

Survey of the pharmaceutical industry in Russia

2012





Introduction

This year Ernst & Young is continuing its tradition of producing surveys of the Russian pharmaceutical industry.

The last survey was carried out in 2010 during a complex period of fundamental changes in the industry's legislative framework. Participants in the market were reeling from the pace at which new legislative initiatives were being introduced.

The period covered by the present survey has been characterized by market stabilization and the phasing-in of the new rules of play introduced by the state in 2010. However, many problems remain unresolved. The pharmaceutical market is expected to undergo further changes and new developments. Our 2012 survey reflects recent and planned changes in legislation which have significance for the industry, and illustrates 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

Main conclusions: 2011-2012 – reform goes on	3
State of the pharmaceutical industry and the healthcare sphere	5
2012: continuation of legislative reform and initial results of changes	8
Development prospects for the industry	15
Reaction to changes and development plans	19
Participants in the survey	20
Contact information	21



Main conclusions: 2011-2012 – reform goes on

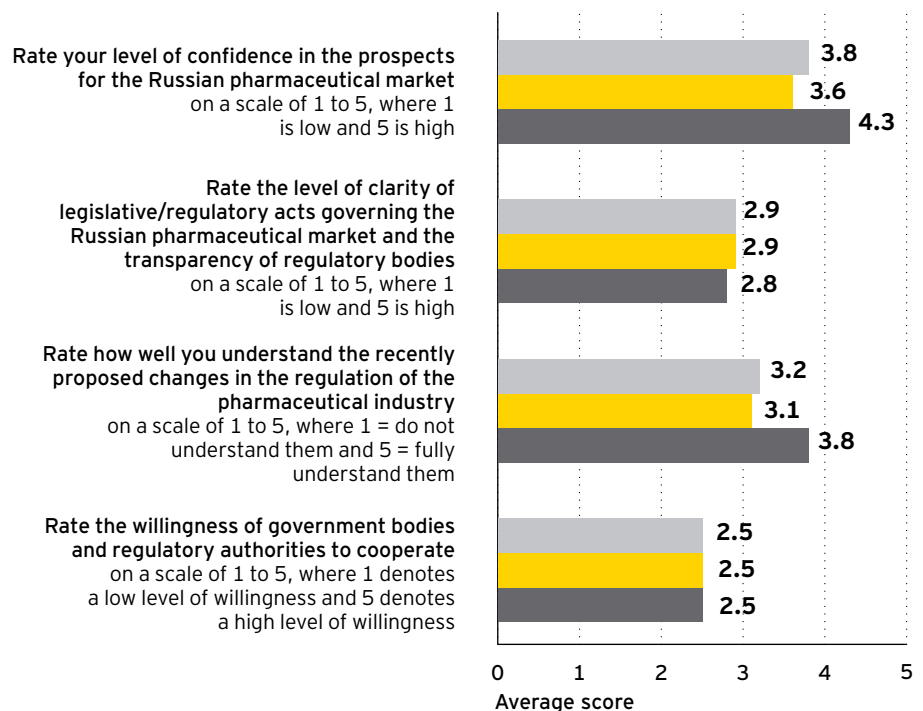
The reform of the pharmaceutical industry which was initiated by the Government in 2008 is still actively progressing. The year 2012 saw the adoption of a number of highly important legislative acts as well as amendments and corrective adjustments to existing industry legislation. The Government is keeping to its strategy of developing the domestic pharmaceutical industry and supporting Russian manufacturers.

Responses from survey participants indicated that they all rated the development prospects of the Russian pharmaceutical market at above medium (3.8 points out of 5). The support promised by the state possibly gives Russian manufacturers a greater degree of confidence, and they are more optimistic in their predictions, rating the development prospects of the market at 4.3 points. It is clear that confidence among Russian manufacturers in the positive development of the Russian market has grown compared with the results of our 2010 survey (when the equivalent score was 3.8 points).

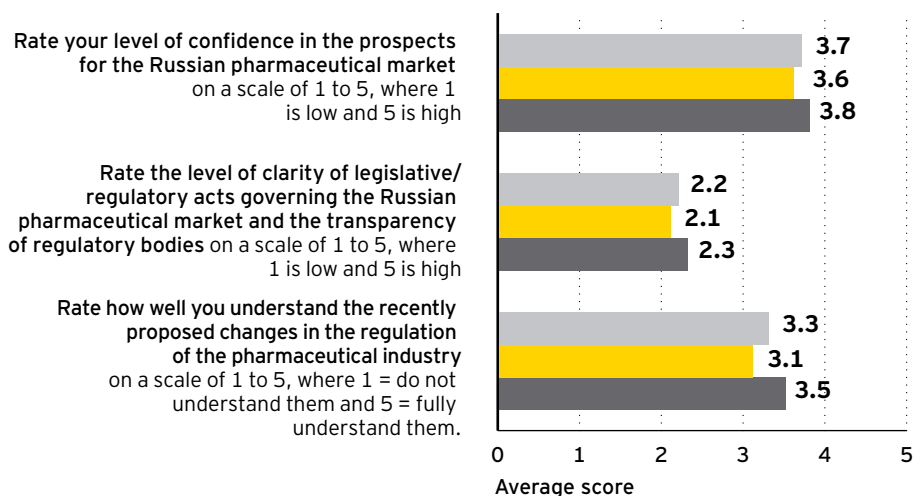
Meanwhile, the evaluation of the industry's prospects among foreign manufacturers remained the same as before. Survey responses indicate that the participants have noticed increased clarity in the legislative framework. This has undoubtedly been helped by the reworking of current industry legislation as well as by legislative amendments aimed at eliminating grey areas.

Figure 1. **Evaluation of the development prospects of the market and the level of clarity of legislation (results of 2012 and 2010 surveys)**

2012



2010

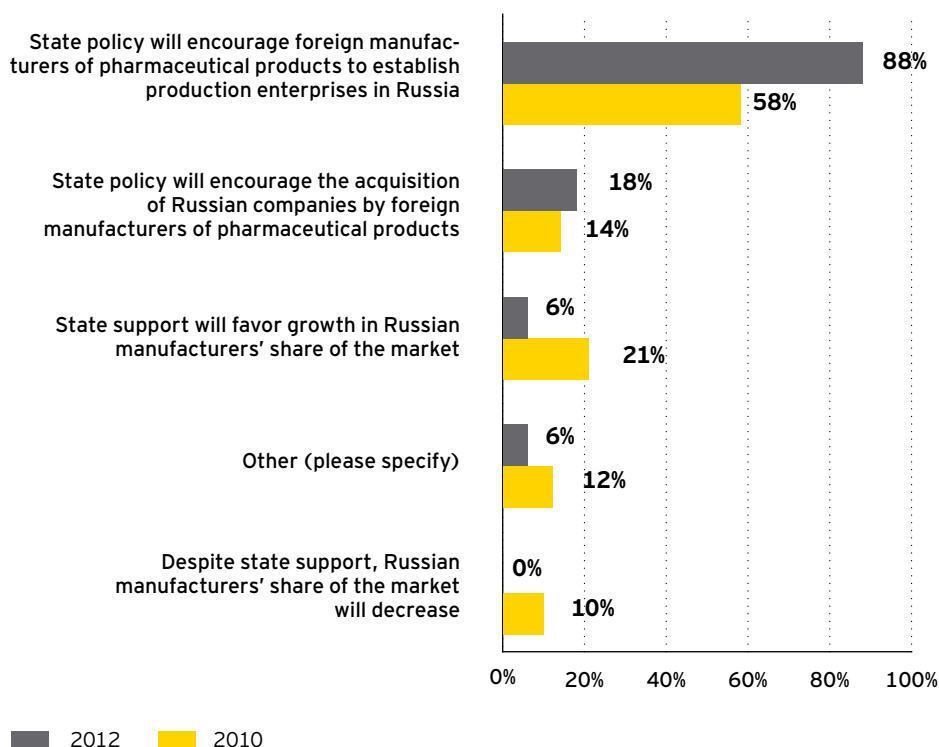


Legend: All respondents (grey), Foreign manufacturers/importers (yellow), Russian manufacturers (dark grey)



The majority of respondents see the localization of drug manufacturing as the main trend in the development of the market over the next five years (Figure 2). The proportion of responses indicating this scenario rose from 58% to 88% compared with 2010. Meanwhile, only 6% of those surveyed regard the growth in the market share of Russian manufacturers, aided by state support, as driving the development of the market. This trend is clearly a direct consequence of the state's program aimed at developing the domestic pharmaceutical industry while encouraging foreign manufacturers to localize their manufacturing operations in Russia.

