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Public policy and access to new drugs: evidence from
Russian pharmaceutical market

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Executive summary

This paper presents some outcomes of research project held in 2008-2009 at the State University – Higher School of Economics. The aim of the project was to study factors that affect consumers' choice on Russian pharmaceutical market and to explain reasons for strong regional distortions in drug consumption. The author discusses major factors that can explain difference in pharmaceutical market structure with special focus on drug policy evaluation (registration, price regulation and federal reimbursement program – DLO).

Different estimates show high rates of Russian pharmaceutical market growth during last 10 years, main driving forces being population purchasing power growth and federal spending on healthcare.

The paper proves that despite these positive trends Russian pharmaceutical market has inefficient structure compared to more mature markets: in general the share of original drugs is less than 40% in cash and less than 10% in kind, while branded generics with no proven efficiency dominate in the market. However Russian regions differ dramatically with respect to these rates.

To understand high variation of pharmaceutical market structure evidence from federal and regional drug policies are discussed in the paper. While regional authorities use different criteria for price regulation and mark-ups limitations the study revealed that difference in price policy has no influence on consumers' choice.

The study has shown that federal reimbursement program (called DLO) had no significant effect on drugs consumption in Russian regions principally due to small number of participants eligible for the DLO and high level of those who preferred to leave the program.

At the same time the results of empirical analysis showed that difference in regional market structure is explained by regional economic and social characteristics, such as the share of rural population and income-related factors.

1 Introduction

Pharmaceutical innovations are proved to have significant welfare gains both for producers and consumers (Wu 1980, 1984; Philipson, Jena 2005). Innovative new drugs improve quality and length of life, reduce cost of medical care, substituting surgeries and decreasing hospital stays (Lichtenberg, 1996, 1998; Kleinke, 2001; Zweifel, Breyer 1997; Meyer, 2002). National governments are interested in pharmaceutical innovations due to positive therapeutic and economic effects. However creating and launching new drugs is associated with high R&D and advertising costs and evidently with high prices. Since public spending on drugs is constantly increasing government officials face the trade-off between promoting innovations and containing drugs budgets.

In most countries pharmaceutical market is regulated with respect to safety, efficacy, quality, promotion, intellectual property right protection etc. While the kind of regulation use differs widely among the countries price regulation and reimbursement are among main policy instruments affecting the appearance of new drugs in a market. A number of studies are devoted to drug policy evaluation. Some of them (Vernon, 2004; Golec and Vernon 2006, for example) focus on company decision whether to develop new drugs. Using company-level data they prove that price constraints negatively affect R&D spending².

Other empirical studies examine the links between price regulation and new drugs launches. They tend to explain how public policy affects market performance. Hence Kyle (2003) examined data on drugs developed and launched in 28 pharmaceutical markets from 1980-2000 and proved that drug launches into price-controlled markets are delayed. Also Danzon et al. (2003) studied the effect of pharmaceutical price regulation on delays in new drug launches using data from 25 major markets of 85 new chemical entities (NCEs) launched in the UK or US between 1994 and 1998. Their results suggest that countries with lower expected prices or smaller expected market size experience longer delays in new drug access, controlling for per capita income and other country and firm characteristics. Similarly, Danzon and Ketcham (2003) find that launch lags are longer in countries with more stringent reference pricing systems.

² For detailed review on empirical literature and discussion about price contains and company R&D spending see Kessler (2004)

Lanjouw (2005) analyzed the impact of price regulation and patent rights on new drugs appearance. The analysis covered a large sample of 68 countries at all income levels and included all drug launches over the period 1982-2002. He used information on legal and regulatory policy and analyzed the determinants of drug launch in poor countries. He proved that strong price control tends to discourage rapid product entry. Therefore Kessler (2004) concludes that price regulation delays drug launches and distorts consumers' choice towards less innovative drugs.

Reimbursement policies also may have a strong impact on new drugs appearance and consumption as they increase the demand for selected drugs. Smith (2005) provides theoretical framework for priority setting in health care. He develops a set of rules for the inclusion of a health technology in the subsidized healthcare package and indicates that optimal levels of subsidy depend on cost-effectiveness of technology, its price elasticity of demand, epidemiology of the associated disease, and policy maker's attitude towards equity.

According to Mossialos et al. (2004) reimbursement policies operating within Europe vary markedly. However most countries appear to operate, or are moving towards, a positive list – the list of drugs that can be totally or partly reimbursed. The impact of positive lists on new drugs appearance depends on the criteria used for selection, openness to adequate consultation/discussion and flexibility, such that once a decision has been reached it is possible to reverse if new information is disclosed. If price of a new drug is set with regard to the improvement it provides compared with other drugs in the same therapeutic class on the positive list such a policy can promote innovation both in terms of R&D spending and launches.

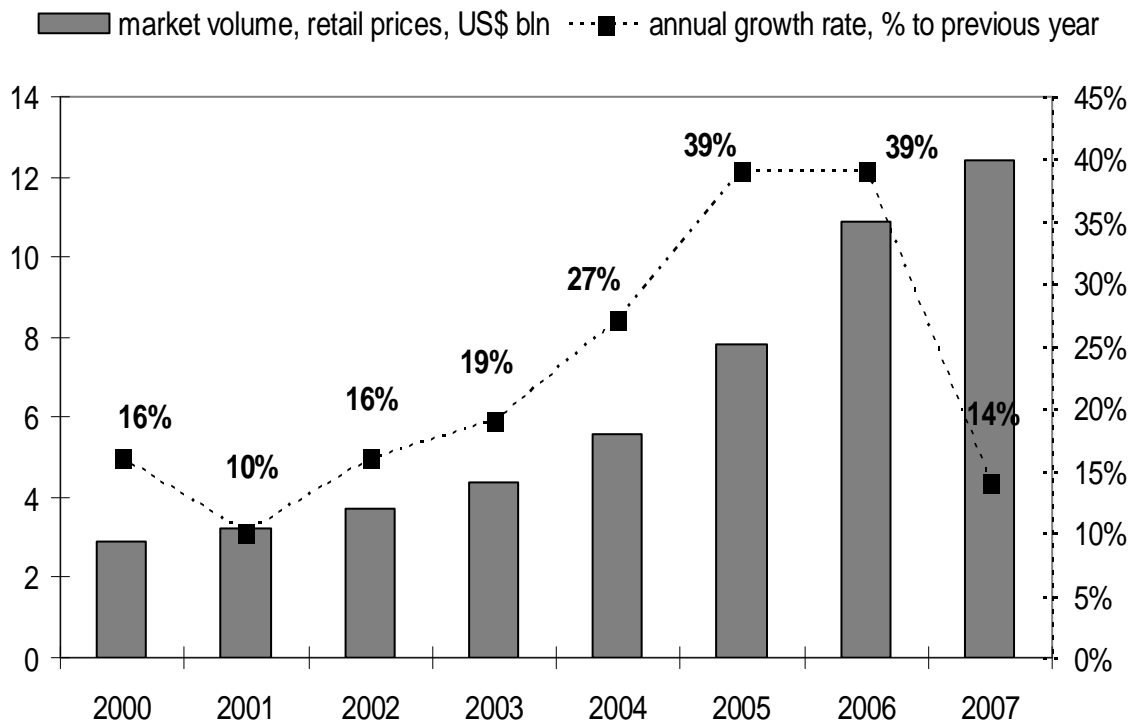
Nowadays seeking to contain the costs of drugs spending, government officials in many countries revise compensation mechanisms: limit reimbursement of drugs, de-list drugs considered non-essential, introduce co-payments, change prescription procedures etc. Russia is not an exception. In 2005 a priority national project "Health" with about 80 bln ruble budget for the year 2006 was initiated. Also federal reimbursement program called DLO started in 2005. The tremendous growth of public expenditures on medicines in 2005-2008 attracts considerable political attention because of mismanagement problems and vague impact on access to essential drugs and on new drugs consumption.

