

Conference “Can We Afford the Current Model of Medical Innovation? Towards New Models of Innovation”

November 18, 2010, European Parliament, Brussels, Belgium
Organized by TACD, HAI Europe, KEY, Oxfam, IQ sensato group

Intervention

Access to pharmaceuticals in Eastern Europe (10 min)

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Thank you for the opportunity to contribute to this meeting with a perspective from the new EU member states and neighbourhood. I will speak about problems there and less about solutions for balancing access and innovation.

Bulgaria, Latvia, Lithuania, Poland and Estonia – all *new* member states - have the lowest healthcare budgets per capita and highest death rates within the EU.¹ We citizens in those countries may be paying less for staff and hospital expenditures, however our smaller budgets have to accommodate costs for pharmaceutical products and lab equipment which are as high as elsewhere in the EU. Naturally, this has major implications in terms of health inequalities, like a 50% higher combined standardized death rate across diseases. In addition, in order to be treated, many of our patients have out of pocket expenses to receive the medicines they need. For example, in my home country Lithuania up to 66% of all costs for medical supplies are covered by patients themselves.² This would be unacceptable for many EU member States.

Thus, we have to stop cutting health budgets and spend more on health care from public funds in order to increase access to medicines and diagnostics. Furthermore, other drastic changes would need to take place for us to be able to receive medicines when we need them. Let’s have a look at two diseases – hepatitis C and HIV.

Hepatitis C is a hidden disease, since it is often asymptomatic. The current treatment standard is a combination of two medicines, pegylated interferon-alpha and ribavirin. There is a patent held on pegylated interferon-alpha and the price, which is solely defined by its two manufacturers, is prohibitively high: from 10,000-20,000 EUR per 48-week course^{3,4} in both developed and developing countries. In the neighbouring

¹ Latest available data for the WHO EURO from 2008 in the European health for all database at <http://data.euro.who.int/hfadbl/>, show average healthcare costs in new EU member states of 1195.05 USD per capita per year; in the EU-15: 3319.93 USD per capita, i.e. around 3 times more. Standardized death rates: 877.36 per 100,000 population in new EU member states and 564.82 per 100,000 population in EU-15, thus the new EU MS had more than 50% higher than in EU-15!

² The percent is reported even higher in Bulgaria (79%) and Cyprus (82%); data for 2005 as presented in a table “*Medical goods dispensed to out patients (HC.5) financed by selected financing agents: Government (HF.1), Social Security (HF.1.2, Private insurance (HF.2.1 & HF.2.2, and Out-of-pocket (HF.2.3), 2005 (sorted by General government financing)*” in Eurostat/Van Mosseveld, C, Kawiorska, D, De Norre, B (2008). Health expenditure 2003-2005. Eurostat Data in Focus. Issue No 26/2008, available at http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-QA-08-026/EN/KS-QA-08-026-EN.PDF

³ CEEHRN/EHRN (2007). Hepatitis C prevention, treatment and support among injecting drug users in the new EU Member States and neighboring countries: situation, guidelines and recommendations. Eurasian Harm Reduction Network, 2007, Vilnius, Lithuania. Available at: <http://www.harm-reduction.org/images/stories/documents/hcv/hepatitis-c-112-2007.pdf>

countries, like Ukraine, Georgia, prevalence is high but neither governments nor insurance schemes cover hepatitis C treatment.

New EU member states might do better but they too have major access issues which were documented earlier by the Eurasian Harm Reduction Network. A limited number of treatment courses are available in my own country, Lithuania, and some recent positive change is that patients no longer have to co-pay for treatment. In Latvia, treatment is available only if someone co-pays for it. Four years ago, people had to co-pay 25%,⁵ since 2010 they have to co-fund half of the price.⁶ Prices vary substantially across countries. The Harm Reduction Network's analysis found that the Czech Republic was found to pay almost double the price in comparison to other new member states (20,000 EUR).

Thus high price is a major obstacle for increasing access to this treatment. At the recent regional workshop on access to essential medicines in Eastern Europe and Central Asia and on other occasions activists, practitioners and researchers also point out that in the East it is hard to draw attention to the issue, as there is no recognition of the issue at the political level – and although there is abundant indication of the issue if one would want to acknowledge it, we simply do not have robust enough data available to show mortality or prevalence rates, also as 80 and more percents of cases remain undiagnosed.⁷

HIV has received more attention than hepatitis C. It is on the global and EU agenda and is part of the Universal Access and Millennium Development Goals which all our countries have committed to reach by respectively 2010 and 2015.

- In the new EU member states, coverage of life saving HIV treatment for those in need is below 50%, thus lower than in some neighbouring countries like Georgia or Moldova.⁸ In Latvia, only 15% of those in need for treatment receive it, 22% in Hungary, 38% in Estonia, according to the UN and the ECDC.^{9,10}

⁴ Hoover, Jeff (2009). Shining a Light on a Hidden Epidemic. Why and How Advocates Can Support the Expansion of Hepatitis C Treatment in Eastern Europe and Central Asia. Open Society Institute, August 2009. Available at:

http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/hepc_20090821/light_20090821.pdf

⁵ see CEEHRN/EHRN, 2007 report.

⁶ From presentation of Aleksandris Molokovskis, Apvieniba HIV.LV on Reimbursable and Essential Medicines in Latvia at the workshop "Access to Essential Medicines in Eastern Europe and Central Asia", September 2010 in Vilnius.

