

Access to Treatment:

- EATG position paper
- Upcoming initiative on affordability of ARVs and other medicines in the EU
- Access in Russia

EATG discussion on access and innovation

- Innovation:
 - Major advancement in medicines and devices for testing, monitoring and treating HIV
 - More needed: new better medicines, medical devices and finding a preventive vaccine and the cure
- Access:
 - Extremely low access in Eastern Europe / Central Asia
 - EU in face of financial crisis and increased diversity of economies: more access challenges
 - Political commitment is a major challenge but so is affordability of medicines
- ***Need to find a balance between innovation (paying for innovation) and access to medicines (affordability).***
- ***Current link: through patents (innovation is rewarded by market exclusivity)***

Improving affordability of access

- Supporting reaching universal access through affordable prices: Encouraging price reduction through:
 - price negotiations;
 - differential pricing;
 - pooled procurement;
 - voluntary licensing;
 - the use of TRIPS flexibilities by developing and other countries facing serious burdens.
- [TRIPS = World Trade Organization's agreement that establishes minimum standards for patents including those for medicines]
- Opposing EU introduction and promotion of protection patent rights beyond the minimum standards

Improving affordability of access

- Discussion of the need to explore “de-linking” of innovation and access through:
 - alternative incentives and strategies research and development (other than the market exclusivity award through which monopoly pricing limits access as new drugs come to market in vast majority of the countries)
- The EATG position on Access & Innovation will come out by September '12 and we will encourage others to review it and join the position

Affordable medicines in the EU

- Some previous attempts to make ARVs more affordable:
 - First initiative towards the Baltic states (2004-2006?);
 - DG Industry, DG Market, DG Sanco, Community, Pharma, Government procurement agencies
 - results not clear but clearer positions on a few aspects;
2012 Baltics established a legal framework for pooled procurement
 - Bremen Initiative under Germany's leadership (2007-2010)
 - Bulgaria, Estonia, Romania + Germany, the EC and industry
 - Community – involvement at country level varied
 - Some report increased affordability, some challenge
 - Belgium EU Presidency Conclusions on Innovation and Solidarity in Pharmaceuticals
 - Better sharing of clinical data; Clinical Trial Directive
 - Tries to balance between pharmaceutical sector solidarity and equitable access. Additional focus on early access to medicines

Some ongoing processes

- DG Competition report encouraging more use of generics
- Analysis commissioned by the EP (ENVI 2011):
 - More exchanges of information among Member States on different policy mechanisms and their results, with a view to further harmonising methods such as HTA [health technology assessment] and, more generally, reducing price differences and improving access.
 - EU policies can encourage greater use of generic medicines, which could lead to significant price reductions in a number of markets.
 - Parallel trade in pharmaceutical products continues to raise concerns and deserves further study and policy discussion at EU level
- Multi-stakeholder Think Tank on differentiating pricing within the EU in collaboration with the Belgium government representatives / Pharma / civil society..

Revitalizing initiative for affordability

EATG proposes a one-day meeting to revitalize affordability initiatives (possibly beyond HIV)

- Possible participants:
 - selected national government representatives,
 - key EC/EP bodies,
 - NGO/community groups,
 - industry representatives
- Looking for co-organizers to shape agenda and participants
- Input on which bodies / countries to prioritize

Russia – treatment access

- Country where government took on donor role (at least for ARVs)
- Almost 100,000 people are on ART (estimated needs vary – 150,000 according to Rospotrebnadzor)
- After few years with major ARV interruptions, in 2011 less interruptions with medicines but major problems with monitoring
 - Previous years the Global Fund financed projects managed to address various interruptions and lack of WHO-recommended medicines for first line (like Tenofovir) but this support is no longer available
 - Special program for supporting migrants (funded by the GF) is closed

The key challenges that PLHIV community prioritizes

- Improving forecast of needs:
 - Evidence based protocols
 - Register of patients and treatments
- Adequate procurement:
 - Transparency in procurement
 - Decentralization was being considered but without consensus; from Romania and others experience that might bring more stockouts and challenges
- Reduction of prices
 - [WTO accession comes with the whole package of high patent protection, particularly data exclusivity which will prevent use of generics which so far were
 - Current prices are at the EU level (EU prices are used for reference)
- Treatment literacy and adherence support
 - Less discussed; harm reduction including OST was not included in the agenda for this particular meeting: there is a special working group on OST
- Strengthening collaboration (within the community and with other agencies)

WHO, UNDP, UNAIDS

- Lower role of UN agencies in the country
- UNDP:
 - particular challenges with the WTO accession and need to mobilize
 - Will support monitoring of patient rights in relation to HIV in Russia, Ukraine, Belarus, Moldova, others (EU support)
- WHO:
 - Readiness to collaborate with the community groups on specific issues (protocols, possibly procurement..)
 - Question: how the European Plan for HIV will be monitored – stockouts should be one of the indicators
- UNAIDS:
 - Support partners meetings to address various issues