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Poland: Law and Practice

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POLAND

Law and Practice

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Contents

Monika Duszyńska Law for Lifesciences is a boutique law firm focusing on the life sciences sector, providing services for pharmaceuticals companies and manufacturers of medical devices. Three senior lawyers offer daily support in commercial and regulatory matters, advising on intellectual property (licences and purchases of registration dossiers, R&D agreements), contracts with healthcare professionals, patient organisations, contract manufacturers, suppliers, grants and donations. The firm assesses permitted relationships with HCPs, and provides advice on or audits marketing studies and activities. It counsels on regulatory affairs, pharmaceuticals advertising, clinical trials and reimbursement, as well as on the distribution and manufacturing of medicines and medical devices, including the drafting of contracts.

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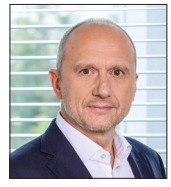

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1. Regulatory Framework

1.1 Primary Laws & Regulations

There are a number of laws in Poland that govern the production, distribution and use of medical cannabis and cannabinoids. The principal law regulating medical cannabis and cannabis in general is the Law on Preventing Narcotics Addiction (LPNA), and corresponding regulations of the Minister of Health (MoH). The most popular cannabinoids are tetrahydrocannabinol (THC) and cannabidiol (CBD); therefore, this article will focus on regulations concerning these two.

It should be noted that medical cannabis typically contains higher levels of THC, whereas CBD is primarily derived from hemp. Both medical cannabis and hemp are different varieties of the same species — Cannabis sativa.

The Law on Preventing Narcotics Addiction – LPNA (Ustawa o przeciwdziałaniu narkomanii)

The LPNA addresses numerous aspects concerning medical cannabis and hemp, including their classification, holding and permitted use, placing on the market, cultivation and harvest. It also imposes the obligation to obtain various authorisations or permits before engaging in any of these activities.

Classification

The LPNA splits the cannabis genus (cannabis L) into two categories:

- hemp (literally, fibrous cannabis); and
- non-fibrous cannabis.

These terms are used throughout Polish regulations applicable to cannabis. Non-fibrous cannabis is, in practice, equivalent to medical cannabis; other varieties are considered hemp.

Fibrous cannabis (hemp) is defined in the LPNA as a plant belonging to the cannabis species (cannabis sativa L), in which the content of the delta-9-tetrahydrocannabinol and tetrahydrocannabinolic acid (delta-9-THC-2-carboxylic acid) in flowering or fruiting tops of the plant from which the resin has not been removed does not exceed 0.3% (until May 2022, this was 0.2%) of its dry weight. In contrast, any other cannabis containing higher content than the above THC combination will be considered non-fibrous cannabis. This is a very important differentiation, because cannabis (and its derivatives listed in the LPNA) containing THC of up to 0.3% will not

be considered a narcotic drug and, therefore, many activities concerning it will be allowed (or merely limited) in contrast to those concerning cannabis where concentration of THC is higher than 0.3%.

The LPNA refers to the following:

- herb – defined as any terrestrial part of a cannabis plant (alone or in a mixture) of non-fibrous cannabis, excluding seeds, containing over 0.3% of THC; and
- cannabis resin – defined as resin and other cannabis products containing THC (delta-9-tetrahydrocannabinol or delta-9-tetrahydrocannabinolic acid) (please note that resin may come from either regular hemp or non-fibrous cannabis, and the key difference is in THC content).

All herbs and extracts, pharmaceutical tinctures and all other extracts of non-fibrous cannabis (that is, containing THC of over 0.3%) and cannabis resin are considered narcotic drugs (I-N group); they are listed as narcotic drugs in Annex 2 (Part 1) to the MoH Regulation regarding the list of psychotropic substances, narcotics and new psychoactive substances. Manufacturing, use and distribution of such narcotic drugs is either prohibited or strictly limited, while the same activities regarding hemp are considerably less regulated.

CBD is not listed as a narcotic drug or other regulated substance under the LPNA.

Possession

According to the LPNA, possession of any narcotic drugs is authorised only for entities or individuals who are allowed to possess them under binding statutory provisions. The police or customs authorities may seize and secure any possessed narcotic drugs in the absence of such entitlement.

The LPNA authorises the following entities to possess narcotic drugs:

- pharmacies;
- healthcare institutions and physicians, provided they obtained a special permit issued by the regional pharmaceutical inspector; and
- certain other entities.

Medicinal products containing narcotic drugs (such as those defined above regarding derivatives of medical cannabis) for individuals are available in pharmacies, on special medical prescription. Otherwise, possessing medical cannabis, which is in principle qualified as a narcotic drug, is subject to criminal liability (though in the case of small quantities, held for one's own use, criminal proceedings may be dismissed). For details, please see **1.6 Enforcement & Penalties** and **3.3 Decriminalisation**.

Possession of products including just CBD is not regulated under the LPNA.

Permitted use

According to the LPNA, all narcotic drugs (I-N and II-N) – including, therefore, herbs and extracts, pharmaceutical tinctures and all other extracts of medical cannabis, as well as cannabis resin, as defined in the LPNA – may be used only for medical, industrial or research purposes (upon meeting other applicable requirements).

For medical purposes, such derivatives and resin may be considered pharmaceutical raw materials that might serve for the preparation of pharmaceutical materials in pharmacies, and which are available on medical prescription (and subject to special marketing authorisation).

It should be noted that recreational use of medical cannabis is currently not allowed in Poland and is subject to criminal liability (please see above, under Possession).

