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НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ
КАФЕДРА СОЦІАЛЬНОЇ ФАРМАЦІЇ

СОЦІАЛЬНА ФАРМАЦІЯ: СТАН, ПРОБЛЕМИ ТА ПЕРСПЕКТИВИ

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Збірник містить матеріали міжнародної науково-практичної дистанційної конференції «Соціальна фармація: стан, проблеми та перспективи», в яких розглянуті питання щодо сучасного стану впровадження концепції соціальної фармації як складової ефективної сфери охорони здоров'я; особливостей нормативно-правового регулювання фармацевтичного забезпечення населення та тенденцій управління фармацевтичним сектором сфери охорони здоров'я; перспектив та розвитку соціально-ефективних механізмів забезпечення доступності фармацевтичної допомоги населенню; раціональної фармакотерапії як головного елементу ефективного та безпечного фармацевтичного забезпечення населення; сучасного стану діджиталізації та інформаційного забезпечення сфери охорони здоров'я; соціальних тенденцій менеджменту та маркетингу у фармації та соціальної відповідальності бізнесу в фармації; фармакоекономічного аналізу схем лікування соціально-небезпечних захворювань; організації фармацевтичної допомоги в умовах надзвичайних ситуацій; соціально-психологічних та морально-етичних аспектів фармацевтичної діяльності в сучасних умовах; історичних аспектів медицини та фармації; викладання організаційно-економічних дисциплін у закладах вищої медичної та фармацевтичної освіти в умовах воєнного стану.

Матеріали подаються мовою оригіналу.

За достовірність матеріалів відповідальність несуть автори.

Редколегія не завжди поділяє погляди авторів.

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COMPARATIVE AND MARKETING ANALYSIS OF MEDICAL SUPPLY OF THE POPULATION IN UKRAINE AND EU COUNTRIES

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Introduction. The system of medical provision of the population in the countries of the European Union is an example of the quality and safety of the use of medicines, since the primary principles are the proper pharmaceutical production of effective, safe and affordable medicines and the provision of quality medical and pharmaceutical services.

The entire cycle from the development to the use of medicinal products is subject to regulatory regulation, since the conceptual basis of the legislation on the circulation of medicinal products in the EU countries is the regulatory and procedural support of the quality assurance system, known in the sequence of the GXP cycle, where X defines the component of this chain: GDP – good distribution practice; – D; GLP – good laboratory practice, proof of pharmaco-toxicological characteristics – L, GMP – good manufacturing practice, production requirements – M, GRP – good pharmacy practice – P, and so on in this sequence to V – good pharmacovigilance practices (Good pharmacovigilance practices – GVP).

The purpose of the study: to determine the conceptual foundations, normative and regulatory basis and strategy for the development of the medical care system in Ukraine and the EU countries.

Research methods: comparative analysis of the legislative and regulatory framework, scientific sources, systematization of research in the pharmaceutical sector of EU countries.

Research results and their discussion. The cycle of the drug quality assurance system from the point of view of the responsibility of the participants in the drug market consists of two parts: (1) the creation and release of the drug to the market according to the requirements of the EU directive No. 2001/83 and (2) the use of the drug, treatment according to the requirements of WHO recommendations.

Bringing the inspection of pharmaceutical production into compliance with the requirements of the recommendations of the international system of cooperation of pharmaceutical inspections (PIC/S 002) and the instructions of the European Medicines Agency (EMA) on inspections and information exchange (17th edition dated 03.10.2014 , EMA/572454/2014).

Pharmacy activity in the EU countries is regulated by the general EU legislation in the field of health care and national legislation arising from point a) of Art. 85 of Chapter VII of Directive 2001/83/EC, taking into account WHO recommendations common to all countries, since its main goal is the health of the population.

The main concepts in the system of medical care in European countries: "pharmaceutical care" (pharmaceutical care) and "pharmacotherapy management" (medicines management, Yan Mil F.J.W., Schulz M., 2006) are generally accepted in European countries. However, resources, traditions, influencing factors at the level of individual countries are different, health care systems have certain differences due to the peculiarities of providing pharmaceutical services and pharmacy activities.

The WHO recommendations on good practice for newly independent countries (2001) became the basis for the organization of pharmaceutical activities, as they take into account the radical changes in the health care system in these countries and the new roles of pharmacies.

Pharmaceutical practice (pharmaceutical practice) is an activity that includes the production, distribution of medicinal products, pharmaceutical service and pharmaceutical assistance and includes all the above types of activities and services carried out in the pharmaceutical sector of the health care system of the EU countries [1-3].

At the current stage, the strategy of reforms of the pharmaceutical sector of the EU countries is aimed at maximally meeting the patient's needs regarding quality medicines and safety of use, promoting the availability of medicines and responsible use of medicines in view of costs and effectiveness.

