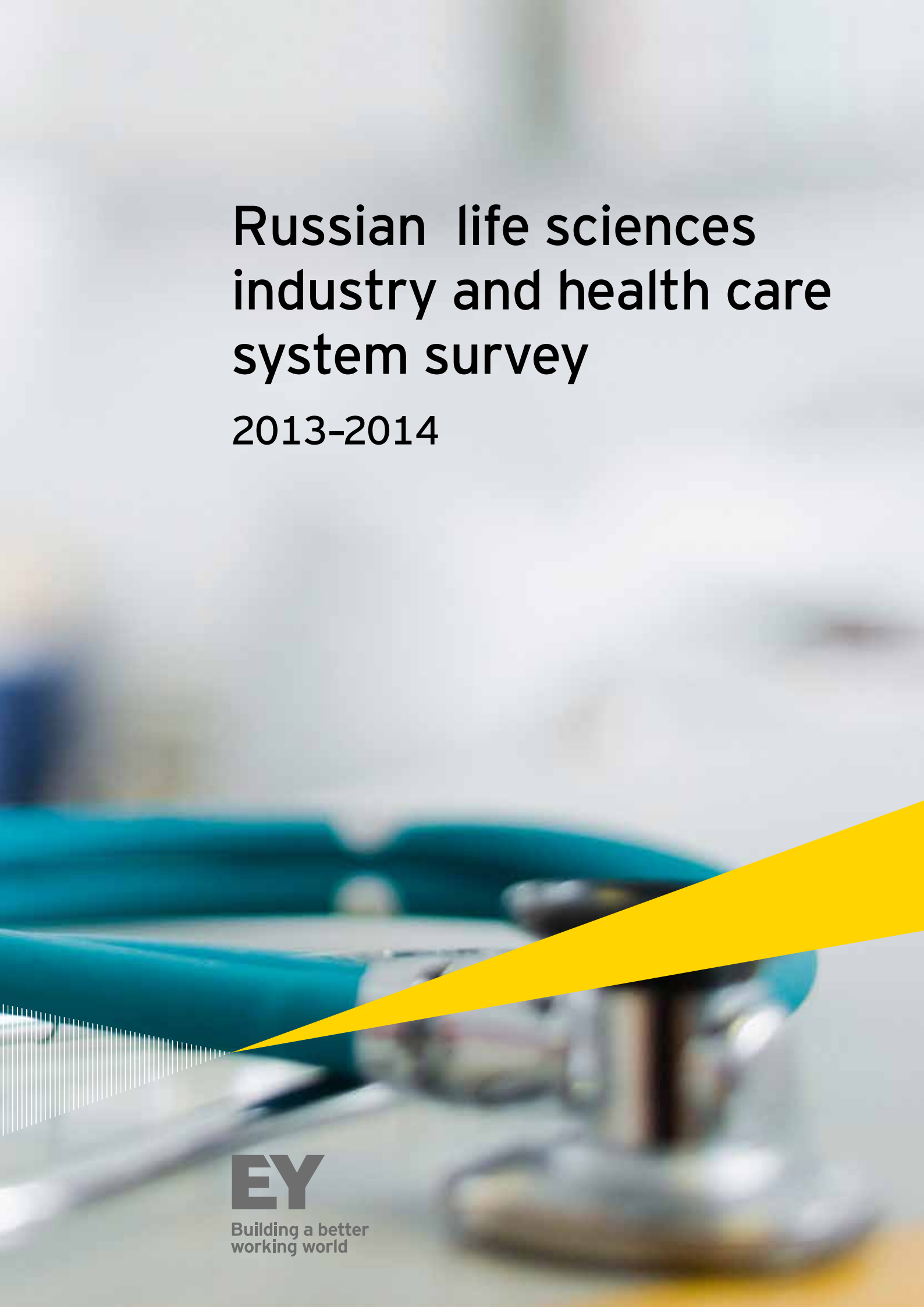
Russian life sciences industry and health care system survey

2013-2014



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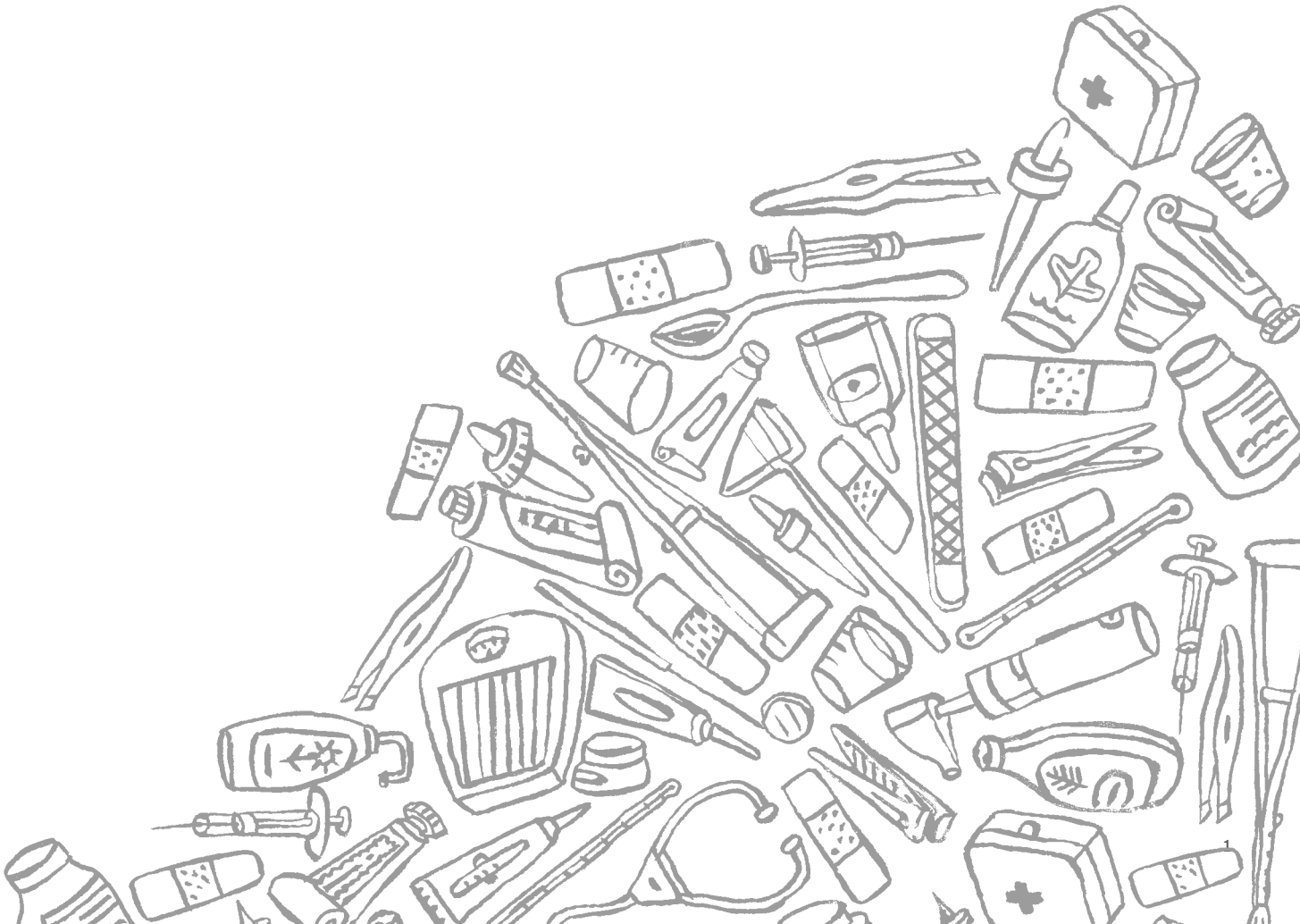
Introduction

This year EY is continuing its tradition of producing surveys of the Russian life sciences industry. The last survey was carried out in 2012 during a complex period of fundamental change in industry legislation and was devoted solely to the pharmaceutical industry.

This year we have included the medical devices sector and the health care system in our survey in addition to the pharmaceutical industry. We expect to see active development in the life sciences industry and health care in Russia this year and beyond, owing to the introduction of measures of State support and protection for domestic manufacturers.

Our survey for 2013-2014 reflects recent and planned changes in legislation which are relevant to the industries in question. It also indicates how the respondents view the current situation and the long-term prospects for the market.

We would like to thank all participants in the survey who shared their opinions with us, and especially our regular respondents. We also hope that those companies who took part in the survey for the first time will become regular participants in the future.



