

## Multi-Factor Competitiveness Analysis of the Chemical and Pharmaceutical Industry in Eueu Member States

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### Abstract

This paper aims to assess the degree of influence of various factors on the competitiveness of the chemical and pharmaceutical industry in EAEU member states. The analysis results made it possible to determine the level of competitiveness in pharmaceutical markets in individual EAEU member states, and to assess how much their competitiveness is impacted by such factors as the ratio between pharmaceutical imports and exports in the external market; prices offered by pharmaceutical manufacturers and output of pharmaceutical products. Upon completion of the research, the authors defined main development trends for the unified pharmaceutical market in EAEU member states, including how to harmonize laws, elaborate measures of price regulation and introduce new pricing approaches towards pharmaceutical products. Moreover, to improve competitiveness and strengthen the export potential of the EAEU pharmaceutical industry it is necessary to tighten regulatory requirements for the production of safe and high-quality pharmaceuticals in accordance with the unified EAEU GMP standards.

**Keywords:** Chemical and pharmaceutical industry; EAEU; Pharmaceutical industry; Multi-factor analysis; Export potential; Price regulation; Competitiveness.



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### 1. Introduction

The Eurasian Economic Union (EAEU) is a relatively young economic integrated association, and the relevant establishment agreement took effect on January 1, 2015. EAEU member states are currently five countries (Russia, Kazakhstan, Belarus, Kyrgyzstan and Armenia), with a total population of over 180 million and aggregate GDP exceeding USD 1.5 trillion.

In accordance with the UNIDO classification, EAEU member states are currently at different stages of industrial development as Russia and Belarus are industrially developed countries with above-average manufacturing competitiveness indices, Kazakhstan is a developing industrial economy with manufacturing competitiveness measured as average, while Armenia and Kyrgyzstan are developing economies whose manufacturing competitiveness indices are below average and low, respectively (United Nations Industrial Development Organization. [United Nations Industrial Development Organization \(2018\)](#)).

One of the most important socially significant industries in the integrated union's economy is chemicals and pharmaceuticals. All people who currently live in EAEU member states consume medicines for a total of USD 17 billion per year ([Livansky, 2017](#)).

Although pharmaceuticals production has been on the rise in all the integrated union's countries over the past few years, the chemical and pharmaceutical industry makes a modest contribution to GDP in EAEU member states. National pharmaceutical markets in EAEU member states are currently marked by high import dependency, the absence of equal terms for pharmaceutical manufacturers, the lack of the broad breakdown of a product lineup for external economic activities, and a high degree of fixed asset obsolescence suffered by most producers.

EAEU priorities include the establishment of a common medicine market, thus creating new possibilities for domestic and foreign companies from the chemical and pharmaceutical sector. In 2017, EAEU national pharmaceutical markets merged and commenced operations within a single space. EAEU pharmaceutical manufacturers will be able to apply for registration of medicines and distribution by following unified procedures and to reduce administrative costs and the cost of entry into pharmaceutical markets of neighboring countries. The establishment of the common market aims to improve the competitiveness of medicines that are produced and distributed in EAEU member states by improving the quality, safety and effectiveness of medicines.

At the same time, it should be noted that the shift towards the common pharmaceutical market requires the resolution of some problems such as how to harmonize laws related to the output and circulation of pharmaceutical products among EAEU member states; to unify requirements for drug registration terms; to create a single information system to keep records of pharmaceutical drugs; to introduce new pricing approaches for vital pharmaceutical drugs, etc.

Furthermore, insufficient competitiveness of the pharmaceutical industry in EAEU member states is stipulated by the impact of many factors such as inflation components (which drive up medicine prices); innovative weakness that reduces the affordability of advanced medicines for the public; and inefficient spending of government funds, etc.

Based on the foregoing, the topical area for further research is the analysis of factors that improve competitiveness on the foreign market of products manufactured by EAEU chemical and pharmaceutical businesses within the common pharmaceutical market.

## 2. Literature Overview

Aspects of competitiveness for various sectors of the economy were broadly analyzed and results are available in the literature (Bekarev and Bekareva, 2015). In light of modern studies dedicated to global competitiveness, it can be said that EAEU member states should find innovative solutions to become notable generators of knowledge in key promising technologies and vital high-technology sectors.

The pharmaceutical industry is one of these sectors, and it is designed to play a decisive role in stimulating growth and competitiveness in EAEU countries in the external market.

On a global scale, most studies related to the pharmaceutical industry concern its impact on the healthcare sector (Mills *et al.*, 2002; Rhee, 2008; Shabani and Shabani, 2018) and the compliance by pharmaceutical companies with the rules of competition (Melani, 2018). International competitiveness has become more important for the pharmaceutical sector. Competitiveness means the ability of countries to increase market shares, profit, added value and remain competitive during long periods. This is materialized through market authority and the establishment of activities based on competitive advantages (Musavi *et al.*, 2018).

