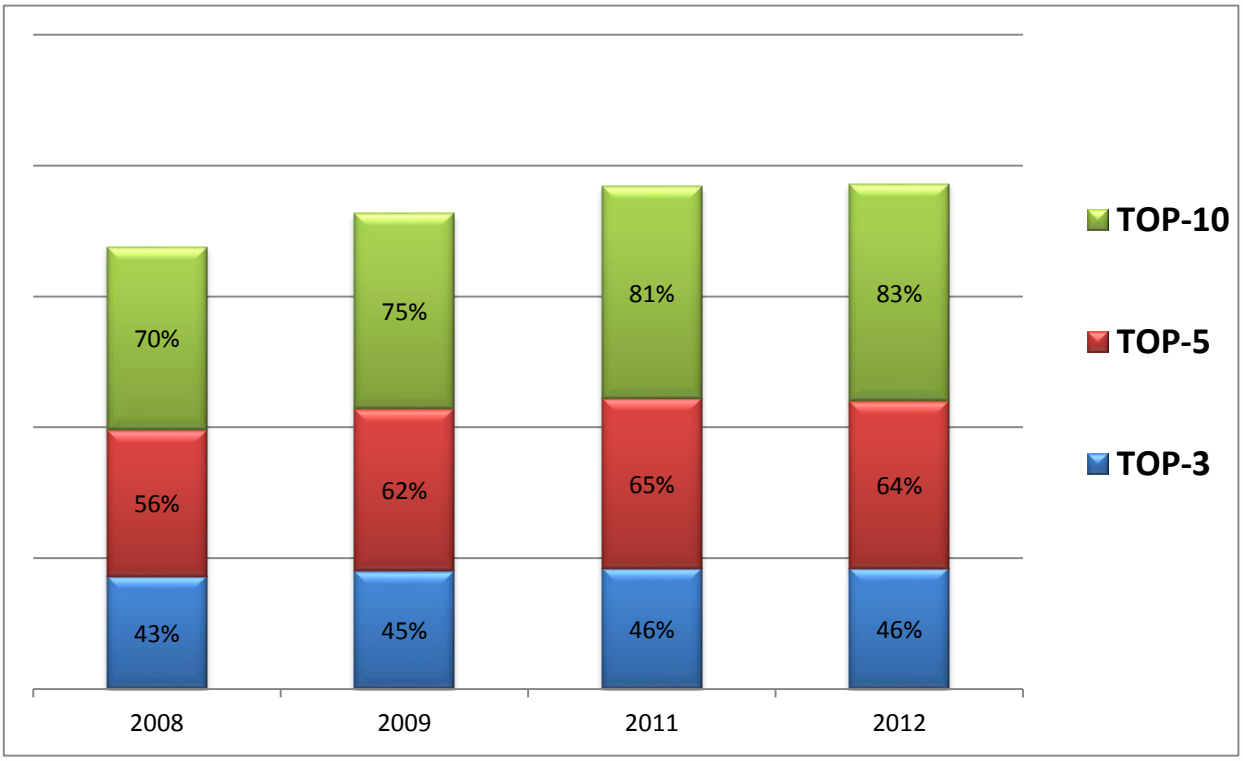
Cases & analytics for the OECD

Brief analytics:

In the Russian Federation continues the trend of horizontal and vertical integration in the pharmaceutical market.

Experts estimate that the level of concentration of the wholesale pharmaceutical market in Russia has an obvious dynamics of growth. In 2011, the share of the top-10 distributors was approximately 83%. Share of leading distributors included in the top-3 was 46%.

Concentration in the distribution segment



Despite significant volumes of distribution of medicinal products in the Russian Federation, within the confines of the Russian Federation these companies are often do not occupy a dominant position.

Based on the analysis of retail sale market of medicinal products, products of medical purpose and accompanying goods on the results of 2010-2011 on the local markets in the boundaries of municipal entities revealed 1312 economic entities with signs of dominance in accordance with paragraph 1 of Art. 5 of the Federal Law № 135-FZ of July 26th 2006 «On Protection of Competition» (when the share

of the economic entity more than 50%) and 1878 economic entities with signs of dominance in accordance with paragraph 3 of Art. 5 of the Federal Law «On Protection of Competition» (collective dominance).