Use of products including only CBD at present is not regulated under the LPNA; however, limitations on such use may result from other legal regulations, in particular those concerning novel food (for details, please see under *"Other Regulations"* below, and see also **3.2 Non-Controlled Cannabinoids in Food**). However, the Ministry of Health has prepared a draft amendment to the LPNA which provides for the explicit prohibition of the sale of CBD products for smoking or inhalation. According to the amendment, fibre hemp may only be used for food, cosmetic and industrial purposes. The proposed changes triggered strong criticism from Poland's hemp industry, which is concerned about the prohibition – and related criminalisation – of selling products with CBD for smoking or inhalation. The LPNA amendment has also been widely criticised for its alleged lack of compliance with The Single Convention on Narcotic Drugs of 1961.

The amendment is currently in the early stages of Polish legislative procedure, with first round of public consultations concluded.

Marketing medical cannabis

Most of the terms applicable for marketing medical cannabis are included in the LPNA. Marketing medical cannabis requires a special marketing authorisation, designed specifically for medical cannabis (that is, herbs of non-fibrous cannabis and cannabis resin – please see the definitions discussed above), and referred to in the LPNA and a corresponding MoH Regulation. This concerns the application form for the marketing authorisation of pharmaceutical raw material for the preparation of prescription medicines in the form of non-fibrous cannabis herbs and extracts, pharmaceutical tinctures, and other extracts of non-fibrous cannabis and resin, as well as a detailed range of data and a list of documents covered by this application. Also provided are details of specific proceedings, in which the marketing authorisation specifically for medical cannabis is issued, such as concerning the content of the application and the required documents (including, in particular, the manufacturing authorisation). The marketing authorisation, in the case of medical cannabis, is issued for a pharmaceutical raw material (and not a medicinal product); specifically, no summary of product characteristics is issued.

Other general requirements on marketing authorisations that would also apply to medical cannabis are included in the Pharmaceutical Law (see below under The Pharmaceutical Law); and the LPNA refers to a number of specific provisions regarding renewals, fees and refusals to grant.

Manufacturing

The LPNA regulates two basic stages of manufacturing of medicines, including narcotic substances, such as the derivatives from medical cannabis.

The first stage consists of manufacturing the active pharmaceutical ingredient for the further manufacturing of a pharmaceutical raw material containing medical cannabis, and, as is explicitly defined in the LPNA, of grinding dried parts of plants and carrying out physicochemical operations (as a result of which the substance is produced) including extraction, and packaging in bulk packaging. The requirements of Good Manufacturing Practice for active pharmaceutical ingredients, included in the Pharmaceutical Law and in the corresponding MoH Regulation concerning the requirements of Good Manu-

facturing Practice, apply to such operations. One such requirement is the obligation for the manufacturer to be registered in the register of manufacturers of active substances.

The second stage is manufacturing the pharmaceutical raw material, and consists of repackaging from bulk into packaging in which the raw material will be delivered to pharmacies. These operations should observe the requirements of the manufacturing of medicinal products, contained in the Pharmaceutical Law and in the corresponding MoH Regulation on Good Manufacturing Practice. The key requirement is holding a regular manufacturing authorisation.

The LPNA also requires a separate specific authorisation for the manufacturing, processing, importation and distribution of narcotic drugs, including medical cannabis. For details, please see **1.2 Regulatory Bodies**.

Cultivation and harvest

Cultivation of hemp (fibrous cannabis) is allowed only for explicitly listed purposes; however, their scope is quite large and covers numerous industrial purposes. Both cultivation and buying hemp from its manufacturer require prior registration in a special register run by the National Support Centre for Agriculture.

The LPNA provides for numerous requirements applicable to manufacturers and buyers of hemp, and determines the required content of applications and the documents that should be submitted with them in order to be registered. It also provides for the right to inspect manufacturers and buyers to ensure they are compliant with applicable requirements.

Cultivation of medical cannabis (non-fibrous cannabis) is strictly regulated. Until 2022, only varieties of cannabis other than hemp could be cultivated for research purposes, and by very limited categories of research institutions, upon special authorisation issued by the Chief Pharmaceutical Inspector.

Since May 2022, in Poland it is permitted to cultivate non-fibrous cannabis (medical cannabis), as well as to harvest herbs and resin from it, for the purpose of the manufacturing of pharmaceutical raw material, with a special permit issued by the Chief Pharmaceutical Inspector. Such permit may be issued only to research institutions, supervised by the Minister of Agriculture. In practice, domestic authorised cultivation of medical cannabis has not yet begun, to the best of the authors' knowledge; therefore, all requirements for medical cannabis on the Polish market are satisfied by imported medical cannabis only.

Distribution

Wholesale of medical cannabis is also strictly regulated by the LPNA and requires special authorisation (for details, please see **1.2 Regulatory Bodies**).

The Pharmaceutical Law

The second major legal act applying to medical cannabis (only) is the Pharmaceutical Law (*Ustawa prawo farmaceutyczne*), which establishes legal requirements for the manufacturing, importation, wholesale and retail distribution of medicinal products in general.

The following provisions of the Pharmaceutical Law apply to medicinal products containing derivatives of medical cannabis:

- on the marketing authorisation, including those on special proceedings concerning market approvals for raw pharmaceutical materials;

- on the manufacturing and importation of medicinal products, and Good Manufacturing Practice;
- on the manufacturing of active pharmaceutical ingredients, including Good Manufacturing Practice of active pharmaceutical ingredients;
- on wholesale distribution of medicines;
- on retail sale of medicines; and
- on prescriptions.

