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RECENT DEVELOPMENTS IN COMPETITION ENFORCEMENT

A key problem of competition development in the pharmaceutical segment is a lack of a notion of pharmaceutical interchangeability and a clear criterion for its definition. In registering of interchangeable pharmaceuticals some modifications of indications that are inessential, at first sight, are made in application instructions. Later it is used by state customers in drafting of requirements to pharmaceuticals to be supplied in order to protect a monopoly position held by suppliers of certain medicines.

For the purpose of competition development in the pharmaceutical market and decrease in budgetary expenses on purchase of medicines some changes to the Federal law "On placement of orders to supply goods, carry out works and render services for state and municipal needs" were added. The changes provide for a duty on customers to form separate lots for each International Nonproprietary Name (INN) of purchased medicines in case the initial (maximum) price of a contract exceeds the limit value established by the Government of the Russian Federation as well as to purchase medicines only in INNs. Similar norms are foreseen in the Federal law "On the contract system in state and municipal procurement of goods, works and services".

Nowadays , purchasing in trade names is possible only for those pharmaceuticals that are included in the Pharmaceuticals List that is subject to approval by the Government of the Russian Federation. Placement of an order for supply of the pharmaceuticals is carried out according to their trade names. The FAS Russia believes that formation of the Pharmaceuticals List should be of the maximum transparency. An unreasonable inclusion some pharmaceuticals which have interchangeable medicines registered in the Russian Federation into that List should not be allowed. Inclusion of pharmaceuticals in that list may take place only in exceptional cases.

Besides, a possibility to purchase a specific trade name of medicine is foreseen for a patient in case there are medical indications by the decision of a medical commission, which is recorded in medical documents of the patient and in the log of a medical commission.

Adopted acts will make it possible to reduce considerably violations in purchasing of medicines, increase in a number of participants of purchases, increase in competition among producers of interchangeable pharmaceuticals, which, eventually, should lead to economy of budgetary funds allocated for purchase of medicines.

Moreover, in 2012 at the FAS Russia's insistence the RF Ministry of Health issued the order specifying the fact that prescription of medicines should be carried out by a medical worker in accordance with an international nonproprietary name, in case of its lack - according to a grouping name. Introduction of requirements to prescribe medicines in prescription forms according to the INNs excludes possibility to prescribe specific medicines to patients under an arrangement between a doctor and a pharmaceutical company, which increases in assortment and price availability of medicines to patients and provides equal conditions to producers of competing medicines.

It should be noted that the Regulation of the Government of the Russian Federation approved the Plan of Measures (Road Map) that is a project of the National Enterprise Initiative "Development of the competition and improvement of the antimonopoly policy". The Plan specifies priority measures on competition development in certain segments. Realization of the Road Map's actions will allow improving in life quality of Russian citizens in the short run.

According to the Plan, a number of problems in the market of medicines is identified. They are as follows:

- a lack of conditions for reduction in prices for medicines;
- imperfection of procedures for state registration of medicines;
- reduction in a range of medicines caused by imperfection of a procedure for state registration of limit sale prices for medicines in the List of Essential Medicines established by producers;

- a lack of unified requirements to production of medicines.

Profile ministries and departments are engaged in solving problems specified in the Plan in the pharmaceuticals market. Realization of certain actions is assigned among the Ministry of Health, the FAS Russia, the Ministry of Industry and Trade, the Ministry of Economic Development, the Federal Tariff Service, the Ministry of Agriculture.

The FAS Russia drafts and presents reports on results of assessment of availability of medicines on the basis of analyses of consumer prices and pricing in the Russian Federation and comparable markets in other countries, including CIS-countries as well as BRICS-countries.

