Report
On the promotion of competition in the pharmaceutical market of the Russian Federation

In the opinion of the Federal Antimonopoly Service of Russia, the key issues of promotion of competition in the Russian pharmaceutical market are the following:

1. Absence of interchangeability of drugs concept and clearly defined criteria thereof;
2. Inadequate interaction of pharmaceutical companies with the medical community and officials participating in the process of forming requests for the procurement of medicinal products for the account of budget funds;
3. Use of lists of pharmaceuticals as a mechanism to restrict competition and discriminate certain manufacturers of pharmaceuticals;
4. Exclusive agreements with manufacturers of pharmaceuticals and distributers.

1. Absence of the interchangeability of drugs concept and clearly defined criteria thereof;

The absence of the drug interchangeability concept and lack of clearly defined criteria thereof remains to be the core issue in the Russian pharmaceutical market.

Federal Law #61-FZ "On circulation of drugs (Pharmaceuticals)" introduced the concept of "reproduction of a medicinal product" which contains the same pharmaceutical substance or a combination of the same pharmaceutical substances in the same pharmaceutical form as the original medicinal product, and which was launched into circulation after the original medicinal product was launched, as well as the concept of " generics" (analogues of medicinal products) having the same international non-patented name, pharmaceutical form and dosage.

At the time, when generics are considered to be interchangeable all over the world, the prescription of such pharmaceuticals and the procurement thereof for government purposes is determined by general practitioners at their own discretion. This is one of the barriers for coming out into pharmaceutical market, the main means to discriminate Russia manufactured medicinal products and to eliminate competition at tenders. It is also an infringement upon the rights of patients who are pressed to buy similar but more expensive medicinal products.

When drugs and generics that are interchangeable with the already existing original medicinal products are registered, certain differentiating details which do not seem to be significant at first sight are entered into the instructions for the use thereof. Such instructions are

used by government customers when requirements to medicinal products offered for supply are formed with the purpose of preserving the monopoly status of suppliers of certain pharmaceuticals.

The FAS of Russia has repeatedly detected the problem of data distortion by drug manufacturers in their instructions for medical use which are thus misleading the state customer, medical community and patients with regard to specifications of medicinal products. In order to eliminate such a possibility for manipulation by companies and to create conditions for bringing down prices for medicinal products, the FAS of Russia believes that it is necessary to:

- Bring all the instructions for the use of original medicinal products in conformity with the original instructions in the original languages thereof as registered by the US FDA and EMEA;
- Bring instructions for medical use of generics in conformity with the instructions of original medicinal products;
- Enhance administrative liability and introduce criminal liability for misleading consumers, state and municipal customers with regard to the specifications and qualities of medicinal products.

Making use of the vagueness of requirements regarding interchangeability of drugs issues, state customers commit multiple violations of Federal Law #94-FZ "On placement of orders for supply of goods, rendering services for state and municipal needs" of 26 July 2006 and Article 17 of Federal Law #135-FZ "«On protection of competition»". Such violations lead to restriction of competition in the organization and holding of tenders for the procurement of medicinal products. The most frequent violations committed by state customers when they procure medicinal products are the following:

- including into tender documentation or the notification on filing a request regarding quotations of trade names without indicating whether there is a possibility to supply an equivalent pharmaceutical, or not, and including excessive requirements which directly specify a certain concrete trade name of a medicinal product;

- including into one lot (batch) medicinal products, products of medical designation and services relating to the issuance of medicinal products, and the requirements with regard to the supply of specific software (sic.);

- including into one batch a long list of medicinal products which belong to different pharmacological groups;

- unjustified denial of access to participation in tenders, requests for quotes, etc.

In order to prevent the above violations, the FAS of Russia approved the amendments to the Law "On placement of orders" that provide for the obligation of customers to form separate lots for International Nonproprietary Name (INN) for Pharmaceutical Substances (generics) of procured medicinal products in the event the start up (maximal) price of a contract (price of a batch) exceeds 500 thousand rubles.

Apart from that, in order to promote competition on the pharmaceutical market, the FAS of Russia is holding negotiations with the Ministry of Healthcare and Social Development regarding the incorporation of the concepts "interchangeable drugs", "interchangeable immune and interchangeable biological medicinal products" into Federal Law #61-FZ "On circulation of drugs" dated 12 April 2010.

The introduction of such concept will considerably decrease the number of violations which restrict competition in holding tenders for the procurement of medicinal products. Meanwhile reproduced pharmaceuticals (generics) could compete with original drugs that are procured today without any alternative, - and this would lead to considerable saving of federal and regional budget funds allocated for the procurement of pharmaceuticals.