Other Regulations

Reimbursement

In Poland, medicinal products containing medical cannabis are not currently reimbursed; therefore, a person wishing to buy such product and holding a medical prescription will have to bear its entire cost. In May 2024, the pharmacy price for such products ranges between PLN60 and PLN80 (EUR14-EUR18) per gram.

Lifestyle products

Various products (other than medicinal products) containing cannabinoids (especially CBD) are available on the Polish market. These products may be divided into the following categories (among others):

- cosmetic products;
- food; and
- smoking accessories (however, according to the draft amendment to the LPNA, these might become prohibited).

It should be noted that food and cosmetics laws and regulations are often EU-wide and, therefore, are directly applicable throughout the entire EU. However, it must be emphasised that in Poland there are no regulations dedicated specifically to non-controlled cannabinoids (especially CBD). There is a wide variety of such products on the market, in terms of both their ingredients and their quality.

1.2 Regulatory Bodies

There are numerous authorities responsible for enforcing laws regarding cannabis in Poland.

The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products – ORMP (Prezes Urzędu Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych)

The President of the ORMP is responsible for issuing marketing authorisations for human and veterinary medicines.

The President of the ORMP issues marketing authorisations specifically concerning medicinal cannabis (coming from a determined supplier), as a pharmaceutical raw material from which a medicine available in pharmacies can be manufactured. Such marketing authorisation is issued for five years, in special proceedings regulated by the LPNA, an MoH Regulation and the Pharmaceutical Law (for details, please see **1.1 Primary Laws & Regulations**).

The Chief Pharmaceutical Inspector – ChPhI (Główny Inspektor Farmaceutyczny)

The ChPhI is the governmental authority for supervision of manufacturing, importation, wholesale distribution and advertising of medicinal products, and is a major governmental agency dealing with medical cannabis, whose determined derivatives (please see the definition in **1.1 Primary Laws & Regulations**) are considered narcotic drugs. The various authorisations and permits issued by this authority are listed below.

Regular manufacturing authorisation

The ChPhI issues regular manufacturing authorisation required to manufacture any medicinal

product, including medical cannabis, as the raw pharmaceutical material. Also, importation of medical cannabis (ie, from countries outside the EEA) and its testing and distribution would require an import authorisation issued by the ChPhI.

Specific manufacturing authorisation for narcotic drugs

The ChPhI is also responsible for issuing specific authorisation required to manufacture, process, import or distribute narcotic drugs, such as medical cannabis. This is issued for an undefined time period (ie, unlimited in time). To obtain this authorisation, the applicant should first have obtained a regular manufacturing authorisation.

Regular wholesale distribution authorisation

Wholesale distribution of any medicinal product, including medical cannabis, would also require a regular wholesale authorisation granted by the ChPhI.

Specific wholesale distribution authorisation for narcotic drugs

A separate authorisation is also necessary for wholesale distribution of narcotic drugs.

Import and export licences

The ChPhI is also responsible for issuing special licences required for the importation, exportation or intra-community supply of narcotic drugs. These licences should be obtained for each such specific import, export or supply, and should determine the volume and the term in which these can be performed (eg, one-off licences). It should be noted that there are annual limits in force that determine the maximum volume of all medical cannabis imports into Poland. Estimated world requirements for determined narcotic drugs (including medical cannabis and separately cannabis resin) for all the countries are available on the International Narcotics Control Board (Microsoft Word – EstMar25). These requirements are regularly updated, and in Poland they also set thresholds for annual imports of the narcotic drugs listed there.

In general, the ChPI will issue one-off import licences for certain narcotic drugs on condition that the annual limit for Poland for the drug is not exceeded. The annual limit in 2025 for importing medical cannabis is 20 million grams (50 grams for cannabis resin). The limit for cannabis for Poland has been significantly increased from 6 million grams in 2024.

Permits for cultivation and harvesting of non-fibrous cannabis

Cultivation and harvesting of medical cannabis require a special permit issued by the ChPhI. As stated above, to the best of the authors' knowledge, no such permits have been issued yet, and all local requirements need to be met with imported cannabis.

The National Support Centre for Agriculture (Krajowy Ośrodek Wsparcia Rolnictwa)

The Director of the National Support Centre for Agriculture maintains a register of poppy and hemp, in which producers (cultivators) of hemp and entities purchasing hemp from them should already be registered before cultivation begins. In other words, the producer must have all production contracted before they start cultivation.

1.3 Self-Regulatory Authorities

In Poland, there are no self-regulatory authorities, but there are a number of industry associations that promote use of cannabis for various purposes.

One such organisation is Free Cannabis (*Wolne Konopie*), which describes itself as an associa-

tion acting for the reasonable and effective use of cannabis, established in 2006.

Examples of other organisations active in the market include the following.

The Polish Association of Hemp Producers and Processors – headquartered in Warsaw – was founded in early 2019. The Association's goals include disseminating knowledge about hemp and developing a concept for the development of the hemp market in Poland.

The Polish Federation of Patients is an organisation that represents the interests of patients in Poland. The Federation's goals include fighting for the legalisation of medical cannabis in Poland and providing patients with easier access to this form of treatment.

CannabiMed Foundation is an organisation dedicated to promoting knowledge about the uses of medical cannabis in the treatment of various diseases and conditions. The Foundation is also working to change Polish law regarding the legalisation of medical cannabis.