Cooperation between competition authority and the IP agency, the drug approval agency and the standard setting body in enforcing competition in pharmaceutical sector

The FAS Russia cooperates with the Ministry of Health of the Russian Federation at drafting of amendments to the Federal law "On the circulation of medicines". The Federal Antimonopoly Service managed to get included in the draft law the following norms directed at:

- simplification of a procedure for introduction of orphan medicines to the market;

- securing a mechanism to obtain export licenses to bring to the Russian Federation of medicines designed for clinical and preclinical studies as well as examinations;

- introduction of a notion “interchangeable medicine” and connected with it notions "therapeutic equivalence of medicines" and "bioequivalence of medicines" and exception of a norm on impossibility of recognition of biological medicines being interchangeable;

- introduction of mechanisms aimed at withdrawal from circulation of medicines not meeting requirements of quality, efficiency and safety;

- exclusion of a marketing notion “patent medicine”;

- securing an appellate procedure for decisions of experts of the Federal State

Budgetary Institution with use of results of independent arbitration examination;

- setting up requirements on transparency of decisions made by the Expert Council and the Ministry of Health of the Russian Federation in registering of medicines;
- precise definition of a group of medicines that can be registered without any clinical studies;
- introduction of requirements for registration of combinations for earlier registered medicines;
- setting up an obligation for the Ministry of Health of the Russian Federation to form a list of prescription medicines;
- exclusion of an obligation for an applicant to specify an approximate cost of the medicine in the application on state registration of the medicine;
- setting up an accelerated procedure for registering of medicines designed for treatment of infants;
- exclusion of a requirement on submitting by an applicant of information on epidemiology of the orphan disease in the Russian Federation in which therapy it is supposed to use a declared medicine for the purpose of its state registration;
- development of rules on proper laboratory practices that are obligatory for all subjects of medicines circulation of appropriate laboratory practices, rules on appropriate clinical practices, rules on appropriate practice of storage and transportation of medicines, rules on appropriate practices of realization of medicines for medical application, rules of appropriate pharmaceutical practices;
- setting up a closed list of documents required from an applicant for state registration of medicines
- strengthening of a post-registration control over quality of medicines.

The FAS Russia also cooperates with federal authorities within realization of the Chapter “Pharmaceuticals market” of the Plan “On realization of measures on competition development in certain markets” adopted by the Regulation of the Government of the Russian Federation.

Incentives for generic entry and the process generic challengers have to follow to enter the market

In Russia an admission procedure of medicines to the market consists of two stages carried out by various bodies. The first stage is examination carried out by an expert organization that isn't an executive authority; the second stage is registration carried out by the Ministry of Health of the Russian Federation. Thus, according to the Federal law of 12.04.2010 No. 61-FZ "On circulation of medicines" the registration is followed by results of examination that dilute responsibility for adoption of unreasonable decisions on admission of or refusal to admit medicines for circulation.

In December, 2011, the antimonopoly authority carried out an unscheduled inspection to check execution by Ministry of Health of Russia of its state functions on registration of medicines. During the inspection numerous facts of violations of procedures and terms of the state registration of medicines at all stages of execution of the state function and terms of state registration which led to a delay in release of new medicines to the market and could have led to competition restriction in the relevant commodity markets were found.

In Russia there is no possibility to provide references to results of clinical studies of original medicines in registering generics. Moreover, results of clinical studies made abroad are not recognized. There is also a requirement to carry out local clinical studies irrespectively to availability of results of multicenter international clinical studies. Thus, assessment of clinical researches conducted should be based on quality of clinical studies, but not on a territorial criterion of its carrying out. This requirement is considerably impedes and delays time for entering to the market of medicines that are already applied abroad. Moreover, it also makes almost impossible to enter medicines intended for treatment of rare diseases in connection with a small amount of patients, difficulty detect them, and also strict requirements to doctors and patients participating in researches.

The requirement on obligatory implementation of comparative clinical studies of reproduced medicines in medicinal forms not providing for implementation of bioequivalence leads to impossibility to introduce a large amount of the reproduced vital

medicines for a stationary sector to the market because of a high cost of researches that is comparable to cost of researches of original preparations.

