Survey results
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Introduction

Since the end of 2014, the Russian pharmaceutical industry has been affected by the overall economic situation in the country (devaluation of the national currency, economic slowdown and decreasing purchasing power of the population etc.) and the global geopolitical situation (sanctions imposed against Russia, etc.). All the above has translated into the necessity for government action including adjustments to certain legislative provisions (for example, with respect to the regulation of prices for vital and essential drugs) and the actual implementation of the previously announced policy aimed at import substitution to meet state and local needs (for example, in February 2015 the Government adopted a resolution on restrictions for certain medical devices, and a corresponding draft resolution concerning medicines has been submitted to the government for consideration).

Despite the current state of the Russian economy and key drags on market development (flaws in industry regulation and insufficient governmental funding in certain areas), the majority of industry players are still optimistic about the growth potential of the Russian pharmaceutical industry. This optimism is proven by the actions of businesses aimed at the construction of manufacturing facilities in Russia and establishment of alliances between foreign and Russian companies. However, economic factors may affect the plans of foreign companies that are considering production localization with respect to the method of localization and timing. Companies that already have localization projects underway may have to increase the processing depth in Russia (depending on how the government establishes the criteria for defining the local product) in order to be able to participate in public procurement.

In this third edition of Deloitte’s annual survey of the Russian pharmaceutical industry, respondents share their opinions on various aspects of the pharmaceutical industry: effects of legislative changes, main issues faced by the pharmaceutical industry, expectations and strategic business development trends. Furthermore, we analyzed the change in the opinions of market participants with respect to the key issues concerning the Russian pharmaceutical market over the past two years.

Over 70 respondents representing 50 Russian and foreign manufacturers of original medicines and generics in Russia and abroad, and pharmaceutical distributors participated in the survey. We would like to thank all respondents for providing their expert opinions on the current development of the pharmaceutical market and prospects for its growth in Russia over the next few years.

We hope you will find this survey interesting and useful.

Yours sincerely,

Oleg Berezin
Partner,
Head of the LSGHC Group, Deloitte CIS
Russian pharmaceutical industry: current situation and forecast

Key market indicators analysis
The Russian pharmaceutical market remains one of the fastest growing in the world with an average annual growth rate (from 2008 to 2014) of about 14 percentage points (pp).

Market volume: dynamics and forecast, RUB billion

Source: DSM Group (data includes parapharmaceutical products)

In 2015, the Russian pharmaceutical market is expected to continue to grow. Various expert groups expect 11-15 pp growth. In particular, DSM Group experts forecast market growth in rubles of 12 pp up to RUB 1.3 billion. However, the USD value of the Russian pharmaceutical market is forecast to decrease by 18 pp to USD 24.8 billion due to ruble devaluation.

Market volume: dynamics and forecast, USD billion

Sources: DSM Group, Ministry of Economic Development, Deloitte estimates
According to DSM Group, in 2015 finished pharmaceutical products in the state sector will grow by 5 pp in monetary terms, while in 2014 the state sector grew by 10. According to forecasts by RNC Pharma, the hospital segment will stagnate from +5 pp to -10 pp.

It should be noted that in 2014, public procurement accounted for 30% of the total market excluding parapharmaceuticals, while, according to forecasts by DSM Group, the state sector will slightly decrease in 2015 (28%).

**Market volume, RUB billion**

<table>
<thead>
<tr>
<th>Year</th>
<th>Commercial segment of finished pharmaceutical products</th>
<th>Commercial segment of parapharmaceutical products</th>
<th>State segment of finished pharmaceutical products</th>
<th>Share of state procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>406</td>
<td>118</td>
<td>211</td>
<td>29%</td>
</tr>
<tr>
<td>2011</td>
<td>468</td>
<td>130</td>
<td>225</td>
<td>27%</td>
</tr>
<tr>
<td>2012</td>
<td>537</td>
<td>149</td>
<td>234</td>
<td>25%</td>
</tr>
<tr>
<td>2013</td>
<td>609</td>
<td>169</td>
<td>267</td>
<td>26%</td>
</tr>
<tr>
<td>2014</td>
<td>675</td>
<td>183</td>
<td>294</td>
<td>26%</td>
</tr>
<tr>
<td>2015</td>
<td>776</td>
<td>201</td>
<td>309</td>
<td>24%</td>
</tr>
</tbody>
</table>

