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ADMISSIBILITY OF HEMP CROP OTHER THAN FIBROUS IN POLAND

Abstract

Implementation in the Polish legal system of the amendment of the Act on Counteracting Drug Addiction on 7 May 2022 allowed for a possibility of cultivating in Poland hemp other than fibrous for the needs of the pharmaceutical industry. The paper discusses the path that has led from the legalization of cannabis and its products to a gradual change of attitude both in international and national legislation. The aim of the study is also to familiarize the reader with the requirements the Polish legislator has placed on entities that intend to grow hemp other than fibrous for the production of pharmaceutical raw material.

KEYWORDS

cannabis, Indian hemp, cannabis cultivation, medical marijuana, medical cannabis use

SŁOWA KLUCZOWE

konopie, konopie indyjskie, uprawy konopi, marihuana medyczna, medyczne zastosowanie konopi

1. INTRODUCTION

Statutory restrictions on the possibility of cultivating agricultural crops¹ are of exceptional nature in Polish legislation. At present, there are basically three cases of such restrictions: genetically modified plants², poppy and cannabis³. There are different reasons for introducing rules restricting the cultivation of agricultural crops. In the case of poppy and cannabis cultivation, these are to protect health and social welfare, and prevent the diversion of narcotic drugs into the illicit market⁴. It is much more difficult to determine the rational reasons for restricting the possibility of cultivating genetically modified crops in Poland. The justification for the draft of the Act of 22 March 2018 amending the Act on Microorganisms and Genetically Modified Organisms and certain other acts⁵ may indicate that such reasons include: protection of beekeepers and preservation of high quality products produced by beekeepers, nature conservation, protection or maintenance of habitats, ecosystems and landscape. Restrictions on the cultivation of genetically modified crops are not, however, the subject/interest of this study.

The Act on Counteracting Drug Addiction (hereinafter A.C.D.A.), defines hemp as plants of the *hemp genus* (*Cannabis L.*)⁶ and at the same time introduces their division into fibrous hemp and hemp other than fibrous. According to A.C.D.A., fibrous hemp includes plants of the true hemp species (*Cannabis sativa L.*) in which the sum of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid) in flowering or fruiting tops of plants from which the resin has not been removed does not exceed 0,3 per cent on a dry weight

¹ There is no legal definition of the term “crop” or “agricultural cultivation” in the current legislation. The case law of the Supreme Court, in particular the resolution of the Supreme Court – Civil Chamber of 14 April 1994 in the case Bering reference symbol of files III CZP 46/94 (Jurisprudence of the Supreme Court of the Civil, Labour and Social Insurance Chamber (OSNCP) 1994, No. 10, item 191) and the resolution of the composition of seven judges of the Supreme Court of 19 May 2015 in case bearing the reference symbol of files III CZP 114/14 (Jurisprudence of the Supreme Court of the Civil Chamber (OSNC) 2015, No. 12, item 134, p. 1) allow for the thesis that the concept of “agricultural cultivation” shall be interpreted according to its common understanding, as any type of cultivation carried out on agricultural land, which is the result of human activity closely related to the productive function of land as a means of production.

² Restrictions on the admissibility of cultivation of genetically modified plants are introduced by the provisions of Art. 49a and the next ones of the Act of 22 June 2001 on Microorganisms and Genetically Modified Organisms (“Journal of Laws” 2022, item 546).

³ Restrictions on the admissibility of cultivation of poppy and cannabis are regulated by the provisions of Art. 45 and the next ones of the Act of 29 July 2005 on Counteracting Drug Addiction (“Journal of Laws” 2020, item 2050, as amended).

⁴ Art. 22, sec. 1 of Single Convention on Narcotic Drugs of 1961 (“Journal of Laws” 1966, No. 45, item 277).

⁵ “Journal of Laws” 2018, item 810.

⁶ Art. 4, item 4 of the Act on Counteracting Drug Addiction.

basis; this sum shall be rounded to one decimal place⁷. Still, A.C.D.A. does not define the concept of the “hemp other than fibrous”. However, the scheme of that legislative act shows that the legislature treats as “hemp other than fibrous” all other cannabis which does not meet the statutory definition of fibrous hemp. At the same time, hemp other than fibrous is commonly referred to as cannabis or marijuana⁸. However, the term “marijuana” is derived from Spanish and means “Indian hemp”⁹. It should be emphasized that the legal division of hemp presented above deviates from their botanical system. In natural sciences, it is now recognised that the genus *Cannabis* includes only one species of *Cannabis sativa* L. (seed hemp), comprising both fibrous hemp (*Cannabis sativa* L. var. *sativa*) and Indian (narcotic) hemp (*Cannabis sativa* L. var. *indica*)¹⁰.