In Russia the most significant feature of a procedure for registration of medicines is combination of clinical studies of new preparations and their registration in one permission procedure process. Respectively, a procedure of registration begins with an application on permission of clinical studies. It complicates and prolongs a registration process. The more so because it is not always possible to achieve objectives of clinical studies. Therefore, carrying out of clinical studies doesn't cause a subsequent registration of medicine in relation to which it was carried out. Thus a considerable part of registration information, including information on methods of production and control, as well as stability provided by the applicant before clinical studies has been carried out can become outdated by the moment of consideration of possibility to register medicines. Besides, it is possible to register generics without bioequivalence researches.

A necessity to file an application on state registration in order to obtain a permission for clinical studies of medicine also entails impossibility of its carrying out before expiration of a six-year period of protection of information that is stipulated by the Law “On circulation of medicines” according to obligations accepted by the Russian Federation on observance with the agreement “On trade aspects of intellectual property rights” concluded in Marrakesh on 15.04.1994. However, carrying out of clinical studies can't be regarded in quality of "unfair commercial use" as at this stage it is impossible to get profit. As a result, the existing procedure for obtaining a permission to carry out clinical studies leads to a delay of entry into the market of reproduced medicines for a period from 1 year to 3 years.

Thus, the FAS Russia considers that it is necessary to divide a process of carrying out clinical studies and a process of state registration of medicines as in filing of application on state registration of medicine the applicant represents, among others documents, a report on a clinical research conducted.

In Russia a procedure for obtaining a permission to carry out clinical studies is excessively complicated. So, an applicant has to receive, at first, a "decision on possibility to issue a permission to carry out clinical studies of a medicine". Having

repeatedly submitted a new application and a document package one can get a permission to carry out clinical studies. It delays terms of receiving such permissions.

Evaluation of the benefits of generic entry and competition for consumers

In Russia a great number of registered medicines affect insufficiently a competition level. Considerable budgetary expenses have fallen on original preparations so far. It is connected with the fact that holders of patents seek to hold monopoly by trying to find new ways of extension of the patent at the expense of invention of new indications to application or conclusions of agreements with producers of generics (so-called "green patents") as well as questions of interchangeability of medicines are not solved. Even when terms of a patent protection are over, sales of original preparations in Russia are not always reduced; prices can be changed slightly, so generics don't compete fully with original preparations.

According to the DSM Group, in Russia a sales volume of generics made 54% in 2012, and 51% in 2013.

Regarding government procurement of medicines, according to experts, sales of generics made 55% in 2012, and 48% in 2013.

At the same time, in the Russian Federation there is no accurate data on quantity and a share of original medicines in a total amount of registered medicines as the Rules on keeping the state register of medicines approved by the Resolution of the Government of the Russian Federation doesn’t specify the sign of "originality" for medicines.

The Ministry of Health and Social Development of the Russian Federation together with the Single Commission of this Ministry didn't allow a supplier of the medicine with the trade name "MaySept" to participate in an auction on the grounds of inequality of contents of demanded indications in other sections of the instruction on medical application of the preparation "MaySept" to requirements of the customer.

The price for the original CellCept (INN "Micophenolate mofetil") significantly fell down right after MaySept’s generic entered into the market, which saved up to

104,3 million rubles (2,6 mln. US dollars) to the federal budget at the first auction.

Nowadays, the market of original biotechnological medicines purchased by the state within various programs makes 19,1 billion rubles (500 million US dollars). If these medicines continue to be purchased within trade names then by 2020 the market can make 29,34 billion rubles (700 million US dollars) while sales volumes in natural indicators are at same level.

In case state procurement continues to be carried out in accordance with an existing procedure (purchase in INN), then after bio analogues have entered into the market and got an admission to participate in the procedure for competitive auctions during 2013-2020, the saving will make up to 257,8 billion rubles (6,4 billion US dollars), which will allow to redirect the money to purchase of larger volumes of medicines or allocate the saved funds to other needs for health care.

Evaluation of the impact of patent protection and generic competition on R&D investments and innovation by originators

Patents for pharmaceutical products are designed to protect "new medicines" and stimulate researches in the field of medicine and pharmaceutics. However, it isn't true. The number of patents for really new medicines keeps constantly decreasing and a total number of patents for pharmaceutical products increase at the expense of so-called "evergreen" or "me-too" patents - patents for slightly modified options of already existing preparations.

