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Legal Aspects of Off-Label Treatment with "Medical Marijuana" in Terminally Ill Patients – a Medical Experiment or an Embodiment of the Patient's Right to Receive Services in Accordance with Current Medical Knowledge?

Aspekty prawne pozarejestracyjnego leczenia „medyczną marihuaną" pacjentów chorych terminalnie – eksperyment medyczny czy realizacja prawa pacjenta do pobierania świadczeń zgodnych z aktualną wiedzą medyczną?

ABSTRACT

The subject of the use of medicinal products containing "medical marijuana" during the therapy of terminal patients has been the subject of extensive discussion until recently. Currently, such action is legal, but questions still arise not so much about the possibility of using medical marijuana

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in the treatment of terminally ill patients, but about the implementation of off-label use treatment. The analysis of the applicable legal provisions, views of scholars in the field, and the case law allow us to conclude that treatment involving medical marijuana inconsistently with the SmPC (Summary of Product Characteristics) is an acceptable action that should not be equated with a therapeutic experiment in the strict sense. The above is confirmed by the admissibility of using marijuana raw materials as the basis for the preparation of a pharmacy-compounded (prescription) medicine. The production of pharmacy-compounded drugs requires the use of pharmaceutical raw materials, the amount and composition of which depend on an independent decision of the person prescribing the medicine. The admissibility of any composition of the contents of a pharmacy-compounded drug containing medical marijuana speaks for the admissibility of its use in any way. The above leads to adoption of similar requirements in relation to pre-made drugs containing marijuana. Regardless of the admissibility of using medical marijuana outside the SmPC or in the form of a compounded drug, medical marijuana treatment is the implementation of the patient's right to treat pain and receive health services in accordance with the current state of medical knowledge.

Keywords: medical marijuana; off-label drug use; marijuana pain management; patient's right to treat pain

INTRODUCTION

The use of medicinal products off their strict registration as defined in the Summary of Product Characteristics (SmPC) is most often analysed in legal literature from the perspective of similarity of such activities to a medical experiment within the meaning of the Act of 5 December 1996 on the professions of medical practitioner and dentist.[1] As a general rule, the off-label use of medicinal products is equated with an acceptable action intended to optimise the treatment process and reduce the health risk in patients who require special medical treatment. This issue earns particular importance in the context of admissibility of the off-label use of "medical marijuana", the very legality of the use of which during the treatment of terminal patients has been widely discussed until recently.

Herein, the term "medical marijuana" is used, reflecting the specificity of the use and not the recreational purpose of the use of the substance, but there is no such term in the legal language. The Polish legislature uses the terms "cannabis", "fibrous cannabis", and "plant of non-fibrous cannabis".[2] Both the "plant of non-fibrous cannabis" and "fibrous cannabis" are derived from the same plant species, Cannabis sativa L. Fibrous cannabis does not contain tetrahydrocannabinol (THC), a chemical organic compound of the cannabinoid group, and therefore does not have a psychoactive effect. Marijuana (plant of non-fibrous cannabis – Cannabis indica) is a species of cannabis with an increased THC and CBD content, i.e., a cannabi-

[1] Consolidated text, Journal of Laws 2022, item 1731, as amended, hereinafter: APMPD.

[2] Act of 29 July 2005 on counteracting drug addiction (consolidated text, Journal of Laws 2022, item 2050, as amended).

noid group compound found in cannabis. Unlike its isomer, tetrahydrocannabinol, it has no psychoactive effect but affects the course of THC-induced intoxication.

The literature points out that the use of medical marijuana[3] is considered to be reasonable and effective in oncology patients and terminal patients undergoing palliative therapy, in whom the minimization of persistent pain symptoms using standard, typically used pharmacological therapy is not sufficient.[4] When referring to the patient's right to treat pain set out in Article 20a (1) of the Act of 6 November 2008 on the rights of patients and the Commissioner for Patients' Rights,[5] the very possibility of using lawful treatment with medical marijuana to treat pain is essentially self-evident. However, a controversial and vaguely regulated issue is the legitimacy of using medicinal products containing cannabinoids contrary to the provisions of the SmPC, including indications not mentioned in the SmPC or for other age population than those indicated in the SmPC.

This paper is aimed at carrying out an analysis of the admissibility and appropriateness of medical marijuana treatment, the admissibility of use of such medicinal products apart from the indications of the SmPC, and answering the question whether the medical use of marijuana contrary to its registration as defined in the SmPC in end-of-life patients is similar to a medical experiment, or rather the exercise of the patient's right to be provided medical services in line with the latest medical knowledge and pain treatment.

When making the analysis in question, the study uses a method of analysing the content of existing legislation as well as an analysis of the current line of scholarly opinion and judicial decisions on the subject. It should be emphasized that, although the use of medical cannabis is now more and more frequent, both the legal literature and the case law have addressed these issues quite scarcely.