Restrictions on cannabis cultivation in Poland cover both fibrous hemp and hemp other than fibrous. The scope of these restrictions varies. With regard to fibrous hemp, it is significantly narrower and its purpose is, in essence, to enable public authorities to verify that the operator running such cultivation is not attempting to produce controlled substances from hemp other than fibrous. The restrictions on the cultivation of hemp other than fibrous are much more severe. This study focuses on the issue of restrictions on cultivation of hemp other than fibrous, taking into account recent legislative changes in this area.

2. PROPERTIES AND APPLICATION OF HEMP OTHER THAN FIBROUS

Cannabis has been an agricultural plant known to human being for almost 12 thousand years¹¹. The characteristic feature of cannabis is that it produces, among others, specific chemical compounds called cannabinoids. Due to the

⁷ Art. 4, item 5 of the Act on Counteracting Drug Addiction.

⁸ P. Bołtryk, *Kryminologiczne i prawne aspekty posiadania narkotyków w Polsce (na przykładzie pochodnych konopi innych niż włókniste)* [Criminological and legal aspects of drug possession in Poland (as exemplified by the hemp derivatives other than fibrous)], Białystok 2014, p. 210.

⁹ M. Kuna, *Warunki medycznego zastosowania marihuany w Polsce – aspekty prawa administracyjnego* [Conditions of medical use of marijuana in Poland – aspects of administrative law], “Przegląd Prawa Administracyjnego” 2019, No. 2, p. 82.

¹⁰ M. Strzelczyk, R. Kaniewski, *Konopie siewne Cannabis sativa L. – jeden z najstarszych gatunków roślin użytkowych* [*Cannabis seed Cannabis sativa L. – one of the oldest species of useful plants*], “Postępy Fitoterapii” 2021, No. 1, p. 53.

¹¹ P. Gała, *Bariery prawne twórczej hodowli nowych odmian konopi włóknistych w Polsce*, (in:) E. Calka, A. Jakubecki, M. Nazar, A. Niewęglowski, R. Poździk (red.), *In varietate concordia. Księga jubileuszowa Profesora Ryszarda Skubisza*, Warszawa 2022, pp. 421–422 and the literature called there.

presence of cannabinoid receptors in the human body¹², these substances affect many human tissues, including the brain¹³. This effect may in turn be psychoactive or non-psychoactive¹⁴. Delta-9-tetrahydrocannabinol, commonly known as THC, and cannabidiol or CBD, were the best investigated of the cannabinoids isolated so far. Hemp other than fibrous and therefore, from a botanical point of view, hemp belonging to the sub-species of cannabis, is characterized by several times higher THC content than fibrous hemp. THC displays anti-inflammatory, anticancer, analgesic, smooth muscle relaxant¹⁵, and antispasmodic effects¹⁶. With these properties, therapies using THC can effectively alleviate the side effects of cancer chemotherapy, support the treatment of Alzheimer's disease, Parkinson's disease, Huntington's disease, atrophic lateral sclerosis, chronic neuropathic pain, asthma, epilepsy, and glaucoma¹⁷. However, THC also has significant negative health effects: it causes memory and cognitive deficits, impairs motor coordination, and when used at an early age, with an increased risk of addiction, it can also cause chronic mental disorders, including schizophrenia¹⁸. Recent studies show that CBD has anti-anxiety, anti-arthritis, antipsychotic, anti-inflammatory, analgesic, sedative, and immunomodulatory properties, and prevents nausea¹⁹. After all, it has the potential to treat epilepsy, neurodegenerative diseases, schizophrenia, multiple sclerosis²⁰. In addition, CBD reduces the side effects of using THC, and thus is able to reduce the danger of taking preparations derived from hemp other than fibrous²¹.

In addition to the above-mentioned medicinal properties of selected cannabinoids, other chemicals present in cannabis, such as terpenes and phenolic compounds, also show beneficial health properties. A characteristic feature of

¹² Cannabinoid receptors (CB1) were discovered in 1988. They are present throughout the central and peripheral nervous system of human being. More on this subject T. Dzierżanowski, *Kannabinoidy – możliwości zastosowania w medycynie paliatywnej* [Cannabinoids: Potential applications in palliative medicine], "Medycyna Paliatywna" 2018, No. 10, pp. 1–2.