Prices for patented medicines are much higher than prices for medicines with an expired patent validity period and reproduced medicines in the market. It is caused by the necessity to compensate costs for researches and production as well as to get profit. However, in fact, pharmaceutical industry spends more funds for marketing, than for development of new products. It is a private consumer and the state who pays for it. "Evergreen" patents don't give the chance to enter reproduced medicines into the market and reduces prices due to competition.

The existing patent legislation doesn't stimulate original pharmaceutical companies to create new medicines as it allows them to get excessively high profits by means of insignificant modification of already existing medicines.

For the purpose of guarantee of a high quality patents for medicines and reduction of consequences of patenting of additional or new applications of the known medicine, therapeutic methods, and consequences of unreasonably granted patents as well, including artificial extension of "monopoly", the FAS Russia sent to the Government of the Russian Federation a suggestion for improvement of a patent system, that included the following:

- to toughen criteria of patentability that have limited an issue of patents for discovery of any new feature or new application of already known substance (salts, ether, polymorphs, metabolites, size of particles, isomers, mixes of isomers, complexes, combinations and other derivatives of known substances should be considered as the same substance, except cases when drug action efficiency differ sufficiently);

- to grant exclusive rights only on "new chemical structural units but not for new indications, medicinal forms, isomers, etc.;

- to consider objections that interfere an issue of the patent;

- to apply a system of compulsory licensing to production of patented pharmaceutical products in order to solve problems of public health care.

CASES CONCERNED COMPETITION BETWEEN ORIGINATOR AND GENERIC COMPANIES

The FAS Russia receives a large number of complaints regarding actions of state customers according to facts of access restriction on participation in an auction while organizing and tendering process on purchase of medicines. Examples of investigations carried out by the FAS Russia concerning the competition between originator and generic companies are below:

1. INN «Samotropin»:

The Ministry of Health and Social Development of the Russian Federation artificially divided lots of an open auction on interchangeable medicines containing the same active ingredient “Somatropin”. As a result of consideration of the case the FAS Russia found interchangeability of medicines with INN "Somatropin", and also the instruction on actions aimed at providing the competition at carrying out in future an auction on the right of conclusion of state contracts for supply of medicines with INNn “Somatropin" was issued.

2. INN «Mycophenolate mofetil»:

The Ministry of Health and Social Development of the Russian Federation together with the Common Commission of the Ministry of Health and Social Development of the Russian Federation didn't allow the supplier of medicine with the trade name "MaySept" to participate in an auction for the reason of inadequacy of contents of demanded indications in other sections of the instruction on medical application of the medicine "MaySept" to requirements of the customer. After interchangeability of the preparations "Sellsept" and "Maysept" had been set up, the suppliers of the above medicines were admitted to an auction that led to decrease in the initial (maximum) price of the contract for one lot up to 88%, and for another – up to 56%. It saved 104,3 million rub to the federal budget.

Besides, the FAS Russia also found the fact of prevention by the Ministry of Health and Social Development of the Russian Federation of modification of documentation on the medicine Supresta (INN Mycophenolate mofetil), which led to impossibility of participation of suppliers of Supresta medicine in the state auctions.

3. INN «Epoetin alfa»:

A case on violation of the competition connected with inclusion by the state customer in auction documentation of the requirements directed on narrowing of

competitive space has been considered. As a result of consideration of the case, interchangeability of Eprex and Eralfon medicines was established.

An inspection within the whole country in relation to the Eralfon medicine for evidence of requirements limiting the competition in auction documentation on placement of orders for delivery of goods, performance of work, rendering services for the state and municipal needs was carried out. As a result, in 33 regions of the Russian Federation, signs of violation of the competition law and the legislation on auctions were found, 28 cases were initiated in the relation to state customers and their authorized organizations. The economy of budgetary funds for the first half of the year 2009 with participation in the auction of interchangeable preparations INN of Epoetin an alpha could make 88,9 million rubles.