Figure 2. **How, in your opinion, will the Russian pharmaceutical market develop over the next five years? (Results of 2012 and 2010 surveys)**



State of the pharmaceutical industry and the healthcare sphere

According to data produced by industry experts, the volume of the Russian pharmaceutical market grew by 12% in 2011 over the previous year, amounting to RUB824 billion (including VAT) at end consumer prices. This growth figure is a long way off the pre-crisis level (20-25% per year), but easily better results seen on the global market (5-7%).

The growth in the market for packaged pharmaceutical goods stands at a much more modest 1%. This reflects the main trend of 2011 – a decrease in sales of low-cost drugs (less than RUB50 per package) and an increase in sales of expensive drugs (more than RUB500 per package) (Figure 3).

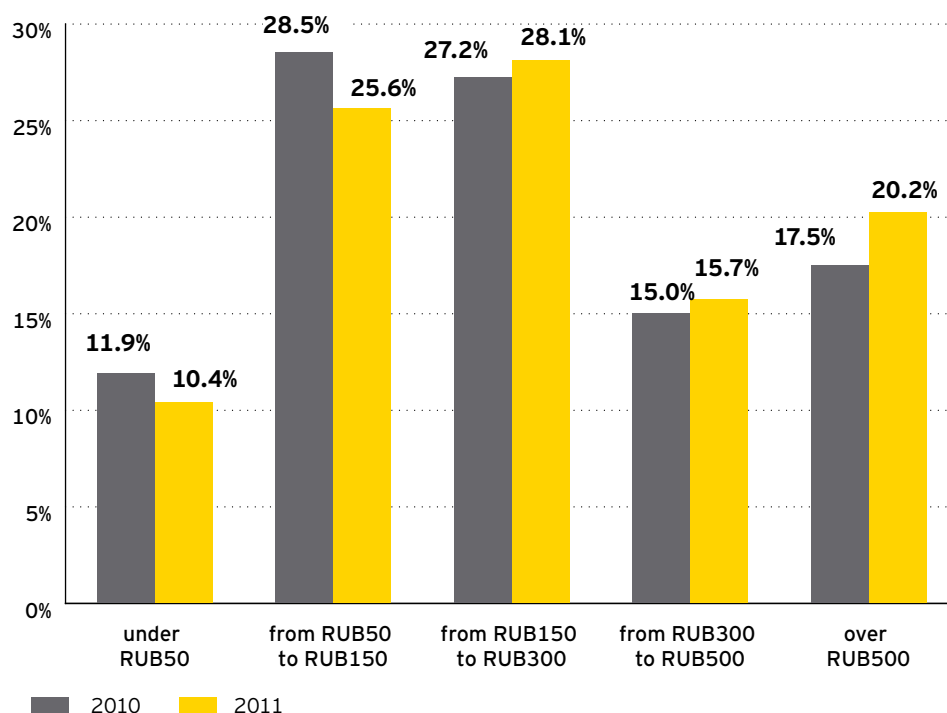
The main factor in the growth of the commercial market is the increase in the price index for medicinal drugs. At 8.8%, it outpaced the State Statistics Service's consumer price index (6.1%) by 2.7%. It is notable that the price index for drugs included in the essential and vital drug list (EDL) was only 3.3%, while the index for drugs not included in the EDL list was as high as 10.8%¹. This difference reflects the effectiveness of measures taken by the state to restrain the growth of prices for EDL, and of the reforms consistently implemented since 2010. As a consequence of these price-restraining measures, prices for those drugs not affected by the restrictions have increased. This is partly due to attempts by market participants to offset losses caused by the state-imposed restrictions in relation to EDL.

Brief Overview of the Healthcare Sphere

According to Ministry of Health data, total state expenditure on healthcare in 2011 amounted to RUB1.933 trillion, or 3.56% of GDP. The greatest increases are observed in expenditure on outpatient (88%) and extended care (81%) (Table 1).

In accordance with Federal Law No. 212-FZ of 24 July 2009 "Concerning Insurance Contributions to the Pension Fund of the Russian Federation, the Social Insurance Fund of the Russian Federation and the Federal Compulsory Medical Insurance Fund", insurance contributions for compulsory medical insurance rose by two percentage points from 3.1% to 5.1% with effect from 1 January 2011. Contributions for the non-working population also increased. In the long term there are plans for transition to a full-reimbursement system and single-channel financing, and for emergency care (from 1 January 2013) and high-technology care (from 1 January 2015) to be included in the compulsory medical insurance system. This would result in a substantial increase in resources within the compulsory medical insurance system, which would be used to provide additional funds for programs aimed at modernizing healthcare.

Figure 3. Structure of sales of medicinal drugs on the retail commercial market by price band



Source: "Monthly Retail Audit of the Pharmaceutical Market of the Russian Federation", DSM Group.

¹ DSM Group, "Russian Pharmaceutical Market 2011"



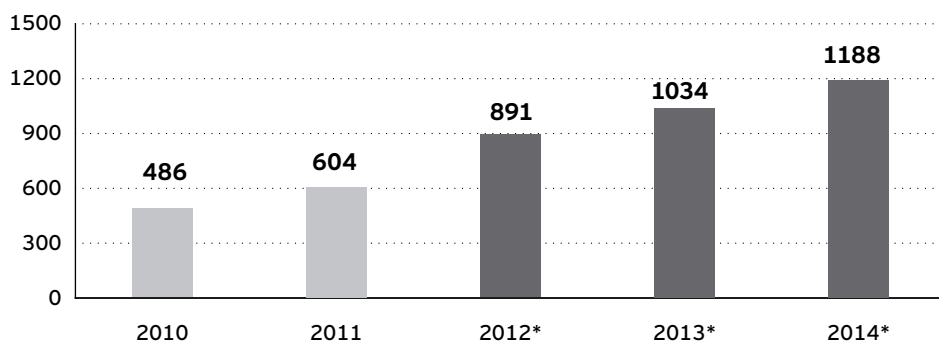
Table 1. **State healthcare expenditure over the period from 2010 to 2011, billions of rubles**

Indicator	Budget/budgets										Increase, %
	Federal		Regional, consolidated		State non-budgetary funds		Territorial state non-budgetary funds		Total		
	2011	2010	2011	2010	2011	2010	2011	2010	2011	2010	
Inpatient medical care	222.38	195.09	198.02	340.86	126.43	0.00	2.20	1.47	749.03	537.42	39
Outpatient care	143.61	48.37	181.67	115.90	4.96	0.00	24.16	24.25	354.40	188.52	88
Medical care in all kinds of day-patient facilities	0.00	0.00	2.19	1.82	0.00	0.00	0.11	0.21	2.30	2.03	13
Emergency medical care	0.35	0.43	67.57	58.21	18.90	0.00	1.12	0.49	87.94	59.13	49
Extended medical care	37.45	21.64	13.73	12.23	10.32	0.00	0.23	0.15	61.73	34.02	81
Procurement, processing, storage and safekeeping of donor blood and components thereof	5.66	5.88	11.00	9.21	3.13	00.00	0.25	0.22	20.04	15.31	31
Disease control	13.02	11.65	0.43	0.51	3.32	0.00	0.00	0.00	16.77	12.16	38

* Does not include expenditure on physical education and sport, research relating to healthcare, physical education and sport and other issues relating to healthcare, physical education and sport.

Source: The Ministry of Finance of the Russian Federation

Figure 4. **Movement in the level of insurance contributions for compulsory medical insurance, billion rubles**



* Value given in accordance with Federal Law No. 370-FZ of 30 November 2011 "Concerning the Budget of the Federal Compulsory Medical Insurance Fund for 2012 and the Planning Period 2013 and 2014".

Source: Federal Service for Financial Markets



According to figures from the Ministry of Economic Development, RUB153.12 billion was allocated for the implementation of the “Zdorovye” (“Health”) national project in 2011, which was 14% more than in 2010. Analysts point to the following results of the implementation of the project and of demographic programs:

- ▶ A 5.2% decrease in mortality rates compared with 2010 (the best figure for the last 19 years), including a 6.2% decrease in mortality from cardiovascular diseases, 7.4% for tuberculosis, 5.6% for traffic accidents and 1% for oncological diseases

- ▶ The achievement of a positive figure for population growth (0.12%)
- ▶ An increase in life expectancy by 1.5 years.

Active implementation of the Strategy for the Development of the Pharmaceutical Industry in the Period up to 2020 began in 2011. A special-purpose program entitled “Development of the Pharmaceutical and Medical Industry of the Russian Federation in the Period up to 2020 and Beyond” was approved. This resulted in over 140 contracts being concluded, including for the development of technologies for the manufacture of EDL, the transfer of foreign designs for innovative drugs and pre-clinical and clinical drug research.