¹³ M. Strzelczyk, R. Kaniewski, *op. cit.*, p. 54.

¹⁴ C.H. Ashton, *Pharmacology and effects of cannabis: A brief review*, "The British Journal of Psychiatry" 2001, Vol. 178, issue 2, p. 102.

¹⁵ C.M. Andre, J. F. Hausman, G. Guerriero, *Cannabis sativa: The plant of the thousand and one molecules*, "Frontiers in Plant Science" 2016, p. 4.

¹⁶ P. Pacher, S. Batkai, G. Kunos, *The endocannabinoid system as an emerging target of pharmacotherapy*, "Pharmacological Reviews" 2006, No. 58, p. 394.

¹⁷ M. Strzelczyk, R. Kaniewski, *op. cit.*, p. 57.

¹⁸ T. Iseger, M. Bossong, *A systematic review of the antipsychotic properties of cannabidiol in humans*, "Schizophrenia Research" 2015, No. 162, p. 158.

¹⁹ S. Burnstein, *Cannabidiol (CBD) and its analogs: A review of their effects on inflammation*, "Bioorganic & Medicinal Chemistry" 2015, No. 5, p. 1379.

²⁰ A.J. Hill, C.M. Williams, B.J. Whalley, G.J. Stephens, *Phytocannabinoids as novel therapeutic agents in CNS disorders*, "Pharmacology & Therapeutic" 2012, Vol. 133, issue 1, pp. 83–84.

²¹ A. Englund, J.M. Stone, P.D. Morrison, *Cannabis in the arm: What can we learn from intravenous cannabinoid studies?*, "Current Pharmaceutical Design" 2012, Vol. 18, issue 32, pp. 4912–4913.

preparations made from cannabis, and in particular hemp other than fibre, is that they exert their pharmacological effects in humans through the synergistic or antagonistic action of the individual active compounds contained therein. Thus, isolated or artificially synthesized cannabinoids do not exert such effects²².

In view of the above considerations, one may be tempted to conclude that due to the properties of cannabis, and especially those of hemp other than fibrous, they have a dual application in practice. Firstly, they can be successfully used in medicine, often referred to as medical cannabis or medical marijuana. Secondly, due to their psychoactive properties, they find so-called recreational use, as a kind of stimulant or soft drug.

3. HISTORY OF RESTRICTIONS ON THE CULTIVATION OF HEMP OTHER THAN FIBROUS

Restrictions on the cultivation of hemp other than fibrous are intrinsically linked to restrictions on the use of preparations made from it. The origins of such restrictions can be traced back to the provisions of the International Opium Convention, adopted in Geneva on 19 February 1925²³. According to Art. 1 of that Convention, “Indian hemp” means dried flowering or fruiting tops of female plants of *Cannabis sativa* L., from which no resin has been extracted, regardless of the name given to them in trade. It is worth noting that this definition made no distinction between fibrous hemp (non-narcotic) and the other one (narcotic). Afterwards, the Opium Convention required its Parties to adopt legislation restricting the manufacture, import, sale, distribution, export, and use of cannabis extracts and tinctures solely for medical and scientific purposes. The Contracting Parties were to prevent the use of cannabis extracts and tinctures for any other purpose²⁴. In addition, the entire Chapter IV of that Convention is devoted to the prohibition of international trade in cannabis and its resin.

The next step in banning the cultivation of hemp other than fibrous was the passage by the United States Congress of the Marijuana Tax Act in 1937²⁵. In practice, this law allowed only hemp seeds to be used for the production of bird feed and oil, and allowed the use of hemp for medical purposes.

²² H. Wagner, G. Ulrich-Merzenich, *Synergy research: Approaching a new generation of phytopharmaceuticals*, “Phytomedicine” 2009, Vol. 16, pp. 107–108.

²³ “Journal of Laws” 1927, No. 108, item 920.

²⁴ Art. 4 item f, Art. 5 and Art. 6 of International Opium Convention.

²⁵ Marijuana Tax Act of 1937, <https://www.votehemp.com/wp-content/uploads/2018/09/Musto-on-the-MTA.pdf> (accessed 08.01.2023).