With regard to a new competitive environment, it is important to take into account factors influencing the competitiveness of pharmaceutical companies in internationalization and globalization of the market (Kesič, 2009). Primary factors of competitiveness for the chemical and pharmaceutical industry are those which influence the ability of a company to develop and distribute new medicines or to create new chemical compounds, especially those, which are successfully promoted on a global basis (Henry and Lexchin, 2002).

A research work performed by H. Shabaninejad, G. Mehralian, A. Rashidian, A. Baratimarnani, and H.R. Rasekh highlighted ten key competitiveness factors of the pharmaceutical market, namely human capital, politics at the macro level, strategy and operating efficiency of pharmaceutical enterprises, development of auxiliary and related industries and clusters, administrative infrastructure, innovative potential, organized practice, capital market infrastructure; internationalization of businesses and a competitive environment (Shabaninejad *et al.*, 2014).

The analysis of interrelation between the pharmaceutical industry's competitiveness and innovative research and development of medicines is presented in the research works compiled by Guan *et al.* (2006), Rasekh *et al.* (2012) Demirel and Mazzucato (2012) etc.

The influence of measures taken to protect intellectual property on the international competitiveness of high-technology industries, which include the pharmaceutical industry, is presented in research works compiled by Allred and Park (2007), Grace (2004), and Lanoszka (2003).

Publications devoted to healthcare problems and the identification of socio-economic consequences caused by substandard and counterfeit medicines are especially highlighted in the literature. Hoen and Pascual (2015); Borg *et al.* (2011), Kim (2017) and others did research to analyze measures to support the safety of medicine supply at the macro level.

Of some interest are research works compiled by Franculino and Gomes (2017), and others, and they show methodical approaches towards the quantitative assessment of indicators, which describe various aspects of sectoral development in the pharmaceutical industry in some developing countries.

It should be noted that despite a large number of scientific publications on the topic, there has been little research conducted with regard to the impact of factors determining the competitiveness of EAEU medicines.

## 3. Methods

The empiric part of the paper is devoted to the development of the pharmaceutical industry in EAEU member states in 2014-2018. Data for this study were taken from public sources (official statistical data from EAEU member states, the UNO, the World Bank, reports and analytical publications from the Eurasian Economic Commission (EEC), the World Health Organization (WHO), the World Trade Organization (WTO), the World Bank Group, the International Trade Center (ITC) of the UNCTAD/WTO, etc.).

In the course of study, the authors applied a complex of scientific methods, including monographic analysis, comparative analysis of development indicators of the pharmaceutical market, factor analysis and the method of ranking countries by the competitiveness of the pharmaceutical industry in EAEU member states. A correlation matrix was used in making a multi-factor regression model.

A variable is an integral indicator of competitiveness for the EAEU pharmaceutical industry that is calculated by the following formula:

$$I_n = I_{x1} + I_{x2} + I_{x3} / 3$$

where

$I_{x1}$ ,  $I_{x2}$ ,  $I_{x3}$  are competitiveness indices by factor features. To calculate them the following formula is used:

$X_{n1} = (X - X_{min}) / (X_{max} - X_{min})$  for stimulators;

$X_{n2} = 1 - (X - X_{min}) / (X_{max} - X_{min})$  for de-stimulators;

Factor features of competitiveness are

X1 – the ratio between pharmaceuticals imports/exports on the external market.

X2 – the consumer price index for medicines.

X3 – the pharmaceuticals production index.

X1 and X2 are de-stimulators, i.e. their higher indicators impair the assessment of the industry's competitiveness;

X3 is a stimulator, i.e. higher indicators improve assessment of competitiveness.

#### 4. Development of the Chemical and Pharmaceutical Industry in Eaeu Countries

The pharmaceutical industry is a fast-growing economic sector in EAEU member states. Specifically, pharmaceuticals production increased by 51% over the past three years, while output in the Union's manufacturing sector increased by 20% (Table 1).

**Table-1.** Pharmaceuticals production in EAEU member states in 2015-2017, USD million\*

EAEU countries	2015	2016	2017	Change, 2017/2015	
				+/-	%
Armenia	16	16.9	19.9	3.9	24.4%
Belarus	509.9	496	594.6	84.7	16.6%
Kazakhstan	143.5	124	225.3	81.8	57%
Kyrgyzstan	3.4	3.3	4.2	0.8	23.5%
Russia	4,700	5,569.5	7,267.8	2,567.8	54.6%
<i>Total</i>	<i>5,372.8</i>	<i>6,209.7</i>	<i>8,111.8</i>	<i>2,739</i>	<i>51%</i>
Total output, EAEU manufacturing sector	596.1	567.8	715.2	119.1	20%