⁷ Merkinaite S, Lazarus J, and Gore C, "Addressing HCV infection in Europe: reported, estimated and undiagnosed cases". Cent Eur J Public Health 2008; 16 (3): 106–110.

⁸ In non-EU Eastern Europe, the access levels are generally low: The Eastern European and Central Asian region has the second lowest ARV coverage in the world (23%), after the MENA region. In comparison, in 2009 coverage in Africa stood at 44%.

⁹ ECDC, WHO (2010) Implementing the Dublin Declaration on Partnerships to Fight HIV/AIDS in Europe and Central Asia. 2010 Progress Report. Available at: http://www.ecdc.europa.eu/en/publications/Publications/1009_SPR_Dublin_declaration_progress_report.pdf

¹⁰ Those rates are average across countries. For example, average for Latvia is 15% but in prisons the coverage is only 5% according to personal communication with the Baiba Purvlice by Peter Wiessner

- At the same time, **Latvia** has the highest **mortality** rate among people living with AIDS among the new EU member states.¹¹
- Also, along with Estonia, Latvia has the highest rates of **new infections**.¹² This is not surprising, given that the prevalence is higher than in most EU countries and also the fact that people who receive treatment are less infectious.

The key issue our new EU member states are struggling with is the high cost of medicines. The medicines are rather new and cost around 4,400 EUR per year¹³ just for the cheapest first line medicine cocktail. And here one needs to remember that HIV treatment does not represent a cure and needs to be continued throughout a HIV-positive person's life. Outside the EU, it looks as if in terms of pricing Eastern Europe is doing much better than the EU: Ukraine managed to reduce the first line therapy to less than 230 EUR (300 USD) per patient per year.¹⁴ So why does Estonia, Latvia, and others pay 19 times more than Ukraine? For one, Ukraine and other Eastern European countries still can introduce good quality generic medicines for many antiretrovirals which are cheaper; secondly, pharmaceutical companies that produce original ARVs set differential prices based on regions, income (GDP, World Bank classifications) and epidemic levels. But once countries join the EU, prices there change and rise to the EU level, without differentiating by income or epidemic levels that is burden of the disease in question. The single Internal (EU) Market basically implies a single level of reference pricing, particularly for newer and more expensive medicines.

In the EU, some attempts to address the pricing issue for antiretrovirals have been made - under the leadership of the European Commission, then also Germany.¹⁵ Over the last two or three years, several rounds of high level and operational meetings with a few countries took place. In July 2010, the European Commission singled out Bulgaria as a good practice case. Surprisingly, Bulgaria reported that after two years of discussions they managed to reach a 'good dialogue with the pharmaceutical industry,' however, it seems that in terms of price they have not managed to reach any reduction so far.

The main reason why new EU member states cannot import cheaper anti-HIV medicines, like generics that are used in Ukraine, is a long protection period of clinical and preclinical data, so-called data exclusivity, which is established in the European legislation.¹⁶ The rationale provided for it, as well as patents for medicines in general, is

¹¹ ECDC, WHO (2009) HIV/AIDS Surveillance in Europe 2008. Surveillance report. Available at: http://www.ecdc.europa.eu/en/publications/Publications/0912_SUR_HIV_AIDS_surveillance_in_Europe.pdf

¹² *ibid* : 406.4 per million in Estonia and 157.6 per million in Latvia in 2008. The EU average was 60.6

¹³ For example, the report by Trapencieris, M, Molokovskis, A (2010) *Missing the Target: Access to Treatment for People Living with HIV - Latvia* for the Apvieniba HIV.LV says "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)." The report is available at: http://www.apvienibahiv.lv/docs/729/projekti_2010/LatviaMTT8Final5April.pdf

¹⁴ From presentation by Konstantin Lezhentsev on the process of standing up against efforts to monopolize the ARV market in Ukraine at the workshop "Access to Essential Medicines in Eastern Europe" (September 2010, Vilnius)

¹⁵ Germany's leadership was based on the Bremen Declaration on Responsibility and Partnership – Together Against AIDS adopted in 2007 during the German EU presidency. The declaration text is available online at: http://www.eu2007.de/en/News/download_docs/Maerz/0312-BSGV/070Bremen.pdf

¹⁶ Council Directive 2004/27 and to Regulation 726/2004

the alleged need claimed by pharmaceutical companies to recover the costs of R&D and innovation, in addition to covering for other costs which are paid also for generic medicines - manufacturing, marketing and profits of the pharmaceutical industry.

Access and innovation are both important. Therefore the European AIDS Treatment Group advocates for the fastest possible access to standard of care treatment for everyone in need – whether inside the EU, living in Eastern Europe, Central Asia and elsewhere.¹⁷ Too few of us receive HIV treatment in Latvia, too many of us in Romania experience drug stock-outs that threaten our lives. Thus we need to urgently rethink how we can better support access which falls under the responsibility of national governments which often fail to provide it. And we need to rethink how to better support innovation so that patients from new EU member states can eventually access the treatment they need, including TB patients or patients suffering from other rather neglected diseases, which are killing us in the East and in many other places outside the EU – so that these diseases would get adequate attention in research. In the meantime, we should not export our high-brand medicine protective policies through EU trade partnership agreements - neither to neighbouring Ukraine, nor to the pharmacy of the world, India – but work on balancing access and innovation within the EU as well.

¹⁷ EATG's mission is to achieve the fastest possible access to state of the art medical products, devices and diagnostic tests that prevent or treat HIV infection, and to improve the quality of life of people living with HIV/AIDS in Europe.