RESEARCH AND RESULTS

The admissibility of the use of medical marijuana in the therapeutic process is a relatively new issue under Polish law, although treatment of this kind was used as early as in ancient times, as evidenced by the world's oldest pharmacopoeia documenting the use of cannabis, for example, in the treatment of malaria or disorders of the female reproductive system.[6] Due to its diastolic effect and intestinal peristalsis

[3] P. Siudem, I. Wawer, K. Paradowska, *Konopie i kannabinoidy*, "Farmacja Współczesna" 2015, no. 8, p. 2.

[4] T. Dzierżanowski, *Kanabinoidy – możliwości zastosowania w medycynie paliatywnej*, "Medycyna Paliatywna" 2018, vol. 10(1), p. 1.

[5] Consolidated text, Journal of Laws 2020, item 849, hereinafter: ARP.

[6] A.W. Zuardi, *History of Cannabis as a Medicine: A Review*, "Brazilian Journal of Psychiatry" 2006, vol. 28(2), pp. 153–157.

stimulation effect, Asian physicians used hemp seeds as a remedy for problems of the digestive system.[7] In 1890, J.R. Reynolds, who was a physician to the Court of Queen Victoria, summarized more than 30 years of experience with cannabis in "The Lancet". The author found cannabis to be the most useful medicine for various painful conditions (facial neuralgia, migraine, painful menstruation, and the numbness and other cases of paresthesia so common in the extremities of people with gout). The medical recommendations described by Reynolds correspond in principle to today's uses of medical marijuana, except for the possibility of using marijuana for teething problems.[8]

In the peace treaty that ended World War I, a provision was made obliging all the parties to ratify the Hague Convention of 1912, which had introduced a prohibition on opium, cocaine, and marijuana.[9] During the talks of the Second Opium Conference of the League of Nations in Geneva in 1925, it was recognized that cannabis was addictive and as dangerous as opium. In 1952, the World Health Organization Expert Committee concluded that drugs containing marijuana should not be used. In 1961, the Single Convention on Narcotic Drugs was adopted to bring about an end to the use in any manner (including medicinal use) of three plant-based substances: opium, cocaine, and marijuana.[10] In 1988, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances obliged its signatories to prohibit the cultivation of medical poppy, coca bushes, and cannabis for the production of drugs, and to make it a drug-related offence to possess, cultivate and sell drugs for personal use.[11]

Issues related to psychoactive substances were regulated in Poland for the first time under the Act of 31 January 1985 on preventing drug addiction,[12] which was successively replaced by the Act of 24 April 1997 on counteracting drug addiction,[13] and then by the Act of 29 July 2005 on counteracting drug addiction.[14] According to Article 4 (4) ACDA, cannabis should be understood as plants of the genus cannabis (Cannabis L.). Fibrous cannabis is defined as "plants of the genus Cannabis sativa L. in which the sum of the delta-9-tetrahydrocannabinol and tetrahydrocannabinolic

[7] M. Touw, *The Religious and Medical Uses of Cannabis in China, India and Tibet*, "Journal of Psychoactive Drugs" 1981, vol. 13(1), pp. 23–34.

[8] M.A. Crocq, *History of Cannabis and the Endocannabinoid System*, "Dialogues in Clinical Neuroscience" 2020, vol. 22(3), pp. 223–228.

[9] Treaty of Versailles (1919), United Kingdom Treaty Series 4 (Cmd. 153), signed 28 June 1919, entered into force 10 January 1920).

[10] Single Convention on Narcotic Drugs, New York, 30 March 1961, United Nations Treaty Series, vol. 520, p. 151

[11] M. Kuna, *Warunki medycznego zastosowania marihuany w Polsce – aspekty prawa administracyjnego*, "Przegląd Prawa Administracyjnego" 2019, no. 2, p. 82.

[12] Journal of Laws 1985, no. 4, item 15, as amended.

[13] Journal of Laws 1997, no. 75, item 468, as amended.

[14] Journal of Laws 2005, no. 179, item 1485, as amended, hereinafter: ACDA.

acid (delta-9-THC-2-carboxylic acid) content of the floral or fruiting tops of plants from which the resin has not been removed does not exceed 0.3% on a dry-weight basis; this sum shall be rounded to one decimal place" (Article 4 (5) ACDA).

In the context of admissibility of the medical use of marijuana, noteworthy are the actions taken by the Polish Constitutional Tribunal, which submitted to the Sejm comments on the advisability of taking legislative action aimed at regulating the issue of the medical use of marijuana.[15] The Constitutional Tribunal stressed that the prevention of uncontrolled spread of substances, the use of which may lead to drug addiction, completely ruled out the possibility of using marijuana for medical purposes. As a side note, the Constitutional Tribunal stated that the possibility of importing medical marijuana as part of the targeted importation provided for by the pharmaceutical law, related to the prohibition of its purchase and use for medical purposes directly in Poland, may infringe the right to health protection guaranteed under Article 68 (1) of the Constitution of the Republic of Poland.

