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**Improving access to
ARV medicines
for people living
with HIV/AIDS
in Russia**



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Improving access to ARV medicines for people living with HIV/AIDS in Russia

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Introduction



The HIV/AIDS pandemic has become a humanitarian, social, and economic crisis with far-reaching consequences for individuals, communities, and entire countries. Almost everywhere, HIV disproportionately affects young people, thereby negatively impacting labor markets and families. Heavily affected countries may face serious social, economic, and security crises unless decisive steps are taken now.

According to the Russian Federal Ministry of Health and Social Development, about 284,000 Russians living with HIV/AIDS have been registered by June 2004. Experts from the World Health Organization (WHO) and UNAIDS estimate that the real number of people living with HIV/AIDS (PLWHA) in Russia may be two to five times higher¹, or between 800,000 to 1.5 million. More than 85 percent of HIV-infected Russians are young people aged 15–39.

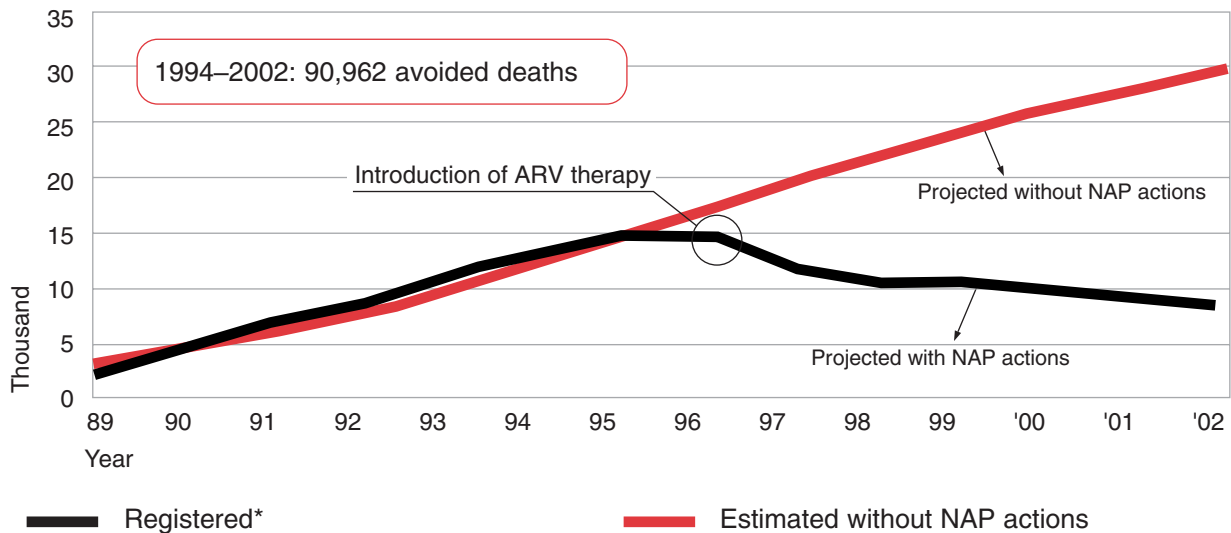
Individuals infected with HIV generally have few serious symptoms during the first 4-6 years after acquiring the virus. Unless treatment with antiretroviral (ARV) medicines² is available and effective, HIV infection progresses into the terminal stage of the disease, known as AIDS, followed by lethal outcome 8-12 years after being infected. Considering this fact and the recent trend in the number of newly registered HIV-infection cases, the number of young people dying each year of HIV/AIDS in Russia may reach several tens of thousands by 2007.

ARV medicines provide a real opportunity to extend the lives of PLWHA by many years and transform HIV/AIDS from a death sentence to a manageable chronic disease for millions of people around the world. ARV medicines are not a cure for HIV/AIDS, but many PLWHA taking these medicines do not develop AIDS or severe HIV-related opportunistic illnesses such as tuberculosis and certain kinds of cancer – and thus retain their ability to work and care for their families.

