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EXTERNAL REFERENCE PRICING: THE MARKET OF MEDICINES IN THE REPUBLIC OF BELARUS

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Abstract

The article reflects the results of the study of the medicines market, trends in its development. The authors substantiate the main reasons, possibilities and problems of the introduction of the external reference pricing as a way to determine the marginal selling prices for medicines. Proposed approaches and the mechanism for forming a “basket” of reference countries, inclusion criteria and evaluation indicators, methods and ways of calculating the limits of price caps were implemented in the relevant regulations adopted in the republic in the regulation of registration and pricing mechanisms for cancer and cardiovascular medicines. The set of measures of state regulation of the medicines market, which is considered in the article, will have a significant effect in reducing the level of costs by health organizations and accordingly the budgetary expenditures, to ensure keeping the inflation rate in the control parameters, will ensure a balance of interests of the state, the real sector of the economy and the population in the field of medical prevention and treatment of diseases. In assessing the effectiveness and effectiveness of the developed mechanism, the problem field of application and specific features of the price regulation of the drug market in the Republic of Belarus were identified, as well as the directions were developed to solve the identified problems and to reduce the risk of the project realization. Positive results of the "pilot project" will allow to extend this mechanism to the regulation of the entire market of medicines or to modify individual elements.

Keywords: Economic interests medicines, external reference pricing, government regulation, selling process.

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1. Introduction

The existence of intellectual property rights to new medicines provides a monopoly position to the manufacturer, allowing to set high prices. This reduces the availability of medicines and increases the financial burden on the health system, which is significant for low-income countries. There are huge differences in the cost of medicines per person (from $7.61. U.S. in low-income countries to $431.6. U.S. in high-level countries) (Lu, Hernandez, Abegunde, & Edejer, 2011).

The World Health Organization has developed recommendations for market regulation in middle- and low-income countries. The expediency of the "cost-plus" method in setting prices; regulation of supply chain surcharges; promotion of generic medicines; use of reference prices is noted (World Health Organization, 2015). The most common combinations of reference pricing and limiting profits in the selling prices of pharmaceutical companies are most often used. In the Republic of Belarus until 2018 the regulation of the medicines prices was carried out by limiting the profitability of manufacturers and trade allowances. At the same time, there is a need to eliminate the emerging imbalances in the prices of medicines in the domestic and foreign markets, for which the mechanism of external reference pricing can be used.

2. Problem Statement

The process of developing and bringing a new medicine to market takes about 15 years. Only one or two medicines out of every 10,000 synthesized undergo all stages of research. Out of 20 new medicines registered annually, only 5-7 are first-in-class molecules (EFPIA, 2017). The development of medicines involves significant investment and development time but the creation of the most new medicines is interrupted at one of the stages. At the same time, only 40% of failures from the development of medicines are connected with the problems of their safety or effectiveness, more than 60% of failures is connected with financial or other reasons (Venkatachalam & Saberwal, 2012).

Rising prices of new drugs often do not correspond to their clinical benefits, it is determined by the following reasons : - innovations require the involvement of unique professionals and increased labor costs; - medicines development is risky because the development and market-taking process is lengthy; - many market participants are developing medicines on the venture capital terms and investors are looking forward to super-profits (Venkatachalam & Saberwal, 2012); - many developments do not bring a new product to market, which encourages pharmaceutical companies to look for reimbursement from rising prices for successful medicines (Ehtesham & Mansingh, 2008); - the availability of regulation of the medicines market increases the interest of companies in setting the initially high starting price, and marketing costs may exceed the cost of research and development (OECD, 2008). In these circumstances, low prices may lead to the problem that important medicines will not be sold in a particular country or will be sold with significant delays (Espin, Rovira, & De Labry, 2011). This problem is particularly relevant for developing countries where the markets are not so large.

In the Republic of Belarus, 73 organizations have a license to manufacture medicines, 80.9% of them - organizations of private ownership. The largest increase was observed in 2016, when the number of enterprises increased from 55 to 72. Significant growth rates are determined by the reasons: the high

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level of profitability of this type of economic activity; ageing the population; increased morbidity due to the adverse effects of man-made and environmental factors; low demand elasticity and high rates of growth in drug prices.

The high rate of increase in the prices is largely due to the increase in the supply of foreign medicines in the absence of price parity in national and related markets.

External reference pricing assumes that the national price is formed taking into account prices in the "basket" of reference countries. In recent years, the ERP mechanism has been widely used by governments not only by developed but also developing countries. At the same time, the synthesis of 25 published studies showed that its implementation was often ineffective (Rida & Ibrahim, 2017). Effective regulation must ensure that prices on medicines can be reduced or contained; the ability of the state to oversee the implementation of the price-regulation mechanism; transparency and predictability of the mechanism used for pharmaceutical market participants.