Regardless of the above, it should be emphasized that the pejorative perception of marijuana use cannot be identified with a universal negative choice, because, as J. Gray points out, different and sometimes distant goods can be equally right.[16]

As a result of the actions taken by the Constitutional Tribunal, as well as the ongoing public discussion on the reasonableness of legal use of marijuana for medicinal purposes,[17] on 1 November 2017, the Act of 7 July 2017 amending the Act on counteracting drug addiction and the Act on the reimbursement of medicines, foodstuffs intended for particular nutritional uses and medical devices,[18] which introduced in the ACDA the content of Articles 33a–33d. Noteworthy is the wording of Article 33a ACDA, according to which "the plant of cannabis other than fibrous and pharmaceutical extracts, tinctures, as well as all other extracts from non-fibrous cannabis and resin from cannabis other than fibrous referred to in the regulations issued based on Article 44f, may be a pharmaceutical raw material (…), intended for the preparation of prescription drugs (…), after obtaining a marketing authorisation issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (…)". It is necessary to indicate that the requirements provided for by the ACDA regarding the submission of an application[19] for marketing authorisation of a pharmaceutical raw material used to prepare

[15] Decision of the Constitutional Tribunal of 17 March 2015, SK 3/15, OTK-A 2015, no. 3, item 39.

[16] See B. Wojciechowski, *Wybór stylu życia a świadomość praw podstawowych*, "Archiwum Filozofii Prawa i Filozofii Społecznej" 2022, vol. 31(2), p. 104.

[17] B. Kmieciak, *Prawo do świadczeń zdrowotnych wobec dyskusji dotyczącej legalizacji miękkich narkotyków*, "Acta Universitatis Lodziensis Folia Iuridica" 2016, vol. 76, pp. 89–100.

[18] Journal of Laws 2017, item 1458.

[19] The model application was set out in the content of the Regulation of the Minister of Health of 5 December 2017 on the model application for marketing authorisation of pharmaceutical raw

medicines using non-fibrous cannabis plant, as well as pharmaceutical extracts and tinctures, turned out to be too restrictive for many pharmaceutical companies, and as a result, no single application was submitted in the area in question.[20]

This situation changed as a result of the entry into force of the Act of 20 July 2018 amending the Act on counteracting drug addiction and the Act on the State Sanitary Inspectorate,[21] which liberalised the existing requirements. It must be pointed out that the real possibility of purchasing medical marijuana upon a medical prescription was introduced on 17 January 2019, when the first distributor managed to obtain a licence issued by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. It should be emphasized that the question concerning the legitimacy of legalizing the so-called "soft drugs" for medical purposes had been analysed in the literature before.[22]

Beside the analysis, it should be noted that while the actual possibility of acquiring medical cannabis in a pharmacy open to the public in Poland appeared in 2019, since 2001 it had been possible to use medical cannabis imported into Poland as so-called targeted importation, which was provided for by the Pharmaceutical Law[23] from the beginning of its application. The basis for targeted importation, i.e. importing a medicinal product from abroad for a particular patient, was and is now the order of a hospital or a medical practitioner supervising an outpatient therapy, confirmed by a consultant in the given field of medicine (Article 4 (2) APL).

ADMISSIBILITY OF THE USE OF MEDICAL MARIJUANA CONTRARY TO THE REGISTRATION SET OUT IN THE SMPC

Pursuant to Article 4 APMPD, one of the basic duties of a medical practitioner is to diagnose and treat diseases with due diligence. Due diligence in the treatment process is, among other things, the implementation of the pharmacological therapy in an optimised manner, tailored to the patient's needs. Each ready-to-use medicinal product has an SmPC which specifies, i.a., the registered indications, the age

materials for the preparation of prescription drugs in the form of plant of cannabis other than fibrous and extracts, pharmaceutical tinctures, as well as all other extracts of non -fibrous cannabis and resin of non- fibrous cannabis and the detailed scope of data and list of documents covered by this application (Journal of Laws 2017, item 2337).

[20] M. Gazdowicz, N. Susłowska, K. Piątkowska, A. Zimmermann, *Status prawny medycznej marihuany – badanie wiedzy i opinii studentów farmacji*, "Prawo Farmaceutyczne" 2020, no. 5, p. 252.

[21] Journal of Laws 2018, item 1490.

[22] A. Habib, *Medyczny aspekt legalizacji miękkich narkotyków – zagrożenie czy szansa na skuteczne leczenie?*, "Acta Universitatis Lodziensis. Folia Iuridica" 2016, vol. 76, pp. 77–88.

[23] Act of 6 September 2001 – Pharmaceutical Law (consolidated text, Journal of Laws 2022, item 2301), hereinafter: APL.

group in which the product may be used, the dosing schedule, and the route of administration. In clinical practice, medicinal products are also used outside the SmPC (off-label use), which is due, among other things, to the individual needs of the patient and for strictly formal reasons, i.e. the lack of verification of the content of the SmPC defined a few or a dozen years earlier.

The literature emphasizes that a medical practitioner should plan a methodology for treatment based on EBM (evidence-based medicine).[24] The term "evidence-based medicine" means medicine based on facts and scientific evidence.[25] The literature points out that EBM is a conscientious, unambiguous, reasonable use of modern, best evidence when deciding on the individual care of patients.[26] R.D. Capras, A.E. Bulboaca and S.D. Bolboaca point out that EBM is an approach to medical practice aimed at optimising decision-making by stressing the use of evidence supported by systematic and important medical research.[27] The use of EBM treatment often requires the use of pharmacotherapy outside the registration strictly defined in the SmPC.