Contents


P. 9

2013:

Continuation of Industry Reform and Main Problems in Applying Industry Legislation


P. 20

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in the Survey

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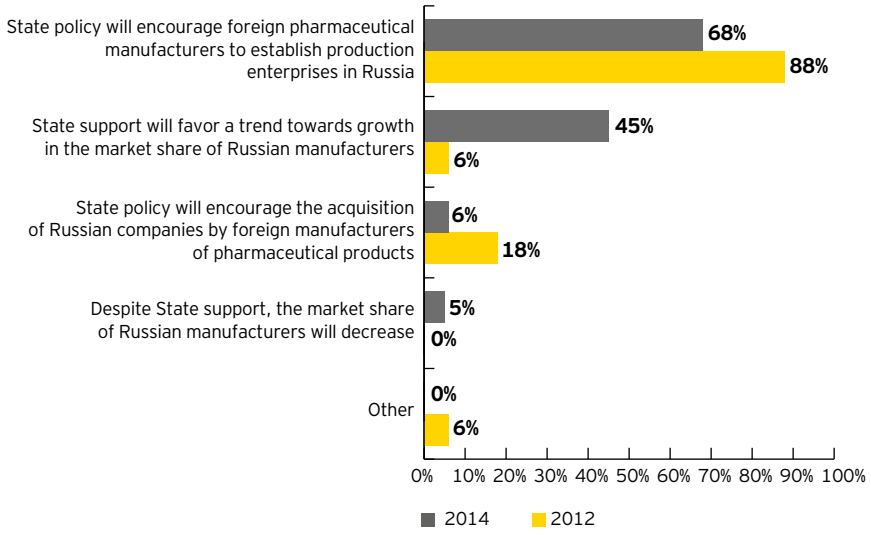
Main Conclusions: 2013-2014 – Reform Continues

The reform of the pharmaceutical industry which the Government initiated in 2008 is still actively progressing. The year 2013 saw the adoption of a number of highly important legislative acts as well as amendments and corrective adjustments to existing industry legislation. The Government is keeping to its strategy of developing the domestic pharmaceutical industry and supporting Russian manufacturers.

The majority of participants in our survey[1] see the localization of drug manufacture as the main trend in the development of the market over the next five years. However, the proportion of respondents making that forecast fell from 88% in 2012 to 68% this year. There was a significant increase in the number of those who believe that State policies are aiding market growth for Russian manufacturers. This view is held by 45% of respondents, compared with only 6% in 2012. Meanwhile, only 6% of those surveyed regard growth due to the acquisition of Russian pharmaceutical companies by foreign companies as driving the development of the market, compared with 18% in 2012.

Most survey participants expect the health care market to grow in quantitative and value terms over the next three to five years. Some respondents also pointed to shareholder changes as one of the possible changes in the business.

Figure 1. How, in your opinion, will the Russian pharmaceutical market develop over the next three years?



[1] The survey was conducted before the introduction of sanctions against the Russian Federation.

The Present State of the life sciences industry and the Health Care system

Health Care

In August 2014 President Vladimir Putin set a target of increasing average life expectancy in Russia from 71 years in 2013 to 76 years in 2020.

In accordance with this ambitious objective for domestic health care, work is continuing on implementing the State Programme for the Development of Health Care in the Russian Federation, which will have a direct impact on the medical services sphere and the life sciences industry.

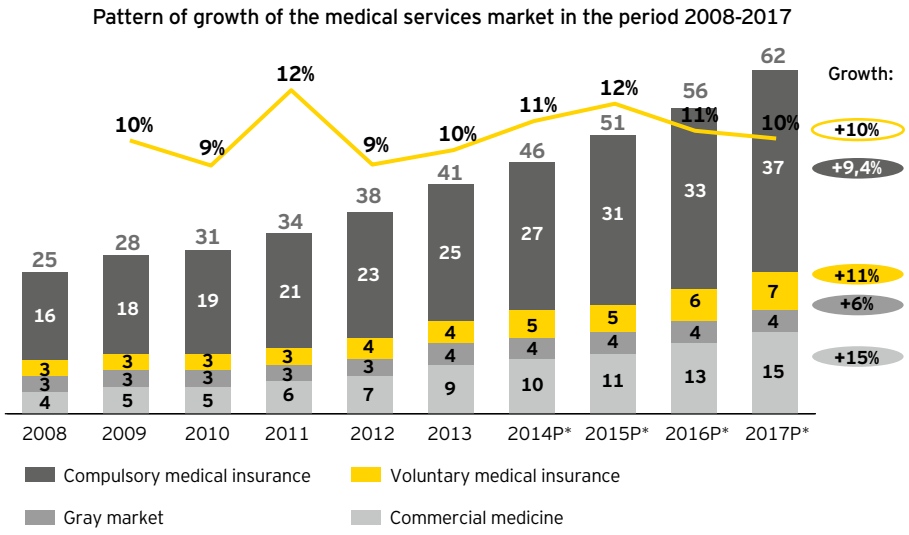
The programme involves the continued transition of the State health care sector to a single funding channel in the form of compulsory medical insurance resources.

The results of our survey indicate that the shortfall of investment for the development of health/medical institutions is on average between 1 and 5 billion roubles.

Market players argue that compulsory medical insurance rates are not high enough. Respondents in our survey hold a similar view. Also unresolved is the issue of the inclusion in the rate structure of an investment component, for example to cover the cost of major building repairs and purchases of equipment.

The overwhelming majority believe that raising compulsory medical insurance rates, combined with the granting of substantial tax concessions, would aid the development of the industry as a whole.

Figure 2. Significant growth of the medical services market and increased share of the commercial and insured medicine sectors



** P – predicted (calculated using an exchange rate of 29.49 roubles to 1 US dollar (average for the period 2008-2012))*

Source: Goskomstat, EY Knowledge, EY analysis

Figure 3. Estimate the amount of funding needed to rebuild/modernize your health care institution during the next three years (if applicable)

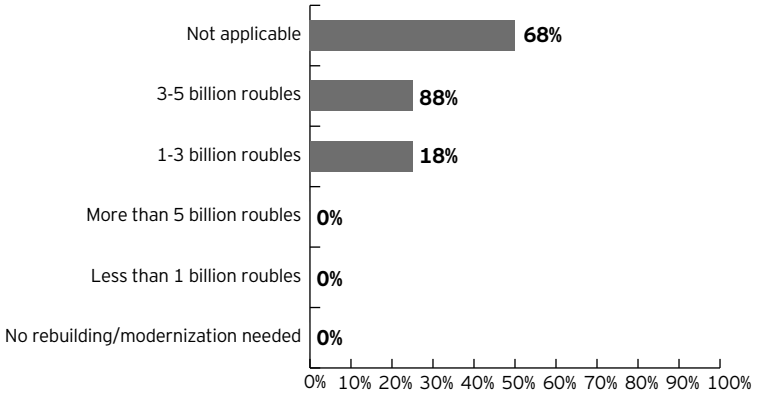


Figure 4. Which of the following factors have a positive impact on the development of the industry?

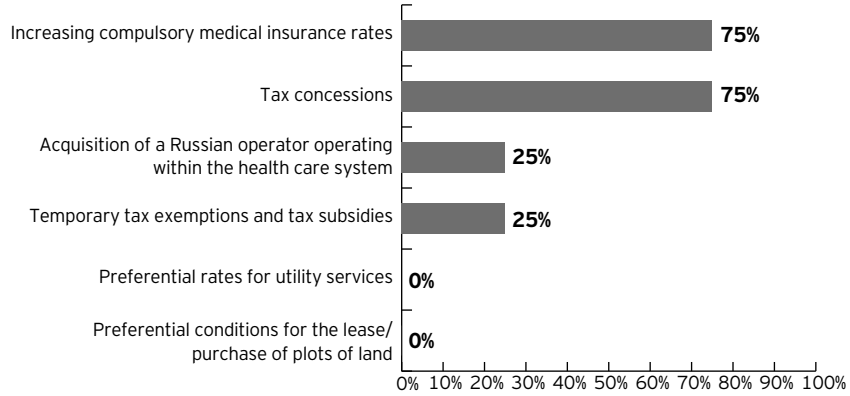


Figure 5. Which of the listed forms of business development is being considered by your organization in Russia?

