

Medical cannabis regulation in Ukraine

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In Ukraine, a law has come into force that paved the way for the use of medical cannabis. The law, published on 15 February 2024, has already entered into force, and its application will begin 6 months after its publication, i.e., on 16 August 2024.

1. Fundamentals of medical cannabis regulation in Ukraine

First of all, it should be understood that there is no separate law that would exclusively deal with cannabis in Ukraine. The law published on 15 February 2024 (hereinafter referred to as the "Law") is referred to in the media as the "Cannabis Law" (the "Law on cannabis legalisation", etc.). The Law amended a number of regulations governing the circulation of narcotic substances and precursors.

However, the Law of Ukraine "On Narcotic Drugs, Psychotropic Substances and Precursors" has been and remains the primary law regulating medical cannabis in Ukraine, and the vast majority of regulatory acts will be adopted on its basis and in accordance with it.

A number of regulations referred to in the Law are yet to be developed (on the dispensing, production and use of medicinal products from cannabis plant substance in medical practice, requirements for the cultivation of cannabis plants, etc.).

Naturally, all these regulatory acts may have a significant impact on the practical implementation of changes related to the legalisation of cannabis in Ukraine. Yet, the framework defined by the Law already provides guidance in planning investments in this new industry for Ukraine.

2. What does the legalisation of medical cannabis in Ukraine entail?

Firstly, the legalisation of medical cannabis does not mean that it will be allowed for widespread and uncontrolled use. The Law defines such use as "recreational use" and means the consumption of narcotic drugs, psychotropic substances, cannabis plants (their parts) without a doctor's prescription and for reasons not related to medical use. The sale of cannabis plants and their products with any tetrahydrocannabinol content for recreational use is prohibited.

Secondly, the sale of medical cannabis and its derivatives must be carried out through pharmacies, provided they have a licence for this type of activity. Retail sales of medicinal products containing cannabis shall be carried out exclusively on the basis of an electronic prescription issued by a doctor.

When issuing such prescriptions, doctors shall inform patients about the possible consequences of using cannabis-based medicines, including indications, counterindications and potential side effects.

At the same time, all information on the dispensing of cannabis-containing products is registered in the electronic healthcare system.

Thirdly, the legalisation of cannabis in Ukraine does not entail the lifting of all restrictions on its circulation (cultivation, storage, sale, etc.), but only moves cannabis from the "Particularly dangerous narcotic drugs (or precursors), the circulation of which is prohibited" category to the "Narcotic drugs (or precursors), the circulation of which is restricted" category.

In addition, the Law introduces a new list, namely: "Plants containing narcotic drugs and psychotropic substances, the circulation of which is allowed for use for teaching purposes, educational, scientific and scientific-technical activities, in the production of narcotic drugs, psychotropic substances and medicines for further use in medical practice". The name of this list eloquently reflects almost the entire spectrum of permitted medical cannabis in Ukraine.

This list shall include plants of the genus Cannabis as follows:

- grown from conditioned and certified seeds of at least the 2nd generation, and
- whose concentration of tetrahydrocannabinol in dried straw is equal to or exceeds 0.3%, and

- used to produce medicines.

All in all, the legalisation of cannabis in Ukraine means that the production and use of cannabis will be possible, but limited, within the framework of the Law and special regulatory acts. Cannabis-based medicines will be available only in pharmacies, and cannabis will be grown only in compliance with complicated and costly requirements and conditions.

3. How is medical cannabis defined in Ukraine?

It should be understood that all terms related to the regulation of medical cannabis in Ukraine should be used exclusively in the meaning established by the legislation of Ukraine. This is especially important for investors who have experience in this industry in other countries and may build an incorrect understanding of their activities in Ukraine based on the terminology established by the laws of other countries.

Thus, in Ukraine:

- cannabis means the tops of the cannabis plant with flowers or fruits (except for seeds and leaves if they do not contain tops), from which resin has not been separated. The name by which such tops are labelled is irrelevant;
- cannabis plant means any plant of the genus Cannabis;
- hemp for medical purposes means plants of the genus Cannabis, which are grown from conditioned and certified seeds of at least the 2nd generation. Such plants must belong to the group of medicinal plant crops and to the list of narcotic drugs, psychotropic substances and precursors established by the legislation of Ukraine. The concentration of tetrahydrocannabinol in the dried straw of such plants must be equal to or greater than 0.3%. These plants must be used for the production of medicines;
- cannabis plant substance is an active pharmaceutical ingredient (API) produced from hemp for medical purposes or imported into Ukraine. Such an ingredient must be included in the State Register of Medicinal Products and permitted for the production of medicinal products;
- cannabis resin is a separated resin, whether unrefined or refined, obtained from the cannabis plant;
- a medication is a mixture of substances in any physical state containing one or more narcotic drugs (psychotropic substances, precursors, plants) from the list established by the legislation of Ukraine, or substances derived from them (if the circulation of such substances is regulated by the Law "On Narcotic Drugs, Psychotropic Substances and Precursors").