In places where ARV treatment is already widely available, such as most of Western Europe and North America, morbidity and mortality rates from AIDS have declined significantly. For example, in New York City, which has the highest prevalence of HIV/AIDS in the United States, death rates from AIDS and rates of new AIDS cases have been cut in half since the introduction of ARV therapy in the mid-1990s.³ It is estimated that in Brazil, which has the most advanced national ARV treatment program among countries with developing economies, almost 100,000 deaths were averted between 1994 and 2002 because of widespread access to ARV therapy (Fig 1). Similar trends have been seen everywhere else that therapy is available.

As international experience demonstrates, access to ARV treatment has a significant positive impact on already existing interventions designed to prevent HIV infection. When people have hope that they can receive treatment and lead productive lives, their incentive to learn their HIV status and to protect themselves and others is much greater. Evidence and experience show that rapidly increasing the availability of ARV treatment leads to increasing rates of voluntary testing and counseling for HIV.

Fig. 1. Number of deaths from AIDS in Brazil: actually registered and projected as if in the absence of the National AIDS Program (NAP), 1994–2002.

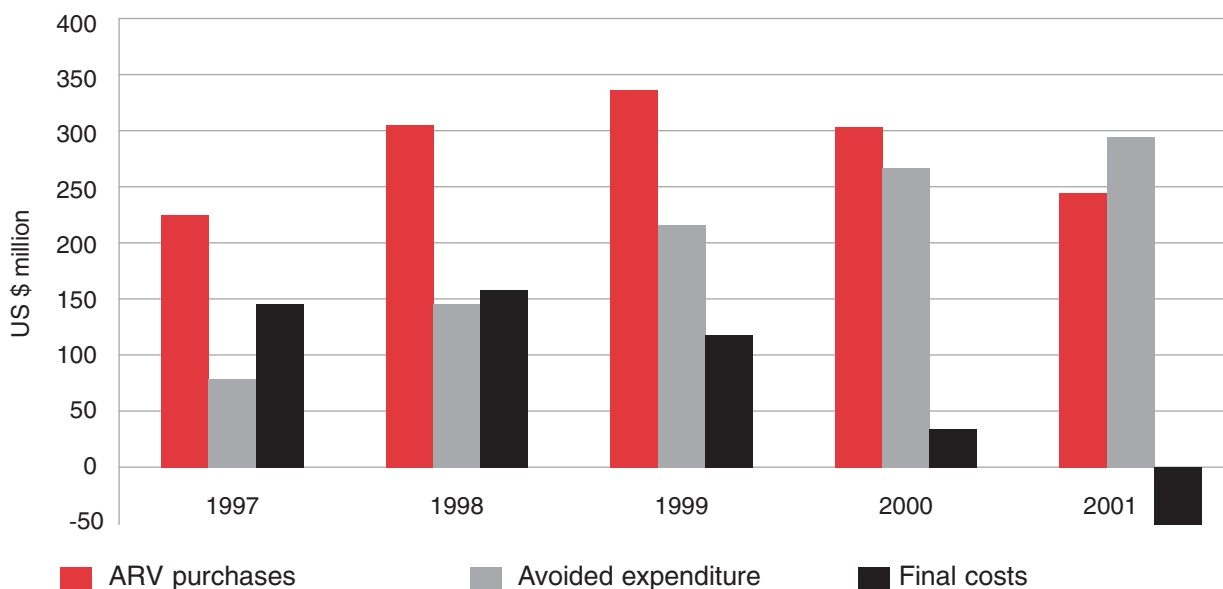


* Estimated deaths after 1999, using real trend

Source: Ministry of Health of Brazil, 2003.