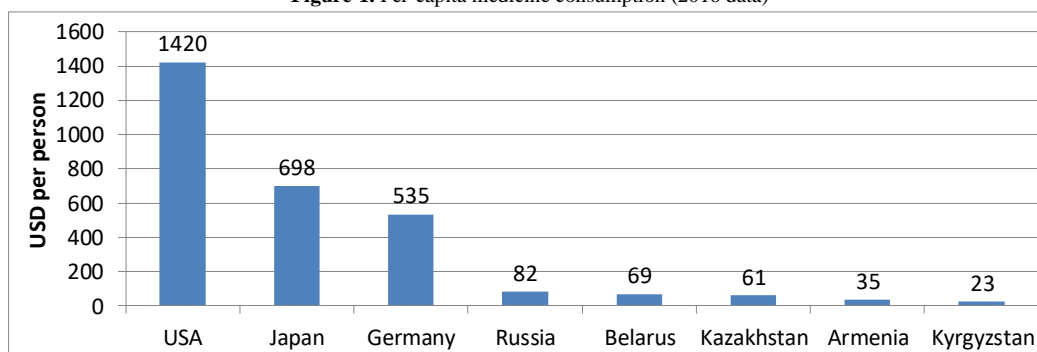
\*Compiled by the authors on the basis of EEC periodical reports on the state of the industrial sector in EAEU member states

[http://www.eurasiancommission.org/ru/act/prom\\_i\\_agroprom/dep\\_prom/Pages/Мониторинг%20и%20анализ/monthlyreview.aspx](http://www.eurasiancommission.org/ru/act/prom_i_agroprom/dep_prom/Pages/Мониторинг%20и%20анализ/monthlyreview.aspx)

Although production volumes somewhat grew, the share of the pharmaceutical industry in the EAEU manufacturing sector remains low (0.9% in 2015, 1.09% in 2016 and 1.13% in 2017).

As regards medicine consumption, EAEU member states lag far behind developed economies (Figure 1).

**Figure-1.** Per-capita medicine consumption (2016 data)



All EAEU member states are net medicine importers, with total pharmaceutical imports in the EAEU exceeding pharmaceutical exports to third countries by 22.3x. EAEU foreign and mutual pharmaceutical trade data are given in Table 2.

**Table-2.** EAEU foreign and mutual pharmaceuticals trade in 2017, USD million

Indicator	Armenia	Belarus	Kazakhstan	Kyrgyzstan	Russia	EAEU
Medicine imports	173.4	708.1	948.8	145.5	11,394.6	13,370.4
Medicine exports to third countries	7.8	24.2	12.2	0.3	514.2	558.7
Mutual trade	15.2	180	16.4	0.6	280.3	492.5
Net imports	150.4	503.9	920.2	144.6	10,600.1	20,431
Domestic output	19.9	594.6	225.3	4.2	7,267.8	8,111.8
Size of the pharmaceutical market	170.3	1,098.5	1,145.5	148.8	17,867.9	20,431

In 2017, the EAEU pharmaceuticals market totaled USD 20.4 billion, with Russia accounting for 87.5%, 5.6% fell to Kazakhstan, 5.4% to Belarus, 0.8% to Armenia and 0.7% to Kyrgyzstan.

The share of EAEU member states on the global pharmaceuticals market remains small, around 1.7% (according to international research firm Evaluate Pharma, the global pharmaceuticals market reached USD 1,200 billion in

2017 (EvaluatePharma, 2017). By comparison, the United States commanded 38% of the market, 13.8% fell to China, and 10% to Japan.

In 2017, pharmaceutical imports in the foreign trade of EAEU member states exceeded pharmaceutical output by 65%. In comparison with output and imports, pharmaceutical exports in external and mutual trade are modest (USD 558.7 billion and USD 492.5 billion, respectively). The share of imported pharmaceuticals is the lowest in Belarus (54.4%), and the highest in Kyrgyzstan (97.2%).

It should be noted that nearly 80% of pharmaceutical imports to EAEU countries comes from Europe, above all Germany and France. As regards exports, key export markets for EAEU pharmaceuticals are post-Soviet states. The main reason behind the weak export potential of the EAEU pharmaceutical industry is the fact that pharmaceutical producers do not comply with the requirements of the international standard GMP.

The Russian pharmaceutical market is the biggest in the EAEU. Russia currently ranks 14<sup>th</sup> worldwide by the size of the pharmaceutical market. A shift to production standards GMP (Good Manufacturing Practice) produced a substantial impact on the development of the pharmaceutical market. Changes covered nearly all production processes related to vaccines and biological products. Notably, 527 licenses for the manufacturing of pharmaceutical and medical products were valid in Russia as of early 2017.

In 2011-2017, over RUB 150 billion of government and private funds were invested in the Russian pharmaceutical industry. This made it possible to launch 30 production facilities since 2013, and to reach the high rate of pharmaceutical output. However, production growth slowed down in 2017. The state-backed program "Development of the Pharmaceutical Industry" is a key tool to support production. However, the current version of the State Program suggests that the amount earmarked for 2018-2020 is nearly 30% less than the money provided in 2013-2016. The Federal Target Program "Pharma-2020", part of the State Program and within which most funds were allocated in previous years, was terminated prematurely.

The pharmacy (commercial) segment makes a key contribution to increasing sales on the Russian pharmaceutical market, and in 2017 this segment showed signs of recovery in terms of natural volume. In accordance with analytical databases from AlphaRM, the size of the Russian pharmaceutical market reached 5.3 billion packs in 2017, or just 0.2% less than in 2016 (AlphaRM, 2017). In 2015-2017, sales of Russian pharmaceutical products climbed conspicuously, implying that the state-run import substitution program is a success. In 2017, Russian pharmaceutical products reached 35% in terms of value and 59% in physical terms.

