Latvia

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Key findings:

- As part of its budget-tightening steps in the face of a severe economic downturn, the Latvian government is cutting the HIV and health services budget and imposing restrictions on the number of PLHIV provided with ART free of charge.
- The government has also so far refused to base its ART eligibility criteria on the new WHO guidelines for initiation of ART.
- Generic medicines are not procured, and as a result, the cost of treatment to the government is shockingly high compared to other middle-income countries. In January 2010, for example, the annual cost per patient for the most commonly used first-line ART (EFV+3TC+AZT) was 3,170 LVL (\$5,882).
- Many primary care providers are reluctant to treat PLHIV because they have insufficient or limited knowledge about HIV, or because of the stigma associated with illicit drug use. This makes efforts to decentralize services (currently there is only one main comprehensive ART centre in Latvia) difficult.
- Lack of integration of HIV care and drug-treatment services is another key reason why IDUsa most vulnerable and affected population in Latvia- lack access to HIV treatment.

Research process and methodology

Research for this report was conducted between November 2009 and January 2010. It consisted of an extensive literature and policy documentation review; a review of letters sent by PLHIV in recent years to Apvieniba HIV.LV, a leading HIV advocacy group; and in-depth interviews with a total of 18 people. Individuals interviewed included HIV/AIDS program managers; health care workers and service providers; representatives from the Ministry of Health, Ministry of Justice, international organizations, and NGOs working in the HIV advocacy field; and eight PLHIV.

1. Overview of country situation

The first HIV-positive person in Latvia was not registered until 1987, when the country was part of the Soviet Union. The number of HIV cases was relatively low over the next decade, with most transmissions attributed to sexual contact (the majority of them among MSM). In 1997, however, HIV started spreading rapidly among IDUs, a community in which it reached epidemic levels within a couple of years.

The number of registered known new infections reached a high of 807 in 2001;¹ of those individuals, more than 80 percent were IDUs. Since then the registered number of new infections has decreased annually. The most recent data (for the year 2009) shows the lowest number— 275²—of new HIV registered cases in one calendar year since 1999. The share of new infections attributed to injecting drug use has declined in recent years, but observers do not agree on whether this means the epidemic is no longer concentrated in that population. A WHO mission report from 2009³ concluded that the Latvian HIV epidemic remains concentrated among IDUs and their sex partners, but some Latvian specialists consider the epidemic to have become more generalized.⁴

HIV and AIDS rates in Latvia are among the highest in the European Union (EU).⁵ The HIV incidence rate in the country in 2008 was nearly three times higher than in the EU overall: 157.6 per million population, compared with 60.6 per million.⁶ By the end of 2009, a total of 4,614 HIV cases had been registered in Latvia since 1987.⁷ Around 60 percent of the total are among former or current IDUs.

¹ The term "registered" is commonly used in many countries, including in Eastern Europe, to refer to individuals who have had contact with health care facilities and whose status and health-seeking information are therefore able to be recorded and collected by government officials. It is important to keep in mind that the number of "registered" cases is nearly always far smaller than the number of actual ("real") cases in a country. That is because many HIV-positive individuals do not know their status or have not had any contact with a facility that would provide services such as HIV testing or care.

² Latvian Infectology Centre, 2010. Official statistics on new HIV infections in Latvia.

³ Joncheere K. et al. "Evaluation of access to HIV/AIDS treatment and care in Latvia", WHO and UNODC (May 2009). Online: www.unodc.org/documents/balticstates//Library/Other/Report ART Latvia.pdf.

⁴ The authors of this study report that this observation is based on a variety of formal and informal discussions over the past few years with Latvian health care officials and providers.

⁵ Latvia became independent in 1991. It joined the EU in 2004.

⁶ European Centre for Disease Prevention and Control/WHO Regional Office for Europe. HIV/AIDS surveillance in Europe 2008. Stockholm: European Centre for Disease Prevention and Control; 2009.

⁷ As in most other countries, the actual number of PLHIV is thought to be much higher. In Latvia, for example, some WHO and UNAIDS estimates suggest that up to 10,000 Latvians—twice as high as the number of cases registered since 1987—may be living with HIV.