While ARV treatment requires significant spending, it can lead to even higher savings, aside from the fact that it saves human lives. For example, the Brazilian government estimates that significantly improved access to ARV medicines (in 2001 more than 100,000 Brazilians were receiving ARV treatment) allowed it to save about \$2.2 billion, which otherwise would have been spent on provision of in-hospital medical care to AIDS patients. Improving access to ARV treatment in Brazil has contributed to a 50 percent reduction in mortality rates, a 60-80 percent reduction in morbidity rates, and a 70 percent reduction in hospitalizations among HIV-positive people (Fig 2.).⁴

Fig. 2. Cost of antiretroviral drug purchases, avoided expenditures and final costs to the Ministry of Health Brazil: 1997–2001*



* Estimated data

Source: Ministry of Health Brazil, 2001

The state of access to ARV medicines in Russia



Russian experts estimate that at the beginning of 2004, between 15,000 and 56,000 Russian citizens living with HIV/AIDS were in need of ARV treatment.⁵ Yet, fewer than 2,000 people nationwide currently receive such treatment. ARV availability varies significantly across Russian regions (oblasts), depending primarily on financial limitations of regional budgets. Over 30 percent of those who receive treatment live in Moscow City. It is estimated that the number of PLWHA in need of ARV treatment in Russia in 2005 will reach almost 140,000, and may well total half a million by 2010.⁶

According to Russia's Federal AIDS Law,⁷ the state guarantees provision of all types of quality and specialist medical care to HIV-positive Russian citizens free of charge, including free medicines in both out-patient and in-patient settings. The Law stipulates that state financing of measures aimed to contain the spread of HIV should be considered a top government priority.⁸ Russia's federal legislation guaranteeing universal access to treatment is consistent with international guidelines and best practices for the provision of care to PLWHA.⁹

To implement the state guarantees on provision of free care and effective ARV treatment to HIV-positive Russian citizens, in November 2001 the Russian government approved the federal program "Prevention and Control of socially significant diseases (2002-2006)", which includes a subprogram "Anti - HIV/AIDS".¹⁰ This subprogram's original budget allocates about 350 million rubles (\$12 million) per year for "procurement of most effective test-systems and medicines". According to the budget, about 90 percent of the above resources are to be provided from budgets of Russian regions. The government decree recommended that administrations of all Russian regions participate in financing the program and develop corresponding regional programs for the prevention and control of socially significant diseases, including HIV/AIDS. Nevertheless, even if all the planned resources were provided in full by both federal and regional budgets, and were spent solely for procurement of ARV medicines, the total amount would have been sufficient to provide quality ARV treatment to no more than 1,200 - 2,400 patients per year. As a result, despite the existence of the state guarantees for universal access to treatment as articulated within the Federal AIDS Law, currently only 2-4 percent of the estimated number of PLWHA in Russia who need ARV treatment now have access to it.

Experts identify the following major reasons for insufficient implementation of the state guarantees of free provision of ARV medicines to HIV-positive Russian citizens:

- **Lack of political commitment.** The need to ensure universal access to ARV medicines for treatment of HIV infection is not widely acknowledged and supported by political leaders at the federal and, especially, the regional levels;
- **Widespread stigma and discrimination against PLWHA** conditioned by lack of knowledge about HIV/AIDS among political leaders, health staff, and the general population;
- **Insufficient financing of HIV/AIDS programs.** Much higher than expected rates of growth of HIV infection since the Federal Law was drafted have led to rapid growth in the number of people who need ARV treatment now. Previously allocated resources are insufficient to meet the needs of the growing population of PLWHA in Russia;
- **High prices for ARV medicines (\$5,000–\$10,000 per patient per year),** together with **insufficient budgetary allocations** for these purposes in the majority of regions of the country;
- **Absence of national guidelines on provision of treatment with ARV medicines** including but not limited to indications and contraindications to initiation of ARV treatment and other pre-conditions (e.g., special care for drug users, who comprise a high percentage of PLWHAs) developed in line with WHO recommendations and approved by the Russian Federal Ministry of Health and Social Development;
- **Lack of capacity in the national medicine procurement and distribution systems,** which must ensure that all necessary ARV medicines of good quality are available at all times at all facilities providing ARV treatment.