TRUSTT is one of two companies in Europe that have emerged to track the manufacturing processes of medical cannabis products and verify regulatory compliance. The company implements solutions based on advanced technology such as blockchain, ensuring the security and immutability of the data obtained. The solution proposed by TRUSTT can be an element of market self-regulation, but above all it can be a tool used by the regulator to control the market.

The list of the organisations involved in the topic of hemp in Poland continues to grow, as interest in the subject has grown in recent years. Most such organisations are focused on spreading awareness of the use of medical cannabis and on providing access to it for those who need it.

None of these organisations has a dominant position in the market, nor have they managed to develop and introduce any significant documents, rules or principles that would already significantly affect the market. There are no commonly accepted *"Good Market Practices"* relating to the production, importation, distribution, or labelling of the composition of products containing cannabinoids which would be followed by market participants. Each of these players is trying to attain a significant position, but so far it is not possible to point to any entity considered to be shaping or significantly influencing market behaviour. The market is still in the early stages of development, where there is a high degree of discretion in the areas not strictly regulated by national law. This causes confidence in this market and its participants to remain quite low.

1.4 Challenges for Market Participants

Key market challenges include the following.

- The lack of quality standards for cannabidiol products. The vast majority of the market operates without any certification or quality monitoring. The market for cannabidiol products is growing rapidly, which causes many operators to try to achieve the best possible sales results at a low cost. Hence, for most products, there is no certainty that the product complies with the declared composition.
- The attitude of the State administration is still highly distrustful, and lack of education of forces responsible for law enforcement (police, customs, etc) causes cannabis to continue being associated mainly with narcotics. This means that the cultivation of hemp

with an acceptable THC content (ie, below 0.3%) is still subject to numerous difficulties.
- The lack of uniform nationwide laboratory methods for determining THC levels to exclude the risk of erroneous or contradictory results, which can have serious consequences, including the risk of criminal liability. There are no standards and scopes for laboratory testing. There is no practice of testing for more cannabinoids, for terpenes or for contaminants such as heavy metals. Of course, standards are in place with pharmaceutical standard laboratories taking into account EU Good Manufacturing Practice, but unfortunately most testing is done in non-standardised units. This also (and perhaps especially) applies to forensic laboratories and customs. Due to the wide disparity in standards and testing methods used, there is large discrepancy with final laboratory results.
- The cultivation of medical cannabis is basically subject to the Ministry of Agriculture, since research institutes (which are the only ones that can apply for a permit for the cultivation of medical cannabis) are supervised by the Ministry of Agriculture and have no experience in the drug manufacturing market, which in the authors' opinion is a systemic error – a farmer will not produce a pharmaceutical product. This creates a great deal of problems and controversy, given the limited number of entities that can cultivate (12 State research institutes), which do not have adequate funds or ways to obtain them from the market, and which do not have the knowledge or competence regarding how to put into practice the provisions of the law and to start growing medical cannabis, not for research but for commercial purposes, and on an appropriate scale.
- After the parliamentary elections in the autumn of 2023, the liberalisation of the cultivation of medical cannabis laws is not on the new government's agenda for the time being. In spite of this fact, the situation with regard to liberalisation of law in respect of not only medical but also recreational cannabis appears to be much better than under the previous conservative government. Moreover, according to one recent public survey, 73.4% of Poles are against punishing individuals for possessing recreational cannabis. Therefore, future changes of the law seem to have only one direction – liberalisation. Of course, the frequently changing regulations are a challenge for those planning to operate in this market.
- The need for improving knowledge of medical cannabis therapy, especially among doctors. Numerous doctors complain about unavailability of adequate training on how and in which indications to prescribe medical cannabis.
- The absence of medical cannabis on the list of reimbursed medicines. Therapy with medical cannabis should be financed entirely by patients; due to relatively high costs of medical cannabis, certainly many patients who could benefit from using it cannot afford it.
- Restrictions on agricultural land trading constitute a barrier for entities that would like to enter the market of industrial hemp cultivation and that do not have the status of a farmer in the understanding of Polish law.
- The pending amendment to the LPNA which will exclude CBD products intended for smoking or inhalation from legal trade, if adopted, may adversely affect the profitability of businesses operating in this sector.

Poland's current regulatory system for medical cannabis is still in the process of development, following the initial amendments allowing, to a limited extent, for the cultivation of medical can-

nabis in Poland. In the authors' opinion, further significant changes are necessary and expected by the market.

A major legal change occurred in 2017, when use of medical cannabis, including THC, became legally allowed for medical purposes (under defined terms). In another recent significant legislative change, since May 2022, cultivation and harvesting of non-fibrous cannabis with THC content over 0.3% became permitted for purposes other than research, and in particular for medicinal purposes (both changes concerned the LPNA), subject, nevertheless, to special regulatory permits. However, this change should only be seen as a prelude to a true opening of the market for medical cannabis cultivation in Poland, since this option is available only to a limited number of State research institutes, which should meet numerous and extremely strict requirements. In practice, this significantly reduces, if not eliminates, any chance for domestic cultivation of medical cannabis.

Given the lack of any experience in this field, the typically excessive formalisation of the State's institutions, and the decision-making process, it is hard to be optimistic about the quick effects of the regulation concerning cultivation of medical cannabis. Therefore, in the coming months, and perhaps even in the longer term of one or two years, it is difficult to expect significant changes and the emergence of marketable volumes of medical cannabis from domestic cultivation.

