Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

30-Jan-2014

English - Or. English

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/GF/WD(2014)33
Unclassified

Global Forum on Competition

COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from the Russian Federation

-- Session III --

This contribution is submitted by the Russian Federation under Session III of the Global Forum on Competition to be held on 27-28 February 2014.

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JT03351739

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Russian Federation --

1. Manufacturing level:

1.1 What kind of regulation, if any, exists on ex-factory prices of originator drugs?

1. The turnover of medicinal products of the Russian Federation is regulated by Federal Law № 61-FZ "On Circulation of Medicines" (further Law on Circulation of Medicines)

2. According to Article 60 Law on Circulation of Medicines the state regulation of prices for medicinal products for medical use is exercised including state registration of the manufacturers' maximum ex-works prices for the medicinal products included in the list of vital and essential medicinal products, determination of maximum wholesale and maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included in the list of vital and essential medicinal products.

3. In calculation of maximum ex-works price the following shall be taken into account:

- To all Russian medicinal products – the price on analogous (by international non-proprietary name, certain dosage form and dosage rate) medicinal products, manufactured in the Russian Federation or in case of absence of such - the price on analogous foreign medicinal products being in civil circulation in the Russian Federation;
- For Russian medicinal products being in circulation in the Russian Federation - the calculation of weight-average actual ex-works price of the medicinal product during the year, preceding the date of presenting of manufacturer's maximum ex-works price to state registration;
- For Russian medicinal products which did not come in circulation in the Russian Federation and originator medicines - the calculation by the Russian manufacturers of medicinal products of costs associated to developing, manufacturing and sales of medicinal products;
- For all foreign manufacturer - the price on analogous (by international non-proprietary name, certain dosage form and dosage rate) medicinal products being in civil circulation in the Russian Federation;
- For foreign medicinal products being in circulation in the Russian Federation the calculation weight-average actual import price of the medicinal product during the year, preceding the date of presenting of manufacturer's maximum ex-works price to state registration
- For foreign medicinal products which did not come in circulation in the Russian Federation - specifying by foreign manufacturers of medicinal products of minimal manufacturer's ex-works price for the medicinal product in manufacturer's country and other countries, where it is registered, with taking into account the costs associated to customs clearance (customs duty and customs fees for the customs clearance) and transport charges.

1.2 What kind of regulation, if any, exists on ex-factory prices of generic drugs?

4. There are not specific characteristics in government regulation prices on original or generic medical products, excluding Russian originator medicines, when maximum prices calculating on the basis of costs associated to developing, manufacturing and sales of medicinal products (maximum prices on originator foreign medicines calculated with universal technology of calculation prices on foreign medicinal products).

1.3 Are you concerned that this regulation may be stifling price competition or innovation?

5. According to the FAS Russia, current procedure of price regulation on vital and essential medicinal products may result for such negative effects:

- Unprofitableness of production of some vital and essential medicinal products, which provide the reduce of investment in economic sector, including into modernization of production for adoption of GMP standards;
- "Leaching out" from the circulation of cheap medicinal products, which provides the growth of population expenses for medicines;
- No interest of manufactures to reduce the prices;
- False polylithism (appearance of excessive number of new medical forms, dosage, packaging, insertion of other not-important changes in registration documents) which provide unreasonable and considerable increase of costs on certain medicines;
- Factors existing of medicinal products with same trade names and different prices on the market due to the fact that introduction insignificant alterations in regulatory documents of medicines producer iteratively undergo price registration procedure on the same medical products;
- Increase of prices on medicinal products, which do not included in the list of vital and essential medicinal products, because producers, wholesale and retail sellers try to cover profit lacks from vital and essential medicinal products realization through the price increase on unregulated medicinal products.

1.4 Have you ever performed a market study that has looked at this regulation?

6. Yes, in 2013 the FAS Russia conducted a research of evaluation of the availability of medicines on the based on a consumer prices analysis and the pricing of medicines in the Russian Federation (including the subjects of the Russian Federation) as well as on comparable markets of EU countries, CIS and BRICS.

1.5 Do you rely mostly on local manufacturers or on foreign ones?

7. In Russia produced mainly reproduced drugs (generics). However, it is estimated that public confidence in generics in Russia in general is not high enough.

8. Thus, the lack of competition in the markets of medicines and lack of confidence of doctors and patients to generics indicates that even after the expiration of patent protection, sales of original products in Russia is not always reduced or changed slightly; many cheap analogues significantly less claim than expensive original medicines.

9. The lack of consumer confidence in the Russian medicines is also linked with the absence of the majority of Russian manufacturers the GMP certificate, allowing individual foreign companies, which are competing with Russian companies, impugn quality of the Russian medicines.