Measures undertaken in Russia to address the problem of access to ARV medicines



Over the past several months, a number of positive steps have been undertaken in Russia that lay a potential foundation for sustainable and widespread access to ARV medicines:

1. Loan agreement with the World Bank.

In April 2003, the Russian government signed a loan agreement with the International Bank for Reconstruction and Development (World Bank) for a project titled "**Prevention and Control of Tuberculosis, HIV/AIDS and STI**". Among other things, the loan will provide \$4 million for the procurement of a limited amount of ARV medicines specifically to prevent mother-to-child transmission of HIV for about 2,500 HIV-positive pregnant women (\$1.7 million) and to provide ARV treatment for 150 children with AIDS (\$2.3 million) over a three-year period. These resources, however, can only partly cover existing needs: approximately 3,100 infants were born to HIV-positive women in 2003 alone, and this number has increased each year;

2. Endorsement by Russia of the joint WHO/UNAIDS "3 by 5" initiative on expanding access to ARV treatment.

In December 2003, WHO and UNAIDS announced a new joint initiative to provide ARV treatment to **three million** people living with HIV/AIDS in developing countries and countries with transitional economies **by the end of 2005**. WHO declared lack of access to ARV treatment to be a global health emergency that requires an immediate international response. The flexible strategy developed to achieve the above goal includes the following: (1) global leadership and strong partnership links; (2) urgent and sustained country support; (3) simplified, standardized tools for delivering ARV therapy; (4) effective, reliable supply of medicines and diagnostics; and (5) rapidly identifying and reapplying new knowledge and successes.

3. A large-scale HIV/AIDS prevention project of the Russian NGO Consortium supported by the Global Fund to Fight AIDS, Tuberculosis, and Malaria.¹¹

In late 2003, the Global Fund approved the application of a consortium of five leading NGOs working in the field of HIV/AIDS in Russia. About 30 percent of the total project budget of approximately \$89 million will be spent on ensuring access to ARV treatment for PLWHA in 10 Russian regions over five years.

4. Preparation and approval of the application to the Global Fund by the Russian National Coordination Committee.

In early 2004, Russia established a National Coordination Committee (RNCC) for cooperation with the Global Fund. In April, the RNCC prepared an application to the Global Fund for a \$120 million grant for a large-scale project specifically aimed at expanding access to ARV treatment in Russia. In June 2004, the Global Fund approved the application, committing to provide Russia with approximately \$34 million during the first two years of the project. The project is to run five years and aims to increase the number of PLWHA receiving ARV treatment to 74,000 by 2009. This target, however, will be achieved only under the condition that the cost of an annual supply of ARV medicines for one patient is reduced to \$2,000 by the start of the project and to \$600 by the end of the project.

It is important to acknowledge that even the above-mentioned measures will not provide sufficient resources to provide ARV treatment to all PLWHA who need it, which the Russian government is obligated to do according to its federal legislation. In a best-case scenario – if (1) in the coming months the purchase prices of ARV medicines were reduced five/six fold, i.e., to \$2,000 per patient per year, and (2) regional administrations ensured financing of their regional HIV/AIDS programs in full – the already committed government and donor (the Global Fund, World Bank, etc.) resources would only meet the needs of less than **10 percent** of the estimated number of people who need ARV treatment, and only for a few years.

International priority approaches to addressing the problem of access to ARV medicines



The prices at which ARV medicines are procured directly affect the potential number of patients who can receive treatment, and, as a result, the rates of morbidity and mortality from AIDS. Therefore, negotiating reduced prices for ARV medicines, as well as securing donations of medicines whenever possible, should be priorities in every country with limited resources to control HIV/AIDS.

In Russia, the prices for ARV medicines remain as high as those in the United States and Western Europe. Nevertheless, many countries with per capita income levels similar to Russia's have successfully reduced prices for ARV medicines since 2000. A series of multilateral negotiations with producers and suppliers of ARV medicines conducted since 2000 have resulted in price reductions for these medicines of 10-12 fold for a number of low- and middle-income countries: from \$10,000 - \$12,000 per patient per year to \$500 - \$800.

A review of international experience points to the following strategic approaches, which can be conducted individually or in combination, to effectively reduce the total cost of ARV medicines:

1. Centralized price negotiations with suppliers of ARV medicines on pooled procurement.

Currently, ARV medicines are procured in Russia by separate regions or even individual health institutions in small amounts (with exception of Moscow City). This reduces Russia's ability to negotiate significant discounts with suppliers interested in large markets. Centralization of procurement not only allows for negotiated price discounts, but could also enable more efficient use of resources through rational planning of required amounts of each medicine used in combination therapy; more effective distribution of medicines; and monitoring of how medicines are utilized across the entire country. In many other nations, pooled procurement of ARV medicines through an open tendering process has been shown to be the most successful means for negotiating reduced prices.¹² Political commitment at the central level is required to pool the funds and establish a transparent and effective pooled procurement mechanism.

