Pharmaceuticals: Management Safety of Circulation of Drugs

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Abstract. The adoption and implementation of EU pharmaceutical directives and regulatory documents in Ukraine will significantly enhance the level of public health protection. Establishing a unified pharmaceutical market with EU countries will also improve the safety, quality, and accessibility of medications in Ukraine. To achieve these objectives, a comprehensive system for managing drug circulation safety has been proposed, with detailed functions and roles elaborated. Key components of this safety management system include robust monitoring mechanisms, stringent regulatory compliance measures, and effective communication channels among stakeholders. By implementing these measures, Ukraine can ensure that drugs are safe, effective, and of high quality, thereby fostering greater public trust in the healthcare system. Additionally, the integration of advanced technologies and best practices from EU countries can streamline drug approval processes, reduce counterfeit medications, and enhance pharmacovigilance. Efforts to improve the circulation of drugs will not only guarantee their safety and quality but also make them more readily available to the population. This will involve upgrading infrastructure, enhancing regulatory frameworks, and fostering collaboration with international pharmaceutical organizations. Overall, these initiatives are crucial for aligning Ukraine's pharmaceutical sector with European standards, ultimately leading to better health outcomes for its citizens and a more resilient healthcare system.

Keywords: pharmaceuticals, management, safety, circulation of drugs, proper GxP practices, pharmaceutical law.

Introduction. The main goal of European pharmaceutical legislation in general is to protect the health of citizens and the individual patient. At the same time, it is important to encourage the development of pharmaceuticals to create a single market of pharmaceuticals in the countries of the European Union (EU) [1].

Currently, the EU unites 28 member states, as well as the countries of the European Economic Area. Provides a single market for pharmaceuticals and is based on [2-11]:

- directives, laws and regulations of the EU outlining the requirements for the stages of circulation (development, production, marketing, safety of drugs for humans and veterinary medicine; these requirements differ from the requirements for the development and authorization of medical devices and in vitro diagnostics in the EU;
- the work of experts of the European Medicines Agency (EMA) on the scientific assessment of EU applications for the registration of drugs for humans and veterinary medicine;
- high standards of quality, safety and efficiency, in order for the product to receive marketing authorization (MA);
- the principles of pharmaceutical law in the system of legal relations "doctor-patient-pharmacist-lawyer".

The principles of pharmaceutical law in the system of legal relations "doctor-patient-pharmacist-lawyer" include [12-14]:

- recognition of health care as a priority area of activity of society and the state, one of the main factors of survival and development of the people of Ukraine;
- observance of human and citizen rights and freedoms in the field of health care and provision of related state guarantees;
- humanistic orientation, ensuring the priority of universal human values over class, national, group or individual interests, increased medical and social protection of the most vulnerable sections of the population;

- equality of citizens, democracy and general availability of medical and rehabilitation assistance and other services in the field of health care;
- compliance with tasks and the level of socio-economic and cultural development of society, scientific justification, material, technical and financial security;
- focus on modern standards of health, medical and rehabilitation care, the use of modern digital technologies, telemedicine and telerehabilitation, a combination of domestic traditions and achievements and the best global experience in the field of health care;
- preventive and preventive nature, complex social, environmental, medical and rehabilitation approach to health care;
- complexity of the health care economy and multi-channel financing, combination of state guarantees with demonopolization and encouragement of entrepreneurship and competition;
- decentralization of state administration, development of self-governance of institutions and independence of healthcare workers on a legal and contractual basis;
- formation of a single medical information space as a set of databases, technologies for their maintenance and use, information and communication systems that function on the basis of uniform principles and general rules, as well as on the basis of interoperability, integration and implementation of electronic health care tools;
- compliance with the principles of barrier-freeness and inclusion in the provision of medical and/or rehabilitation assistance, including the use of telemedicine methods and tools.