4. How to cultivate medical cannabis in Ukraine?

In Ukraine, cannabis cultivation means sowing and growing cannabis plants. The cultivation of cannabis plants for medical purposes is carried out on the basis of a special licence, which is required for companies regardless of their form of ownership. Only legal entities can engage in cannabis cultivation. Cannabis plants must be grown indoors using conditioned and certified seeds of at least 2nd generation. Seeds must be purchased in accordance with the procedure established by law.

An important process that accompanies the cultivation of cannabis for medical purposes is the procedure for determining the concentration of tetrahydrocannabinol in dried hemp straw.

Indeed, this procedure can be crucial for obtaining the results of cannabis cultivation, as harvesting is prohibited until the results of the laboratory test are available.

The determination of the concentration of tetrahydrocannabinol in dried hemp straw is carried out by laboratory testing of samples of the plant genus cannabis by specialised enterprises or state specialised expert institutions.

A sample for laboratory testing (study) is a picked (cut) upper third of the plant containing at least one female inflorescence, which is placed in an individual package for further analysis.

Sampling is carried out with the participation of the National Police of Ukraine in accordance with the established procedures:

- during the flowering period of the cannabis plant in order to determine the quantitative percentage of narcotic drugs or psychotropic substances – procedure "A";
- within 10 days after the end of flowering of Cannabis genus plants for the purpose of additional laboratory testing in case the plants are found to contain more than the maximum permissible content of narcotic or psychotropic substances – procedure "B".

To organise sampling for laboratory testing, a company that cultivates cannabis for medical purposes submits an application. According to Ukrainian legislation, the period for conducting laboratory tests (studies) of samples of the Cannabis genus cannot exceed 5 working days under procedure A and 10 working days under procedure B.

Holders of a licence for the cultivation or use of cannabis plants are obliged to take measures to protect crops, storage, and processing facilities for such plants. They must also ensure video surveillance of the places where such activities are carried out and provide the National Police with free and round-the-clock access to video surveillance data.

Security is provided by the security units of the National Police of Ukraine. A cannabis cultivation company must enter into a relevant agreement with the National Police.

In order to monitor compliance with the rules for the storage, cultivation, accounting and handling of medical cannabis, the National Police inspects facilities and premises intended for the medical cannabis cultivation. Such inspection shall be carried out in a planned manner, no

more than once a year, and with the participation of the company's administration.

5. What activity is subject to licensing?

Cultivation, development, production, manufacturing, storage, transportation, acquisition, distribution (dispensing), importation into and exportation from the territory of Ukraine, use and destruction of cannabis plants and derived substances (medications, medicinal products) are subject to licensing. Legal entities of all forms of ownership are required to obtain licences for these activities.

Also, the production, manufacturing, storage, importation into and exportation from the territory of Ukraine of medical cannabis shall be carried out within the quotas determined by the Ukrainian government.

6. How is cannabis for medical purposes traced in Ukraine?

Under Ukrainian legislation, the traceability of the circulation of hemp for medical purposes, its processed products, cannabis plant substance, and medicinal products manufactured from them is ensured by:

- use of conditioned and certified seeds for cultivation of hemp for medical purposes;
- purchase of such seeds in accordance with the procedure established by law;
- labelling each hemp plant for medical purposes, each batch of its processed products and each unit of packaged products with a unique electronic identifier. Cannabis plant substance and medicinal products manufactured in pharmacies are also subject to labelling;
- ensuring that medicinal products produced (manufactured) from hemp for medical purposes or cannabis plant substance are dispensed only upon a doctor's prescription based on medical indications and based on an electronic prescription;
- functioning of the electronic information system for accounting of cultivated cannabis plants for medical purposes. The movement of cannabis plants, products of their processing, cannabis plant substance, and medicinal products produced (manufactured) from them is also subject to registration in this system.

The changes to Ukrainian legislation on medical cannabis open up new opportunities for patients in need of medical cannabis treatment, as well as for investors and businesses that can participate in the development of this new industry in the Ukrainian market. For instance, the medical cannabis market in Germany, where it was legalised six years ago, is estimated at over EUR 300 million, demonstrating significant economic potential.

The Ukrainian medical cannabis market is also considered to be large and attractive to companies from Europe, as well as Canada and the US, with a forecast to grow to EUR 250 million by 2028.

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The tragic circumstances of Russia's full-scale invasion of Ukraine are driving the potential of medical cannabis in the treatment of war trauma, including post-traumatic stress disorder (PTSD).

Given the high level of social trauma in Ukraine caused by the hostilities, medical cannabis is expected to become an important tool to alleviate the physical and psychological suffering of millions of people.