In the context of the use of medical marijuana, the question arises whether the implementation of off-label treatment is an EBM action, or whether a departure from the content of the SmPC should be interpreted as an action similar to a medical experiment. The answers to the above questions can be provided only by a cursory analysis of scientific research on the legitimacy and effectiveness of the use of medical marijuana. Although the matter of medical analysis is significantly beyond the scope of this paper, a brief reference is made below to several reports on the effectiveness of medical marijuana in the treatment of pain of various origins, including cancer-induced pain.

Reports of researchers regarding the use of medical marijuana in pain ailments and other diseases are ambiguous. J. Aviram and G. Samuelly-Leichtag have shown that the effectiveness of minimising chronic pain using cannabis versus placebo is not unambiguous.[28] On the other hand, E.A. Romero-Sandoval et al.[29] noted that cannabis

[24] M. Norhayati, N. Zanaridah, *Validity and Reliability of the Noor Evidence-Based Medicine Questionnaire: A Cross-Sectional Study*, "PLoS One" 2021, vol. 16(4), p. 1.

[25] D. Sackett, W. Rosenberg, M. Gray, B. Haynes, S. Richardson Scott, *Evidence Based Medicine*, "British Medical Journal" 1996, vol. 312(71), p. 170.

[26] I. Masic, M. Miokovic, B. Muhamedagic, *Evidence Based Medicine – New Approaches and Challenges*, "Acta Informatica Medica" 2008, vol. 16(4), p. 219.

[27] R.-D. Capraş, A.E. Bulboacă, S.D. Bolboacă, *Evidence-Based Medicine Self-Assessment, Knowledge, and Integration into Daily Practice: A Survey among Romanian Physicians and Comparison between Trainees and Specialists*, "BMC Medical Education" 2020, vol. 20, p. 19.

[28] J. Aviram, G. Samuelly-Leichtag, *Efficacy of Cannabis-Based Medicines for Pain Management: A Systematic Review and Meta-Analysis of Randomized Controlled Trials*, "Pain Physician" 2017, vol. 20(2), pp. 755–796.

[29] E.A. Romero-Sandoval, J.E. Fincham, A.L. Kolano, B.N. Sharpe, P.A. Alvadoro-Vazquez, *Cannabis for Chronic Pain: Challenges and Considerations*, "Pharmacotherapy" 2018, vol. 38(6), pp. 651–662.

inhalation was effective in the treatment of pain of various origins.[30] At the same time, the authors pointed to the effectiveness of inhaled marijuana used for a longer period of 6 or 12 months in patients with cancer-induced pain, pain of unspecified origin, and chronic neuropathic pain.[31] In turn, research presented by L. Wang et al.[32] shows that non-inhaled marijuana or cannabinoids cause little to very little improvement in pain relief, physical function, and sleep quality in patients with chronic cancer pain.

In the Polish literature, researchers who examine the effectiveness of medical marijuana argue that the medicinal properties relate primarily to cannabinol, cannabidiol, cannabigerol, and cannabichromene.[33] The authors state that their therapeutic application can be used to alleviate autoimmune disorders, especially those associated with multiple sclerosis or inflammatory bowel disease. Other authors hold that mainly the varieties of cannabis characterized by a high THC content are used in therapy,[34] at the same time indicating the wide use of synthetic derivatives of cannabinoids, e.g. Nabilone or Dronabilone. The literature emphasizes that medical marijuana is used when conventional therapy does not bring the intended effects or does not relieve troublesome pain symptoms,[35] and that cannabinoids can be effectively used to treat neurodegenerative diseases, seizures or vomiting.[36]

Studies on cannabis application are ambiguous, but most of them indicate that it is effective in treating pain. Most medicinal products containing marijuana do not have detailed posology provisions in the SmPC, and section 4.2 of the SmPC refers to the authorised indications and the age population in which the product may be used. A key question in the context of the admissibility of the off-label use of medical marijuana is: Can medical marijuana be used for indications other than those listed in the SmPC, and can medical marijuana be used in the paediatric population if the SmPC formally provides for the admissibility of the use of the product only in adults?

Analysing the above questions, it should be noted that, according to World Health Organization estimates, half of all medicines available on the global phar-

[30] See also B. Wilsey, T.D. Marcotte, R. Deutsch, H. Zhao, H. Prasad, A. Phan, *An Exploratory Human Laboratory Experiment Evaluating Vaporized Cannabis in the Treatment of Neuropathic Pain from Spinal Cord Injury and Disease*, "Journal of Pain" 2016, vol. 17(9), pp. 982–1000; M.S. Wallace, T.D. Marcotte, A. Umlauf, B. Gouaux, J.H. Atkinson, *Efficacy of Inhaled Cannabis on Painful Diabetic Neuropathy*, "Journal of Pain" 2015, vol. 16(7), pp. 616–627.

