Development trends and practical aspects of the Russian pharmaceutical industry – 2014
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Introduction

We are delighted to present the 2014 edition of our annual survey, Development trends and practical aspects of the Russian pharmaceutical industry.

The aim of the survey is to show the most important trends in the development of the Russian pharmaceutical market, which, in our opinion, have a significant effect on the strategic decisions taken by market participants. Our report is based on the opinions of the respondents and those of industry experts and analysts.

The issues detailed in this report are very similar to those covered last year. We have explored how the opinions and expectations of respondents have changed with regard to various aspects of the development of the Russian pharmaceutical industry.

In our view, one of the key factors of industry development is gradual market saturation, resulting in a reduced rate of growth. However, in comparison with the markets in Europe and the USA, the Russian pharmaceutical market is growing more rapidly and continues to show significant potential.

Moreover, according to our survey, this year market players are more optimistic about meeting the requirements of the Pharma 2020 government programme. These expectations are mainly founded in the enhanced activities undertaken by foreign pharmaceutical companies aiming to achieve localisation in Russia.

Despite the active efforts of legislators in 2013, there are many vital issues that still remain unresolved. It is still unclear how to determine what constitutes a local pharmaceutical manufacturer. Among other outstanding issues, are the pricing procedure for the List of Essential Drugs, which is in need of improvement, as are some purchasing procedures within the state procurement system, and the procedure for compiling the list of drugs which may be purchased by brand names. We believe that the method and speed by which these issues are addressed will be key factors in the future development of the market.

Our respondents are mainly representatives of foreign companies engaged in the production of original medicines in Russia and abroad. We would like to thank all of our respondents for providing their views and expertise on the current situation and the development prospects of the pharmaceutical industry in Russia.

We hope that you find this report both useful and interesting.

Kind regards,

Oleg Berezin
Partner,
CIS Life Sciences & Health Care Industry Group Leader
The Russian pharmaceutical industry is one of the fastest-growing in the world, with annual growth over 10 percent. In 2013, the market turnover was more than RUB 1 trillion.

According to analytical data released by DSM Group, in 2013 the size of the Russian pharmaceutical market increased by almost 14 percent, but in terms of volume it reduced by 2 percent to 5.46 billion packages. The commercial segment of the market (i.e. the sale of medicines and natural pharmaceutical products in pharmacies) increased by 13.5 percent (to RUB 609 billion) during the same period.

At the end of Q1 2014 the Russian pharmaceutical market was up 5.4 percent compared to the same period of 2013, amounting to RUB 284.9 billion. However, in physical terms the pharmaceutical market fell by 3.6 percent: 1.3 billion packages were sold, compared to 1.4 billion during Q1 2013.

Based on these figures, it seems that the growth of the pharmaceutical market has resulted from increased medicine prices in the non-regulated segment, increased inflation and the rapid devaluation of the Russian Ruble. It can also be explained by the fact that people have begun to buy more expensive medicines.

In 2013 medicine prices grew at one of the fastest rates of any segment, along with food, fuel and tourism services.

According to forecasts by DSM Group, in 2014 market growth will be 12 percent. However, IMS Health analysts have halved their forecast for growth in 2014, from an earlier figure of 10 percent to 5 percent.
Besides the slowdown in market growth, one of the most important trends is increased competition in the distribution and retail segments, which has resulted in decreased profitability. In a bid to increase their market share, some distributors are forced to cut price markups that have a direct effect on their profitability.

According to the National Research Institute of Public Health, there are currently 77,000 pharmacies in Russia – an average of one company per thousand people. In contrast, 20 years ago there was one pharmacy for every 9,000 people. In the UK, each pharmacy serves an average of 4,700 people, and in the U.S. each serves around 4,500 people.

According to RNC Pharma, in 2013 the top 15 pharmaceutical distribution companies controlled 87.1 percent of the market. With the current high level of market consolidation, high competition leads to decreased profitability. This is forcing distributors to diversify their business, either by establishing pharmacy chains or building production facilities.