However, the adoption of the 1961 Single Convention on Narcotic Drugs was of particular importance for restrictions on non-Indian hemp cultivation²⁶. It defined hemp as flowering or fruiting tops of hemp plants (excluding seeds and leaves, if not present together with the tops), from which no resin has been extracted, regardless of the name given to them, while indicating that “hemp plant” means all plants of the genus of hemp. The Convention also devoted the whole of Art. 22 to the issues concerning cultivation of hemp, stating that:

1. Where conditions in the country or territory of any Party require, in its opinion, the prohibition of the cultivation of the poppy, coca bush or hemp plant as the most appropriate means of protecting health and social welfare and of preventing the diversion of narcotic drugs into illicit trade, the Party concerned shall prohibit the cultivation.
2. A Party which prohibits the cultivation of the opium poppy or hemp plant shall take appropriate measures to confiscate and destroy any illegally grown plants, except for small quantities required by the Party for scientific and research purposes.

At the same time, however, Art. 28 sec. 2 of the Single Convention provided that its provisions did not apply to hemp plants grown solely for industrial purposes (fibre and seeds) or for horticultural purposes.

The last act of international law that had a significant impact on national (including the Polish) regulations on the restriction of the cultivation of hemp other than fibrous was adopted in 1988. It was the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances²⁷. The Convention redefined the hemp plant as any plant of the genus hemp²⁸. By contrast, in Art. 3 sec. 1 item a(ii), it required each Contracting Party to take such measures as may prove necessary to criminalise under its national law the cultivation of hemp plants for the production of narcotic drugs, carried out in a manner incompatible with the provisions of the Convention.

The first Polish national legislation indirectly relating to hemp was the Law of 23 June 1923 on the Subject of Narcotic Substances and Preparations²⁹. This extremely laconic law (only 12 articles) in Art. 1 prohibited the manufacture, processing, import and export, storage, trade, and any marketing of, among others, hashish. On 30 May 1930, following the entry into force of the Regulation of the Minister of the Interior in agreement with the Minister of Industry and Trade of 15 March 1930 on the recognition of certain intoxicating substances and prepa-

²⁶ 1961 Single Convention on Narcotic Drugs drawn up in New York on 30 March 1961, “*Journal of Laws*” 1966, No. 45, item 277.

²⁷ Drawn up in Vienna on 20 December 1988 (Appendix – “*Journal of Laws*” 1995, No. 15, item 69).

²⁸ Art. 1 item b) the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

²⁹ “*Journal of Laws*” 1923, No. 72, item 559.

rations as having harmful effects on health³⁰, the index of substances of hemp origin covered by the Act of 1923 was extended to include *Herba Cannabis Indicae* (herbs of cannabis), *Cannabinonum* (cannabinoids) and *Tinctura Cannabis Indicae* (cannabis tinctures).

Another Polish law relating to hemp products was the Act of 8 January 1951 on Pharmaceuticals, Narcotic Drugs and Sanitary Articles³¹. Art. 5 of the Act classified narcotics as hashish, cannabis herb, and the preparations and mixtures of these. At the same time, the legislator stipulated in Art. 18 of the same law that their manufacture, processing, export, transport within the country and transit, storage and placing on the market was permissible only for medicinal, scientific or industrial purposes, and only after obtaining the authorisation of the relevant minister³². Only the processing and placing on the market of narcotic drugs were exempted from the authorisation requirement if these activities were carried out in pharmacies for medicinal purposes.

On 31 January 1985, Poland adopted the Drug Addiction Prevention Act³³, which was the first act of law comprehensively covering this issue in Poland. From the point of view of restrictions on cultivation of hemp other than fibrous, it should be emphasized that this law, for the first time in the Polish legal system, defined the concept of hemp as all plants of the genus of hemp (*Cannabis*). It also clarified the concepts of hemp herb, hemp resin and hemp cultivation³⁴. Hemp herb meant flowering or fruiting hemp tops from which no resin had been removed. The hemp resin consisted of resin and other hemp products containing biologically active substances. The cultivation of hemp, on the other hand, included planting of these plants regardless of the area under cultivation. Chapter 2 of the Act is devoted to the cultivation of poppy and cannabis. In the case of cannabis, the law stipulated that its cultivation could only be carried out for the needs of the textile industry. In addition, subjective restrictions have also been applied here. The cultivation of cannabis could be carried out by a natural person or an organizational unit only on the basis of the authorisation of the competent local authority of the basic level of state administration and a contracting agreement concluded with the authorized social economy unit. Only research institutes, universities, botanical gardens, agricultural and horticultural seed companies and the Central Research Centre for Cultivated Plant Varieties were excluded from the requirement to obtain the authorisation described above, but only within the

³⁰ "Journal of Laws" 1930, No. 36, item 304.