About two-thirds (3,082) of the 4,614 people officially registered as having HIV are also registered with the Latvian Infectology Centre (LIC).⁸ This means that about one-third of all Latvians who have tested positive for HIV have not sought out treatment at the only facility in the country that provides specialized care for HIV infection.

Many of the HIV-positive individuals registered at the LIC are co-infected with other serious infections. Most notably, nearly two-thirds (1,888) of LIC-registered HIV-positive patients have also tested positive for hepatitis C, a virus that is common among IDUs. Smaller but still significant levels of co-infection have been recorded in regards to hepatitis B (250 patients) and TB (72 persons).

Universal access

Government officials have not specified universal access targets. The National HIV/AIDS Strategy⁹ does state that all in need (100 percent) should receive HIV treatment, including ART, treatment for OIs, and social services for those on treatment. Yet neither that plan nor other relevant policy documents actually indicate how "those in need" is defined.

Estimates vary widely in the absence of specific definitions. According to representatives from one NGO, the number of persons currently in need of ART who are not receiving it is at least 130.¹⁰ They add that ideally, assuming the clinical threshold for ART initiation were raised above its current CD4 level of 200 cells/ mm³, the number of persons who could be eligible for treatment and would benefit from it might be between 1,000 and 1,500. Those estimates are based on initiating treatment among all PLHIV with CD4 counts below 500 cells/ mm³. As one respondent noted, the higher threshold is preferable because "clinical research studies suggest better outcomes, including a decreased likelihood of developing resistance to drugs, if treatment is started at an earlier stage." ¹¹

According to some treatment specialists, meanwhile, there are around 800 people who need treatment. If true, that would mean that, as one said, "ART is received by roughly one-half of persons who need it" 12

2. Sources of HIV treatment delivery and related issues

- 10 Interview with Agita Sēja, NGO DIA+LOGS, in January 2010
- 11 As per Aleksandrs Molokovskis, a co-author of this report (January 2010).
- 12 Interview with Dr. Inga Januškēviča from the LIC, January 2010.

⁸ The LIC is the only facility in the country providing HIV treatment.

⁹ Cilvēka imūndeficīta vīrusa (HIV) infekcijas izplatības ierobežošanas programma 2009-2013.gadam (National Programme for Limiting HIV and AIDS in Latvia 2009-2013).

Currently there is only one facility in Latvia, the LIC, that provides a comprehensive suite of services free of charge for HIV-positive people—including provision of ART, HIV-specific diagnostic tests, treatment for OIs and social support. In 2007, a total of 328 patients were on ART through the LIC; by January 2010, that number had risen to 439 individuals (including 26 children). Of that total, 189 (43 percent) were IDUs and 301 (69 percent) were male. The data on IDUs suggests that members of this vulnerable population are far less likely to be on ART. They comprise about two-thirds of all people who have ever tested positive for HIV, yet their share of PLHIV on ART is much lower.

Of the 439 PLHIV receiving ART through the LIC, a total of 35 were receiving it in prisons (as of the end of December 2009). At the time data for this report was being collected, 20 HIV-positive pregnant women were receiving ART as part of an effort to prevent vertical transmission.

A total of 25 ARVs currently are available free of charge in the public sector. This compares favourably with neighbouring Estonia, for example, where only 13 first- and second-line medicines are available free of charge. ¹⁴ In total, first-line treatment regimens were prescribed to 312 patients, or 71 percent of all people on ART. The most commonly used first-line treatment regimen was efavirenz (EFV) in combination with lamivudine (3TC) and zidovudine (AZT), which was prescribed to 203 patients as of 1 January 2010. (See Table 1 for information on first-line regimens used in Latvia.)

Table 1. Most commonly used first-line ART regimens in Latvia

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	1 March 2009 (number of	1 January 2010 (number of patients
	patients on each)	on each)
EFV+3TC+AZT	139	203
EFV+ABC+3TC	41	54
ABC+3TC+AZT	10	16
EFV+3TC+d4T	11	12
EFV+3TC+ddI	10	7
Other first-line treatment regimens	14	20
Total	225	312

Second-line ART is available free of charge to patients as well. As of 1 January 2010, a total of 110 patients had been prescribed a second-line regimen. The most commonly used second-line treatment regimens were those involving lopinavir/ritonavir (Kaletra): regimens with that medicine were prescribed to 50 patients, and commonly it was used in combination with 3TC and AZT. (An additional 17 persons were on individual "salvage" treatment regimens.)

