Testing Times in Russia: how to facilitate access to essential drugs and get more value out of pharmaceutical expenditures?[1]

This note assesses how the current economic downturn is affecting drug prices and the affordability of medicines, particularly among vulnerable population groups. A related question concerns possible measures that could be adopted in Russia to facilitate access to essential drugs and ensure rational drug use. While the note focuses on special issues of affordability and access, it also suggests the need for an assessment of the regulatory role of government in different areas of the pharmaceutical market in Russia in order to provide policy makers, insurance and health care institutions with a critical analysis of its impact on key objectives such as efficiency, quality, equity and cost control.

Introduction

Pharmaceutical products are key components in the provision of medical care: from diagnosis and treatments to prevention of illness and disease. Since the 1920's, the introduction and wide use of new drugs along with improved living conditions have contributed to accelerating the decline in death rates and improving overall social welfare. As a result of the growing demand for pharmaceuticals, global drug sales have almost doubled since 1997, reaching about US$902.4 billion in 2009.

Out-of-pocket payments account for most of drug spending in Russia. In large measure, this is due to the relatively low level of public health spending in the country (about 3.6% of GDP in 2008) that underlines the significant gap between the constitutional commitment to a range of medical care services and the actual funding to pay for them. Indeed, while drugs are supposed to be provided to hospital patients free of charge, it is estimated that around 80% of inpatients still have to pay part of the cost of their medicines, and most outpatients must purchase them from pharmacies. The outpatient drug program under mandatory health insurance covers only around 16 millon people, with more than half of them opting to receive cash rather than in-kind benefits under the 2005 "monetization" of prescription drug benefits. Those that continue with the in-kind benefit seem to be those with the greatest need for drugs. Although federal and regional governments have lists of essential drugs, even these are often paid by the patients out-of-pocket due to financial constraints of public providers of care. This situation is further

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aggravated in Russia by the ineffective enforcement of controls on wholesale and retail mark-ups for medicines.

Household expenditure on drugs account for about 30% of total health expenditures in Russia as compared to 12% in OECD countries. This reflects the negative correlation that is commonly observed elsewhere between high out-of-pocket pharmaceutical expenditures and low per capita public health spending.

Recent evolution of drug prices in Russia

Drug prices in Russia increased substantially during the ongoing economic crisis, partly reflecting the substantial depreciation of the ruble since the onset of the crisis in September 2008. While the official Consumer Price Index (CPI) has increased by 15% between March 2008 and March 2009, retail drug prices have increased by 29%. As shown in Figure 1, most of the relative increase in drug prices began after the start of the depreciation of the ruble. According to a recent report[2], Russia has seen a growth in the global price per standard unit index (defined as total reported sales divided by total volume for each country for each quarter) in the first quarter of 2009 as compared to the first quarter in 2008. This is higher than in other countries such as Romania and Ukraine that were also hit hard by the crisis[3]. Early indications are that prices will continue to rise in the private sector.

Sources: Rosstat; www.gks.ru, DSM group: report www.dsm.ru[4].

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[2] IMS Health, "Indicators for Tracking the Effect of the Economic Crisis on Pharmaceutical Consumption, Expenditures and Unit Prices," report prepared for the WHO, May 20, 2009.

[3] Global Price per Standard Unit Index", 1th quarter 2009/1th quarter 2008. global price per standard unit indexes are: Russia 1.29,Romania 1.20, Ukraine 1.19.

[4] Rosstat monitors prices of 20 selected drugs. DSM group publishes Laspeyres retail price index for all drugs on the market, with weights taken proportional to sales volume in 2007.

Drug prices not only increased substantially as a whole, but also showed substantial price variability. Drugs can generally be prescribed and purchased as brand-name medications or as generic equivalents. Prices between these two types of drugs can vary significantly. Generic drugs are in general less expensive than brand-name drugs but are usually just as safe and efficacious. To assess recent drug price variability in Russia, the changes in median, minimum and maximum distributor prices of equivalent drugs in St. Petersburg[5] were examined. The assessment showed that overall median drug prices increased by about 40% between March 2008 and March 2009, but the maximum prices, usually for brand name drugs, increased by 105% on average. On the opposite end of the spectrum, the minimum prices, usually for generic drugs, increased by 14%.

High overall variability is accompanied by higher variability in prices for the same class of drugs in the Russian market; moreover, drug prices in Russia are much higher than in the international market. While in March 2008, the average ratio of maximum to minimum distributor prices for the same drug was about 5 times, by March 2009, the ratio had increased almost 10 times[6]. Comparison of median distributor prices in St. Petersburg with the international reference prices for 52 drugs[7] shows that prices in Russia are on average 3 to 4 times higher than international reference prices.

