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

Summary of the Civil Society Forum of 4 November 2021

Contents

All presentations can be found on the website of the Civil Society Forum:

https://www.csfhivheptb.eu/eu-hivaids-viral-hepatitis-and-tuberculosis-civil-society-forum-november-2021

1. Coordination team report

EU4health programme advocacy: On 25 October, Stella Kyriakides, the European Commissioner for Health and Food Safety, announced that operating grants will be reinstated though eligibility criteria, timeline are still unclear. Advocacy is ongoing on the 2022 work programme, including in relation to harm reduction.

European Travel Information and Authorisation System (ETIAS): There were concerns over reported ETIAS requirement to disclose HIV, TB, and viral hepatitis status. However, after checking, it turned out that the website with this information was not the official one. Moreover, upon CSF CT request, DG Home reported the falsehood of the information and clarified*: "For the purpose of ETIAS, only high epidemic risks will be considered. These are defined as: "any disease with epidemic potential as defined by the International Health Regulations of the World Health Organization (WHO) or the European Centre for Disease Prevention and Control (ECDC) and other infectious diseases or contagious parasitic diseases if they are the subject of protection provisions applying to nationals of the Member States" (Article 3(8) of Regulation 2018/1240).*

As such, the diseases you have mentioned do not fall under this category of high epidemic risks.

Furthermore, applicants when applying for a travel authorisation will not be asked in the application form to provide information about their health status."

This point could be used to question national practices to ask non-EU nationals to undergo an HIV test with unclear framework for interpretation and used for the residence application procedure.

ECDC/EATG/AAE/CSF Survey of Stigma among People Living with HIV: **the** survey to help to understand the experience of stigma for people living with HIV in Europe and Central Asia. The survey is available in more than 20 languages (further languages will be added as translations are available).

ARVs stock-outs in Romania: In collaboration with partners in Romania, EATG/ CSF reached out to EC, WHO, UNAIDS and GF CCM to raise awareness about the stockouts and to establish a dialogue with the Romanian Government to find short and medium term solutions to the shortages. There will be a follow up with the new government (the previous government fell in October).

The EC is currently exploring legislative measures to "enhance security of supply and address shortages of medicines. These include stronger obligations for supply, earlier notification of shortages, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages." The EC supports exchanges between national competent authorities on pricing, payment and procurement policies, to improve the affordability and cost-effectiveness of medicines and health system's sustainability.

The EC is conducting a public consultation (till 21 Dec): see here

2. European Commission update on EU4Health and European Health Union.

Rimalda Voske, EC DG SANTE, reported on the EU4Health programme and the EC EU Health Union proposals. The proposals seek to strengthen the EU's preparedness and response to future health threats. Negotiations are on-going. This new framework aims to strengthen health crisis preparedness. National plans will be prepared and with the support of ECDC and other EU agencies. This plan will be audited, and stress tested by the Commission and EU agencies.

HIV, AIDS, hepatitis, and TB are currently subject to surveillance at EU level. It will be in an integrated surveillance system on an EU level.

- It will be using artificial intelligence and other technological means.
- To improve data quality, Member States will be required to step up reporting on health systems indicators
- The declaration of the EU emergency situation will trigger and increase coordination

ECDC and EMA have been at the forefront of the EU's response to COVID 19. The crisis pointed to the need to reform them. ECDC´s mandate will be reinforced in the following areas: epidemiological surveillance, integrated systems, surveillance preparedness and response, reporting and auditing, provision of long-binding recommendations, options for risk management, capacity to mobilize and deploy EU task force to assist local response in MS, as well as building a network of EU reference laboratories.

The EC launched the European Health Emergency preparedness and Response Authority. The agency will facilitate coordination at EU level around monitoring, risk assessment and mitigation, scientific advice on medicines, support to clinical research, coordinating studies to monitor the effectiveness and safety of vaccines, addressing availability of medical countermeasures.

The presentation was followed by discussion on the role of NGOs:

It was noted that civil society responses are instrumental, and they must play an increasing role in addressing the epidemics. Service support is needed to broaden the reach of services, as well as supporting retention in treatment and care, and very importantly, advancing human rights and combating stigma and discrimination.

The Commission answered that a number of actions have been published in the EU4Health work programme and a number of actions are actually already published with open form. Therefore, 5 million euros will be used to support Community based organizations, to support these services in Member States for the implementation of people-centered, effective and integrated interventions for HIV, AIDS, TB, hepatitis and other STI. This call has been published and it is open until 25th of January for applications.