**Market volume, million units sold**

<table>
<thead>
<tr>
<th>Year</th>
<th>Commercial segment of finished pharmaceutical products</th>
<th>Hospital purchases and extensive drug coverage</th>
<th>Share of hospital purchases and extensive drug coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>4,437</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2011</td>
<td>4,480</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>4,458</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>4,429</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>4,223</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sources:** DSM Group
The commercial segment of parapharmaceutical products is expected to grow by 10 pp in rubles, while in 2014 this sector grew by 8 pp.

The commercial sector for finished pharmaceutical products is expected to grow by 15 pp (2014: 11 pp) which is higher than in other segments and the pharmaceutical market as a whole. The faster growth of the commercial segment can be explained by inflation and rising retail consumption at the expenses of a decreasing share of the public procurement.

According to DSM Group, in 2014 Russian-produced medicines comprised 24.3% of the commercial retail market while dominating pharmacy sales in terms of units sold (55.3%). It should be noted that in 2014, as compared to 2013, the share of domestic medicines declined by almost 2 pp in physical terms, while it remained unchanged in monetary terms. According to forecasts by DSM, in 2015 medicine consumption will decrease by 4-5 pp in terms of units sold.

Under the Federal Special-Purpose Program Development for the Pharmaceutical and Medical Industry up to 2020 and Beyond (“Pharma - 2020”), in 2020 not less than 90% of items included in the list of vital and essential drugs (VED) should be manufactured locally. Currently, according to the Ministry of Industry and Trade of the Russian Federation, 68% of medicines included in the VED list (413 out of 608) are manufactured in Russia as finished dosage forms. However, these statistics are not representative of the number of VED manufactured from Russian active pharmaceutical ingredients (APIs). Therefore, the evaluation of the efficiency of Pharma-2020’s implementation in terms of import substitution with full-cycle production in Russia is currently a complex task.

Thus, the key trends of the pharmaceutical market are as follows:
1. Finished pharmaceutical products sold in the commercial sector will account for the major growth.
2. The price per unit will continue growing due to the expected increase in market size by value and the projected decline in volume of units sold.
3. There is gradual growth (though not fast enough) in the share of domestic drugs in terms of value, and substantial growth in the share of domestic drugs in terms of volume as well as the number of items on the VED list. However, given the depth of localization, the recent performance indicators may not be entirely optimistic.

Sale price indices in 2014

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-vital drugs</td>
<td>15.8%</td>
</tr>
<tr>
<td>Vital drugs</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

Source: Roszdravnadzor and DSM Group

Vital and essential drugs sale price indices in 2014

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over RUB 500</td>
<td>3.9%</td>
</tr>
<tr>
<td>From RUB 50 to RUB 500</td>
<td>4.7%</td>
</tr>
<tr>
<td>Up to RUB 50</td>
<td>7.2%</td>
</tr>
<tr>
<td>Imported vital and essential drugs</td>
<td>5.7%</td>
</tr>
<tr>
<td>Russian vital and essential drugs</td>
<td>9.7%</td>
</tr>
</tbody>
</table>
Inflation, forecast for 2015

![Inflation chart]

Source: up to Q1 2015 DSM Group, Roszdravnadzor, Rosstat; 2015: forecast by Deloitte


According to the Russian Federal State Statistics Service, in March 2015, inflation in Russia slowed down by 1.2 pp versus 2.2 pp in February and 3.9 pp in January 2015,

The cost of the minimum food basket in Russia on average grew by 1.2 pp at the end of March 2015 (by 13.7 pp year-to-date).

In general, the Russian pharmaceutical market is experiencing sales price growth at 11.2 pp (year-on-year as at the end of 2014).

The major growth in sales prices is seen in the non-regulated segment, i.e. medicines not included in the VED list, and the price growth index in this segment is more than twice as high as in the segment of VED (15.8 pp and 6.6 pp respectively).