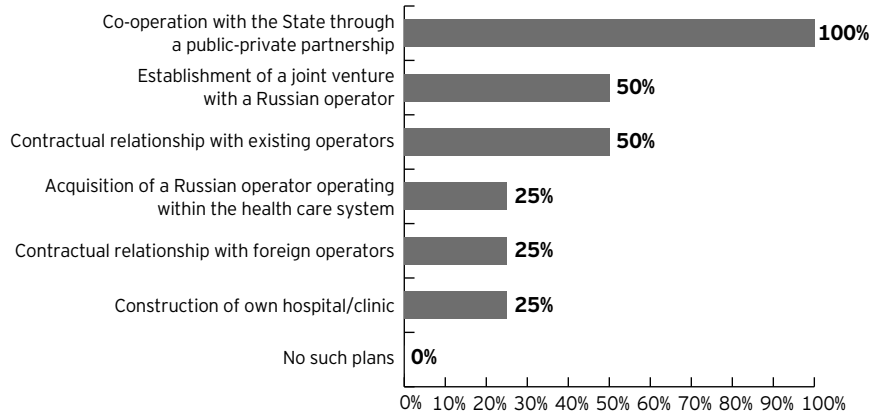
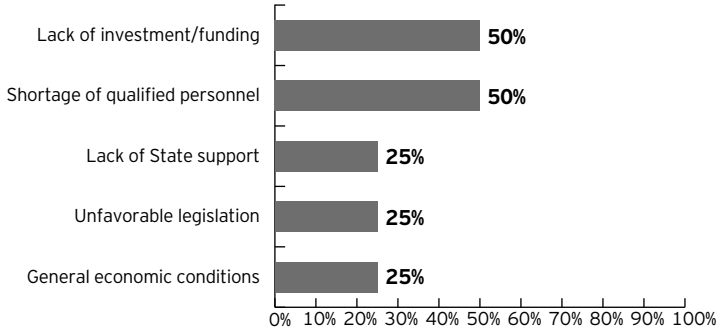


Figure 6. Which of the following factors have a negative impact on the development of the industry?



On the other hand, the positive changes targeted by the reforms have already begun to yield results. For instance, a number of private clinics have already begun to provide compulsory medical insurance services, using this way of attracting patients not only to increase the utilization of their treatment and diagnostic facilities but also to boost sales of supplementary paid medical services. In general terms, the development of the private health care sector is increasingly drawing new players and financial investors to the market. Around 10 M&As have occurred on the private medical services market in the Russian Federation during the last five years. There are 20 or so public-private partnerships (PPPs) in health care at varying stages of development. The first public offering of a Russian company from the health care sector has also taken place.

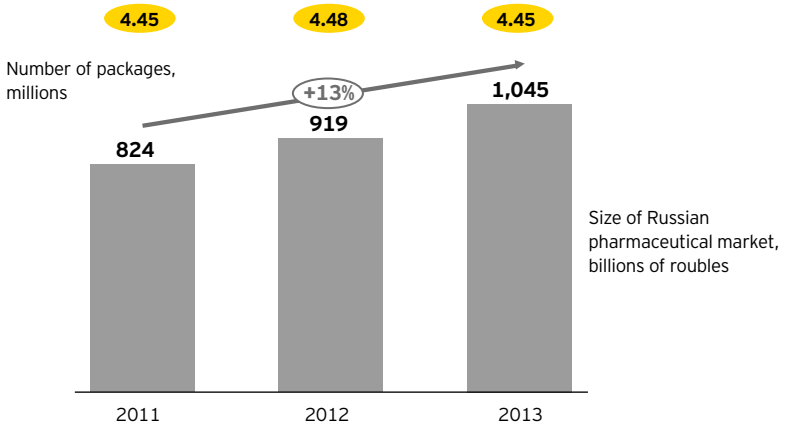
The level of interest in PPP projects is corroborated by the results of our survey. All the respondents view PPP as one of the most promising forms of business development. Half of those surveyed see partnership or collaboration with other companies on the market as a possible alternative to PPP.

Shortage of funding continues to be highlighted as a problem area, as does the shortage of qualified personnel.

The Pharmaceutical Market

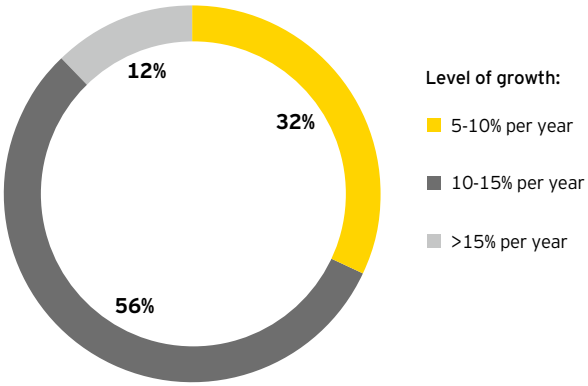
The Russian pharmaceutical market demonstrated double-figure growth between 2011 and 2013, prompting company managers to devise fairly optimistic plans when looking ahead to 2014. Data from EY's survey indicate that more than two thirds of pharmaceutical companies expected growth of 10% or more in 2014.

Figure 7. The Russian pharmaceutical market demonstrated significant growth rates during the last three years



Source: results of survey of pharmaceutical companies

Figure 8. Most companies on the pharmaceutical market expect production growth of more than 10% in 2014



Source: results of survey of pharmaceutical companies

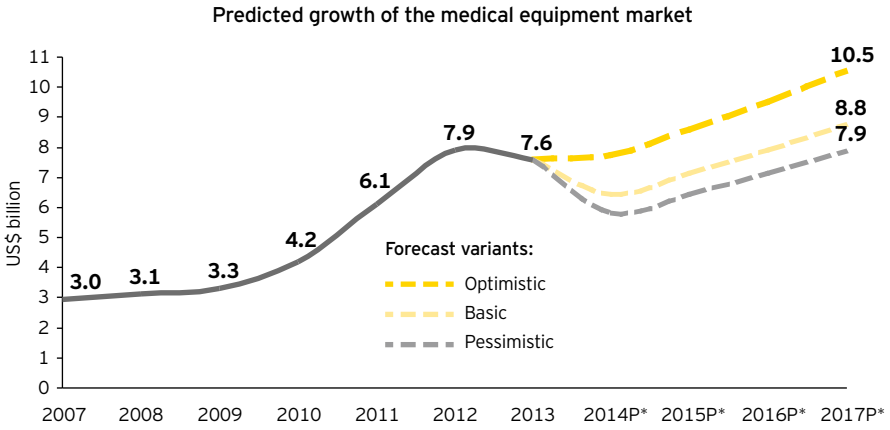
Nevertheless, the beginning of 2014 was not an easy time for the Russian market, and the 5% fall in sales in terms of number of packages compared with the same period of 2013 was reflected in the reduction of the rate of market growth to 7.5% in rouble terms. In view of the decline in the rouble exchange rate at the beginning of the year, there is, for the first time in a long time, a real possibility of the pharmaceutical market contracting in dollar terms in 2014. Our survey indicates that the market may be greatly affected by the deterioration of general economic indicators and the expiration of patents for a number of bestselling drugs.

Major events on the Russian market included (a) the acquisition of VEROPHARM by Abbott, (b) the purchase of an interest in BIOCAD by Pharmstandard together with Millhouse and (c) the purchase of the Pfizer pharmaceutical plant by the Russian company R-Pharm. In line with the course the Government set in favor of the localization of drug production in Russia, many foreign players continued to invest in their own Russia-based production operations and to conclude transactions for licensed manufacture at existing plants belonging to other firms.

The Medical Devices Market

The medical devices market showed a decline in 2013 following the completion of the health care modernization programme which began in 2011. The market was also affected by difficulties many companies experienced in obtaining registration certificates for new products. Despite the setbacks that manufacturers of medical equipment and consumables encountered, the market may resume its growth trajectory as early as 2015. By that time, experts predict, the next phase of the upgrading of hospitals and clinics will have begun, aimed at bringing them into line with all the approved standards for the provision of medical care.

Figure 9. The medical devices market will resume growth in 2015 thanks to the implementation of the health care development programme



*P = predicted.

Source: GK Bureau, EY analysis

2013: Continuation of Industry Reforms and Key Problems in the Application of Industry Legislation

Import Substitution and Localization of Production

The year 2013 may be described as a period of reassessment of the results of reforms and new legislation. Throughout the year State bodies and the pharmaceutical community actively discussed amendments to the Federal Law Concerning the Circulation of Medicinal Products, which entered into force on 1 September 2010.

The key defining trend of the period is the Government's endeavor to increase the share of Russian products on the market and, as far as possible, to meet the population's requirements with domestically manufactured goods.