³¹ "Journal of Laws" 1951, No. 1, item 4.

³² Accordingly, authorisations for import from abroad, export abroad and transit were granted by the Minister of Foreign Trade in agreement with the Minister of Health. Permits for other activities were granted by the Minister of Health.

³³ "Journal of Laws" 1985, No 4, item 15.

³⁴ Accordingly, Art. 9, item 11, 12, 13 and 14 of the Drug Addiction Prevention Act of 31 January 1985.

scope of their statutory activities. For the first time, this law excluded the possibility of growing cannabis in Poland for medical purposes.

The Drug Addiction Prevention Act of 1985 was repealed by the Act on Counteracting Drug Addiction of 24 April 1997³⁵. The new law introduced a new definition of fibrous hemp – plants of the species hemp seed (*Cannabis sativa* L.) with a content of delta-9-tetrahydrocannabinol below 0.20 % in the dry mass of the herb and other cannabis whose cultivation was prohibited³⁶. At the same time, the cultivation of fibrous hemp was prohibited³⁷. The only exception to these rules was the possibility of growing hemp (both fibrous and other than fibrous) by a university, a research and development unit or other scientific institution and the Central Research Centre for Cultivated Plant Varieties – if this is done as part of the statutory activity, as well as by an entity engaged in plant breeding and using fibrous hemp for insulation purposes. The law therefore maintained the principle of non-cultivation of cannabis for medical purposes.

Summing up, since 1925, international legislation and subsequent Polish national regulations have imposed increasingly far-reaching restrictions on the cultivation of cannabis, especially hemp other than fibrous. In the Polish legal order, these restrictions have led to the exclusion of the possibility of cultivating hemp other than fibrous for medical purposes. The cultivation of fibrous hemp has also been significantly reduced, but this issue is outside the concern of this study.

4. CURRENT RESTRICTIONS ON THE CULTIVATION OF HEMP OTHER THAN FIBROUS

The Act of 1997 on Counteracting Drug Addiction was repealed by the current Act of 29 July 2005 on Counteracting Drug Addiction³⁸. Until the date of entry into force of the provisions of the Act of 6 April 2022, amending the Act on Counteracting Drug Addiction³⁹, the regulations of this Act regarding restrictions on cultivation of hemp other than fibrous did not differ fundamentally from the model adopted in the previously applicable regulations. This meant that the cultivation of non-fibrous hemp could only be carried out by a scientific unit and the Central Research Centre for Cultivated Plant Varieties, as part of their statutory activity, as well as by an entity engaged in plant breeding and using hemp for iso-

³⁵ Consolidated text “Journal of Laws” 2003, No. 24, item 198, as amended.

³⁶ Art. 32 sec. 4 of the Act on Counteracting Drug Addiction of 1997.

³⁷ Art. 32 sec. 3 of the Act on Counteracting Drug Addiction of 1997.

³⁸ Consolidated text “Journal of Laws” 2020, item 2050, including alterations.

³⁹ “Journal of Laws” 2022, item 763.

lation purposes. However, those operators could only carry out such cultivation after obtaining an authorisation issued by the Chief Pharmaceutical Inspectorate (hereinafter CPhI) at the request of the operator concerned. Before issuing such an authorisation, CPhI sought the opinion of the organizational unit of Police, whose task in turn was to determine whether the entity intending to carry out such cultivation is able to protect it from access by unauthorized persons⁴⁰.

However, the law did not allow the cultivation of hemp other than fibrous for medical purposes. This approach seemed to be dictated by a very restrictive and at the same time limiting approach to the implementation of obligations arising from international conventions binding our country, described in section 2 of this study.

The first impulse to change such an approach was made by the Constitutional Tribunal (hereinafter the Constitutional Tribunal), which by its decision of 17 March 2015 issued under the reference symbol of files S 3/15, within framework of the so-called signalling moving for to the Sejm of the Republic of Poland, decided to submit comments on the appropriateness of taking legislative measures aimed at regulating the issue of the medical use of marijuana⁴¹. In support of its intervention, the Constitutional Tribunal stated that:

In the current legal situation, the prevention by the legislator of the uncontrolled distribution of substances whose use may lead to drug addiction completely excludes the possibility of using marijuana for medical purposes. On the other hand, from the point of view of a specific group of citizens benefiting from health care services, allowing the medical use of marijuana needs to be considered in view of the therapeutic usefulness of marijuana in certain medical conditions.