In overall terms, good foundations have been laid for the future development of the healthcare sphere. In accordance with the Strategy for the Long-Term Socio-Economic Development of the Russian Federation, the volume of state healthcare expenditure will increase over the next nine years and will amount to 5.5% of GDP by 2020.

Table 2. **Volume of state healthcare expenditure as a proportion of GDP (%), 2011-2020**

Indicator	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Expenditure of budgets of all levels, billion rubles	1933.00	2230.05	2773.38	2993.56	4238.30	4505.32	4789.15	5090.87	5411.59	5752.52
Increase, %	-	15	24	8	42	6	6	6	6	6
Proportion of GDP	3.56	3.80	4.28	4.13	5.50	5.50	5.50	5.50	5.50	5.50

Source: The Ministry of Finance of the Russian Federation

2012: continuation of legislative reform and initial results of changes

The reform of healthcare and pharmaceutical legislation which began in 2010 has continued apace in 2011 and 2012. The past year has witnessed the implementation of a number of weighty legislative initiatives, including the entry into force from 1 January 2012 of important provisions of the Federal Law "Concerning the Fundamental Principles of Public Healthcare in the Russian Federation". Numerous debates continue to rage over the need for amendments to the Federal Law "Concerning the Circulation of Medicinal Drugs". The new law "Concerning the Fundamental Principles of Public Healthcare in the Russian Federation" establishes and regulates, among other things:

- ▶ The fundamental principles of public healthcare
- ▶ The powers of state authorities
- ▶ The rights and obligations of citizens
- ▶ The organization of healthcare
- ▶ The activities of medical/pharmaceutical workers and medical organizations
- ▶ The rules governing free medical care for citizens
- ▶ The procedure for the financing of the healthcare sphere
- ▶ Supervision in the healthcare sphere

Even though executive and legislative bodies held lengthy discussions with industry representatives when the law was in its draft stage, the final law required pharmaceutical companies to make changes in the way they operated. Particularly affected were the relationships between representatives of pharmaceutical companies and medical and pharmaceutical workers.

Market participants and regulatory authorities have now come to grips with the new rules and regulations in the Law "Concerning the Circulation of Medicinal Drugs", which entered into force in September 2010. This process was aided by the elimination during 2011 of certain deficiencies and ambiguities in the law which created difficulties for market participants (including in regard to the conduct of clinical trials, the importation of drugs for the purpose of conducting clinical trials, etc.).

Reform of the pharmaceutical market is far from complete, however, and further changes are expected in the future. As from 1 January 2014 it will be compulsory to comply with international Good Manufacturing Practice standards. The President's program also requires executive bodies to develop a drug reimbursement system with a view to implementation in 2016.

The survey participants predict that the state will continue to encourage foreign pharmaceutical manufacturers to establish production enterprises in the Russian Federation. It only remains to be hoped that the Government will opt for a policy of granting preferences and concessions to Russian manufacturers rather than taking prohibitive measures against foreign companies.

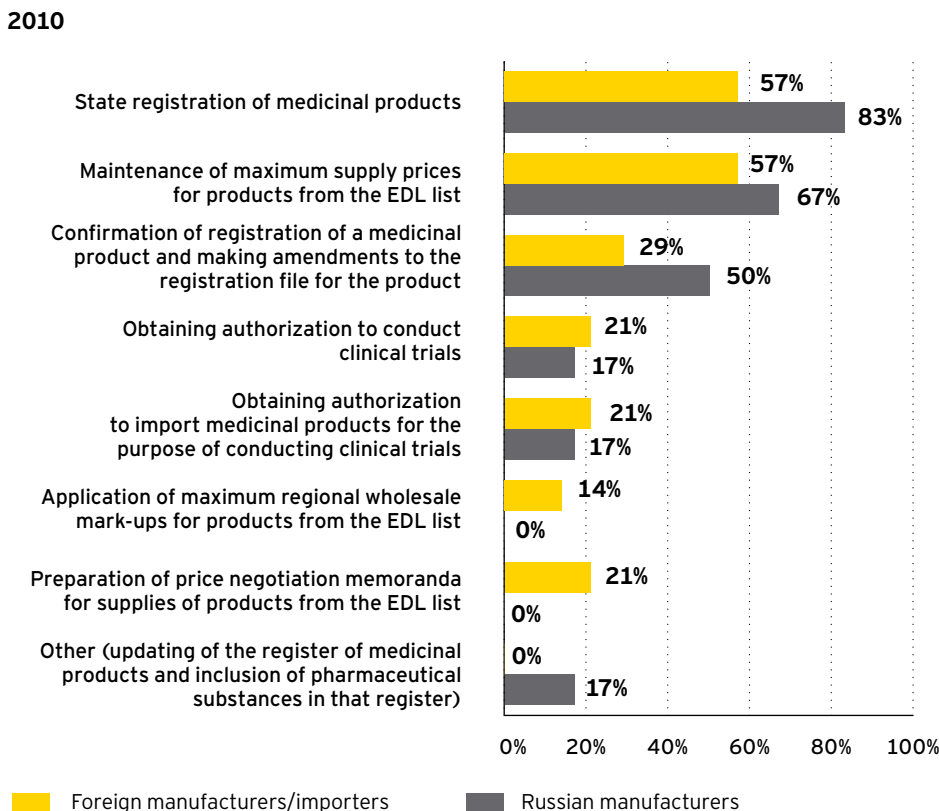
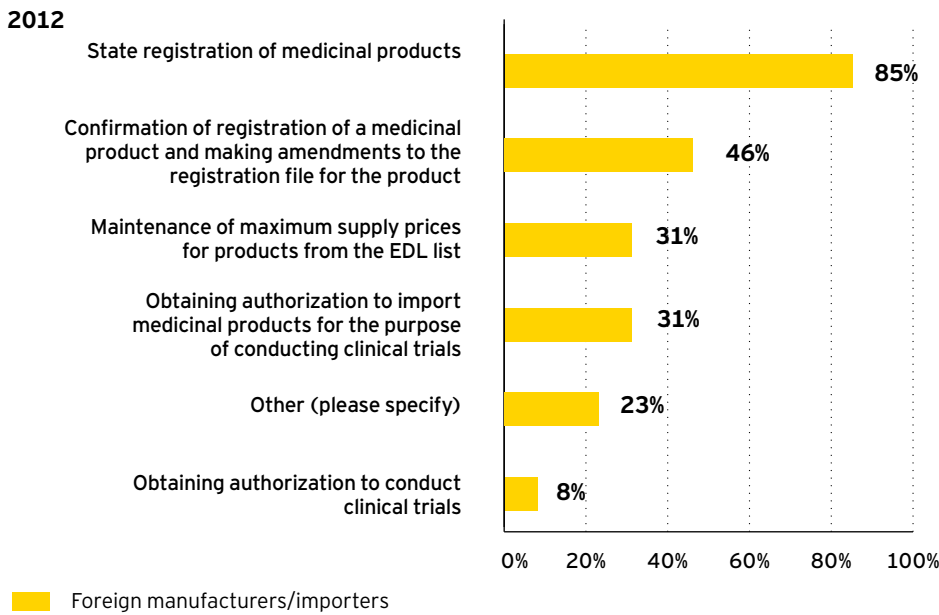
Main problems associated with the application of the new legislation

State registration of medicinal drugs

The majority of respondents (85%, see Figure 5) still regard the process of the state registration of medicinal drugs as one of the most problematic aspects of the current Law "Concerning the Circulation of Medicinal Drugs". This may be because the introduction of the new law brought about a fundamental revision and re-allocation of the operating procedures and functions of executive bodies in the field of healthcare. In particular, responsibility for the state registration of medicinal products was transferred from the Federal Service for Healthcare Supervision to the Ministry of Health. The transfer of functions and the shortage of personnel might explain why the process of the state registration of medicinal products, like the process of obtaining confirmation of their registration and registering prices, continues to be viewed by respondents as a key problem area.



Figure 5. In what areas does your company encounter the greatest difficulties?
(Results of 2012 and 2010 surveys)



Pricing

Despite the fact that the rules for the state regulation of pricing for medicinal products included in the EDL list have been in effect since 2010, the respondents (31%, see Figure 5) continue to indicate difficulties associated with the registration of maximum manufacturer supply prices for EDL.

State regulation of prices for medicinal products included in the EDL list involves monitoring of maximum supply prices set by manufacturers for those products and monitoring of the application by wholesale and retail organizations of appropriate mark-ups on actual supply prices of manufacturers of EDL. In this respect, the rules governing the state registration of prices for EDL differ in certain ways for Russian and foreign manufacturers, for instance in allowing for Russian manufacturers to revise and re-register maximum supply prices and in allowing them to adjust the maximum supply price for the inflation index (not possible for foreign manufacturers).