3. Research Questions

According to the European Medicine Pricing and Reimburation Information Network, external reference pricing refers to the use of medicines prices in one or more countries for the development standard or reference price to establish or negotiate the price of a product in a given country (Rémuzat et al., 2015). The parameters for implementing this mechanism vary from country to country with differences in the number of reference countries; criteria for selecting reference countries; pricing based on the prices of reference countries. Criteria for the selection of reference countries may include: 1) geographical neighborhood; 2) a similar level of economic development; 3) the tightness of economic ties; 4) similarity in the working conditions of national health systems. The following basic approaches may be used in determining prices based on the information about the reference country prices: 1. Price is defined as the average price from a selected basket of countries; 2. The price may not exceed the highest price among reference countries; 3. The price may not exceed the lowest price in reference countries; 4. others.

The advantages of ERP are the ease of comparisons, transparency and objectivity, low cost. However, there are also problems arising from the interest of pharmaceutical companies in finding ways to maximize their benefits under the conditions of various approaches in different countries. Thus, there is a need to develop a mechanism for price regulation of the medicine market on the basis of external reference pricing in the Republic of Belarus, assess the possible effectiveness of its use, identify potential problems arising from its application, as well as the search for solutions to overcome the problems identified.

4. Purpose of the Study

The aim of the work was to explore the possibilities and features of the implementation of an external reference pricing mechanism in the Republic of Belarus to ensure the interests of the state, producers and consumers. To achieve it, the following tasks were set and solved: the study of the price

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regulation in the medicine markets abroad, the order and criteria for determining reference countries, the development of a methodology for determining marginal selling prices for medicines.

5. Research Methods

To solve this problem, a systematic structured review of literature has been carried out to identify and characterize the use of ERP in some countries; formation of a field of possible ERP implementation problems for the national pharmaceutical market; - research of the market of medicines of the Republic of Belarus, the dynamics and the structure of marginal selling prices for medicines.

The systematic structured literature review was based on an analysis of EBSCO, SPRINGER, WHO databases. The analysis of the medicine market was carried out according to the data of the National Statistical Committee and materials of the Ministry of Health and the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus for 2014-2017. The research was supplemented by the results of the discussion of the identified problems during the meeting of the working group on the implementation of reference pricing, created under the Ministry of Antimonopoly Regulation and Trade of the Republic of Belarus.

6. Findings

ERP is the most widely used method of regulating prices on medicines in OECD countries (used in 24 out of 30 countries) (OECD, 2008). In the EU it is not used only in Sweden and the UK (Rémuzat et al., 2015). ERP is also used in lower-income countries, such as Brazil, Indonesia, Jordan, Colombia, Mexico, UAE, Russia, South Africa, Turkey (Nguyen, Knight, Roughead, & Mant, 2015; Rida, & Mohamed, 2017). In most EU countries (23 out of 31) ERP was used as the main systematic criterion in determining the price of a new drug, only Belgium, Germany, Spain, Italy, Poland and Finland used ERP as an auxiliary parameter (Rémuzat et al., 2015). The average number of countries used as a reference ranges from 4 to 8 (Espin, Rovira, & De Labry, 2011), while in the EU the number of reference countries ranges from 1 (Luxembourg) to 31 (Hungary and Poland) (Rémuzat et al., 2015). Some experts recommend listing up to 10 countries (Nguyen, Knight, Roughead, & Mant, 2015, p. 269). Being in one region as a justification for the choice of reference countries is used in more than 50% of cases (Espin, Rovira, & De Labry, 2011). Many developing countries include EU countries as a reference country, due to experience in the use of ERP, as well as the stability of health systems. In the Russian Federation the list of reference countries includes neighboring countries (Belarus, Kazakhstan, Ukraine), as well as 16 EU countries and Turkey. In the EU, the most frequently included reference countries are France (included in the number of reference countries 19 EU states), Great Britain and Germany (17), Austria, Spain and Slovakia (16) (Toumi, Rémuzat, Vataire, & Urbinati, 2013). The most commonly used method of determining the price is to determine the average value among the prices of countries selected as reference. In the EU 15 countries use the average price but 7 countries use the lowest price (e.g. Bulgaria, Hungary and Poland), and 7 countries use other methods of calculation (for example, the average of the three or four lowest prices of the countries in the basket was used in Greece, Slovakia and the Czech Republic).