ARV costs

In March 2009, as the consequences of the economic crisis on the Latvian government's national budget became more apparent, the LIC proposed to set a limit on the number of ARVs available free of charge to patients. That proposal, which was expected to have

¹³ Data obtained from the Latvian Infectology Centre in January 2010.

¹⁴ See www.ehpv.ee; accessed February 2010.

reduced the number of ARVs provided for free, was eventually abandoned in the face of strong opposition from NGOs represented on the national HIV coordination council. Most physicians supported the NGOs because they believe, as two noted, that patients "should be treated with the best medicines and doctors should not take costs into consideration."¹⁵

Although the LIC backed down, there has been no subsequent effort to address the main reason behind its proposal: the high cost of all medicines used to treat HIV. In Latvia, all ARVs used in treatment are solely originator brands. As a result, the cost to the government is relatively high in comparison with countries where generic medicines are available. In January 2010, for example, the annual cost per patient for the most commonly used first-line ART (EFV+3TC+AZT) was 3,170 LVL (\$5,882). That total was less than what the government was paying in March 2009 (3,714 LVL). However, it remains several times higher than the cost per patient of a few hundred dollars when generic versions are used—including in other middle-income countries.

Decentralization efforts

Under new HIV treatment guidelines, patients can obtain a one-month supply of ARVs at the pharmacy of their choice. (Those who have demonstrated regular adherence can, if their doctors approve, receive a three-month supply each time.) Perhaps more importantly from the standpoint of simplified access to HIV treatment, the system is slowly changing towards a more decentralized approach. This means that although the treatment regimen still can be set <u>only</u> by the medical council at the LIC (consisting of four doctors), medicines can be prescribed by infectious diseases specialists throughout the country once a month. Moreover, steps are being taken to permit practitioners (GPs) to prescribe medicines, a development that would make ART even more accessible across Latvia.

There are some concerns, however, about whether decentralization will be effective, at least initially. Respondents to this study identified current and potential obstacles, including the following:

- lack of specialists in many regions of the country outside of Riga, and
- many GPs' unwillingness to be involved in HIV treatment.

The first obstacle may in fact be easier to address because it is simply about numbers. The second, though, is more complicated. Many primary care providers are reluctant to treat PLHIV because they have insufficient or limited knowledge about HIV in general or treatment specifically. Some, however, would rather not be involved with PLHIV because of the stigma associated with illicit drug use. ¹⁶ Their actions and behaviour raise serious concerns about HIV-related human rights violations.

16 As noted during interviews with representatives from NGOs and the LIC.

¹⁵ Interview with two physicians (Drs. Januškēviča and Ķūse) from the LIC in January 2010.

A final point about HIV treatment sources is worth noting. Recent policy changes also allow NGOs to apply for funding for social care for PLHIV from municipal budgets. According to respondents, most NGOs consider this a good idea but are not certain as to how useful it will be. Their uncertainty stems from lack of clarity so far as to whether the available funds would be sufficient for them to hire full- or part-time staff to provide such services on their own.¹⁷

3. Factors influencing access to treatment

Numerical limits on ART access. The LIC's medium-term strategy (2005-2009) placed implicit caps on ART access. It specified that with initial levels of funding (in 2005), the government would be able to support ART provision to a total of 250 individuals—and added that with additional funding, up to 470 people could receive treatment. Advocates consider such prescribed limits to be a major obstacle to efforts to reach real universal access in Latvia. They also believe the limits essentially make it impossible for the government to meet its vow to provide treatment to everyone in need—a vow that was made with no specific indication of numerical limits for any reason whatsoever.

<u>IDUs</u>' access to <u>ART</u>. As noted in Section 1, IDUs' share of all HIV infections has declined over the past few years. However, the longstanding association of the epidemic with IDUs and their sex partners has led to some controversial policies over the years based on persistent drug use-related stigma and discrimination across society.