[31] M.S. Wallace, T.D. Marcotte, A. Umlauf, B. Gouaux, J.H. Atkinson, *op. cit*.

[32] L. Wang [et al.], *Medical Cannabis or Cannabinoids for Chronic Non-Cancer and Cancer Related Pain: A Systematic Review and Meta-Analysis of Randomised Clinical Trials*, "BMJ" 2021, vol. 374(1034).

[33] M. Motyka, J. Marcinkowski, *Używanie pochodnych konopi. Część II. Zastosowanie w medycynie vs. konsekwencje zdrowotne*, "Problemy Higieny i Epidemiologii" 2014, vol. 95(1), p. 22.

[34] P. Siudem, I. Wawer, K. Paradowska, *op. cit.*, p. 2.

[35] A. Zakrzeska, T. Grędziński, W. Kisiel, E. Chabielska, *Kannabinoidy a hemostaza*, "Postępy Higieny i Medycyny Doświadczalnej" 2016, no. 70, p. 762.

[36] G. Silska, *Konopie (Cannabis L.) jako źródło kanabinoidów stosowanych w terapii*, "Postępy Fitoterapii" 2017, no. 4, p. 288.

maceutical market are at least incidentally administered in a manner not covered by the instructions.[37] In 1997, the Food and Drug Administration defined the method as "off-label use", referring to the use of medicines for an unregistered recommendation, dose or schedule that deviates from the SmPC, or in a patient population for which the medicine has not been registered.[38]

In the literature, it is claimed that the rate of off-label use of medicines is 7.5–15% for typical outpatient general internist indications, 30–50% in oncology patients, and even 90% in neonatology and paediatric oncology departments. Branches of medicine where off-label pharmacological therapy is particularly frequent include paediatrics, oncology, dermatology, haematology, and palliative medicine.[39] M.M. Saiyed, P.S. Ong and L. Chew point out that off-label use in hospitalised oncology patients ranges from 18% to 41%.[40] The main reasons for off-label use were the lack of registration of the product for treating a disease diagnosed in the patient or the need to deviate from the dosing schedule provided by the SmPC.[41] The scale of the needs for off-label treatment in oncology is illustrated by the research carried out by A.K. Herbrand et al. during 2015–2018. The studies carried out in the Swiss population have shown that 45% of first-line treatment cases in 3,046 cancer patients were associated with the decision to initiate off-label use therapy.[42] In a paper published in 2021, Japanese researchers showed that the diseases most commonly treated with off-label use therapy were sarcoma, urological tumours, and gastrointestinal neoplasms.[43] A study conducted at the Peter MacCallum Cancer Center in Australia found that off-label prescribing is widespread in the population of patients hospitalised due to acute cancer disease, with approx. 22% of all prescriptions regarding non-authorised or unlicensed medicines.[44]

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[37] G.J. Dal Pan, *Pharmacovigilance Focus: Monitoring the Safety of Off-Label Medicine Use*, "WHO Drug Information" 2009, vol. 23(1)p. 21 ff.

[38] R.S. Stafford, *Regulating Off-Label Drug Use – Rethinking the Role of the FDA*, "New England Journal of Medicine" 2008, vol. 358, pp. 1427–1429.

[39] S. Bun, K. Yonemori, H. Sunadoi, R. Nishigaki, E. Noguchi, T. Okusaka, T. Nishida,Y. Fujiwara, *Safety and Evidence of Off-Label Use of Approved Drugs at the National Cancer Center Hospital in Japan*, "JCO Oncology Practice" 2021, vol. 17(3), pp. 416–425.

[40] M.M. Saiyed, P.S. Ong, L. Chew, *Off-Label Drug Use in Oncology: A Systematic Review of Literature*, "Journal of Clinical Pharmacy Therapeutics" 2017, vol. 42(3), pp. 251–258.

[41] *Ibidem*.

[42] A.K. Herbrand, A.M. Schmitt, M. Briel, H. Ewald, M. Goldkuhle, S. Diem, A. Hoogkamer, M. Joerger, G. Moffa, U. Novak, L.G. Hemkens, B. Kasenda, *Association of Supporting Trial Evidence and Reimbursement for Off-Label Use of Cancer Drugs*, "JAMA Netw Open" 2021, vol. 4(3).

[43] S. Bun, K. Yonemori, H. Sunadoi, R. Nishigaki, E. Noguchi, T. Okusaka, T. Nishida,Y. Fujiwara, *op. cit.*, p. 418.

[44] S.G. Poole, M.J. Dooley, *Off-Label Prescribing in Oncology*, "Supportive Care in Cancer" 2004, vol. 12(5), pp. 302–305.