At the same time, the permitted concentration of THC in cannabis derivatives was increased from 0.2% to 0.3%, which is reported as having a potential to boost crops and general use of cannabis, and to decrease the legal risk connected with the use or handling of cannabis in general.

As regards lifestyle products, including CBD from hemp, the regulations are very widespread and sometimes difficult to identify. It is widely discussed that with respect to lifestyle products, quality criteria and certification proceedings are missing, which can adversely affect their quality. For certain categories of popular lifestyle products, supervision by regulatory authorities is rather weak or ineffective. The considered amendment to the LPNA aimed at prohibiting the sale of CBD products for smoking and inhalation should also be noted.

1.5 Legal Risks

The Polish cannabis market is still in the early stages of development both in terms of legislation and market practices. Legal risks include the following.

- Numerous laws (no single act comprehensively regulating the cannabis market) – ie, for medical cannabis, cannabinoids and industrial hemp – makes it difficult for start-ups to know all their rights and obligations.
- It should be remembered that hemp and cannabis are still widely and strongly perceived as narcotics in Poland, which is why the cannabis business still faces a certain amount of suspicion and mistrust, especially towards newcomers to the business. However, the awareness of state authorities is increasing and medical cannabis is already seen as a drug used in many therapies. Recently, the Polish Police, when queried by the Ombudsman, confirmed that persons with a prescription for the use of medical cannabis are treated like any other patient in the event of an inspection. Of course, this does not apply to the situation of driving under the influence of medical cannabis.
- Polish authorities are significantly focusing on even small discrepancies of the legalised THC

percentage, which has resulted in bans on product importation, penalties for businesses and delays in delivery, and even exposure to criminal liability.
- The lack of standards and methods for determining THC that are uniform for all domestic laboratories may mean an increased risk of violating norms regarding permissible THC levels.
- Compliance procedures can be quite complicated and time-consuming, and differences in the interpretation of the law between State control services (police, customs, pharmaceutical inspectors, etc) sometimes extend the procedures or cause previously unforeseen legal complications.
- Changing legislation, which is still in the early stages of development make long-term business development planning difficult.
- There is also limited access to the agricultural land enabling the cultivation of hemp, due to the restrictions of Polish law on agricultural land trading and leasing.

1.6 Enforcement & Penalties

Certain derivatives of medical cannabis are considered narcotic drugs (see **1.1 Primary Laws & Regulations**), and activities concerning them are penalised. In Polish law, sanctions – both criminal and administrative – are included in the Criminal Code and legal regulations regarding specific categories of products (ie, narcotics, medicinal products and food).

Criminal Sanctions and the Authorities Enforcing Them

The LPNA

As referred to in **1.1 Primary Laws & Regulations**, the LPNA classifies non-fibrous hemp as a narcotic drug, which results in the application of severe criminal sanctions for various activities related to it. Polish law also penalises certain activities involving fibrous hemp.

Penalties for individual offences vary depending on the type of offence and the amounts of narcotic drug involved, as follows.

- Placing narcotic drugs on the market or taking part in such activities: imprisonment for six months to eight years. In the case of significant amounts: imprisonment for two to 12 years, and a fine.
- Importation, exportation, transportation, intra-community acquisition or intra-community supply of drugs: imprisonment of up to five years, and a fine. In the case of significant amounts, or where the perpetrator acts for their own financial or personal advantage: imprisonment from three years to 20 years, and a fine.
- Manufacturing and reprocessing of narcotic drugs: imprisonment for up to three years. In the case of significant amounts, or where the perpetrator acts for their own financial or personal advantage: imprisonment from three years to 20 years.
- Unauthorised possession of a narcotic drug: imprisonment for up to three years. In the case of significant amounts: imprisonment for one to ten years.
- Advertising or promoting narcotics drugs: a fine, restriction of liberty or imprisonment for up to one year.

There is a separate offence specifically concerning non-fibrous hemp (and certain other plants), as follows.

- Cultivation and harvesting of non-fibrous hemp (unauthorised): imprisonment for up to three years. Where the crops may produce

significant amounts of non-fibrous hemp: imprisonment for six months to eight years.

It should be noted that according to the general provisions of the Polish Criminal Code, a fine can always be inflicted by the court upon a perpetrator condemned to imprisonment, where this perpetrator committed the offence to obtain financial advantage, or where they obtained financial advantage. The maximum fine under the Polish Criminal Code is PLN1.08 million, which corresponds to roughly EUR235,000.

Certain practical aspects concerning possession of medical cannabis are presented below.

Possession of medical cannabis

According to the LPNA, narcotic drugs (including medical cannabis) may only be possessed by an entrepreneur, organisational unit or individual authorised to possess them under the provisions of the LPNA, Regulation 273/2004 or Regulation 111/2005. An individual who does not have a medical cannabis treatment certificate commits a criminal offence.

Responsibilities of a person in possession of medical cannabis

A person in possession of medical cannabis should:

- keep it in its original packaging (unless a smaller amount has been measured at the pharmacy, in which case in an airtight package from the pharmacy);
- carry a medical cannabis treatment certificate;
- carry an identity card; and
- carry documents that confirm the purchase of medical cannabis in accordance with the law – eg, a scan of a prescription from a pharmacy with a receipt.

Prohibition on processing medical cannabis

A patient who has legally acquired medical cannabis with a doctor's recommendation cannot process the acquired dried product (in theory, even shredding may be considered such processing).