Unlike the EU and the USA, the Russian market is largely controlled by the commercial segment, rather than government purchasing. In contrast, the majority of EU countries compensate 65-80 percent of patients' expenses incurred on purchasing most prescribed medicines.

DSM Group cite that in Q1 2014 the commercial segment controlled 72 percent of the Russian market, inclusive of dietary supplements and natural pharmaceuticals.

Despite the gradual slowdown in market growth and decrease in medicine consumption volume compared to Europe, the Russian pharmaceutical market is experiencing relatively high growth. IMS Health expects the Russian pharmaceutical market to be the eighth largest in the world by 2017.
This year has seen a major slowdown in the growth rate of the Russian pharmaceutical market. Even so, when compared to European countries, it is developing quite dynamically. As the market gradually becomes saturated, companies are forced to become more efficient, update their strategies and seek out new opportunities.

According to DSM Group, the growth rate should remain steady at 10 percent up to 2017. However, although analytical agency IMS Health had earlier forecast growth of 10 percent for 2013-2018, it has reduced its expectations, and now forecasts growth of 8.1 percent during that period.

Because of the unstable political situation, it is impossible to make a long-term growth forecasts for the Russian economy or the pharmaceutical industry; however, the market has huge potential, and many experts expect the targets set within the Pharma 2020 programme to be attained.

Global pharmaceutical concerns that have already invested in the construction of new facilities in Russia are not planning to change their strategies; indeed, having positively assessed the potential of the market, they are working to increase their presence in the country.

### List of countries by pharmaceutical market size

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<tr>
<th></th>
<th>2008</th>
<th>2013</th>
<th>2017</th>
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<tbody>
<tr>
<td>1</td>
<td>USA</td>
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<td>2</td>
<td>Japan</td>
<td>China</td>
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<td>4</td>
<td>France</td>
<td>Germany</td>
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<td>Russia</td>
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<td>9</td>
<td>Spain</td>
<td>Canada</td>
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<td>Russia</td>
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<td>Greece</td>
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<td>19</td>
<td>Poland</td>
<td>Argentina</td>
<td>Indonesia</td>
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<td>20</td>
<td>Belgium</td>
<td>Belgium</td>
<td>Poland</td>
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Source: IMS Health
Share of imported medicines on the Russian market now and in the future

According to DSM Group, in May 2014 Russian medicines comprised 23 percent of the market in terms of value, and 56 percent overall.

A state programme entitled Development of the Pharmaceutical and Medical Industry for 2013-2020 was developed to increase the share of Russian medicines on the Russian market and to provide Russian-made substitutes for imported strategically-important medicines.

Many market experts expect the share of imported medicines on the market to decrease in the near future due to the localisation of foreign companies in Russia.

Based on the IMS Health and the DSM Group forecasts, if the forecasted growth rates remain constant until 2020, the volume of the market will reach the targets set by the Pharma 2020 strategy for 2017-2020.

Market development forecast in accordance with state programme Development of the Pharmaceutical and Medical Industry for 2013-2020

<table>
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<tr>
<th>Indicator</th>
<th>2020</th>
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<tr>
<td>Share of Russian medicines (in monetary terms), percent</td>
<td>50</td>
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<tr>
<td>Medicine exports, billion RUB</td>
<td>75</td>
</tr>
<tr>
<td>Organisations that implement technological innovations in the pharmaceutical and medical industry as a percentage of the total number of manufacturers</td>
<td>50</td>
</tr>
<tr>
<td>Share of Russian medicines in the Nomenclature of Essential Drugs and Strategically-Important Medicines, percent</td>
<td>90</td>
</tr>
<tr>
<td>Share of the pharmaceutical and medical industry in the GDP, percent</td>
<td>0.58</td>
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<tr>
<td>Market volume (innovative scenario of the Pharma 2020 strategy), billion RUB</td>
<td>1,498</td>
</tr>
<tr>
<td>Market volume (inertial scenario of the Pharma 2020 strategy), billion RUB</td>
<td>1,076</td>
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We interviewed representatives of pharmaceutical industry players on their expectations regarding the decreasing share of imported medicines on the Russian market.

