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URGENT ISSUES OF ANTITRUST REGULATIONS IN PHARMACEUTICAL INDUSTRY IN PANDEMIC

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Abstract

The article is devoted to the research of prevention and suppression of illegal monopolistic activity of pharmaceutical companies. The authors discuss the issues of unfair business practice, making anti-competitive agreements, price control. There has been studied the new experience of different countries to bring out better practices of anti-trust statutory application during the spread of coronavirus and to find gaps and conflict of regulations which can have unfavorable impact on pharmaceutical industry in the future. Legal mechanisms have been proposed which will allow to provide sustainable functioning of pharmaceutical industry in different countries. The reasons of anti-competitive conduct of pharmaceutical companies have been analyzed. The criteria of possible exemptions from anti-trust legislation have been distinguished; their introduction will allow to provide development of competitive interaction in pandemic. The approach is aimed at determining the limits of the manifestation of the market power of companies and identifying effective ways of administrative and legal influence on the economic processes in the pharmaceutical industry. Issues of anti-trust regulation of pharmacy are being described like the ones keeping the balance between public and private interests. Some measures have been set to protect intellectual rights of pharmaceutical companies when it is necessary to apply the mechanism of compulsory licensing within the framework of anti-trust regulation. However, the key objective of development of competition and suppression of monopolistic activity on the pharmaceutical market is to protect the rights and interests of consumers.

Keywords: Antitrust legislation, pharmaceutical market, licensing, competition, agreement

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1. Introduction

Nowadays the issue of antitrust regulation of pharmaceutical companies is extremely urgent due to appropriate and full provision of population with medications. At present monopolistic activity and unfair business practice can influence the final dates of the coronavirus pandemic because of the lack of access to necessary treatment.

2. Problem Statement

The process of development of effective antitrust regulations of pharmacy is connected with a number of statements which should be considered. Pharmacy is one of the high-tech industries which need a wide range of investment capital to develop new medications. Thus, the activity of the companies, which is considered to be violating legislation, can result in objective financial losses. The situation becomes worse because pharmacy is one of the high-tech sectors of economy and it requires significant amount of investment to develop new medicines. Moreover, it is vital to preserve the balance between private and public interests as well as to account of the transborder character of pharmacy and to unite the work of antitrust departments of different states.

3. Research Questions

There are different norms connected with prevention, discovery and suppression of illegal monopolistic activity and unfair business practice, formulated in different level regulations. The most significant ones are the laws, defining the elements of offences, which can be committed by the companies within the sphere of drug circulation and by-laws, which define the order of activity of the agencies handling antitrust law breaches. However, the by-laws must comply with realities of development of pharmaceutical market, leading to the necessity of working out the offers to improve them.

4. Purpose of the Study

The pseurp of the article is to analyze the regulations, stating the measures of antitrust procedures of pharmacy in different countries, to find out crucial issues influencing the development of industry in pandemic. Such measures will eliminate the difficulties and support the provision of rights and best interests of members of economic relations as well as improvement of health services. According to the survey which was held from 15th February to 20th of March 2021 by the SSLA Center of Socio-Political Research together with the Institute of Public Health, Health Servises and Humanetarian Issues of Medicine of Razumovskii SSMU, 6,4 % of respondents consider it to be good, 59,6 % think it is satisfactory and 34 % are not satisfied with it.

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5. Research Methods

We applied a number of methods of academic research. General dialectic method was used to scrutinize key elements of commercial practices from the point of view of their flexibility in statutory regulation which helps to distinguish special features of their applicability in anti-trust legislation. Formal and logical methods of scientific knowledge (analysis, synthesis, abstraction) allowed analyzing statutory instruments in accordance with the means of future improvement of administrative vehicles of counteraction to breaches of anti-trust legislation. The application of comparative legal method resulted in specifying anti-trust regulation of relations, which are typical to pharmaceutical industry in pandemic in the Russian Federation and in foreign countries.

6. Findings

One of the areas of anti-trust regulation of pharmaceutical industry is price control. It should be based on the fact that increase of drug prices may reflect the new economic difficulties resulting in the growth of the costs of academic research. However, price control may not be connected directly with the need of conducting the research, but it may reflect the intention of economic entities to make a profit illegally, using the situation of the economic crises. In the Russian Federation, there is the mechanism of price survey on vital goods including medicines and the government of the Russian Federation is authorized to fix the terminal level of prices on medicines within the term of 90 days. It is stipulated that in emergency situations or if there is the threat of spreading of dangerous disease, the Government of the Russian Federation can fix cost price ceiling and surcharges for drugs that are not included in the list of vital and essential.

