

Wiadomości Lekarskie Medical Advances



VOLUME LXXVII, ISSUE 4, APRIL 2024

Official journal of Polish Medical Association has been published since 1928

ISSN 0043-5147
E-ISSN 2719-342X



INDEXED IN PUBMED/MEDLINE, SCOPUS, EMBASE, EBSCO, INDEX COPERNICUS,
POLISH MINISTRY OF EDUCATION AND SCIENCE, POLISH MEDICAL BIBLIOGRAPHY

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Traceability and control as levers to prevent leakage from legal circulation when legalizing medical cannabis

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ABSTRACT

Aim: To reveal traceability and control as levers to prevent leakage from legal circulation when legalizing medical cannabis.

Materials and Methods: The methodological basis of this research work is based on a systematic approach. Methods of structural and logical analysis, bibliosemantic, abstraction and generalization were used in this article.

Results: The analysis of the regulatory framework and regulatory initiatives in the field of circulation of narcotic drugs, in particular, cannabis (in total 56 documents) demonstrated repeated attempts to reform it in Ukraine in order to increase the availability and efficiency of medical and pharmaceutical services. Recently adopted law on the legalization of medical cannabis pays special attention to the traceability of the circulation of medical cannabis and cannabis-based medicines (CbMs) by digitalization and creation of the appropriate electronic information system.

Conclusions: With the adoption of the law on the legalization of medical cannabis Ukraine became the 57th country in the world to legalize such cannabis. The study and analysis of the regulatory framework of Ukraine, taking into account the best world practices, showed that the legalization of medical cannabis will allow for providing more effective care to many patients including wounded defenders.

KEY WORDS: cannabis, medical cannabis, traceability, drug policy, narcotic drugs, control

Wiad Lek. 2024;77(4):635-639. doi: 10.36740/WLek202404103 DOI

INTRODUCTION

Over the past decade, drug policies at the global level have prioritized decriminalization and human rights, harm reduction, and innovative and voluntary treatment. An important role is given to regulating the legal circulation of cannabis, primarily for medical use. Currently, the world has collected enough scientific data that confirm the effectiveness of the use of cannabinoids in the treatment of over 50 pathological states, primarily in the treatment of pain, PTSD, epilepsy and seizure disorders, and multiple sclerosis [1-3]. The integration of Ukraine into the European Union, and the need for modern, affordable, and effective methods of pain relief and treatment of PTSD require, in particular, the updating of the legal framework regarding the circulation of medical cannabis in accordance with the best world normative practices.

Many countries around the world have already legalized the medical use of cannabis. These countries

include Albania, Argentina, Australia, Barbados, Brazil, Canada, Chile, Colombia, Costa Rica, Croatia, Czech Republic, Cyprus, Denmark, Ecuador, Finland, Georgia, Germany, Great Britain, Greece, Israel, Ireland, Italy, Jamaica, Lebanon, Luxembourg, Malawi, Malta, Mexico, Netherlands, New Zealand, North Macedonia, Norway, Panama, Peru, Poland, Portugal, Rwanda, Saint Vincent and the Grenadines, San Marino, South Africa, Spain, Sri Lanka, Switzerland, Thailand, Uruguay, Vanuatu, Zambia, Zimbabwe. Some of them have more restrictive laws that only allow the use of certain medicinal products derived from cannabis. In the United States, 38 states, 4 territories, and the District of Columbia have legalized the medical use of cannabis, but at the federal level, its use remains forbidden [3,4].

Clear rules for the circulation of cannabis for medical purposes are being worked out in Ukraine, taking example of such countries as Austria, Belgium, Czech Republic, Great Britain, Denmark, Finland, France, Germany,

Slovakia, Sweden, Switzerland, and others. However, the experience of these countries is recent and, given the development of modern information technologies in Ukraine, our state can, under certain conditions, become one of the best in ensuring the proper legalization of cannabis and preventing its illicit traffic.

AIM

In the light of the adoption of the law on the legalization of medical cannabis, the issue of the scientific justification of ensuring control through traceability in general and, in particular, of the problems of proper control in the sphere of circulation of narcotic drugs, psychotropic substances, and precursors, are becoming especially relevant. Therefore, the purpose of this article is to reveal traceability and control as levers to prevent leakage from legal circulation when legalizing medical cannabis.