46 percent of respondents expect the share of imported medicines on the Russian market to drop by 2016-2017, but by no more than 5-10 percentage points. 31 percent of respondents are of the opinion that, in the same period, the share of imported medicines will reduce by more than 10 percentage points, but only 3 percent of respondents think that such a decline is possible in the next 2-3 years. A fifth of respondents said that the share of imported medicines on the Russian market will only slightly reduce in the next 3-4 years.

It should be noted that last year half of the respondents did not expect the share of imported medicines to drop at all in the foreseeable future.

This shows that market participants are becoming more confident that Russia’s dependency on imported medicines will fall in the coming years, and that the targets set within the state programme will be achieved. The localisation of foreign pharmaceutical manufacturers in Russia, the depreciation of the Russian Ruble and increasing prices for foreign pharmaceuticals in the unregulated segment will help this process along.
Will the share of imported medicines in the Russian market reduce in monetary terms/in kind? 2013

- Yes, in the next 2-3 years: 12%
- Yes, but after 2015-2016: 50%
- No: 38%

How quickly will the share of imported medicines in the Russian market reduce in monetary terms/in kind? 2014

- It will reduce by more than 10 p.p. in the next 2-3 years: 46%
- It will reduce by more than 10 p.p. after 2016-2017: 31%
- It will reduce by no more than 5-10 p.p. by 2016-2017: 3%
- It will reduce by no more than a few p.p. over the next 3-4 years: 20%
Government measures aimed at reducing the share of imported medicines

State procurements in the hospital segment and government financing aimed at providing medicines are two of the main growth drivers of the pharmaceutical industry and the market as a whole. The Russian Ministry of Industry and Trade has suggested the introduction of a differentiated system of preferences for state procurements, providing various privileges to manufacturers depending on their level of localisation, as a result of which foreign manufacturers are interested in localising in Russia and obtaining “Russian producer” status, with all of the benefits that come with it.

We asked industry representatives what government measures could have the biggest effect on the share of foreign medicines on the Russian market.

According to a quarter of the respondents, the most effective government measure in reducing the share of imported medicines on the Russian market would be to encourage foreign manufacturers to switch to full-cycle production by granting various privileges and exemptions, including tax relief. Almost as many (24 percent) think that foreign (non-localised) manufacturers should be restricted or banned from state procurement.

20 percent of respondents believe that the share of imported medicines would be reduced by government support of Russian manufacturers, manifesting itself in the form of subsidies and various privileges and exemptions, and by boosting investment into innovative Russian pharmaceutical projects.

The respondents also mentioned measures such as making the process of registration of medicines more complicated for foreign-produced drugs and/or simpler for drugs that are already registered (approved) abroad to enable their production in Russia (12 percent of respondents), the indexation of registered prices for locally-produced essential drugs and/or the absence of indexing (proportionally less indexing) for imported Essential Drugs (11 percent), and measures aimed at fighting corruption and increasing competition (8 percent).
This shows that the prevailing opinion of market participants is that the most efficient measures to localise manufacturing and reduce the share of imported medicines would be the provision of privileges to foreign manufacturers that conduct a full-cycle production line in Russia, preferences for Russian and localised manufacturers in the sphere of state procurement, and increased investment in Russian manufacturing and innovative medicines.
State procurement is one of the main instruments of government support to the pharmaceutical market. In order to establish a transparent state procurement system and improve support to domestic manufacturers, Federal Law No.44-FZ “On the state procurement system in regard of goods, work and services to meet state and municipal needs” (“the Law on State Procurement”) came into effect on 1 January 2014, replacing Federal Law No. 94-FZ “On the placement of purchase orders, performance of work, rendering of services to meet state and municipal needs”.

According to the Law on State Procurement, from 1 January 2014 open auctions and open tenders will be organised for the state procurement of medicines, and a list of medicines that can be purchased under brand names will be drawn up (subject to approval by the Russian government). In accordance with the Law on State Procurement, the purchase of multiple medicines under a single contract/lot is prohibited, and the government sets limits on funds that can be spent on diversified lots.