In 2013 for the purpose of prevention of violations in holding auctions on purchasing medicines, the FAS Russia sent official clarifications on interchangeability to all state customers of the Russian Federation:

- anti-retrovirus medicines;
- medicines applied for anesthesia in stomatology;
- having INN "Epoetin Alfa";
- having INN " Docetaxelum";
- having INN "Salbutamol".

UNILATERAL CONDUCT PRACTICES

Programs of circulation of commodities and loyalty

1. The FAS Russia considers that competition development on pharmaceutical markets is interfered by the following main violations committed by economic entities dominating in the markets of wholesale trade in medicines:

- exclusive agreements between producers and distributors on supply of medicines;

- agreements of pharmaceutical companies with authorities for the purpose of obtaining advantages in the address, including at the bidding;

- participation of companies in formation of demands for purchase of certain medicines and in documentation preparation for the bidding;

- lack of coherent policy of dominating economic entities in their relations with distributors, as well as accurate criteria of their assessment and decision making on cooperation that leads to discrimination of buyers of wholesale parties of medicines or unreasonable refusals to certain buyers from deliveries;

- absence in separate companies of system of office-work and written correspondence with contractors that in some cases violates the rights of market participants for the appeal of actions of partners for unreasonable refusal in the conclusion of the contract for delivery of medicines as such offers and refusals aren't fixed;

- vertical agreements directed on the commodity market of medicines sharing by territories and buyers.

The FAS Russia suggests measures for creation of non-discriminatory access of wholesale and retail sellers to medicines through formation of selection public rules for contractors by companies dominating in the market that could resolve these problems.

2. Besides, FAS revealed that the largest foreign producers of medicines have provided essential bonuses, awards and discounts to production price, bonuses in the form of the irrevocable financial help, etc. to the direct buyers (distributors). Moreover they are attached as a percentage to the value of the acquired medicines. It turns out that at the same time there were selling of drugs at contractual prices within the vertical relations and return cash flows determining the real price of medicines.

Application by foreign pharmaceutical companies of such system of flows has at least two objectives: tax planning and avoidance of state price regulation working by regulation of the size of a price extra charge. As a result of this scheme of flows exclusive importers and distributors have direct interest in acquisition of as much as possible expensive medicines which cost is paid either by final consumer, or by state purchasing medicines at the funds of the state budget.

3. There is an issue within the state bidding concerned with supplies of international pharmaceutical companies of medicine on which they dominate. The FAS Russia considers that to ensure competition at the bidding and to reduce prices of purchases it is expedient to such companies to present a confirmation of necessary standard items of medicine at the identical prices on suspensive terms equally for all potential participants (on condition of medicine delivery to the winner of the bidding).

Originator position in the market

The FAS Russia defines the market power of any pharmaceutical company (not only an originator) researching the commodity market.

According to the Procedure of carrying out the analysis of competition in the commodity market (hereinafter – Procedure), approved by the FAS Russia's Order No. 220 of 28.04.2010, one or several of the following methods are used to identify interchangeable goods:

- "the hypothetical monopolist test";

- the analysis of pricing and dynamics of the prices, changes of volume of demand at the change in price;

- calculation of an indicator of cross elasticity of demand according to point 3.10 of the Procedure.

As a result of carrying out "the hypothetical monopolist test" (for definition of grocery borders of the commodity market) the consumers opinion on the structure of interchangeable goods is investigated. For this purpose consumers have to answer the question: "What goods and in what volume they will prefer to replace the previous one if its price raises by 5 - 10 percent for a long period (more than one year), and the prices of other goods remain invariable?".

At the same time, the feature of the market of medicines is low price elasticity of demand for medicines from the population, and also that formation of demand for medicines is carried out not by their final consumers, but doctors and druggists.

Compensation of certain medicines by the state and the centralized public purchases of medicines have a considerable impact on the structure of the market.

Thus, definition of borders of the commodity market requires not the consumers opinion on substitution of drugs so much as doctors, medical organizations and other state customers.