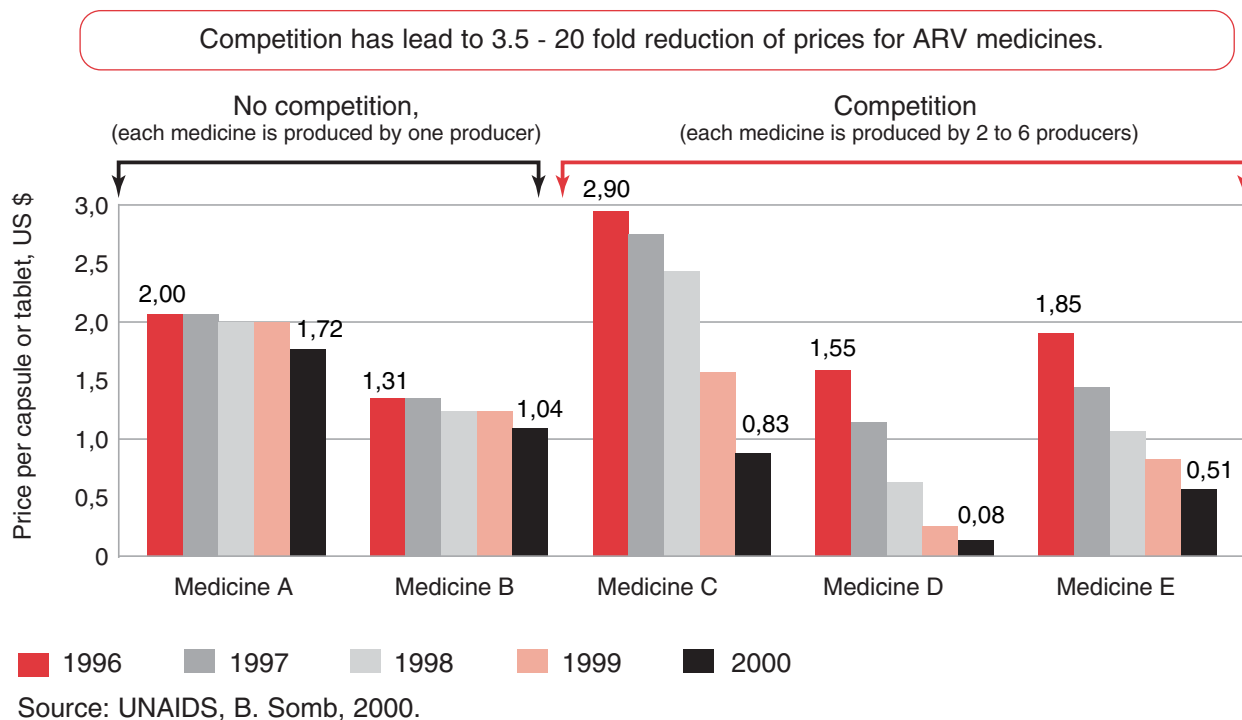
2. Procurement of generic medicines.¹³

Most ARV medicines are available as patented products at very high prices from the companies that researched and developed the medicines and now hold patents on them. The current patent system is designed to award innovation, allow companies to recoup their costs, and guarantee profits in order to provide incentives for research on the next generation of ARV medicines. Since multinational pharmaceutical companies finance the vast majority of new research on ARV therapies, there is a strong case to be made for their continued investments in the development of new medicines using revenues generated by current medicines on the market.

After expiry of the patent or other exclusivity rights on the original ARV medicines, other pharmaceutical companies can legally start producing *generic medicines* (i.e., analogues identical to the original in chemical composition and therapeutic action) and selling them at prices that are usually much lower than the original product. International experience demonstrates that the entry to the market of generic medicines at the end of the originator's term of exclusivity is one of the most effective mechanisms of price reduction, especially if the same generic medicine is produced by several companies. Competition between the suppliers of generic medicines leads to significant price reductions. (Fig. 3).