This mechanism may be more preferable to the direct influence of the competent authorities, but it requires taking into account the current situation in terms of the necessary goals of state regulation and maintaining a balance of interests. The basis of applying must be enshrined in legislation. Within the Russian Federation such basis can be considered as existing threat of spreading of the disease, which is extremely dangerous to the population and results in substantial growth of prices. It is allowed to limit the price ceiling in case of its unreasonable increase of more than 30 %. In 2020, re-registration of medication prices was done for the first time and the medication prices reduced 25 % on average. Budget savings were about 30 milliard rubles due to the decrease of governmental costs to provide the patients eligible for benefits with free medicines (FAS Russia Prevented Price Increase …). The possibility to introduce cost price ceiling requires to define the list of medicines, including their name and classification, as well as the proposed maximum size of the manufacturer's selling price, wholesale and retail allowances to the initial price.

Another area of anti-trust regulation is counteraction to the anticompetitive activity in advertising sphere. A typical case is when the advertising material contains inaccurate information about the qualities of the drug (FAS Fired “Oticifarm” for …). Presently the global practice demonstrates effectiveness of the preventive measures which can be applied when something was mixed up or when the customers were disorientated about the effects of the drugs and methods of treatment of coronavirus infection (COVID-19 and Antitrust Law: Avoiding …).

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Furthermore, it is necessary to prevent and suppress agreements and associations which limit competition. It is necessary to stop the illegal practices aimed at reaching an agreement by violating anti-cartel legislation, as well as leading to the establishment and maintenance of the cost of medicines, restricting competition in the pharmaceutical market. However, the agreements of pharmaceutical companies do not always reveal breaches of legislation. Since their conclusion can be subject to necessity of cooperation to overcome economic crisis, statutory regulation of different countries can include cases of considering the agreements possible. In particular, at the pharmaceutical market there are both major players who can greatly influence the circulation of goods as well as business entities of small and medium-sized enterprises. Their agreements can be the means of competition with large companies. Therefore, it is reasonable to consider the criteria for admissibility of such agreements. If the agreements bring to increase and maintenance of prices, rigging of the market, limitation of competition, they should be banned. However, it seems to be possible to enshrine in national legislation of states appropriate seizures, which help small and medium businesses, including pharmaceutical companies, to make agreements concerning joint participation in state, municipal and private purchasing. The framework of agreements can be the aim of their creation, total revenues, and market share. Companies should have the right to submit a claim of auditing draft agreement. Coordination of activity should not bring to limitation of competition and unfavorable consequences for the customers. It should be noted that its length must be limited in accordance with reasonableness and feasibility (CMA approach to business cooperation …). The necessity of taking into consideration societal concerns can be enshrined in statutory regulations or become the approach to the application of legal norms by competent subjects. It is obligatory to coordinate formation of associations with national departments or supranational bodies, if their activity has transborder character. They should provide the possibility of free membership. It is also necessary to take into account the specifics of the market. The same company is usually a manufacturer of a wide range of medicines, so the evaluation of agreements should take into account the need to develop, manufacture or supply specific medicines.

Within the framework of antitrust regulation, considerations in the sphere of consumers should be based on the fact that fair competition of pharmaceutical companies is beneficial for the society, because it leads to increase of offer of medicines, their price accessibility and improvement of the properties of drugs, which is connected directly with the efficiency of treatment. Thus, it is important to control the activity of the economic entities which can potentially limit competition within the appropriate markets. The example can be the decision of the USA Federal Trade Commission (FTC) concerning amalgamation of pharmaceutical companies Pfizer and Mylan (FTC Approves Final Order…). Pfizer planned amalgamation of the subsidiary Upjohn with Mylan. According to FTC this decision can limit competition of ten medications in the market. FTC demands asset disposition and preliminary agreement of the bargains. Particular importance is given to creation of supranational bodies coordinating the work of departments while giving assessment to bargains of amalgamation. In particular, FTC initiated creation of follow-up group to fight against monopolies in pharmaceutical industry. The FTC-initiated working group will include the Canadian Competition Bureau, the European Commission's Directorate General for Competition, the United Kingdom's Competition and Markets Authority, the US Department of Justice's Competition Division, and state attorneys general (FTC Announces Multilateral Working Group…).