It should be pointed out that the Ministry of Industry and Trade of the Russian Federation is drafting a decree aimed at limiting access to the State procurement system for foreign-made drugs. Since pharmaceutical companies have made significant progress with the localization of production in Russia, this initiative has not caused much of a stir on the market. However, the Ministry is proposing that medicinal products should be classified as Russian-made goods according to the extent of their processing in the territory of the Russian Federation. In particular, according to one version of the draft, a medicinal product packaged in the territory of the Russian Federation would be considered as a Russian good only up to the end of 2014. It is possible that pharmaceutical manufacturers will find this definition of a Russian medicinal product unsatisfactory, as it would take more time for facilities which begin from the secondary/primary packaging stages to be converted for complete-cycle production. The most recent draft of the decree was published by the Ministry of Industry and Trade on 4 September 2014. In that draft the Ministry proposes that the customs rules for determining the country of origin of goods should be used for the purposes of classifying medicinal products as Russian goods. Time will tell whether that draft becomes law.

Figure 10. Does your company plan to develop drug manufacturing in Russia? If so, in what direction?

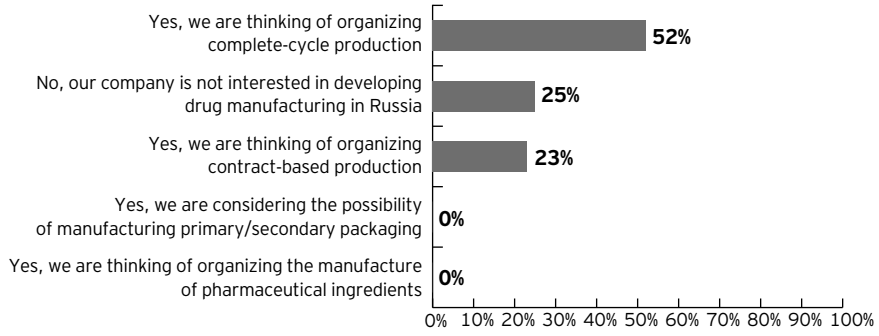
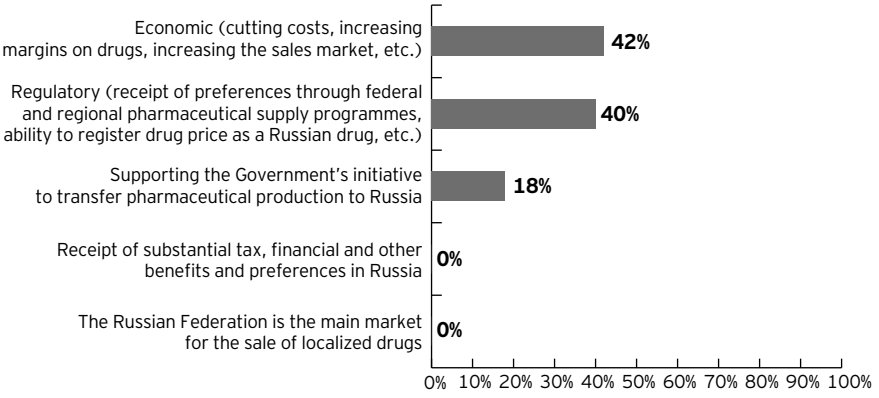


Figure 11. What are your company's reasons for deciding to organize production in Russia?

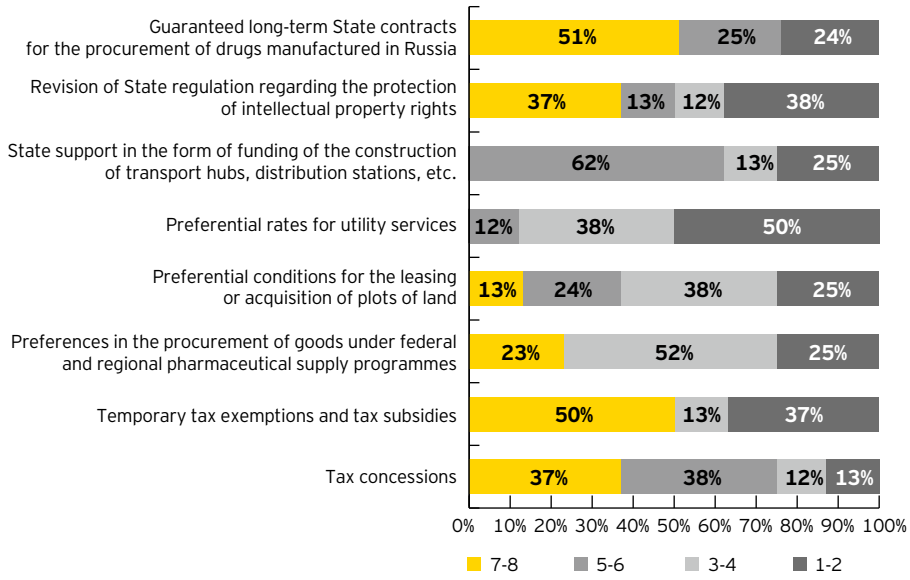


According to the study data, 52% of surveyed representatives of foreign pharmaceutical companies are considering the possibility of setting up complete-cycle production in Russia. Meanwhile, 23% of respondents plan to develop contract-based production, while 25% have no interest in setting up production operations within Russia.

Interestingly, out of the possible factors prompting companies to transfer drug manufacturing to the Russian Federation, around 42% of participants in the study selected purely economic reasons, and 40% indicated regulatory factors. Only 18% indicated that their decision was influenced by the need to support the Government's initiatives.

In terms of key measures of State support, the majority of respondents would like to see guaranteed long-term contracts for the purchase of medicinal products manufactured in Russia, temporary tax exemptions and tax subsidies. Other effective measures of support are tax concessions and review of State regulation regarding the protection of intellectual property rights.

Figure 12. What type of State support for foreign investors at federal and regional levels would you like to see in Russia? Indicate your level of interest on a scale of 1 to 8, where 1 is low and 8 is high



While large international pharmaceutical companies set a course towards localized manufacturing a number of years ago and new facilities were launched in a number of regions of Russia in 2013-2014, the medical industry is lagging far behind the pharmaceutical segment in this area. The conditions of circulation of medical devices and medical equipment in the Russian Federation and the irregular nature of demand for such goods are undoubtedly contributory factors in this situation. In order to accelerate the process of transferring the manufacture of high-technology medical devices to Russia, during 2013 the Ministry of Industry and Trade of the Russian Federation drafted a proposal to restrict and even prohibit access to the State procurement system for certain medical devices. Draft Government decrees the Ministry prepared provoked strong reactions from foreign manufacturers,[2] the medical community and the public.[3] It was felt that the Ministry was proposing an excessively abrupt transition to import substitution without providing for a transitional period or setting out guarantees and preferences aimed at encouraging companies to localize production in Russia. Since, however, import substitution and the development of the domestic medical industry are among the priorities of State policy, the Government is now working on an approach that would meet State requirements while being practicable from the point of view of market participants.[4]

2 Official position of the International Medical Device Manufacturers Association (IMEDA) of 20 March 2014 in regard to the prohibition of access to the procurement system of the Russian Federation for foreign medical devices.

3 Expert report of the working group on health care of the Expert Council attached to the Government of the Russian Federation in response to the draft decree of the Government of the Russian Federation "Concerning the Establishment of a Prohibition on the Admission of Goods (Particular Types of Medical Devices) Originating from Foreign States in Carrying Out Procurements to Meet State and Municipal Requirements for the Purpose of Protecting the Domestic Market of the Russian Federation" of 27 March 2014.

4 According to a statement from the Press Service of the Ministry of Industry and Trade on 28 May 2014.

Unification of Production Practices

On 1 January 2014, under the Federal Law "Concerning the Circulation of Medicinal Products," it became obligatory in Russia to comply with international Good Manufacturing Practice (GMP) standards.

In practice, achieving compliance with this rule is likely to be a long-term process. At the beginning of 2014 State authorities were themselves unprepared for the transition owing to a lack of qualified inspection staff and inadequately formulated Russian standards of good manufacturing practice.

Following a meeting of the Supreme Eurasian Economic Council on 29 May 2014 in Astana, agreement was reached on the formation of a unified market for pharmaceutical products by 1 January 2016. This means compulsory unification of manufacturing practices and rules for drug registration. A Customs Union agreement setting out unified principles and rules governing the circulation of medicinal products is to be concluded by the member states no later than 1 January 2015. The participants in the survey expressed guarded views about the likelihood of such an agreement being signed within that deadline.