At the same time, the Constitutional Tribunal also pointed out that:

De lege lata, the emphasis placed by the legislator on combating addictions leading to loss of the health, puts into question the exercise of the right to health care benefits by the State to some extent. However, it is the task of the legislator to balance these two objectives.

The Constitutional Tribunal also drew attention of MPs to numerous inconsistencies within the domestic legal order of our country. It pointed to the possibility for Polish nationals to import from abroad a medicinal product (including one based on hemp other than fibrous) for their own needs under the provisions of Art. 37 sec. 10 of the A.C.D.A. in conjunction with the provisions of Art. 75 of the Convention implementing the Schengen Agreement of 14 June 1985 between the Governments of the States of the Benelux Economic Union, the Federal Republic

⁴⁰ Art. 49 of the Act on Counteracting Drug Addiction of 2005 before the amendment of 6 April 2022.

⁴¹ The ruling of the Constitutional Court (OTK – acronym in Polish) Series A 2015 No. 3, item 39.

of Germany and the French Republic on the gradual abolition of checks at their common borders⁴².

It should also be noted that the provisions of Art. 4 sec. 1 of the Law of 6 September 2001 Pharmaceutical Law⁴³, which regulates the institution of the so-called destination import, authorizes the marketing of medicinal products imported from abroad without the need to obtain a licence, if their use is necessary to save the life or health of the patient, provided that the medicinal product is admitted to trading in the country from which it is imported and has a valid marketing authorisation. This regulation also allows Polish patients to be provided with medicinal products made of hemp other than fibrous.

The first attempt of the Polish legislator intended to balance the interests of combating addiction on the one hand, and ensuring the right of citizens to health care on the other, was the adoption on 7 July 2017 of the Act amending the Act on Counteracting Drug Addiction and the Act on Reimbursement of Medicines, Foodstuffs for Special Nutritional Purposes and Medical Devices⁴⁴. With this Act, the legislator introduced into the A.C.D.A. the provisions of Art. 33a–33d, allowing the use of herb of hemp other than fibrous and extracts, pharmaceutical tinctures, as well as all other extracts of hemp other than fibrous as pharmaceutical raw material intended for the preparation of prescription drugs. Such raw material requires marketing authorisation within the territory of Poland issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. This provision, due to the impossibility of growing hemp other than fibrous for medical purposes in Poland, allowed import of standardized herb of hemp other than fibrous into Poland in the form of pharmaceutical raw material.

However, this solution proved to be far from sufficient. The implementing provisions of the Regulation of the Minister of Health of 5 December 2017 issued to it⁴⁵, due to their restrictive nature, significantly limited the scope of marketing of pharmaceutical raw material produced from hemp other than fibrous, and thus made prescription drugs based on it still unavailable in pharmacies for Polish patients⁴⁶.

⁴² “Journal of Laws” EU Official Gazette, Polish special edition, chapter 19, Vol. 2, p. 9.

⁴³ Consolidated text in “Journal of Laws” 2022, item 2301.

⁴⁴ “Journal of Laws” 2017, item 1458.

⁴⁵ Regulation of the Minister of Health of 5 December 2017 on the model application for marketing authorisation of pharmaceutical raw material for preparation of prescription drugs in the form of herb of hemp other than fibrous and extracts, pharmaceutical tinctures, as well as all other extracts from hemp other than fibrous and resin of hemp other than fibrous as well as detailed scope of data and list of documents covered by this application (“Journal of Laws” 2017, item 2337).

⁴⁶ Letter from the Ombudsman Adam Bodnar to the Minister of Health of 6 September 2018, <https://bip.brpo.gov.pl/sites/default/files/%2FWystapienie%20do%20Ministra%20Zdrowia%20w%20sprawie%20lecniczej%20marihuany.pdf> (accessed 08.01.2023), p. 2.