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One more measure of anti-trust impact is coercion to concluding licensing agreement. This problem is becoming relevant in the pharmaceutical industry, since the patent holder has the opportunity to use the patent protection mechanism and act contrary to the existing principles of antitrust regulation and the interests of consumers. Such facts as withdrawal of goods from circulation when there is demand and maintaining a monopolistically high price can be considered the abuse of a dominant position. The existence of a mechanism of so-called "compulsory licensing" in the context of a pandemic provides a guarantee to produce pharmaceutical products available to the population when it is necessary. At the same time, the mechanism of compulsory licensing enshrined in national legislation, even if it is not used, can serve as a preventive measure aimed at averting abuse of patent rights of manufacturers of pharmacological medicines.

There take place both judicial and administrative (government use) (Dictionary of WTO Terms…) means of issuing a “forced license”. There is an opinion, according to which application of this vehicle is able to reduce investment activity (Bird & Cahoy, 2008). It is possible to solve the problem to have compulsory preliminary negotiations concerning the reduction of drug price or non-admission of ant-competitive practices.

As part of the consideration of the shortcomings of the compulsory license mechanism, it should be noted that there are no guarantees that the generic pharmaceutical product will be of the same quality as the drug produced by the patent holder. However, it is necessary to note that this risk is closely connected with the issue of creating an effective system of quality control of medicines within the framework of national legal regulation and does not concern the application of a compulsory license within the framework of antitrust regulation. When implementing the release of medicines into circulation, it is possible to use special means aimed at ensuring the proper quality of products, such as the prequalification certificate of the World Health Organization or the mechanisms provided for in the framework of the legislative regulation of a particular state. In particular, in the United States this mechanism is the certification of the US Food and Drug Administration (FDA), in the European Union it is the European Medicines Agency (EMA).

Procurement of drugs should be ensured within a certain quota provided by the budget. The budget costs for the payment of compensation to the copyright holder of the original drug should be carried out in accordance with the legislation of a particular state. The amount of payments should depend on the identified violations of competition law. It follows from this that in the event of a serious violation of national antitrust laws, a proportional reduction in the amount of compensation is allowed.

It should be taken into account that this problem requires ensuring a balance of private and public interests, and therefore, it is necessary to clearly establish the grounds for applying a compulsory license. It is the violation of antitrust legislation in various legal systems that is one of such grounds. It can be applied in case of breach of anti-trust legislation according to the experience of the USA (Non-voluntary use of …), PRC (Implementing Regulations of …), Germany (Decision of Antitrust Senate…), Brazil (Law 9.279/1996).

The practice of some countries having statutory recognition of the possibility to enforce anti-trust legislation is based on the provision of Paris Convention on protection of industrial property (Paris Convention for the Protection …). Under Section A, Article 5, its members have the right to apply the

vehicle to prevent abuse of patent right owners. According to WTO view statutory regulation applied to "forced licensing" must be very precise (Implementation of paragraph 6 of …). While passing laws in "forced licensing" it is necessary to provide uniform approach of different countries, as it is specially indicated in EAEU (Urgent Issues of Competition Protection …, n.d.). In our opinion, application of this vehicle cannot be connected with the impulse to decrease budget spending or sale of import substitution but it should be implemented only in emergent situations, which presuppose inaccessibility of the drug for the population in pandemic.

License transfer must take place only if there is evidence that it is impossible to obtain a license in the usual way. At the same time, the legislative wording of extreme necessity should be of particular importance. The essence of extreme necessity implies the existence of real danger that threatens the rights and legitimate interests of the individual, society and the state. The real danger of compulsory licensing is caused by refusal of the patent owner to manufacture or supply a pharmaceutical product, or by abuse of a dominant position. At the same time, the mechanism of compulsory licensing should imply the end-production of a generic drug in case of elimination of the conditions of extreme necessity.

7. Conclusion

To conclude with, it is necessary to note that nowadays within the framework of anti-trust regulation of pharmaceutical industry it is urgent to solve such problems as establishment of limits to prime cost on medications, counteraction to antitrust activity of pharmaceutical companies, which can be manifested in unreliable information about the medications, concluding agreements limiting competition, initiating mergers, which will help to decrease the level of competition and influence the welfare of the customers. It is necessary to decide how to apply the vehicle of "forced licensing" of the medications. Such a vehicle must be applied only in emergency situations and under special conditions. Finally, application of the stated above measures will lead to improvement of the health sphere in general.

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