How does the increase in drug prices affect Russian households? Rosstat data for 2006 indicate that about 95 percent of survey respondents who purchased medical drugs in the last three months paid out of pocket. The increase in drug prices can therefore have a significant impact on the budgets of families with chronically ill members who require a daily drug intake. According to data from the 2005 Russian Longitudinal Measurement Survey (RLMS), over 75% of households had a member with one or more chronic illnesses[8], with two illnesses reported on average per household member. The average budget share of expenditures on drugs for the poorest 10% of the households that had to purchase drugs regularly was about 9%. As a result of the recent increase in drug price, the poor, *on average,* may have lost on average more than 1% of their total household expenditure. ***However, as discussed below, this average hides the grim reality that this amount could be significantly higher for many households as actual drug spending greatly depends on the particular illness to be treated and which drugs are prescribed.***

[5] Pre-selected list of 80 essential drugs from the publication of *PharmIndex* magazine, on March2008 and March 2009. For each of the 80 drugs, the minimum, median and maximum price of a daily dose of the drug were documented for this note.

[6] For the 5 cases the maximum price was more than 50 times higher than the minimum published price: Ciprofloxacin -56 times, Acetylsalicylic acid - 58 times, Loperamide -67 times, Omeprazole - 144 times, Diclofenac -119 times. These medicines typically have very high brand premiums.

[7] International Drug Price Indicator Guide, http://erc.msh.org

[8] The questions were asked about heart, lung, liver, kidney, gastrointestinal, spinal and other chronic illnesses

Table 1 provides a conservative estimate of the potential monthly expenditures for treating several common chronic illnesses, for a typical household consisting of two pensioners, each receiving a typical subsistence minimum pension of 4000 rubles (this estimate is conservative as the real retail mark-ups are estimated to be much higher than the one used for this note). The last two columns show the median price increases for the recommended drug treatment, and the additional expenses that will have to be incurred by the household due to the price increases for several drugs. For example, the median price of "ademetionine", one of the drugs commonly used for the treatment of liver cirrhosis, increased by almost 2.5 times. This has resulted in almost 4,800 rubles of ***additional expenditure*** for the monthly treatment of liver cirrhosis, relative to what Russians were to have paid if the price of "ademetionine" had increased at the same 15% rate as the CPI. In other words, the cost of treatment of liver cirrhosis has risen from less than 50% to more than 110% of the hypothetical household budget.

In this context, recent evidence indicates that drug affordability has likely fallen. Contributing were an increase in drug prices and a nine-year high unemployment rate of 10.2%, as out-of-pocket drug purchases have already posted three consecutive quarters of declines since 2008. This may imply that many Russian are now unable to purchase needed medications with negative short and medium term effects for the patients and society at large. In the absence of coverage for outpatient drugs under the Medical Program of State Guarantees, price increases might simply deter Russians in need of medicines to access drugs required to control chronic diseases at an early stage (e.g., hypertensive who have to take medications on a daily basis) and may require more expensive medical care later (e.g., unnecessary hospital admissions due to strokes). ***It is obvious, therefore, that poor or average households in Russia stand to benefit greatly not only in terms of reducing their current cost of drugs but also due to fewer hospitalizations and higher productivity if an outpatient drug benefit under the Medical Program of State Guarantees were to be introduced.***

Table 1. Estimated expenditure on drugs using median distributor prices

Condition	Suggested Treatment	Sugges-ted daily dose	Average monthly expenditure, rubles	Share of subsistence minimum budget for two pensioners, %	Median Price 2009/ Median Price 2008	Effect of price increase above the CPI increase, rubles
Liver Cirrhosis	Ademetionine	1200 mg	8874	111	2,48	+4757
Stroke prevention	Clopidogrel	75 mg	3478	43	2,51	+1882
Stroke prevention	Aspirin	100mg	90	1	1,10	-45
Arthritis	Diclofenac	100mg	87	1	2,11	+39
Hypertension	Enalapril	20 mg	186	2	1,40	+33
Diabetes	Insulin soluble	50 ME	1384	17	1,03	-168
Gastric ulcer	Omeprazole	20 mg	143	2	1,53	+36
Prostatitis	Tamsulosin	400 mcg	1595	20	3,06	+996
Prostatitis	Terazosin	10mg	1250	15	1,38	+216
Ischemic heart disease	Trimetazidine	50 mg	238	3	0,97	-44