1.6 Are there barriers to trade and import that constraint the availability of drugs in your country?

10. The main problems of the affordability of medicines to the public according to the FAS Russia are:

- The difficulty of obtaining preferential prescriptions for medications and prescriptions for medicines which are sold commercially in connection with the:
  - necessity of doctors visiting and duration of prescriptions clearance procedures (pre-recording, long waiting in lines and prescribing, doctors send to each other),
  - absence preferential medicines in the required amount in pharmacies (deficit, supply disruptions, overstock of regional warehouses).
- Problems of affordability of medicines in rural and remote areas in connection with low profitability of pharmacy organizations in such areas, reduction the number of pharmacies engaged in the manufacturing of medicines, as well as pharmacies providing a full range of socially significant services (individual manufacturing of medicines, night duty, vacation oxygen, drugs, etc.), personnel deficiency in the pharmaceutical organizations.
- Low level of financing volumes medicinal provision of the population, lack of coverage of the population and low level of state subsidies for medicines.
- Lack of patient registries for all diseases related to system of drug provision, which leads to a lack of effectiveness of controls over expenditures and complexity of planning costs on medicinal maintenance in accordance with the real needs of the population and health.

11. Compounding the above problems the following problems in the existing system of public procurement of medicines:

- Lack of criteria for determining the interchangeability of medicines. Specificity of circulation of medicines is the variety of characteristics associated with the peculiarities of state registration, technological processes or marketing policy of manufacturers, not affecting on the therapeutic properties of medicines, but allowing to government customers unreasonably allocate unique preparations among identical medicines by indicating in the documentation on trades therapeutically not significant characteristics corresponding to a (typically to the sole) manufacturer: the color of tablets, vials filling volume, volume, color, packaging material, etc. The most typical examples of abuse are tender documentation requirements to the supply medications in dosage form "lyophilisate for preparation of solution" at presence of analogues in the dosage forms "concentrate for preparation of solution" or "powder for preparation of solution", in the dosage form "film-coated tablets" at presence of analogues in the dosage form " film-coated tablets" in the form of release of "syringe" at presence of analogues in the form of release "ampin" packed in glass containers at presence of analogues in plastic packaging, etc. From the standpoint of antitrust laws medicines with the same international nonproprietary names, interchangeable dosage forms, interchangeable dosages and different trade names should be recognized “interchangeable”, since in Federal Law dated 26.07.2006 № 135-FZ "On Protection of Competition" under the interchangeable goods means those products that are comparable in terms of their functional purpose, application, quality and technical characteristics, price and more options in such a way, in such a way that the acquirer is really ready to substitute

or substitute one good for another in consumption. In practice, the formation of opinions of the purchaser is influenced by physician exposed to this corruption factor, which require constant intervention of antitrust authorities and cause strongly opposed by the customers, businesses and courts.

- The presence of various expiration dates of identical medicines which allows government customers to present unreasonable demands to the remaining expiry date of medicines, expressed as a percentage whereby number of participants in order placement become limited.
- There are various information in the instructions for medical use identical in all characteristics medicines related to the absence from the Russian Ministry of Health of control of information, information contained in the registration dossiers and reproduced original drugs. Any differences in the documents of the same medicines, which must compete at the auctions, used by unscrupulous customers for purchasing medication of specific manufacturer.
- Absence of prohibition on the association in one lot medicines and other goods or services allows customers to conduct bidding for the supply of medicines and medical devices, to include in one lot supply, storage and release of preferential medicines or buy medicines in conjunction with logistics software.
- Presence in Russian Federation of various lists of medicines, which are based on the basis of public procurement programs, creates advantages of individual manufacturers of medicines in relation to other. In addition many medicines included in the state lists, have no registered analogues. The competitive environment in the commodity markets of such preparations is missing, all participants of these commodity markets had to apply for a supply of certain medicaments or to its unique manufacturer or to a representative office in Russia. At the same distributors in several cases are forced to accept all the conditions of the manufacturer of original medicine (monopolist), to assume and carry out obligations to the state customer for timely and quality delivery of expensive drug in regions, and bear the risks associated with returning of product, late payment of its customer. Furthermore, in the absence of competition between manufacturers of the medicine distributor gets into a situation where finding themselves the only one bidder it may be prosecuted for bid rigging.

3. Wholesale Distribution:

3.1 How is wholesale distribution organised in your country? Are wholesalers buying drugs from manufacturers and selling them downstream or are they simply distribute of manufacturers? Is this changing and if so in what ways?

12. In Russia, there are two common ways of distribution:

- Distributors buy drugs from manufacturers and sell them further along the supply chain;
- Distributors act as agents of manufacturers.

13. However, government regulation of thresholds of the wholesale and retail surcharges to the actual selling prices of producers stimulates wholesale organizations to work directly with manufacturers, which leads to the decrease of distribution chains by reducing the volumes of secondary distribution.

3.2 How many players are involved in wholesale distribution? Is it a very concentrated sector? Are there many layers (e.g. large national wholesalers who supply smaller local wholesalers)? Do retailers usually stock themselves from one wholesaler or do they rely on more than one?

14. Several participants may be engaged in the wholesale distribution (usually from 1 to 3 distributors).

15. The wholesale drug market generally may be characterized as moderately concentrated, although in some regions it is competitive, and in others it may be highly concentrated. Nevertheless, experts have noted a tendency towards a higher degree of concentration of the wholesale market in the entire territory of the country and within individual regions.

16. This sector is a multilayered, i.e., there are large national wholesalers operating throughout the country (about 10 business entities), as well as interregional distributors acting on the territory of several regions and regional (local) distributors.