It also referred to the European Health policy platform where all the stakeholders have been invited to communicate, collaborate and work on joint statements.

HIV Justice Network asked about community engagement in the development of HIV molecular surveillance and secondary use of health data. There are concerns over the repurposing of health data for public health purposes and respect for privacy, autonomy and consent. There are concerns over HIV criminalization and other punitive public health responses. ECDC replied that there has been discussion about molecular surveillance when it comes to monitoring drug resistance. With the advice from Member States, they have agreed not to put those variables in their routine surveillance systems. It is a voluntary reporting

system. It is based on aggregated data, so there is no case based information. The EU and member states are ramping up on molecular surveillance now because of COVID-19. However, from the HIV side, if variables to be included are discussed, it will be in a network meeting and NGOs are part of it to provide their perspective. ECDC is very well aware of the sensitivities around collecting this information. It is not doing so currently and it is not planning to do so, going forward

3. WHO Europe update on guidelines, Global strategy, and Europe action plan

Elena Vovc, WHO Europe

In July 2021, WHO published guidelines consolidating key recommendations on HIV prevention, testing, treatment and service delivery and monitoring.

In December 2019, WHO issued the testing guidelines, a call on countries to use innovative approaches including self-testing, partner notification, social networks-based testing, and update their algorithms for the confirmation of diagnosis.

- Key priority: implement testing guidelines in all countries to avoid late diagnoses.
- No changes for the ART 1st and 2nd line.
- Major community involvement in the changes of the guidelines. The recommendation is to have fewer visits to the clinic and rely more on community services to monitor treatment and reduce this costly visit to the clinics.

ART monitoring (threshold and frequency of VL) and use of point of care and most up to date diagnostics.

Early infant diagnosis.

Initiation of ART in the context of TB screening and TB treatment towards faster initiation.

Guidelines are available in the WHO Apps. Testing App was updated with the latest recommendation, HIV treatment is still being updated.

There are some ongoing discussions on updating the key population guidelines that will probably be ready by the first quarter of 2022, close to CROI and maybe some updates on PreP.

STRATEGIC PLANNING:

WHO Europe is developing a European Action Plan based on the global health sector strategy for 2022-2030. The Global Strategy will be available for comments from December to February, so that it can be adopted at the next World Health Assembly (May 2022). There will be some resolutions related to the costing of global strategy, including estimates for the region. The global strategies will make a clearer delineation in between the strategies for HIV, hepatitis and STIs, in the European region, an action plan will summarise everything.

Contents: one big chapter on the role of leveraging primary health care and looking towards reaching UHC and then the chapter gets more disease specific. There may be important discussions in the target setting for the region (maybe by December). There are some challenges for the targets for STIs and Hepatitis. For HIV is more or less clear, since it relies on indicators that already exist. Hopefully, in September there will be an action plan for the next years for a regional level and in May next year there will be strategies.

The report should be available for the next week. Issues with Russia and Belarus are expected. Currently, there is no potential to make a bigger debate for the Russian communities, for example, with the government. There was no civil society dialogue specifically.

4. UNAIDS update on PCB Special Session on UBRAF and its relevance for the region (EU/EEA + EECA)

Jantine Jacobi, UNAIDS

UNAIDS presented on *Unified Budget Results and Accountability Framework* (UBRAF), which brings together the collective contribution of UNAIDS joint programme to the global HIV and AIDS response. The new policy momentum has catalysed key changes for the UN Joint Programme on HIV and AIDS, allowing focus on:

1. tackling inequalities to ensure equitable access to HIV services and support.
2. Improve enabling legal environments, eliminate stigma and discrimination and promote gender equality in the HIV response.
3. Strengthen community-led responses and societal enablers and champion the empowerment of communities and PLHIV.
4. Advance the increased availability and financing of global response to achieve the 2025 targets.
5. Foster leadership and support innovative approaches for more inclusive HIV services.

RELEVANCE FOR EU/EUROPE/EECA:

Overall, highly relevant not the least because of the epidemic dynamics (i.e., inequalities and barriers), the political context and the challenged funding/focused attention.

