HISTORICAL STAGES OF THE DEVELOPMENT THE COMPLEX OF GOOD PRACTICES IN UKRAINE

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Modern trends of the development pharmaceutical sector of the healthcare system in Ukraine require the introduction of international standards for pharmaceutical provision of the population - a set of good practices (Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), Good Pharmacy Practice (GPP) and etc.) [1]. The joint operation of these practices creates objective prerequisites for providing effective pharmaceutical assistance to the population in according to goals of the National Drug Policy.

The Law of Ukraine dated March 18, 2004 No. 1629-IV approved the National Program of Adaptation of Ukrainian Legislation to the Law of the European Union (EU) [2]. The purpose of harmonization is to achieve compliance of Ukraine's legal system with criteria for states that intend to enter the EU. In this regard, harmonization of domestic pharmaceutical legislation with the requirements of the EU is necessary through the introduction of a system of good practices. The said system should become a guarantor for ensuring the quality of the drug at all stages of their circulation - from production to rational use.

GMP standards (2001) became the first in the development and implementation of domestic pharmaceutical practice. To ensure the competitiveness of pharmaceutical products must comply international quality requirements. Further national standards of GMP repeatedly revised as a result of updating the main text of

GMP EU. From January 1, 2009, all Ukrainian companies had to switch to GMP standards. This became a licensed requirement for the production of drugs and led to a sharp reduction in the number of existing enterprises (from 151 to 111).

The introduction of individual elements GDP began with the adoption of the Ministry of Health of Ukraine of 30.10.2001 No. 436 concerning introduction the institute of authorized persons, the notion of incoming quality control of drugs, quarantine zone, etc. In 2002 and 2008 there were Guidelines "Medicines. Good practice of distribution", with the consistent introduction of changes to the Licensing conditions for the conduct of wholesale business of drugs. Since 2011, in the specified Licensing Terms, there has been a requirement for required compliance with the GDP, as well as Guideline about Good Storage Practices (GSP).

Order of the Ministry of Health of Ukraine of 16.02.2009 No. 95 "On approval of documents on quality assurance of medicines" were approved and enacted guidelines of GMP, GDP, GSP, GLP, GCP. Until now, there are problems with the real introduction into the practical activities of GLP and GCP standards due to the lack of harmonized with the European practice of control procedures for checking the quality of the research for compliance with requirements.

That is, it can be argued that today in Ukraine fully implemented GMP, GDP and GSP. The objective preconditions have been formed for the implementation of GLP and GCP standards with the use of an effective system for monitoring compliance with these requirements (the need to ensure the proper level of pre-clinical and clinical research, guarantee the effectiveness, safety and quality of drugs for the recognition of results in other countries, the obligation to study the bioequivalence of drugs) [3].

Regarding the development of the GPP standard, for the first time in January 2013, the official website of the Ministry of Health of Ukraine published a draft order "On Approval of the Guideline: Medicines. Good Pharmacy Practice" [4]. The basis for the development of industry requirements GPP has become a common guideline of the World Health Organization and the International Pharmaceutical Federation "Good Pharmacy Practice: Quality standards of pharmacy services" (2011) [5].

Several meetings with the participation of the leadership of the State Service of Ukraine for drug addiction, representatives of the retail chain, public organizations were held on this issue, and numerous suggestions and observations were proposed with the requirement of significant refinement of the specified project. In particular, it was recommended to introduce the guideline as a recommendation act and to provide for a sufficient transitional period. Soon to ensure the development of standards GPP order was issued the Ministry of Health of Ukraine of 30.05.2013 No. 455 "On approval of instruction "Good Pharmacy Practice: Quality standards of pharmacy services" [6]. The basic information source for the development of GPP standards was the above-mentioned guideline (2011).

So, today in Ukraine, good practices (GSP, GLP, GMP, GDP, GSP and GPP) are developing disproportionately and fragmentarily. The standardization of the stages of drug production and distribution is preferred. Today, the complex of good practice is not implemented in practice GPP pharmacies. Only the functioning of an integral system of good practices can be a guarantee of quality assurance of the drug at all stages of the life cycle.

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