ANTICOMPETITIVE AGREEMENTS

The FAS Russia in 2011-2012 checked the arrangements between participants of the state bidding on supply of medicines within the federal programs "Seven Nozologiya" and "Tuberculosis" in 2008-2009.

As a result FAS considered a series of cases upon the signs of violations of clause 2 part 1 article 11 of the Federal law "On protection of competition" in the course of open tenders carried out by the Ministry of Health and Social Development of the Russian Federation on the rights to conclude state contracts for supply of medicines for state needs. Such largest pharmaceutical distributors as "Rosta", "Protek", "R-Pharm", "Irvin-2" were pleaded guilty broken the antimonopoly law.

Cases concerned the conclusion of illegal anticompetitive agreements which led to maintenance of the prices at the bidding on purchase of medicines on a state program. The companies were allowed for participation in the tender and were present at it, but serially refused to submit price offers. As a result contracts had to be concluded with the only bidder making the proposal.

Due to the lack of direct proofs of the cartel agreements concluded in an oral form, the antimonopoly authority had to lean only on indirect demonstrations of fault (specific behavior of the pharmaceutical companies, absence on tender, intentionally passive position during the tender and so forth). At the same time, arbitration courts partially confirmed the FAS Russia conclusions of cartels existence.

Besides, in 2011 the FAS Russia the decision on violation of the antimonopoly law concerning "the Center of Implementation "Protek" CJSC (hereinafter – Center "Protek") and "Capital drugstores" (the state unitary enterprise of the city of Moscow). These companies concluded and participated in the agreement that led to price maintenance on a lot No. 3 of open tender on the right to conclude state contract for

providing treatment-and-prophylactic centers of Moscow with specific medicines and medical products in 2008.

Company "Eli Lilly Vostok S. A." (its representative office in Moscow) was also recognized broken the Federal Law "On protection of competition" cause of coordinating economic activities of Center "Protek" and "Capital drugstores".

At the same time, this decision was cancelled by court cause of rejection as the proof of the concluded agreement of the electronic correspondence between the companies presented by FAS.

FUTURE DEVELOPMENT

The FAS Russia believes that the following measures have to be taken to develop competition on pharmaceutical markets in the medium term:

1. Ensuring unconditional transition of all pharmaceutical enterprises on the GMP standards and introduction of a ban of medicines made not on the GMP in Russian territory. It will create common conditions of production both import, and domestic drugs, will guarantee the quality of medicines in the market and will give opportunity to domestic producers to export the production on foreign markets. Authorization of GLP, GCP, GSP, GDP and GPP requirements have to be done by law.

2. Formation of a strong pharmaceutical supervision of circulation of medicines (registration of medicines, control over compliance with GMP requirements, circulation control) with powers to impose sanctions and fines for violation of the medical legislation.

3. Introduction of the concept of interchangeability of medicines in Russian legislation, including containing different international unlicensed names, definition of a procedure establishing the interchangeability of medicines, formation of a database of interchangeable medicines. It could considerably reduce the number of violation on bidding, could lead to economy of budgetary funds allocated for purchase of medicines, and also could stimulate pharmaceutical companies to reduce the prices.

4. Determination of common instructions of the reproduced and original medicines, automatic modification of instructions on medical application of all similar medicines at data changing on contraindications and side effects of one of interchangeable

medicines, and also creation of the nomenclature of the medicinal forms, allowing to unify them, and introduction of registration requirements for standard dosages.

5. Informing the medical community and state customers about interchangeable medicines, and citizens about cheap medicines interchanged to expensive medicines in the market that will stimulate producers to reduce the prices both on original, and reproduced medicines. Determination of obligatory requirements to extract of recipes on prescription forms according to the international unlicensed names allowing patients to choose between several interchangeable medicines at the best price.

6. Removal of unreasonable barriers at registration of medicines, simplification of registration of the reproduced medicines, especially according to those international unlicensed names which have only one trade name. Recognition of the international clinical research and the certificates issued by FDA and EMA in some cases.