Секція 2
АНАЛІЗ РИНКУ ЛІКАРСЬКИХ ЗАСОБІВ РОСЛИННОГО ПОХОДЖЕННЯ, ДІЄТИЧНИХ ДОБАВОК, ЛІКУВАЛЬНО-ПРОФІЛАКТИЧНИХ ТА КОСМЕТИЧНИХ ЗАСОБІВ. СУЧАСНІ ПІДХОДИ ДО ТЕХНОЛОГІЇ ТА АНАЛІЗУ ЛІКАРСЬКИХ ЗАСОБІВ НА ОСНОВІ КОМПОНЕНТІВ РОСЛИННОГО ПОХОДЖЕННЯ

Section 2
ANALYSIS OF THE MARKET FOR HERBAL MEDICINES, DIETARY SUPPLEMENTS, AND MEDICAL, PREVENTIVE, AND COSMETIC REMEDIES CURRENT APPROACHES TO THE TECHNOLOGY OF HERBAL MEDICINES

SPECIFICS OF INTERNATIONAL REGULATION OF CANNABIS AND CANNABINOIDS MARKET IN COUNTRIES OF SOUTH AND NORTH AMERICA

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Introduction. Even though, according to the Single Convention on Narcotic Drugs of 1961 [1] and the Convention on Psychotropic Substances of 1971 [2], cannabis and cannabinoids can be used for medical and scientific purposes, their enumeration into the Schedules of the highest prohibition degree makes the regulation of these substances considerably harder. On the 2nd of December, 2020, the Commission on Narcotic Drugs decided to remove cannabis from Schedule IV of the Convention of 1961 and approved the recommendations of the World Health Organization, but cannabis and cannabinoids for medical and scientific purposes are still not accessible in many countries, including in Ukraine. However, the countries of North and South America found various ways of making cannabis-based medicinal products available for patients.

The purpose of the study is to carry out a general analysis of legal and regulatory norms regarding medicinal cannabis market in countries of South and North America.

Materials and methods. Content-analysis, system and logical analyzes.

Results and their discussion. ***Uruguay*** legalized cannabis and cannabinoids, including for medical purposes, at the end of 2013 by adopting the Law 19.172: Marijuana and its derivatives. Cultivation of psychotropic strains of cannabis (containing more than 1% of tetrahydrocannabinol – THC) for medical purposes, scientific research or ‘other purposes’ is possible after preliminary authorization from

a specially created state institution – the Institute for Regulation and Control of Cannabis (IRCCA). This Institute deals with granting licenses for pharmacies that are allowed to sell cannabis for medical purposes on a physician's prescription. Besides, growing cannabis for personal consumption is allowed (up to six plants with their maximum harvest of no more than 480 grams per year), as well as the organization of clubs cultivating cannabis under the IRCCA control. Despite the liberalization policy of the national legislation of Uruguay, as concerns medicinal cannabis, these products' availability for patients is limited enough. Thus, only a comparatively small number of pharmacies can deal with the sale of medicinal cannabis because of limitations, related to financing via the US banks. The only available product is Epifractan, of the national company Medicplast, with the cannabidiol (CBD) content of 2% or 5%, and with THC – maximum 0.5%. However, patients can also use imported cannabis preparations, containing synthetic and herbal cannabinoids, with the permission of the Ministry of Public Health under a "compassionate use" exception. [3, 4, 5, 6]. In other South American countries, cannabis and cannabinoids are allowed exclusively for medical and scientific purposes in accordance with international Conventions [5]. Thus, in ***Chile***, according to Law 20.000, patients get access to cannabis products and cannabinoids on medical prescriptions, in case necessary medicinal products are absent, they can be imported [7]. It is also allowed by law to grow these plants for home use. In ***Columbia*****,** the flow of cannabis and cannabinoids for medical and scientific purposes is regulated by the state: private companies can get licenses on cultivation, production, export or research. In ***Brazil,*** since 2016, the import of drugs based on CBD oil, and of cannabis flowers for therapeutic use has been allowed. Within the recent period, the national legislations of ***Peru, Argentine, and Mexico*** were liberalized as concerns the use of cannabis and cannabinoids for medical and scientific purposes [4, 5].