In the segment of vital and essential drugs, medicines up to RUB 50 (7.2 pp) and Russian-produced medicines (9.7 pp) account for the major growth of sale prices.

At the end of 2014, inflation of medicines exceeded the overall national inflation (12.7pp vs 11.4pp). Deloitte predicts that in 2015 the medicine inflation rate will rise (to about 15 pp) with the overall inflation rate slightly decreasing (to 10 pp).
The position of the Russian pharmaceutical market in the world

According to the most recent data from IMS Health and Economist Intelligence Unit (EIU), Russia ranks 11th among 15 countries according to per capita consumption of medicines (in US dollars) with Brazil closing the Top-10. In the short term, no major changes in per capita consumption of medicines are expected.

Per capita consumption of medicines, USD

Source: EIU, IMS

In addition, Russia is not a top ten country in terms of sales of pharmaceutical products in US dollars (Rx and OTC drugs). According to forecasts by the EIU, in 2018 Russia will rank 17th in the rating. Last year’s forecasts by IMS Health were more optimistic, however, estimates may be revised due to the ruble’s devaluation.
However, according to more complimentary data from DSM Group, Russia is a top ten country by consumption (per capita) of medicines in 2014, though its consumption is three times lower than the European average and five times lower than that in the USA. Furthermore, according to DSM Group, the per capita consumption of medicines in Brazil is lower than in Russia (by USD 19).
In general, based on forecasts by EIU, IMS Health and DSM Group with respect to per capita consumption of medicines in different countries in 2018, the key trends of the global pharmaceutical market may be presented as follows:

1. The USA is the market leader in per capita consumption, and this is expected to remain unchanged.
2. Despite the high growth rates experienced by the pharmaceutical markets of developing economies, the gap between the per capita consumption of developed markets is still wide.
3. A high growth rate of per capita consumption is expected in China (the world’s second largest pharmaceutical market). However, per capita consumption of medicines in China will only be approximately 9% of per capita consumption in the USA.
Key issues in the Russian pharmaceutical market

For the purposes of an in-depth analysis of Russian pharmaceutical market trends, Deloitte conducts an annual survey involving an expert discussion on key issues and their remedy.

During our study, we asked industry representatives to select and prioritize the three most significant issues facing the current Russian pharmaceutical market. As a result, we received a top list of issues faced by pharmaceutical and healthcare companies in Russia today.

**Top list issues**

Please, select and prioritize the top three issues faced by pharmaceutical and healthcare companies in Russia today.

<table>
<thead>
<tr>
<th>Issue</th>
<th>2013</th>
<th>2014</th>
<th>2015*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current economic situation*</td>
<td>5%</td>
<td>11%</td>
<td>9%</td>
</tr>
<tr>
<td>Insufficient solvency of individuals*</td>
<td>36%</td>
<td>28%</td>
<td>24%</td>
</tr>
<tr>
<td>Shortcomings in the sector’s legal regulation including pricing, antimonopoly, administrative etc.</td>
<td>25%</td>
<td>17%</td>
<td>15%</td>
</tr>
<tr>
<td>Lack of state funding for healthcare programs and support for Russian manufacturers</td>
<td>10%</td>
<td>14%</td>
<td></td>
</tr>
<tr>
<td>Geopolitical situation, related economic risks and negative consequences for the Russian market</td>
<td>24%</td>
<td>22%</td>
<td>6%</td>
</tr>
<tr>
<td>Corruption</td>
<td>2%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Increased competition in the market</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High proportion of counterfeit products</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Trend:

Over the past two years, flaws in the sector’s legal regulation have been the main concern of the representatives of the pharmaceutical industry. This year, however, the current economic situation. This result is representative of the pharmaceutical market’s sensitivity to external factors such as geopolitical and currency risks.