Belarusian, Kazakh and Kyrgyz markets, on the contrary, have delivered growth that looks highly speculative (Livansky, 2017). During the period under review pharmaceutical industries of these countries showed mixed performance.

For instance, the Kazakh pharmaceutical industry reported a decline in production until 2015, with the share of local products on the domestic market decreasing. Since 2015 the Kazakh pharmaceutical industry has been growing at an annual rate of 12-16%. This is primarily driven by the implementation of the Program for Formed Industrial Innovative Development, as part of which around 30 investment projects were executed in the country's pharmaceutical industry and businesses launched output of antibacterial, cardiological, gastroenteric, resolvent, anti-virus medicines, medical apparel, syringes and medical equipment.

The Armenian market faces stagnation.

### 3. Results of Factor Analysis of Competitiveness in the Eaeu Chemical and Pharmaceutical Industry

Estimates used to make a multi-factor model for each of the EAEU member states are given in Table 3.

Table-3. Estimated indicators to make a multi-factor model for each of the EAEU member states

Indicator	2013	2014	2015	2016	2017	min	max
Armenia							
Imports/exports ratio	16.4	16.7	14.0	13.8	22.3	13.8	22.3
CPI for medicines	110.9	103.1	107.9	98.1	103.2	98.1	110.9
Manufacturing index for the pharmaceutical industry	125.1	106	124.8	107.5	116.2	106	125.1
Belarus							
Imports/exports ratio	30.2	32.7	34.7	29.6	29.3	29.3	34.7
CPI for medicines	112.1	113.4	116.8	112	99.8	99.8	116.8
Manufacturing index for the pharmaceutical industry	113.1	93.0	84.6	100.9	110.1	84.6	113.1
Kazakhstan							
Imports/exports ratio	71.1	75.9	60.5	49.9	77.8	49.9	77.8
CPI for medicines	103.4	98.4	79.5	116.8	106.6	79.5	116.8
Manufacturing index for the pharmaceutical industry	100.3	102.7	101.3	103.8	141.8	100.3	141.8
Kyrgyzstan							
Imports/exports ratio	77.3	113.2	87.5	255.3	485.0	77.3	485
CPI for medicines	102.7	108	108.8	106.4	104.4	102.7	108.8

Manufacturing index for the pharmaceutical industry	151	128.3	136.2	98.8	125.6	98.8	151
Russia							
Imports/exports ratio	36.6	31.2	24.6	22.7	22.2	22.2	36.6
CPI for medicines	108.6	105.9	112.4	104.9	96.6	96.6	112.4
Manufacturing index for the pharmaceutical industry	103.9	94.6	108.5	107	112.3	94.6	112.3

At the second stage, competitiveness indices were calculated for the chemical and pharmaceutical industry of EAEU countries by each factor, and results are given in Table 4.

**Table-4.** Results of the competitiveness indices

EAEU countries	2013	2014	2015	2016	2017
Competitiveness indices by X1 – Imports/exports ratio for the pharmaceutical industry					
Armenia	1.00	1.00	1.00	1.00	1.00
Belarus	0.77	0.83	0.72	0.93	0.98
Kazakhstan	0.10	0.39	0.37	0.85	0.88
Kyrgyzstan	0.00	0.00	0.00	0.00	0.00
Russia	0.67	0.85	0.86	0.96	1.00
Competitiveness indices by X2 – CPI for medicines					
Armenia	0.13	0.69	0.24	1.00	0.34
Belarus	0.00	0.00	0.00	0.26	0.68
Kazakhstan	0.93	1.00	1.00	0.00	0.00
Kyrgyzstan	1.00	0.36	0.21	0.56	0.22
Russia	0.37	0.50	0.12	0.64	1.00
Competitiveness indices by X3 – Manufacturing index for the pharmaceutical industry					
Armenia	0.49	0.37	0.78	1.00	0.19
Belarus	0.25	0.00	0.00	0.24	0.00
Kazakhstan	0.00	0.27	0.32	0.57	1.00
Kyrgyzstan	1.00	1.00	1.00	0.00	0.49
Russia	0.07	0.05	0.46	0.94	0.07

In terms of the imports/exports ratio for pharmaceutical products, Armenia, Russia and Belarus hold the strongest positions. The ratio declined the most in Russia, primarily due to the aggressive policy of substituting medicine imports after the government adopted the Development Strategy for the Russian Pharmaceutical Industry and the federal target program Pharma-2020. The situation is critical in Kyrgyzstan as the pharmaceutical imports/exports ratio climbed from 77.3x to 485x in 2013-2017, a sign that the country is 100% dependent on imported pharmaceuticals.