17. It is estimated that the level of concentration of the drug wholesale market in Russia has a growth dynamics. The aggregate share of 10 of the largest distributors in the country is about 84 % of the wholesale market, the combined share of five largest distributors is about 60%. A share of a leader among major national wholesalers of medicines is about 15 % of sales of all companies.

18. Most business entities owning pharmacies (retailers) purchase medicines from no more than 5 suppliers. Less than a third of retailers have 9 or more suppliers. The average number of suppliers is about 8 companies. This is related to the geographical features of the country, to a large number of exclusive wholesalers specializing in the supply of drugs of individual producers and to other factors, in which any pharmaceutical distributor may not meet the needs of its network by 100%.

3.3 Are there vertical agreements in place between wholesalers and manufacturers (e.g. exclusive distribution, and exclusive territories)? What are the main characteristics of these agreements? Do you have concern that these agreements may reduce inter and intra brand competition?

19. Such agreements are common among foreign manufacturers and distributors located in Russia, especially in the commodity markets of medicines that have no analogues. According to the FAS Russia, such agreements may lead to restriction of competition.

20. The decline in profitability on the wholesale market of medicines stimulated the exit of distributors beyond the actual wholesale business and encourages the vertical integration. A number of large companies (primarily national distributors) showed interest in various related sectors. Some companies develop their retail activities by forming their own network of pharmacies, others develop industrial fields, and the others combine both of these ways of development and implement the projects in logistics.

21. Currently, manufacturers tend to trade in products either from their own warehouses in Russia, or from warehouses rented by manufacturers. This is prompted by a desire to ensure uninterrupted supply of medicines, on the one hand, and to provide companies with greater independence from pharmaceutical distributors, on the other hand. Many distributors are aware of these trends and organize their own warehouses and logistics terminals that provide similar services to producers, thus obtaining a new source of profit.

22. Except the desire of major distributors to work with manufacturers without intermediaries in relation to the control of the margins on vital and essential drugs, the interest of distributors is more and more excited by the state attention in the industrial sector: as you know , the pharmaceutical and medical

industries are declared as priority areas of development and modernization. In 2009, the Strategy for the Development of the Pharmaceutical Industry in the Russian Federation was adopted for the period until 2020. Many major retailers have their own production.

3.4 Are wholesalers vertically integrated with retailers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?

23. Such agreements exist. According to the FAS Russia, such agreements may lead to restriction of competition.

24. More pharmaceutical distributors have their own pharmacy chains by buying the existing ones or creating new ones. The large distribution companies in Russia buy retail chains in order to diversify risks and reduce costs. Vertically integrated companies have significant advantages over other market participants, including the advantages which result from the use of wholesale and retail surcharges in aggregate. In addition, the vertical integration allows distributors to receive a guaranteed amount of supplies to pharmacies and additional profits from retail trade.

25. Pharmacies are also interested in integration with distributors against deficiency of equity and debt in the conditions of the crisis and of the tightening of cooperation with suppliers (the cancellation of the placement of goods under distribution, the reduction of a grace period for the goods delivered, refusals to work with small pharmacies because of the small batches of orders, etc.). In the pharmaceutical market actually only distributors may now serve as certain guarantors of financial stability, as they have the ability to borrow funds under the transaction, including bank loans, by taking on the role of a locomotive for further development of retail network. Quantitative composition of large drugstore chains affiliated with the wholesale business recently significantly increased.

3.5 Are there special provisions or regulation in place to ensure that rural and sparsely populated areas are served by wholesalers?

26. There are no such provisions.

3.6 Are wholesalers subject to regulation on prices, profits or margins?

27. In accordance with Art. 60 of the Federal Law On Circulation of Medicines, the State exercises regulation over maximum wholesale mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included in the list of vital and essential medicinal products. The State regulation of wholesales prices for medicinal products which are not included into the list of vital and essential medicinal products is not covered by legislation of the Russian Federation.

28. In accordance with part 3 Art. 61 of the Federal Law On Circulation of Medicines it is prohibited to sell medicinal products included in the list of vital and essential medicinal products, the manufacturer's maximum ex-works price for which have not been registered.

29. In accordance with part Art. 63 of the Federal Law On Circulation of Medicines the executive authorities of the Russian Federation constituent entities determine maximum wholesale and maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included in the list of vital and essential medicinal products in accordance with methodology established by Order of the Federal Tariff Service of the Russian Federation N 442-a of 11.12.2009.

30. The wholesalers and (or) pharmacy institutions shall sell the medicinal products included into the list of vital and essential medicinal products at the prices, the level of which shall not exceed the amount of the actual ex-works price specified by the manufacturer of medicinal products and not higher than the

registered maximum ex-works price, and wholesale and (or) retail mark-ups shall not exceed maximum wholesale and maximum retail mark-ups respectively determined by the Russian Federation constituent entity.

3.6 Are they subject to any other type of regulation that may affect the prices paid by final consumers or the availability of drugs to final consumers?

31. In accordance with Art. 60 of the Federal Law On Circulation of Medicines the State exercises regulation over maximum retail mark-ups to the actual ex-works prices of manufacturers of medicinal products for the medicinal products included in the list of vital and essential medicinal products.

32. The State regulation of maximum retail mark-ups is the same as regulation of maximum wholesale mark-ups mentioned above.