*In 2015 this indicator was divided into two separate options*
Key issues of Russian pharmaceutical market development in 2015:
• Current state of the Russian economy (26%)
  This issue is of particular importance to manufactures of original medicines and distributors (26% and 28% respectively) and for overseas companies with no local manufacturing content (40%).
• Flaws in the sector’s legal regulation (24%)
  This issue is of more importance to distributors (29%) and Russian companies (31%).

Besides the above listed issues, the following are a matter of concern for industry players, albeit to a lesser extent:
• Lack of state funding for healthcare programs and support of Russian manufacturers (15%)
  This issue is of more importance to manufacturing companies (17%-19%).
• The current geopolitical situation and related economic risks (14%)
  This issue is slightly more important to pharmaceutical distributors (17%).

In view of the above, the Russian pharmaceutical market currently has the following flaws:
1. High dependence on imported medicines and APIs;
2. Focus on local consumption;
3. Rigidity of pricing regulation for pharmaceutical products (please, see below the section on Priority government regulation areas to be improved);
4. Lack/inefficiency of state support for local manufactures (please, see below the section on Government measures aimed at reducing the share of imported medicines).

Additional notes
Minimizing the dependency of the Russian pharmaceutical market on imports and boosting exports of pharmaceutical products are the key challenges for the Strategy of the Development of the Russian Federation’s Pharmaceutical Industry by 2020. Today, top importers of Russian pharmaceutical products are former Soviet republics: Uzbekistan (19%), Ukraine (15%), Kyrgyzstan (6%), and Azerbaijan (5%) (according to RNC Pharma, 2014). Despite the upward trends in the growth of exports of Russian pharmaceutical products in recent years, the trade deficit for this item proves that Russia is still a netto-importer of pharmaceutical products.
As part of the creation of the single market of the Eurasian Economic Union (EEU), its participants signed agreements on unified principles and rules of the circulation of medicines and medical devices. These agreements provide for uniform rules for the registration of medicines and medical devices, uniform production standards, uniform rules for clinical studies etc. However, a single market will hardly be an adequate driver of Russian exports due to the small capacity of other EEU members states’ markets.

Purchasing solely locally produced medicines for state needs (see below the section on Government measures aimed at reducing the share of imported medicines) is aimed at minimizing the Russian market’s dependency on imported finished medicines and APIs.

In light of the relevant amendments to the law “On the circulation of medicines”, the Ministry of Health of Russia is developing new approaches to the pricing on vital and essential drugs allowing for drug price indexation depending on the relevant price segment, as well as on imported vital and essential drugs. These efforts aim to create a more flexible pricing regulation framework for pharmaceutical products.

The draft government resolution prepared by the Ministry of Industry and Trade sets forth the procedure and terms for granting subsidies to Russian companies to reimburse a portion of the costs incurred in the implementation of projects related to the production of medicines and/or APIs. In particular, the maximum subsidy per company may not exceed RUB 100 million (no more than 50% of the actually incurred costs and no more than RUB 25 million per one international non-proprietary name obtained by chemical synthesis and RUB 50 million per one international non-proprietary name obtained by biotechnological synthesis). The Federal Law “On the federal budget for 2015 and for the planning period of 2016 and 2017” provides for a total of RUB 891.7 million as subsidies for these purposes.

Russian companies involved in the implementing advanced technology, creating new products or establishing import substituting production may also receive target loans from the Fund for Industrial Development at a rate of 5% per annum. In addition, pharmaceutical companies may obtain a subsidy to reimburse a portion of loan interest costs under loans received for working capital and/or current production operations needs, in accordance with Resolution of the RF Government No. 214 dated 12 March 2015.
We asked our respondents about their plans for future development, and then compared their answers with those of last year’s survey.

**Trend:**
In general, sustained strategic benchmarks for business development have been presenting themselves in the Russian pharmaceutical market. Similarly to previous years, the majority of companies plan to introduce new medicines to the Russian market. Furthermore, a general trend has been persisting - a focus on localization through building new production facilities in the Russian Federation and establishing joint ventures.