In 2011 economic entities with signs of dominance recorded in 96.3% of all examined municipal formations (studied all 2261 municipal formations - urban and municipal districts).

In order to implement the state control over observance of the antimonopoly legislation and economic concentration dominating in the retail market of medicinal products economic entities entered in the register of economic entities (except for financial institutions), having a market share of certain goods in the amount of more than 35% or holding a dominant position on the market of certain goods, if in respect of such market by other federal laws in order of their application established cases of recognizing dominant position of economic entities (hereinafter - the Register).

FAS Russia performs analysis of services of retail trade of medicinal products, products of medical purpose and accompanying goods every 2 years. Results of this analysis - are the foundation for the adoption by the FAS Russia decisions on mergers of pharmacy networks.

However, basically, pharmacy networks grow by opening new points of sale rather than by merging with each other. Increasing the number of pharmacy networks and their growth is due to higher profitability of the business relative in relation to small and single pharmacy organizations, strengthening of positions and competitive advantages, more profitable conditions for wholesale purchases due to large volumes, the presence of vertical integration, which gives financial benefits to pharmacy networks which have advantages in relation to single pharmacy organizations.

In 2012, an analysis carried out by the FAS Russia showed that in 2011 a number of pharmacy networks and pharmaceutical organizations affiliated with them continued to grow. There were 4100 groups of persons and pharmacy networks revealed, which included 31800 pharmaceutical organizations. For 2008-2011 a number of pharmaceutical organizations that belonged to pharmacy networks that were revealed during carrying out the analysis increased by 5115 ones or by 19,2% - from 26671 to 31786 organizations. In 2011, pharmacy networks included 86,43% of all pharmaceutical organizations considered in the analysis. In 2011, in the majority of subjects of the Russian Federation a share of pharmaceutical organizations in pharmacy networks made more than 80% in total quantity of pharmaceutical organizations. Pharmacy networks make the main sales volumes in the market considered.

Information on investigations of exclusive agreements of pharmaceutical producers and distributors:

By results of inspections of antimonopoly law observance by leading pharmaceutical companies, the FAS Russia revealed some problems restricting competition in the Russian pharmaceutical market that are connected with the following:

• existence of exclusive agreements between pharmaceutical companies and distributors on supply of unique pharmaceuticals;

• absence in most companies a clearly defined policy on interaction with distributors as well as an accurate criterion of their assessment and a decision criterion on cooperation, which leads to unreasonable refusals of or evasion from conclusion with certain distributors of contracts for supply of pharmaceuticals in the market where the companies hold dominance;

• coordination by pharmaceutical companies of distributors' supplies of pharmaceuticals aimed at sharing of the commodity market by territories and buyers. It can be carried out through inclusion in contracts with distributors of requirements on presenting reports and forecasts of shipments with information on buyers and regions of deliveries included;

• absence in some companies of book-keeping and written correspondence with contractors that in some cases violate rights of market participants on appeal against actions of partners for unreasonable refusal to conclude contracts for delivery of pharmaceuticals as such offers and refusals aren't fixed;

• participation of companies in forming of applications for purchase of certain pharmaceuticals and in preparing of tender documentation.

In Russia large companies, producers and distributors of pharmaceuticals and medical items get benefits from creation of an effect of exclusivity and non-interchangeability of products and stimulate market demand in the following way by:

- Making minor amendments to standard products documentation with following highlighting of made differences and excessive refinements in auction papers, which correspond only with products produced by such company;
- Creating special delivery conditions that could be managed only by certain company (e.x. handling of volumes and dates of deliveries).

Companies may get such benefits by way of close and unfair (corruption) cooperation with:

- Register Agencies, which are responsible for making amendments into standard pharmaceutical and medical items documentation;
- State Customers and Officials who are responsible for compiling of applications and auction documentation;
- Medical communities, patient and public organizations, exercising pressure on public authorities, and defining procurement conditions.