1. The Joint Programme will continue to be guided by the three overarching objectives:
   - To deploy human and financial resources where they are needed most
   - To reinvigorate country-level joint work and collaborative action
   - To reinforce accountability and results for people.
2. The UBRAF result chain starts with the country UN Sustainable Development Cooperation Frameworks – your UN entry point – through Joint Team and/or Cosponsors/Sec.
3. Focus on evidence-informed disparities and inequalities in your region (population/location)
   - Joint action ECDC, WHO, UNAIDS to get evidence
   - Capture community -led reportingreports

4. The UBRAF places people and communities at the centre – engage with the UN on how to bring in your multisectoral experience and challenges.
5. Focus on achieving all 2025 targets, and particularly 10-10-10 (POLITICAL commitment)
6. AIDS continues to be a global health crisis – within the pandemic context, the need for strong advocacy for sustained funding for the AIDS response, CSOs, GF, and UNAIDS remains. Civil society is a critical point that needs funding to remain in that independent role.
7. Engage in global dialogues and work towards positioning AIDS as part of the global health agenda.

Discussion: back in 2016, in light of the migration crisis and beyond, migrants were therefore considered key populations in strategies. Which probably will not be the case. What do we do with migrants and is there enough work? Will there be some regional variations? The answer was that the guidance for the regional priorities are more detailed for the "Global South". Attention has been asked for undocumented migrants and for a more systematic approach across EU member states. Data should improve.

The starting point for monitoring implementation of the plans and strategies should be a multi-source approach and the views of community partners be incorporated.

5. Consensus definition on HIV-related preventable mortality

Sara Croxford, Public Health England

Getting to zero HIV-related deaths is the stated aim of a number of initiatives in the era of HIV elimination (e.g., Fast Track Cities). However, there is no one clear detailed definition that should be used. Therefore, UKHSA, BHIVA, EACS, and Fast Track Cities London set out to develop a consensus definition of preventable, HIV-related mortality for public health monitoring and identifying areas for intervention to improve patient care.

A secondary purpose is to provide guidance to clinicians completing death certificate details relating to cause of death and contributory factors, or when reviewing local data.

The project has four components:

1. Rapid literature review scoping how preventable, HIV-related death is currently being defined.

- Carried out in March 2021: systematic approach, materials from 2010 onwards, in English, with a measurable definition of mortality to be included.
- Most studies used AIDS coding from either the ICD-10 codes or causes of death in HIV (CoDe) protocol to indicate HIV-related morality. Few studies considered non-AIDS-related causes of HIV-associated mortality. No studies classified suicide or substance misuse as HIV-related.
  A subset of studies described HIV-related conditions or lifestyle risk factors.

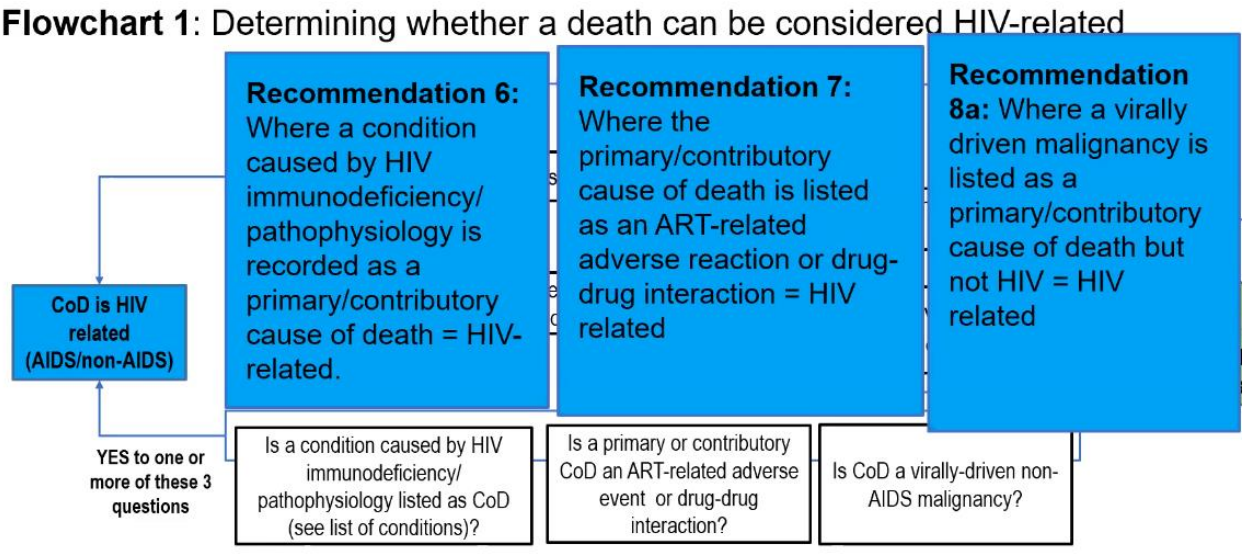
2. Expert review of definition with wider stakeholder discussion, presented in June 2021.
3. Piloting of consensus definition against historical London HIV data.
4. Publication