However, while the Law has no concept of interchangeability of drugs and no criteria with respect to the definition thereof either, the FAS of Russia in each specific case has to conduct trials and research on the basis of which - for the purposes of promoting competition at tenders and forming uniform practices in organizing procurement of drugs - the FAS has to forward clarifications to state customers regarding interchangeability of drugs. Thus, for instance, between 2009 and 2011 the FAS of Russia forwarded clarifications to state customers on the interchangeability of the drugs listed below:

- all medicinal products having INN Somatropin either in high or low concentration;

- Cellcept and Mycept drugs (INN of Mycophenolate mofetil (MMF) Micophenolat mophetyl);

- drugs with INN blood coagulation factor VIII with floating and fixed dosage;

- drugs Eprex and Eralfon (INN Epoetin Alfa));

- pharmaceutical forms "concentrate for solution for infusion" and Liofilizat for solution for infusion" for drugs with INN Octreotide and Zoledronic acid;

- drugs Penkrofton, 200 mg tablets and Mifepriston, 200 mg tablets (INN Mifepriston);

- drugs Mirolute, 0.2mg tablets and Misoprostol, 0.2 mg tablets (INN Misoprostol);

- antiviral combination medication and monomedication in the same combination in the form of two or three tablets designed for the treatment of AIDs patients;

- all drugs with the INN Meropenem registered in the Russian Federation;

- pharmaceutical forms of Liofilizat for solutions for subcutaneous injection/introduction 8 mln ME/05 ml, 8 mln ME/ml with Interferon beta- 1b&;

- in nutrition - protein composite dry mixtures with OKP (All-Russia Classifier) 919760 code ;“ therapeutic and preventive nutrition”, in healthful and dietary meals, OKP 919740 code, and OKP 919741 included into the latter may be interchangeable with OKP 919760 code and OKP919769 code included into the above code.

In conformity with the Law “«On protection of competition»” interchangeable goods shall be understood to mean goods that may be comparable with regard to the functional designation, use, quality and technical characteristics, price and other parameters in such a way that the buyer actually substitutes or is ready to substitute one good for another when using such a commodity (including consumption for production purposes).

Hence, the FAS of Russia believes that interchangeable drugs should be possibly used for the same group of patients with regard to the same designated use and have similar therapeutic effect, without the necessity to offer therapeutic treatment in stationary clinics in the event there is a transition from one drug to another; and interchangeable immune and biological drugs must have indicators of safety and effectiveness analogous to the indicators of the original medication.

2. Inadequate interaction of pharmaceutical companies with the doctor’s community and officials participating in the process of forming application for the procurement of medicinal products for the account of budget funds

In the course of inspections of the major pharmaceutical companies functioning in the territory of the Russian Federation the FAS of Russia detected that as the result of inadequate interaction of pharmaceutical companies and medical community the latter develops a financial and psychological dependency on pharmaceutical companies, as well as financial interest in prescribing drugs manufactured by such companies to the largest possible number of patients. A considerable part of the medical community (particularly in the narrow specialized field of activity) has contractual relationships with one or several pharmaceutical companies under which they receive remuneration on a regular basis for services provided for compensation.

The choice of certain medication by doctors in the process of drafting requests for procurement of pharmaceuticals with the funds of federal and regional budgets is also most often related to the marketing activity of manufacturing companies and is not always optimal either for the state budget, or specific patients. This leads to the growth of the government procurement volume of drugs manufactured by certain companies and creates discriminating conditions for the access of other manufacturers of pharmaceuticals and the suppliers thereof to state orders.

In many countries of the world inadequate practices for the interaction of doctors and pharmaceutical companies are prohibited, and liability is provided for encouraging medical community to prescribe certain drugs. In Russia, however, the relationships between doctors and pharmaceutical business are not yet regulated whatsoever; neither is the liability of doctors, nor pharmaceutical companies provided for.

As a result of the discussion of the above problem, the Government of the Russian Federation issued an instruction to regulate the issues of prevention and elimination of a conflict of interests in the organization of assistance with medicinal products to the population.

The FAS of Russia jointly with the expert community has developed the rules providing for the regulation of issues of prevention and settling of conflict of interests of medical and pharmaceutical workers in the organization of medicinal assistance to the population, establishing mandatory requirements to doctors and pharmaceutical companies and also introducing liability for the violations of such requirements. The respective articles were incorporated into the draft Federal Law "On the basic principles for protecting the health of the citizens of the Russian Federation" and amendments are being drafted to Federal Law #61-FZ "On circulation of drugs" of 12 April 2010.