Thus, a certain degree of preference is accorded to Russian manufacturers in the process of the state regulation of prices for medicinal products included in the EDL list.

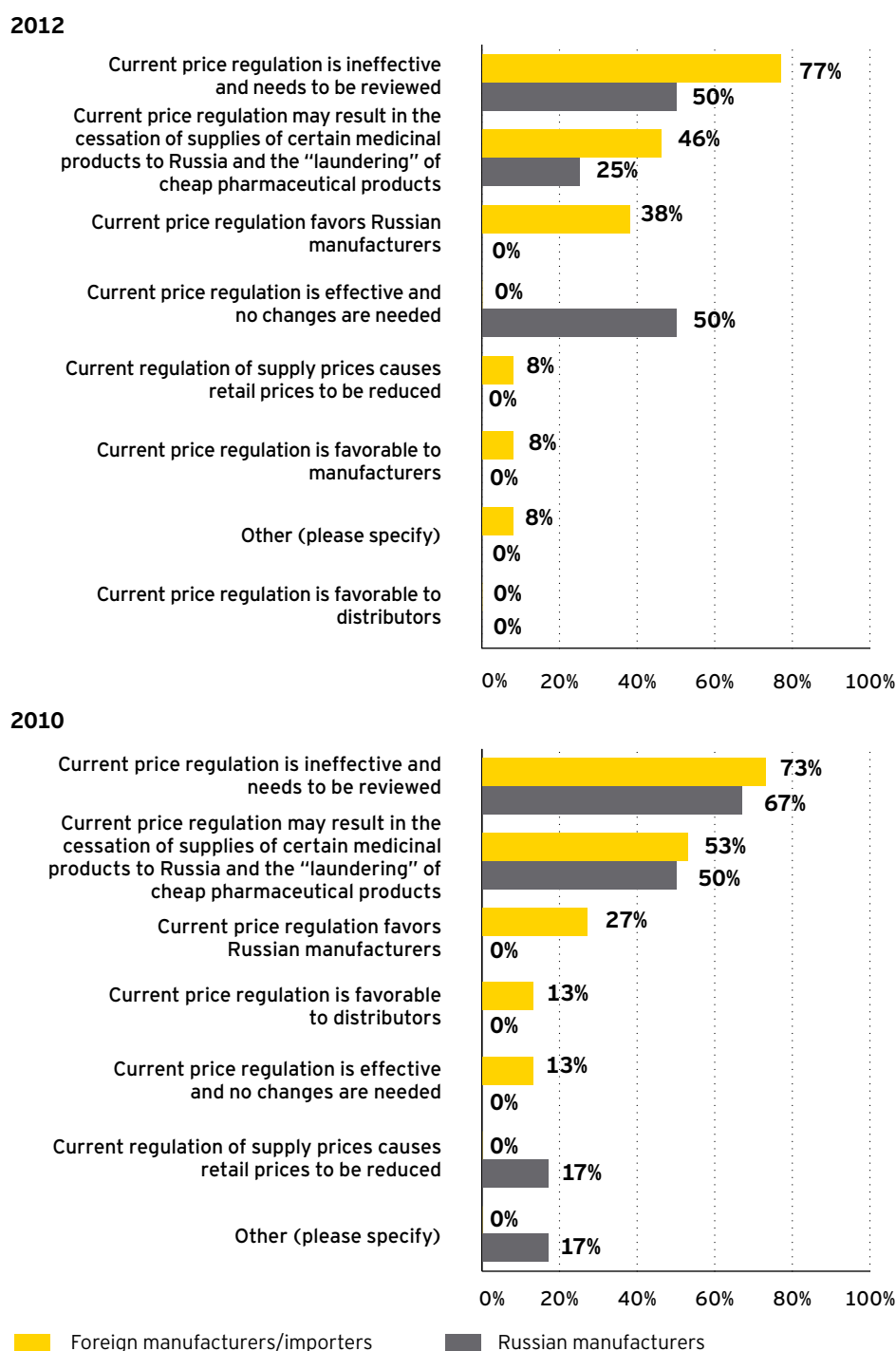


This view is reflected in our survey. Half of the Russian manufacturers surveyed viewed the current system of price regulation as effective (Figure 6).

At the same time, 77% of foreign manufacturers viewed the existing price regulation procedure as ineffective and in need of change. It should be noted that, compared with the 2010 survey, the number of Russian manufacturers dissatisfied with the current price regulation system has fallen by 17%. Meanwhile, the number of foreign manufacturers calling for the current system to be changed has, on the contrary, risen from 73% to 77%.

It is clear that pricing reform in the Russian pharmaceutical industry is incomplete. Various executive bodies (the Federal Anti-Monopoly Service, the Ministry of Economic Development) continue to advance proposals for improving the existing system of pricing regulation. Furthermore, the Ministry of Health is working on a public drug reimbursement strategy which is intended to deliver fundamental changes to the pricing system currently prevailing on the market.

Figure 6. **What, in your view, are the prospects for the state regulation of prices for pharmaceutical products in Russia? (Results of 2012 and 2010 surveys)**



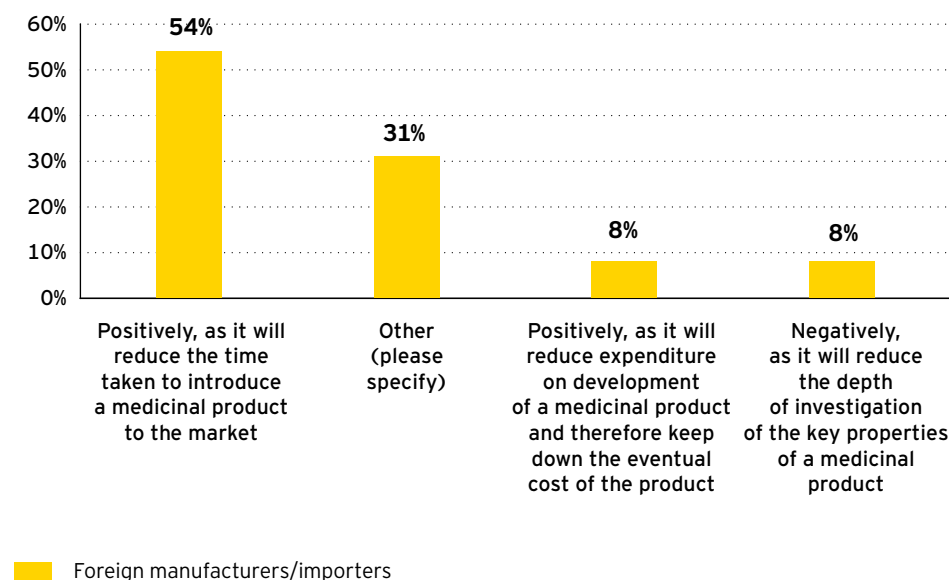
Clinical trials

One important development in the area of the regulation of clinical trials, which attracted public attention, was the bill drafted by the Federal Anti-Monopoly Service in March 2012 for amendments to the Federal Law "Concerning the Circulation of Medicinal Drugs". Among the key proposals is the abolition of the requirement for local clinical trials. This proposal was welcomed by participants in the pharmaceutical market. Our survey shows that half of all respondents are in favor of abolishing the local clinical trial

requirement (Figure 7). It is expected that such a move would reduce the time taken to introduce new medicinal products to the market.

Nevertheless, the proposed changes have yet to be made into law. In practice, clinical trial procedures raise a good many questions. The survey indicates that 10% more respondents in 2012 than in 2010 encountered difficulties in obtaining authorization to import products for the purpose of conducting clinical research (Figure 5).

Figure 7. How do you view the initiative to abolish the local clinical trial requirement?

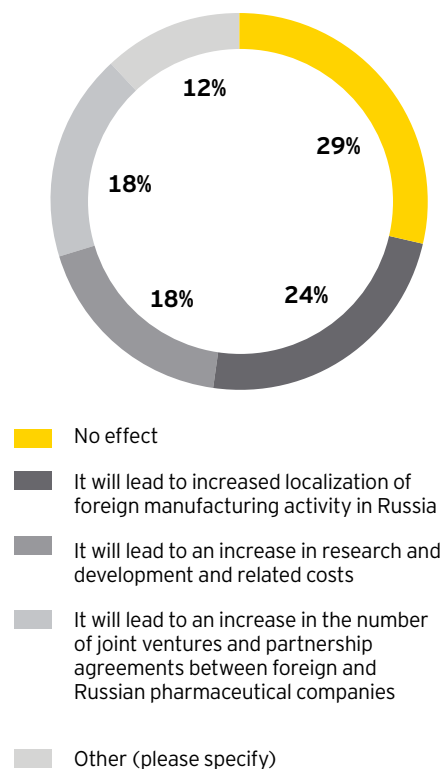


Data protection

An important development in the area of clinical research was the entry into force of the provision of the Federal Law "Concerning the Circulation of Medicinal Drugs" concerning the protection of information on pre-clinical and clinical research (the data exclusivity rule), whose introduction was made necessary by Russia's accession to the World Trade Organization (WTO). Under that rule, information on the results of pre-clinical and clinical research which is presented by an applicant for state registration may not be obtained, divulged or used for commercial purposes or for the purposes of the state registration of medicinal products without the applicant's consent for six years from the date of state registration of a medicinal product.