Source: Distributor prices published in "Pharmindex" on March 2009. A retail mark-up of 10% was used to estimate retail prices and calculate average expenditures. According to federal legislation in Russia, the maximum mark-up over the manufacturer's price is 25%, and retail prices should not exceed wholesale prices by more than 30% for essential drugs; the limit is higher for other drugs. *It is estimated that in general actual mark-ups are much higher than the official ones.*

A typical household drug expense or the cost of a subsidized drug program could, however, be substantially lowered, thereby raising affordability. This could happen if drug prescription practices are based on evidence of demonstrated efficacy and safety of equivalent drugs, as well as on the comparison of their cost. For example, the evidence on the demonstrated efficacy and benefits of "clopidogrel", a drug used in Russia for stroke prevention at a cost of 1,481 rubles/month is scant. The alternative would be to use the lower cost and efficacious and safe generic "aspirin" costing only 50 rubles/month as the "best buy" first-line drug for stroke prevention in most patients rather than "clopidogrel". This would result in a major saving of 1,431 rubles per month while ensuring demonstrated benefits of an alternative drug.

The cost-saving value of more rational drug prescription is demonstrated by the experience of different countries.[9] The measures adopted include requirements for patients to pay larger copayments for brand name drugs than for generic drugs under a pharmacy benefit

[9] W.H. Sharank et al, "Patients' Perception of Generic Medications," Health Affairs (March/April 2009): 546-556.

design with at least three tiers of copayments. Also, insurance companies are stimulating greater use of generic drugs by offering generic medications at no cost, sending coupons by mail for generics, and dispensing free generic samples to prescribing physicians. The successful application of these measures in the United States is noteworthy: while generic drugs account for about two-thirds of all prescriptions they only account for 13% of the costs.[10] In a number of European Union (EU) countries, such as Belgium, Portugal, Italy, the United Kingdom, Sweden, Spain, and the Netherlands, as well as in Australia and certain provinces in Canada, cost-effectiveness criteria are used to determine which drugs are eligible for reimbursement.[11]

There are options for the Russian government to consider to improve access to and affordability of drugs in Russia. One ***option*** to explore for dealing with this challenge under current fiscal constraints would be the adoption of an *essential outpatient drugs benefit package* for priority, high-burden diseases, to be provided as part of the Medical Program of State Guarantees. It could include approximately *70-100 different essential medicines* for high-burden chronic diseases, such as cardiovascular diseases, mental disorders, diabetes, chronic respiratory problems, digestive disorders, and frequent infections,[12] selected on the basis of therapeutic efficacy, efficiency, and value for money criteria. A similar approach is currently followed in several countries to optimize drug selection targeting priority diseases. For example, after the National Institute of Health and Clinical Excellence (NICE) assessed for the UK government all cancer drugs (cancer is a disease priority area in the UK) using comparative clinical and cost effectiveness data to evaluate whether a drug should be made available and funded and for what indication/population subgroup, positive NICE recommendations become a legally enforceable patient entitlement. The adoption of this policy has generated good results measured in terms of reduction in variation in drug use, increase in uptake for drugs that were evaluated and approved by NICE, and better drug prices obtained from industry[13].

How much would a package of essential drugs cost? Taking into account that in middle income countries the per capita cost of an essential medicine package that follows the World Health Organization (WHO) Model Essential List[14] may range from US$10 to US$100 per year,

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[10] IMS Health, "IMS Health Reports"; and K. Jaeger, "A Message from Kathleen Jaeger: It Pays to Invest in Generics," *Pharmacy Times*, April 2006.

[11] A. McGuire, M. Drummond, and F. Rutten, "Reimbursement of pharmaceuticals in the European Union", in *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, ed. E. Mossialos, M. Mrazek, and T. Walley (London: Open University Press 2004).

[12] The 2005 World Bank report "Dying Too Young. Addressing Premature Mortality and Ill Health Due to Noncommunicable Diseases and Injuries in the Russian Federation," provides health and economic arguments to concentrate on these diseases.

[13] Personal communication of author with NICE officials on June 9, 2009.