For example, until recently, active drug use was a contraindication for access to ART through the government health care system. Officially that is no longer true: the new pharmacological HIV treatment recommendations developed and revised in 2009 by the Centre of Health Economics specifically exclude drug use as a factor in deciding whether an individual is eligible for receiving ART.¹⁹ The change in policy has not necessarily changed health care providers' attitudes and behaviour, however. Many respondents said that stigmatization and discrimination of drug users remains extensive among the general population as well as among specialists. As one respondent noted, "On paper the guidelines have changed, but do you think the situation has changed in reality?"²⁰

¹⁷ As per Aleksandrs Molokovskis, a co-author of this report (January 2010).

¹⁸ The LIC's new strategy from 2010 was still being developed when this report was finalized. Specific information about possible numerical caps and limits was therefore not available.

¹⁹ Veselības ekonomikas centrs. Racionālas farmakoterapijas rekomendācijas no valsts budžeta līdzekļiem apmaksātai antiretrovirālai terapijai HIV/AIDS infekcijas ārstēšanai, 2009. (The Centre of Health Economics, Rational pharmacotherapy guidelines for antiretroviral treatment of HIV/AIDS from the state budget, 2009.)

²⁰ Interview with Signe Rotberga, UNODC, in January 2010.

Care and treatment for HIV-positive IDUs in prisons. IDUs' share of the prison population is, perhaps unsurprisingly, several times higher than their share in the general population. Many are HIV-positive, and many continue to use drugs while incarcerated. Since 2006, Latvia and its Baltic neighbours (Estonia and Lithuania) have received funds through a United Nations Office on Drugs and Crime (UNODC) project aimed at reversing the spread of HIV among IDUs in prison settings. The project not only helps support ART provision, but also helped create programs to provide methadone maintenance treatment to both HIV-negative and HIV-positive drug users. Project grants also support health education activities among inmates and prison personnel. These efforts have helped increase uptake of key health services, including HIV testing.

4. Opportunities and challenges

This section summarizes two of the major <u>challenges</u> to improved and enhanced HIV treatment scale-up in Latvia.

1. Government budget cuts for ART provision

Latvia has been hit particularly hard by the global economic downturn. Unemployment has surged and its gross domestic product (GDP) has fallen by double digits over the past two years. In response to the crisis, the government has embarked on a fiscal austerity plan that emphasizes severe spending cuts across the board. Its spending on health and HIV services has not been spared.

The government's reimbursement system for medicines does not have a separate budget line for ARVs. However, its annual budgets are based on estimated costs for ART provision. The most recent budget, for 2010, allocates total spending for the system of about 1.20 million LVL (\$2.32 million). That budget was calculated based on 365 patients receiving ART, a number far less than the 439 people currently on treatment. As a result, advocates are concerned not only that treatment scale-up will be halted, but that some people currently on ART will be dropped due to lack of funds.

In response to advocates' concerns, health officials have said that ART will continue to be provided free of charge to all in need. They have not yet stated, however, how they intend to keep their guarantee in light of the restricted budget. Among the options reportedly being considered by both government officials and advocates are i) removing legal and patent-related barriers to the import and use of cheaper generic medicines, perhaps by using flexibilities in the World Trade Organization's TRIPS agreement (which Latvia has signed)²¹; ii) seeking support from other EU member-states that are not facing such a substantial economic crisis; and iii) applying for assistance from global agencies and

²¹ TRIPS = Agreement on Trade-Related Aspects of Intellectual Property Rights. The agreement includes specific provisions under which signatory countries can override otherwise strict patent-protection regulations when, for example, they claim it is necessary to address public health threats and emergencies.

initiatives such as the Global Fund, a step that would require special permission because of Latvia's EU status and relatively high per capita GDP.

Although officials say they will not revoke no-cost ART from anyone already receiving it, they have implemented some policies in response to the budget crisis that will have the effect of limiting HIV treatment scale-up. For example:

- New regulations at the LIC require patients to present a valid passport every time they visit the centre. This can be problematic for people who for one reason or another do not have valid documentation. According to some NGO respondents, a handful of people on ART have had difficulty obtaining ARVs since the new regulations were passed.²²
- The new HIV treatment recommendations state that "within the limited health care budget possibilities the level of CD4 to initiate treatment is 200 cells/mm³", which is much lower than the new WHO recommended level of 350. That decision holds down the number of people in need of ART, according to the government's clinical definition. Yet it represents a major threat to the health of hundreds of Latvians who could conceivably benefit from initiating treatment at an earlier stage in disease progression.

