacological, immunological or metabolic action (Journal of Laws 2019, item 499).

A necessary condition for the admission of the above mentioned substances to trading is obtaining a permit issued by the President of the Office. It should be added that the prescription drugs received in this way are granted the appropriate category of availability, in accordance with Article 23a, section 1, item 4 of PDA, i.e., i.e. a prescription issued by a physician, containing narcotic drugs or psychotropic substances, specified in separate regulations ("Rpw" availability category). A prescription for a medicine of this category may not be issued by a veterinarian (Ważny, 2019). It is worth noting that allowing cannabis for medical use in some forms is a big step forward, which should be assessed positively, as the mandatory ban has now been eased.

It should be noted that Article 33a, section 1 of PDA provides that substances derived from the processing of hemp other than fibrous may be used as pharmaceutical raw materials, but only after marketing authorization has been granted. That document takes the form of an administrative decision to be issued by the President of the Office for a period of five years. The validity period may be extended or shortened depending on the will of the Marketing Authorization Holder, i.e. an entrepreneur or an entity conducting business activity in a Member

State of the European Union or a Member State of the European Free Trade Association (EFTA) as a party to the agreement on the European Economic Area, who applies for or has already obtained a marketing authorization for a medicinal product.

Medicinal products may be marketed in a defined area. The criterion that plays a key role here is the assessment of the safety of product application, its therapeutic efficacy and quality (Stankiewicz, 2014).

An application for a license may be submitted by the Marketing Authorization Holder. Formal requirements have been specified in the provisions of PDA. Art. 10, mentioned in the Act, contains a number of elements that should be included in an application, in particular:

1. the name and address of the Marketing Authorization Holder, the manufacturer or importer where the batch release of the medicinal product takes place; the manufacturing site, including the manufacturing site where the batch control takes place, or the importing site where the batch control takes place; and the numbers of authorization documents to manufacture the medicinal product or to import the medicinal product,
2. the name of the medicinal product,
3. the quantitative and qualitative particulars of the active substance or substances and other substances relating to the medicinal product as well as their commonly used names or, failing that, their chemical names,
4. pharmaceutical form, strength, route of administration and validity period of the medicinal product, as well as environmental data relating to the disposal of the medicinal product, if necessary and appropriate to the nature of the product.

In addition, the application shall be accompanied by the documents referred to in that Article. Also, when submitting the application, the Marketing Authorization Holder should present the guidelines of the European Commission, the European Medicines Agency or the World Health Organization, which are the basis for the prepared documentation.

In case of justified doubts which arise from the submitted documentation concerning the quality of the medicinal product, the President of the Office may request the submission of an inspection report on the manufacturing site of a medicinal product which has been manufactured abroad in order to confirm the compliance of the manufacturing conditions with the authorization.

In accordance with Article 18 Section 1 of PL, the procedure for marketing authorization of a medicinal product should be completed within 210 days at the latest. In certain situations, the President of the Office has the right to issue a decision on refusal to issue a permit or to issue a decision on withdrawal of a permit (Ważny, 2019). After the issuance of the permit, the President of the Office shall enter the medicinal product in the Register of Medicinal Products Authorized on the territory of the Republic of Poland. The data contained in the permit are public (Stankiewicz, 2016).

Before granting a marketing authorization, the President of the Office shall prepare an assessment report containing a scientific opinion on a medicinal product, together with a justification and a summary of the assessment report understandable to the recipient, containing, in particular, information relating to the conditions of use of that product, and shall issue decisions and communicate information on those decisions to the European Medicines Agency (Journal of Laws 2019, item 499).

According to Directive 2001/83/ec of the European Parliament and of the Council on the Community code relating to medicinal products for human use, a medicinal product falls within the category of availability of "Rpw" if it contains, in a non-exclusive quantity, a substance classified as an intoxicant or a psychotropic substance, or if its misuse may pose a significant risk of abuse which leads to addiction or misuse for illegal purposes. Products containing active ingredients which, because of their innovation or properties, may be classified as substances whose abuse leads to dependence should also be classified in this category. Doctors prescribing such a product are required to write the name of the medicine or active ingredient, the total amount of the product, which is expressed in words or expressed in words in terms of the number of dosage units and the size of the dose. It is permissible to prescribe only one preparation containing narcotic drugs or psychotropic substances on one prescription. It is worth pointing out that other medicinal products may not be prescribed on the same prescription. A doctor may issue up to three prescriptions for successive periods of use not exceeding 90 days of application in total, and must make an annotation in the medical documentation about the issuance of a prescription for “Rpw”.