[14] The essential medicines list concept was developed by WHO in 1977 in order to help countries define a list of medicines to treat with efficacy and appropriate safety 90% or most of the diseases (i.e., excluding highly complicated cases at hospitals). The system has been adopted by more than 30 countries.

and that the average number of medicines used for first-line ambulatory care treatment may not be higher than 50-100 medicines, it is possible to assume that the additional outpatient medicine benefit in Russia as discussed above could cost on a per capita basis per year between US$30 and US$60. These amounts would represent about 8-14% of Russia's total per capita health expenditures of US$367 in 2006, or alternately, about one-third of one percent of GDP (i.e. ~ 0.33 % GDP) per year, given the per capita GDP in 2007 of US$9,079.

Funding options. As discussed in a recent World Bank report[15], Russia probably needs to spend over the medium term more on health care above the current level of 3.6 percent of GDP. The major long-term drivers of health care spending – rising incomes, technological change and demographic change – all point to a significant, long-term rise in health care expenditure. It is reasonable to assume that part of this increase could and should be met by public provision of health services that is likely to remain an important pillar of the system, despite the expected growth of private financing and service provision. An increase in public expenditures would help address some long-standing problems in the health system, particularly the need to ensure proper funding for the constitutionally guaranteed free drug provision during hospitalization and the introduction of an outpatient essential drug program**.**

- **First, the proposed essential drug benefit could be funded by an improved allocation of public expenditures.** This requires improving the effectiveness of overall public expenditures, including a shift toward long-term needs of social sectors such as health and away from less productive categories of public expenditures (e.g., untargeted subsidies and transfers, general administration expenditures and unproductive public investments). ***To promote rational drug use for priority, high-burden diseases on an outpatient basis, a tiered co-payment arrangement could be developed to fully reimburse the cost of generic drugs but set high co-payments for brand name drugs to cover the cost differential. This would create a powerful incentive to shift toward higher use of generic equivalents.***

- **Second, increase in taxes on cigarettes is another potential funding option.** This option is consistent with the International Framework Convention against Tobacco that was ratified by the State Duma in April 2008. In Russia there is room to increase the taxes on cigarettes as the average price of a pack of cigarettes is less than US$2 as compared to the prices in other cities that range from US$12.95 in New York to US$16.80 in London.[16] Most of the high cost in these cities is due to taxes (about 70% of the price). A good international

[15] Marquez, P. et al., Public Spending in Russia for Health Care: Issues and Options, (Moscow: The World Bank, 2008).

[16] For a good discussion on this option see Ross, HZ, Shariff, S., Gilmore, A., *Economics of Tobacco Taxation in Russia* (Paris: International Union Against Tuberculosis and Lung Disease, 2008).

example of the use of this option is the recent decision in February 2009 by US President Obama and the US Congress authorizing the renewal and extension of the Children's Health Insurance Program (CHIP) for poor children by using a 62-cent per-pack increase in the federal taxes of cigarettes to fully fund the program.

- **Third option is to increase the excise tax on hard liquor, including beer** as beer is considered a beverage that is not taxed as liquor in Russia. Alternatively, this tax could simply be adjusted for inflation. In the United States, for example, it has been estimated that merely adjusting the excise tax on alcohol would raise US$5 billion annually to help pay for universal health insurance.[17]

- **Fourth, there is the option of taxing high-sugar soft drinks.** This could, along with increases in the taxes of cigarettes and alcohol, simultaneously raise revenue and improve public health by reducing obesity. In the United States, as part of the current debate on how to pay for health reform, it has been estimated that more than US$10 billion annually could be raised by introducing a tax of a penny per ounce.[18]

Some of these taxes, which should also contribute towards curbing risky behaviors, could, in principle, be earmarked to fund the proposed essential drug benefit. But even without earmarking, they would contribute to higher general government revenues, thereby raising general capacity of the government to fund additional health expenditures such as these.

How to Promote Rational Drug Use in Russia? **E**vidence from other countries suggests that adopting an essential drug list does not necessarily lead to rational utilization of drugs. This measure has to be an integral part of revamped essential drug policies and procedures, legislation and management at both the federal and regional levels, covering drug administration and management, drug selection, drug prescribing, drug dispensing, and drug use and monitoring.[19]

Better use of pharmaceuticals depends on clear understanding of (i) why and how drugs should be used, and (ii) getting people to act on it. Therefore, a key element that needs to be emphasized is the need to support the development of related measures at the service delivery level to improve the prescription behavior of physicians and the adherence of patients to the prescribed drug regime.

Drugs are consumer goods with special characteristics that need to be considered when adopting policy measures aimed at cost containment, increasing drug access, or promoting

[17] "*Paying for Health Reform",* The Washington Post, May 19, 2009.

[18] Ibid.