In the pharmaceutical market of Ukraine, the implementation of the market economic system is based on the principles of pharmaceutical law. Taking into account forensic and pharmaceutical risks at the procurement stage for the safety, quality of drugs, requirements of GxP standards while reducing budget allocations in the field of health care. Against the background of covid, postcovid, long-covid disorders, it is necessary to focus on [15-26]:

- implementation of European pharmaceutical legislation, regulations and EU directives;
- improvement of the system for control of safety, quality, efficiency, and availability of medicines;
- management, decentralization and restructuring;
- introducing new drugs into circulation;
- introduction of new payment systems for medical and pharmaceutical services;
- recognition of the patient's choice;
- fire safety, sanitary and epidemiological regime;
- personnel training and proper payment for labor.

The purpose of the research was to study pharmaceuticals, management of the safety of drug circulation at the procurement stage in accordance with the requirements of GxP and the principles of pharmaceutical law.

Materials and methods. The information base of the study consisted of scientific works of foreign and domestic scientists on issues related to the organization of pharmaceutical business, management, forensic pharmacy, pharmaceutical provision, pricing policy for drugs [25-32].

Modern research methods were used: normative and legal, documentary, retrospective, bibliographic, systemic, forensic and pharmaceutical, comparative, marketing, graphic analysis. Mathematical processing and statistical evaluation of data was performed using Microsoft Excel.

The research of the article is a fragment of research works of Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" on the topic "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029).

Results and discussion. We follow the study of the drug circulation system in the publications of Stefanov O.V., Danilenko V.S., Tolochko V.M., Sosin I.K., Shapovalova V.O., Krasnyanska T.M., Solovyova O.S., Grizodoub O.I., Ponomarenko M.S., Zbrozhek S.I., Gudzenko A.O., Kabachna A.V., Osintsevoi A.O., Shapovalova Valentina V., Vasina Yu.V. etc. [43-51].

Integration processes related to the implementation of EU legislation in Ukraine require the introduction of all elements of the regulatory system in pharmaceuticals for the sake of quality, safety, availability and effectiveness of medicines [52]. The EU regulatory system includes:

- The European Medicines Agency (EMA), which carries out pharmacovigilance, is responsible for monitoring the safety level of all drugs in circulation.
- National competent authorities of all member states;
- Centralized authorization procedure (CAR), which is used for registration of new drugs and biologics, as well as for certain drugs for specific diseases. The EMA marketing authorization is valid in all EU member states.

Reports of detected suspected side effects of drugs are collected, analyzed and processed [53]. EU marketing authorization procedures:

- centralized procedure – transparency in medication regulation; reports on the evaluation of the safety and effectiveness of medicines are open to the public;
- national procedure – regulation of the circulation of generics and over-the-counter drugs operates within the national procedure of the respective state;
- mutual recognition procedure for authorizations for circulation of drugs to facilitate marketing in EU countries;
- decentralized procedure for drugs not approved for circulation.

The procedures of the European Agency (EMA) for pharmacovigilance in EU member states are shown in Fig. 1.

