

Ukraine Takes Ground-breaking Step by Legalising Medical Cannabis to Enhance Patient Care

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The President of Ukraine has officially signed Law No. 3528-IX "On Amendments to Certain Laws of Ukraine Regarding the State Regulation of Cannabis Plants for Use in Educational Purposes, Educational, Scientific and Scientific-Technical Activities, drugs production, Psychotropic Substances and medicinal products with the aim of increasing patients' access to the necessary treatment" simply known as the law on cannabis legalisation (the "**Medical Cannabis Law**"). The Medical Cannabis Law sets forth regulations governing the use of cannabis for educational, scientific, and medical purposes.

This long-awaited Medical Cannabis Law aims to establish a legal framework for the use of cannabis and various cannabis-derived products in a medical context. These products are extensively utilised for addressing conditions such as chemotherapy-induced nausea, epilepsy-related seizures, Alzheimer's disease, Tourette's syndrome, cancer-related symptoms, digestive tract disorders, sleep disorders and drug addiction. However, first and foremost, the use of cannabis drugs aims to alleviate chronic pain and aid with war veterans' recovery by helping them manage both physical and psychological trauma.

The enactment of the Medical Cannabis Law is a pivotal step toward enhancing patient access to vital medical treatments.

Licensing Requirements

The Medical Cannabis Law establishes specific criteria for carrying out the aforementioned activity, particularly with regard to licensing requirements.

A license for engaging in activities related to the utilisation of cannabis plants, including the manufacturing of narcotic drugs and psychotropic substances, is granted to companies upon meeting specific criteria outlined by the Cabinet of Ministers of Ukraine. These criteria aim to prevent the theft of cannabis plants and any products or by-products derived from them.

Furthermore, the Cabinet of Ministers had long ago approved a set of conditions, which mandate companies to operate under a permit issued by the National Police of Ukraine. To obtain this permit, entities must adhere to measures geared towards preventing the theft of plants, as well as the ready-made products or waste resulting from them. Moreover, legal entities are obligated to ensure round-the-clock security of their facilities and premises to prevent unauthorised access.

Production Regulations

With the Medical Cannabis Law entering into force, hemp cultivation for medical purposes and its processed products, along with cannabis plant material, will be permitted for educational, scientific, and medical activities including the production of narcotic drugs, psychotropic substances, and medicinal products. However, adherence to strict control and traceability measures at all stages of cultivation is strictly mandated by this law. These measures include:

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- Utilising conditioned and certified seeds for hemp cultivation (for medical purposes only), acquired in a clearly set procedure;
- Applying a unique electronic identifier to each cannabis plant intended for medical use, every batch of processed products, and each unit of packaged products. This labelling extends to plant material and medicinal products derived from them, which are dispensed either at pharmacies based on a doctor's prescription or pursuant to medical institutions' requisitions, in compliance with pharmaceutical legislation.
- Selling of medicinal products derived from medical hemp or cannabis plant material exclusively by means of a doctor's prescription, aligned with medical requirements, and issued electronically through the established procedure by the relevant healthcare authority.
- Establishing an electronic information system to monitor the cultivation of medical hemp plants, the movement of these plants, their processed products, cannabis plant material, and the resulting medicinal products, throughout the entire process.

Implementation Challenges and Regulatory Measures

Nevertheless, several regulatory measures still need to be enacted in order to ensure the effective implementation of the Medical Cannabis Law.

For instance, the Ministry of Health of Ukraine is tasked with approving medical protocols by specifying the diseases, appropriate dosages, and circumstances under which medicinal cannabis-based treatments should be prescribed. The dispensing of said medicinal products must strictly adhere to medical guidelines and will only be permissible by means of a doctor's prescription, following the same protocol in place for narcotic and psychotropic drugs. Patients will be authorised to possess and store these medications in the quantities specified in a single prescription.

THC Thresholds: Regulatory Stipulations

The principal psychoactive compound in cannabis is tetrahydrocannabinol (THC), which is recognised for its addictive properties and potential to worsen dependency issues, particularly in vulnerable individuals. Currently, only technical varieties of cannabis with a THC content of less than 0.08% are permitted for cultivation. In comparison, various EU countries, Switzerland, and the USA have permissible THC limits that are higher, ranging from 0.2% to 1%.

In Ukraine, the Medical Cannabis Law stipulates that THC content must not exceed 0.3% for industrial purposes and should only surpass this threshold for medical purposes. Recreational cannabis use—consumption for enjoyment rather than medical necessity—remains prohibited.

There is little doubt that the legalisation of cannabis for medical purposes marks a significant step forward, offering invaluable therapeutic relief to individuals in need.

The enactment of the Medical Cannabis Law is scheduled to take effect in mid-August 2024, which is six months after the official publication of the law.

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