The objective of this paper is therefore to shed light on Russian pharmaceutical market structure and explain how price regulation and federal reimbursement program affect the consumption of new drugs by presenting and discussing some evidence from Russian regions. This requires a brief description of Russian pharmaceutical market (section 2), discussion of main policy instruments (Section 3) and empirical analysis (Section 4). Section 5 concludes.

2 Context: Russian pharmaceutical market

Russian market research company Pharmexpert puts the value of Russian pharmaceutical market at \$12.2 billion in 2008, DSM group³ estimates the pharmaceutical market value to \$18.4 billion (including VAT). Although national pharmaceutical market value is not impressive compared to more mature markets, before the crisis Russia was experiencing tremendous growth (Figure 1) compared to the modest 4-6% growth seen in the US and Europe. Even for 2009 Pharmexpert expects a 5-7 % growth.

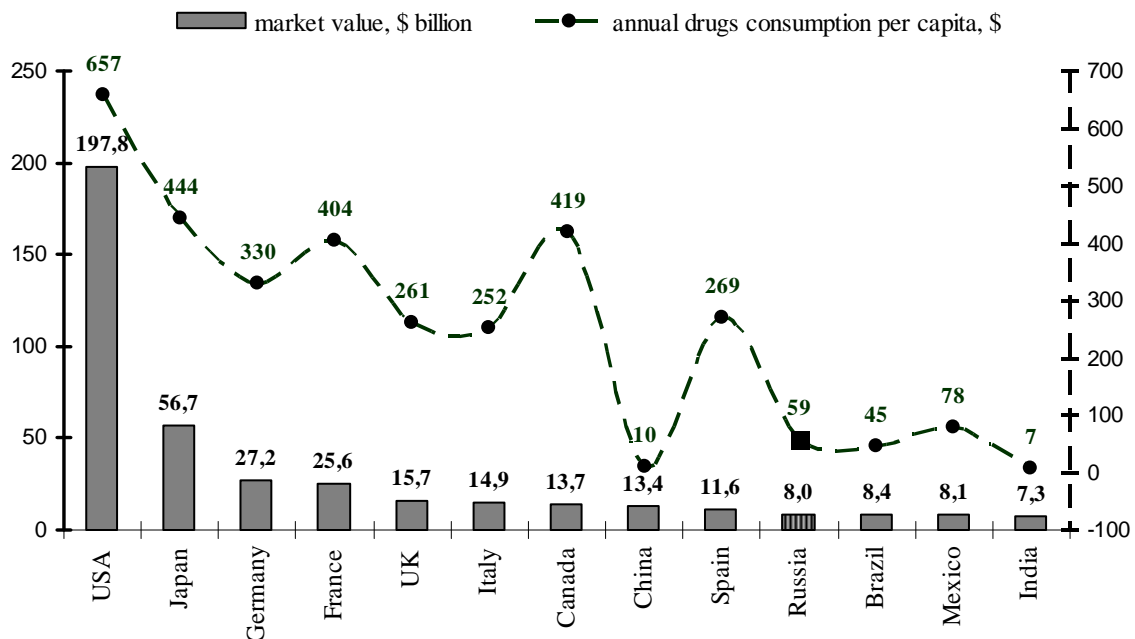
Figure 1 Pharmaceutical market growth in Russia, 2000-2007.



Source: RMBC.

Despite Russia is among most highly growing markets the drug consumption per capita is far behind Western Europe and North America: according to DSMgroup Russian per capita drug expenditures in 2006 were only \$59 compared to average \$250 in these countries (Fig. 2).

³ DSM group- analytical company working in the field of drugstores monitoring and pharmaceutical market research mainly for marketing purpose

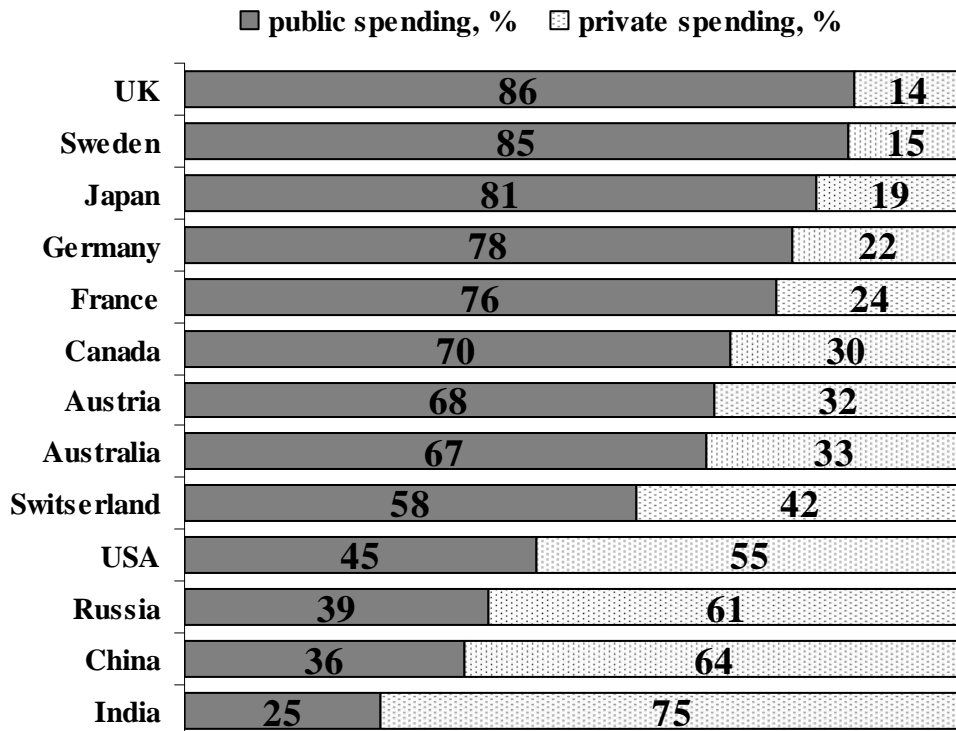
Figure 2 Drugs consumption in Russia and other countries, 2006.

Source: Russian Pharmaceutical Market, 2006. DSM Group.

Russian pharmaceutical market is formed by two sectors: public sector where financing is performed from state sources and commercial sector where drugs are paid mainly by out-of-pocket-expenditures. Private health insurance is still weak, different estimates prove that it covers not more than 4% of population (Kolosnitsyna et al, 2007) and insurance plans rarely include drug compensations.