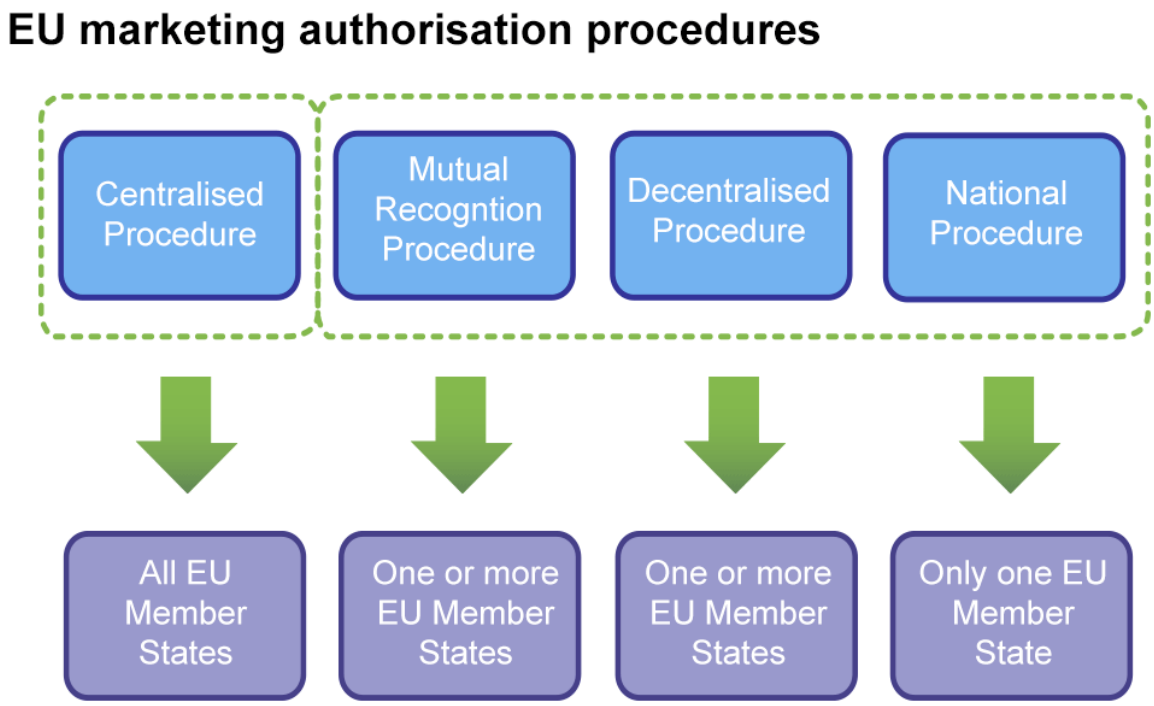

Fig. 1. Procedures of the European Agency (EMA) for pharmacovigilance in EU member states.

Safety, effectiveness, quality and availability of drugs are included in the system of regulating the circulation of drugs. Includes GxP requirements at the manufacturing, wholesale and retail levels. It is based on the principles of pharmaceutical law (Fig. 2).

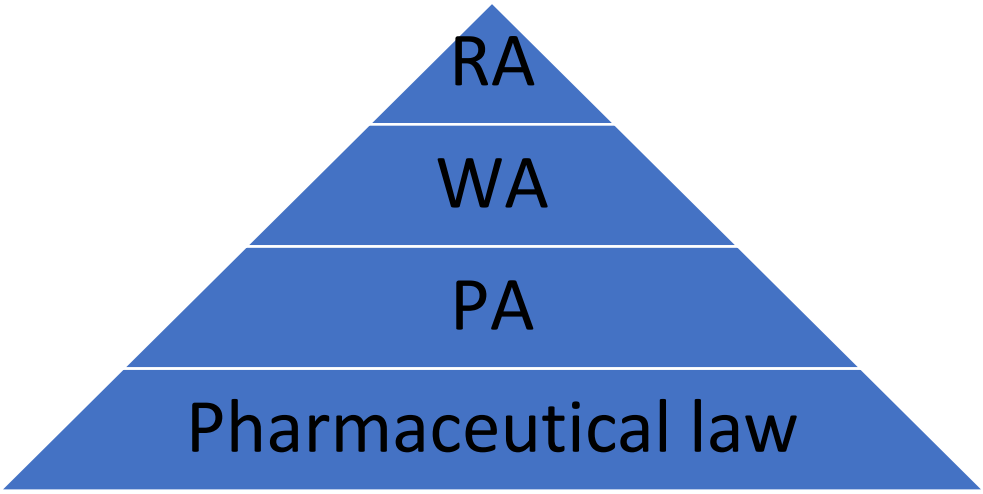

Fig. 1. Components for system of safety management of circulation of drugs.
Note: PA – Production activity
WA – Wholesale activity
RA – Retail activity

Today the system of safety management of circulation of drugs includes the following:

- ✓ *group A* – according to territorial characteristics;
- ✓ *group B* – by sources of purchase of drugs;
- ✓ *group C* – by the volume of the assortment of medicines.

Each group, in turn, is divided into appropriate subgroups. Group A includes national, regional, and local drug distributors. Group B includes primary and secondary drug distributors. In group C there are drug distributors who work exclusively on the distribution of exclusive (limited group) drugs (Fig. 3).