Over 40% of the surveyed participants in the pharmaceutical market believe that the introduction of this rule will facilitate the localization of foreign manufacturing activity in Russia or lead to an increase in the number of joint ventures and partnership agreements between Russian and foreign manufacturers (Figure 8). At the same time, almost one third of the respondents took the view that the development would have no impact at all on the development of the pharmaceutical market in Russia, while one in five thought that it might lead to an increase in research costs.

Figure 8. How, in your view, will the Russian pharmaceutical market be affected by the entry into force of the provision prohibiting information on the results of pre-clinical and clinical research from being obtained, divulged or used for commercial purposes or for the purposes of the state registration of medicinal products without the consent of the rights owner for six years from the date of state registration of a medicinal product (the data exclusivity rule)?



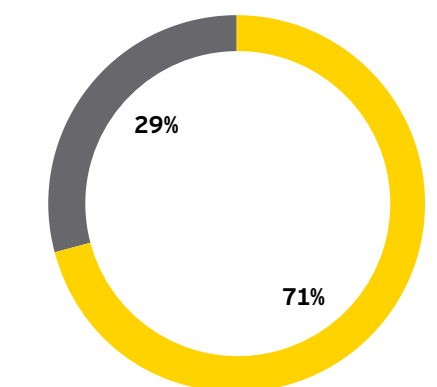
Restrictions on interaction of pharmaceutical companies with medical and pharmaceutical workers

Rules established by the Federal Law "Concerning the Fundamental Principles of Public Healthcare" imposing restrictions on medical and pharmaceutical workers in the conduct of their professional activities came into effect on 1 January 2012. The restrictions are comprehensive in scope and relate to the receipt of gifts and money by medical and pharmaceutical workers from pharmaceutical companies, the making of arrangements whereby particular medicinal products are prescribed, recommended or offered to patients, the receipt of sample products for delivery to patients, the supply of false information, the receipt of visits from representatives of pharmaceutical companies, etc. These restrictions have

been the subject of numerous discussions within the professional community, and diametrically opposed views were expressed in the process of determining how they were to be applied.

The overwhelming majority of respondents took the view that the introduction of the above-mentioned prohibitions had not led to companies reducing the number of medical representatives on their staff and seeking new ways of interacting with the medical and pharmaceutical community. Only a third of the surveyed members of the pharmaceutical community indicated that such an effect had occurred.

Figure 9. How do you assess the impact on your company and on the pharmaceutical industry as a whole of the introduction from 1 January 2012 of restrictions on interaction between medical and pharmaceutical workers and representatives of pharmaceutical companies?

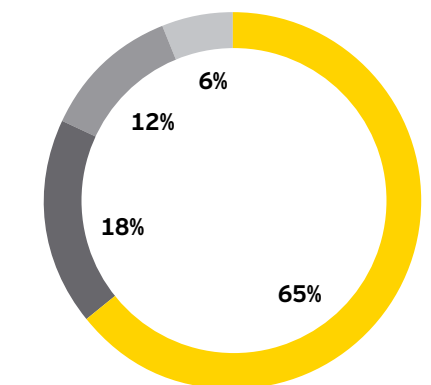


- The restrictions have not resulted in a significant reduction in the number of medical representatives on the company's staff and the need to look for new ways of interacting with pharmaceutical and medical workers
- The restrictions have resulted in a reduction in the number of medical representatives on the company's staff and the need to look for new ways of interacting with pharmaceutical and medical workers

It now remains to be seen how the introduction of administrative sanctions for the violation of these restrictions will impact pharmaceutical companies' strategies for interaction with medical and pharmaceutical workers.

Possible ban on advertising of medicinal products

Figure 10. How do you view the legislative initiative to introduce a ban on the advertising of medicinal products?



- Negatively, as a ban on advertising medicinal products will significantly reduce awareness of available products among patients and doctors
- Positively, as a ban on advertising medicinal products will help to reduce the spread of misinformation about the effectiveness of those products
- Negatively, as a ban on advertising medicinal products will result in higher prices for end consumers owing to the need for market participants to use more expensive methods of promoting their products
- Positively, as a ban on advertising medicinal products is an effective way of combating excessive consumption of expensive drugs

Current legislation establishes a number of requirements in regard to the dissemination of information on prescription drugs, but does not impose restrictions on the placement of information concerning non-prescription drugs. The initiative to impose a total ban on drug advertising has elicited a strong reaction within the mass media and the professional community. The majority of representatives of pharmaceutical companies who took part in our survey expressed a negative view of the initiative. Sixty-five percent of respondents indicated that a total ban on drug advertising would, in their view, significantly reduce the level of awareness of available products among patients and doctors.

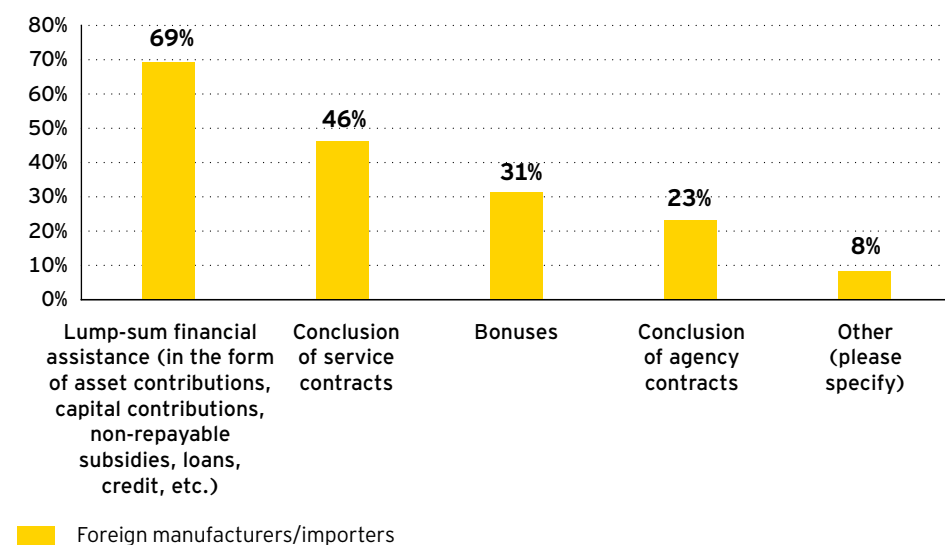
Tax and financing issues

Strict price restrictions often mean that Russian subsidiaries of foreign pharmaceutical manufacturers are unable to cover their operating costs in full. This can result in acute financing problems for Russian subsidiaries.

In 2012 this problem was exacerbated by the entry into force of the new transfer pricing (TP) law. Unlike before, goods subject to state price regulation are not excluded from the scope of the law. This means that the forms of financing used to support the activities of Russian subsidiaries in 2012 must conform to the requirements of transfer pricing legislation as well as tax legislation and internal corporate policies.



Figure 11. How does your company structure financing where there is a need to improve financial performance in Russia?



The survey showed that in 2012 one of the most popular ways of providing additional financing for Russian businesses was through lump-sum financial assistance (69% of respondents preferred this form). It is certainly true that this mechanism has been widely used by Russian companies. Its advantage is in providing a relatively simple procedure for the receipt of financial resources and allowing for effective tax planning. From the point of view of the TP law, however, it is not an effective option as it does not affect the financial results obtained from the sale of products (work and services) to a Russian company and cannot, therefore, be treated as a price adjustment.

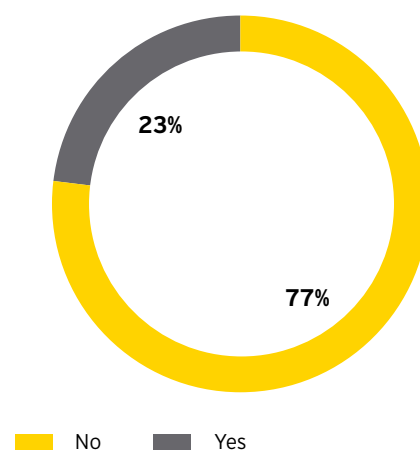
The second most popular financing method is the use of service contracts. These contracts effectively serve as a framework for cost sharing and the rebilling of expenses to companies within a group. Since Russian law does not provide for cost sharing as such, the arrangement has to be structured through service contracts. The disadvantage of this option is the additional VAT costs incurred.

