



A Europe free of AIDS, TB and viral hepatitis - and no one left behind

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1. Civil society concerns regarding medicines availability (non-registration, high price, market withdrawal, stockouts)

Gus Cairns, EATG

Gus notes the unavailability of long-acting injectable cabotegravir for PrEP in Europe, while the US has already approved injectable PrEP for some time now. It is an injection once every two months as HIV pre-exposure prophylaxis instead of having to take a daily pill.

Paul Sommerfeld notes that it was only in the last six to seven years that there have been some properly formulated versions of TB medicines for children. However, the problem for EU is that the market for paediatric formulations in TB is very small, with the result being that it is not worth it for drug companies to go through all the hassle of getting these new formulations approved within Western European countries.

Key Improvements:

- Injectable PrEP has far more effective results as randomized control trials have shown very convincing results, even more effective than oral PrEP.
- Studies concerning injectable PrEP showed how women were particularly interested as they do not particularly like oral PrEP.

Key Concerns:

- Although applications have already been made to EMA to, at least, start the process of registration, injectable PrEP is still not registered in Europe because of considerable delay.

¹ This is a report from the CSF secretariat. The information shared is reported as heard. The report was not run by speakers. Please, treat this report with caution.

- Five generic firms have already made agreements to manufacture it for Africa and low-income settings; whereas, Europe falls in between the two settings:
 - Health systems are unable or willing to pay the amount that this formulation costs in the US.
 - High income European countries are not able to negotiate the kind of deals that low and middle income countries are able to.
- In these times of crises, Europe or some parts of it risk falling behind in access to new tools responding to unmet medical needs.
- Suitable paediatric TB medicine should become accessible in the EU also.
- The vaginal ring is approved by EMA for use in Africa but not in EU.

Example from Ukraine:

- People fleeing from Ukraine faced the problem of not being able to access the same regimens they were getting treated with due to limited availability in the EU.
- WHO cooperated with the Polish government to change the law and be able to access generic medicine; however, it took about a month to access it.

Next Steps:

- See how to ensure smoother and quicker process to access needed medicines .

2. Oral PrEP access in Europe (report) & Country Developments

Nina Tumanyan, AIDS Action Europe (AAE)

Nina presented the preliminary findings of AAE rapid assessment of pre-exposure prophylaxis in the EU and EEA countries.

The reasons behind conducting this rapid assessment lie in highlighting where PrEP is now and the availability, accessibility, affordability, and acceptability of PrEP.

The uniqueness of this rapid assessment is that AAE asked NGOs and community-based organizations to provide the experience and expertise from working directly with clients and communities.

Key Concerns:

- PrEP has **not reached its full potential as the combination prevention in the EU**, remaining the biggest challenge to face in the EU setting and the reason behind conducting this rapid assessment.

Preliminary Findings:

- Although patients do not pay the costs of PrEP on their own, **the prices of PrEP** in countries, such as Italy, Malta, Romania, Greece, Czech Republic, Poland, and Sweden, **are still very high**, even for generics.
- **Restrictive eligibility criteria** and access to PrEP, for example in Slovenia, where people must report whether they have had chemsex recently, and prove that they do not have to have any acute HIV signs or symptoms.
- **Long waiting list** (Finland) to get a prescription for PrEP.
- In most cases, there are few who can prescribe or deal with PrEP treatments.
- **Better access in urban areas.**
- PrEP is still very limited and still delivered in a very centralised manner by HIV clinics, with the consequences of excluding community-based organisations by not giving them the opportunity to increase their coverage.
- Information campaigns on PrEP are often led by NGOs who might not have enough financial support. Whereas, there is an almost non-existent campaign backed up by public money or public health campaigns.
- **Restricted targeted groups:** are often limited to MSM; while, vulnerable groups such as migrants, bisexual MSM, women, women with migration backgrounds and sex workers are left behind.
- Unofficial access to PrEP is higher in countries that do not reimburse the costs to patients, with people accessing PrEP online or by travelling to neighbouring countries.
- Scarce and very limited HIV and STIs tests and diagnosis (good example from Sofia checkpoint prescribing 95% of PrEP in Bulgaria).