The Law on State Procurement provides a more accurate approach to planning and carrying out purchases. However, some experts believe that the Law on State Procurement does not do enough to take into account the characteristics of the pharmaceutical industry, and suggest that a number of bylaws need to be adopted soon in order to establish an efficient system.

We asked our respondents how the introduction of the state procurement system may affect the pharmaceutical industry.

28 percent of respondents think that the state procurement system will complicate the bid procedure.

A quarter of respondents do not expect any dramatic changes with regard to public procurement.

16 percent of respondents believe that the introduction of the state procurement system will lead to a drop in corruption, resulting from open discussion of state procurement and the establishment of special procurement rules. However, 13 percent of respondents think that the introduction of the state procurement system will lead to an increase in corruption in relation to government purchases.

According to 9 percent of respondents, the state procurement system will lead to increased competition for the public procurement of medicines due to reduced barriers to procurement for different market players.

The remaining 9 percent of respondents said that one of the main consequences of the introduction of the state procurement system would be the exclusion of suppliers whose products fail to meet quality standards.
How might the introduction of the state procurement system affect the pharmaceutical industry? (tick the most applicable option)

- Decrease in corruption due to open discussions of government purchases and establishment of special procurement rules (28%)
- Increase in corruption in relation to government purchases (9%)
- More complicated bid procedure (25%)
- Increase in competition for public procurement of medicines due to reduced barriers to procurement for different market players (16%)
- Exclusion of suppliers whose products fail to meet quality standards (13%)
- No dramatic change will occur with regard to public procurement (9%)
We asked our respondents what they believe to be the most serious problems faced by pharmaceutical and healthcare companies in Russia today.

Similarly to last year, the most popular response among respondents is that the most serious problem is the flawed legal regulation in the sector (28 percent of respondents in 2014). Corruption is the second most popular response (22 percent), and a lack of state funding for healthcare programmes and support for Russian manufacturers is in third place (17 percent). It should be noted that the latter of these problems was mentioned by a quarter of respondents last year.

This year, more respondents mentioned problems such as the prevailing economic situation and the lack of solvency among individuals (11 percent, compared to 5 percent last year).

In addition, this year saw the appearance of a new issue, namely the current geopolitical situation, along with the related economic risks and expectations, mentioned by 10 percent of respondents.

Other industry representatives mentioned the increased competition on the market (7 percent) and the high percentage of fake products (5 percent).
The most serious problems faced by pharmaceutical and healthcare companies in Russia today:

2013

- Flaws in the sector’s legal regulations including: pricing, antimonopoly, administrative, etc.
- Current economic situation and insufficient solvency of individuals
- Corruption
- Lack of state funding for healthcare programmes and support for Russian manufacturers
- Increase in competition on the market
- High percentage of fake products

25% 36% 24% 5% 8% 2%

2014

- Flaws in the sector’s legal regulations
- Current economic situation and insufficient solvency of individuals
- Corruption
- Lack of state funding for healthcare programmes and support for Russian manufacturers
- Increase in competition on the market
- High percentage of fake products
- Current geopolitical situation and related economic risks and expectations

28% 22% 17% 11% 5% 10% 7% 5%
Despite uncertainties and imperfect legislative control, market participants and experts noted that there are plenty of opportunities for further market growth and increased activity among pharmaceutical manufacturers. Market growth certainly relies heavily on the actions of the government with regard to legislation. We asked our respondents which areas of state regulation are in particular need of improvement.

Like last year, pricing regulation on the medicine market, including the procedure for updating the List of Essential Drugs, is in particular need of improvement, according to 21 percent of respondents.

Due to the enactment of the Law on State Procurement, regulation of public procurement was the second most popular response, drawing 16 percent of responses.

Tax regulation (including transfer pricing) and the procedure for defining local manufacturers share third place, with each being selected by 13 percent of respondents.

11 percent of respondents opted for state registration of medicines. Last year, this option was the second most popular among respondents.

Other respondents opted for areas such as regulation of product promotion on the medicine market (10 percent), unification of the relevant legislation within the framework of the Customs Union and the WTO (6 percent), protection of intellectual property rights (6 percent), and the provision of privileges to Russian manufacturers (4 percent).