Apart from that, in order to promote competition in the pharmaceutical market, the FAS of Russia believes it necessary to introduce a mandatory requirement that prescriptions be filled out exclusively on receipt forms and only with the use of INNs. In this connection an amendment was drafted and incorporated into the draft law "On the basic principles for protecting the health of the citizens of the Russian Federation" which provides for the obligation of a doctor to fill out prescriptions on special receipt forms, and such obligation must necessarily be enhanced by the requirement to prescribe medicines using INNs, and also by the requirement to provide full information about medicines circulating in the territory of the Russian Federation and conforming to INNs.

3. Use of lists of pharmaceuticals as a mechanism to restrict competition and discriminate certain manufacturers of pharmaceuticals

In the process of work the FAS of Russia saw the interest of pharmaceutical companies to include drugs produced thereby into various lists of medicinal products approved by the Ministry for Healthcare and Social Development, since entering certain medicinal products into the lists guarantees the manufacturer considerable sales volumes in the territory of the Russian Federation. At the same time, specification of qualities determining specific names of medicinal products and manufacturers thereof leads to restrictions on competition in pharmaceutical markets.

For instance, specifying pharmaceutical forms that indicated to a specific manufacturer in the Minimal Assortment of drugs for medical use necessary for providing medical aid (approved by Order#805 of the Ministry for Healthcare and Social Development of 15 September 2010) (hereinafter "the Minimal Assortment"), and also including into the Minimal Assortment medicinal products having the only pharmaceutical form registered in the Russian Federation of the only manufacturer used to lead to restriction of competition at respective commodity markets of pharmaceuticals when medical aid was provided.

As of today, the Ministry of Healthcare and Social Development of Russia, upon the FAS proposal, introduced amendments to the Minimal Assortment relating to the exclusion of certain pharmaceutical forms of medicinal products which are not registered in the Russian Federation, and also inclusion into the list of pharmaceutical forms of medicinal products the conjunction "or" which will enable pharmacy institutions to have medicinal products available in any of the forms included into the list.

The indication of specific pharmaceutical forms in the "List of medicinal products issued for the prescription of a doctor (paramedic) when extra free medical aid is provided to certain categories of citizens who have the right to receive state social aid" (approved by the RF Ministry of Healthcare and Social Development Order #665 dated 18 September 2006) established for state and municipal customers restrictions with regard to the choice of procured medicinal products, which resulted in the restriction of competition among manufacturers and suppliers of procured medicinal products.

On 29 April 2011, in order to fulfill the Instruction issued by the FAS of Russia Commission On hearing cases of violation of antimonopoly laws, the Ministry of Healthcare and Social Development of Russia approved a new List which does not specify pharmaceutical forms of medicinal products. This will allow state and municipal customers to procure medicinal

products in any pharmaceutical forms registered in the territory of the Russian Federation to provide pharmaceuticals for certain categories of citizens.

The Instruction " On the procedure to prescribe medicinal products, products of medical designation and specialized products of nutrition" approved by Order #119 of the Ministry for Healthcare and Social Development of Russia on 12 February 2007, contained restrictions with regard to prescription of medicinal products which were only in the List of vitally necessary and most important medicinal products (hereinafter "life-saving drugs") both for providing for certain categories of citizens who have the right to receive public social aid, and for the governing healthcare bodies of the constituent entity of the Russian Federation. This situation used to result in the limitation of procurement of medicinal products for state and municipal needs.

The Ministry of Healthcare and Social Development by its Order #13N of 20 January 2011 introduced amendments to Order #110, specifically to the Instruction "On the procedure to prescribe medicinal products" which related to the exclusion of the requirement with regard to the constituent entities of the Russian Federation to form territorial lists of medicines on the basis of the list of life-saving drugs, and also the requirement to prescribe drugs when providing out-patient medical assistance on the basis of the list of life-saving drugs.

In conformity with Federal Law #61-FZ "On circulation of drugs" of 12 April 2010 the Government of the Russian Federation will annually approve the List of life-saving drugs for medical use which provides for the priority needs of healthcare to prevent and treat diseases. This means that the inclusion of a medicinal product into the List of life-saving drugs will guarantee the procurement thereof with the funds allocated either from the Federal or regional budgets.

At the same time, the procedure for forming the List of life-saving drugs is non-transparent and creates discriminatory conditions to economic entities with regard to the circulation of medicinal products in the market. The FAS of Russia receives a huge number of complaints from manufacturers regarding ungrounded inclusion or refusal to include certain medicinal products into the List of Life-Saving Drugs.

