UDC 338.4

Roman Simonov

FEATURES OF REGULATORY ARCHITECTURE OF GLOBAL PHARMACEUTICAL BUSINESS

The specific features of the pharmaceutical market along with monopolistic competition inherent in the pharmaceutical business, the high dynamics of its transnationalization, the presence of a large number of trade names of drugs in the market, the increase in the number of reproduced and counterfeited drugs, make the scope of drug trafficking and require the proper regulation norms at national and supranational levels that include appropriate standards of quality control, efficiency and safety in accordance with current international practice in this area. Thus, in recent decades, two institutional levels, national and supranational, have been clearly distinguished in the overall regulatory framework of the global pharmaceutical market. They differ in both the spectrum of functional powers of regulators and institutes, and the scope of legal relationships arising in the global pharmaceutical industry, and the dominant mechanisms and levers of its institutionalization. The main purpose of this work is to identify the modern features of the regulatory architecture of the global pharmaceutical market in the context of turbulent development of world economic processes.

Multilevel representation and diversified activities of regulatory institutes at national and supranational levels in recent decades have shaped the regulatory framework of the global pharmaceutical market. They actively work in the field of regulation of legal relations in the sphere of market circulation of medicines; their registration, licensing, storage and transportation; standardization of quality control systems and regulation of drug prices; stimulation of R&D in the pharmaceutical sector; maintaining a system of good practices for the development of medicinal products, their clinical research, production, distribution and sales; protection of intellectual property rights, etc.

Optimization of the regulatory parameters of the market in terms of the ratio of protectionist and liberalization instruments and levers becomes a priority for each country. This requires greater coordination of efforts of different countries to address these issues in order to increase the access of the world population to high-quality, safe and affordable medicines while stimulating the innovation activity of pharmaceutical corporations.

Keywords: *pharmaceutical market; EU transnationalization; innovation; pharmaceutical business.*

References

1. Aitian, T. V. (2018). Sravnenie sistem lekarstvennogo obespecheniia v Evrope i SSHA uroki dlia Rossii [Comparison of drug supply systems in Europe and the USA: lessons for Russia]. *Regionalnaia ekonomika teoriia i praktika – Regional Economics: Theory and Practice*, 4, 624–639 [in Russian].

2. Havrylenko, N. I., Kulych Ya. V. (2015). Tendentsii ta perspektyvy rozvytku farmatsevtychnoho rynku [Trends and prospects of pharmaceutical market development]. Problemy i perspektyvy ekonomiky ta upravlinnia – Problems and prospects of economics and management, 1, 69–76 [in Ukrainian].

3. *Deiatelnost reguliatornykh organov v sfere obrashcheniia LS ikh funktsii i napravleniia raboty Analiz osnovnykh elementov gosudarstvennoi sistemy obespecheniia kachestva lekarstvennykh sredstv [The activities of regulatory authorities in the field of drug circulation - their functions and areas of work. Analysis of the main elements of the state system for ensuring the quality of medicines]*. Retrieved from http://quality.nuph.edu.ua/wp-content/uploads/2017/01/%D0%A2%D0%B5%D0%BC%D0%B0-3-%D0%9D%D0%A4%D0%9F-%D1%80%D1%83%D1%81%D1%81.pdf.

4. Zasimova, L. S. (2008). Gosudarstvennoe regulirovanie i stimuly k innovatsiiam na rossiiskom farmatsevticheskom rynke [State regulation and incentives for innovation in the Russian pharmaceutical market]. *Innovatsii – Innovation*, 11 (121), 79–82 [in Russian].

5. Ilchuk, V. P., Harbuz, T. V. (2018). Formuvannia ta rozvytok medychnoho strakhuvannia v ukraini ta sviti [Formation and development of health insurance in Ukraine and the world]. *Problemy i perspektyvy ekonomiky ta upravlinnia – Problems and prospects of economics and management*, 1, 112–118 [in Ukrainian].

6. Klunko, N. S., Reta, M. V. (2011). Mirovoi opyt tsenoobrazovaniia na rynke lekarstvennykh sredstv i vozmozhnosti ego ispolzovaniia v Rossii [World experience of pricing in the pharmaceutical market and the possibility of its use in Russia]. *Ekonomika promislovosti – Economics of industry*, 2-3, 257–263 [in Russian].

7. Rosliakova, E. A. (2015). Ekonomicheskii analiz sostoianiia i razvitiia mirovoi farmatsevticheskoi otrasli v usloviiakh protsessa globalizatsii [Economic analysis of the state and development of the global pharmaceutical industry in the context of the globalization process]. *Vestnik Omskogo universiteta. «Seriia Ekonomika» – Bulletin of Omsk University. Series «Economics»*, 1, 42–47 [in Russian].

8. Khoseva, E. N., Morozova, T. E. (2013). Organizatsiia kontrolia kachestva effektivnosti i bezopasnosti lekarstvennykh sredstv na gosudarstvennom urovne za rubezhom i v Rossii [Organization of quality control, efficacy and safety of medicines at the state level abroad and in Russia]. *Kachestvennaia klinicheskaia praktika – Good clinical practice*, 2, 53–58 [in Russian].

9. Danzon, P. M. Y. Wang (2003). The impact of price regulation on the launch delay of new drug – evidence from twenty-five major markets in the 1990s. *NBER Working Paper* 9874.

10. Europe's partnership for health. IMI. Retrieved from https://www.imi.europa.eu.
11. Golec, H. J. A. John Vernon (2006). European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending. *NBER Working Paper* 12676.
12. Lanjouw, O. J. (2005). Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry. *NBER Working Paper* 11321.
13. McCalman, P. (2004). International Diffusion and Intellectual Property Rights: An Empirical Analysis. Journal of International Economics. Department of Economics. U. C. Santa Cruz.
14. Support to research. EMA. Retrieved from https://www.ema.europa.eu/en/about-us/support-research.
15. Vernon, J. A. (2003). Drug Research and Price Controls. *Regulation Magazine*, 3, 22-25.