Recommendations, capturing the definition:

1. Deaths among people with HIV should be categorised as: HIV-related (including AIDS), Possibly HIV-related, Not HIV-related, Unknown cause of death.
2. Deaths among people with HIV should, for surveillance purposes, initially be categorised based on information on death certificate
   - WHO guidance when data systematically inadequate
   - Where data is routinely available, but cause is missing, cause of death should be recorded as unknown.
3. The definition applies to those people who have tested HIV positive:
   - Diagnosis may be made post-mortem
   - In high prevalence countries with inadequate data on HIV status of cases, apply WHO tools.

How to determine whether a death can be considered HIV-related?

1. In a setting where information is routinely available, but cause is missing, cause of death should be recorded as UNKNOWN. Where we do have a cause of cause of death information and an AIDS diagnosis is listed as the primary or contributory to the cause of death, the death should be categorised as HIV related [AIDS] (Recommendation 4).
2. If AIDS is not listed as primary/contributory CoD, we should ask, is HIV infection listed as primary or contributory CoD? If YES, is it mandatory to list HIV as CoD for HIV ? YES, is HIV included in the direct sequence of causation? YES, then CoD is possibly HIV-related. If it is not mandatory to list HIV as CoD for HIV
3. then CoD is possibly HIV-related (Recommendation 5). In countries like Spain where it is mandatory to include HIV on the death certificate, we recommend looking at whether it is included in the direct sequence of causation.
4. If HIV is not listed as primary or contributory CoD, then:



5. If none of this applies, then is CoD a non-viral non-AIDS malignancy? If YES, possibly HIV-related (Recommendation 8b) – *this step still has to be agreed*. If NO, was the CD4 Count less than 200 cells per microliter? Possibly HIV-related (Recommendation 8c).

6. No HIV-related: death is suicide, substance misuse or other co-morbidities including conditions occurring more frequently in people living with HIV.

Determining whether an HIV-related death was preventable.

1. The first thing to consider is whether the death was due to AIDS and whether the patient was diagnosed late. A HIV-related death should be considered preventable when a person is diagnosed late with a CD4 count less than 350 per microliter and dies within 12 months of their HIV diagnosis of AIDS. If a late diagnosis happens more than 12 months prior to the death, the death should be categorised as potentially preventable. Further investigations will be required to determine whether they should be categorised as actually preventable.
2. For non-AIDS deaths (people not diagnosed late), clinical care data should be reviewed to assess whether the death was preventable, including surveillance markers, might not have been one effective treatment.

Some examples:

CATEGORISED AS PREVENTABLE where:

- ART was not commenced in a timely fashion,
- A person is not on ART in the 12 months prior to death
- Viral suppression has not been continuous in the three years prior to death.

CATEGORISED AS PREVENTABLE where:

- an intervention or screening known to reduce the incidence the HIV-related condition was not received (including interventions on vaccination and screening for cervical cancer).

It needs to be adapted to different countries in order to consider when the intervention or screening was available and if an intervention was not available at the relevant time, the death should be categorized as potentially preventable.

What remains to be done?

- Incorporate feedback on draft definition from stakeholders
- Pilot with 2019 London HIV surveillance data to set baseline for monitoring
- Write-up of definition as a publication
- Meet with FTC reps from cities across UK to promote definition
- Role of HIV Guidelines and Standards, and engagement in treatment and care services on preventable non-HIV causes of and contributors to death
- Minimum data set

Discussion: Is there a requirement from WHO on CD4 percentages as ART monitoring, as opposed to total CD4 count, because CD4 percentage is actually a more accurate estimate of how HIV is progressing and whether there are any kind of comorbidities as compared to the the actual CD4 count. In other words, CD4 percentages would be a more accurate picture of a person's health and that also relates to the malignancies. The problem is many countries do not use CD4 percentage anymore (e.g., Latvia). The second one is whether these new dual type regimens are considered, which, although they keep the viral load low, can cause more inflammation in the body according to some research and can create malignancies. Were these different regimens taken into consideration?

A1: We have only counted data because the definition was meant to be quite practical, given the accounts are routinely through our national surveillance mechanisms so we have not considered any proportion CD4.