The limited availability of pharmaceutical raw material produced from hemp other than fibrous and the high price of prescription drugs prepared from it in Polish pharmacies became a major incentive to undertake work on the amendment of the regulations of A.C.D.A. The result of this work was the adoption of the Act of 24 March 2022, amending the Act on Counteracting Drug Addiction⁴⁷. The Act introduced a number of significant changes from the point of view of the admissibility of growing hemp other than fibrous in Poland. Firstly, it modified the definition of fibrous hemp (and thereby indirectly redefined the concept of hemp other than fibrous). At present, fibrous hemp means plants of the species hemp (*Cannabis sativa* L.) in which the sum of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid) in the flowering or fruiting tops of plants from which the resin has not been removed does not exceed 0.3% on a dry weight basis; the sum shall be rounded to one decimal place. Moreover, as a consequence of the above, the legislator amended the definition of “herb of hemp other than fibrous”, indicating that it is constituted by any terrestrial part of a hemp plant (single or in a mixture), excluding seeds, containing more than 0.3% of the sum of delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid); the sum shall be rounded to one decimal place. The term “hemp resin” has also been clarified due to prejudging that hemp resin is only resin and other hemp products containing delta-9-tetrahydrocannabinol or delta-9-tetrahydrocannabinol acid. Secondly, under the amendment of A.C.D.A., the legislator decided that in Poland it would be permissible to cultivate hemp other than fibrous, as well as to harvest its herb or resin, for the purpose of manufacturing pharmaceutical raw material⁴⁸. However, the cultivation and harvesting of hemp other than fibrous is subject to a number of restrictions. First of all, such cultivation (and harvesting) may only be carried out by research institutes⁴⁹ supervised by the Minister responsible for agriculture. Moreover, such cultivation and harvesting requires a prior authorisation issued by CPhI on the basis of an administrative decision.

A research institute intending to cultivate and harvest herb of hemp other than fibrous (or resin of such hemp) in order to obtain the authorisation referred to above shall have to comply with a number of strict conditions. It shall have to employ qualified persons who will be responsible for supervising the cultivation of hemp other than fibrous and for collecting its herb and resin, as well as persons who will be responsible for supervising the place of cultivation of hemp other than

⁴⁷ It should be noted that on 24 March 2022, the Polish legislator also adopted the Act amending the Act on Counteracting Drug Addiction and Certain Other Acts (“Journal of Laws” 2022, item 764), which included a number of changes concerning the rules for growing fibrous hemp in Poland.

⁴⁸ Art. 4, item 5, 37 and 38, Art. 49a sec. 1 of the Act on Counteracting Drug Addiction.

⁴⁹ Within the meaning of the Act of 30 April 2010 on Research Institutes (Consolidated text “Journal of Laws” 2022, item 498).

fibrous and the premises for storing that harvest. Moreover, all persons engaged in the cultivation and harvesting of hemp other than fibrous shall not be punished for offences under Art. 63 and 64 of the Act on Counteracting Drug Addiction⁵⁰ and violation of Art. 65 of the Act on Counteracting Drug Addiction⁵¹. The Institute shall also have to ensure that the place where the hemp other than fibrous is grown, the herb or the resin of hemp other than fibrous is harvested, and the premises where the harvest is stored are protected from unauthorised access. These safeguards shall include:

1. to keep a list of persons authorised to enter the place of cultivation of hemp other than fibrous, the harvest of herb or resin of hemp other than fibrous and the premises for the storage of such harvest,
2. to keep a list of vehicles authorised to enter the place of cultivation of hemp other than fibrous, the harvest of herb or resin of hemp other than fibrous and the premises for the storage of such harvest,
3. to be technically capable of recording the date and time at which the authorised person or the authorised vehicle is present at the place of cultivation of hemp other than fibrous or harvest of herb or resin of hemp other than fibrous or at the premises for storing such harvest as well as capable of verifying such data;
4. to have means to signal a breach of the security against unauthorised access and means for continuous observation of planned sites of cultivation of hemp other than fibrous, harvest of herb or resin of hemp other than fibrous and premises for storing such harvest, in particular for image recording,
5. to have technical means to prevent unauthorised persons from entering the place of cultivation of hemp other than fibrous, the harvest of herb or resin of hemp other than fibrous and the premises for the storage of such harvest,
6. to prepare the marking of the place of cultivation of hemp other than fibrous, the harvest of herb or resin of hemp other than fibrous and premises for storing such harvest and for keeping records of crops grown, harvested and destroyed,
7. to have means to monitor the location where the cultivation of hemp other than fibrous is carried out, the harvest of herb or resin of hemp other than fibrous and the premises for the storage of that harvest.

Compliance by the research institute with the above-mentioned requirements shall have to be confirmed in the opinion that CPhI obtains before issuing the authorisation from the organisational unit of the Police competent for the place of cultivation of hemp other than fibrous. This opinion is issued by an organizational

⁵⁰ That is, for the illegal cultivation and harvesting of poppy (except low morphine poppy), cannabis (except fibre hemp) and coca bushes and the theft of narcotic drugs, psychotropic substances, new psychoactive substances, poppy milk or poppy straw.