Moreover, as it results from the Act under analysis, prescriptions on which preparations containing drugs were prescribed are implemented no later than within 30 days from the date of their issue, except for prescriptions for imported medicinal products containing narcotic drugs or psychotropic substances which do not hold a marketing authorization, yet which are necessary to save the lives or health of patients. Such prescriptions may be implemented within 120 days (Journal of Laws 2015, item 1889).

6. Destined import

In addition to allowing hemp plant matter other than fibrous and extracts, pharmaceutical tinctures and all other extracts of hemp other than fibrous and hemp resin other than fibrous as a pharmaceutical raw material for the preparation of prescription drugs by means of a marketing authorization issued by the President of the Office, and at the same time pursuant to Article 4 of PL, other medicinal products containing cannabinoids, which do not have a marketing authorization in Poland, may still be imported to Poland if their use is necessary for saving the

life or health of a patient, provided that the medicinal product is authorized for marketing in the country from which it is imported and has a valid marketing authorization (MZ, 2018).

Importation of a medicinal product in accordance with the legal definition set out in Article 2, item 7a of PL means any action consisting in importing a medicinal product from outside the territory of the Member States of the European Union or the Member States of the European Free Trade Association (EFTA) – parties to the Agreement on the European Economic Area, including their storage, quality control at batch release and distribution. Therefore, importation thus understood does not involve trade in medicinal products within the EU and EEA, but only the first introduction of a product to the market of a given EU country from a country outside the European Union.

Medicinal products may be imported within the framework of destined import if they meet the following cumulative conditions:

a) the use of the medicinal product is necessary to save the life or health of the patient,
b) the medicinal product is authorized in the country from which it is imported,
c) the medicinal product has a valid marketing authorization in the country from which it is imported.

Destined import may include medicines which:

a) do not have an equivalent in Poland (there is no medicine that contains the same active ingredient, form and dose),
b) have not been the subject of proceedings in which the President of the Office refused to admit them to trading, to renew such permission or revoked the permission, or in which he revoked the permission to trading.

Within the scope of destined import, the product can be imported on the basis of the needs of a hospital or an out-of-hospital doctor. Each requisition must be approved by a national or provincial consultant in the respective field of medicine. The consultant has 7 days from the date of its receipt to confirm the demand (Kondrat, 2016). The ordered dried hemp must have a precisely defined percentage of THC and CBD content adjusted to the treatment of a specific disease (Januszaniec, 2019).

The procedure of destined import within the scope of executive regulations is governed by the Regulation of the Minister of Health of 21 March 2012 on the import of medicinal products necessary to save the life or health of patients admitted to trading without the requirement to obtain a permit (Journal of Laws, item 349).

The Regulation contains boilerplate versions of:

- a requisition form,
- an acknowledgement form by the minister in charge of health,
- an application form for a refund of an imported medicinal product which is necessary to save the life or health of a patient, and which has been admitted to trading without the need to obtain a permit.

The Minister of Health, within 21 days from the day of receiving the requisition, issues a decision concerning the possibility of importing the product. After obtaining the consent of the Minister of Health, there is a 60-day period for transferring the requisition to a pharmacy which imports the medicine through a pharmaceutical wholesaler (MZ, 2019).

7. Social aspects – selected issues

Despite the constant progress in medicine, there are still many diseases that cannot be eradicated, even though it is possible to reduce the related ailments. Drug manufacturers and research laboratories are trying to create medicines that have a broad spectrum of applications in the treatment of many diseases, while minimizing side effects.

Medical marijuana is a controversial subject. Doubts about whether it is really harmful should therefore be resolved. In addition, the question arises as to whether legalizing cannabis for medical use will result in an increase in cannabis use in society and, further, whether it can lead to fatal consequences. The literature indicates that the lethal dose of cannabis and cannabis resin is unspecified, as no fatalities have been reported after using these drugs (Jędrzejko, 2008, p. 159). The question therefore arises: can marijuana be considered a safe drug? At this point, it is worth referring to a study that was conducted in all 50 states of the USA between 1999 and 2010, when medical cannabis was legal in only 10 of them. The study found that where cannabis used for therapeutic purposes was legally available, mortality from an overdose of hard drugs was 24.8% lower than in states where cannabis had not yet been legalized for medical use (Bachhuber, 2014).

Some people also argue that the legalization of cannabis for medical use will make this product more accessible to young people (Grotkowska, and Kobyliński, 2016). However, common sense should be maintained here, as the same is true for alcohol consumption or smoking. Both addictions are pathological and cause negative effects.

First of all, it should be noted that whether cannabis causes intoxication or assists patients in the treatment of various diseases is due to the appropriate ratio of concentration between the two main substances contained in cannabis leaves, THC and CBD (Habib, 2016). It must be stressed that legalizing cannabis for medical use is not tantamount to allowing ordinary cannabis leaves with high THC concentration to circulate legally.