Some companies guard relations with their partners (distributors) for exercising corrupt cooperation. In the frameworks of corrupt cooperation the chief goal of company is to provide exclusivity of vertical agreement by means of restricting access of competitive distributors to the product. An exclusive distributor has to exercise responsibility of fiscal agent, providing acquisition, adaptation and redistribution of funds among state officials and company's managers.

However the FAS Russia recognizes a company dominant at the market when such company creates an exclusive position for it products at the market. The following restrictions apply to companies possessing dominant position at the market (in accordance with Art. 10 of the Federal Law «On Protection of Competition»):

- economically or technologically unjustified refusal or evasion form concluding a contract with individual purchasers (customers) in the case when there are possibilities for production or delivery of the relevant goods
- economically, technologically or otherwise unjustified establishment of different prices (tariffs) for the same goods
- creation of discriminatory conditions;
- creation of barriers to entry into the goods market or leaving from the goods market for the other economic entities;

With the purpose of control over compliance of the Federal Law «On Protection of Competition» by the biggest pharmaceuticals' companies the FAS Russia made a research of the twelve commodity wholesale markets of innovation pharmaceutical products, which centrally purchased by federal budget resources, aimed for treatment of seven high-cost nosology, including hemophiliacs, cystic fibrosis, pituitary dwarfism, Gaucher disease, myeloid leukemia, multiple sclerosis, as well as after organ transplantation and (or) tissues and including in the Register following subsidiaries including in the group of persons of the largest international pharmaceutical companies:

- «IHCC» (Swiss company IHCC, which represents interests of Johnson&Johnson);

- «Johnson&Johnson» (USA company Johnson&Johnson, Janssen-Cilag International N.V., Belgium);
- «Galena Pharma» (Teva Pharmaceutical Industries Ltd, Israel);
- JSC «Roche-Moscow» (F.Hoffmann-La Roche Ltd, Switzerland);
- «Novartis Pharma» (Novartis Pharma Stein AG, Switzerland);
- «BIOTEK» (Russia);
- «Nycomed Distribution Center» (Nycomed Holdings A/S, Switzerland);
- JSC «AO Schering» (Schering AG, Germany);
- «Astellas Pharma» (Astellas Pharma GmbH, Germany);
- «Novo Nordisk» (Novo Nordisk A/S, Denmark).

In 2009-2013 the FAS Russia has made a research about competition environment on the markets of insulin preparations, antiviral and other preparations, according to results an additional in the Register was included:

- «Novo Nordisk » (Novo Nordisk A/S, Denmark);
- F. HOFFMANN-La Roche Ltd (Switzerland) и JSC «Roche - Moscow»;
- ELILILLYVOSTOK S.A. (Switzerland);
- Bayer Consumer Care AG (Switzerland) и JSC «Bayer»;
- Baxter Healthcare S.A. (Switzerland);
- Shire Pharmaceuticals Ireland Limited (Ireland).

It should be noted that it was the first time when the FAS Russia included the largest international companies (transnational companies) rather than their subsidiaries.

In 2010-2011 the Swiss pharmaceutical company «Eli Lilly VOSTOK S.A.» has appealed the order of the FAS Russia for inclusion in the Register. However, the Moscow Arbitration Court, the Ninth Arbitration Court of Appeal and the Federal Arbitration Court of the Moscow District have confirmed the legality of the order of the FAS Russia, pointing to the correct definition of the boundaries of products commodity markets, which are large wholesale batch of each medicine, according to one international non-proprietary name, a single dosage form and dosage imported and sold in Russian Federation.

In 2011 the Swiss pharmaceutical company «F. HOFFMANN-La Roche Ltd» and JSC «Roche-Moscow» also appealed against the order of the FAS Russia on their inclusion in the Register. However, the Federal Arbitration Court of the Moscow District upheld the legality of the order of the FAS Russia, pointing to the correct definition of product and geographic boundaries of the market-specific

product market and the product itself - the medicine, as well as features of its consumption.