33. The State regulation of retail prices for medicinal products which are not included into the list of vital and essential medicinal products is not covered by legislation of the Russian Federation.

3.7 Does the existing regulation of wholesalers cause distortions that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?

34. The FAS Russia considers that existing state regulation of wholesale prices for medicinal products leads to:

35. acceleration of the process of reduction of the cheap medicinal products from wholesalers and pharmacy shops assortment as in the conditions of restricted mark-ups wholesalers and retailers are interested in selling more expensive medicine products (in accordance with Roszdravnadzor statistics half of a medicinal products included in the list of vital and essential medicinal products are absent in the pharmacy shops of some regions. Though State regulation of the specific medicinal products restrains their price escalation in the whole public costs on medicinal products are increasing; increase of medicine products prices which are not included into the list of vital and essential medicinal products because producers, wholesalers and retailers try to compensate undrawn profit after realization of medicinal products included in the list of vital and essential medicinal products at the expense of increasing prices on nonregulated medicinal products.

36. The FAS Russia believes that it is necessary to consider a question of transition from maximum wholesale and retail mark-ups percentage to maximum natural mark-ups and fixed indications in rubles with price line differentiation. It will provide equal competitive conditions for producers of the similar medicinal products and will stimulate producers to reduce maximum sale prices as demand of their products will be determined by needs of final purchasers.

3.8 Have you ever performed a market study that has looked at this regulation?

37. Yes, in 2013 the FAS Russia made an evaluation analysis of availability medicinal products in (including subjects of the Russian Federation) based on analysis of consumer prices and price formation of medicinal products in the market of the Russian Federation and on comparable markets of the CIS, EU and BRICS.

3.9 Do wholesalers/importers source drugs in countries that have lower prices (often referred to as parallel imports)?

38. No, as in accordance with Art. 1487 of the Civil Code of the Russian Federation, actions of business entities defined as a "parallel import" contradicts with principle of exhaustion of exclusive rights on trademark.

4. Retail distribution

4.1 How is retail distribution organized in your country? Who can sell prescription drugs and who can sell over-the-counter drugs?

39. Part. 1 Art. 55 of the Federal Law «On Circulation of Medicines» states that retailing of the medicinal is carried out by pharmacy institutions, veterinary pharmacy institutions, individual entrepreneurs licensed to carry out pharmaceutical activity, medical organizations having a license for pharmaceutical activity and their separate subdivisions (ambulance stations, paramedic's and paramedical-obstetric centers, centers (departments) of general (family) practice) located in rural settlements which have no pharmacy offices, and veterinary organizations licensed to carry out pharmaceutical activity.

40. Order of Ministry of Public Health and Social Development of the Russian Federation N 553n of 27.07.2010 determines the following list of pharmacy institutions:

- Pharmacy
- Production pharmacy
- Production pharmacy licensed to carry out aseptic pharmaceuticals
- Pharmacy store
- Pharmacy stand
- Order of Public Health and Social Development of the Russian Federation N 785 determines the order of pharmaceuticals supply and in accordance with part 1.4 of stated Order pharmaceuticals issued by doctor's prescription should be spread by pharmacies and pharmacy stores, and pharmaceuticals issued without doctor's prescription can be sold by any pharmacy institution.

4.2 Are there separate retail outlets for paying out of their pocket patients and for reimbursed/non-paying patients?

41. No, only a few of state or municipal pharmacy institutions issued favorable medicines (for free or with discount).

42. There are some problems connected with provision of the population with medicines it remains a large number of recipes stoned on a delayed provision in the pharmacies, the majority of citizens applications to Roszdravnadzor received in connection with the lack of necessary medicines in pharmacy organizations and failures in prescriptions. In addition, many citizens having the right on preferential medicinal maintenance, does not receive the required drugs due to their absence in the relevant schedules.

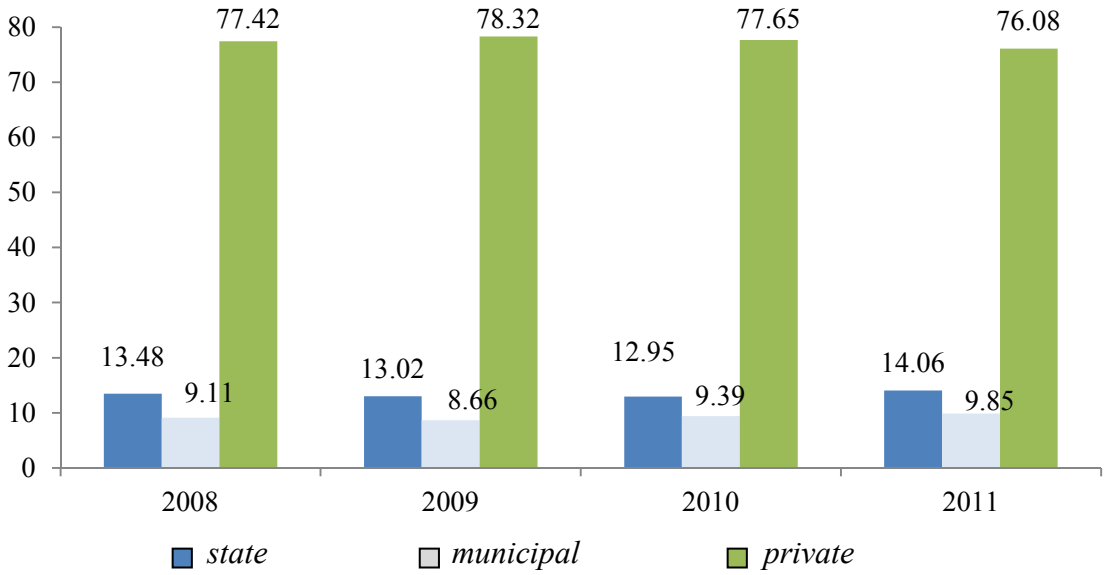
4.3 Are there publicly owned pharmacies and what is their role?