The review of literature on the subject more and more often reveals analyses that are devoted to the medical use of cannabis. According to the neurobiologist J. Vetulani, when indicating the positive influence of THC on the human body, attention should mainly be paid to the analgesic effect, muscle relaxation, bronchial dilatation, reducing saliva, stimulating appetite, and inducing sleep. Moreover, Vetulani adds that marijuana, hashish, hemp plant matter and flower extracts reduce intraocular pressure. What is even more, they have a positive effect on

the survival of neurons. Further, M. Jot indicates a positive effect of cannabis use in the therapy of rheumatoid arthritis.

It is worth mentioning that M. Jędrzejko, discussing B. Szukalski's research, emphasizes that cannabinol (CBN) can be used for therapeutic support, e.g. as an aid in reducing vomiting after cancer chemotherapy or in treating digestive tract diseases. They can also be used in the therapy of multiple sclerosis.

M. Motyka and J. Marcinkowski pointed out that apart from the above-mentioned use of cannabis, it also has a positive effect in the treatment of autoimmune disorders, i.e. inflammation of the intestines. A positive effect was also observed in patients with amyotrophic lateral sclerosis. What is more, the use of cannabis contributes to the relief of chronic neuropathic pain in patients with diabetes, MS and AIDS. Cannabinoids also exhibit anti-cancer effects, e.g. they delay the development of cancer and prevent metastases. They alleviate symptoms associated with multiple sclerosis, as well as they are used to alleviate itching and soothe pain, relieve swelling of joints, prevent their destruction in rheumatoid arthritis.

8. Conclusions

The issue of cannabis use for medical purposes is a constant source of strong emotions. On the one hand, we observe suffering people and their relatives, and on the other hand, the word "cannabis" itself for many people is associated with concerns about the occurrence of addiction.

The Act legalizing cannabis for medical use came into force in Poland on November 1, 2017. However, experts indicate that access to medical cannabis is still difficult. The main obstacles are: lack of domestic crops, sale of only one product in pharmacies so far and lack of sufficient knowledge of Polish doctors about the possibilities of using cannabis.

There is no reason to fear that the cultivation of cannabis for medical use will, in practice, mean an increase in recreational cannabis consumption, since it would be carried out under strict supervision. This would ensure proper quality, product control and sales with special precautions for young people in particular. In addition, it is important that cannabis used for therapeutic purposes should only be derived from products that have undergone clinical trials and have been approved by regulatory authorities. We should also not forget the real financial benefits for the state of restricting the trade in cannabis on the black market. The funds obtained in this way could be used for educational and preventive actions aimed at making people aware of the dangers of drug abuse.

Hemp is a plant with great medicinal potential. Depending on the crop and variety, it contains various amounts of CBD and THC – active compounds responsible for psychoactive effects (only THC) and medicinal effects. Therefore, such drugs have been developed that contain specific amounts of CBD and THC. However, cannabis intended for medical use requires further clinical trials, which will comprehensively demonstrate its effectiveness. In addition, it is important to stress the need for a clear distinction between medicinal cannabis and other cannabis applications.

References

1. Abrams, D.I. (2018). *The therapeutic effects of Cannabis and cannabinoids: An update from the National Academies of Sciences, Engineering and Medicine report*. Retrieved from https://www.researchgate.net/publication/322335155_The_therapeutic_effects_of_Cannabis_and_cannabinoids_An_update_from_the_National_Academies_of_Sciences_Engineering_and_Medicine_report, 10.08.2019.
2. Act on Patients' Rights and the Commissioner for Patients' Rights of 6 November 2008, Journal of Laws 2019, item 1127 (2019).
3. Act on Pharmaceutical Law of 6 September 2001, Journal of Laws 2019, item 499 (2019).
4. Act on Prevention of Drug Abuse of 29 July 2005, Journal of Laws 2019, item 852 (2019).
5. Bachhuber, M. (2014). *Lower Opioid Overdose Death Rates Associated with State Medical Marijuana Laws*. M.D. of the Philadelphia Veterans Affairs Medical Center, and colleagues, JAMA Intern Med. http://archinte.jamanetwork.com/article.aspx?articleid=1898878, 11.089.2019.
6. Constitutional Tribunal Resolution of 17 March 2015, reference symbol: S 3/15, (2015).
7. Constitutional Tribunal verdict of 1 September 2006, reference symbol SK 14/05. Journal of Laws of 2006, no. 164, item 1166 (2006).
8. Directive 2001/83/ec of the European Parliament and of the Council. Journal of Laws L 311 of 28 November 2001 (2001).
9. European Parliament Resolution on use of cannabis for medical purposes of 13 February 2019 (2018/2775(RSP)). Available online http://www.europarl.europa.eu/doceo/document/TA-8-2019-0113_PL.html, 10.08.2019.
10. Glanc, M. (2019). Legalizacja bez edukacji. Problemy lekarzy z medyczną marihuaną. *Polityka*. Retrieved from https://www.polityka.pl/tygodnikpolityka/spoleczenstwo/1779968,1,legalizacja-bez-edukacji-problemy-lekarzy-z-medyczna-marihuana.read, 10.08.2019.
11. Grotkowska, K., and Kobyliński, K. (2016). Analiza argumentu zdrowia publicznego w dyskusji nad legalizacją miękkich narkotyków. *Acta Universitatis Lodziensis, Folia Iuridica, 76*, 69-70.