The relevance of the SmPC was addressed by the Court of Appeal in Warsaw in its judgment of 14 February 2014, in which the Court stressed that "the SmPC is one of the documents necessary for the authorisation of marketing of medicinal products, it contains data on the manufacturer, composition, effect, posology, and risks identified in relation to the use of a particular product, but it is not normative but informative, establishing the state of knowledge about the product at a certain moment in time. In view of the continuous progress of medical knowledge, the medical practitioner must have sufficient freedom to use medicines in a manner that is adapted to the current medical achievements and needs of the patient concerned".[45]

In its judgment of 24 November 2011, the Supreme Court referred to the relationship between the provisions of the SmPC and the doctor's decision on the dosage of the medicine. According to the Court, "the medical practitioner's right to prescribe a dosage considered appropriate is based on the fact that he takes and is responsible for therapeutic decisions and cannot therefore be bound by the method of dosing prescribed in the summary of product characteristics. The medical practitioner's decision on dosing must take into account the individual needs determined by the patient's state of health and other professionally evaluated circumstances; otherwise, § 8 (1) (2) of the Regulation of the Minister of Health of 17 May 2007 empowering the medical practitioner to prescribe the method of dosing would be completely unnecessary or would have to lead to an absurd conclusion that the medical practitioner is obliged to automatically duplicate only the method of dosing specified in the summary of product characteristics".[46]

The Supreme Court expressed a similar opinion in the resolution of 26 October 2011, emphasizing that "Article 45 of the Act of 5 December 1996 APMPD, (…) and Article 10 (1) (11) and Article 11 (1) (4) of the Act of 6 September 2001 APL, do not provide grounds for assuming that a medical practitioner, when determining the method of dosing a medicine, is bound by the posology contained in the summary of product characteristics of a medicinal product" and that "it is the medical practitioner's prerogative to determine the method of treatment, including the dosage of medicines needed. Where there is a need to use medication, it is the medical practitioner who, taking into account the necessary knowledge and the circumstances of the specific case, should select the appropriate medicine and determine the manner of its dosing and the amount of medication necessary for an effective treatment. He bears responsibility in this respect, taking into account the requirements of effectiveness and safety of the treatment applied (…)".[47]

[45] Judgment of the Court of Appeal in Warsaw of 14 February 2014, VI ACa 1000/13, LEX no. 1469448.

[46] Judgment of the Supreme Court of 24 November 2011, I CSK 69/11, OSNC 2012, no. 5, item 63.

[47] Resolution of the Supreme Court of 26 October 2011, III CZP 58/11, OSNC 2012, no. 5, item 59.

The presented case law indicates that the provisions of the SmPC are only of a formal nature and do not constitute in each case a guarantee of acting in accordance with the guidelines of current medical knowledge. At the same time, it should be noted that legal provisions do not explicitly define which sources of knowledge a medical practitioner must or should use. Scholars in the field point out that medical knowledge resulting from research must be made public in a verifiable form, so as to make it possible not only to examine and possibly criticize the correctness of the method used, but also to recreate the research according to the proposed method in order to compare the results obtained.[48] At the same time, the literature emphasizes that "no regulation requires that, for a valid and effective exercise of the medical practitioner's competence to prescribe a medicine (in whatever form), the medicinal product must be prescribed in accordance with the registered indications" and "there are no specific rules that would limit the medical practitioner's right to prescribe a medicinal product of his own choice, of course taking into account the diagnostic and therapeutic findings in the specific case, with adherence to the legal and extra-legal directives of medical diligence. This conclusion also applies to off-label treatments".[49]

For the legitimacy of dispensing a medicine outside the SmPC, it does not matter whether the service was provided in person or remotely. The admissibility of using ICT media in the context related to the prescription of medicinal products constitutes the implementation of the patient's right to virtual healthcare.[50]

According to I. Vrancken, the term "off-label use" should be understood primarily as the use of medicines in a population not listed in the SmPC and also not in accordance with the registered indication.[51] It is also argued in the literature that off-label use may mean the use of a medicine in other age group, with other dosage or contrary to its intended use.[52]

In Vrancken's opinion, it is essential to distinguish the primary meaning of the term "off-label use", which should be understood as a departure from the registered indication or the use of the product in a different age group than that specified in the

[48] T. Widłak, *Interpretacja klauzuli „aktualna wiedza medyczna" w polskim prawie – zarys zagadnień epistemologicznych i metodologicznych*, "Gdańskie Studia Prawnicze" 2017, vol. 38, pp. 603–613.

[49] O. Luty, *Zaniechanie zlecenia produktu leczniczego poza zarejestrowanym wskazaniem a odpowiedzialność cywilna lekarza. Obowiązek zlecenia leku off-label i konsekwencje jego niewykonania, cz. 2*, "Prawo i Medycyna" 2014, no. 2, pp. 132–150.

[50] More on this topic, see O. Hevchuk, O. Bululukov, O. Lysodyed, V. Mamonova, Y. Matatt, *Human Right to Virtual Reality in the Healthcare: Legal Issues and Enforcement Problems*, "Juridicial Tribune" 2021, vol. 11 (Special Issue), pp. 302–315.

[51] I. Vrancken, *Off-Label Prescription of Medication*, "European Journal of Health Law" 2015, vol. 22(2), pp. 165–186.