43. In 2008-2011 slowed down but continue a tendency of growth of share of private retailers in relation to state and municipal retailers. For the period of 2008-2011 it had increased only for 2.8% and in

2011 it was 87,35%. The share of pharmaceutical organizations belong to private economic entities was 76,08% in 2011.

44. Such differences in the shares exist due to the large number of pharmacy networks of state form of ownership. If one business entity of private ownership has an average of 3-4 pharmacies, each state entity accounts for about 14 pharmacy institutions.

Dynamics of the share of pharmacies in 2008-2011, by forms of ownership, %



45. Pharmacy institution of private ownership prevails over state and municipal practically in all regions of the Russian Federation.

4.4 Are doctors allowed to sell the medicines they prescribe?

46. Part 1 article 55 of the Law on circulation of medical drugs prescribes that retail sale of medical drugs is executed by individual entrepreneurs as well, in case they are licensed to conduct pharmacological activities, and also by outpatients' clinics, nurse clinics and midwifery clinics, centers (departments) of general practice (family doctors) located in rural areas where no other pharmacies exist.

47. Thus, a doctor, a nurse or a midwife under certain circumstances can sell medical drugs which they have prescribed.

4.5 Can hospital pharmacies also sell to external patients?

48. Yes, they can. Part 1 article 55 of the Law on circulation of medical drugs prescribes that retail sale of medical drugs is executed by pharmacies, as well as medical organizations that are licensed to licensed to conduct pharmacological activities and by their separated subdivisions (outpatients' clinics, nurse clinics and midwifery clinics, centers (departments) of general practice (family doctors)) located in rural areas where no other pharmacies exist.

4.6 Are on-line pharmacies allowed?

49. Legislation of the Russian Federation do not provide for functioning of on-line pharmacies. The Order of Ministry of Health and Social Development of 27.07.2010 № 553н defines the following types of pharmacies:

- Pharmacy of ready-made medical drugs;
- Production pharmacy;
- Production pharmacy with the right to produce aseptic medicine;
- Pharmacy station;
- Pharmacy stand.

50. Thus, Russian legislation defines a closed list of economic entities that have the right to execute retail trade of medical drugs.

51. On-line pharmacies executing sales of medical drugs as a rule do not hold a license for pharmacological activities, warehouses and transportation means conforming the requirements of the Russian legislation, official address and etc. moreover there are cases when such on-line pharmacies sell unregistered in Russia medical drugs, inclusive of analog medicine of the drugs which are under patent protection, and also counterfeit and bad quality medical products.

52. Such trade often includes the whole spectrum of violations:

- Sale of medical drugs without license;
- breach of license agreements;
- counterfeit, false and bad quality medical products;
- delusion of customers in regards to origins and characteristics of medical drugs sold over the internet.

53. Currently the issue of functioning and regulation of internet sites of pharmacies which are officially licensed is being discussed.

4.7 Is it possible to locate pharmacies in supermarkets?

54. Placing of pharmacies is possible at any location, in a separate place, separate premises which conform to sanitary-epidemiological requirements and Regulation on licensing of pharmacological activities, adopted by the resolution of the Government of the Russian Federation № 1081 of 22.12.2011.

55. Moreover, presently the possibility to permit selling of certain medical drugs over the counter directly at supermarkets is being considered.

4.8 Are chains allowed? What percentage of all existing pharmacies are chains??

56. Yes, pharmacy chains are allowed.

57. According to results of the analysis conducted by the FAS Russia on the state of competition in the market of retail trade of medical drugs, products intended for medical use and accompanying goods for years 2010-2011in 2011 **86,43%** of all examined pharmacies belonged pharmacy chains.

4.9 Are their restrictions imposed on opening hours of pharmacies?

58. No.

4.10 Are their restrictions on the number and locations of pharmacies? And other retail outlets of drugs?

59. No. There are no such restrictions. In case competing pharmacies merger the FAS Russia has to examine the influence of such activity on the state of competition and can prohibit the merger or impose restrictions.

60. The FAS Russia considers that restrictions on where pharmacies are located can lead to reduction of competition in the retail market, and consequently lead to increase of prices and lack of physical accessibility of pharmacy services to citizens.

