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S.P. Mytych,
Chief of the Department for the Investigation
of Crimes in the Field of Offices of the Investigation
Department of the Holosiivsky Police Department of The
Main Directorate of the National Police in Kyiv, Kyiv

FEATURES OF THE STATE REGULATION AND CONTROL IN MANUFACTURING AND TURNOVER OF REMEDIES IN UKRAINE

Paper is devoted to the consideration of features of state regulation and control in the field of production and circulation of medicines in Ukraine. It has been determined that in Ukraine in the years of independence, various models of state regulation of the sphere of manufacturing and circulation of medicines have been tested on the basis of numerous reforms of state bodies that regulate and control the activities of business entities that manufacture and distribute medicinal products in Ukraine. In this connection, it has been proved that the constant transformation of the state regulatory body in the sphere of production and circulation of medicines has negatively affected the regulatory environment, which necessitates the development of appropriate proposals for improving the work of these state bodies.

As a result, paper deals with the system of state bodies that carry out state regulation and control of the sphere of production, quality control and sale of medicinal products, with the statement of tasks, functions and powers of these state bodies. This allowed to characterize the model of state regulation of the sphere of manufacture and circulation of medicinal products as a multiple (multilevel) state, implemented in Ukraine, because it includes three institutions: the Ministry of Health (MoH), the State Service of Ukraine for Drugs and Drug Control (State Committee for Drugs and Medical Services) and the State Expert Center of the Ministry of Health of Ukraine. As a result, paper substantiates the conclusion that the process of managing and coordinating the work of state regulatory bodies in the field of production and circulation of medicinal products is more complex in the multiple model, there are duplication of functions of these bodies, conflicts of interests, which, in turn, increases the potential for corruption. Possible corruption risks in the activity of the State Service of Civil Service are represented. The necessity of solving the problem of the lack of a clear, unambiguous and logical delineation of the areas of responsibility of state regulators in the field of production and circulation of medicines is stressed.

Due to the generalization and systematization of all shortcomings of the state regulation and control of the sphere of production and circulation of medicinal products, it was emphasized that the presence of a significant number of state bodies involved in state regulation and control of the sphere of manufacture and circulation of medicinal products as well as the allocation of their significant powers and normative and regulatory functions in the activities has not led to the high quality of such regulation and control.

Finally, the paper substantiates the conclusion on the appropriateness of combining all functions of state regulation and control of the sphere of manufacture and circulation of medicinal products in a single state regulatory body – the State Service of Ukraine for Drugs and Drug Control. In addition, the paper proposes to eliminate the artificial division of the licensing function for the registration (re-registration) of medicines and medical products between two state bodies, namely the transfer of authority to make final decisions on the registration of medicinal products in the State Medical Service, which already carries out the registration of medical products.

Keywords: drugs, government regulation and control, import, wholesale and retail trade in drugs, pharmaceutical market, regulatory activity, State Register of Medicinal Products, active pharmaceutical ingredients, pharmacovigilance, medical products.

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