The Analysis of Medicine Single Market Start-up in EEU

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On April 5 the President of the Kyrgyz Republic signed the Law of KR "On Ratification of the Protocol on Accession of the Republic of Armenia to the Agreement on Common Principles and Rules for the Circulation of Medicinal Products Within the Framework of the Eurasian Economic Union" from December 23, 2014, and signed on December 2, 2015 in Moscow. 10 days after signing the Law becomes valid, which means the abolishment of the last barrier impeding proper performance of single pharmaceutical market of EEU countries. Its participants will gradually proceed working by new, improved rules. This shall have positive impact on the quality, safety, efficacy of medicinal products and medical goods. Nevertheless, it is not clear yet how will the establishing of single pharmaceutical market affect the situation in local markets, what impact will it have on physical and economical availability of pharmaceuticals. The analysts of QuintilesIMS company tried to answer these questions. The results of their investigation are offered to your attention (the report was announced by Alexey Savin, Head of Consultancy for Russia and CIS at QuintilesIMS at the Pharmaceutical Forum of EEU and CIS countries).

Thus, to-day the members of Eurasian Economic Union are five countries – **Russia,** **Kazakhstan, Belarus, Kyrgyzstan, and Armenia**. 180 million people live on their territory. The aggregate GDP of these five countries is $1.5 trillion, which corresponds to the fifth position in the ranking of the world leading economies.

In total, according to the results of 2016, **the volume of the pharmaceutical market of the EEU countries amounted to $17.2 billion**. The lion’s share (depending on the exchange rate of 80-85%) of the united market belongs to Russia ($14.7 billion). Kazakhstan holds a 7% stake ($1.3 billion), Belarus holds 5% ($0.8 billion), Kyrgyzstan holds 2% ($0.3 billion), and 1% stake ($0.1 billion) belongs to Armenia.

Undoubtedly, **the work in conditions of single market will change the competitive landscape**. There are threats and new opportunities for domestic and foreign manufacturers, as well as for distributors of pharmaceutical products. At the same time, from the point of view of QuintilesIMS analysts, the most problematic consequences for local markets will be related to regulatory solutions in three key areas:

* harmonization of registration procedures,
* the status of local manufacturers and its extension to the manufacturers of the other member states in terms of procurement preferences,
* the effect of restrictions (or their lack) on competition in redistribution of goods, i.e. in parallel importing.

Therefore, in the course of study there was analyzed precisely their effect on the price level, volumes and market structure. At the same time, the retail segment and the public procurement segment were considered separately, and the range of pharmaceutical products was divided into groups:

* in the retail segment: (a) individual original brands and branded [generics](http://gmpnews.ru/terminologiya/generic/) and (b) medicinal products having price difference of more than 15-20%, that can be the subject of cross-border trade and parallel importing;
* in the public procurement segment: (а) in individual original molecules, (b) medicinal products having a competitive environment (offered by 3 or more manufacturers), and (с) medicinal products having a price difference of more than 10%.

*The study covered medicinal products that are sold in several markets and have the largest sales volume – Top 25 original brands and branded generics.*

The Effect on the Price Level

Among the main factors that affect the price level there are: *(а) parallel importing, (b) currency fluctuations, (с) VAT rates and margin levels in the supply chain to differences in markets’ structure*.

а. Redistribution of Commodity Flows

It should be noted that the **difference in** [**medicine**](http://gmpnews.ru/terminologiya/medical-products/) **prices between the EEU countries is more conspicuous in the retail segment**, than in the public procurement segment. The prices for some medicinal products differ manifold, and in some cases — **5-10 times** (!). Thus, for the medicinal products included in the Top-5 CC for retail sales volume in value terms at 2016 year-end, the difference in maximum and minimum prices for the medicine dose were the following: Kagocel — 1.8 times, Actovegin – 2.1 times, Ingavirin – 2.2 times, Cardiomagnyl – 2.3 times, Detralex — 3.3 times. In Top-5 INN (international nonproprietary names) in the public procurement segment, the maximum price for the medicine lenaninomide exceeded the minimum one-fold, for rituximab – 1.3 times, for transtuzumab — 1.5 times, for [insuli](http://gmpnews.ru/terminologiya/insulin/)n glargine – 1.6 times, for bortezomib – 2.1 times. Difference in prices opens up great opportunities for redistribution of goods from the countries where they cost cheaper, into the countries where they are more expensive. It is important that such a redistribution of import flows will lead to the price equalization. However, all this will become possible only in case of no barriers to parallel importing.