[52] D.C. Radley, S.N. Finkelstein, R.S. Stafford, *Off-Label Prescribing among Office-Based Physicians*, "Archives of Internal Medicine" 2006, vol. 166(9), pp. 1021–1026.

content of the SmPC, from the secondary meaning, which should be associated with a change in dosage scheme, route of administration or a change in other indications for the use of the medicine expressed in the content of the SmPC. While a modification of the dosage may be justified by individual disease specificity or personal characteristics of the patient, the use of medicines outside the registered indications or in an age group other than that indicated in the SmPC should be justified by the purposes of saving human life or health, ineffectiveness of the previous therapy, depletion of available registered medicinal products, while anticipating that the positive effects of implementing the treatment outside the SmPC will outweigh the potential risks related to its use.

The off-label use of medical marijuana in the primary sense should not be equated with a medical experiment in the strict sense, but at most with an action similar to a medical experiment. Pursuant to Article 21 (2) APMPD, "a therapeutic experiment is the introduction of new or only partially tested diagnostic, therapeutic or prophylactic methods in order to achieve a direct benefit to the health of an ill person. It may be carried out if the methods used so far has proved to be ineffective or if their effectiveness is not sufficient (…)".

The main difference between a medical experiment and the off-label use of medicinal products in the primary sense is that experimental activities are a complete novelty or are only partially tested. An off-label use of medicinal products or in an age group other than those indicated in the SmPC should be based on EBM, medical literature and guidelines of expert teams. In the case where EBM and other objective evidence indicate that it is safe to use medical marijuana off label, this type of action should be equated with an ordinary medical service, which in the literature is not identified as an experimental activity.[53]

Undertaking a personalized treatment with medical marijuana, which is a response to the individual needs of a terminally ill patient, is undoubtedly the implementation of the right to pain treatment, but also the right to be provided medical services that meet the requirements of the latest medical knowledge, referred to in Article 6 (1) ARP. The use of medical marijuana is not only the implementation of the patient's rights indicated above, but also the implementation of the very availability of services, which, as indicated in the literature, have been significantly limited during the COVID-19 pandemic.[54]

According to the Court of Appeal in Lodz, a certain minimum in terms of up-to--date status of medical knowledge is "information obtained by a medical practitioner

[53] M. Safjan, *Prawo i medycyna. Ochrona praw jednostki a dylematy współczesnej medycyny*, Warszawa 1998, p. 172.

[54] See M. Łaszewska-Hellriegel, *Trudne wybory – kto może liczyć na odpowiednią opiekę zdrowotną podczas pandemii COVID-19*, "Krytyka Prawa. Niezależne Studia nad Prawem" 2020, vol. 12(4), pp. 105–123.

during studies, available in textbooks in a broad sense, but also, due to the current pace of scientific and technical development, enhanced by improving professional expertise".[55] Noteworthy is also the judgment of the Voivodeship Administrative Court in Warsaw of 26 February 2018, in which the Court stated that "the term 'up-to-date medical knowledge' cannot refer to internet publications, brochures of the manufacturer of medical equipment, scientific papers, etc., but to the entirety of medical knowledge along with evidence-based theories and formalized clinical tests. The rule is to refrain from using unproven methods that are still at the experimental stage and is not sufficiently recognized in the medical community, because it is associated with high risk, and from using abandoned activities that have been found to be ineffective, incorrect or dangerous (…). Relevant for the assessment whether the treatment complied with the requirements of current medical knowledge is the state of knowledge at the time of the procedure, which is of particular importance given the rapid progress in medicine".[56] Current medical knowledge regarding medical marijuana is constantly evolving, which results from the exponential increase in the literature on the subject.[57]

Regardless of the above, the off-label use of medical marijuana should be analyzed in the context of the admissibility of using the above-mentioned product in the form of pharmacy-compounded medication (officinal formula), i.e., a medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by such pharmacy, and which is based on pharmaceutical raw materials. Pharmaceutical raw materials are substances or mixtures of substances used for the preparation or manufacture of medicinal products (Article 2 (40) APL). "Medicinal product" in accordance with Article 2 (32) APL means a substance or combination of substances presented as having properties for the prevention or treatment of diseases in humans or animals or administered with a view to making a diagnosis or to restoring, correcting or modifying the physiological functions of the body by pharmacological, immunological or metabolic action. Pharmaceutical services provided by pharmacies include also production of prescription drugs from pharmaceutical raw materials (Article 2 (12) in conjunction with Article 2 (32) and (40) APL), based on a prescription presented by the patient (Article 86 (2) (2) APL).

[55] Judgment of the Court of Appeal in Lodz of 27 November 2014, I ACa 745/14, LEX no. 521717624.

[56] Judgment of the Voivodeship Administrative Court in Warsaw of 26 February 2018, VI SA/Wa 2179/18, LEX no. 2689804.

[57] An analysis of the PubMed database indicates that a total of 328 papers describing the use of "medical marijuana" were published in 1990, while in 2017 the figure was as many as 3,137 publications. As cited in L.B. Schleider, R. Abuhasira, V. Novack, *Medical Cannabis: Aligning Use to Evidence-Based Medicine Approach*, "British Journal of Clinical Pharmacology" 2018, vol. 84(11), pp. 2458–2462.