A2: In terms of the regimens, I guess it would depend on what information is recorded on the death certificate. This study would not give any real information about the contribution of two - three different drug measurements. That would need perspective studies on a long term that it would be too biased

7. HIV criminalisation

Sini Pasanen - HIV Finland – Recent supreme court decision in Finland

Until September, it was unclear in Finland whether taking preventive measures for transmission, such as being on ART (undetectable viral load) or using condoms, are considered sufficient for not being considered as exposure to HIV.

In 2015, there were two cases:

1. The accused was on ART, had had unprotected anal intercourse without disclosing his HIV-status to the sexual partner. The HIV transmission had not happened. The accused was convicted of imperilment.

2. One vaginal intercourse and taking into account all circumstances the charge of aggravated assault (attempt) was dismissed).

In 2017, many unprotected intercourses with a spouse (no condom, no ART) HIV transmission occurred. Convicted of aggravated assault.

September 2021:

A had been aware of his HIV infection and had once unprotected sex with B. HIV infection has not been transmitted to B.

ART used by A and the low viral load in his blood, and taking into account the circumstances of the case:

- The charge of aggravated assault (attempt) was dismissed.
- A had not caused a danger to the life or health of B, so the alternative charge of causing the danger (imperilment) was also dismissed.

- Precise information on the viral load of A at the time of sex is not available. The viral load has probably been between 487 and 55 copies per millilitre, probably 100 to 300 copies per millilitre.
- In addition, the risk of infection has been reduced by the fact that A has ejaculated on the sheet and not inside B.
- HIV is still regarded as a dangerous infection.

DOES THE SUPREME COURT BELIEVE U=U, DO WE STILL HAVE TO DISCLOSE?

Since the 2015 preliminary rulings, medical research data on HIV infection and the impact of medication on HIV not being transmittable have increased.

According to expert opinions, there is no risk of contracting HIV infection even during unprotected intercourse when an HIV-positive person is on successful ART (blood virus below 200 copies per millilitre).

The Supreme Court considers that the risk of infection in such a situation is essentially theoretical and would not be a question of the specific danger required by the hazard characterisation.

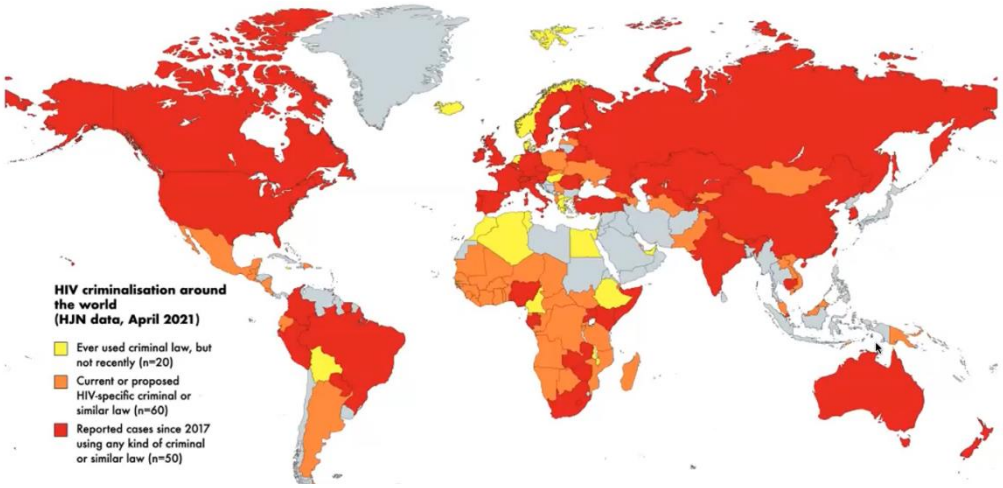
Edwin Bernard, HIV JUSTICE NETWORK – Key developments in HIV criminalisation in EU/EECA and around the world

Fewer reported HIV criminalisation cases worldwide in 2021: 46 in 2021 VS 87 in 2020.

However, most EU/EECA cases in Russia (16), then Italy (2) and single case reports in Belarus, France, Iceland, Kazakhstan, and UK. Most for non-disclosure prior to sex (only some alleged transmission). The UK case was for biting, one Russian case related to sharing injecting drug equipment and one Italian case was for intent with HIV-infected blood in needles.

The previous example shows when the law, the legal environment is clear for people living with HIV. However, there are huge amounts of uncertainty, particularly in countries that use non-HIV specific laws (most of the EU), andEastern and Central Asia. The uncertainty and the fear of prosecution remains central for those living with HIV.