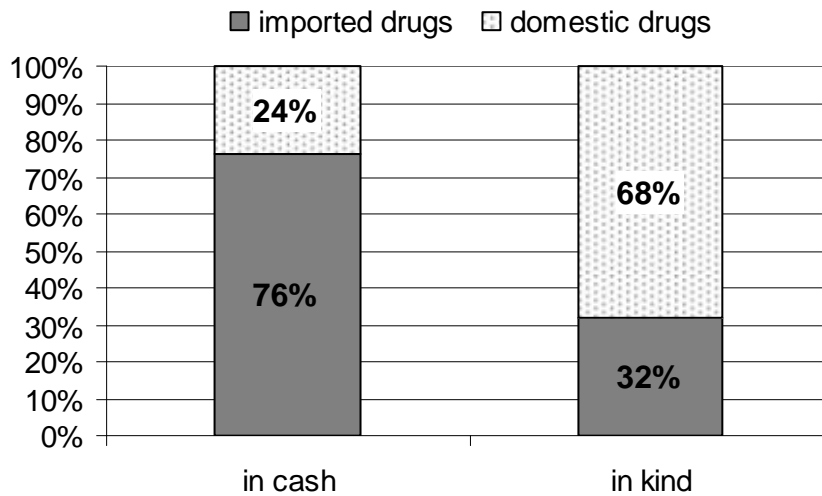
The role of public sector as drugs purchaser, while declining, is still significant because of the volume needed to carry out its nationwide programs (including reimbursement program) and public hospitals provision. In the year 2006 the share of public expenditures in pharmaceutical market was rather low compared to the major pharmaceutical markets (even those that prefer private insurance to the system of collective financing) (Fig.3).

Hence the dominant part of economic burden of medical treatment falls on patients. Even “free” staying in public hospital doesn’t protect the inpatient from drugs expenditures: while inpatient prescription costs are meant to be covered from hospital budget or (rarely) by the insurer, often inpatients are asked to purchase drugs. Unlike European pharmaceutical markets Russian market is largely formed by out-of-pocket expenditures.

Figure 3 Public and private drugs expenditures, 2006.

Source: Russian Pharmaceutical Market, 2006. DSM Group.

Domestic drugs cover only one fourth of Russian commercial market in sales value while prevail in terms of sales volume (Fig. 4). Before the break-up of the Soviet Union, domestic producers covered a substantial portion of Russian pharmaceutical market with the balance made up by imports from Central European countries. After the break-up of the Soviet Union the industry was largely out-dated and poorly maintained. While some domestic producers have initiated modernization and installation of new production facilities modern western drugs as well as generic drugs from other countries have seen particularly strong sales growth.

Figure 4 Imported and domestic drugs, RF, 2006.

Source: Russian Pharmaceutical Market, 2006. DSM Group.

Russian pharmaceutical industry consists of nearly 600 enterprises. In 2008 more than thousand manufacturers (514 domestic companies and 501 foreign companies) offered their products in Russian pharmacies, while only 20 companies covered 46% of commercial segment. Among 514 Russian manufacturers 50 companies (11%) produced more than 67% of domestic drugs. Other domestic enterprises are small companies not able to develop and launch new drugs.

Only 2 domestic manufactures – “Pharmstandard” and “Otechestvennyye lekarstva” reached the TOP 20 list (according to DSMgroup retail audit rating – Appendix 5).

While world pharmaceutical industry is highly innovative domestic industry annual R&D expenses form less than 2% of total expenses. This is explained by domestic industry weakness, small scale of production, absence of company R&D departments, technological gaps etc. Those few domestic manufacturers that introduce new drugs focus mainly on incremental innovations, not drastic.

However new drugs regularly enter Russian pharmaceutical market: 150 new trade names appeared in 2004, 160 in 2005, 130 in 2006 and more than 230 in 2007. Most of them are generic drugs and belong to foreign manufacturers.

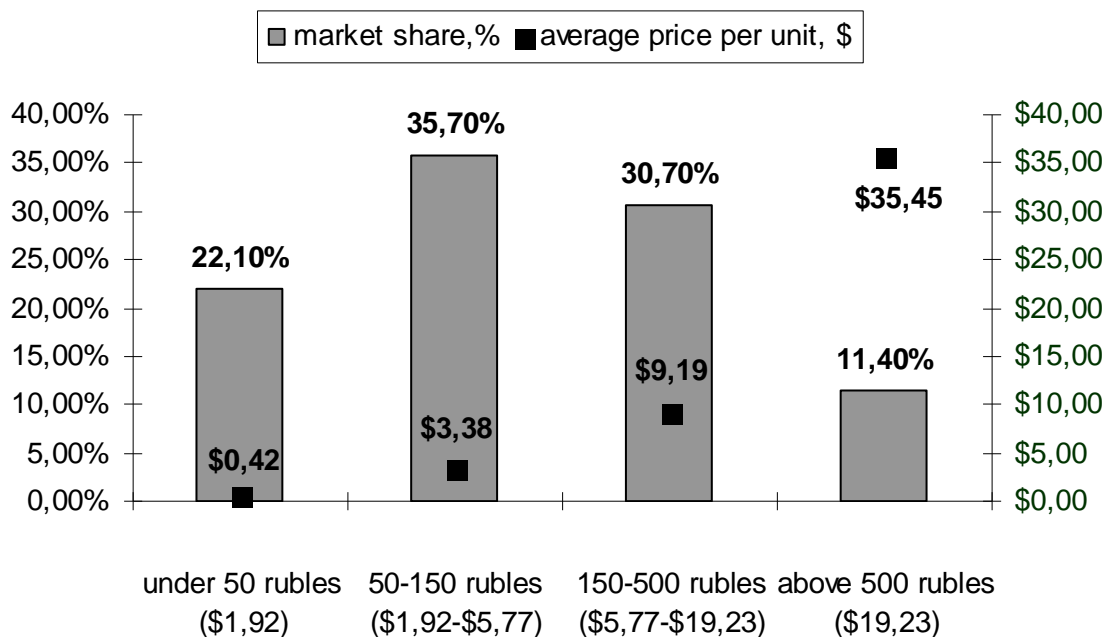
The commercial market structure (Fig.5) shows that drugs at second and third price segments (50-150 and 150-500 rubles per unit) with average unit price \$3.38 and \$9.19 respectively prevail in the market. High share of out-of-pocket spending on drugs

limits the potential market available to new drugs: many Russians have been unable to purchase needed medications.

To prove RLMS surveys conducted in 2004 show that the lack of money is major reason for drugs unavailability: this was the reason given by 59% of Russians who were unable to obtain their prescribed medications (Zasimova, Khorkina, 2007). Another factor that limits Russian pharmaceutical market development is cultural traditions: Russians tend to prefer traditional methods and treatments or be passive in the face of ill.

However experts (DSMgroup, Farmexpert) note that the purchasing power of population was constantly rising before the crisis and more individuals were able to pay for drugs driving the market growth. Significant increase in investment into public health provision seen in 2005-2007 also encouraged drug consumption growth.

Figure 5 Drugs market structure for different price categories, RF, 1st half, 2007.



