CONCEPT NOTE

EAST AND SOUTHERN AFRICAN REGIONAL MEETING

HARNESSING OF THE TRIPS FLEXIBILITIES TO PROMOTE ACCESS TO MEDICINE

Proposed Date: 15 – 17 October 2018
Proposed Venue: KAMPALA, UGANDA

Context:

The East African region (EAC) suffers from multiple health challenges and it is reported to be the second most affected region by HIV and AIDS in the world after southern Africa. The East and South African region is estimated to have 19,600,000 people living with HIV and in 2016 the estimated AIDS related deaths in the region stood at 340,000 but among the East African Countries, Kenya and Uganda account for the highest HIV prevalence rates while in the Southern region, South Africa is the highest. Although the recent health indicators show a reduction in HIV prevalence rates due to increased access to 1st line Anti-retroviral treatment, opportunistic diseases such as Tuberculosis (TB) and Non Communicable Diseases (NCDs) like cancer and cardiovascular diseases remain a challenge among people living with HIV.

In fact evidence indicates that while people on anti-retroviral therapy are experiencing improved survival, they are increasingly at a risk of developing opportunistic diseases such as TB & NCDs. Health workers now worry that patients saved from AIDS related illness may die due to NCDs including cardiovascular diseases, cervical cancer and diabetes among others. This was recently emphasized by the World Health Organization statistics which reported TB and Cardiovascular disease among the top 10 causes of death in low to middle income countries. In 2016 alone, TB related deaths among people living with HIV within the East and Southern Africa was estimated at 430,000.

The related 90-90-90 targets have been blamed as a contributory factor to the above statistics because lack of knowledge on HIV status and non-adherence to treatment further compromises the immunity of people living with HIV/AIDS making them more susceptible to NCDs. There is also an increase of resistance against affordable first-line HIV and TB treatments which means that access to second and third line treatments is becoming crucial. The 2017 WHO HIV drug resistance report indicated that over 10% of people starting

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1 The East African Region is made of 5 countries of Kenya, Uganda, Rwanda, Burundi and Southern Sudan
3 UNAIDS 2018 estimates
4 Available at Aidsinfo.unaids.org
7 WHO 2016 TB estimates
ARVs were resistant to some of the most widely available HIV medicines. The WHO recommends that people with drug resistance should be moved to a different regimen that could be more expensive and out of reach for low income countries due intellectual property rights.

This emphasizes the need for continuous development of generic local manufacturing capabilities in the regions since Africa depends heavily on imported medicines both patented and generics, with very little or no local manufacturing presence. Available data indicates that in Africa, 37% of HIV medicines are patented products, whereas 63% are generics. About 85% of the generic ARV medicines used in the South African Development Community (SADC) are imported and only 15% are manufactured within the SADC region. Similarly the EAC locally produces only 30% of its medicine while the share of imports is estimated to be at 70% with 62% market share of generics.

The increase in access to essential, generic life-saving medicines over the past ten years has been pivotal in reducing HIV and TB prevalence rates in sub-Saharan Africa but to effectively address the public health crisis, East and Southern African member states also need access to new care diagnostics products and medicines. However, intellectual property (IP) rights continue to play a role in undermining access to diagnostics, medicines and other devices for Africa and the rest of the developing world.

In particular, the 1995 Trade Related Aspects on Intellectual Property (TRIPs) Agreement has an impact on prices of medicines since all WTO members with the exception of Least Developed countries were obliged to provide intellectual property protection on pharmaceuticals. To minimize the effects of the TRIPS Agreement, the East and South African region must be keen on utilizing the opportunities under the TRIPS Agreement which included flexibilities that were reaffirmed by the Doha Declaration (2001).

At a regional level the East African Community has taken some initiative to promote the utilization of the TRIPS through developing an EAC policy that encourages the EAC partners to incorporate the flexible provisions in their national laws. Kenya and Uganda have now incorporated some flexibilities into national laws however there has been little evidence of full utilization of the available space to promote access to medicine. With the exception of Kenya, all East African countries are classified as Least Developed Countries (LDCs) while in the SADC region, eight out of the sixteen member states remain LDCs which gives them the potential to become local generic manufacturing hubs during the exemption period.