A third of respondents use the payment of premiums/bonuses as a financing mechanism. Conclusion of agency contracts was in fourth place. The survey showed that many companies use a combination of financing mechanisms in order to achieve maximum efficiency and spread risks.

Customer incentives

The issue of how premiums/bonuses granted by a seller of goods to a purchaser should be taxed has been raised on numerous occasions over the last few years. A new wave of discussions on this subject was prompted by a recent court case involving an international chain of hypermarkets selling do-it-yourself and construction goods. However, 77% of the companies surveyed are not intending to switch to other forms of customer incentives despite the uncertainty over the tax treatment of bonuses and the possible tax risks. At the same time, 23% of respondents have considered switching to other forms of client incentives.

Figure 12. Do you plan to make changes to your existing system for incentivizing sales channels, including the granting of bonuses (premiums), discounts, etc., in view of the uncertainty over the applicability of VAT to bonuses paid as a result of the fulfillment of particular contract conditions, particularly in regard to the volume of purchases?



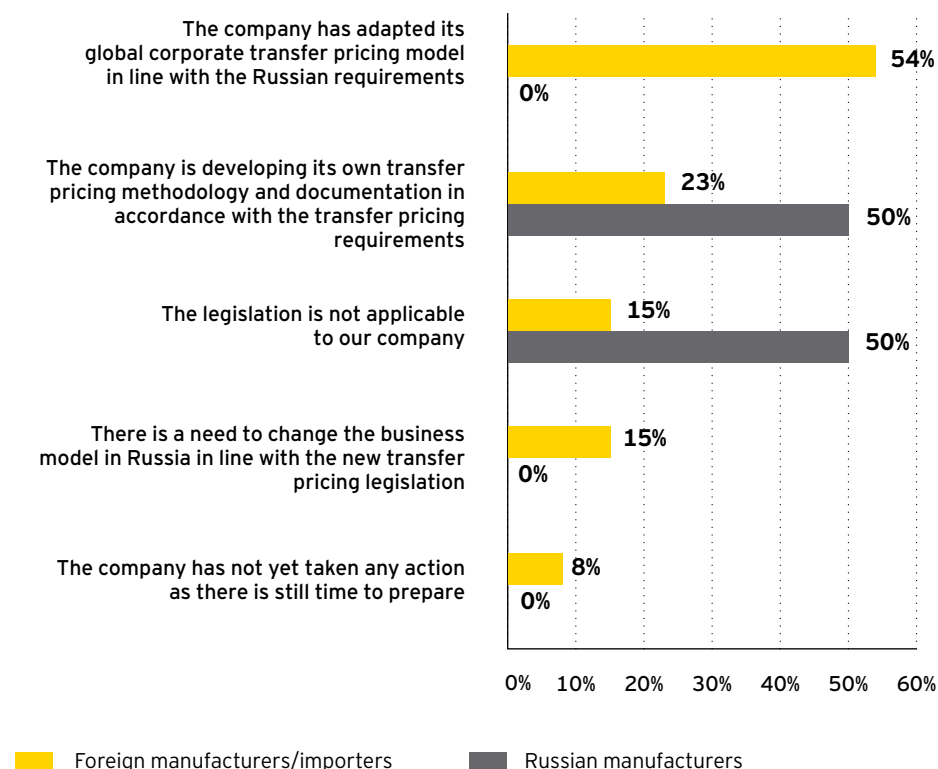


New transfer pricing rules

The entry into force of the new TP law has created further complications for taxpayers and tax authorities, since it is a fundamentally new development in Russian legislation.

The survey showed (Figure 13) that more than 50% of Russian and foreign pharmaceutical companies have already begun to review their operations and prepare necessary documentation in accordance with the new law. Particularly interesting is the fact that a half of respondents representing Russian companies believe that the requirements of the TP law are not applicable to them. Representatives of foreign companies are less certain in their assessment of the law: only 15% of respondents consider that it does not apply to their activities.

Figure 13. What action has your company taken in connection with the introduction of new transfer pricing legislation with effect from 1 January 2012?



Development prospects for the industry

The respondents continue to see unfavorable legislation as the chief threat to the industry. This year saw corruption occupy second place among both foreign and Russian participants in the survey. In the last survey, the second biggest problem for the Russian market was thought to be the shortage of skilled staff, which rated third in the new study, being of greater concern to Russian manufacturers (50%, Figure 14). It follows from the responses to this and other questions in the questionnaire that despite the difficult economic climate, market players are not experiencing substantial shortages of financial resources needed to support and develop their activities.

Russia's accession to the WTO

On 22 August 2012 the Protocol of Accession of the Russian Federation to the World Trade Organization entered into force. Under that Protocol the level of import duty rates will be gradually reduced beginning from 2013. In particular, import duty rates for medicinal drugs will come down from their existing level (10-15%) to 5-6.5% (no later than 2016), while rates for medical devices will fall on average from 5% to 3% (no later than 2014). Another condition of Russia's membership of the WTO was the improvement of intellectual property protection, including by means of the creation of specialized intellectual property courts. Despite this, the respondents expect Russia's membership in the WTO to have no effect on the development of the pharmaceutical industry. Over two thirds of respondents predict that prices for foreign and Russian medicinal drugs will remain the same as before. Only a third of those surveyed expect an increase in the proportion of foreign drugs and a decrease in the proportion of domestically manufactured products (Figure 15). This is most likely to happen by reason of the simplification of procedures for the importation of products or the decrease in prices for imported drugs in certain "low-cost" categories.

Figure 14. Which of the following factors pose the greatest threat to the industry? (Results of 2012 and 2010 surveys)

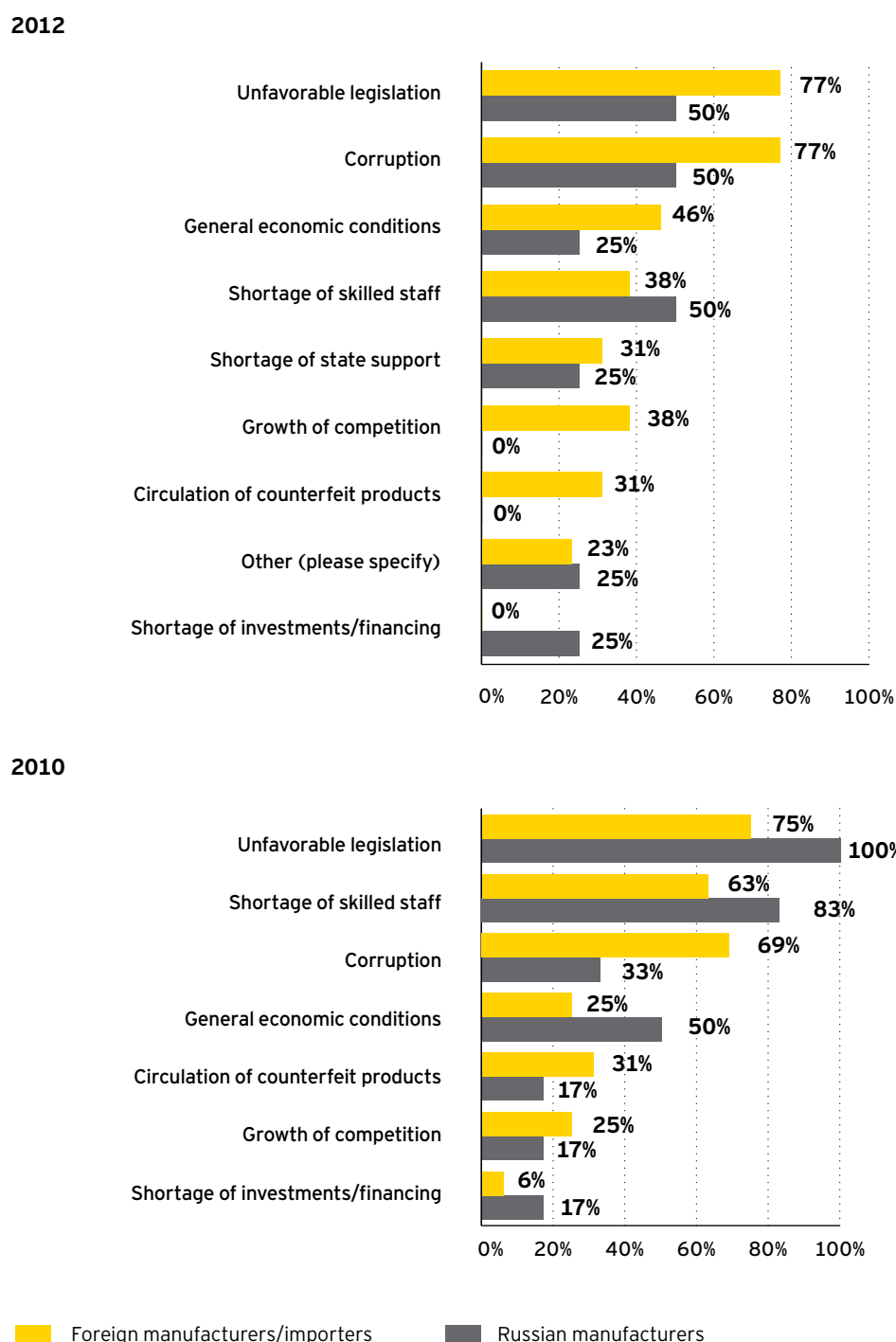
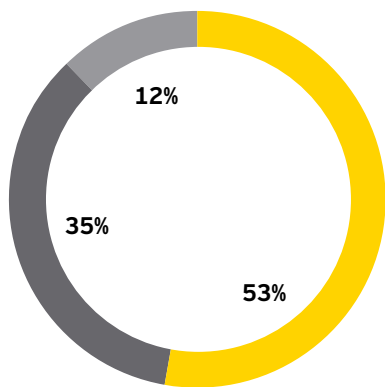