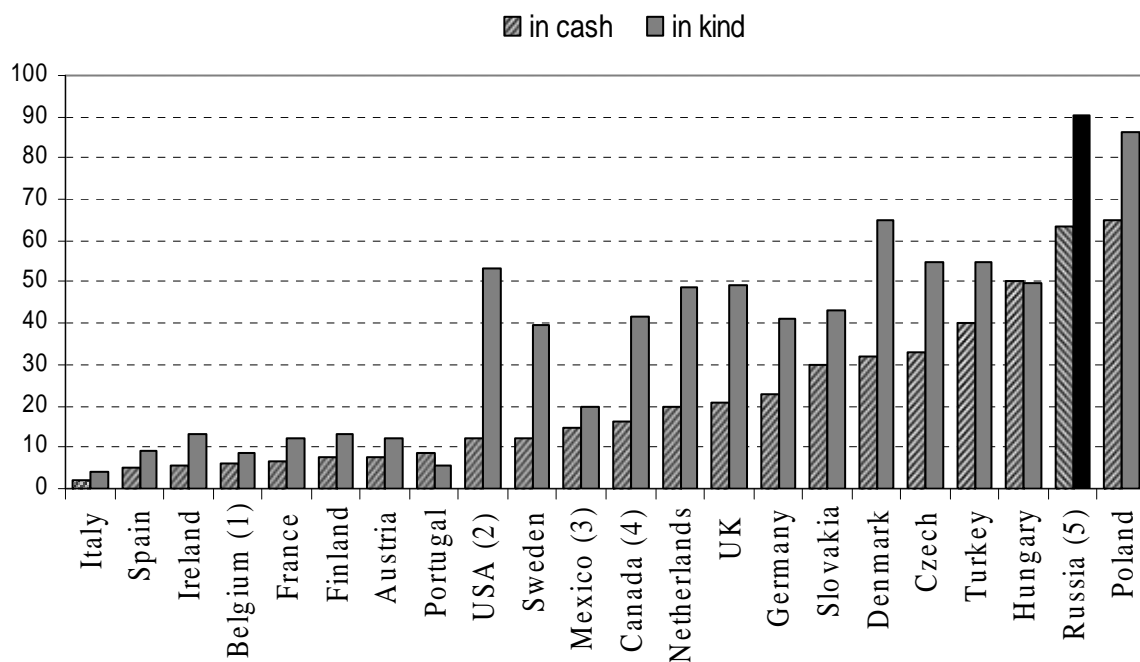
Source: Russian Pharmaceutical Market, 1st half, 2007. DSM Group.

While overall access to prescribed medications in Russia was constantly improving, the quality of drugs purchased by Russians is still low: the share of original drugs is less than 40% in cash and less than 10% in kind (Fig.6). Also much evidence prove that branded generics dominate in the market (Appendix 1). It is often far from clear to what

extent the prices of brands really reflect the costs of their development, production and to what – marketing expenditures. Often producer sets the highest price that the market can bear.

One reason for brands dominance in Russia is that growing purchasing power makes the Russian market extremely lucrative for foreign pharmaceutical companies, many of which have been aggressively advertising.

Figure 6 Market share of generic drugs in Russia and other countries, %, 2004.



Source: (1) EFPIA; (2) IMS health; (4) CGPA; (5) DSM group. Other- EGA data.

Note: (3) EGA 2002data.

Also recent study on non-monetary determinants of demand for drugs has revealed that Russian consumers perform 47% of drug expenditures without consulting a doctor but other sources (mainly advertisement and family members, friends) (Zasimova, Khorkina, 2007) or use their previous experience.

The tradition of self-curing together with little government assistance, absence of drugs insurance and information asymmetry on drugs' quality requires tough regulation and governmental control. The section below gives brief description of registration policy, price control mechanisms and federal reimbursement program (DLO).

3 Pharmaceutical market regulation

3.1 Registration

Registration policy determines general conditions for drugs admission to national market. After the break-up of the Soviet Union and market liberalization Russian registration rules became very liberal despite bureaucratic procedures. As a result the number of drugs registered for sale increased dramatically from 5000 in 1992 to more than 12000 in 1998. Such extreme liberalization of pharmaceutical products made control impossible. Currently the State Register contains more than 18 000 products, many of which have no proven pharmacological value but are widely advertised.

Experts from both Russian and foreign pharmaceutical companies indicate that current registration rules do not hamper new drugs launches⁴. However while stimulating overall drugs launches the system sets no priorities and no criteria for drugs selection. As a result Russian market is overfull of similar drugs. For example there are 117 analogues for Diclofenac Na, 64 – for aspirin etc. In these circumstances pharmaceutical companies prefer to compete by price not by quality, use cheaper substances and increase promotion budgets instead of R&D expenditures.

Unlike Russia European countries do not face these problems because together with liberal system of registration they have two deterrents: quality control mechanisms and compensation systems. While in most European countries compensation system include all citizens, theirs market structures depend on positive lists that are formed on principles of therapeutic and economic efficiency. In Russia liberal drugs admission without pharmaco-economic assessment brings excess launches of brands with no proven efficiency.

3.2 Compensation policy

Experts often name poor access to pharmaceuticals through public health provision as major obstacle to new drugs appearance in Russian market. Last few years, as the economy was strengthening, Russia was investing in improving access and quality of healthcare by introducing federal reimbursement program – DLO. It was aimed at drugs accessibility and affordability growth as well as at smoothing distortions in drug

⁴ According to results of research project “ Long-term forecast for Russian R&D development” held by Interdepartmental Analytical Center, Moscow 2008-2009

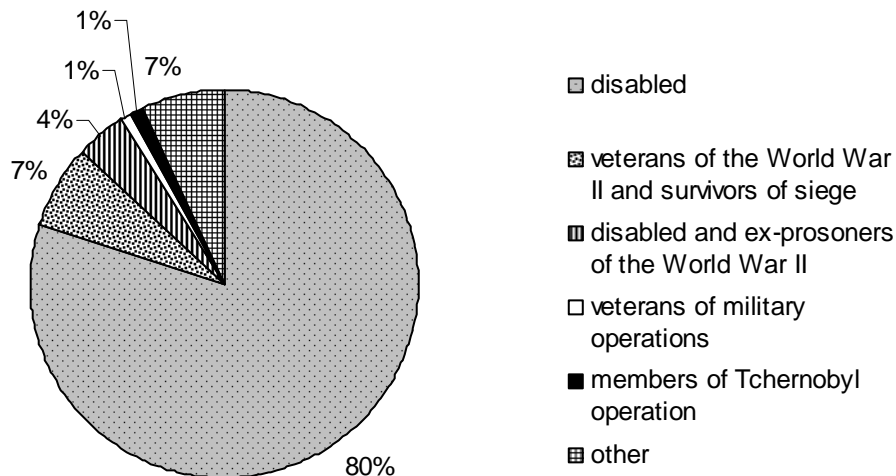
consumption between urban and rural citizens. Besides, the DLO put real money behind spending commitments which had previously been largely unfunded.

Analysts (Pharmexpert, DSM Group) argued that DLO was responsible for 15-20% of Russia's pharmaceutical market growth.

To compare Russian reimbursement system with those prevailing in Europe one should know, that health care systems in Europe are largely based on the principles of health as a human right, on equitable access to health and health services, quality of health care, on solidarity, etc. As a rule, patients have very little insight into the actual cost of providing them with health services. This is particularly the case where there is a system of collective financing; the patient is rarely confronted with the cost of whatever commodity or service he or she has received, and is inclined to believe that prices and payments are not his concern (Mossialos et al., 2004).

In contrast to most European countries only special categories of population in Russia (mainly disabled) are eligible for reimbursement programs (fig.7).

Figure 7 Participants of Federal Reimbursement Program (DLO), 2006.