Driving after consuming medical cannabis

When determining a case for an offence against safety in communication committed under the influence of an intoxicant, the court must determine in each case whether the drug had a real effect on the psychomotor performance of the driver of the vehicle to a degree similar to that of being under the influence of alcohol.

The LPNA also penalises:

- manufacturing, storing, purchasing, selling or adapting equipment which may be used for the unauthorised manufacturing or reprocessing of narcotic drugs;
- preparations to commit offences penalised by the LPNA;
- inducing other persons to use narcotic drugs, and providing them with, or making it possible or easier to use, such drugs; and
- certain other activities regarding use of narcotic drugs.

The law also penalises the following activities in relation to fibrous hemp:

- illegal cultivation or buying of hemp – punishable with a fine; and
- providing inaccurate information about the surface of crops – also punishable with a fine.

The Food Law

The Polish Law on Food and Nutrition Safety (*Ustawa o bezpieczeństwie, żywności i żywienia*) (the *"Food Law"*) penalises the following activi-

ties, which may concern food products containing cannabinoids:

- manufacturing or placing on the market a food supplement or novel food harmful to health or life – subject to a fine, restriction of liberty or imprisonment of up to three years; and
- placing on the market novel foods without authorisation to be obtained in accordance with EU law – subject to a fine, restriction of liberty or imprisonment of up to two years.

The Act also provides for fines for non-compliance with the labelling requirements applicable to foodstuffs, including presentation, advertising and promotion.

The Polish Criminal Code

Bringing danger to the life or health of many people by manufacturing or marketing substances, foodstuffs or pharmaceuticals that are harmful to health and that do not meet the applicable quality conditions is a crime listed in the Polish Criminal Code. Such an act is punishable by the basic penalty of imprisonment for six months to eight years.

Enforcement authorities

In enforcing criminal law provisions, the key role is played by the authorities conducting criminal proceedings – ie, the police, public prosecutors and common courts. The police and public prosecutors conduct criminal investigations, which may result in bringing charges to a common criminal court, which conducts judicial proceedings that may result in conviction and determined penalties.

Enforcement by Administrative Authorities

The Pharmaceutical Law

The Pharmaceutical Law applies to narcotic drugs within the meaning of the provisions on preventing narcotics addiction and which are considered medicinal products. The enforcement authorities for medicinal products are the Chief Pharmaceutical Inspector (*Główny Inspektor Farmaceutyczny*) and the regional pharmaceutical inspectors.

Pharmaceutical inspectors may issue decisions:

- on suspension or withdrawal from the market or of use of medicinal products in the event of suspicion or finding that a given product is not authorised in Poland;
- prohibiting placing on the market, or on the withdrawal of an active substance from the market; or
- on suspension or withdrawal of prohibited products from public pharmacies and pharmaceutical wholesalers.

Importantly, in the event of violation of the conditions for the manufacturing or importation of medicinal products, which are very restrictive in relation to drugs containing cannabinoids, the Chief Pharmaceutical Inspector may issue a decision prohibiting the placing of a medicinal product on the market or on withdrawing a medicinal product from the market.

Medicinal products containing narcotic substances may be dispensed only upon a medical prescription. Conducting wholesale trade in narcotic drugs requires an additional permit, whereas brokering in narcotic drugs is prohibited.

In addition, it is prohibited to advertise medicinal products containing narcotic drugs to the public. In accordance with the Pharmaceutical Law,

breaking this prohibition is punishable by a fine (ie, it is a criminal offence).

Under the Food Law

The State Sanitary Inspection is the Polish authority responsible for supervision over the health conditions of food. The Chief Sanitary Inspector (*Główny Inspektor Sanitarny*) as the central government administration authority, may, after receiving a notification about the first time a food has been placed on the market, conduct explanatory proceedings regarding this product (eg, a food supplement). The investigation procedure is aimed at clarifying whether the product covered by the notification is a foodstuff in accordance with the qualification proposed by the food business operator and whether it meets the requirements for a given type of foodstuff (eg, for a food supplement). In addition, the procedure determines whether or not the food meets the requirements of a product of another category (eg, a medicinal product).

In the event of suspicion that a food product not meeting the specified requirements is on the market, the regional sanitary inspector may decide to temporarily suspend the marketing of this food product or to withdraw it from the market until the end of the procedure.

2. Cross-Jurisdictional Matters

2.1 Cross-Jurisdictional Issues

Given the lack of uniform regulation of hemp and medical cannabis at the level of EU legislation, players in the European market must take into account and analyse national regulations.

The problem is even more significant in the case of cross-border trade with non-EU countries. Although there is a common trend across the EU towards liberalisation of THC levels in cannabis products and availability of medical cannabis, differences remain. Therefore, any market player which intends to engage in cross-border transactions must carefully examine the legal environment of the country in question before entering into such transactions. There is a lack of organisations, platforms or other initiatives at the international level that would transparently present the differences in regulations from one country to another. This is even more important given the fact that national laws are constantly being amended, and, although they are usually aimed at liberalising regulations (note, however, the amendment to the LPNA under consideration), these constant changes make it difficult to operate across borders.

3. Legal and Regulatory Developments

3.1 Access to Medical Cannabis

Use of medical cannabis for medical purposes is allowed, under strictly defined terms. These terms are included in the LPNA and in the Pharmaceutical Law. At present, access to medical cannabis requires a special medical prescription for narcotic substances. This can be issued by any physician; however, many do not have appropriate training and expertise for treating patients with medical cannabis. There are no official guidelines on indications in which medical cannabis may be used, and at which dosages. Each physician should decide individually on whether to prescribe medical cannabis in given circumstances, bearing personal liability. However, at least several dozen thousands of prescriptions are issued in Poland for medical cannabis, what makes Poland a country where the medical cannabis market grows quickly.