Specifically, the number of surveyed Russian and foreign pharmaceutical manufacturers who believe that the unification of standards and rules for drug registration may happen in the long term (from five to ten years) is more or less equally split, while only 12% believe that it will happen in the short term (within one to three years).

Figure 13. In what areas does your company encounter the most difficulties?

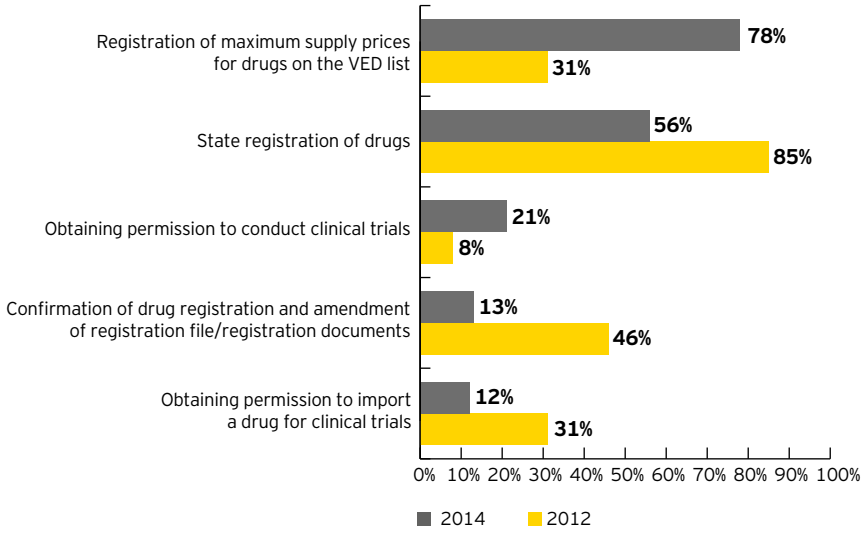
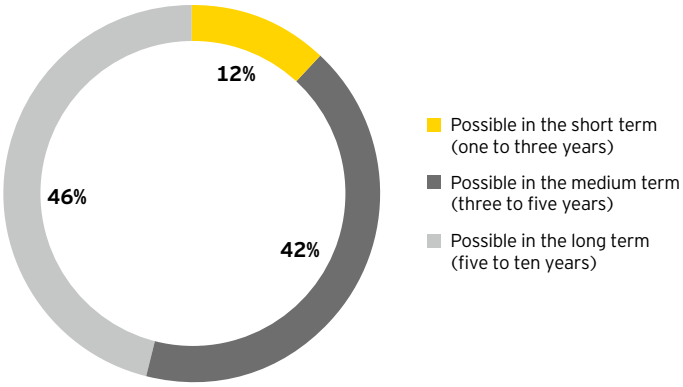


Figure 14.Rate the likelihood of the unification of the rules for the circulation of medicinal products and GMP requirements within the Customs Union and the Common Economic Space in terms of the timeframe.



State Registration of Medicinal Products and Prices for Vital and Essential Drugs

As in 2012, the majority of respondents consider the process of the State registration of drugs and maximum supply prices for drugs on the VED list as one of the most problematic aspects of the Federal Law "Concerning the Circulation of Medicinal Products."

In this respect, the proportion of respondents pointing to the factor of the registration of maximum supply prices for vital and essential drugs rose from 31% in 2012 to 78% in 2014. The proportion of respondents indicating the factor of the State registration of drugs fell from 85% in 2012 to 56% in 2014.

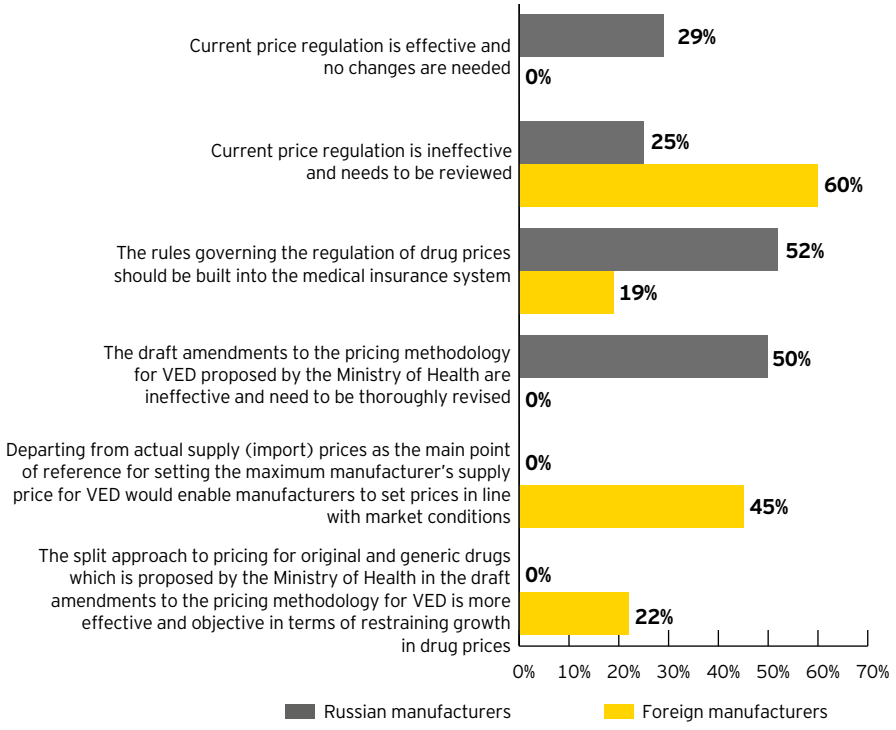
In November 2013 amendments were made to the law aimed at improving the process of drug registration. Nevertheless, the process still takes a lot of time and requires thorough preparation and the provision of a large amount of information.

The methodology manufacturers use to set maximum supply prices for drugs on the VED list has not undergone major changes since 2010.

In 2013 State bodies responsible for pricing policy in the area of drug circulation and the supply of medicines to the public discussed amendments to the current methodology. Approaches to amending the methodology changed during the course of the year, starting with minor adjustments and ending with a fundamental rethink of pricing principles. The current pricing methodology is expected to be amended in 2014 with a view to resolving immediate problems such as the laundering of cheap products, polymorphism and the lack of transparency in the determination of maximum supply prices. In the future the Government plans to continue improving the pricing mechanism for vital and essential drugs so that the updated methodology facilitates transition to the public pharmaceutical supply system (the Strategy for the Supply of Pharmaceuticals to the Population up to 2025 was approved by an order of the Ministry of Health of the Russian Federation of 13 February 2013).

One half of Russian manufacturers surveyed support the Government's initiative to introduce the public pharmaceutical supply system and bring the pricing methodology into line with that system. Representatives of foreign pharmaceutical manufacturers take a more skeptical view of the introduction of the unified pharmaceutical supply system and would primarily welcome a change in the approach to the determination of the manufacturer's price for drugs. In particular, 45% of those surveyed expect to see a departure from actual supply (import) prices as the main point of reference in setting the maximum manufacturer's supply price for vital and essential drugs. This is because it is a flawed mechanism that does not allow manufacturers to lower drug prices when appropriate (seasonal discounts, etc.), as this may result in the maximum supply price being reduced in line with those lower-priced supplies.

Figure 15. What, in your view, are the prospects for the State regulation of prices for pharmaceutical products in Russia?



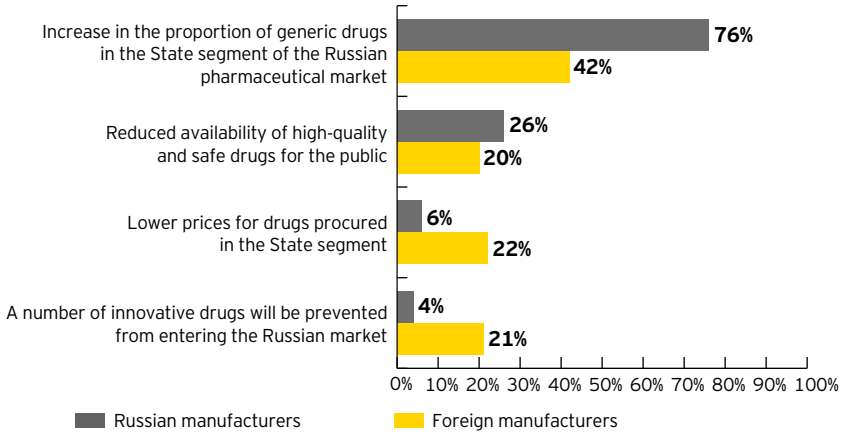
Draft Amendments to the Federal Law "Concerning the Circulation of Medicinal Products"

Discussion of the need for amendments to the Federal Law "Concerning the Circulation of Medicinal Products" began from the moment when it entered into force in 2010.