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The research of the Belarusian pharmaceutical market revealed the following trends: the pharmaceutical industry has great potential growth(growth in the share of industrial production from 0.5% in 2011 to 1.2% in 2017); industrial pharmaceutical production is mainly represented by large and medium-sized organizations (85.5%); - high profitability of enterprises in this sector (return on capital 20% with an industrial average of 6.6%); - reducing the share of innovative products in the volume of shipped products (from 20.5% in 2014 to 11.5% in 2017) with an increase in the share of innovative products shipped to the domestic market (from 75.0% in 2014 to 84.0% in 2017);- low patent activity at national and international levels (11 per 1 million population, Switzerland -250, USA -70, Germany - 45); - exports of pharmaceutical industry products grew by 25.7% from 2014 to 2017, with exports dominated by shipments to CIS countries (95% in 2017); - import of pharmaceutical products decreased by 13.62% between 2014 and 2017. Imports are dominated by non-CIS countries, with EU countries accounting for more than 52%; - the average prices of medicines packaged for retail sale in 2017 when exporting to CIS countries amounted to 17,915 dollars US per tonne, when importing from non-CIS countries - $76,623 US, the ratio of import prices to export prices was 4.3 (in 2014, the ratio was 5.7); - increase in the share of health spending in total consumer spending from 3.6% in 2014 to 4.6% in 2017; including the cost of medicines and medical products from 2.5% to 3.3%.

Based on the results of the study of existing publications, as well as taking into account the peculiarities of the market of the Republic of Belarus, it is possible to form the following problematic field of implementation of the ERP mechanism: - limited access to price information in many countries;- price heterogeneity also makes it difficult to compare prices; - complexity of identifying the same medicine due to different commercial names, compositions, dosages and packaging sizes. This tactic is used by manufacturers to limit the capabilities of ERP (Espin, Rovira, & De Labry, 2011); - the stated prices may differ materially from the prices of real deals, including discounts provided by the manufacturer; - in the context of ERP, companies are interested in registering initially high prices in key markets in order to prevent price declines in other markets. Thus, one study notes that a reduction in German prices on medicine by 1 euro will lead to a reduction from 0.15 to 0.36 euros in the EU countries that use ERP (Stargardt & Schreyogg, 2006); - the introduction of ERP is characterized by the "path dependence" and prices are influenced by the choice of markets by companies that will be the first to be withdrawn. It is possible to delay or avoid the launch of new drugs in countries with lower prices, especially in smaller markets referred to by countries with larger markets (Espin, Rovira, & De Labry, 2011). For example, there is evidence that pharmaceutical companies systematically delayed filing files in Belgium to avoid the Belgian price (Rémuzat et al., 2015); - countries with lower prices have fewer affordable medicines and suffer longer delays in the launch of medicine. It has been reported that ERP may lead to companies refusing to supply the medicine to countries that use the lowest price from the reference basket (e.g. Bulgaria) (Rémuzat et al., 2015); the decline in prices in reference countries is not automatically accompanied by re-registration of prices in the national market but price increases in reference countries lead to re-registration of prices by producers.

It is also relevant for the Republic of Belarus: in some cases, the methods of state regulation are reduced due to the disappearance of low-price drugs, which Increases in the cost of acquiring them; conflict of interest in regulating the pharmaceutical market creates discriminatory conditions for different

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market participants; lack of transparency in registration procedures; long registration periods and periodic violations.

7. Conclusion

In the Republic of Belarus, medicines of foreign manufacturers hold a significant share in the structure of sales of medicines. At the same time, prices for foreign products supplied to Belarus may differ significantly from those in similar national markets. A widely used tool to address such imbalances is the external reference pricing As of February 22, 2019, prices for 31 INNs (international generic), or 83.8% of the total, including for the total number of manufacturers for medicines, were registered and included in the State Register of Limit Selling Prices for Medicines. treatment of cancer sat on 10 INNs (62.5%), for the treatment of cardiovascular diseases - 21 INNs (100%). Its use is relevant in areas where quality treatment of patients requires expensive medicines. Taking into account the high rates of morbidity, mortality rate and cost of treatment in the Republic of Belarus, the market of medicines for the treatment of cancer and cardiovascular diseases is considered as a pilot direction for the implementation of the ERP mechanism. Thus, the incidence of malignancies in the country increased by 11.2% between 2014 and 2017, and by 28.5% in cardiovascular diseases. At the same time, cancer and cardiovascular diseases caused more than 70% of deaths in 2017.