MATERIALS AND METHODS

The methodological basis of research work is based on a systematic approach. Methods of structural and logical analysis, bibliosemantic, abstraction, and generalization were used in this article. An analysis of the current legal framework of Ukraine for the years 1991-2024 was carried out on the subject of regulation of the circulation of cannabis and its derivatives, as well as relevant draft laws and subordinate legislation (in total 56 documents from the official websites of the Verkhovna Rada of Ukraine, the Cabinet of Ministers of Ukraine, the Ministry of Health of Ukraine, the State Service of Ukraine on Medicines and Drugs Control).

RESULTS

At the international level, the circulation of cannabis is regulated by UN conventions [5,6,7]. In accordance with World Health Organization (WHO) recommendations, in December 2020, the United Nations Commission on Narcotic Drugs removed cannabis and its derivatives from Schedule IV of the Single Convention on Narcotic Drugs of 1961, which includes strictly controlled drugs. At the same time, it kept it in Schedule I - the list of all drugs subject to international control [8].

Until now, the main documents regulating the status of cannabis in Ukraine were the Law of Ukraine "On narcotic drugs, psychotropic substances and precursors" [9] and the Resolution of the Cabinet of Ministers of Ukraine "On approval of the list of narcotic drugs, psychotropic substances and precursors" [10]. The circulation of cannabis and tetrahydrocannabinol in

Ukraine was prohibited. In April 2021, the government resolution added nabilone and nabiximols to the list of psychotropic substances whose circulation is restricted [11]. However, these drugs were never submitted for the state registration of medicinal products and, accordingly, they did not enter real circulation in Ukraine.

On December 21, 2023, the Verkhovna Rada of Ukraine adopted the Law "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, production of narcotic drugs, psychotropic substances, and medicinal products with the purpose of expanding patients' access to necessary treatment" (hereinafter - the Law) [12].

According to the academic dictionaries, legalization is "the act of allowing something by law, e.g. the legalization of drugs" [13], "the process of making something legal when it was previously illegal" [14]. Full legalization is that is limited only by the quality of the product itself, and low-quality products are prohibited for sale [15]. Therefore, we can only talk about full and incomplete legalization or its absence. Incomplete legalization has its own characteristics depending on what is being legalized. In the case of cannabis plants, the latter are a kind of "case", which, with more than a hundred different cannabinoids in terms of their pharmacological effect on the human body, contains one that needs restrictions in its distribution - tetrahydrocannabinol (hereinafter - THC). Depending on its content, hemp varieties, and their circulation usually differ in different countries.

Traceability is a concept that originates from the food industry and is used to ensure the quality of the respective products. Yes, in accordance with clause 15 of Art. 3 of a Regulation of the European Parliament and of the Council (of the EU) No. 178/2002, "traceability" means the ability to trace and track at all stages of production, processing and distribution of food products, fodder, productive animals or substances that are intended to be included or expected to be included in food or feed [16]. The traceability of medical cannabis is necessary not so much to ensure quality, but to limit the leakage of tetrahydrocannabinol from legal circulation.

In the adopted Law it is stated that the circulation of hemp for medical purposes, products of its processing, the plant substance of cannabis, medicinal products produced (made) from them is allowed in medical practice, educational purposes, educational, scientific and scientific and technical activities on condition of control and traceability ensured at all stages of such circulation. Thus, it is traceability and control that must become necessary conditions of circulation. Proper control over

the circulation of medical cannabis can be qualitatively organized only on the basis of appropriate traceability from the seed to the sale to the consumer. The Law also states that circulation traceability is ensured by implementing a number of measures that should be considered [12].

The procedure of purchase of hemp for industrial purposes is currently provided by the relevant Resolution of the Cabinet of Ministers of Ukraine of December 27, 2008 No. 1129 [17], which states that the purchase is carried out by economic entities from entities of production of seeds and planting material entered in the State Register of Seed Producers. This procedure is clarified by clause 33 of the Resolution of the Cabinet of Ministers of Ukraine of April 6, 2016 No. 282 [18], since not any economic entity, but only a properly licensed one specifically for sowing and growing, can purchase industrial hemp today. In general, the Law of Ukraine “On narcotic drugs, psychotropic substances and precursors”, adopted in 1995, actually equated technical hemp with drugs, applying the corresponding legislative regulation on licensing, which excessively complicated conducting economic activity of growing hemp [9].