Although a number of amendments were made to the law over the period 2011-2013 to address immediate problems, some matters require further attention. The proposals the Federal Anti-Monopoly Service put forward regarding the need to introduce the concept of an "interchangeable" drug and to allow for a drug to be substituted by another with a view to preventing the limitation and elimination of competition on the market provoked animated discussion within the community during the whole of last year. Meanwhile, there was a lack of agreement between the bodies responsible for drafting the amendments in regard to the reference to "interchangeable" drugs. In March 2014 the Ministry of Health announced that this matter had been resolved and that the relevant amendments had been referred to the Government of the Russian Federation. However, the text of the amendments has yet to be published.

In the opinion of the overwhelming majority of foreign and Russian companies, introducing the concept of an "interchangeable" drug would result in an increased proportion of generic drugs in the State segment of the pharmaceutical market. A decline in the availability of high-quality and safe drugs is predicted by 26% of Russian and 20% of foreign manufacturers.

Figure 16. What, in your view, will be the consequences of introducing the concepts of "interchangeable drug" and "comparator drug" under the recent Ministry of Health bill of 22 January 2014 for amendments to Federal Law No. 61-FZ "Concerning the Circulation of Medicinal Products"?



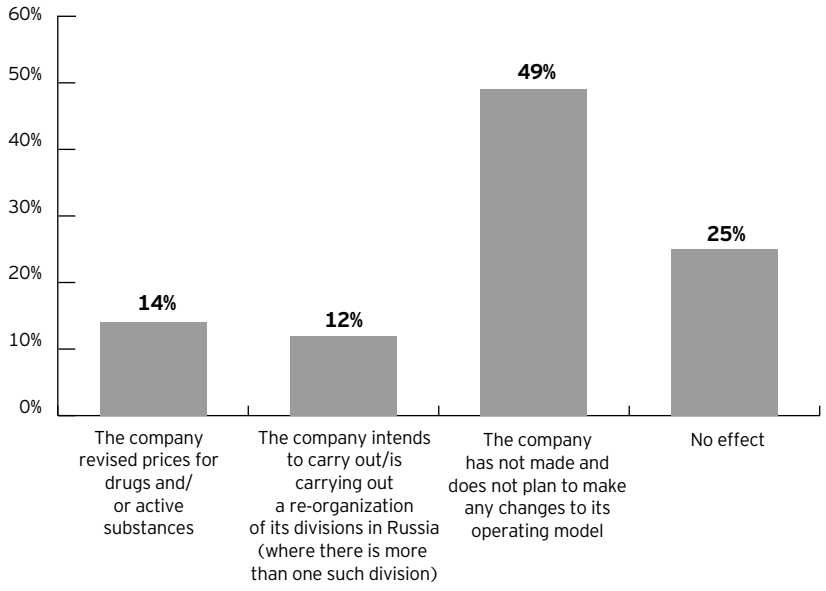
Another much-discussed topic was the period of protection of results of pre-clinical and clinical trials of original drugs (the data exclusivity clause), owing to the fact that some Government departments insisted on a reduction of that period from six to four years. Since the introduction of such a standard was one of the conditions of Russia's accession to the WTO, market participants hope that the provisions of the law will, once amendments have been made, be in keeping with the commitments the Russian Federation undertook when joining that international organization.

Taxation Aspects and Funding Problems

New transfer pricing (TP) rules began to operate in Russia in 2012. During the transitional period companies doing business in Russia assessed whether their pricing and commercial policies conformed to the new rules and, on the basis of the results they obtained, made decisions on the need to make changes to their activities.

Approximately one half of surveyed foreign and Russian pharmaceutical companies indicated that the introduction of the new TP rules had not resulted in the need to make changes to their operating model, i.e., their pricing principles and chain of supply conform to the requirements of Russian legislation. Almost equal numbers of those surveyed (14% and 12%) acknowledged that their company had revised intragroup transfer prices for drugs and/or active substances imported into Russia or planned to re-organize their divisions in Russia. In any case, the validity of companies' conclusions regarding their compliance with current regulations may be confirmed or refuted through tax audits, which are expected to take place in 2014. It is possible that the results of tax audits will result in more companies recognizing the need to make changes to their internal policies and intragroup supply systems.

Figure 17. What effect did the introduction of the new transfer pricing rules from 1 January 2012 have on the operating model of your company in Russia?



Owing to the nature of the State regulation of prices for drugs included in the VED list, many international pharmaceutical manufacturers are encountering the problem of additional funding for their Russian subsidiaries. According to the results of the 2012 survey, one of the most popular forms of additional financing for Russian businesses was lump-sum financial assistance (69% of respondents preferred this). It should be noted that the popularity of this funding method declined to 40% in 2014, which is possibly due to the fact that this method is not effective and not recommended for use from the point of view of the TP rules. The survey showed that foreign companies gave equal preference to such funding methods as lump-sum financial assistance, the conclusion of service contracts and incentive payments (bonuses) in the context of foreign trade product supply contracts.

It will be recalled that service contracts effectively serve as a framework for cost sharing and the rebilling of expenses to companies within a group. Since Russian law does not provide for cost sharing as such, the arrangement has to be structured through service contracts. The survey indicates that some companies are continuing to combine multiple funding mechanisms in order to maximize efficiency and distribute risks.

VAT on Medical Services

One of the major topics of the 2013-2014 period was the issue of the application of Russian VAT in relation to medical devices, whether imported into or sold within the territory of the Russian Federation. Tax legislation provides for a VAT exemption and the application of a lower 10% VAT rate in relation to particular medical devices and drugs. Until 2013 there was much debate about the application of preferential tax treatment to such goods. Since the lists of goods eligible for concessions upon importation into Russia often differed from the lists of products sold in the territory of the Russian Federation, the tax and customs authorities would challenge the inclusion of a product in the exempt category. However, the situation worsened in 2013 owing to the entry into force on 1 January 2012 of the new definition of "medical device" which was introduced by Federal Law No. 323-FZ "Concerning the Fundamental Principles of Public Health Care in the Russian Federation." Furthermore, on 1 January 2013 the new rules for the registration of medical devices entered into force, which effectively required the replacement of the majority of registration certificates issued before 1 January 2014 (the deadline was later extended to 1 January 2017). The concepts of "medical products" and "medical equipment" which were previously used in registration certificates were changed to "medical device" in the new registration certificates. The provisions of the Tax Code were brought into line with the new definitions from 1 January 2014, but subsidiary regulations dealing with VAT were not amended. As a result of the inconsistencies between industry and tax legislation, many manufacturers of medical devices found that they were denied preferential VAT treatment for medical devices. The problem arose primarily in the case of the importation of goods into the territory of Russia, including goods which were previously imported with preferential treatment. Subsequent clarifications from the tax authorities regarding the application of VAT to medical devices did not improve the situation. At present, the applicability of a VAT exemption (or reduced VAT rate) to imported medical devices is decided upon in each individual case. In view of the current difficulties in regard to the application of VAT, the Ministry of Health is working with the Ministry of Finance on the drafting of a new decree regulating groups of medical devices which are eligible for preferential VAT treatment when imported into and sold in the territory of Russia.

Development Prospects for the Industry

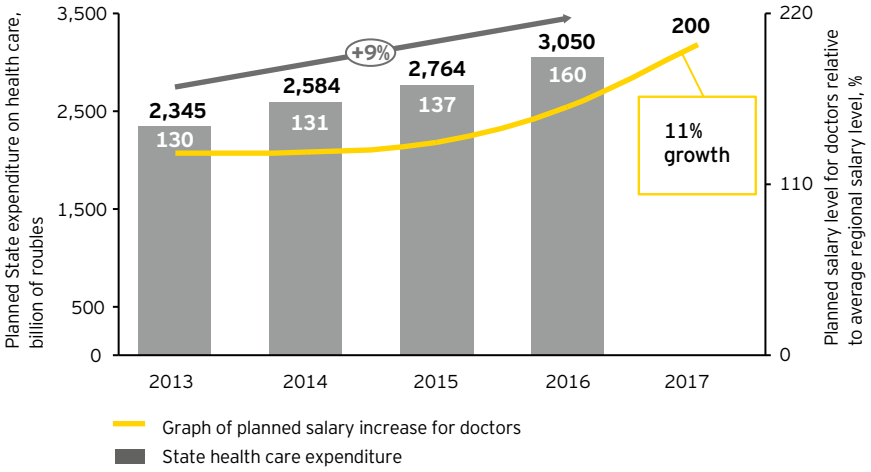
The Ministry of Economic Development predicts that no fiscal or monetary stimuli will be able to compensate for the tightened restrictions on capital raising and increased risk premiums caused by the escalation in geopolitical tensions. The negative trend in economic indicators observed at the beginning of the year is continuing and overall GDP growth is falling to 0.5%. It is especially important in these conditions to keep the development of industrial manufacturing at the level achieved in the last few years and to promote greater efficiency at various stages of drug development (including at research centers).