2. Limited interaction of ART and drug-treatment services.

Recent policy decisions to expand access to methadone maintenance treatment suggest that drug-treatment specialists' attitudes are changing for the better and drug use-related stigma in the medical and social care fields is declining. This is an important trend, but integration of HIV care and drug-treatment services—both important for HIV-positive drug users—remains limited.

This lack of integration makes it far less likely that members of the population most vulnerable to and affected by HIV (IDUs) are able and willing to access both crucial services in the most convenient and effective way possible. IDUs are less likely to be on ART in the first place and are more likely to be non-adherent to ART and to drop out of treatment altogether. As one HIV specialist observed, that is because "we do not have access to this population."²³

One potentially useful step would be to allow HIV treatment (including ART provision) to be provided directly by "medium level" medical personnel at low threshold centres for drug users. Those individuals could also be trained to help guide IDUs to HIV testing; to initiate HIV treatment, if deemed necessary; to provide adherence support; and to provide referrals to social and legal services used by PLHIV.

5. Recommendations

22 As observed by personnel and clients of Apvieniba HIV.LV.

23 Interview with Dr. Inga Januškēviča from the LIC in January 2010.

Recommendations for the Latvian government:

- Adequate funding must be made available to provide ART free of charge to all in need. This priority should be taken into account during all budget discussions and decisions.
- Adequate funding must be ensured for all activities and priorities identified in the National HIV Strategy.
- The purchase and use of generic ARVs should be a priority, given that it would greatly lower the government's costs per patient and create more flexibility in HIV/AIDS programming. The first step in this effort should be to make necessary amendments in national legislation to utilize flexibilities in the World Trade Organization's TRIPS agreement, such as parallel importing and compulsory licensing.

Recommendations for the Ministry of Health regarding access:

- The MoH should take the lead in ensuring that all stakeholders (the LIC, NGOs, etc.) agree on one, clear set of values, priorities and principles to guide the HIV treatment and care response in the future. Such efforts should include more specific data on the number of people in need of ART and understanding of universal access goals and targets.
- The MoH should immediately carry out the prime minister's explicit order to allocate HIV-specific funding to NGOs on an annual basis. Those additional financial resources should be used primarily to provide counselling and support services for PLHIV, services that are currently provided almost exclusively at government-run treatment facilities.
- The MoH should fund the development and implementation of integrated drug treatment, harm reduction (e.g., methadone maintenance) and HIV treatment services across the country. This step could help to improve IDUs' access to ART and other crucial services, and to increase relatively low rates of ART adherence among members of this population.
- The MoH should take the lead in working with NGOs to develop strategies to improve awareness and outreach among hard-to-reach populations (e.g., IDUs and sex workers).
- The MoH should establish a protocol and system to increase HIV treatment literacy among all health care workers in the country. This would help improve efforts to scale up ART access outside the main urban centre, Riga, and in prisons.

Recommendations regarding treatment guidelines:

- The MoH should oversee a process in which national treatment guidelines are revised to comply with international best standards as determined by WHO. This would include, most importantly, a requirement that ART be initiated when a patient's CD4 count falls below 350 cells/mm³.
- The Centre of Health Economics should conduct an effectiveness study of treatment regimens currently being used in the country. The findings of the study should directly influence the revision of national treatment guidelines.

Recommendation for advocacy partners:

NGOs should take the lead, in cooperation with the MoH, to develop information and educational materials to help increase treatment literacy. A wide range of materials should be created in order to target different vulnerable groups, each of which has different needs and expectations. Civil society groups should also focus on working with the MoH to draft materials for health care workers, with particular focus on reducing HIV-related stigma and upholding human rights standards.

SIDE MARGIN QUOTES

Near 'IDUs access to ART" section

"On paper the guidelines have changed, but do you think the situation has changed in reality?" –Head of the Project Office for the Baltic States at the United Nations Office on Drugs and Crime (UNODC)

Near "Limited interaction of ART..." section

"We do not have access to this population."- HIV treatment specialist at the Latvian Infectology Centre (LIC), in regards to IDUs