The structure of DLO-participants shows that the program is focused on most vulnerable categories of population, mainly with chronic diseases while other members of the society (including children) are out of compensation system.

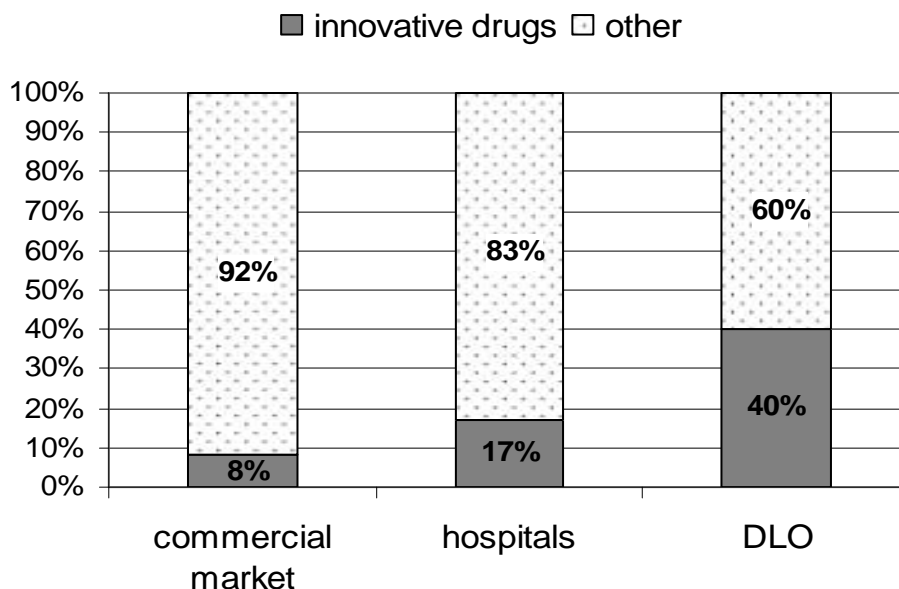
The DLO program was initiated in 2005 as part of a wider reform to replace various in-kind entitlements with monetary transfers- so called monetization of in-kind benefits. With its 50.8 billion rubles (about \$2 billion) first-year budget, the DLO immediately raised the international profile of Russian pharmaceutical sector.

The list of subsidized drugs was determined by the federal authority, with 70 per cent of listed drugs intended to come from domestic producers. (In reality, the domestic share remained about 9 per cent in 2006).

According to DSMgroup higher-end drugs - for cardiovascular disease, diabetes, cancer etc dominate in the DLO segment, the implication being that the DLO has succeeded in bringing costly drugs to people who would not otherwise be able to afford them. The DLO therefore encouraged the take-up of more expensive drugs than were normally purchased in the commercial market.

Experts often point that the share of innovative drugs in the DLO list is much higher than on commercial market and hospital segment. (fig.8).

Figure 8 Share of innovative and other drugs in Russia, %, 2006.



Source: Krivoshapkina, 2007.

Unfortunately soon after DLO started serious problems became evident. These included funding miscalculations (medicines prescribed in 2006 exceeded that year's

budget by two-and-a-half times, reimbursements failed to cover supplier costs, shortages ensued) and mismanagement.

Main policy efforts therefore were directed towards budget restrictions: cutting drugs from the approved list and price cuts for remaining drugs. However in the second part of 2006 the DLO accrued a debt of 40 billion rubles. As a result of this debt the commercial players of the DLO Program decreased their participation in it in 2007.

It is to note, that before the reform there were numerous categories of beneficiaries who had the right to get free drugs package (according to the positive list) with zero, 50% or 70% co-payment. The categorical principal of benefits was inherited from Soviet safety net, and led to targeting problems that DLO was not to solve. In 2005 the DLO program offered the eligible an alternative (a monthly cash benefit of 350-450 rubles) to a free package of medicines defined in the "Provision of Supplementary Medicines" program list. There were 14 million of beneficiaries (about 10% of population) at the beginning of the Program mainly disabled together with some other deserving social groups. While overall number of participants had fallen from 10% in 2005 to nearly 5% in 2006 the share of DLO-leaving participants differs across the regions (Appendix 2).

Hence, by January 2006, the number of DLO beneficiaries had dropped nearly by half. Some analysts believed that major factor contributing to this drop was high transaction costs of getting the prescription and then the medicine (in terms of waiting time). Other studies (Zasimova, 2008) revealed a strong impact of monetary factors (average personal income or average salary) affecting participants behavior. Using regional data on DLO participation in 2005 - 2006 and data on patients' visits to doctors we proved that physical access to medical services had no influence on decision to leave the program in 2006 controlling for the state of health characteristics.

As DLO participants received the right to choose between free drugs package and monthly cash benefits, participants in "poor" regions were more likely to take money instead of free medications. They did not consider drugs as essential goods, the result being underconsumption of drugs. The DLO therefore was mainly focused on relatively "rich" eligible participants and thus brought further distortions in regional drugs consumption.

3.3 Price regulation

Prices for medicine in Russia vary significantly across regions. To illustrate the figure 9 presents data on average price of a drug pack in 41 Russian Regions. As it can be seen from the graph regional prices in Moscow are more than three times higher than in Kemerov region.

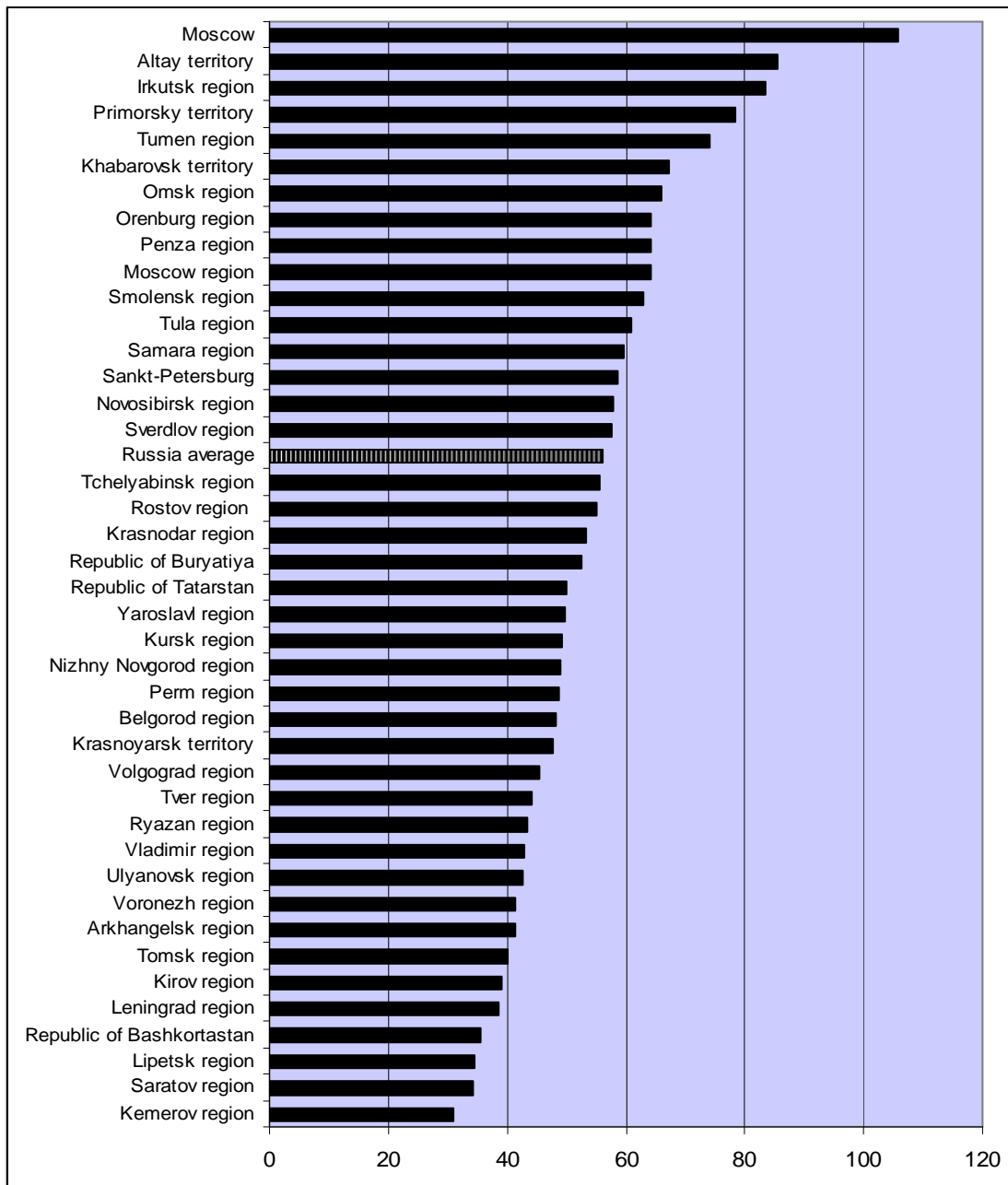
To some extent the variation is explained by difference in transportation costs, by consumer habits and also by regional price policies.