Another important indicator of the pharmaceutical industry's competitiveness is the Consumer Price Index for medicines. By this factor, Russia and Belarus are the strongest. Pharmaceutical prices dropped by 3.4% y-o-y and 0.2% y-o-y, respectively, in December 2017. Until 2016, Kazakhstan held leadership by this indicator, with consumer prices sliding 1.6% and 20.5%, respectively, in 2014-2015. However, since 2016 Kazakhstan has seen the highest consumer prices in the pharmaceutical market among EAEU countries.

The third competitiveness ratio is the manufacturing index for pharmaceutical products. By this indicator, the countries show mixed performance. Kazakh and Kyrgyz pharmaceutical industries expanded at the highest pace in 2017.

Table 5 shows the calculation of the EAEU pharmaceutical industry's average competitiveness.

**Table-5.** Average competitiveness

	2013	2014	2015	2016	2017
Armenia					
X1	1	1	1	1	1
X2	0.13	0.69	0.24	1	0.34
X3	0.49	0.37	0.78	1	0.19
Iar, average	0.54	0.69	0.67	1.00	0.51
Belarus					
X1	0.77	0.83	0.72	0.93	0.99
X2	0	0	0	0.26	0.68
X3	0.25	0	0	0.2	0
Iar, average	0.34	0.28	0.24	0.46	0.56
Kazakhstan					
X1	0.1	0.39	0.37	0.85	0.93
X2	0.93	1	1	0	0

X3	0	0.27	0.32	0.57	1
Ibl, average	0.34	0.55	0.56	0.47	0.64
Kyrgyzstan					
X1	0	0	0	0	0.39
X2	1	0.36	0.21	0.56	0.22
X3	1	1	1	0	0.49
Ibl, average	0.67	0.45	0.40	0.19	0.37
Russia					
X1	0.67	0.85	0.86	0.96	1
X2	0.37	0.5	0.12	0.64	1
X3	0.07	0.05	0.46	0.94	0.07
Ibl, average	0.37	0.47	0.48	0.85	0.69

The influence of key factors on the EAEU pharmaceutical industry's competitiveness was assessed at this stage of analysis. Models of multiple linear regression, which reflects the dependency of the pharmaceutical industry's competitiveness in individual EAEU countries, are given in Table 6.

**Table-6.** Results of regression analysis of the pharmaceutical industry's competitiveness in individual EAEU countries

	<i>Ratios</i>	<i>Standard error</i>	<i>t-statistic</i>	<i>P-value</i>
Armenia				
Intersection of Y	4.436	0.588	7.542	0.084
X1 variable	-0.038	0.007	-5.512	0.114
X2 variable	-0.033	0.010	-3.330	0.186
X3 variable	0.003	0.005	0.492	0.709
R <sup>2</sup> = 98.5%; F= 21.9; Significance F = 0.156				
Belarus				
Intersection of Y	4.120	1.060	3.886	0.160
X1 variable	-0.056	0.022	-2.591	0.234
X2 variable	-0.012	0.005	-2.576	0.236
X3 variable	-0.007	0.004	-1.653	0.346
R <sup>2</sup> 97.4%; F= 12.676; Significance F = 0.203				
Kazakhstan				
Intersection of Y	0.460	0.684	0.672	0.623
X1 variable	-0.002	0.007	-0.325	0.800
X2 variable	-0.004	0.005	-0.781	0.578
X3 variable	0.006	0.005	1.207	0.441
R <sup>2</sup> = 63.9%; F= 0.591; Significance F = 0.716				
Kyrgyzstan				
Intersection of Y	1.808	1.968	0.919	0.527
X1 variable	0.000	0.000	-0.946	0.518
X2 variable	-0.021	0.017	-1.250	0.429
X3 variable	0.007	0.002	2.840	0.216
R <sup>2</sup> = 96.2%; F= 8.348; Significance F = 0.248				
Russia				
Intersection of Y	2.589	3.255	0.795	0.572
X1 variable	-0.024	0.022	-1.072	0.478
X2 variable	-0.009	0.019	-0.478	0.716
X3 variable	-0.004	0.020	-0.180	0.887
R <sup>2</sup> = 71,9%; F=0,852; Significance F = 0,642				

The pharmaceutical industry in Armenia and Belarus is the most sensitive to the impact of X1 – imports/exports ratio for the pharmaceutical industry. Such a factor as the Consumer Price Index for medicines substantially impacts the pharmaceutical industry's competitiveness in Armenia, Belarus and Kyrgyzstan. The manufacturing index, to a lesser extent, impacts the pharmaceutical industry's competitiveness in all EAEU countries. At the same time, the lack of advanced production technologies, obsolescent production equipment at many pharmaceutical enterprises, shortage of qualified staff able to work in accordance with international standards impair the pharmaceutical industry's competitiveness in EAEU countries.

The presented multi-factor model, which is used to assess competitiveness, makes it possible to forecast changes in the integral competitiveness ratio provided that the current factor ratios remain unchanged. By substituting actual

variables in the regression equation, it is possible to find the forecast value of the competitiveness index for the pharmaceutical industry in EAEU countries (Table 7).