### What are your business development plans for the next two years?

<table>
<thead>
<tr>
<th>Plan</th>
<th>2013</th>
<th>2014</th>
<th>2015*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introducing new medicines to the Russian market</td>
<td>47%</td>
<td>34%</td>
<td>57%</td>
</tr>
<tr>
<td>Establishing new production facilities in Russia</td>
<td>29%</td>
<td>15%</td>
<td>36%</td>
</tr>
<tr>
<td>Establishing a joint venture with a Russian (foreign) manufacturer</td>
<td>13%</td>
<td>19%</td>
<td>28%</td>
</tr>
<tr>
<td>Business acquisitions or mergers</td>
<td>3%</td>
<td>13%</td>
<td>16%</td>
</tr>
<tr>
<td>No significant changes</td>
<td>8%</td>
<td>11%</td>
<td>15%</td>
</tr>
<tr>
<td>Divesting and/or selling a non-core (non-priority) business unit</td>
<td>8%</td>
<td>7%</td>
<td></td>
</tr>
</tbody>
</table>

*In 2015, this was a multiple choice question*
The Top-3 business development strategies remain unchanged for 2013-2015:
1. Introducing new medicines to the Russian market (57%)
2. Establishing new production facilities in Russia (36%)
   Mainly Russian companies (63%) and non-localized foreign companies (38%) are pursuing this strategy.
3. Establishing a joint venture with a Russian (foreign) manufacturer (28%)
   These are primarily manufacturers of original medicines (35%).

Additional notes
• 29% of distributors plan no significant changes to their business (most likely due to the high concentration of wholesale pharmaceutical businesses and the prevailing availability of production facilities typically orientated towards contract manufacturing) unlike manufacturers of original medicines none of which selected the “No significant change” response for their core strategy.
• The horizontal integration strategy is more often mentioned by foreign companies (23% — localized and 21% — non-localized).
• Only manufacturers of original medicines (12%), represented primarily by localized foreign companies (15%), are following the strategy of divesting and selling a non-core business unit.
• 70% of CEOs mentioned establishing a joint venture over the next two years as a priority business development strategy.
One of the key targets of the program «Pharma-2020» is reducing the share of imported medicines. For the purposes of an independent evaluation of the efficiency of this program, we regularly ask respondents to our pharmaceutical market surveys about whether they expect any changes to the share of imported medicines in Russia.

**Economy of expectations: the share of imported medicines in Russia**

**How will the share of imported medicines in the Russian market change over the next two years?**

Number of respondents expecting a reduction in the share of imported medicines in the Russian market over the next two years

![Bar chart showing the percentage of respondents expecting a reduction in the share of imported medicines from 2013 to 2015.](image)

**Trend:**
Over the last three years, a steadily growing number of respondents have been expecting a reduction in the share of imported medicines in the Russian market within the next two years.

The majority of survey respondents believe that the share of imported medicines will be decreasing both in monetary terms (68%) and in terms of units sold (75%) over the next two years with a significant decrease (from 10 pp) more often forecast specifically in terms of units sold (43%), while the growth of the share of imported medicines is more often mentioned in monetary terms (26%).
Expectations from changes in the share of imported products in monetary terms and in terms of units sold

**Trend:**
The average level of the expected decrease in the share of imported medicines in monetary terms does not exceed the average level of the expected decline in the share of imported medicines in kind, which indirectly suggests the expected price growth in the market.

**Additional notes**
The forecast for the change in the share of imported medicines in the Russian pharmaceutical market correlates with the job functions of respondents:

- Thus, the increase in the share of imported medicines is mentioned solely by representatives of commercial and financial functions. CEOs are strongly inclined to forecast a decrease in the share of imported medicines in the market over the next two years with the majority of them (64%) expecting a significant decrease in the share of imported medicines over the next two years (by 10 pp or more).

It should be noted that the forecast for the change in the share of imported medicines in the Russian pharmaceutical market correlates with business development strategies:

- Companies contemplating horizontal integration (mergers and/or acquisitions) forecast growth in the share of imported medicines (40%) more often than other companies.
- The decrease in the share of imported medicines is primarily expected by companies planning to set up a joint venture with a Russian (foreign) manufacturer; in particular, 41% and 65% of respondents expect a significant decrease in monetary terms and in terms of units sold, respectively.
Government measures aimed at reducing the share of imported medicines

Import substitution targets are defined in the Development of Pharmaceutical and Medical Industry for 2013-2020 state program. During our study, we asked representatives of the pharmaceutical industry what government measures, they believe, could have the biggest effect on the share of imported medicines in the Russian market.