Recommendations:

- To extend needs assessments towards sub-communities that are left behind to review national guidelines to make the eligibility criteria more inclusive.
- To review the pricing strategy for PrEP to find out the reasons why in some countries, insurance or health care systems pay such a high price for generic.
- To scale up information campaigns to get support from national funding and perhaps international as well.
- To develop awareness-raising campaigns that are focused more on communities that are currently left behind.
- To promote low threshold community-based service delivery because they already have access to communities.
- To enable direct referrals where community-based organizations can already refer for PrEP, where doctors should not have to review the case again, but just take it as a direct referral without reviewing the case from the beginning again.
- To extend the list of medical practitioners that can prescribe PrEP by extending that list to GPs.
- Countries that do not reimburse should strive and aim to include prep under the Public Health Reimbursement scheme.

General agreement on the usefulness of reports by NGOs and CBOs as they are able to highlight the real problems happening on the ground, whether reports by ECDC might be limited.

Next steps: There is a need for UNAIDS and Fast Track city initiatives to consider PrEP as a tool for combination prevention as much as anything else.

On 16 November 2022, the European Parliament's Intergroup on LGBTI Rights, in partnership with UNAIDS, AIDS Action Europe, Aidsfonds, European AIDS Treatment Group, and the European Public Health Alliance are organising a policy dialogue on measures to be taken to scale up equitable access to Oral Pre-Exposure Prophylaxis (PrEP) for HIV as part of HIV prevention combination strategies within the EU and beyond.

The presentations and meeting report can be found [here](#).

3. EU pharmaceutical strategy and civil society advocacy

Rosa Castro, Senior Policy Manager for Healthcare Delivery & Networks Coordinator at European Public Health Alliance

Pharmaceutical Strategy for Europe:

- Adopted on 25th November 2020
- To create a future-proof regulatory framework; support industry in promoting research and technologies that actually reach patients in order to fulfill their therapeutic needs while addressing market failures + consider weaknesses exposed by the coronavirus pandemic and take appropriate actions to strengthen the system, especially during emergencies.

4 pillars with legislative and non-legislative action:

- Ensuring access to affordable medicines for patients, and addressing UMN (AMR, rare diseases)
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry & development of high quality, safe, effective and greener medicines → providing a good framework for them to develop and provide better services.
- Enhancing crisis preparedness and response mechanisms, diversifying, and securing supply chains, address medicines shortages.
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

Important:

- Interaction with other policies: new industrial Strategy for Europe, European Green Deal, Europe's Beating Cancer Plan, the European Digital Strategy
- The pharma industry view is an extension of the UE's 'industrial policy' but in the public health and public health NGOs tend to see these as a public health-related strategy.

What the European Commission intends to address:

- Unmet needs.
- Access to affordable medicines.
- Digitalisation and new technologies.
- Anticipation and response to major health crises and open strategic economy.

Where are we now?

- Re-drafting of Impact Assessment and Staff Working Document after a negative opinion of the Regulatory Scrutiny Board (leaked impact assessment in August)
- There are some positive aspects in this leaked document but they realized that there are negative issues, such as the creation of new exclusivities that will likely pose a problem they will virtually apply to any product and mainly to the blockbusters of the companies. Consequently, it could be used as a precedent for market exclusivity which would have a negative impact on affordable medicines.

What's next?

- Drafting of a high-level document including main recommendations in each of the areas of the pharmaceutical legislation revision, which will be circulated next month.

4. CSF & European Health Policy Platform thematic network

CSF Coordination Team

CSF has applied to the call from the European health policy platform, which called for a thematic network on HIV, TB, viral hepatitis and STIs. There will be a public meeting on 17TH October to present what the plan is.

CSF will organize three webinars and draft a statement with the intention of engaging with external stakeholders.

Establishing 3 working groups that will focus on the areas covered by the thematic statement.

Next CSF meeting and external webinar looking at Access to Medicine. Following, CSF meeting on Stigma and Discrimination in January and Improving Cross-border Healthcare, Standards of Care Measures are also to be planned in early 2023.

→ Important to join the European Health Policy Platform to participate and engage with external stakeholders.

5. Global fund replenishment and advocacy

Ganna Dovbakh, Executive Director at Eurasian Harm Reduction Association

Last year, Global Fund adopted a new strategy that includes plenty of community language, human rights, and language priorities on gender equality.

The majority of countries in Eastern Europe and Central Asia are waiting for allocation letters, which will be allocated from the Secretariat approximately in December. Proposals will be drafted until March 2023.

Key Concerns:

- Italy and the UK have not yet committed to the Global Fund.

[Here](#) is the technical assistance to support the meaningful engagement of civil society within Global Fund's NFM4.