Currently, generic ARV medicines are widely available on the international market. WHO's "pre-qualification project" conducts rigorous evaluations of available generic ARV medicines to ensure quality and maintains a list of all medicines that have successfully passed the evaluation. The list of these pre-qualified medicines is easily available from WHO to all countries seeking to procure ARV medicines of good quality and at affordable cost.¹⁴ Although the track record of generics is not perfect, ensuring the quality of ARV medicines by WHO has allowed many countries to simplify their procedures for registration of medicines included into the WHO's pre-qualification list.

Рис 3. Impact of competition on prices for ARV medicines in Brazil



3. "Compulsory Licensing" or "Government Use".

Patent laws sometimes may hinder the registration of patented generic ARV medicines, but there are various mechanisms to overcome these difficulties. According to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO), member states can apply "compulsory licensing" or "government use", i.e. authorizing the use of a patented product by a third party in the public interest without receiving formal approval from the patent holder. This right can, for example, be invoked when there is a need to provide medicines to treat serious illnesses, such as HIV/AIDS, which are deemed to be threatening to a country's national security. This approach has been used in Brazil, where, thanks to compulsory licensing, the price of an annual course of WHO-recommended combination therapy for HIV/AIDS has been reduced several times. In November 2001, a WTO ministerial conference in Doha, Qatar issued the so called Doha Declaration,¹⁵ which proclaimed the primacy of public health in international trade and reaffirmed the flexibility that the TRIPS agreement provides to countries seeking to utilize the concept of "compulsory licensing" in the interests of public health.

4. Elimination of tariffs, duties and taxes.

A large majority of ARV medicines are imported into Russia since domestic production is very limited. Exempting ARV medicines from any tariffs, duties, and taxes (e.g. customs duties, VAT, etc.) could have a tangible and immediate effect on the reduction of prices for ARV medicines.¹⁶ With this goal in mind, a number of countries (e.g., Ukraine) have issued special governmental decrees exempting ARV medicines from all VAT, customs duties, and other tariffs.¹⁷

5. Scaling up domestic production of ARV medicines.

Scaling up Russian domestic production of ARV medicines-independently or in partnership with existing international producers-may not improve access to ARV medicines in the short run, because building the necessary pharmaceutical infrastructure and achieving high quality in the production of medicines as sophisticated as ARVs would likely take several years. However, this approach can be very beneficial in the long run since Russia's requirements for ARV medicines by the end of this decade will grow exponentially. The quality of domestic medicines can be ensured through internationally recognized certification procedures (i.e., good manufacturing practice, or GMP, certification) and participation in WHO's pre-qualification project.

Conclusions and Recommendations



Improving access to effective ARV treatment in Russia is urgently needed to prevent catastrophic consequences of the HIV/AIDS epidemic for Russia's demographic situation, public health, and economy. Effective treatment with ARV medicines certainly requires more than just a stable supply of high-quality medicines at an affordable price, however. It is also important to address issues such as distribution networks, health care and delivery structures, education and training for medical personnel, and scaling-up of social and psychological support services for AIDS patients. At present, however, reducing prices for ARV medicines remains an urgent prerequisite for any further action to improve access to ARV treatment for PLWHA in Russia.

In light of the issues noted above, the following priority actions are recommended to improve the free access to ARV medicines, which is guaranteed by the Russian Federal Law on AIDS:

1. High-level political commitment.

Senior political commitment and engagement is necessary to guarantee the full implementation of the national strategy on free and universal access to ARV medicines and to ensure adequate and sustainable financing of stable and sufficient supplies of good quality ARV medicines over many years.