What government measures could have the biggest effect on the reduction of the share of imported medicines in the Russian market?

- **Restricting or banning foreign (non-localized) manufacturers from state purchases**: 24% (2014), 57% (2015*)
- **Encouraging foreign manufacturers to switch to full-cycle production by granting various privileges and preferences (including for state purchases), and boosting investments in innovative Russian pharmaceutical projects**: 25% (2014), 56% (2015*)
- **Government support for Russian manufacturers through granting subsidies and privileges/preferences (including for state purchases), and boosting investments in innovative Russian pharmaceutical projects**: 20% (2014), 49% (2015*)
- **Indexation of registered prices for locally-produced vital and essential drugs, and no indexation (or a slower rate of indexation) for vital and essential drugs produced abroad**: 11% (2014), 29% (2015*)
- **Introducing a more complicated procedure for the registration of imported medicines, and/or simplifying this procedure for medicines already registered (approved) abroad for their further manufacturing in Russia**: 12% (2014), 24% (2015*)
- **Anti-corruption measures aimed at increasing competition**: 8% (2014), 15% (2015*)

*T in 2015, this was a multiple choice question*

**Trend:**
As compared to the 2014 survey findings, differentiation of registration procedures for medicines depending on their localization of production and anti-corruption efforts have become slightly lower priorities. On the whole, the top three measures aimed at reducing the share of imported medicines in the Russian pharmaceutical market have remained quite stable.
The following government efforts were identified as having the maximum potential to reduce the share of imported medicines (Top-3):

1. Restricting or banning foreign (non-localized) manufacturers from state purchases (57%)
   *This measure is of higher value to distributors (65%) and non-localized foreign companies (69%).*

2. Encouraging foreign manufacturers to switch to full-cycle production (56%)

3. Government support for Russian manufacturers through the granting of various subsidies (including for state purchases) and boosting investments into innovative Russian pharmaceutical projects (49%)
   *Manufacturers of generics (57%) and Russian companies (62%) lay great hopes on state support for Russian manufacturers.*

Additional notes
Manufacturers of generics (29%) generally view anti-corruption efforts as an effective measure to reduce the share of imported medicines.

Currently, Order of the Ministry of Economic Development No. 155 dated 25 March 2014 sets a preference of 15% for local manufacturers of medicines purchased for state and municipal needs effective until 31 December 2015.

In February 2015, the Ministry of Industry and Trade of the Russian Federation submitted a draft resolution to the RF Government restricting state purchases of medicines. Under this draft resolution, imported medicines will not be admitted to the bidding procedure if there are two or more bid applications submitted by drug manufacturers from the EEU. However, the criteria for qualifying the product as originating from the EEU are still unclear. The Ministry of Industry and Trade of the Russian Federation has also prepared a draft government resolution providing for the criteria for qualifying certain products, including pharmaceuticals and medical devices, as goods produced in the Russian Federation. In particular, it is expected that depending on their category, medicines will be deemed produced in Russia provided that, starting from a certain date (1 January 2019-2023), they are produced from an API by a legal entity residing in an EEU country or that an API is produced in the EEU (depending on the category of drugs).

Restrictions on state purchases of imported medical devices included in the relevant list were introduced by RF Government Resolution No. 102 dated 5 February 2015, and the Treaty on the Rules for Determining the Country of Origin of Goods in the CIS should be used for the purposes of identifying the country of origin of medical devices under the Resolution.
We tracked the changes related to the enforcement of Federal Law No. 44-FZ "On the procurement of goods, work and services to meet state and local needs" effective 1 January 2014.

How did the introduction of the state procurement system affect the pharmaceutical industry?