In course of study, it was shown that parallel importing would have a great impact on the situation in the single pharmaceutical market. But redistribution of goods will affect the pharmacy segment and the public procurement segment in different ways. In the absence of barriers for goods redistribution in the retail market, product redistribution will affect about 23.5% ($2.7 billions) of the range, and in the public procurement segment — 88% ($4.9 billions).

b. Foreign Exchange Differences

The dynamics of the exchange rates of EEU countries largely depends on the prices for oil and gas. Their slump in 2015 led to devaluation of national currencies. These fluctuations strongly affected the commodity flows between Kazakhstan and Russia. At the present time, the exchange rates in EEU countries have been stabilized and synchronized, but have become more in line with Russian tendencies. However, despite the fact that there is a correlation between the exchange rates, the existing difference creates background for redistribution of goods in EEU markets.

c. Harmonization of VAT Rates and Margin Levels in the Supply Chain

It is expected, that in conditions of single market the final prices for [medicinal products](http://gmpnews.ru/terminologiya/medical-products/) will be equalized. Moreover, **the rate of VAT** on this type of goods **will be agreed** between the EEU member states. At the present time, there is no VAT on [medicinal products](http://gmpnews.ru/terminologiya/medical-products/) in Kazakhstan and Belarus, in Armenia it is 20%, in Kyrgyzstan – 12%, in Russia – 10%. If the VAT rates are not leveled, the conditions will be created in which the countries with lower VAT will become more attractive to distributors. After all, at averaged final prices in this situation they will receive a large margin. This can lead to a shortage of pharmaceutical products in countries with higher VAT. Meanwhile, not all the countries are ready to introduce a single VAT rate. The states having high VAT level would not like to reduce it because this will reduce tax revenue. Kazakhstan fears that the introduction of VAT will disimprove the situation of local pharmaceutical manufacturers. In either event, the introduction / change to increasing or decreasing the VAT rate will affect the price of medicinal products in all countries. Nevertheless, this will be a one-time impact.

In conditions of averaged final prices, the distributors may prefer to purchase goods in those countries where the manufacturers sell it at the lowest prices. At the same time, they may be scared away by high logistics costs and undeveloped infrastructure, which can also affect the economical and physical accessibility of pharmaceutical products.

What Will Happen After Start-Up of Single Pharmaceutical Market?

1. Reduction of Market Volume

According to the forecasts of QuintilesIMS analysts, only the equalization of final prices will decrease the aggregate **volume of the pharmaceutical market of EEU countries by 6%** from $17.2 billion in 2016 to $16.2 billion in future. The greatest impact in this case will be observed in the public procurement segment. It is estimated that its total volume within the framework of EEU will decrease by $1 billion. It is not so critical, but the retail market will also decrease in volume. There will be a loss of $100 million. This will be an additional saving received by the consumers and state budgets at the expense of price equalization and harmonization of markets. At the same time, the consumers from Russia, Kazakhstan, and Belarus will benefit most from the single market, as far as 76% ($788 million) from the «lost billion» will be for Russia, 17% ($176 million) — for Kazakhstan, 5% ($56 million) – for Belarus. Kyrgyzstan and Armenia will have only 1% each.

In the context of therapeutic groups, **anti-infective agents (J group) and oncological agents and immunomodulators (L group)** will be most affected from the point of view of price reduction.

2. Impact on the Market Volume

Single pharmaceutical market functioning implicates the harmonization of medicine registration procedure and its acknowledgement in the markets of EEU countries, thus the medicinal products that have been registered in one country can be sold in other countries. The largest number of pharmaceutical products is registered in Russia, and if all of them are exported to the markets of EEU countries, the range of products will expand, especially in the public procurement segment. This will create conditions for product range expansion and for new purchases (especially in the public procurement segment), and, therefore, will lead to an increase in market volume by 2% in physical terms. This effect will be manifested in a greater degree in Kazakhstan and Belarus, and in Armenia and Kyrgyzstan it will be less visible due to the small capacity of the markets.

3. Assignment of “Local” Status to All Manufacturers of EEU countries

Now all the EEU countries give support to the domestic manufacturers. At the same time, the most effective support tool is the preferences in public procurement. Meanwhile, **only Russia**, of all the EEU member states, **has granted the “local” status to all the Union manufacturers**. The analysis revealed that the prices for some medicinal products manufactured in Kazakhstan and Belarus are lower than in Russia. This means that they can win a tender and increase their production and sales. For Russian manufacturers it, on the contrary, means losses, while for foreign manufacturers, in general, it means the exit of tender system. As a result, the share of local manufacturers in physical terms in the public procurement segment of Russia will increase by 26%.

Conclusions

Summarizing all the effects, we can conclude that **a single pharmaceutical market will lead to lower prices for medicinal products, and the main driving force of this process will be parallel importing**. Largely, this effect will be expressed in the segment of public procurement. Price equalization will bring the consumers (governments and population) a saving of 6%. For pharmaceutical manufacturers it means losses, which, however, are partially compensated by harmonization of registration procedure of medicinal products. In general, taking into account losses due to price equalization and savings brought by harmonization of the registration procedure, revenues of pharmaceutical manufacturers from the current sales may decrease by $0,5 billion (-3% from today’s market volume). Localization rules in Russia will provide a 26% growth potential for Kazakh and Belarusian manufacturers. An important factor is the VAT rates. Countries with a lower rate will be more attractive to the distributors. In this case, a commodity deficit may spring up in markets with high VAT rate. Russia is the only exception. In view of large capacity of Russian market, and the developed pharmaceutical industry, the problem of physical availability of medicinal products shall scarcely arise there. Another factor that may cause product deficit is high logistics costs and undeveloped infrastructure. The countries with such peculiar properties will be less attractive to the distributors of pharmaceutical products.

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