The International Pharmaceutical Federation (FIP, Besanson L., 2015) is at the origin of the main legislative provisions of good pharmacy practice in EU countries. FIP, together with WHO, introduced the Good Pharmacy Practice Guidelines in 2011.

The development of pharmaceutical science, education and professional pharmaceutical activity in Ukraine is integrated with EU countries [4].

It is worth citing the example of our closest neighbors - Poland, because the volume of the Polish pharmaceutical market reaches 5 billion euros (in manufacturers' prices), which makes it the 6th among the leading countries in the EU. First of all, it should be noted that Poland has compulsory health insurance for the entire population. The insured patient has access to doctors (general practice and narrow specialists), and also has the opportunity to purchase medicinal products, the cost of which is subject to reimbursement. The Polish reimbursement system is based on the principle of copayment: part of the cost of prescription drugs is reimbursed by the state. Under the new system, not all prescription drugs are subject to reimbursement: the list of drugs whose cost is reimbursed includes about 3,500 items. The list is revised every 2 months. Medicines that are reimbursed are included in "limited groups" (statins, antibiotics, etc.). The reimbursement level is calculated on the basis of the medicinal product, which is the limit in each group. When calculating the reimbursement level of other drugs in the group, the value of the established daily dose (DDD) of the limited drug is used. These limits change every 2 months.

Anticoagulants dominate among the top 20 consumer brands in Poland. One of the biggest problems is that the value of these brands in the Western EU markets is much higher than in Poland, so they are exported. Also, the demand of the Polish pharmaceutical market is aimed at drugs from groups C, N, A of the ATS classification.

The number of pharmacies in Poland is increasing, but the average turnover is stable. Today, 1 pharmacy serves about 2,600 patients. Pharmacy chains, which include 5 or more outlets, accumulate 39% of the pharmacy market, their share in turnover is 52%, 36% of the market is occupied by individual pharmacies, their specific weight is 25% of turnover. Small chains (2–4 pharmacies) account for 26% of pharmacies and 23% of turnover, which, according to experts, contributes to meeting the demand of the population.

In Poland, as well as in neighboring Germany, which is a leading country in the EU countries in terms of the level of development and introduction into production of

new pharmaceuticals, almost all pharmacies are engaged in extemporaneous production aimed at maximally satisfying the individual needs of patients.

In comparison with other European countries with a developed pharmaceutical sector, there are pharmacies per 100,000 population: in Spain – 46 pharmacies, in Italy – 30 pharmacies, in Great Britain – 21, in Germany – 26 pharmacies, Fig. 1

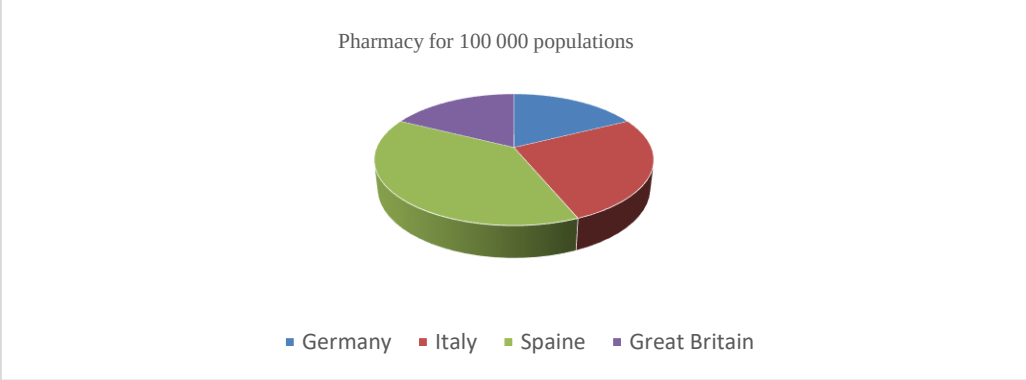

Fig. 1. Diagram of the distribution of the number of pharmacies in EU countries with a developed pharmaceutical healthcare sector.

Licensing of the pharmaceutical activities of pharmacies is subject to the uniform norms of the EU regulatory framework, but there are certain peculiarities. For example, in Belgium, in case of opening a new pharmacy, the license can be transferred only during the first five years of operation. In many EU countries, licensing regulation is carried out by granting licenses in compliance with licensing conditions to a pharmacy institution and a specific manager (example of Austria) [5].

Conclusions. EU countries have introduced systems of self-regulation in the pharmaceutical industry, which allows relevant organizations to take an active part in the development and implementation of important legal documents, increase the level of pharmaceutical assistance and protect the interests of pharmaceutical specialists. The strategy of reforms of the pharmaceutical sector of the EU countries is aimed at maximum satisfaction of the patient's needs regarding quality medicines and safety of use, promotion of availability of medicines and responsible use of medicines in view of costs and effectiveness.