Unfortunately, even though LDCs are not obliged to give higher IP protection than the minimum required by TRIPS, some of their IP / Patent legislations unnecessarily adhere to higher standards which are not required by the TRIPS Agreement, and in some instances these countries are also bound to unilateral agreements. Moreover, countries like India, which have been the biggest supplier of cheaper generic drugs to the region.

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9 The 2nd EAC-Regional Pharmaceutical Manufacturing Plan of Action 2017-2027
10 World Trade Organisation to which all East African countries are members with the exception of Southern Sudan
11 The Doha Declaration emphasised that WTO members should use the TRIPs in a way that benefits them and protects public health interests.
13 LDCs are exempted from protecting pharmaceutical patents until 2033 under the TRIPS extension
are also expected to be TRIPS compliant which limits access to medicines for low income countries in the two regions with minimal manufacturing capacity.

To ensure optimal access to medicines, the SADC and EAC recognize the use of the TRIPS flexibilities as a strategy for achieving this objective. The 2015 – 2019 SADC Pharmaceutical Business Plan has incorporated the use of the flexibilities as one of its core pillars and as a strategy for ensuring the availability of essential medicines. SADC therefore undertook to “coordinate the implementation of TRIPS flexibilities to improve access to essential medicines within the SADC region.”

To this end, the Southern African Programme for Access to Medicines (SAPAM) and The Aids Rights Alliance for South Africa (ARASA) have undertaken a mapping of the IP laws and policies in the 16 member states and are working closely with civil society organizations in southern Africa, to effect legal reform of their national IP/ Patent legislations; through working with the various Technical Working Groups that were convened with support of UNDP and DFID in 2014. Both organizations have produced country-specific snapshots, which provides an overview of where each member state is in terms of legal reform and where intervention areas are required in the near future.

The Center for Health, Human Rights and Development (CEHURD) and the Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) are currently conducting a study on the strengths, weaknesses, opportunities and threats to the use of TRIPS flexibilities in Kenya and Uganda with a view of developing a list of priorities where TRIPS flexibilities can be useful to increase access and reduce the cost of selected medicines for HIV, TB and related NCDs.

Without a doubt, the EAC and SADC region can take advantage of the TRIPs flexibilities to increase competition, reduce prices and expand access to medicines for HIV, TB and other opportunistic diseases but there is need to examine the limitations faced by individual member countries. This would inform the development of innovative strategies to motivate and support better utilization of the available policy space.

It is against this background that CEHURD, KELIN, SAPAM and ARASA are partnering to convene a regional meeting for the East and Southern Africa region on harnessing of the TRIPS Flexibilities to promote access to medicines for People Living with HIV (PLHIV) and affected by diseases such like Tuberculosis and Non-Communicable Diseases.

Objectives:

To galvanize regional consensus, these partners will convene a regional meeting with Intellectual Property experts and civil society representatives from the east and southern Africa region, with the following objectives.

1) To share the findings from the ongoing research study on the strengthens, weaknesses, opportunities and threats of utilizing the TRIPs flexibilities in Kenya and Uganda

2) To share updates on the work that is being done in the SADC region and progress in countries which have started amending their IP/ Patent legislations to incorporate the TRIPS-flexibilities
3) To build consensus and enhance the capacity of civil society organizations (targeting those working in HIV and TB and the NCDs) to build a solid African access movement, which demands for the prioritization of access to medicine at national level.

4) To develop a roadmap which will enable the use of innovative strategies for the in-country civil society access movements to support efforts towards the full utilization of the TRIPS flexibilities, to increase access and reduce the cost of selected medicines.

Expected:

The proposed meeting will aim to elicit the following outcomes:

1) A regional consensus on opportunities and challenges to utilization of TRIPs flexibilities in promoting access to medicines.

2) Agreed actions that would put pressure on national governments and the east and southern African communities to fully utilize TRIPS flexibilities to improve access to affordable medicines on a long term basis.

3) An outcome document with a list of innovative strategies that can be implemented by all stakeholders within the EAC to motivate full utilization of TRIPs flexibilities.

Participants

The three day meeting is aimed at IP experts, policy makers and civil society organizations working on access to medicines within the East and Southern African region. The invitation will be extended to 30 representatives from the said categories.