So courts and appeals rulings confirmed legitimacy of the FAS Russia's decisions on including of international pharmaceutical companies in the Register and also found accuracy in the FAS Russia's methodology on defining boarders of the product markets considering a specific character of pharmaceuticals and their consuming features. Decisions of the courts are precedents and specify the peculiarities of defining borders of pharmaceuticals markets when consuming choices are made by doctors instead of buyers.

The FAS Russia's requirement on ensuring an access to the products of the public company, possessing a dominant position on the market, aims at elimination of exclusivity of vertical relations which is a head element of the corruption.

The FAS Russia's position consists in provision for the companies, possessing dominant position on the market, non discriminatory access to their products, as well as exclusion of requirements of subjective character for purchasers (distributors), as it enables monopolistic pharmaceutical company to dismiss or unreasonably avoid signing of purchase-sale agreements with buyers.

As a result of inspection conducted by the FAS Russia against LLC «Novo Nordics» it was determined that the company, possessing dominant position on the market of almost all range of supplied pharmaceuticals, was working with only five distributors for a long period of time avoiding conclusion of agreements with other business entities that led to creation of discriminating conditions for potential partners. LLC «Novo Nordics» had also imposed unprofitable conditions to its contractors.

While determining product and geographical borders of product market the FAS Russia used a method based on expert evaluations of the goods characteristics and their consuming features.

Insulins are aimed for treatment of pancreatic diabetes. In accordance with letters of the Federal Agency on Health Care and Social Development, FGU «Endocrinology Science Centre» of the Ministry of Health Care of the Russian Federation, different trade names of insulins were found inconsistent and non-interchangeable. So it was noticed that insulins produced by different companies have different effects due to existing differences in production technologies, components and other factors. Such differences may cause threat to the health of ultimate consumers if they decide to change insulin of one producer to another one. Such transfer from one insulin to another should be made personally for each

patient strictly under doctors' control (endocrinologists) and sometimes such patients should be hospitalized to special endocrinology clinics.

Bearing in mind the information mentioned above the Ministry of Economic Development and Trade, Ministry of Health and Social Development and the FAS Russia jointly took a decision to allow since 2007 procurement placement for insulin according to their trade name without accompanying them by words «or equivalent».

Analysis of the actual public procurement orders of insulin in Russia is indicative of the fact that primarily procurements are performed according to the trade names and as a consequence the product boundaries of product market were defined as large-scale batches of every insulin trade name by «Novo Nordisk», imported and sold on the territory of the Russian Federation.

Specifics of medical drugs market in the Russian Federation is the obligatory registration of all medical drugs which are sold on the territory of the Russian Federation. Thus, right of access to the insulin market is limited to registering of products by the authorized federal executive agency and entering the product name into the list (register) of permitted medical drugs on the territory of the Russian Federation for the whole period of validity of state registration.

LLC Novo Nordisk is a 100% subsidiary of Novo Nordisk A/S, Denmark. Novo Nordisk A/S is the producer and the supplier of all the above mentioned insulin types directly to LLC Novo Nordisk; and LLC Novo Nordisk executes large wholesales of insulin in the volumes which fully cover all the needs for insulin on the all territory of the country. There are no other suppliers of insulin in the Russian Federation.

The buyers of insulin have the possibility to purchase insulin from LLC Novo Nordisk in the Russian Federation and have no possibilities for purchasing insulin outside Russia. That is the reason to set the geographical boundary of the markets under examination as the territory of the Russian Federation.

In 2010 upon results of the consideration of the case the FAS Russia recognized LLC Novo Nordisk as a violator of points 5 and 8, of part 1 Art. 10 of the Federal Law «On protection of competition», i.e. conduction of activities that resulted in economically and technically ungrounded refusal to conclude agreements for supply of medical drugs produced by Nova Nordisk group of companies with such companies as: LLC «Biotech», CJSC «BSS», CJSC «Center for Implementation «Protech», CJSC «SIA International Ltd», CJSC «Imperia-Pharma», LLC «Pharm-Trade», LLC «Pharmaimpex», LLC «Pharm-Syb», CJSC «Firma Euroservice» as well as creation of discriminatory conditions for other counteragents as compared to LLC «Norbert», CJSC «Pharnacevt», CJSC «North-West», CJSC «PKF Fortune plus Inc.», LLC «Sanda-Pharm».