- **New legislation will result in no dramatic change in public procurement**: 25% (2014) vs. 28% (2015)
- **More sophisticated bid procedure**: 28% (2014) vs. 32% (2015)
- **Increased competition in the public procurement of medicines due to the weakening of barriers**: 9% (2014) vs. 17% (2015)
- **Decreased corruption due to open discussions of government purchases**: 16% (2014) vs. 9% (2015)
- **Increased corruption in public purchasing**: 13% (2014) vs. 9% (2015)
- **Exclusion of suppliers whose products fail to meet quality standards**: 9% (2014) vs. 5% (2015)

**Trend:**
Currently, representatives of the pharmaceutical market have been affected by increased competition in public procurement to a greater extent (by 8 pp) as a result of the introduction of the state procurement system. Reducing corruption is mentioned less frequently (by 7 pp).

In general, the perception of the consequences of the new legislative efforts has been quite stable, with 28% of respondents expecting no dramatic changes.
The main consequences of introducing the state procurement system:

- A more sophisticated bid procedure (32% of respondents)
  This is mentioned solely by representatives of companies engaged in the production of original medicines (as tenders are conducted for international non-proprietary names) and distributors (as it is distributors who typically participate in tenders) (30% and 35% respectively).

- Increased competition in public procurement of medicines due to weaker barriers (17% of respondents)
  Increased competition in public procurement is more frequently mentioned by manufacturers of generics and distributors (29% and 23% respectively).

Additional notes

- Manufacturers of generics mention the exclusion of suppliers whose products fail to meet quality standards more often (by 10 pp).
- Russian companies mention decreased corruption in the procurement process more often (14%).
- Localized foreign companies proved to be two times more sensitive to the increased competition in the state procurement of medicines due to weakened barriers (31%). Furthermore, these companies note the complication of the bid procedure (38%).
Similarly to last year, we interviewed our respondents to find out what areas of state regulation they believe to be in particular need of improvement.

<table>
<thead>
<tr>
<th>What areas of state regulation, in your opinion, are in particular need of improvement?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pricing regulation for medicines, including the procedure for updating the list of vital and essential drugs and their pricing regulation</td>
</tr>
<tr>
<td>Regulation of public procurement (for example, application of preferences or restrictions in public purchasing; purchasing by brand names)</td>
</tr>
<tr>
<td>State registration of medicines</td>
</tr>
<tr>
<td>Tax regulation, including transfer pricing</td>
</tr>
<tr>
<td>Regulation of drug promotion practices</td>
</tr>
<tr>
<td>Unification of the legislation on the circulation of drugs and pharmaceutical products within the EEU</td>
</tr>
<tr>
<td>Granting preferences to Russian manufacturers</td>
</tr>
<tr>
<td>Intellectual property rights protection</td>
</tr>
</tbody>
</table>

* In 2015, it was a multiple choice question

**Trend:**
In 2015, the necessity of improvements to the procedures for the state registration and promotion of medicines is rising.

On the whole, the priority areas of state regulation in need of improvement did not change much, with 2014’s trends only strengthening.
The following areas are in particular need of improvement (Top-3):

1. Pricing regulation for medicines (63%)
   This issue is of more importance to manufacturers of original medicines and distributors (73% and 62% respectively).

2. State procurement (41%)
   This issue is of higher priority to manufacturers of original medicines (by 9 pp) and to localized foreign companies as a whole (56% of localized companies and 45% of non-localized companies) than to Russian companies (24%).

3. State registration of medicines (41%)
   This issue is critical for manufactures of generics (71%).

Additional notes:
- Intellectual property rights protection is of higher priority to manufacturers of original medicines (by 10 pp above the average).
- The regulation of medicine promotion practices and granting privileges to local manufacturers is of higher importance to manufacturers of generics (by 10 pp and 13 pp above the average respectively).
- The regulation of medicine promotion practices and tax regulation are of higher importance to distributors (by 12 pp and 9 pp above the average).
- Russian companies place higher value on the provision of preferences to local manufacturers (33%) (a Top-3 issue for this group).
- Localized foreign companies are much more concerned about the unification of the legislation on the circulation of medicine within the EEU (38%) (a Top-3 factor for this group).
- CEOs more often mention the necessity of improving the regulation of pricing on medicines (82%). The unification of the legislation on the circulation of medicine within the EEU is also of higher priority to them (36%).
In 2014, a large number of legislative initiatives in the area of healthcare and pharmaceutical regulation were adopted. Below are the most significant of them:

- The Federal Law “On the circulation of medicines” defines a number of terms, such as ‘biological medicine’, ‘interchangeable medicines’ etc. for the first time.