2. Comprehensive national strategy for improving access to ARV medicines.

Access to ARV medicines needs to be ensured and planned as part of the Russian national policy on access to medicines and in the context of the nation's overall health system development. The use of donors, NGOs, the Global Fund or government financial resources for the procurement of ARV medicines needs to be carefully planned and managed as part of a sustainable long-term plan for national public health financing. The Russian national strategy for improving access to ARV medicines can be strengthened through the inclusion of the following approaches, all of which have proved to be highly effective internationally:

- centralized negotiations with producers and/or exclusive suppliers of original ARV medicines about pooled procurement;
- elimination of taxes, duties and tariffs for ARV medicines;
- procurement of legal and licensed generic ARV medicines through open tendering;
- "compulsory licensing" (also known as "government use") of ARV medicines; and
- scaling up domestic production of ARV medicines.

3. Research and analysis.

Comprehensive studies should be initiated on the short- and long-term costs and benefits and the direct and indirect impact of approaches to price reduction on the supply of ARV medicines.

4. Sufficient and sustainable financing.

The budget of the Russian Federal Program on prevention of socially significant diseases such as HIV/AIDS needs to be increased so that significantly more funds are allocated for (1) procurement of ARV medicines, and (2) strengthening the capacity of the national systems for procurement, distribution and quality assurance of medicines, including but not limited to training health and pharmaceutical staff nationwide. The need for ARV medicines in Russia will only continue to increase upon completion of projects supported by the World Bank, the Global Fund, and other foreign donor-organizations. Therefore, Russia needs to seek sustainable mechanisms to rely on its own resources for ensuring long-term financing of stable provision of all necessary ARV medicines to all PLWHA who need it.

5. Tax exemption of ARV medicines.

Currently, customs duties and VAT taxes increase the cost of ARV medicines in Russia by up to 22 percent. Because HIV/AIDS presents a serious and immediate threat to the country's national security, exclusive

exemption of ARV medicines from all taxes, duties, and tariffs can be justified. Issuing a special decree in this regard should be considered urgently by the Russian government.

6. "Government use" of generic ARV medicines.

As Russia is not yet a WTO member, the government can and should use the flexibilities specified in its current national patent legislation, which allows compulsory licensing for national security, emergency or non-commercial use purposes.¹⁸ With an eye toward likely future membership in WTO, the Russian government and partners in civil society and the private sector should actively evaluate the flexibility that WTO's TRIPS¹⁵ agreement provides to promote access to affordable ARV medicines. It is important that during negotiations on joining WTO, the flexibility afforded by TRIPS in regard to use of generic ARV medicines is fully retained. Achieving these goals requires effective coordination among at least three government agencies: the Ministry of Health and Social Development, the Ministry of Economy and Trade, and the Ministry of Justice.

7. Streamline registration of ARV medicines pre-qualified by WHO.

Currently, registration procedures for ARV medicines in Russia are slow (they can take well over a year) and costly. Many countries have simplified registration procedures for ARV medicines that have been pre-qualified by WHO. This not only saves time and costs, but also the lives of people in urgent need of ARV treatment.

8. Pooled procurement of ARV medicines.

To maximize advantages of a **pooled procurement mechanism**, the procurement of ARV medicines should be centralized at the national level. In addition to existing international experience in this regard, lessons learned in Russia from the national procurement of medicines used to treat tuberculosis can be particularly useful.

9. Building the foundation for scaling up domestic production of quality ARV medicines.

Before large-scale domestic production of ARV medicines can be introduced, the quality of domestically produced medicines must be certified. This can be done through internationally recognized certification of Russian pharmaceutical companies (e.g., good manufacturing practice, or GMP, certification) and their participation in the WHO's pre-qualification project. Joint projects with international pharmaceutical companies with expertise in this field may be especially promising.

¹ 2004 Report on the Global HIV/AIDS Epidemic: 4th global report. Joint UN Programme on HIV/AIDS (UNAIDS), 2004. UNAIDS/04.16E.

² Antiretroviral (ARV) medicines are pharmaceuticals that inhibit the replication of retroviruses such as HIV. Effective ARV therapy requires the simultaneous use of three or four different ARV medicines, a so-called combination therapy.

³ HIV/AIDS in Eastern Europe and the Commonwealth of Independent States. Reversing the epidemic. Facts and Policy options. United Nations Development Program, UNDP, Bratislava, 2004.