Many issues concerning the Russian pharmaceutical market remain unresolved. Preferences for Russian manufacturers have a long way to go before being established. GMP transition, with mandatory compliance as early as 1 January 2014, gives rise to many questions. The Law on State Procurement currently serves only as a basis for the development of bylaws. The list of medicines that may be purchased by brand names has yet to be drawn up, and the criteria used for including or excluding medicines from this list are open to much interpretation.
Areas of state regulation which, in your opinion, are in particular need of improvement: 2013

- Pricing regulation in the medicine market: 19%
- Regulation on promoting products in the medicine market: 11%
- Provision of privileges to Russian manufacturers: 11%
- Unification of the relevant legislation within the framework of the Customs Union and the WTO: 8%
- State registration of medicines: 8%
- Protection of intellectual property rights: 6%
- Tax regulation: 6%
- Regulation of public procurement: 8%
- Definition of local manufacturer: 15%

Areas of state regulation which, in your opinion, are in particular need of improvement: 2014

- Pricing regulation in the medicine market, including procedure for updating the List of Essential Drugs: 21%
- Regulation on promoting products in the medicine market: 13%
- Provision of privileges to Russian manufacturers: 10%
- Unification of the relevant legislation within the framework of the Customs Union and the WTO: 6%
- State registration of medicines: 6%
- Protection of intellectual property rights: 4%
- Tax regulation, including transfer pricing: 11%
- Regulation of public procurement: 13%
Regarding the transfer pricing rules as of 1 January 2012, among the most important issues, the respondents mentioned the procedure for justifying transfer prices for goods/services and/or procedures for preparing transfer pricing documentation and notifications, as well as the need to provide financing to companies to increase their profitability to the market level.

Almost a quarter of the respondents stated that the transfer pricing rules apply to their operations, but do not require them to change their business model and do not raise any questions as to their application and compliance.

17 percent of respondents said that the transfer pricing rules do not apply to their operations.

Only 3 percent of respondents said that the transfer pricing rules required them to revise their business model when working in Russia (e.g. supply chain, transfer prices, etc.)

Like last year, the business community is concerned about of the procedure for preparing documents and notifications, and only a few companies are ready to change or review their business models in order to comply with the transfer pricing rules (as is common in countries where these rules have been applied for a long time).

This is most likely to be because the regulations have only applied since 1 January 2012, and because in order to review its business model a company needs to understand the rules set by the regulators, including with regard to medicine pricing system.

Please indicate the most important issue for your company in terms of the application of and compliance with the transfer pricing rules, active since 1 January 2012:

- Transfer pricing rules do not apply to our operations
- Transfer pricing rules do apply to our operations, but do not require us to change our business model and do not raise any questions as to their application and compliance
- The procedure for justifying transfer prices for goods/services and/or procedures for preparing transfer pricing documentation and notifications (e.g. issues regarding the search for comparable data, choice of transfer pricing method, etc.)
- We need to finance the company (e.g. by receiving bonuses from suppliers, recharging expenses, etc.) to increase profitability up to market level
- Transfer pricing rules require revision of the business model for Russia (e.g. supply chain, transfer prices, etc.)
2013 was characterised by dynamic legislative efforts in the sphere of healthcare and pharmaceutical regulations. Among the most substantial changes were:

• On 1 January 2014 the Law on State Procurement came into effect, introducing significant changes to the system of government purchases.

• From 1 January 2014 Russian medicine manufacturers must comply with GMP international quality standards in accordance with Federal Law No. 61 “On the circulation of medicines”. The Ministry of Industry and Trade must monitor compliance with these standards.

• On 28 November 2013 the Russian Government adopted the Resolution “On the procedure for approving the list of medicines ordered by brand names”.

• The Strategy for providing medicine to the population of the Russian Federation up to 2025 was adopted. The document provides for the modernisation of medicine supply to certain sectors of the population, financed by federal and regional budgets, and for improving state regulation of prices in accordance with the price reference system, with the implementation of respective optimal models based on pilot projects to be carried out in 2015-2017.