During the COVID-19 pandemic, medical consultations and online prescriptions were permitted on a large scale. As a result, internet portals specialising in medical consultations related to medical cannabis treatment were established. This resulted in a certain market pathology, in which a prescription for medical cannabis could have been obtained online literally within minutes. The problem has already been recognised by the MoH and in consequence, a regulation was adopted, which became binding in August 2023. The regulation introduced an obligation on each doctor prescribing medical cannabis to a patient to verify the number and kinds of other medicines which were prescribed to this patient, and to examine the patient, on an on-site or online consultation, if the time since the last examination exceeded three months. The regulations were tightened again by the MoH on 29 October 2024, with access to prescriptions for medical cannabis restricted. Since 7 November 2024, prescriptions for certain controlled substances – such as medical cannabis, fentanyl, morphine, and oxycodone – can only be issued after an in-person examination by a physician. This change effectively ends the practice of prescribing these medications via teleconsultation, particularly impacting private medical facilities. An exception exists for patients under primary healthcare (POZ) within the public system, where follow-up prescriptions can still be issued remotely, provided the initial consultation was conducted in person. The regulation aims to enhance oversight of controlled-substance prescriptions and mitigate risks associated with their misuse.

In 2024, more than 7.8 tonnes of medical cannabis were dispensed from Polish pharmacies. This is a huge increase compared to previous years. Compared to 2023, pharmacists dispensed as much as 4.6 tonnes more medical cannabis. This indicates a growing interest in medical cannabis in Poland.

The values of medical cannabis dispensed in Poland between 2019 and 2023 are as follows:

- 2019 – 33,219 grams;
- 2020 – 94,038 grams;
- 2021 – 427,017 grams;
- 2022 – 1,167,752 grams;
- 2023 – 4,658,759 grams; and
- 2024 – 7,800,000 grams.

The amendment to the LPNA of May 2022 (see **1.4 Challenges for Market Participants**) has established a framework for the cultivation, production and distribution of medical cannabis in Poland. Some key aspects of this amendment include the following.

- The amendment requires entities that want to cultivate medical cannabis to obtain a licence from the Polish Pharmaceutical Inspectorate. The licence is granted for a period of five years and is subject to renewal.
- The amendment sets out quality control standards for medical cannabis, including testing for contaminants and ensuring consistency of the active ingredients.
- The amendment regulates the supply chain for medical cannabis, from cultivation to distribution for patients. It requires that all entities involved in the supply chain be licensed and comply with relevant regulations.
- The amendment aims to improve patient access to medical cannabis by allowing licensed entities to produce and distribute medical cannabis products. Patients will still need a valid prescription from a licensed physician to obtain medical cannabis, but the amendment may help to ensure a more

reliable and consistent supply of medical cannabis products.

As a result of current unavailability of domestic cultivation of medical cannabis, all the requirements for it have so far been met by imports from other countries (mostly the EU). This certainly affects access to it, since imported medical cannabis is expensive. Considering that medical cannabis is not reimbursed in Poland, patients wishing to purchase it must pay for it with their own resources. Where dosages prescribed by treating physicians are high, the monthly costs of treatment (which may be close to the minimum monthly salary in Poland) may be unaffordable for some patients.

There have been discussions about expanding the list of medical conditions for which medical cannabis can be used, but no significant changes have yet been made. The Polish government has been generally cautious about cannabis legalisation, so any changes to the legal elements affecting access to medical cannabis may take time. However, with the growing awareness of the potential benefits of medical cannabis, it is possible that the legal landscape may evolve in the future.

3.2 Non-Controlled Cannabinoids in Food

Under the current legislation in force in Poland, non-controlled cannabinoids cannot be used in food due to the application of Regulation (EU) 2015/2283 on novel foods. This Regulation is applied directly in Poland. The Polish Food Law refers to EU law as regards novel foods.

EU Regulation 2015/2283 defines novel food as a product that was not used to a significant degree as a food or food ingredient before 15 May 1997. To place such food on the market in the EU (including in the Polish market), a safety assessment and an EU authorisation under Regulation 2015/2283 is required. The list of novel foods requiring authorisation is included in Commission Implementing Regulation (EU) 2017/2470. The European Commission determined that cannabidiol (CBD) can be considered as a novel food. No such authorisation has yet been granted for non-controlled cannabinoids; therefore, they cannot be used in food.

An important issue should be emphasised in this context. Some cannabis sativa L products (such as seeds, seed oil, hemp seed flour and defatted hemp seeds) are widely used in the EU, have a long history of use and are not considered novel foods. In contrast, extracts from cannabis sativa L that contain cannabinoids (such as cannabidiol (CBD), and foods enriched with extracts from cannabis sativa L or with cannabinoids such as CBD (eg, hemp seed oil with CBD or dietary supplements with CBD)) are considered novel foods, as history of consumption has not been demonstrated. This applies to both the extracts themselves and to any products to which they are added as an ingredient (such as hemp seed oil). This also applies to extracts of other plants containing cannabinoids. Synthetically obtained cannabinoids are also considered novel foods.