One of the main factors affecting the State health care sphere will be the planned raising of salaries of doctors and medium-level medical personnel to 200% and 100% respectively of regional average salary levels. This significant increase, which is planned for 2017, will not be accompanied by a comparable increase in funding from the State budget. This may point to possible cuts in the number of medical personnel or the re-allocation of funds from other cost items, which could have an adverse impact on the health care system as a whole.

Another significant event in the social sphere will be the integration of the health care system of the Republic of Crimea. This will involve, among other things, significant changes in the basic operating mechanisms of the republic's health institutions and transition to Russian standards of medical care.

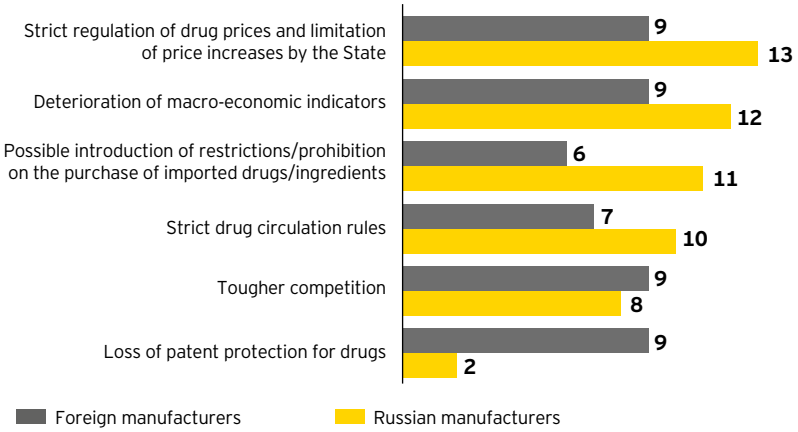
The results of our survey indicate that the main problems that pharmaceutical manufacturers will encounter in the future will be the preservation of excessively strict regulation of pricing for drugs on the VED list, the deterioration of macro-economic indicators and tougher competition due to slower market growth and an increase in the proportion of generics.

Figure 18. The planned salary increase for medical personnel will outstrip the growth in State expenditure on health care



Source: Ministry of Finance of the Russian Federation, Government Order No. 2599-r of 28 December 2012

Figure 19. Main risks for the growth of pharmaceutical companies on the Russian market (on a scale of 1 to 15)



Source: Results of survey of pharmaceutical companies

Although the situation on the Russian pharmaceutical market is not easy, companies are sticking to their development plans. While macro-economic indicators go downhill, regulation becomes more complex and uncertainty grows over future market trends, market players are focusing on raising business efficiency, primarily by optimizing the sales process and deploying appropriate tools and by launching programmes aimed at cutting costs and working capital, including inventories. With the development of new means of communication between doctors and patients, companies are willing to invest in evaluating and raising the effectiveness of their marketing instruments and improving business planning and automation.

As patent protection periods expire for a number of bestselling drugs, the issue of the development and optimization of product strategy is becoming ever more important. The respondents see drugs used to treat respiratory and endocrine diseases and cancer treatment drugs as having the greatest potential.

The majority of those surveyed are sure that the future development of the market will involve the creation of new production facilities by foreign companies or the purchase of local players and an increase in the market share of Russian companies owing to preferences accorded by the State. In this respect, practically all foreign participants in the market either already manufacture their products in Russia or plan to organize independent or contract-based production operations. In exchange for siting their drug manufacturing activities in the territory of Russia, foreign players would like to see reciprocal measures from the State aimed at supporting pharmaceutical companies, including the granting of tax concessions and holidays and the conclusion of long-term contracts for the supply of medicines.

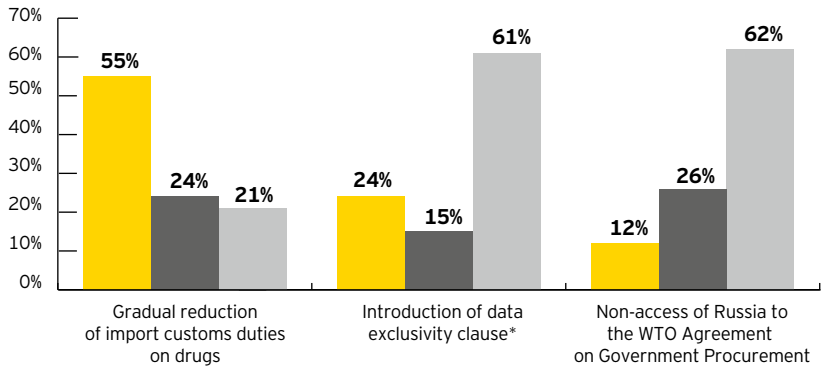
Russia in the WTO

More than a year has passed since the entry into force of the Protocol confirming the accession of the Russian Federation to the World Trade Organization.

In addition to the introduction of the special clause for the protection of pre-clinical and clinical research data (the data exclusivity clause), another implication of accession to the WTO for the pharmaceutical industry is the gradual reduction of import customs duties.

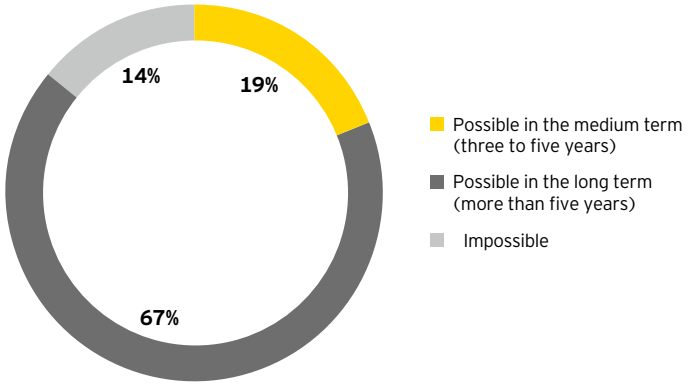
One half of foreign and Russian pharmaceutical manufacturers surveyed indicate the decrease in import customs duties as one of the most important factors affecting the Russian pharmaceutical industry. Some survey participants express regret that Russia has not acceded to the WTO Agreement on Government Procurement.

Figure 20. Based on the experience of the 2012-2013 period, which key factors of Russia's accession to the WTO, in your view, have/will have the greatest impact on the development of the Russian pharmaceutical market? Assess their impact on a scale of 1 to 3, where 1 signifies a low degree of impact and 3 signifies a high degree



* Data exclusivity consists in a prohibition on the receipt, divulgence and use for commercial ends or for the State registration of drugs of information on the results of pre-clinical and clinical drug research which an applicant has presented for the purpose of the State registration of a drug, without that applicant's consent, for six years from the date of State registration of the drug.

Figure 21. Rate the likelihood of a pharmaceutical reimbursement system (outpatient clinical care) being introduced throughout the territory of the Russian Federation in relation to all population groups



The Pharmaceutical Supply System

The system for the supply of pharmaceuticals to the population of the Russian Federation up to 2025 was approved by an order of the Ministry of Health of the Russian Federation in February 2013 in the course of the implementation of President Putin's May edicts (Edict No. 598 of the President of 7 May 2012 "Concerning the Improvement of State Policies in the Area of Health Care").

However, the text of the documents lacks details regarding the extent of application of the pharmaceutical supply system and the timeframe for rolling out the strategy throughout the territory of the Russian Federation.

Of the representatives of international and Russian pharmaceutical manufacturers which took part in our survey, 67% believe that the implementation of the pharmaceutical supply system throughout the territory of the Russian Federation can only happen in the long term (not earlier than five years from now). One possible reason for this prediction is the lack of the regulatory framework needed for the implementation of the system and the need for additional funding if it is to cover all sections of the population in all regions of Russia.