⁵¹ The sign of this offence exhausts the cultivation or purchase of low-morphine poppy or hemp fibre contrary to the provisions of the Act on Counteracting Drug Addiction.

unit of the Police in the form of a resolution. Failure to submit an opinion within 30 days from the date of referral is tantamount to issuing a positive opinion on how to protect the crop from unauthorised access.

Apart from the requirements described above concerning the protection of crops against unauthorized access, which are verified by an organizational unit of the Police, a research institute shall also have to meet a number of other requirements in order to obtain the authorisation to grow hemp other than fibrous. These requirements shall cover:

1. to have RFID system⁵² that allows reading data on the number of plants,
2. to employ a qualified person who holds a master's degree, master's degree in engineering or equivalent obtained as a result of the completion of studies related to education in the field of: medical analytics, biology, biotechnology, chemistry, pharmacy, medicine, veterinary medicine and at least 2-year work experience with the holder of the authorisation for the manufacture or import of medicinal products, referred to in Art. 38 sec. 1 of the Act of 6 September 2001 Pharmaceutical Law,
3. to have procedures and a control system in terms of the activities carried out, in particular that cover ensuring the continuity of operations, including the division of responsibilities and provision of deputising,
4. to have quality systems for harvesting,
5. to have a laboratory with equipment for assessing the quality of plants and harvesting.

Compliance by the research institute with the above requirements shall be verified periodically (not less than every 3 years) by the voivodeship pharmaceutical inspector.

A favourable decision by CPhI authorising a research institute to grow hemp other than fibrous as well as harvest herb or resin of hemp other than fibrous shall specify:

1. the institute for which it is issued,
2. the area under hemp Rother than fibrous,
3. the location of the operations covered by the authorisation,
4. the term of validity of the authorisation (no longer than 5 years), and
5. the date of issue of the authorisation.

⁵² According to Art. 4, item 23a of the Act on Counteracting Drug Addiction, RFID means a remote plant monitoring technology (Radiofrequency identification) which uses radio waves to read and transmit the data contained in the label applied to each of the cultivated plants, enabling the identification of each of the plants in the reading field.

5. CONCLUSIONS

The amendment to the Act on Counteracting Drug Addiction (A.C.D.A.) made by the Act of 24 March 2022 (which came into force on 7 May 2022), after more than thirty-seven years, allowed the return in Poland of cultivation of hemp other than fibrous for medical purposes. Furthermore, it is to be noted that the Polish legislator adopted a solution of a very liberal nature. It limited subjectively and strictly controlled only the cultivation of hemp other than fibrous and the harvesting of herb and resin from such hemp. The Polish legislator entrusted the powers of controls in this regard to the Pharmaceutical Inspectorate. In addition, supervision over this process is also exercised by the Minister responsible for agriculture on the basis of the provisions of Art. 35 of the Act on Research Institutes. At the same time, the Polish legislator has not introduced any subjective restrictions on the processing of the crop from cultivation of hemp other than fibrous into the active substance and subsequently into the pharmaceutical raw material. These activities may be carried out by any entity that obtains the appropriate authorisations and permits⁵³. The similar model of admissibility of non-fibre cannabis cultivation has been adopted by many other countries, which have allowed the legalization of marijuana cultivation for medical purposes⁵⁴.

Since the amended provisions of A.C.D.A. entered into force only just nine months ago, it is not yet possible to assess their effectiveness. The implementation in Poland of cultivation of hemp other than fibrous for the production of pharmaceutical raw material requires research institutes not only to be equipped with appropriate technical infrastructure, but also to obtain necessary authorisations and permits as well as to receive biological starting materials (hemp seedlings). Therefore, for the results of the legislative changes, especially in the respect of the availability for Polish patients of prescription drugs manufactured from hemp other than fibrous, we will have to wait.

⁵³ In particular, a permit under Art. 35 sec. 1 of the Act on Counteracting Drug Addiction, i.e. a permit for the manufacture, processing, processing, import or distribution of narcotic drugs or psychotropic substances issued by the Chief Pharmaceutical Inspector, or a permit under Art. 33a of the Act on Counteracting Drug Addiction, i.e. a permit for the marketing of pharmaceutical raw materials issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

⁵⁴ V. Rathí *et al.*, *Legality of worldwide cannabis use and associated economic benefits*, (in:) T. Belwal, N.C. Belwal (eds.), *Revolutionizing the potential of hemp and its products in changing the global economy*, Springer 2022, pp. 57–60.

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