In the ***USA*****,** cannabis for medical purposes is prohibited at the federal level as marijuana, according to the Controlled Substances Act, is attributed to Schedule I. That is, it is classified as the substance which has a high potential for abuse and is not used in medical practice. However, in 33 states, District of Columbia, Guam, Puerto Rico, and U.S. Virgin Islands various schemes as to the access to medicinal cannabis are in operation. For instance, home cultivation is allowed, as well as access to the products' use via dispensaries and other institutions, and via various comprehensive medicinal cannabis programs. In the states, where medicinal cannabis is legalized, there are usually patient registers, enabling patients to get protection against a possible arrest for cannabis storage for individual medical use. Besides, in various states there are special local requirements concerning recommendations, dispensing, and application possibility of medicinal cannabis for patients from other states, etc. [8].

It is worth noting that the process of cannabis and cannabinoids legalization in the USA usually takes two directions: via a referendum (California, Washington, Alaska, Nevada, Colorado, and others) and via legislative initiatives (Illinois, Vermont, Minnesota, Maryland, Pennsylvania, New Mexico, etc.). The adoption of Farm Bill in 2018 enabled the hemp to be differentiated (THC content – less than 0.3%) from marijuana (THC content is over 0.3%). Hemp legalization at the federal level created

favorable conditions for developing business connected with hemp and CBD production and sale in the USA [4, 9].

The legislation of ***Canada***, relating cannabis and cannabinoids, is the most progressive in the world thus far. After the Cannabis Act was adopted in 2018, cannabis became legal not only for medical but also for recreational purposes [10]. This legal document regulates the activity of federal license holders in the market dealing with cannabis and cannabinoids, namely: production, distribution, sale, importation, and exportation. According to the Cannabis Act, in Canada, as well as in the USA, there is a legal differentiation of cannabis between hemp with THC lower than 0.3% and marijuana with THC higher than 0.3%. Marijuana traffic regulation includes licensing (cultivating and processing cannabis, sale of cannabis for medical purposes, analytical testing and research of cannabis), permissions for exporting and importing for scientific or medical purposes, requirements for license holders, packing and coding. For instance, when coding Cannabis products, the health warnings, standardized cannabis symbols, specific information about the product are mandatory. To get access to cannabis and cannabinoids products, a patient must receive a respective medical document from a doctor that allows a license holder to register or get a permission for independent cultivation of medicinal cannabis in a limited quantity with Health Canada [4, 11].

Conclusions. Legal and regulatory norms regarding the medicinal cannabis market in countries of South and North America make cannabis-based medicinal products much more accessible for patients in comparison with other countries. The most progressive legislation on cannabis and cannabinoids is developed in Canada. It allows Canadian patients to improve their life quality and health, and to strengthen the positions of this country on the international market of cannabis-based medicinal products.

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LEGAL BACKGROUND OF COMPLEMENTER MEDICINE AND FOLK MEDICINE IN SLOVAKIA

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Introduction. Based on the Constitution of the Slovak Republic, everyone has the right to health protection, right to free health care and medical aids provided by health insurance under the conditions established by law. The Slovak health care legislation is based on a monopolistic health care system that does not allow lay concepts. Despite this fact, there is a great expansion of the application of various methods of complementary medicine, such as folk medicine, as well as treatment with plants in the lives of an increasing amount of people. The aim of the study is to point out the need for a comprehensive legislative solution to the issue of complementary medicine, the use and sale of products containing active substances of medicinal plants, such as nutritional and other supplements, spread uncontrollably among the population.

Materials and methods. Medicinal herbs have been present in human culture since ancient times. They have been used effectively in the fight against diseases for thousands of years, and the renaissance of their practice has occurred in recent decades. They are a storehouse of natural active substances. The basic chemical groups of substances contained in medicinal plants beneficiary for human use [1, 2] mainly include primary and secondary metabolites.

The possibilities of using the potential of plants have been dampened mainly by the development of synthetic chemical technologies, which have been preferred in recent decades in the pharmaceutical, cosmetic and food industries. In developed countries, at present, there is an increase in dissatisfaction and a lack of trust in synthetic products throughout their lives. Products with a large proportion of natural