The FAS Russia issued instructions to LLC «Novo Nordisk» to eliminate revealed violations and considered the company administratively liable with issuing of a fine.

On 28 of July 2011 the FAS Russia and LLC «Novo Nordisk» which represents interests of «Novo Nordisk» group of companies in Russia agreed on out-of-court settlement which prescribes creation of clear-cut and transparent criteria for Russian distributors to access products of LLC "Novo Nordisk".

In accordance with the agreement settled LLC "Novo Nordisk" admitted violation and fully complied with the statement of the FAS Russia, in particular, affirmed new policy on commercial partners and standard delivery contract providing for standard requirements, clear criteria and procedures of working with distributors and made these documents publicly available on the company's official website for any interested person to be able to get acquainted with them.

Due to voluntary elimination of violation of antimonopoly legislation the court reduced the amount of the administrative fine up to 53.5 mln. rub. (about 1,34 mln. euros) – Minimum amount of penalty under the Article 14.31 of the Administrative Code of the Russian Federation. LLC «Novo Nordisk» fully laid the penalty.

Under the implementation of the statement of the FAS Russia LLC «Novo Nordisk» developed new «Policy on commercial partners» (which includes criteria and time of assessment of potential commercial partners and decision-making about cooperation with them) and new form of delivery contract (the contract excludes the requirements which lead to discrimination of potential or existing partners). These documents are available for acquainting on the official Russian web site of the «Novo Nordisk» group of companies.

The FAS Russia uses the same requirements to all the dominated pharmaceutical companies concerning the issues of relations with commercial partners. The requirements developed for dominated economic entities and their relations with contractors are the basis for developing of similar documents by others major pharmaceutical companies such as, for example, LLC «Lilly Pharma», CJSC «Aventis Pharma», LLC «Johnson&Johnson», LLC «Abbott Laboratories», JSC «Pharmstandard», etc.

Within the eliminating of the exclusiveness of vertical agreements and reducing of risks of conducting of antimonopoly investigation, the FAS Russia suggests other dominated companies to formulate commercial policies including:

- clear, countable, achievable and manageable requirements to potential (existing) contractors;

- description of decision making process (procedures, responsible executives, timing, clamping and holding) about formation or deny of commercial treaties with contractors;
- decision notification procedure (written notification, registration of correspondence).

Commercial policies should be available for all the potential contactors (distributors) of dominated companies.

The existence of commercial policy describing clear requirements and procedures of access to goods for potential or existing contractors and its abidance denounce risks of investigation suggesting possible violations of antimonopoly legislation.

By the results of the trial of the FAS Russia with «Novo Nordisk» interpretation of the problem is identified foreign pharmaceutical companies with the requirements of FAS Russia as contrary to U.S. law on corruption (Foreign Corrupt Practices Act, hereinafter - FCPA) and UK law on bribery (UK Bribery Act, hereinafter - UBA).

These laws prohibit companies (including all international group of companies) bribery in foreign countries (both directly and indirectly, using agents) and require them to exercise due diligence in collaboration with local distributors to ensure that distributors will not have been involved in corruption. FAS Russia found that under the pretext of enforcing legislation FCPA and UBA and prevent prosecution for violation of the FCPA and UBA dominant individual in the Russian market pharmaceutical companies conduct a thorough selection of its distributors, during which violate Russian law on protection of competition.

The results of the case caused international headlines - in 2011-2012 conducted a large number of international events, to discuss the rules of conduct of market-dominant companies. For example:

September 2, 2011, FAS Russia together with the American Chamber of Commerce in Russia, with the support of the U.S. Embassy in Moscow had a Russian-American round table «U.S. law prohibiting the use of corrupt practices in activities abroad and the Russian antimonopoly legislation,» in which was attended by 229 representatives of the business community and major law firms. At the round table discussed the requirements for dominant pharmaceutical companies in the Russian market, taking into account the simultaneous application of the FCPA and the Russian antimonopoly legislation. Participants appreciated the experience of FAS Russia to develop cooperation with «Novo Nordisk» instruments governing cooperation with commercial partners.