4.11 How it is ensured that a sufficient number of retailers are located rural and sparsely populated areas?

61. As a result of continuous market analysis services to retail pharmacies, conducted at the end of the 2010-2011., FAS Russia found that in average for the Russian Federation in 2011 to 1 pharmacy resident accounts for 3751. In addition, five Russian regions revealed a lack of pharmacy organizations (5-20 thousand people per one pharmacy) and in 11 subjects of the Russian Federation revealed normal density of pharmacies (4-5 thousand people per 1 pharmacy). In the rest regions of the Russian Federation accounts 1 pharmacy per 1.2-4 thousand people.

62. Retail development of drugs mainly occurs in the capital and major municipalities, where there are sufficient demand for medicine as well, in small urban districts and municipalities drugstores much less, especially in small rural and remote regional centers of municipalities with low numbers and population density. It is connected with high costs, low solvency of the population of such municipalities and personnel shortages.

63. Although granted feldsher-midwife station right carry out retail trade of medicine reduced problems of accessibility of medicine in such municipalities as of 2011, FAS Russia found that in 262 municipalities operated only one entity. High level of market concentration perceived in 2011 in municipal unit which includes municipal units in number more than 100 thousand people.

64. FAS Russia perceived that in Kamchatka Cray, Murmansk and the Chelyabinsk Region in Nenec, Khanty-Mansisk, Chukot, Yamalo-Nenets Autonomous okrug and in Jewish Autonomous Region at all urban district revealed a high level undeveloped competition (concentration of market).

65. Business entities with a market share of over 35% were found in 81.7% municipalities with signs of dominance - of 58.4%. 964 businesses and groups of persons included in the FAS Russian register of economic entities having a market share of certain goods in the amount of more than thirty-five percent or dominant position in the market for a particular product.

66. FAS Russia considers that the purpose of the drug provision of the population of small municipalities is necessary to develop and implement national programs containing measures to develop a network of drugstores in remote and inaccessible areas, in urban districts and municipal districts with low numbers and density, as well as low-income population. Such programs could include the provision of state and municipal preferences entity engaged in pharmaceutical activities in these areas, including the provision of pharmacy organizations preferences on lease agreements and municipal space rental benefits.

4.12 Do NGOs run retail outlets in your country? What impact does it have on affordability and availability? Does their presence spur price competition?

67. There are public organizations (Russian Association of Pharmacy Network, Pharmacy Guild, Soyuzpharma), but they do not control pharmacies, but only represent the interests of their founders (participants) in relations with government bodies and other organizations.

4.13 Are retail outlets vertically integrated with wholesalers and/or manufacturers? Do you have concern that vertical integration may reduce inter and intra brand competition?

68. Creation of vertically integrated structures and large pharmacy network causes a number of problems for development of the competitive environment:

- fee for «entrance» in a pharmacy network for producers;
- priority promotion of its own brands (if available);
- price dumping.

4.14 Have you had cases of abuse of dominance or collusion? Are market conditions conductive to these types of infringements

69. Summarizing results of analysis of the FAS Russia in the market of medicines retail trade, medical products and related goods according to the results of 2010-2011 in the local markets in the boundaries of municipal formations 1312 economic entities were found with signs of dominance in accordance with part 1 of article 5 of the Federal Law of 26.07.2006 № 135-FZ «On Protection of Competition» (when the share of an economic entity is more than 50%) and 1878 economic entities with signs of dominance in accordance with part 3 of article 5 of the Federal Law of 26.07.2006 № 135-FZ «On Protection of Competition» (collective dominance). In 2011, the economic entities with signs of dominance were found in 96.3% of all the municipalities (in total 2261 municipal formations - city districts and municipal areas were studied).

70. According to results of the research of the markets of services of medicines retail trade, medical products and related goods conducted by Regional Offices of the FAS Russia in 2008-2011 964 economic entities and groups of persons were included in the register of economic entities, which have more than thirty-five percent of shares in the market of certain product or occupy a dominant position in the market certain product in order to exercise state control over the observance of Antimonopoly legislation and economic concentration.

4.15 Are retailers subject to regulation on prices, profits or margins?

71. State regulation of extreme dimensions for retail markups to actual retail prices set by manufacturers of medicinal products for medicines included in the List of Vital and Essential Drugs is realized in accordance with article 60 of the Law on Circulation of Medicinal Products. State regulation of retail prices for medications, which are not included in the List of Vital and Essential Drugs, is not stipulated by the legislation of the Russian Federation.

72. According to article 63 of the Law on Circulation of Medicinal Products, the Executive Authorities of the subjects of the Russian Federation set extreme dimensions for retail markups to the actual retail prices set by manufacturers of medicinal products for medicines included in the List of Vital and Essential Drugs, in accordance with the methodology approved by the Order № 442-a of 11.12.2009 of the Federal Tariff Service.

73. Pharmacy organizations, individual entrepreneurs, which have the licence for pharmaceutical activity, sale medicines included in the List of Vital and Essential Drugs at prices to a level which does not exceed the amount of the actual selling price set by the manufacturer of drugs and not exceeding registered marginal selling price and the size of the wholesale markup and (or) the size of the retail price not exceeding respectively marginal wholesale markup and (or) marginal retail price established in the subject of the Russian Federation.

4.16 If so does this type of regulation cause distortion that may limit the availability and affordability of drugs for final users (for example margin regulation favours the distribution of branded over generic drugs)?