[19] W.H. Campbell, R.E.Johnson, and S.L. Levine, "Managing the Pharmacy Benefit in Prepaid Group Practice," in *Toward a 21st Century Health System, e*d. A.C. Enthoven and L.A. Tollen (San Francisco:Jossey-Bass, 2004).

their appropriate use. The main difference between drugs and other consumer goods is the role played by patients and physicians during an episode of care: as consumers of medicines the patients in most cases do not decide which medicines to buy, nor choose from among different drugs; the physicians as the "learned intermediaries" select and decide which drug be prescribed and consumed by the patient based on technical knowledge without considering the cost of the drugs.

A critical measure that would need to be supported in Russia as part of health system restructuring efforts to complement the introduction of outpatient drug benefits is the development of new methods and approaches to strengthen rational drug prescription processes. These could be in the form of new or revised evidence-based clinical guidelines to treat some diseases, therapeutic pocket guides that offer quick consultation guidance to the doctors on how to treat the most common health problems; and continuing in-service medical education programs. Additionally, there are electronic modules that can be incorporated as part of the development of health information systems that could facilitate on-line consultations by physicians before prescribing. Given the ever growing number of drug therapies, if physicians do not have access to scientific information and do not have enough technical knowledge for making a critical appraisal of new medicines, the prescription process will be vulnerable to marketing techniques by the pharmaceutical industry and decisions will not be taken in terms of the best option for the patient and the health system as a whole.

The incentive framework for physicians also needs to be improved by regulating perverse financial incentives. These include prescribers earning money from the sales of medicines which only encourages over-prescription of medicines. Generic drugs could be promoted by setting up incentives in the form of performance-based payments as is currently done in some Russian regions such as in the Chuvash Republic[20] to reward doctors for achieving programmatic targets, improve health outcomes and lower overall medical spending.

Another important related issue that needs to be addressed in Russia is the widespread perception among patients that generic drugs are cheaper because they are lower quality drugs that are not as efficacious or safe as their equivalent branded name drugs. To address this challenge, as done in other G8 countries, broader efforts by health insurance agencies, policy makers and providers are needed to educate patients about generic medications, help them make informed decisions and influence personal preferences for generic use, which in turn could result in improved adherence to essential medications.[21]

Finally, building upon recent efforts by the Russian Government, it would be important that drug pricing and procurement reforms be developed to support the

[20] Developed as part of the health system restructuring program supported under the World Bank-funded Health Reform Implementation Project over 2004-2008.

[21] W.H. Sharank et al, "Patients' Perception of Generic Medications," Health Affairs (March/April 2009): 546-556..

implementation of demand side priorities as defined by the adoption of an outpatient essential drug list targeting priority, high-burden diseases and related rational drug use measures. Indeed, proper consideration needs to be given to supply side practicalities such as wholesaler/pharmacist mark-ups and differential margins for the establishment of an uniform drug pricing framework; enforcement of price controls; procurement and tendering processes, including possible negotiated arrangements with producers and suppliers to contain drug price inflation; government taxes (e.g., VAT on imported drugs); the competitiveness of the generics market; and the availability of pharmaceuticals in rural regions.

Conclusion

Reforming social programs, including health services, in order to improve the lives of Russian citizens is high on the government's agenda.[22] As argued in this note, incorporation of outpatient drug benefits under a possible new Mandatory Medical Guarantee Program in Russia that would focus on a limited number of essential drugs and cost no more than about a third of 1 percent of GDP per year, would make sense from an efficiency and equity point of view. There is plenty of evidence worldwide to show that timely access to essential medicines yields large overall savings through fewer hospitalization, tips the balance in favor or survival when a person is affected by a chronic disease or prevents the disease altogether, and contributes to higher productivity when the patient is at work.[23] Also, from an ethical and medical point of view, protecting and/or increasing expenditures on medicines are critical to avoid stopping the treatment of conditions such as tuberculosis and HIV/AIDS, and hence to prevent the onset of drug resistance, in some cases untreatable, among patients. While the current economic downturn imposes rigid budgetary constraints, improved access to and better use of pharmaceuticals under public subsidy arrangements should not be delayed as in the medium term it would contribute to improve the health status of the Russian population, reduce the risk of impoverishment of vulnerable population groups, and enhance overall social welfare.

[22] "Interview with Dmitry Medvedev, President of the Russian Federation," Financial Times, March 24, 2008.

[23] "Prescription for change. A survey of pharmaceuticals," The Economist, June 18, 2005.