Figure 15. How will Russia's accession to the WTO affect the development of the pharmaceutical industry?



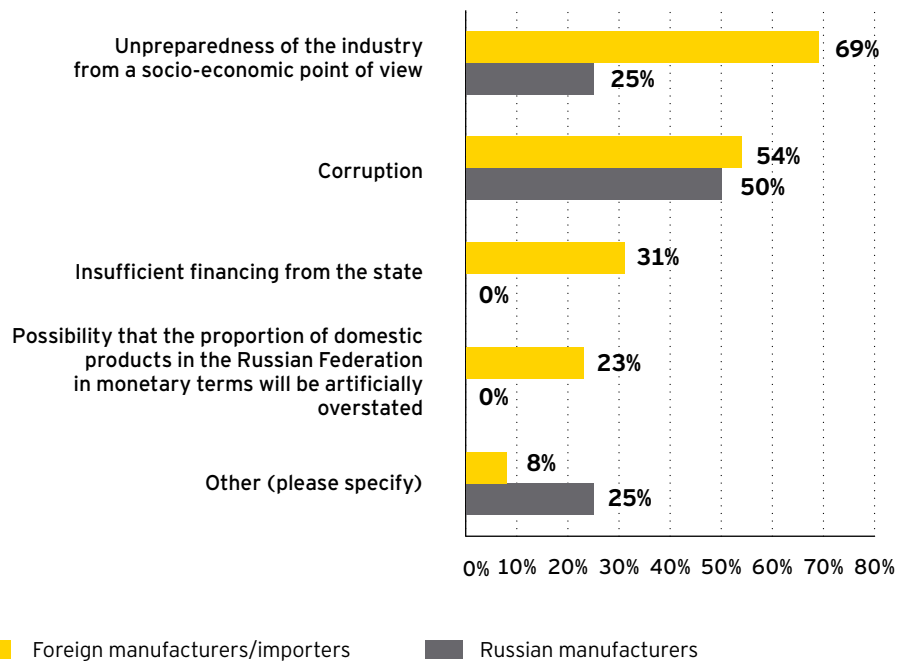
- It will not affect the relative proportions of foreign and domestic drugs
- It will cause an increase in the proportion of foreign drugs and a decrease in the proportion of domestic drugs
- Other (please specify)

Prospects for the Federal Special-Purpose Program and related reforms

A federal special-purpose program entitled "Development of the Pharmaceutical and Medical Industry of the Russian Federation in the Period up to 2020 and Beyond" was approved on 17 February 2011. The main objective of the program is to aid the development of Russian manufacturing of competitive pharmaceutical and medical products. The volume of consumption of medicinal products manufactured in Russia is expected to rise in both monetary and quantitative terms as a result of the program.

The overwhelming majority of foreign companies (69%) expressed the view that the Russian market is not ready for the program from a socio-economic point of view. The same view is held by 25% of Russian manufacturers. Over half of the participants in the study indicated corruption as another obstacle to the implementation of the program. This factor is foremost among Russian companies and occupies second place among foreign respondents.

Figure 16. How do you rate the prospects for the "Development of the Pharmaceutical and Medical Industry of the Russian Federation in the Period up to 2020 and Beyond" federal special-purpose program and what obstacles do you see to its implementation?

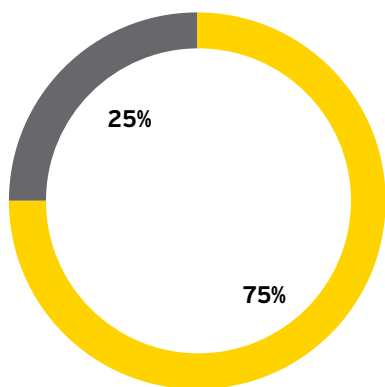




Transition to new manufacturing standards

The Russian manufacturers surveyed are firmly in favor of the requirement to adopt Good Manufacturing Practice standards by 2014 (Figure 17). The respondents believe that the transition to GMP standards will improve the quality of products manufactured and will be essential to the development of contract manufacturing with Western companies. However, there is still uncertainty as to the readiness of the sector to adopt the standards as early as 2014.

Figure 17. How do you view the planned transition to new manufacturing standards (Good Manufacturing Practice) by 2014?



Proportion of respondents within the total number of Russian manufacturers who responded

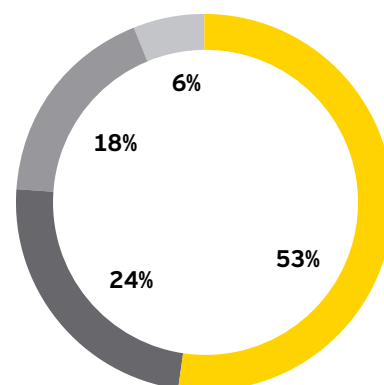
- Positively, as GMP standards will increase the quality of manufacture of medicinal products
- Positively, as manufacturing in accordance with GMP standards is essential for doing business with foreign manufacturers

Public drug reimbursement

Market participants and representatives of regulatory authorities view the current system of free drug reimbursement in Russia as flawed. It is a problem that arises especially frequently in regard to outpatient treatment. It is often the case that only a narrow section of the population is able to obtain medicines free of charge. Most have to acquire them out of their own pocket. For this reason there is active discussion in the professional community regarding the introduction of a public drug reimbursement strategy. The strategy proposes a gradual transition to a drug reimbursement system whereby citizens would be able to obtain certain prescribed products within a group of interchangeable drugs either free of charge or for a small charge.

However, it would be difficult at present to implement such a plan. On the one hand, the regulatory framework would need substantial reworking to make it compatible with a public drug reimbursement system. On the other hand, the infrastructure needed to administer such a system does not exist. The majority of respondents believe that the new system could be introduced in five to ten years' time. Meanwhile, 24% of respondents take a more optimistic view and expect it to be introduced within the next five years.

Figure 18. Rate the extent to which the regulatory framework and state resources are ready for the introduction of a public drug reimbursement system in Russia



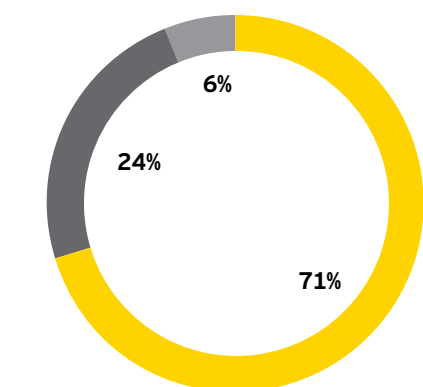
- Possible in the medium term (5-10 years)
- Possible in the short term (1-5 years)
- Possible in the long term (more than 15 years)
- Not possible



The survey showed that almost three quarters of representatives of pharmaceutical companies took a favorable view of the decision by the Ministry of Health to involve them in discussions of the problems relating to public drug reimbursement.

The overwhelming majority of those surveyed are highly interested in the development of the Strategy for Public Drug Reimbursement in the Russian Federation in the Period up to 2025, which the Russian President has ordered the Government to draw up.