Reaction to Changes and Development Plans

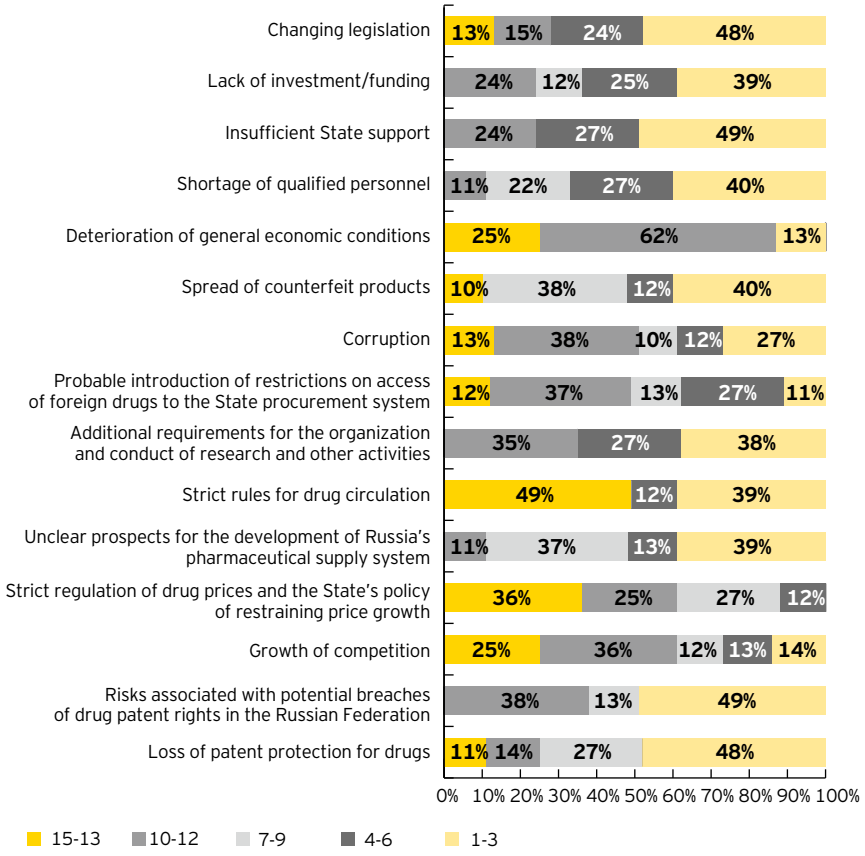
According to the results of the survey, the principal factors constraining revenue growth for Russian and foreign manufacturers are the strict rules governing the circulation of medicines, including State requirements relating to the conduct of clinical research, drug registration and quality, manufacturing rules, etc.

The next most significant factors indicated by the participants in the study are the regulation of drug prices and the State's policy of restraining price growth. The respondents also indicate increased competition and the deterioration of overall economic conditions as barriers to successful business development.

The respondents are clearly of the opinion that there is a need to amend the legislation governing the circulation of medicinal products, including the system of drug registration and the State regulation of drug pricing. During 2013-2014 the Government worked at length on preparing changes to the rules governing drug circulation. In our view, this work will soon be complete and Russia's drug circulation rules will become comprehensive and clear for industry participants and consumers.

The course in favor of import substitution and meeting demand with domestically produced drugs, which was set by the Government and has been actively implemented over the 2013-2014 period, was supported by foreign manufacturers and pharmaceutical companies. Further refinements of industry legislation and modifications to the system of preferences for Russian manufacturers should increase Russia's appeal to foreign companies and support foreign investors at a time of difficult political and economic circumstances. The development of the Russian life sciences industry and the launch of new drugs and medical devices will help to raise the quality of medical care provided to the public and aid the development of new medical technologies and services.

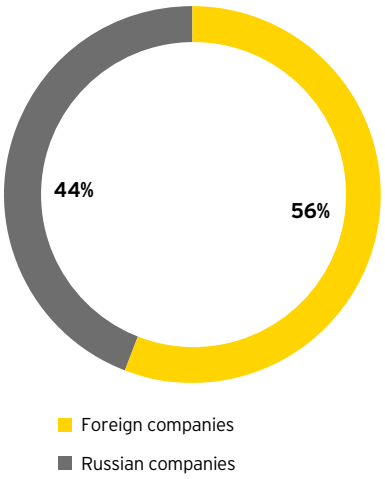
Figure 22. Which factors might hinder revenue growth for your company during the next three years? Rate the degree of probability on a scale of 1 to 15, where 1 is low and 15 is high.

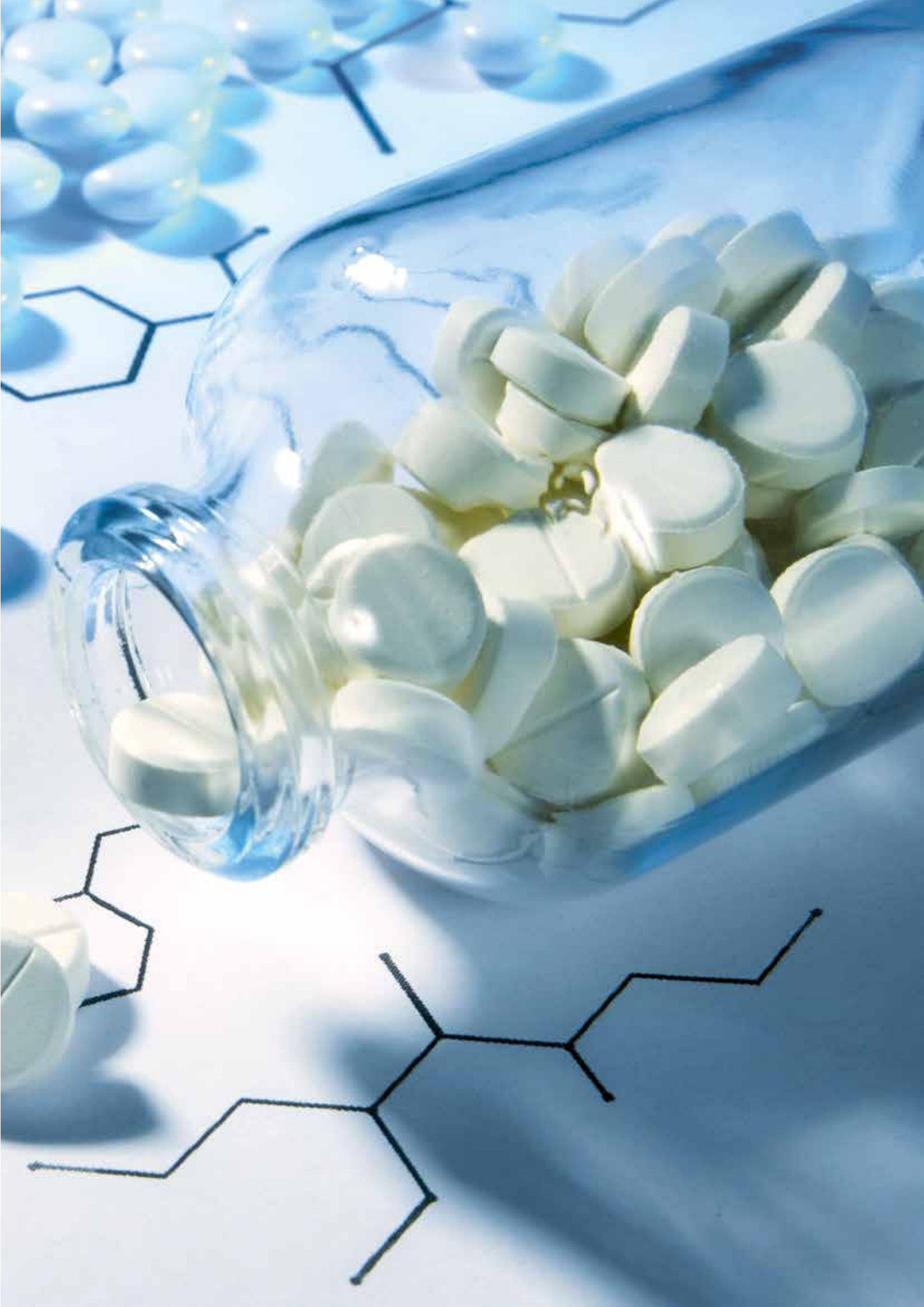


Participants in the Survey

The respondents included both Russian (44%) and foreign (56%) companies.

Figure 23. Participants in the survey





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