Today, upon the assignment of the Government of the Russian Federation, the Ministry of Healthcare and Social Development of Russia is working on the draft law of the Order "On the procedure to form the draft list of life-saving drugs". The Federal Antimonopoly Service identified in the text of the draft corruption risks hindering equal access to the pharmaceutical

market [of manufactures and suppliers] and forwarded in this connection its criticism and proposals to the draft law.

Novo Nordisk

Exclusive agreements with manufacturers of pharmaceuticals and distributers

The FAS of Russia upon the result of inspections regarding the observance of rules of antimonopoly legislation by major pharmaceutical companies detected problems limiting competition on the Russian pharmaceutical market. Which relate to:

- The existence of exclusive agreements between pharmaceutical companies and distributors for the supply of unique medicinal products;
- Absence in most companies of a clearly defined policy with regard to the interaction with distributers, as well as clear criteria for the reassessment of distributors and decisions with respect to cooperation therewith, which results in unjustified refusals to conclude or avoiding to conclude with certain distributors contracts for supply of medicinal products in the markets of which they (the manufacturing companies) take a dominant position;
- Coordination of medicinal products supplies by distributors which is aimed to divide the commodity market into territories and groups of customers; this is done also through including into contracts with distributors of requirements to provide reports and projections for the future regarding shipments with the indication of customers and regions of supply;
- Absence of documentation flow system and written correspondence in certain companies, which in a number of instances violates the rights of market participants to complain about the actions of the counterparts thereof regarding ungrounded refusal to conclude a contract for supply of medicinal products since such offers and refusals are not registered;
- Participation of companies in forming requests for the procurement of certain medicinal products and in the preparation of package of tender documents.

In order to monitor the observance by major pharmaceutical companies of the Law «On protection of competition» the FAS of Russia analyzed the markets of innovative medicinal products and insulin and included into the Register of economic entities companies having a market share of a certain commodity of over 35%, specifically: Eli Lilly Vostok S.A, AHCC Ltd., Johnson &Johnson Ltd., Galena Pharma Ltd., F. Hoffmann-La Roche Ltd., Roche Moscow CJSC, Novartis Pharma Ltd., BIOTECH Ltd., Nikomed Distribution Center Ltd., Shering CJSC, Astellas Pharma CJSC, Novo Nordisk Ltd..

As the result of an inspection conducted by the FAS of Russia at Novo Nordisk Ltd., it was detected that while holding a dominating position in the market with regard to actually all

assortment of drugs supplied by Novo Nordisk, the company for a long period of time had been working only with five distributors only avoiding to conclude contracts with other economic entities; it created discriminating environment for potential partners as compared to those already acting in the market and also pressed on its counterparts disadvantageous conditions which did not relate to the subject of the contract.

In 2010 upon the results of the case hearing, the FAS of Russia adjudged that Novo Nordisk violated subparagraphs 5, 8, paragraph 1 of Article 10 of the Law «On protection of competition», found the company administratively liable and placed an administrative fine on it amounting to Rub 85,934,000.25. It also issued an order to stop violations which had been detected. The violations involved unjustified avoidance to conclude contracts of supply with certain customers and creation of discriminatory conditions for potential partners as compared to those operating in the market.

Today within the framework of negotiations on an amicable agreement Novo Nordisk jointly with the FAS of Russia has developed drafts of the new Novo Nordisk policies with regard to commercial partners (which now contain measurable criteria and terms for the assessment of potential partners and adoption of decision on cooperation therewith) and a new form of a contract for supply (the requirement leading to discrimination of potential and operating partners is excluded from the new [model] contract). It is planned to place the above documents on the Novo Nordisk Russian language version web-site for all persons concerned to get familiarized with it.

The FAS of Russia plans to apply similar requirements to all pharmaceutical companies in dominating position with regard to issues of its relationships with commercial partners.

In 2011, the FAS of Russia adjudged that Eli Lilly Vostok S.A. violated Article 11 of the Law «On protection of competition», since it took decisions on the necessity to participate in the tender of Protek Center for Implementation and state unitary enterprise of the city of Moscow “Pharmacies of the Capital”, that is, it acted as a coordinator in conclusion of an agreement between them which resulted in keeping up the price in the open tender of the Healthcare Department of the city of Moscow.

Similar cases on pharmaceutical companies heard by the FAS of Russia should encourage the pharmaceutical companies to reconsider their stand with regard to the participation thereof in further supply of medicinal products by distributers, since such actions will be regarded as coordination of or participation in agreements and agreed actions leading to restriction of

competition, keeping up of prices at tenders and the division of the market into territories and among customers.