74. In the opinion of the FAS Russia, the existing regulation of retail prices of drugs leads to:

75. - acceleration of the process of reduction of cheap drugs from drugstores, as wholesale and retail sellers in the conditions of limited allowances are interested in working with the most expensive drugs (according to data of the Federal Service on Surveillance and Health Care (Roszdravnadzor), in a number of regions in pharmacies there is no almost a half of the assortment of the Vital and Essential Drugs. As a result, although the state regulation of prices for specific drugs keeps prices down, in general, expenditures of the population on medicines are increasing);

76. - increasing of prices for medicines, which are not included in the list of Vital and Essential Drugs (VED), as manufacturers, wholesalers and retailers seek to compensate the loss of profit from realization VED by increasing prices on the unregulated drugs.

77. The FAS Russia believes that it would be appropriate to consider the question of transition from marginal wholesale and retail markups, expressed in percentages, to establishment of marginal markups in natural and fixed rates (rubles) differentiated by price groups. It will provide the producers of similar medicines with equal competitive conditions and will encourage them to reduce the marginal selling prices as demand for their products will be determined not by tendency of wholesale sellers to maximize their profits, but by needs of the end customers (inhabitants).

4.17 Have you ever performed a market study that has looked at this regulation?

78. Yes, in 2013 the FAS Russia conducted a research of evaluation of the availability of medicines on the based on a consumer prices analysis and the pricing of medicines in the Russian Federation (including the subjects of the Russian Federation) as well as on comparable markets of EU countries, CIS and BRICS.

4.18 Is there price competition between retail outlets? And service competition?

79. Yes, price competition exists and is very serious. Prices in the two pharmacies, located on the same street, may differ by 30-40%.

5. International Donors

5.1 Are international donors of medicines active in your country?

80. No.

5.2 How they distribute medicines? Do they use traditional distribution chain (local distributors or local pharmacies) or do they have their own channel?

81. No.

5.3 Does their presence create any pressure on the prices of the medicines not provided by donors?

82. No.

6. Public and private insurers

6.1 Do public insurers try to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?

83. No.

6.2 Do private insurers, if present, play a role In trying to exert control over the distribution chain in order to contain the price of drugs (e.g. do they run tenders to buy medicines)?

84. No.

7. Generics competition

7.1 How extensively are generics used in your country? Has their usage increased in the last few years? Do you think it has had an effect on prices of originators?

85. According to experts in 2012 in Russia sales of packs of original products was 16.8%, and generics - 25.4%, in monetary terms - of original medicines - 47%, and generics - 22%. It should be borne in mind that the prices of generic medicines is much lower than for original medicines, so generics sales in monetary terms has always lagged sales in physical units (packages).

86. The largest volume of sales (in monetary equivalent) constitutes original medicines with the expired license and medicines which have never had original equivalent (e.g. charcoal, korvalol, saline infusions etc.) as such medicines are not generic drugs, as far as there no evidence of reproduction of the original drug.

87. In Russia up to this moment significant budget expenses fall on original drugs. This is connected to the fact that Patent holders try to keep their monopoly by means of prolongation of Patents through "establishment" of new indications for use or conclusion of agreements with generics' producers (the so-called "green patents"), as well as by existence of uncertainty on issues of interchangeability of medicines. Even after the expiration of patent protection term sales volume in Russia do usually not reduce or change significantly, i.e. generic drugs do not compete with original drugs to the full extent. Original medical drugs constituted 45% of public procurement volume in 2012, and 52% in 2013.

88. For the past three years the correlation of generic and original drugs in the structure of medicine consumption has not virtually changed.

89. Entry of generic drugs into the market leads to significant reduction of prices for medicines belonging to the same therapeutic group.

7.2 Are generics subject to the same quality and safety controls as originator drugs?

90. In Russia quality and safety controls are the same for all drugs.

91. The streamlined proceedings of expertise may be applied to generics, aiming at state registration of drugs. At the same time, the streamlined proceedings of expertise do not mean reducing of requirements for safety, quality and efficiency of drugs.

92. Two ways of verification of products' quality are implied in Russia: conformity declaration and certification. The choice of the way of verification of drugs' quality is established by the Government of the Russian Federation and depends on the list the product is included in.

93. Conformity declaration of products is a special document which confirms that the products putting into circulation meet the requirements of technical regulations. Conformity declaration is supposed to be one of the most progressive forms of drugs' quality confirmation all over the world.

94. Declaration is one of the ways of obligatory confirmation of products' conformity. When adopting the declaration a producer declares that the product putting into circulation meets the requirements of quality standards of the Russian Federation. Conformity declaration could be adopted on a basis of the producer's evidences or on a basis of evidences of the third party – certifying authority or independent testing laboratory.

95. Declaration makes the process of obligatory confirmation of meeting the requirements easier for drugs' producers (sellers). Moreover it increases significantly its responsibility for the products delivering to the Russian market. Period of validity of conformity declaration is settled for the period which is not exceeding the storage period of the exact drugs' batch. Declaration, in contrast with certification, is the document of producer by which he or she grantees quality and safety of its products.