12. Habib, A. (2016). Medyczne aspekty legalizacji miękkich narkotyków – zagrożenie czy szansa na skuteczne leczenie? *Acta Universitatis Lodziensis, Folia Iuridica, 76,* 79.
13. Jędrzejko, M. (2011). *Marihuana fakty: marihuana mity*. Wrocław: Wrocławskie Wydawnictwo Naukowe ATLA 2.
14. Jot, B. (2014). *Marihuana leczy*. Bydgoszcz: Wydawnictwo AMJI.
15. Karkowska, D. (2016). *Ustawa o prawach pacjenta i Rzeczniku Praw Pacjenta. Komentarz*. Warszawa: Wolters Kluwer Polska.
16. Kędziora, R. (2009). *Odpowiedzialność karna lekarza w związku z wykonywaniem czynności medycznych.* Warszawa: Wolters Kluwer Polska.
17. Kondrat, M. (2016). *Prawo farmaceutyczne. Komentarz*. Warszawa: Wolters Kluwer Polska.
18. Ministerstwo Zdrowia. Available online https://www.gov.pl/web/zdrowie/sprowadzac-leki-z-zagranicy-import-docelowy-, 10.08.2019.
19. Motyka, M., and Marcinkowski, J.T. (2014). Używanie pochodnych konopi. Część II. Zastosowanie w medycynie vs. konsekwencje zdrowotne. *Probl. Hig. Epidemiol, 95(1)*, 22.
20. Olszewski, W. (2016). *Prawo farmaceutyczne. Komentarz*. Warszawa: Wolters Kluwer Polska.
21. Purgoł, M., and Barcik, J. (2018). Ustawa legalizująca tzw. marihuanę dla celów medycznych w świetle standardów prawa międzynarodowego. *Przegląd Prawa Publicznego, 7-8*, 191-192, 194-195.
22. PWN (Polish Scientific Publishers PWN). Available online https://sjp.pwn.pl/slowniki/kannabinol.html, 10.08.2019.
23. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Official Journal of the EU L 136 of 30 April 2004 (2004).
24. Regulation of the Minister of Health of 11 September 2006: *Rozporządzenie Ministra Zdrowia z dnia 11 września 2006 r. w sprawie środków odurzających, substancji psychotropowych, prekursorów kategorii 1 i preparatów zawierających te środki lub substancje.* Journal of Laws 2015, item 1889 (2015).
25. Regulation of the Minister of Health of 17 August 2018: *Rozporządzenie Ministra Zdrowia z dnia 17 sierpnia 2018 r. w sprawie wykazu substancji psychotropowych, środków odurzających oraz nowych substancji psychoaktywnych.* Journal of Laws 2018, item 1591 (2018).
26. Stankiewicz, R. (2014). *Model racjonalizacji dostępu do produktu leczniczego. Zagadnienia publicznoprawne*. Warszawa: C.H. Beck.
27. Stankiewicz, R. (2016). *Instytucje rynku farmaceutycznego*. Warszawa: Wolters Kluwer Polska.

28. Taccket, B. (2018). *History of Marijuana*. Retrieved from https://www.recovery.org/marijuana/history/, 10.08.2019.
29. The Single Convention on Narcotic Drugs of 1961, signed in New York on 30 March 1961. Journal of Laws 1966, no. 45, item 277 (1961).
30. Vetulani, J. (2014). Lecznicze zastosowania marihuany. *Wszechświat, 115, 1-3*, 15-16, 21.
31. Ważny, A. (ed.) (2019). *Ustawa o przeciwdziałaniu narkomanii. Komentarz*. Warszawa: Wolters Kluwer Polska.
32. Wolf, L., and Wolf, M. (2019). *Medyczna marihuana. Praktyczne zastosowanie*. Białystok: Wydawnictwo Vital.