- Effective 16 March 2015, the RF Government shall have the right to prescribe mechanisms of state regulation of maximum sales prices on vital and essential drugs depending on economical and/or social criteria.

- Both Russian and foreign manufacturers are subject to the indexation of prices on vital and essential drugs following the application submitted prior to October 1 of every year.

- At the end of 2014, a new list of vital and essential drugs as well as, a new list of medicines under the “seven rare diseases” program.

- RF legislative acts related to counteracting counterfeit drugs have been amended.

- Optimization and simplification of certain procedures for the state registration of medicines.

- A new procedure for monitoring the efficiency and safety of medicines circulating in Russia (pharmacovigilance) has been introduced.

- Transfer of the deadline for the transition to GMP standards to 1 January 2016.

We interviewed representatives of pharmaceutical companies to find out in what way legislative efforts have affected their businesses in Russia.

Please select the statement that most accurately describes the effect of legislative initiatives in the area of healthcare and pharmaceutical regulations on your company’s business in Russia.

<table>
<thead>
<tr>
<th>Statement</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Our business is primarily affected by the market environment rather than legislative initiatives</td>
<td>8%</td>
<td>24%</td>
</tr>
<tr>
<td>Impossible to estimate the effects at the moment</td>
<td>12%</td>
<td>22%</td>
</tr>
<tr>
<td>Increased legal risks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Necessity of revising the business model</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased production/sales costs</td>
<td>22%</td>
<td>13%</td>
</tr>
<tr>
<td>Creating additional opportunities for product promotion in the Russian market</td>
<td>20%</td>
<td>12%</td>
</tr>
<tr>
<td>Decreased costs/risks of doing business</td>
<td>2%</td>
<td>9%</td>
</tr>
</tbody>
</table>

We interviewed representatives of pharmaceutical companies to find out in what way legislative efforts have affected their businesses in Russia.
The key 2015 trend is that market conditions are steadily gaining more value over legislative initiatives (which is supported by the closed nature of the Russian pharmaceutical market and its dependence on imports). Indeed, by 2015, the share of companies sensitive to structural market changes in the pharmaceutical industry has risen by 16 pp.

The number of respondents uncertain about the effect of legislative initiatives has grown significantly (by 10 pp).

The main consequences of legislative initiatives:

1. Increased legal risks (19%)
   *Compared to 2014, much fewer respondents mentioned increased legal risks (by 17 pp).*

2. The necessity of revising business models (13%)

3. Increased production/sales costs (12%)
   *By 2015, the number of companies planning to and having to revise their business models and increase their production/sales costs (due to legislative changes) declined by nearly two times.*

Additional notes:

- On the whole, foreign companies experience greater difficulties in assessing the impact of RF legislative changes (25%) than Russian companies do (14%).
- Legislative initiatives offer additional opportunities only to Russian companies (19%) and localized foreign companies (12%).
- Additional opportunities resulting from legislative initiatives are more often mentioned by manufacturers of generics (22%).
- Increased legal risks (25%) and increased production costs (19%) affect localized foreign companies more seriously.
- None of the CEOs indicated that the legislative initiatives create additional opportunities for their businesses.
About our respondents

The majority of respondents to our survey are representatives of foreign companies (69%) with every second being a representative of a non-localized foreign company (45%) and every forth (24%) — a representative of a localized foreign company.

One in three (31%) is a representative of a Russian company, while last year, only 14% of the participants in the survey were Russian companies.

The majority of respondents represent the finance function (58%).

In second place are CEOs (17%) followed by commercial staff (12%).

The majority of respondents represent manufacturers of original medicines (42%).