Drugs prices in Russia are regulated at federal and regional levels. At the federal level the Ministry of Health and Social Development registers manufacturers' products and prices and sets the mark-up limitations, intended to hold down retail prices of pharmaceuticals. These limitations specify the maximum percentage of mark-up for wholesalers and retailers.

According to federal legislation, the maximum mark-up over the manufacturer's price was 25%, and retail prices could not exceed wholesale prices by more than 30% for drugs included in the list of essential drugs (the limit was slightly higher for other drugs). In practice, the mark-ups within these limits are the responsibility of regional authorities and therefore vary from region to region (Tragakis E. Lessof S. 2003).

As a result each of 87 regions has its own cost-plus formula for manufacturers, wholesalers and retail drugstores. Maximum percentage mark-up may depend on type of producer (external or internal), drug category, drug price and even buyer (public or private hospitals).

Until recently there was no regulation of the entry drug price (the first price of the wholesaler did not need to be disclosed), resulting in huge profit margins. In 2000 the government introduced the registration of import prices, which are also used to regulate prices.

Figure 9 Average price of drug pack in Russian regions in 2006 (rubles).

Source: RMBC retail drugstores audit.

In 2009 the price regulation measures were changing towards tough control on wholesales' and retailer's mark-ups. Despite this pharmaceutical prices in Russia were among the highest in Europe.

To break the situation two key ministries have prepared special measures. The Ministry for Health and Social Development is trying to pass new law on pharmaceuticals. According to the law the federal authority should become the only

responsible for price regulation policy and mark-up limitations. The Ministry for Industry and Trade has developed a special program (called Pharma 2020) aimed at stimulating generic drugs launches on Russian territory. This should not only support local producers but help the government control drug prices.

4 Empirical analysis of regional pharmaceutical market structures

Most previous studies as shown above (see section 1) are mainly focused on policy impact on company decision about new drugs development and launches and thus deal with the supply side. However our main goal was to get evidence from the demand side. This is partly because there is the lack of information from pharmaceutical companies and mainly because local companies are rarely engaged in development of new drugs, let alone innovative drugs. Hence we intended to study the effect of reimbursement policy and price regulation on drugs market structure, using data from regional pharmacy audit.

The data used in the study is from different sources. The 2005-2006 years data on regional economic and health indicators was taken partly from the Federal State Statistics Service -Rosstat (population, personal income, average regional salary etc.) and partly from Russian Ministry for Health and Social Development (DLO-related information). Regional market structure was evaluated for 34 Russian regions on the basis of TOP 100 drugs information which is published monthly by DSMgroup (www.dsm.ru). In order to eliminate seasonal effect the DSM group monthly information was aggregated to get the annual average data. The information about regional pricing policy was taken from regional legislation acts.

In contrast to many other countries, Russian regions differ dramatically with respect to living standards and personal income. Besides, the regulation of Russian pharmaceutical sector is twofold: responsibilities are divided between the federal and regional levels (see section 3). Hence drugs regulating mechanisms in Russian regions also differ in some aspects. That's why we decided to study to what extend regional pharmaceutical market structure reflects regional socio-economic features and to what extend it depends on special policy measures.

Different indicators can be used to characterize regional market structure in terms of price segments, morbidity structure etc. This paper focuses on ability to buy new innovative drugs. Hence, the best indicator would be the share of innovative drugs in the market. However we failed to get this information and had to use other indicators. We decided to take separately three dependent variables and make three regressions in order to understand how public policy affects the market structure:

(Y1) The share of new drugs in TOP100 drugs sold in 2006

(Y2) The share of branded drugs in TOP100 drugs sold in 2006

(Y3) The share of imported drugs in TOP100 drugs sold in 2006

The share of new drugs⁵ reflects consumers' ability to purchase new drugs that are usually more expensive compared to other drugs. It may also correspond to the level of "openness" to new medical treatment and local policy efforts to promote the use of new drugs.

Drugs were classified as "branded" if there were patents for drugs brand names (no matter original drugs or generics).

Drugs were classified as "imported" if they were not produced by domestic company.

It is to note, that the percentage of new drugs as well as branded and imported varies significantly across the regions (Appendix 1). The share of new drugs in the TOP100 list forms 11 - 26% of most popular drugs in commercial segment. The share of branded drugs shows even larger fluctuation from 64 to 93%. The percent of imported drugs varies from 57 to 84%.

In order to study the nature of this differentiation the following indicators defining regional development were taken:

(X1) The share of rural population

We expected the share of rural population to have negative effect on new drugs appearance because of patients' conservatism and lower distributors' activity in rural areas. The shares of branded and imported drugs were also expected to depend negatively on the share of rural population.

(X2) Average personal income

Average personal income was corrected for regional subsistence levels to eliminate distortions in local price levels and purchasing power of the Russian ruble in different regions⁶. We understand the multicollinearity problem (average personal income depends on the share of rural population), but we tried however to distinguish the

⁵ Drugs, that appeared in the market within last 5 years. We classified drugs as "new" if they were first registered in the State Register after the year 2001 because the data from pharmacy audit was collected in 2006.

⁶ In some regressions we used average salary instead of average income but the results were almost the same.

effects of these two factors by (1) taking logarithm of average income and (2) using WLS regressions applying Berkson's method for aggregated data⁷.

As new drugs are usually more expensive than old due to R&D and/or marketing costs we expected to have positive correlation between the share of new drugs and regional personal income. The same with branded drugs. As domestic drugs are usually less expensive than imported we supposed that consumers in regions with relatively low average personal income would prefer domestic drugs.