**Table-7.** The pharmaceutical industry's competitiveness index (forecast) in EAEU countries

Country	Regression equation	Competitiveness index If (Actual)	Competitiveness index Ip (Forecast)
Armenia	$4.436-0.038*22.3-0.033*103.2+0.003*116.2$	0.51	0.44
Belarus	$4.12-0.056*29.3-0.012*99.8-0.007*110.1$	0.56	0.56
Kazakhstan	$0.46-0.002*77.8-0.004*106.6+0.006*141.8$	0.64	0.65
Kyrgyzstan	$1.808-0*485+0.021*104.4+0.007*125.6$	0.37	0.36
Russia	$2.589-0.024*22.2-0.009*96.6-0.004*112.3$	0.69	0.77

Results of the study show that competitiveness of such countries as Armenia and Kyrgyzstan will deteriorate provided that the current indicators of pharmaceutical imports/exports, CPIs for medicines and the growth rate of pharmaceutical production remain unchanged. Belarus's competitiveness will remain the same, the Kazakh competitiveness index will rise marginally, while Russia's competitiveness will increase substantially.

Results of the study confirm that it is necessary to elaborate measures aimed at creating additional competitive advantages for EAEU member states.

## 4. Discussion

Pharmaceutical experts point out that the pharmaceutical industry's growth has been driven by the establishment of the EAEU. Specifically, pharmaceutical and medical products association PharmMedIndustria Kazakhstan pointed out that the establishment of a common market sharpened the industry's investment appeal as the construction of pharmaceutical and medical equipment and other facilities got under way (the Kazakh Pharmaceutical Bulletin).

The common medicine market in EAEU member states was launched in May 2017. The pharmaceutical industry's operation within the common EAEU market will make it possible to create an additional competitive advantage for member states. First, cancelled duties will enable local manufacturers to raise exports and easily enter other EAEU markets. Second, the introduction of unified medicine registration procedures will allow local manufacturers to save funds and reduce the time spent to register and bring new products to the market.

Results of the study conducted in this paper show that prices are a substantial competitive factor for the pharmaceutical industry in EAEU member states.

It is noteworthy that at present, EAEU countries do not have any uniform approach towards regulation of pharmaceutical prices and not all EAEU countries approved regulation of pharmaceutical prices by law.

Unrivalled leaders are Russia and Belarus that, among the first, passed specific statutory and normative legislative acts in this regard.

In Russia, key documents that regulate pricing on the pharmaceutical market are ([Government Resolution № 865, 2010](#)) and approved methods of calculating maximum manufacturer-set selling prices for medicines that are on the Vital and Essential Drugs List (VEDL) when they are under state registration and re-registration ([Russian Government, 2015](#)).

Pursuant to Russian laws, all VEDL medicines are subject to price regulation regardless of distribution channels (via government procurement programs or commercial shipments). Russian laws also require mandatory registration of a manufacturer's maximum selling price and the acceptable level of wholesale and retail price increases.

Many aspects of price regulations in Belarus are similar to the principles set in Russia and are regulated by [Decree № 366 By The President Of Belarus \(2005\)](#). The difference from Russian rules is that price regulation is extended to all medicines, while price regulation in Russia applies only to VEDL pharmaceutical drugs.

Furthermore, with regard to some medicines produced in Belarus, the Ministry of Health of Belarus additionally sets maximum producer's selling prices.

In addition to the Code "On the Public Health and Healthcare System", the Pricing Rules for medicines and medical items as part of the guaranteed scope of free medical assistance (№ 639, 2015) are in effect in Kazakhstan. Price regulation applies only to drug shipments as part of the guaranteed scope of free medical assistance to a single distributor (SK-Pharmacia Ltd.). The Ministry of Healthcare of Kazakhstan annually determines a list of medicines to be purchased by the single distributor and their maximum purchase prices for the purposes of government procurement as part of the Guaranteed Scope of Free Medical Assistance (GSFMA).

Since 2009 Kazakhstan has signed annually the Memorandum on Maximum Retail Prices for Pharmaceutical Drugs that are most often used by socially unprotected categories of the population. Measures are currently taken to improve effective regulation. Specifically, on September 28, 2017 the Pharmaceutical Committee provided the business community (the National Chamber of Entrepreneurs Atameken) with draft amendments to the Price Regulation Rules. Moreover, on September 14, 2017 the Ministry of Healthcare of Kazakhstan announced the elaboration of a draft law to gradually introduce price regulation for all medicines. The amendments can be expected

to be adopted and, according to the information from the Ministry of Healthcare, will take effect as of October 2018 with regard to prescription drugs (Rx) and to non-prescription (OTC) drugs as of 2023.

Price regulation laws are under development in Kyrgyzstan and Armenia. There is no drugs price regulation in Kyrgyzstan at the moment, although it can be introduced in the near future. Back in 2015, the Kyrgyz government developed a draft Resolution that contains general requirements for the acceptable level of wholesale and retail prices for Vital and Essential Drugs (VED).