HIV criminalisation around the world
(HJN Data, April 2021)



developments:

2020

- Sweden: Parliament votes to abolish the obligation to disclose HIV status after a long process begun in 2008
- Spain: Supreme Court upholds acquittal of man accused of HIV transmission as evidence points to complainant being aware of his status
- Russia: analysis of use of HIV-specific criminal law shows all of the (at least) 60 people prosecuted between 2018-20 were convicted
- Poland: Country's Criminal Code amended to increase sentencing in cases of HIV exposure

2021

- Ukraine: new bill proposes expanding HIV-specific criminal law with harsher sentences for transmitting all serious communicable diseases
- HIV (de)criminalization one of the 10-10-10 targets in Global AIDS Strategy and HLM Political Declaration
- US state of Illinois completely repeals HIV-specific criminal law; Nevada and Virginia modernise their laws (US has historically been the leader in HIV criminalisation, along with Russia)
- UNDP issues critical Guidance for Prosecutors (EN-FR now; ES and RU soon). They basically put together all the recommendations from UNAIDS, UNDP and the Global Commission on HIV and the Law, and the expert consensus statement on the science of HIV in the context of criminal law that was published in 2018, and help prosecutors understand how to limit the abuse of the law. UNDP and the International Association of Prosecutors will hopefully deliver training for civil society.
- UK: England and Wales CPS agrees to publish updated guidance without broadening to 'deliberate deception'. This should not apply to HIV.
- HJWW publishes *Molecular HIV Surveillance: A global review of human rights implications* (published in Oct 2021)

Tuesday, 30 Nov 2021: Webinar: Beyond Blame – Challenging Criminalisation for HIV Justice Worldwide.

8. Shortages/stock outs - medication, vaccines, OST and diagnostics

Nicoleta Dascalu (ARAS)

The situation regarding current shortage is being handled. Hospitals have received money and/or medications. However, there is an interim government only. There are uncertainties about treatments for January.

In collaboration with the Association of People Affected by Hepatitis, a letter has been sent to responsible institutions because Romania has not had treatment for hepatitis C for five months. The negotiations with the company finished five months ago and

the governmental decision exists but it has not been signed yet. Therefore, patients diagnosed with hepatitis C five months ago have not started their treatment yet. The Ministry of Health puts the blame on the Ministry of Finances.

Q: Shortages of stockage across the region: In the past, the CSF used to take note of shortages and stock-outs every six months and share this information with WHO and UNAIDS. Is this something that we should take note of in the future and integrate in our activities?

It is an important issue that should be monitored, especially taking into account these changes in the ECDC and in the European Medicine Agency.

Besides treatment, there are also countries with shortages on diagnostics and testing and access to prevention, so it could be a broader monitoring task for CSF.

Information should be gathered in time, probably on a quarterly basis. The CSF coordination team.

9. Harm reduction Conference

Roberto Perez Gayo – Correlation- European Harm Reduction Network

The European Harm Reduction Conference will take place from 10-12 November. The session with WHO will examine integrated person-centered care models, good practices and actions to be taken. There will be a pre-conference about HIV and AIDS section focusing on HIV prevention, treatment and care (specifically of people who use stimulant drugs). The programme is here: https://www.harmreductionconference.eu/index.php/programme/

10. AOB

Vitaly Djuma, **ECOM**, a regional association of LGBT organizations and allies working in the field of HIV response based in Tallinn, Estonia). Raising one issue of the discussion from the Global Fund Board :– a proportion of funds that goes to the three diseases: HIV, tuberculosis, and malaria. According to the previous and current methodology, TB response gets 1.80 %. This proportion should be increased without jeopardizing the progress that we have been making on HIV and malaria. COVID-19 has been a very big blow to TB programmes. Support from the global society is therefore required. There is a sign-on letter prepared by a TB activist that will be forwarded to the Forum to sign it.

Robert Hejzak: we were invited as representatives of civil society for the ECDC- STI network coordination committee meeting which took place last month. The coordination committee is in charge of organizing annual meetings for the European network of STI surveillance (not meeting in person since 2016). It will take place next January/February. The topic is what has been happening on the STI scene in Europe over the COVID-19 pandemic (dropping number of cases of STIs – with the exception of syphilis which is increasing). New EU legislation on testing for STIs next year. Emphasis will be put on PReP and STIs.

NEXT MEETING 3rd February 2022