The safety of products with CBD as a novel food is currently being investigated by the European Food Safety Authority (EFSA). According to the official information provided by EFSA, its scientists cannot currently establish the safety of cannabidiol (CBD) as a novel food due to data gaps and uncertainties about potential hazards related to CBD intake. According to EFSA, there is insufficient data on the effect of CBD on the liver, gastrointestinal tract, endocrine system, nervous system and people's psychological well-being. Therefore, as long as the scientific assessment

of CBD in terms of its safety remains incomplete, and foodstuffs containing CBD remain not authorised by the European Commission, products containing CBD cannot be placed on the Polish market as food.

Jurisprudence of Courts and Positions of State Authorities

In one of the more interesting court cases concerning cannabis sativa L in the context of novel foods, the Voivodeship Administrative Court in Warsaw held that only the following are novel foods:

- cannabis sativa L plant extracts containing cannabinoids;
- products derived from these extracts – ie, any products to which these extracts have been added (such as seed oil);
- extracts from plants, other than cannabis sativa L, containing cannabinoids; and
- synthetically obtained cannabinoids.

The court explained that the cannabis sativa L herb is not a novel food, because it has a long history of use and does not constitute a novel food according to catalogues published by the EU. In the opinion of the court, the EU list of novel foods does not by definition list all food products and ingredients that can be used in food production. The fact that a food or ingredient is not explicitly mentioned does not automatically mean that it is a novel food. The list of novel foods includes only those products and ingredients for which the European Commission has received a request for an opinion on whether a given product or ingredient should undergo the authorisation procedure. On this basis, the court concluded that cannabis sativa L (the herb) is not a novel food.

The court's reasoning has led to some belief that this might be a step towards wider acceptance of hemp products as food; however, it seems that the court has only made it clear that, in assessing the novel status of a given food, a case-by-case approach is appropriate, and made a clear indication that certain products containing cannabinoids are novel foods, so their placing on the market requires European Commission authorisation (judgment of the Voivodeship Administrative Court in Warsaw of 17 February 2022, Case No V SA/Wa 5258/21).

The position on the use of hemp in food was also analysed by the sanitary authorities. For example, the Voivodeship Sanitary Inspector in Białystok stated that some products derived from the cannabis sativa L plant (seeds, seed oil, hemp seed flour and defatted seeds) are not considered novel foods. Nevertheless, when placing food containing the above-mentioned raw materials on the market in Poland, the supplier should have current and reliable results of the analysis of the finished food, confirming the absence of psychotropic substances (ie, tetrahydrocannabinol (THC) above acceptable levels).

Issues related to hemp are also within the scope of the Polish tax authorities. Although the decisions of these authorities are not generally applicable law and do not determine whether a given commodity can be legally traded as food, they indirectly (by reference to the circumstances of a given case) show the industry practice and the variety of problems and issues related to the marketing of the products in question. For example, in one of the decisions clarifying the combined nomenclature (CN) classification for the purpose of taxation, dried hemp inflorescences were presented to the tax authorities as a product not intended for human consumption, and such classification was accepted (Director

of the National Tax Information 0115-KDST1-1.440.16.2022.3.ANJ).

Market practice

Despite the aforementioned, products containing CBD are available on the market in Poland. However, they are not promoted as food, and their labels do not contain information suggesting that the products are edible. Such information can sometimes be obtained from the sellers. Interestingly, manufacturers or sellers provide information on the characteristics of a product, without stating explicitly that the described effects require its consumption as food. However, this conclusion can quite easily be drawn from the context of the product's presentation.

Some CBD-containing products are also presented as food supplements; however, due to the lack of authorisation under novel food regulations, this is not legally allowed. Such controversial practices are partly a result of inefficient market supervision. The Polish supervisory authorities for compliance with food law and that are responsible for performance of official food inspections are the State Sanitary Inspection and the Chief Sanitary Inspector, which is the relevant central government administration authority.

Each food business operator is obliged to make a notification regarding the first placement on the market of a food supplement, and the Chief Sanitary Inspector may conduct explanatory proceedings regarding the product to clarify it is a foodstuff in accordance with the qualification proposed by the food business operator, and whether it meets the requirements for a given type of foodstuff. In addition, the procedure may aim to determine whether the food is not in fact a different category of a product (eg, a medicinal product). Despite the broad competences of the Sanitary Inspection, the great number of notifications (roughly 25,000 in 2020) makes it difficult to control the market.

3.3 Decriminalisation

In Poland, until 2000, possession for personal use of small amounts of substances covered by the regime of the LPNA was not punishable. The situation changed when the provisions of Article 62 were adopted, stipulating that possession of any type of drug is punishable, regardless of the quantity and purpose of possession. The rationale behind this step was to increase the effectiveness of police operations. Among other things, the idea was that a dealer arrested with a prohibited substance should not escape responsibility by declaring possession for personal use. The 2000 amendment caused the number of detected drug possession offences to rapidly increase – from nearly 1,900 in 1999 to over 31,200 in 2007 (data from the Polish Drug Policy Network).

Prosecutors have the option to discontinue prosecution for possession of insignificant amounts of psychoactive substances. Today, one in three cases for possession is dropped.

In recent years, a growing number of countries around the world have begun to liberalise their cannabis policies, which has led to increasingly more debate about legalising recreational cannabis in Poland.

In Poland, a parliamentary panel on the legalisation of recreational cannabis was established in 2019. However, until 2023, the output of this panel's work was very modest. Currently, the parliamentary panel is leaning towards the solution to decriminalise the possession of 15 grams of dried or one bush of cannabis. However, it is still difficult to predict when and if a bill to this effect will be presented and subject to legislative process.

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