Amendments to the Federal Law “On the circulation of medicines” are currently under development, and are aimed at further clarifying the process of regulating the circulation of medicines, for example of biopharmaceuticals.

We asked industry representatives about the potential effects of these regulations on their business in Russia.

36 percent of respondents noted that changes to healthcare and pharmaceutical regulations had increased the legal/compliance risks faced by their companies. 22 percent of respondents said that the legislative changes had required their companies to revise their business models, while 20 percent said that they had had to increase production/sales costs. 12 percent of respondents found that it was impossible to estimate the effects at the time of asking.

This shows that over three quarters of the respondents expect these changes to Russian legislation to lead to increased business risks and expenses, and consider that both new investors and companies that have operated on the market for a long time should take this into account.
How have the changes (already approved or planned) to healthcare and pharmaceutical regulations affected (or how will they affect) your business in Russia?

2014

- Increased our production/sales costs
- Increased legal/compliance risks
- Decreased costs/risks of doing business in Russia
- Required us to revise our business model
- Market conditions mainly affect our business, not legislative initiatives
- Impossible to estimate the effects at the moment
We asked our respondents about their plans for future development, then compared their answers with those of last year’s survey.

Similarly to last year, the most popular response was the introduction of new medicines to the Russian market (34 percent of respondents). This is understandable; new medicines appear on the pharmaceutical market every year – not only generics, but also original medicines. However, medicines that enter the market are often only modifications of existing ones. Few completely new medicines appear on the market each year.

19 percent of respondents plan to establish a joint venture with a Russian or foreign manufacturer.

15 percent of respondents aim to establish new production facilities in Russia, whereas almost a third (29 percent) voiced similar plans last year. The production arm of the industry requires huge investment, particularly taking into account the GMP standards, with which all manufacturers must comply as of 1 January 2014. Only major pharmaceutical companies can afford to make this size of investment, and many of them have already done so. In most cases, it is expensive for foreign manufacturers to construct their own production facilities in Russia, so they are forced to search for Russian partners in order to localise their operations via alternative routes, such as contract manufacturing, manufacturing and commercialisation license transfer, etc.

This year 13 percent of respondents speak of plans to purchase or merge with other companies from the same sector.

8 percent of this year’s respondents intend to sell off a non-core business unit.

One of the trends of market development is the merging of pharmacy chains, resulting from a desire to reduce costs and extend the product range. According to industry experts, reduced production costs and the introduction of a complete range of medicines can be attained only by way of a merger. In this case, it may be possible to communicate directly with producers, or at least to take a strong position in dialogue with distributors.

Among other trends in the market are the consolidation of pharmacy chains with major distributors with the goal of exerting influence over producers and optimising costs, and the development of private labels.
Your business development plans for the coming years:

2013

- Establishing new production facilities in Russia: 47%
- Purchasing of existing production facilities: 29%
- Establishing a joint venture with a Russian (foreign) manufacturer, including contract manufacturing: 13%
- Introducing new medicines to the Russian market: 11%
- No significant change: 3%

2014

- Establishing new production facilities in Russia: 34%
- Purchasing or merging with a company from the same sector: 15%
- Separation and/or sale of a non-core business unit: 13%
- Establishing a joint venture with a Russian (foreign) manufacturer, including contract manufacturing: 8%
- Introducing new medicines to the Russian market: 19%
- No significant change: 11%
44 percent of our respondents are representatives of foreign companies, most of which do not conduct localised manufacturing in Russia and which specialise in manufacturing original medicines, including abroad.

More than a third of respondents are representatives of companies that distribute medicines.

Others (21 percent) either exclusively or predominantly manufacture generics, including abroad.

Like in 2013, the majority of respondents are representatives of foreign companies that are not localised in Russia (60 percent in 2014, compared with 58 percent in 2013).
Your company is:
2013

- Russian: 34%
- Foreign without localisation: 8%
- Foreign with localisation (your own production facilities and/or contract manufacturing): 58%

Your company is:
2014

- Russian: 26%
- Foreign without localisation: 14%
- Foreign with localisation (your own production facilities and/or contract manufacturing): 60%
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