96. Obligatory certification of drugs is carried out by certifying authority whose the area of accreditation extends to the drugs on the basis of the contract between applicant and certifying authority according to the schemes established by technical regulations. Certification of quality system is carried out in accordance with the scheme of obligatory certification. In case of positive tests results, certifying authority processes the Certificate of Compliance for the drug according with a form established by federal authority for technical regulation, registers it and handles to the applicant. Period of validity of Certificate of Compliance is not exceed the storage period of the exact drugs' batch.

7.3 Does price or margin regulation at manufacturing, at wholesale and at retail level encourage the production and sale of generics? If so how? Could it be improved?

97. No

7.4 To what extent you consider that manufacturers affect the above incentives by providing the wholesalers and retailers with financial incentives when they sell originators rather than generics?

98. Cases are known when original producers of drugs stimulate the consumption of its drugs through incorrect interaction with public customers, doctors, pharmacists and through providing for significant discounts and bonuses for its distributors.

99. The FAS Russia found out that significant part of the medical society (especially those ones of narrow professional profile) has agreements with one or several pharmaceutical companies in accordance with which they received payment for compensatory services rendered. Selection of drugs under the

process of drawing up drugs' purchase requests very often is connected with marketing activity of producers and it is not always effective as for government budget as for certain patients.

100. At the same time, in 2013 on the initiative of the FAS Russia the legislation of the Russian Federation was amended including the following:

- definition of conflict of interests of medical officers and pharmaceutical companies was set; requirements and proscriptions of medical officers were formalized, administrative liabilities of doctors and pharmacists for hiding the conflict of interest was established;

- requirements were formalized for medical officers to prescribe drugs only on the official prescription forms for International non-proprietary names;

- requirements were imposed which prohibit to exercise unfair marketing policy by pharmaceutical companies and their representatives in the form of giving remuneration to doctors, organizing their vacations and limit significantly possibilities to promote drugs using "point" (and often corrupt) interactions with certain doctors and heads of medical organizations;

- equal opportunities for all pharmaceutical companies producing or selling similar (interchangeable) drugs were established concerning information of medical officers about their drugs in the framework of holding scientific events; a ban was imposed for pharmaceutical companies which are organizers of scientific event to create discriminating conditions for participators in these events.

7.5 Does any other type of regulation favour/foster the sale and use of generics? For Example are doctors required of incentivised to prescribe generics? Do doctors have maximum dispensing budget? Are pharmacists required to substitute originators with generics whenever possible? Are there other types of financial incentives for doctors or pharmacists aimed at favouring the prescription and dispensation of generic drugs?

101. Since 2013, on the initiative of the FAS Russia established a requirement for health professionals to prescribe drugs only on prescription forms for international nonproprietary names, and now pharmacies or patients have the choice of drugs within one written out by international nonproprietary name.

7.6 Are there financial incentives on consumers to request generics rather the originator drugs?

102. No, the only incentive purchase generics is their lower price.

7.7 To what extent you consider that manufacturers affect the above incentives by providing doctors with financial incentives when they sell originators rather than generics?

103. There are cases when the original manufacturers of drugs to stimulate the consumption of drugs through their incorrect interaction with government customers, doctors, pharmacists, as well as by providing significant discounts and bonuses to their distributors.

104. FAS Russia found that a significant portion of the medical community (especially narrow profile activity) has a contractual relationship with one or more pharmaceutical companies, according to which on a regular basis receive payment for services rendered by the compensatory.

105. Selecting doctors of various drugs in the process of drawing up proposals for the purchase of medicines from the budget are also often associated with marketing activities of manufacturers and not always the best for the state budget, as well as for individual patients.

106. However, in 2013 at the initiative of the FAS Russia amended the legislation of the Russian Federation that:

- Set the definition of conflict of interest medical professionals and pharmaceutical companies , as well as consolidated requirements and prohibitions imposed on health care providers, introduced administrative liability of doctors and pharmacists for failure information about a conflict of interest;

- Consolidated requirements for medical professionals to prescribe drugs only on prescription forms for international nonproprietary names;

- Requirements imposed prohibiting pharmaceutical companies and their representatives to exercise unfair marketing policy in the form of transfer of doctors remuneration, the organization of their stay by companies, as well as significantly restrict the ability of medical representatives to promote products using a «point» (and often corrupt) interaction with specific doctors and heads of medical institutions;

- Ensure equal opportunities for all pharmaceutical companies producing or implementing similar (interchangeable) drugs to inform health professionals about their medicines as part of the research activities, a ban on the creation of pharmaceutical company - the initiator of the scientific activities of discriminatory conditions for participants of such an event.

7.8 Do consumers perceive generics as safe and effective drugs, or does the suspicion that these drugs may be sub-standard or counterfeit encourage consumers to require/buy originators? How aware are they of the price difference between generics and originators?

107. There are two groups of consumers: some consider lower quality generic drugs and buy only original drugs, other medicines selected depending on the price.

108. According to estimates, the confidence of the general population to generics in Russia is not high enough. Even after the completion of the terms of patent protection , sales of original products in Russia is not always reduced or changed slightly, with many cheap analogues significantly less Claim than expensive original drugs . Lack of consumer confidence in the Russian drug is also associated with the absence of the majority of Russian manufacturers certificate GMP, allowing individual foreign companies competing with Russian, question the quality of the Russian pharmaceuticals.