To explain the difference in regional market structure by difference in regional price regulation mechanisms the following dummy variable was created:

(X3) strong price regulation

To create variable (X3) we studied regional legislation in order to find out how maximum percentage margin for wholesalers and drugstores is fixed. The dummy is equal to 1 if retail prices did not exceed wholesale prices by more than 30% or if the maximum retail margin was set subject to drug price⁸. In other cases we defined price regulation policies as "weak" with (X3) equal to zero.

We supposed that regions with lower expected prices would experience less new drugs, less branded and less imported drugs controlling for average income and share of rural population.

Unfortunately we had Top 100 drugs rating only for 34 regions out of 87. However the selected regions were from different federal areas and therefore could be viewed as representative at national level.

As DLO program was more oriented towards innovative drugs we decided to evaluate its impact on regional market structure by introducing the following variable:

(X4) percentage of DLO participants receiving free drugs.

The percentage of eligible population within DLO varied across the regions from nearly 10% in Moscow to 3,6% in Saratov region. The share of those, who applied for DLO in 2006 (instead of receiving monetary benefit) also varied. We supposed that percentage of DLO participants receiving free drugs package may have a positive effect on the

⁷ For more information about Berkson's method see, for example Gouriéroux Ch. (2000).

⁸ Only five regions introduced differentiating rates. Usually higher mark-ups were set for cheaper drugs to stimulate local drug stores sell both cheap and expensive medications.

share of new drugs and negative effect on the share of branded drugs. This supposition is based on official statements that the key criteria for selection drugs for the DLO list are efficacy, safety and price. Also as only 9% of DLO drugs are domestic we expected to see positive correlation between percentage of DLO participants and the share of imported drugs.

While analyzing regressions (appendix 6) we revealed that the share of new drugs in TOP100 drugs (Y1) depends negatively on the share of rural population (X1) and doesn't depend on other factors. The shares of branded drugs (Y2) and imported drugs (Y3) in TOP100 drugs depend negatively on the share of rural population (X1) and average personal income (X2).

It is not surprising that difference in regional pharmaceutical market structure could be explained by difference in share of rural and urban population. The significance of income-related factors in last two regressions is also obvious. The fact that new drugs consumption doesn't depend on average personal income seems surprising and needs further analysis.

Unfortunately we haven't revealed any effect of drug policy measures on regional market structure: neither regional price regulation characteristics nor the percentage of DLO participants have impact on new/branded/domestic drugs consumption. As for the price regulation mechanisms one explanation could be that we analyzed the legislation acts that introduced maximum mark-ups. However we didn't know the real mark-ups fixed for different types of drugs that could differ from the maximum possible. The other reason is that the mark-ups apply to the first producer/importer, but "...in practice there are various mechanisms by which mark-ups can be avoided for distributors further down the chain, resulting in real mark-ups varying from 120 to 200%". (Tragakos E. Lessof S. 2003), making officially fixed caps useless.

The insignificance of DLO factor could be explained by relatively small number of participants of the program (taking into account that about half of the eligible prefer cash benefits instead of free drugs package) and by relatively small variation in their number: most regions showed about 6% of participants involved in the program.

5 Conclusion

Considerable evidence suggests that Russian pharmaceutical market has inefficient structure in terms of new and out-of-date drugs as well as imported and domestic drugs. The federal and many regional governments are taking steps to improve the situation: they introduce drugs control policies, compile lists of essential drugs to promote access, especially for vulnerable groups, increase public spending on drugs. However the study proves that main policy instruments (registration policy, price contains and DLO program) don't increase the affordability of new innovative drugs.

The study shows that no matter how the maximum mark-up is fixed in a region it has no influence on pharmaceutical market structure. Hence changing price control legislation in order to introduce unique mark-ups would hardly be successful because main problems with price regulation lie in the field of enforcement.

The DLO program needs rethinking not only with respect to better management but also with respect to its main principles: as mentioned above the DLO-participants are mainly disabled and therefore belong to the low-income segment. Hence any alternative (cash benefits or free drugs package) would encourage most vulnerable participants to prefer cash benefits instead of getting free drugs.

Many experts having studied European models of price regulation suggest that according to the evidence-based medicine concept Russia should develop the pharmaco-economic evaluation of pharmaceuticals and fix price contains with respect to such evaluation. This means that in order to promote innovations the mark-ups for new efficient drugs should be higher than for less efficient ones. However in a market with more than 60 percent of out-of-pocket expenditures and 18000 registered drugs higher mark-ups for efficient drugs may encourage people to buy less efficient ones, just because they are cheaper. Moving towards evidence-based medicine is important but in case of drugs it will bring positive results only if the percentage of insured (within public or private systems) increases and the share of out-of-pocket expenditures goes down.

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Appendices

Appendix 1. Pharmaceutical market structure in Russian regions, 2006

Region	share of new drugs in TOP100, %	share of brands in TOP100, %	share of imported drugs in TOP100, %
Amur region	11	64	57
Belgorod region	14	78	71
Bryansk region	24	83	74
Chelyabinsk region	25	87	71
Chita region	17	87	78
Irkutsk region	21	83	76
Khabarovsk territory	19	89	78
Kirov region	21	82	76
Krasnodar territory	19	84	72
Krasnoyarsk territory	16	85	77
Kursk region	18	76	66
Moscow	24	93	84
Moscow region	20	87	76
Nizhny Novgorod region	20	80	70
Novosibirsk region	26	90	81
Orenburg region	16	79	66
Penza region	17	80	69
Perm region	23	88	76
Primorskiy territory	27	87	79
Republic of Bashkortostan	20	81	72
Republic of Tatarstan	19	83	74
Republic of Udmurtia	22	82	70
Rostov region	21	89	78
Ryazan region	16	83	71
Samara region	19	82	72
Saratov region	18	83	70
Smolensk region	17	83	76
Sverdlov region	24	89	82
Tver region	17	79	67
Ulyanovsk region	17	79	67
Vladimir region	20	84	75
Volgograd region	21	87	74
Voronezh region	14	81	70
Yaroslavl region	23	84	74
Source: DSM group pharmaceutical audit			

Appendix 2. Participation in DLO program, 2006

Region	Share of population eligible for DLO, % of total population	Share of DLO participants who applied and received free drugs, % of total population	share of DLO participants who preferred monetary benefits instead of free drugs, % of all eligible
Amur region	6,86	4,93	22,85
Belgorod region	8,89	6,26	57,50
Bryansk region	6,61	4,86	46,30
Vladimir region	5,03	3,35	56,65
Volgograd region	4,43	3,40	46,90
Voronezh region	5,65	3,93	58,37
Irkutsk region	6,15	4,25	29,80
Kirov region	5,52	3,89	47,81
Krasnodar territory	5,46	3,78	42,33
Krasnoyarsk territory	6,49	5,20	23,64
Kursk region	5,87	4,35	52,06
Moscow	9,91	7,45	16,49
Moscow region	6,26	5,72	33,03
Nizhny Novgorod region	5,56	4,10	56,02
Novosibirsk region	5,46	4,09	33,78
Orenburg region	5,79	4,09	51,79
Penza region	5,65	4,42	41,12
Perm region	6,23	4,62	34,60
Primorskiy territory	5,02	3,45	36,59
Republic of Bashkortostan	4,48	3,35	55,22
Republic of Tatarstan	5,05	3,22	45,43
Rostov region	5,23	3,39	53,34
Ryazan region	6,98	6,51	51,07
Samara region	5,56	4,11	38,53
Saratov region	3,61	2,27	51,33
Sverdlov region	6,46	5,09	29,18
Smolensk region	5,54	4,03	56,70
Tver region	5,86	3,66	44,18
Republic of Udmurtia	3,90	2,93	52,75
Ulyanovsk region	5,66	4,05	51,22
Khabarovsk territory	5,51	4,18	23,35
Chelyabinsk region	4,39	3,15	40,90
Chita region	5,30	3,70	41,12
Yaroslavl region	5,94	5,69	48,63