As for Armenia, drugs price regulation can be introduced in the country approximately as of 2018. New standards were set in the country's new law ("On Medicines" dated May 17, 2016). Laws will regulate base prices, maximum wholesale and retail increases in prices for refundable medicines (prices of which are fully or partially compensated from the state budget).

It is necessary for Kazakh, Kyrgyz and Armenian governments to finalize measures to bring their national drugs laws into compliance with the EAEU requirements, and to continue the development of new pricing approaches for the pharmaceutical industry.

Safety, quality and effectiveness of medicines remain important features of the pharmaceutical market's competitiveness. An important area of cooperation among EAEU countries is to ensure that medicine production meets GMP requirements.

In global practice, there are lots of standards regulating the output of all possible products and services. However, all these standards regulate the final product quality, while GMP sets requirements directly for production and processes.

Pursuant to Article 100 of the Treaty on the EAEU, the compliance with the GMP rules has been mandatory since January 1, 2016. Following the GMP standards creates a whole set of procedures to exclude the possibility of manufacturing substandard products, regulating the integrated approach towards production and laboratory tests. Raw materials, intermediary products and finished products are under full control throughout the period of validity.

As GMP practices have proven themselves as effective in the United States, Europe, Japan and other developed countries, it can be seen that laws in developing countries are absolutely identical to GMP requirements for the production of medicines and other products. Specifically, unified GMP rules for the EAEU were approved in 2016 (Decision No. 77 adopted by the Council of the Eurasian Economic Commission (EEC) on November 3, 2016). Vladislav Shestakov thinks that the shift to GMP standards when issuing licenses for the manufacture of medicines in the EAEU will make it possible to set unified requirements for production both domestically and overseas (Shestakov, 2016).

Further efforts should be taken to create a strong inspectorate and introduce the practice of mutual recognition of inspection results among EAEU countries. Certain issues related to the development and examination of pharmaceuticals, drugs production, and to the details and formalization of inspection procedures should be specified in the EEC's individual guides and recommendations.

The implementation of these EEC regulatory measures will make it possible to ensure quality, effectiveness and safety of medicines for the public in EAEU countries, and to create optimum conditions for the development of the chemical and pharmaceutical industry and improve the competitiveness of EAEU products.

## 6. Conclusion

Results of the study conducted lead the authors to conclude that the competitiveness of the chemical and pharmaceutical industry in EAEU countries have improved substantially in recent years, with Russian and Belarusian pharmaceutical markets being the most competitive among EAEU countries.

In the article, the authors identified factors impacting the competitiveness of individual EAEU countries (the manufacturing index of the pharmaceutical industry, the consumer price index for medicines, and the level of import substitution expressed as the pharmaceutical import/export ratio).

For the purpose of further development of the common pharmaceutical market and improved competitiveness of EAEU medicines, it is necessary to further enhance approaches towards price regulation and measures to ensure quality and safety of products by introducing unified GMP EAEU rules.

## References

- Allred, B. B. and Park, W. G. (2007). Patent rights and innovative activity, Evidence from national and firm-level data *Journal of International Business Studies*, 38(6).
- Bekarev, A. A. and Bekareva, S. (2015). Competitiveness of national pharmaceutical industry, The Russian case. *Journal of Chemical and Pharmaceutical Research*, 7(5): 710-15.
- Borg, J.-J., Aislaitner, G., Pirozynski, M. and Mifsud, S. (2011). Strengthening and rationalizing pharmacovigilance in the eu, Where is Europe heading to? A review of the new EU legislation on pharmacovigilance *Drug Safety*, 34(3): 187-97. Available: <https://www.scopus.com/record/display.uri?eid=2-s2.0-79951788370&doi=10.2165%2f11586620-000000000-00000&origin=inward&txGid=2dc9f28c22002684a0c7ab583dc1d3f7>
- Decree № 366 By The President Of Belarus (2005). On the pricing of medicines medical products and medical equipment. 11.
- Demirel, P. and Mazzucato, M. (2012). Innovation and firm growth, Is R&D worth it? *Industry and Innovation*, 19: 45-62.