It should be noted that the pharmaceutical form of a pharmacy-compounded product is not specified by the law, which allows its production in the form of solution, drops, suspension, emulsion, ointment, powder, etc. A pharmacy-compounded product also lacks an SmPC, which means that it can be used in the patient according to the individual recommendations of a medical professional, who also decides the composition, proportion of ingredients, and the age group in which the product can finally be used.

At the same time, it should be emphasized that the decision to apply prescription medicines should be taken on the basis of EBM and the due diligence rules referred to in Article 4 APMPD. In the absence of rigid rules on the principles and manner of use of prescription medicines, it would be unreasonable to question medical decisions relating to their use for a specific patient and the indication in which they will be applied.

This leads us to the use, in the context of the analysis, of the *maiori ad minus* argument as a basis for the assertion that, since medical marijuana can be used in any way through its application in the form of a pharmacy-compounded medicine, it is all the more possible to implement off-label use treatment using a ready-to-use medicine containing medical marijuana that has been authorised for marketing for the treatment of pain-related ailments, for example.

CONCLUSIONS

Medical marijuana treatment is now legally permitted and is becoming an increasingly used treatment for persistent pain in terminally ill patients. Undoubtedly, the use of medical marijuana constitutes, irrespective of the risk of negative consequences associated with it, including psychoactive substance dependence syndrome, the implementation of the patient's right to treatment of pain and to be provided services corresponding to the requirements of current medical knowledge. The treatment of pain should be based on verified, up-to-date medical knowledge, EBM, as well as guidelines of expert teams that respond to dynamically changing medical knowledge.

The context of the admissibility of the off-label use of medical marijuana is a complex issue, but it is nevertheless necessary in this case to refer to general rules and EBM insofar as they relate to the use of medicinal products outside of the SmPC. Given that many medicinal products are used in oncology and palliative care not in accordance with their original registration, it must be assumed that medical marijuana may be used in cases chosen by the medical practitioner not only contrary to the list of registered indications, but also in an age group that has not been indicated as a target group in the content of the SmPC.

This thesis is undoubtedly supported by the possibility of using medical marijuana in the form of a pharmacy-compounded product prepared on the basis of

pharmaceutical raw materials. The above clearly excludes adherence to the content of the SmPC since it is absent, as well as allows the use of any composition and proportion of pharmaceutical substrates to an individual patient.

These considerations lead to the following conclusions:

1. Medical marijuana treatment is fully permissible in the light of Polish law and is an action consistent with the current state of medical knowledge.
2. Minimizing pain, including the use of alternative methods of treatment, is the implementation of the patient's right to pain treatment.
3. Activities consisting in medical treatment with off-label marijuana do not constitute a medical experiment, if the use of such treatment is dictated by the considerations of saving human life or health, ineffectiveness of the existing therapy, the need to use coexisting therapy as an element determining the optimization of the therapeutic process, and the potential benefits of therapy outweigh the possible risk of negative consequences.
4. Medical marijuana treatment is increasingly being discussed and implemented in clinical practice, which is due to the increase in medical literature relating to the issue in question.

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ABSTRAKT

Tematyka stosowania produktów leczniczych zawierających „marihuanę medyczną" w terapii pacjentów terminalnych była do niedawna przedmiotem szerokiej dyskusji. Obecnie takie działanie jest legalne, ale wciąż pojawiają się pytania, związane nie tyle z możliwością stosowania medycznej marihuany w leczeniu pacjentów nieuleczalnie chorych, ile z wdrożeniem leczenia poza wskazaniami rejestracyjnymi. Analiza obowiązujących przepisów prawa, stanowiska doktryny i linii orzeczniczej pozwala stwierdzić, że leczenie marihuaną medyczną poza ChPL (Charakterystyka Produktu Leczniczego) jest działaniem dopuszczalnym, którego nie należy utożsamiać z eksperymentem leczniczym *sensu stricto*. Potwierdzeniem powyższego jest dopuszczalność wykorzystania surowców marihuany jako podstawy do przygotowania leku aptecznego (recepturowego). Produkcja leków farmaceutycznych wymaga użycia surowców farmaceutycznych, których ilość i skład zależy od samodzielnej decyzji osoby przepisującej lek. Dopuszczalność dowolnej kompozycji zawartości leku aptecznego zawierającego medyczną marihuanę przemawia za dopuszczalnością jej użycia w jakikolwiek sposób. Powyższe prowadzi do przyjęcia podobnych rygorów w stosunku do gotowych leków zawierających marihuanę. Niezależnie od dopuszczalności stosowania marihuany medycznej poza ChPL lub w postaci leku aptecznego, leczenie marihuaną medyczną jest realizacją prawa pacjenta do leczenia bólu i korzystania ze świadczeń zdrowotnych zgodnie z aktualnym stanem wiedzy medycznej.

Słowa kluczowe: medyczna marihuana; stosowanie leków poza rejestracją; leczenie bólu marihuaną; prawo pacjenta do leczenia bólu