DISCUSSION

With the adoption of the Law, the actual launch of the medical hemp market will take place and industrial hemp should move to the plant market, and medical hemp should be regulated in the similar way to the current one regarding industrial hemp, with the condition of increased traceability and control. Such an increase should first of all be ensured by proper digitalization, because the latter can simplify all legal procedures with hemp and at the same time increase the traceability of these processes. Modern artificial intelligence programs are able to use video cameras to calculate the number of seeds for planting and record them. Then, the number of labeling units and further stages of the procedures regarding the plant will be determined by the number of seeds. Thus proper digitalization is also ensured by appropriate labeling of each plant, each batch of products of medical cannabis processing and each unit of packaged products, which is further specified in the Law [12].

All relevant transactions will be included in a common database, including the date of manufacture and series of medicines in which medical cannabis is used. In this way, both the leakage of medical cannabis from legal circulation and attempts to sell a falsified drug will be prevented. This will allow tracking of the entire production and supply chain of medicines containing tetrahydrocannabinol contained in hemp for medical purposes, including sale

to a patient specifically defined by a doctor's prescription. Traceability of circulation for educational, scientific purposes as well as scientific and technical activities should also be ensured through the labeling of each hemp plant and each derivative thereof containing THC.

According to the order of the Ministry of Health of Ukraine [19], since October 13, 2023, the dispensing of narcotic (psychotropic) medicinal products in pharmacies began to be carried out exclusively based on an electronic prescription throughout Ukraine. In our opinion, electronic accounting should also be applied to extemporaneous narcotic medicinal products, which are appropriately manufactured directly in pharmacies and now may be one of the exceptions from the rule.

The Law provides to create an electronic information base for further analysis in order to determine the demand and quotas for the cultivation of medical cannabis [12]. Such base should become a component of the unified state electronic system for managing the circulation of narcotic drugs, psychotropic substances and precursors.

The system must contain information on all elements related to circulation, except for personal data, which can be disclosed only to supervisory and law enforcement authorities.

That is, the system must contain all possible information that can confirm the chain of traceability of the origin of medical cannabis and its derivatives and the legality of the corresponding products. The processing and protection of personal data in the system must be carried out in accordance with the Laws of Ukraine “On protection of information in automated systems” [20] and “On protection of personal data” [21].

The results of manipulations with hemp plants and their derivatives must be entered into the system by the relevant entities and the employee responsible for the state not later than a day after receiving the relevant information, which must also be recorded by the electronic system.

It is advisable to use artificial intelligence (AI) to ensure control and traceability of circulation at all stages.

According to the adopted law, the cultivation of hemp for medical purposes is carried out in accordance with the requirements of the proper practice of cultivation and collection of raw materials of plant origin. In Ukraine, the proper practice of cultivation and collection of raw materials of plant origin was put into effect by order of the Ministry of Health of Ukraine [22]. This practice, taking into account its multifactorial nature, can also, in the future, be controlled using AI technologies, but this is already a prospect for further research into traceability and control over the circulation of relevant plants and substances.

CONCLUSIONS

With the adoption of the Law “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, production of narcotic drugs, psychotropic substances, and medicinal products with the purpose of expanding patients’ access to necessary treatment”, Ukraine

became the 57th country in world legalizing medical cannabis. Among them, there are the USA, Canada, EU countries, etc. The study and analysis of the regulatory framework of Ukraine, taking into account the best world practices, showed that the legalization of medical cannabis will give an opportunity to provide more effective care to many patients including wounded defenders.

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The article was made in the framework of research works of Bogomolets National Medical University "Scientific substantiation of improving the organizational foundations of the health care system under conditions of modern transformational changes"; (2023-2025, № state registration 0123U101432).

CONFLICT OF INTEREST

The Authors declare no conflict of interest

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RECEIVED: 11.12.2023

ACCEPTED: 24.03.2024