- EvaluatePharma (2017). World preview, outlook to 2022. Available: <http://info.evaluategroup.com/rs/607-YGS-364/images/WP17.pdf>
- Franculino, K. A. S. and Gomes, R. (2017). Public policies and competitiveness in the pharmaceutical industry, The case of brazil and india. *Espacios*, 38(26): 29. Available: <https://www.scopus.com/inward/record.uri?eid=2-s2.0-85020183279&partnerID=40&md5=ab6831240300f424f4591bc5de66ecd4>
- Government Resolution № 865 (2010). On state regulation of prices for medicines on the vedl.
- Grace, C. (2004). The effect of changing intellectual property on pharmaceutical industry prospects in india and China. *DFID Health Systems Resource Centre*: 1-68. Available: <http://www.who.int/hiv/amds/Grace2China.pdf?ua=1>
- Guan, J. C., Yam, R. C. M., Mok, C. K. and Ma, N. (2006). A study of the relationship between competitiveness and technological innovation capability based on dea models. *European Journal of Operational Research*, 170(3): 971-86. Available: <https://www.scopus.com/inward/record.uri?eid=2-s2.0-27744483854&doi=10.1016%2fj.ejor.2004.07.054&partnerID=40&md5=1c114dc39f7c6807ff241731d7e2ab8d>
- Henry, D. and Lexchin, J. (2002). The pharmaceutical industry as a medicines provider. *Lancet*, 360(9345): 1590-95. Available: <https://www.journals.elsevier.com/the-lancet/>
- Hoen, E. and Pascual, F. (2015). Viewpoint, Counterfeit medicines and substandard medicines, Different problems requiring different solutions. *Journal of Public Health Policy*, 36(4): 384-89. Available: <https://www.scopus.com/inward/record.uri?eid=2-s2.0-84945123238&doi=10.1057%2fj.php.2015.22&partnerID=40&md5=a66c00580a9e643eef3b8699caf5cb02>
- Kesič, D. (2009). Strategic analysis of the world pharmaceutical industry. *Management*, 14: 59-76.
- Kim, D. (2017). Transparency policies of the european medicines agency, Has the paradigm shifted? . *Medical Law Review*, 25(3): 456-83. Available: <https://www.scopus.com/record/display.uri?eid=2-s2.0-85031756678&doi=10.1093%2fmedlaw%2ffwx002&origin=inward&txGid=4db6d3831aaf43a42ff0d930728295d5>
- Lanoszka, A. (2003). The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *International Political Science Review*, 24(2): 181-97.
- Livansky, S. M. (2017). Competitive environment, Assessment of the eaeu market. *Magazine Remedium*, 10: 18-20. Available: <http://dx.doi.org/10.21518/1561-5936-2017-10-16-20>
- Melani, P. (2018). Competition in the pharmaceutical industry. *Magazine Monitor*: Available: <http://www.monitor.al/konkurrenca-ne-industrine-farmaceutike-2/>
- Mills, A., Brugha, R., Hanson, K. and McPake, B. (2002). What can be done about the private health industry in low-income countries? *Geneva, Bulletin World Health Organization*, 80(4).
- Musavi, S. Z., Rasekhi, S., Golestani, M. and Name, A. (2018). Study of the international competitiveness of the pharmaceutical industry in selected developed countries. *Asian Journal Of Pharmaceutical And Clinical Research*, 11(3): 451-60. Available: <https://www.scopus.com/record/display.uri?eid=2-s2.0-85042944133&doi=10.22159%2fajpcr.2018.v11i3.21554&origin=inward&txGid=56158622466358ef9b47101c67ca3739>
- Rasekh, H. R., Mehralian, G. H. and Vatankhah-Mohammadabadi, A. A. (2012). Situation analysis of r&d activities, An empirical study in iranian pharmaceutical companies. *Iranian Journal of Pharmaceutical Research*, 11: 1013-25.
- Rhee, J. (2008). The influence of the pharmaceutical industry on healthcare practitioners prescribing habits in The Internet. *Journal of Academic Physician Assistants*, 7(1).
- Russian Government (2015). Resolution № 979 of the on making amendments to resolution № 865 of the russian government dated october 29, 2010 and on the approval of the methods for the calculation of maximum selling prices set by pharmaceutical producers for pharmaceutical drugs included in the vital and essential drugs list when they are under state registration and re-registration. *Garant*, 15: Available: <http://base.garant.ru/71192234/>
- Shabani, H. and Shabani, A. (2018). Pharmaceutical competitiveness and impact on the health of the population in kosovo 2010-2017,. *Journal of Pharmaceutical Sciences and Research*, 10(3): 509-10. Available: <https://www.scopus.com/record/display.uri?eid=2-s2.0-85044755132&origin=inward&txGid=9022749256fae17fad00987ec7ee0f00>
- Shabaninejad, H., Mehralian, G., Rashidian, A., Baratimarnani, A. and Rasekh, H. R. (2014). Identifying and prioritizing industry-level competitiveness factors, Evidence from pharmaceutical market. *DARU. Journal of Pharmaceutical Sciences*, 22(1): 35.
- Shestakov, V. N. (2016). Report on GMP inspectorate in the pharmaceutical industry. Available: <https://gilsinp.ru/?news=gmp-inspektorat-v-farmatsevticheskoy-otrasli>
- United Nations Industrial Development Organization (2018). Industrial development report. Demand for manufacturing, driving inclusive and sustainable industrial development. *Vienna*: Available: [https://www.unido.org/sites/default/files/files/2017-11/IDR2018\\_FULL%20REPORT.pdf](https://www.unido.org/sites/default/files/files/2017-11/IDR2018_FULL%20REPORT.pdf)
- AlphaRM (2017). The size and performance of the pharmaceutical market in 2017 in end consumer prices. Available: [https://alpharm.ru/sites/default/files/obem\\_i\\_dinamika\\_farmacevticheskogo\\_rynka\\_rossii\\_po\\_itogam\\_2017\\_goda.pdf](https://alpharm.ru/sites/default/files/obem_i_dinamika_farmacevticheskogo_rynka_rossii_po_itogam_2017_goda.pdf)