Following the event it was decided to continue the discussion on the topic of the round table and discussion in working groups of requirements to counterparties dominant markets of the Russian Federation entities.

In the period from 28 January to 3 February 2012, a delegation of FAS Russia in Washington (USA), dedicated to the continuation of the discussion of these issues, in which agreements were reached on cooperation FAS Russia and the U.S. Department of Justice on the curb corrupt activities of international pharmaceutical companies on the territory of the Russian Federation.

March 21, 2012 at the 4th Russia and CIS Summit on Anti-Corruption, organized by the American Institute Conference, in the session «The compliance, due diligence and post your distributors Novo Nordisk» FAS Russia presentations and a presentation on «Legislation on Corruption abroad (FCPA, Bribery Act) and the Russian antimonopoly legislation: contact points».

April 12, 2012 the American Chamber of Commerce in Russia with the participation of the FAS Russia and the U.S. Embassy in Moscow held the second Russian- American round table with the participation of 300 companies , where I.Artemiev , S.Pyzyrevskiy and T.Nizhegorodzev held a session on the issue of compliance by pharmaceutical companies of antitrust law with regard to anti-corruption standards of the U.S. «On the prohibition of the use of corrupt practices in the activities abroad» and the FAS Russia policy for the conclusion of agreements with distributors.

April 26, 2012, FAS Russia held a joint meeting with the non-profit partnership «Promoting Competition» on the possible failure criteria of market-dominant economic entities to enter into agreements with counterparties.

In 2013, FAS Russia continued to identify similar violations related to unreasonable refusals to dominate the market of pharmaceutical companies to enter into contracts for the delivery medicaments.

Information on investigation of prohibited horizontal agreements (cartels):

In 2011-2012 the FAS Russia conducted examination on presence of collusion between participants of public tenders for supply of medicines within the framework of Federal programs «Seven nosologies» and «Tuberculosis» in 2008-2009.

According to the results of investigations the FAS Russia has considered a series of cases on the grounds of violations of paragraph 2 of part 1 of Art. 11 of the Federal law «On Protection of Competition» in the process of conducting auctions by the Ministry of Health and Social Development of the Russian Federation for the right to conclude state contracts for supply of medicines for the needs of state institutions.

Such largest pharmaceutical distributors as companies «GROWTH», «PROTEK», «R-Pharm» and «Irvin-2» were recognized as violators the antimonopoly law.

Cases apply to conclusion of illegal anti-competitive agreements that led to maintenance of prices at the auction on procurement of pharmaceuticals under the state program. Companies were admitted for participation in the auction and attended in the course thereof, but alternately withdrew from competitive activity-submission of price proposals. As a result, the contracts were concluded with the only bidder who made the proposal

In connection with the lack of direct evidence of cartel agreements, which were orally concluded, the Competition Authority had to base on indirect evidence of guilt (specific behavior of pharmaceutical companies, non-appearance at the auction, deliberately passive position during the auction and other). However, the arbitration courts partially confirmed conclusions made by the FAS Russia on availability of cartels.

Besides, in 2011, the FAS Russia has issued a decision on violation of the Antimonopoly legislation against the firm CJSC CV «PROTEK» and the State Unitary Enterprise of the city of Moscow «Stolichnye Apteki». These companies entered into and participated in the agreement that led to price fixing for lot № 3 of the open auction for right to conclude the state contract on the provision of medical institutions of the city of Moscow with specific medicine and medical devices in 2008.

Company «Eli Lilly Vostok C. A.» in the person of the Moscow representative office «Eli Lilly Vostok» was also recognized as violated the Law on Protection of Competition, so as the coordinated economic activities of the firm CJSC «Center Vnedreniya «PROTEK» and the State Unitary Enterprise of the city of Moscow «Stolichnye Apteki».

However, this decision was reversed by the court because the email correspondence between companies presented by the FAS Russia as evidence of the agreement concluded was ignored.