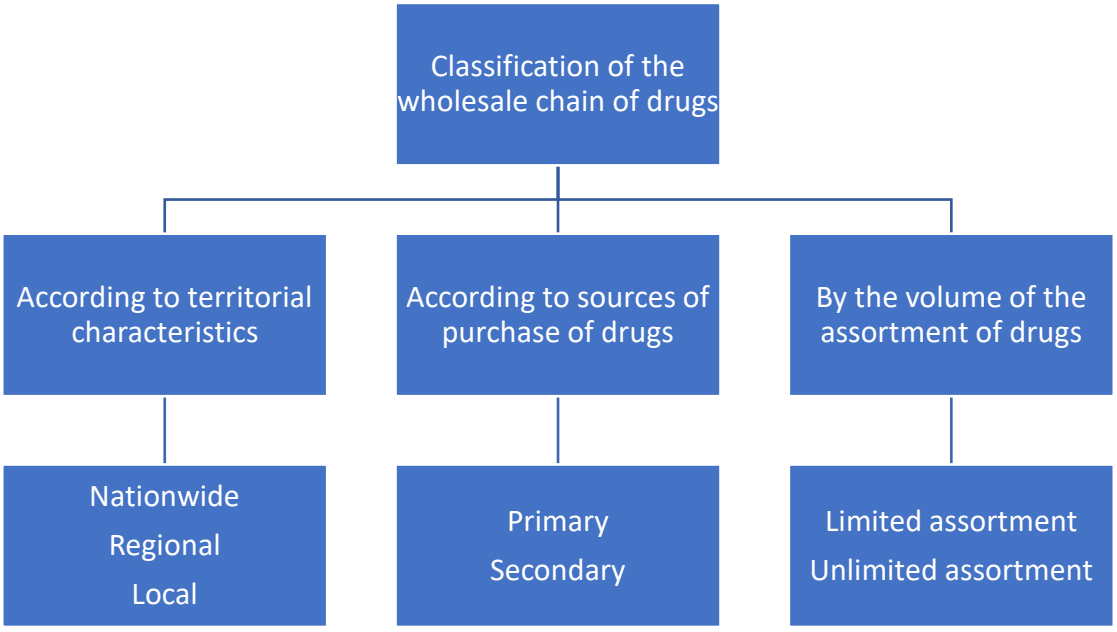

Fig. 2. System of safety management of circulation of drugs.

The author systematized unsolved issues in the drug circulation safety management system. Including:

- ☑ risks of drug circulation at the level of production, wholesale and retail activities,
- ☑ imperfection of legislative and regulatory documents
- ☑ personnel shortage

- ☑ insufficient work experience of responsible persons in market conditions
- ☑ lack of experience in managing the drug circulation safety system that is adapted to market conditions and meets the requirements of GxP
- ☑ lack of a comprehensive approach at all stages of drug circulation.

The effectiveness of drug safety management depends on the implementation of the following regulatory procedures:

- circulation of the most economically available, effective, safe and high-quality medicines in accordance with the morbidity of the population;
- quantitative calculation of the need for medicines according to the conditions of each region;
- fulfilling the requirements of GxP good practices;
- quality control of medicines;
- drug safety.

Inadequate and irregular government funding also affects the safety, quality, and availability of medicines. If production and wholesale activities do not guarantee timely payment of contracts, this invariably leads to drug shortages and inefficiency of the system as a whole. Manufacturers and suppliers often refuse to provide drugs on credit. The relative financial independence of the health care system in matters of drug circulation security gives it the ability to respond flexibly.

Decentralization of production, wholesale and retail activities is of particular importance. With small volumes of production and purchases, drug prices, as a rule, increase significantly. There is practically no mechanism for monitoring compliance with quality, safety, and availability, which leads to a shortage of necessary drugs, irrational use of the already limited regional budget.

The lack of objective information about the safety of drugs leads to the fact that low-quality drugs can be in circulation at inflated prices, and it also creates an opportunity for various groups of people to influence the processes of purchasing drugs for personal interests.

Lack of highly qualified specialists in the region. The lack of qualified personnel in the safety management system of drug circulation negates even the presence of other necessary conditions. But low wages and lack of prospects for professional growth do not attract highly qualified specialists.