⁴ 2004 Report on the Global HIV/AIDS Epidemic: 4th global report. Joint UN Programme on HIV/AIDS (UNAIDS), 2004. UNAIDS/04.16E.

⁵ "Promoting a Strategic Response to HIV/AIDS and TB Treatment and Care for Vulnerable Populations in the Russian Federation". Russian National Coordination Committee for cooperation with the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Round 4 grant proposal to the Global Fund, 2004.

⁶ Ibid.

⁷ The Federal Law dated March 30 1995. N 38-FZ "On prevention of the spread of the disease caused by the Human Immunodeficiency virus (HIV-infection) in the Russian Federation" (amended on 12 August 1996; 9 January 1997, 7 August 2000). Approved by the State Duma of the Russian Federation on 24 February 1995 (chapter 1, article 4, section 1).

⁸ Ibid. Chapter 1, article 6, section 2.

⁹ United Nations General Assembly (2001) Declaration of Commitment on HIV/AIDS: "Global Crisis-Global Action". United Nations Special Session on HIV/AIDS, New York, 25-27 June 2001.

¹⁰ Decree of the Government of the Russian Federation of 13 November 2001 № 790. Federal program "Prevention and fight with socially important diseases (2002-2006)". Subprogram "Anti- HIV/AIDS".

¹¹ The Global Fund to Fight AIDS, Tuberculosis, and Malaria (the Global Fund or GFATM) is the largest international donor, providing grant support for the global fight against these epidemics.

¹² "Drugs and money. Prices, affordability, cost containment". WHO Regional Office for Europe. Seventh edition, 2003.

¹³ Generic medicines are medicines that are identical in chemical composition and therapeutic action to original medicines manufactured and patented by innovator companies. Generics are usually manufactured without a license from the innovator company and are only marketed after expiry of the latter's patent or other exclusivity rights. Therefore, by providing precisely the same medical benefit at a lower price, generics are affordable alternatives to more costly brand name products and reduce the cost of pharmaceutical care.

¹⁴ The WHO pre-qualification project's website: <http://mednet3.who.int/prequal>

¹⁵ The Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health was issued by the ministerial conference of the World Trade Organization (WTO) in November 2001 in Qatar. The Declaration made it clear that public health and access to medicines for all are primary concerns in applying international trade rules. It reaffirmed the flexibility that the TRIPS Agreement provides to countries in authorizing use of patented products-often called "compulsory licensing"-in the interests of public health. The Declaration also extended the transition period to 2016 for least-developed countries to issue patents in the pharmaceutical sector. WTO ministers at the Doha conference acknowledged (in paragraph 6 of the Declaration) that countries with insufficient pharmaceutical manufacturing capacities could face difficulties in effectively using compulsory licensing under the TRIPS Agreement because of the limitation on exports under compulsory licensing. On the eve of its ministerial meeting in Cancun in September 2003, WTO agreed to a case-by case system for waiving the export limitation in TRIPS so that countries without manufacturing capacity of their own could find sources of generic medicines. However, by mid-2004 the waiver system has not been used by any country.

¹⁶ World Health Organization/ World Health Report 2000, "Health systems: improving performance", World Health Organization, Geneva, Switzerland, 2000.

¹⁷ V.V.Rudyi. Zakonodatelstvo Ukrainy v sfere borby s VICH/SPIIDom. Sovremennoe sostoyaniye i puti sovershenstvovaniya. (Legislation of Ukraine in the area of fight with HIV/AIDS: the current state and approaches to improvement). Ukrainian Harm Reduction Association. Kiev. 2004.

¹⁸ Federal Law N 22-FZ3 dated 7 February 2003, "On amendments to the Patent Law of the Russian Federation". Adopted by the State Russian Duma on 24 January 2003. Approved by the Russian Federation Council on January 29, 2003. Articles 11 and 13.4.

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Transatlantic Partners Against AIDS (TPAA) is an independent, non-governmental organization that leverages the political, civic, scientific, and economic resources of North American, European, and Eurasian partners to combat the rapid and devastating spread of HIV/AIDS in Russia, Ukraine and neighboring countries.