Taking into account the formed problem field of ERP implementation in the pilot project, the following solutions were implemented: - the ERP mechanism is used as one of the ways to set restrictions in the formation of the marginal selling price for medicines along with other regulatory tools; based on international experience, a wide list of reference countries (14 countries) has been formed; - in order to ensure comparability of conditions, the list includes countries with the following conditions: access to reliable price information in national markets; - similar market conditions - Armenia, Kazakhstan, Moldova, Russia, Kyrgyzstan; - geographically close countries (Eastern European countries) - Bulgaria, Hungary, Latvia, Lithuania, Poland, Romania, Czech Republic, Estonia; the list also includes a producing country; - Belarus is included in the list of reference countries only by Russia and Kazakhstan, which reduces the risk of delays, refusal of supply of medicines or attempts to purposefully inflate the price of manufacturers; - taking into account the complexity of identification of the same drug in other countries, the average cost of the active substance, rather than the commercial name of a particular medicine is calculated; - due to the low attractiveness of the markets of countries using minimum price values in ERP, the calculation of the price is based on the average arithmetic values of prices in the Republic of Belarus is used to ensure the availability of medicines reference countries.

As for February 22, 2019, prices for 31 INNs (international nonproprietary name) or 83.8% of the total, also including the treatment of cancer disease on 10 INNs (62.5%) and the treatment of cardiovascular diseases on 21 INNs (100 %) were registered and included in the State Register of Limit Selling Prices for Medicines. A slight increase (from 1.09% to 5.56%) in marginal selling prices compared to the actual selling price in fact was observed for 76 positions. For 101 positions the price decrease was from 0.26% to 64.59%, including: 39 positions - up to 20%; 46 - from 20 to 40%; 16 - from 40 to 64%. Prices were set at the actual level for 27 positions.

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In order to further develop the market of medicines and ensure effective regulatory impact, it is advisable to: - prohibit unfair practices of interaction between pharmaceutical companies and the medical community at the legislative level, as well as to develop requirements for prescribing medicines using INN; - improve the procedures for state registration of medicines; -change flexibly the mechanism of price regulation in case of changes in market conditions; - introduce the Institute of interchangeability of medicines; - improve legislation in the field of procurement of medicines; - regulate issues of intellectual property protection; develop competition between enterprises of the pharmaceutical industry.

References

EFPIA. (2017). The Pharmaceutical Industry in Figures. Retrieved from https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf

Ehtesham, S., & Mansingh, N. (2008). Conflicting interests in drug pricing: Innovation vs social need. *Current Science, 2,* 168-169. Retrieved from http://web.b.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=5&sid=75ffde02-03f5-4cc6-b378-2537554b3bf9%40pdc-v-sessmgr01

Espin, J., Rovira, J., & De Labry, A. O. (2011). WHO/HAI project on medicine prices and availability-Working paper 1: External reference pricing. Retrieved from http://www.haiweb.org/medicineprices/24072012/ ERPfinalMay2011.pdf

Lu, Y., Hernandez, P., Abegunde, D., & Edejer, T. (2011). *The World Medicines Situation 2011. Medicine Expenditures.* Geneva: World Health Organization. Retrieved from https://www.who.int/health-accounts/documentation/world_medicine_situation.pdf

Nguyen, T. A., Knight, R., Roughead, E. E., & Mant, A. (2015). Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries. *Health Policy and Planning, 30,* 267-280. https://doi.org/10.1093/heapol/czt10

OECD. (2008). Pharmaceutical Pricing Policies in a Global Market. Retrieved from https://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm

Rémuzat, C., Urbinati, D., Mzoughi, O., Hammi, E., Belgaied, W., & Mondher, T. (2015). Overview of external reference pricing systems in Europe. *Journal of Market Access & Health Policy, 3.* https://doi.org/10.3402/jmahp.v3.27675

Rida, N. M. A., & Ibrahim, M. I. M. (2017). Pricing strategies for pharmaceuticals in developing countries: what options do we have? *Generics and Biosimilars Initiative Journal, 6,* 4-6. https://doi.org/10.5639/gabij.2017.0601.002

Stargardt, T., & Schreyogg, J. (2006). Impact of cross-reference pricing on pharmaceutical prices: manufacturers' pricing strategies and price regulation. Applied *Health Economics and Health Policy, 5,* 235-247. https://doi.org/10.2165/00148365-200605040-00005.

Toumi, M., Rémuzat, C., Vataire, A. L., & Urbinati, D. (2013). External reference pricing of medicinal products: Simulation-based consideration for cross-country coordination. Retrieved from http://ec.europa.eu/ health/healthcare/docs

Venkatachalam, S., & Saberwal, G. (2012). Bio-business in brief: a case for new drugs at generic prices from India. *Current Science, 10,* 1375-1381. Retrieved from http://www.indiaenvironmentportal.org.in

World Health Organization. (2015). WHO guideline on country pharmaceutical pricing policies. Retrieved from https://apps.who.int/medicinedocs/documents/s21016en/s21016en.pdf