Source: RF Ministry for Health and Social Development

Appendix 3. Price regulation in Russian Regions, 2006

Region	margins depend on price criterion (1=yes, 0=no)*	maximum retail margin on drugs, % of retail price *	strong price regulation**
Amur region	0	50	0
Belgorod region	1	35	1
Bryansk region	1	30	1
Vladimir region	0	40	0
Volgograd region	0	35	0
Voronezh region	0	50	0
Irkutsk region	1	45	1
Kirov region	0	50	0
Krasnodar territory	0	30	1
Krasnoyarsk territory	0	35	0
Kursk region	0	30	1
Moscow	0	35	0
Moscow region	0	35	0
Nizhny Novgorod region	0	30	1
Novosibirsk region	0	50	0
Orenburg region	0	40	0
Penza region	0	50	0
Perm region	0	40	0
Primorskiy territory	0	70	0
Republic of Bashkortostan	0	40	0
Republic of Tatarstan	0	45	0
Rostov region	1	45	1
Ryazan region	0	45	0
Samara region	0	30	1
Saratov region	0	20	1
Sverdlov region	0	60	0
Smolensk region	0	35	0
Tver region	0	40	0
Republic of Udmurtia	0	55	0
Ulyanovsk region	0	40	0
Khabarovsk territory	1	70	1
Chelyabinsk region	0	40	0
Chita region	0	50	0
Yaroslavl region	0	40	0
* - according to regional legislation acts			
** - experts' judgments			

Appendix 4. Regional disparity in economic situation

Region	share of rural population,%*	average personal income corrected for regional subsistence level	average salary, rubles
Amur region	34,2	170	11069,0
Belgorod region	34,8	224	8428,1
Bryansk region	31,6	211	6385,7
Chelyabinsk region	18,2	255	9364,9
Chita region	36,1	192	10039,4
Irkutsk region	20,7	242	11069,1
Khabarovsk territory	19,4	219	12512,6
Kirov region	28,2	169	7187,7
Krasnodar territory	46,5	200	8065,2
Krasnoyarsk territory	24,3	238	12454,0
Kursk region	38,8	205	7150,6
Moscow	0	597	18698,6
Moscow region	20,7	224	11752,4
Nizhny Novgorod region	21,8	223	8147,9
Novosibirsk region	24,9	214	9120,5
Orenburg region	42,2	204	7752,8
Penza region	34,9	172	6492,3
Perm region	24,7	278	9584,7
Primorskiy territory	21,7	184	10887,3
Republic of Bashkortostan	36,0	273	8474,8
Republic of Tatarstan	26,2	287	8839,1
Republic of Udmurtia	30,3	182	7881,6
Rostov region	32,4	243	7485,3
Ryazan region	31,1	187	7763,1
Samara region	19,4	297	9630,5
Saratov region	26,4	187	7170,8
Smolensk region	29,2	216	7827,6
Sverdlov region	12,1	304	10942,5
Tver region	26,9	203	8115,1
Ulyanovsk region	26,8	180	6733,9
Vladimir region	20,3	158	7515,5
Volgograd region	24,8	236	7679,4
Voronezh region	38,1	216	6666,7
Yaroslavl region	19,1	232	9012,8
* according to population census, 2002			
source: Rosstat			

Appendix 5. TOP-20* Drug manufacturers by pharmacy sales value on the
commercial market in Russia in 2006-2007

RATING	MANUFACTURER	SALES VALUE, \$ MLN 2006	SALES VALUE, \$ MLN 2006
1	SANOFI-AVENTIS	208	241
2	PHARMSTANDARD	149	226
3	BERLIN-CHEME/A.MENARINI	168	205
4	NYCOMED	117	165
5	GEDEON RICHTER	133	164
6	NOVARTIS	118	160
7	PHIZER	130	151
8	LEK D.D	144	143
9	SERVIER	121	140
10	BAYER SCHERING PHARMA AG	98	121
11	KRKA	97	117
12	SOLVAY PHARMACEUTICALS BV	80	108
13	GLAXOSMITHKLINE	84	104
14	BOEHRINGER INGELHEIM	56	88
15	“OTECHESTVENNYE LEKARSTVA”	58	80
16	DR.REDDY’S LABORATORY LTD	64	77
17	F.HOFFMANN LA ROCHE LTD	68	76
18	EGLS	63	74
19	ASTELLAS PHARMA INC	59	74
20	SCHERING-PLOUGH	63	73

*The share of TOP 20 ready-to-use drug manufacturers by import volume in Russia in 2007 amounted to 56%.

Source: Russian Pharmaceutical Market 2007, DSM group

Appendix 6. The results of empirical analysis

Table 1 A Cross-Regional Regression for New Drugs

Dependent Variable: (Y1) - The share of new drugs in TOP100 drugs sold in 2006				
Included observations: 34				
Weighting series: WEIGHTS				
Variables	Coefficient	Std. Error	t-Statistic	Prob.
Constant	-0,04322	0,002486	-17,3876	7,02E-17
X1 RURAL	-17,1001	6,002278	-2,84893	0,007987
X2 INCOME	-0,68463	0,614739	-1,1137	0,274555
X3 PRICE	-0,54203	1,228194	-0,44133	0,66225
X4 DLO	-35,5257	55,80382	-0,63662	0,529367

Table 2 A Cross-Regional Regression for Branded Drugs

Dependent Variable: (Y2) The share of branded drugs in TOP100 drugs sold in 2006				
Included observations: 34				
Weighting series: WEIGHTS				
Variables	Coefficient	Std. Error	t-Statistic	Prob.
Constant	0,036443	0,005037	7,235138	5,76E-08
X1 RURAL	-33,196	10,7461	-3,08912	0,004397
X2 INCOME	5,714349	1,180143	4,842082	3,93E-05
X3 PRICE	-0,56444	2,339853	-0,24123	0,811076
X4 DLO	-102,389	108,2131	-0,94618	0,351875

Table 3 A Cross-Regional Regression for Imported Drugs

Dependent Variable: (Y3) The share of imported drugs in TOP100 drugs sold in 2006				
Included observations: 34				
Weighting series: WEIGHTS				
Variables	Coefficient	Std. Error	t-Statistic	Prob.
Constant	0,026664	0,004528	5,88893	2,16E-06
X1 RURAL	-17,1024	7,22143	-2,36828	0,024751
X2 INCOME	2,788102	0,77458	3,599503	0,001172
X3 PRICE	0,058212	1,570028	0,037077	0,970678
X4 DLO	-36,182	70,87005	-0,51054	0,613537

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