Based on the results of the conducted research, the main functions of the safety management of drug circulation are formulated:

1. *Circulation of economically available, effective, safe and high-quality drugs in adequate quantities.* To fulfill this task, it is necessary to develop an algorithm for the procedure for calculating the required number of drugs determined for production, wholesale, and retail activities in order to ensure their uninterrupted supply.
2. *Selection of reliable manufacturers, suppliers and distributors of drugs.* It is necessary to pre-select reliable suppliers of high-quality and safe products. At the same time, programs to ensure the safety, quality, efficiency, and availability of drugs must be clearly implemented, which includes monitoring the circulation, testing, and auditing.
3. *Adherence to the requirements of good GxP practices.* The management of the safety of drug circulation includes the timely delivery of the necessary number of drugs, as well as the rational distribution of drugs to those medical institutions where they are needed.
4. *The functioning of a stable management system for the safety of circulation of drugs with minimum total costs* for the performance of the tasks is achieved with minimum total costs.

   To do this, it is suggested to take into account the following factors:

   a) the actual purchase price of medicines for this region;

   b) hidden costs due to low quality of drugs, unsatisfactory work of manufacturers, suppliers, distributors or short storage period;

   c) expenses for the safety of drug circulation at various stages;

   d) prevention of risks in the safety management of drug circulation.

Need to note that Ukraine and the EU are discussing one of several urgent issues for the safety of drugs in the work of the pharmaceutical business - the return of the requirement to provide a GMP opinion by international manufacturers during state quality control when importing drugs [54].

Since the beginning of the full-scale invasion, the requirement to provide a GMP opinion when importing drugs has been suspended. Such a step on the part of state authorities was made for a business meeting. The pharmaceutical business urgently set up new logistics chains to continue the uninterrupted supply of medicines to Ukrainian patients during the war. Taking into account the increasing challenges for the state and the pharmaceutical business, the general security situation in the country and the objectively imperfect GMP confirmation procedure, the requirement to provide a GMP opinion when importing drugs could lead to a forced reduction in the volume of their supply to Ukraine.

Against the background of the return of the requirement to provide a GMP opinion when importing drugs into Ukraine from April 17, 2024, despite the lack of changes in the security situation in the country, there was a need for simultaneous changes to the GMP confirmation procedure. Such changes, namely the improvement of the procedure in terms of extending the validity period of GMP conclusions on the basis of valid original GMP certificates issued by the authorities of the EU countries, Great Britain and the USA, were supposed to provide conditions for the unhindered passage of the procedure by manufacturers and, accordingly, prevent problems during importation.

On April 3, 2024, the draft order was published on the website of the Ministry of Health of Ukraine. A mechanism for extending the validity period of GMP conclusions has been established. The requirement to provide a mandatory GMP opinion when importing drugs came into force almost at the same time – on April 17, 2024. Thus, a situation arose when the order of the Ministry of Health, which was supposed to ensure the requirements adopted by manufacturers, still did not come into force, and new rules regarding the import of drugs has already begun to operate.

Unfortunately, this situation has already led to problems with the import of medicines. In the near future, it will be reflected in the level of availability of medicines for patients.

Pharmaceutical companies are very concerned that there are different interpretations of the future provisions of the order of the Ministry of Health by the experts of the State Medical Service.

The attention of representatives of the state authorities of Ukraine is focused on the existence of a need for a thorough review of the entire system of prevention of falsification of drugs, control of their quality, and safety in Ukraine. Requires amendments and additions to the new edition of the Law of Ukraine "On Medicinal Products" [55].

Conclusion. A study of pharmaceutical management in the field of drug safety was conducted. The principles of pharmaceutical law, on which the safety of medicines is based, are described. EMA procedures for drug pharmacovigilance were analyzed. Components for system of safety management of circulation of drugs were proposed. The main functions of safety management of drug circulation have been elaborated. Ways of improving the circulation of drugs to guarantee safety, quality, efficiency, and availability were given.

Conflict of interest. The author confirms the authorship of this work and have approved it for publication. The author also certify that the obtained data and research were conducted in compliance with the requirements of moral and ethical principles based on the medical and pharmaceutical law, and in the absence of any commercial or financial relationships that could be interpreted as a conflict or potential conflict of interest.

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