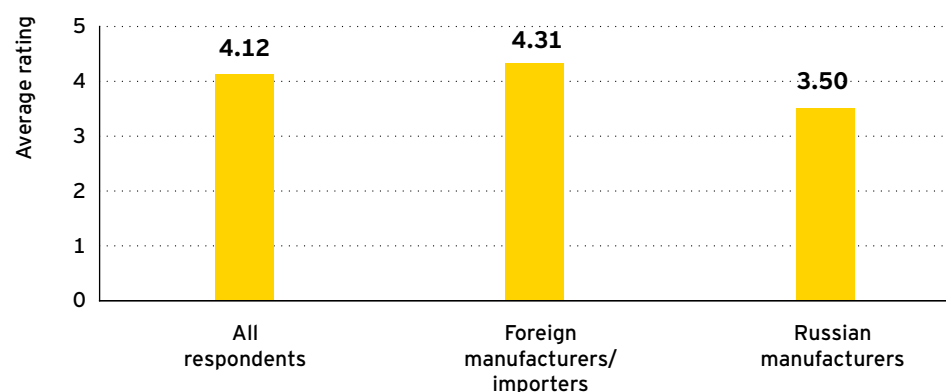
Figure 19. What is your view of the recent initiatives of the Ministry of Health to involve representatives of the pharmaceutical industry in the discussion of problems relating to the improvement of public drug reimbursement in Russia (including the organization of roundtables)?



- Positive
- Neutral
- Other (please specify)

Figure 20. Rate the level of your interest in the development of the Strategy for Public Drug Reimbursement in the Russian Federation and the road map for its implementation

on a scale of 1 to 5, where 1 is low and 5 is high.



Reaction to changes and development plans

The experience of the last two years has shown the state's commitment to a policy of systematic changes in the industry. This is evident in its reform of industry legislation and in the implementation of a strategy and special-purpose program for the modernization of pharmaceutical production and the medical industry as a whole. On the one hand, the Government's actions lay solid foundations for the development of the market, while on the other hand certain legislative initiatives bring about complications in doing business in Russia.

Set in this context, the survey indicates that foreign and Russian companies alike take a positive view of the prospects for the market. At the same time, they recognize the need for certain legislative provisions and regulations to be revised, particularly in regard to the regulation of drug prices.

The introduction of new products to the market is indicated by the respondents as a primary business development goal for 77% of foreign and 75% of Russian companies (Figure 21). Fifty-four percent of foreign manufacturers/importers are looking at the possibility of contract-based production at Russian manufacturing sites. This shows that Russian manufacturing sites are gaining in appeal, as only 44% of respondents were considering this option in 2010. Also noteworthy is the intention indicated by over 75% of Russian respondents to expand into foreign markets. Russia's accession to the WTO will facilitate the distribution of Russian drugs abroad. The building of new production facilities, which was indicated by 50% of Russian manufacturers as a development goal, should also help to increase the volume of domestic medicinal products in Russia and abroad.

Figure 21a. Which of the following forms of business development is your company considering in Russia?



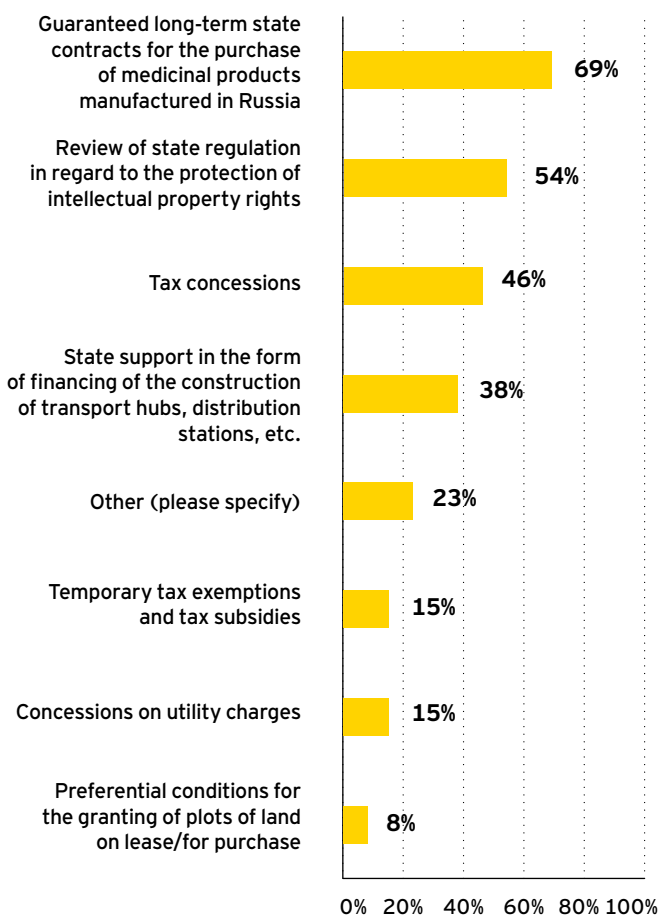
Figure 21b. Which of the following forms of business development is your company considering in Russia?



Participants in the survey

In this context, given the plans expressed by the majority of respondents to introduce new products to the market and develop their manufacturing activity, the main form of support that foreign manufacturers would like to see offered by the state is guaranteed long-term state contracts for the purchase of medicinal products manufactured in Russia – this was indicated by almost 70% of those surveyed (Figure 22). Other forms of state support might be improved protection for intellectual property rights, tax concessions for investors and state financing for the construction of necessary infrastructure.

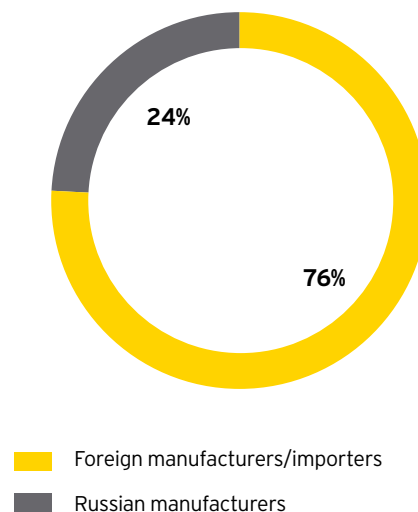
Figure 22. **What form of state support for foreign investors would you like to see in Russia at federal and regional levels?**



Foreign manufacturers

The respondents mostly comprised foreign manufacturers/importers (76% of those surveyed). The remaining participants in the study (24%) were Russian manufacturers of pharmaceutical products.

Figure 23. **Composition of Respondents**



Contact information



Dmitry Khalilov

Partner, Tax & Law, CIS Life Sciences Leader

Tel.: +7 (495) 755 9757

Dmitry.Khalilov@ru.ey.com



Ivan Butyagin

Partner, Advisory

Tel.: + 7 (495) 705 9713

Ivan.Butyagin@ru.ey.com



Alexander Khorovitch

Partner, Assurance

Tel.: +7 (495) 755-9844

Alexander.Khorovitch@ru.ey.com



Andrey Novikov

Partner, Assurance, Fraud Investigation
and Dispute Assistance Services

Tel.: + 7 (495) 648 9618

Andrey.Novikov@ru.ey.com



Anna Guseva

Partner, Transaction Advisory Services

Tel.: +7 (495) 641-2944

Anna.Gusev@ru.ey.com



Sergei Stefanishin

Partner, Tax & Law

Tel.: +7 (495) 755 9872

Sergey.Stefanishin@ru.ey.com

Ernst & Young

Assurance | Tax | Transactions | Advisory

About Ernst & Young

Ernst & Young is a global leader in assurance, tax, transaction and advisory services.

Worldwide, our 167,000 people are united by our shared values and an unwavering commitment to quality. We make a difference by helping our people, our clients and our wider communities achieve their potential.

Ernst & Young expands its services and resources in accordance with clients' needs throughout the CIS. 4,000 professionals work at 19 offices in Moscow, St. Petersburg, Novosibirsk, Ekaterinburg, Kazan, Krasnodar, Togliatti, Vladivostok, Yuzhno-Sakhalinsk, Almaty, Astana, Atyrau, Baku, Kyiv, Donetsk, Tashkent, Tbilisi, Yerevan, and Minsk.

For more information about our organization, please visit www.ey.com.

Ernst & Young refers to the global organization of member firms of Ernst & Young Global Limited, each of which is a separate legal entity.

Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients.

© 2012 Ernst & Young (CIS) B.V.
All Rights Reserved.

This publication contains information in summary form and is therefore intended for general guidance only. It is not intended to be a substitute for detailed research or the exercise of professional judgment. Neither EYGM Limited nor any other member of the global Ernst & Young organization can accept any responsibility for loss occasioned to any person acting or refraining from action as a result of any material in this publication. On any specific matter, reference should be made to the appropriate advisor.