Eastern and Southern African Regional Meeting
Harnessing of the TRIPS flexibilities to promote access to medicines

Held at Best Western Hotel, Entebbe – Uganda on the 5th to 8th November 2018

Contents

1. List of ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ARASA	AIDS and Rights Alliance of Southern Africa
ARIPO	African Regional Intellectual Property Organisation
BONELA	Botswana Network on Ethics, Law and HIV/AIDs
BUBU	Buy Uganda Build Uganda
CEHURD	Center for Health Human Rights and Development
CSO	Civil Society Organization
EAC	East African Community
HEPS	Coalition for Health Promotion and Social Development
HIV	Human Immunodeficiency Virus
ICW	International Community of Women Living with HIV
INN	International Non-proprietary Names
IP	Intellectual Property
IPR	Intellectual Property Rights
ITPC-EA	International Treatment Preparedness Coalition East Africa
KELIN	Kenya Legal and Ethical Issues Network on HIV & AIDS
LDC	Least Developed Countries
LMIC	Low and Middle Income countries
MeTA	Medicines Transparency Alliance
MoH	Ministry of Health
MSF	Médecins Sans Frontières
NCDS	Non Communicable Disease
PLHIV	People Living with HIV
R&D	Research and Development
RAME	Réseau Accès aux Médicaments Essentiels
SADC	South Africa Development Community
SRHR	Sexual and Reproductive Health and Rights
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Trade Related aspects of Intellectual Property Rights
UHC	Universal health coverage
UN	United Nations
UNAIDS	United Nations Programme on HIV/AIDS
UNCDA	Uganda Non-Communicable Disease Alliance
UNDP	United Nations Development Programme
URSB	Uganda Registrations Services Bureau
WHO	World Health Organization
WOCACA	Women's Coalition Against Cancer in Malawi
WTO	World Trade Organization

2. BACKGROUND

2.1 Introduction

This meeting was convened by CEHURD and KELIN with support from AIDSFOND to feed into a study on intellectual property rights (IPRs) and access to medicines in East Africa. In partnership with ARASA and OXFAM, the meeting brought together 35 participants from 7 countries of Uganda, Kenya, Tanzania, South Africa, Botswana, Burkina Faso, and Malawi. Participants included IP experts, Pharmacists, policy makers, representatives from Government and Civil Society Organizations working on access to medicines within the East and Southern African region

The report captures a two-day programme of presentations, panel discussions and interactive sessions at the Eastern and Southern African regional meeting on harnessing of the TRIPS flexibilities to promote access to medicines. It details key issues that arose from different presentations including; opportunities and challenges of utilizing TRIPs flexibilities to promoting access to medicines; CSO actions that can 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. The report also highlights some strategies proposed in this meeting to be implemented by all stakeholders within the East and Southern Africa to motivate full utilization of TRIPs flexibilities

2.2 Meeting objectives

The meeting objectives were as follows;

1) To share the findings from the ongoing research study on opportunities and gaps in utilizing TRIPs flexibilities to promote access to medicine in Kenya and Uganda;
2) To share experiences on work done in the East Africa and SADC region and gather learnings from countries which have started amending their IP/ Patent legislations to incorporate the TRIPS-flexibilities;
3) To identify both country and regional gaps in reference to Intellectual Property Rights (IPR) and access to medicines and how we leverage on organizational experiences to build momentum for campaigns, and
4) To develop strategies and define a roadmap to support efforts towards the full utilization of TRIPS flexibilities for increased access and affordable cost of medicines in East and Southern Africa
5) To build consensus and enhance the capacity of civil society organizations to build a solid African access movement, which demands for the prioritization of access to medicine at national and regional level

2.3 Welcome note

In his opening remarks, the Executive Director of CEHURD, Mr Mulumba Moses informed the meeting that the convening originated from the realization that enforcement of Intellectual Property Rights (IPR) continues to be one of the biggest challenges in the region where rewarding of those that have innovated needs to be reconciled with their role in giving back to the community. With the current IP conversations moving from accessing medicines for HIV to include diseases like NCDs and TB, Mr Mulumba emphasized that it was key to identify gaps and opportunities for Civil Society Organization (CSO) interventions hence the convening. He wrapped up by welcoming all participants and partners (KELIN, ARASA, OXFAM and AIDSFOND) and commending them for being part of this engagement emphasizing that even with existing IP laws in some countries, it was of utmost importance to campaign and advocate for their implementation.

2.4 Opening remarks

During this session, Mr Koch the Country Director at OXFAM Uganda informed the meeting of the approach Oxfam is taking regarding IPR which is to fight inequality. He specifically spoke to the fact that pharmaceutical industries are the most powerful in driving wealth therefore this could easily lead to inequality as prices are exorbitantly high and mostly affect women and girls. Mr Koch then moved on to share with participants some of the work Oxfam is directly involved in to enhance IPR including; 1) Direct partnership with United Nations (UN) to ensure equality, 2) co-hosting convening with CEHURD and ARASA to reflect on access to medicines in relationship to patents rights and 3) holding policy and decision makers accountable to IP commitments. He concluded his remarks with wishing all participants a productive and successful deliberations.

2.5 Introduction to the meeting agenda and objectives

Mr Allan Maleche (Executive Director, KELIN) took the meeting through the agenda for the meeting highlighting the objectives as;

I. To share experiences of work on Intellectual Properties (IP) and access to medicines for HIV, TB and NCDS.
II. To identify both country and regional gaps in reference to Intellectual Property Rights (IPR) and access to medicines and how we can leverage on organizational experiences to build momentum for campaigns.
III. To develop strategies on how we can move forward in improving access to medicine in East and Southern Africa.

3. CURRENT HEALTH TRENDS AND CHALLENGES WITHIN THE EAC AND SADC REGION

In this session, speakers were Mr Maleche, Mr David Mulabi, Ms Lynette Mabote and Ms Vicki Pinkney were tasked with setting an overview of key health data, indicators and trends in East and South African region while highlighting the state of HIV/AIDS, TB and NCDs. Detailed below are key areas highlighted by each speaker;

3.1 Current health trends and challenges within EAC

Mr Maleche started with sharing KELIN's engagements in advancing IPR in the East Africa Community (EAC); Uganda, Kenya, Tanzania, Rwanda and Burundi. Further highlighted that even with treaties like the East African HIV law, these aren't effectively implemented in many of the countries. With reference to the legal framework, he emphasized the limited regulations and laws in the region although there are many protocols in relation to access to medicines and health services, Mr Maleche also pointed out to the aspects of; 1) Universal Health Coverage, (UHC), whose growing challenges are in public health care facilities that mostly experience lack of medicine and poor quality services resulting in increased out of pocket expenditure and also discriminatory in nature giving the rich more opportunities compared to the less privileged. 2) Majority of the health interventions in the EAC are dependent on donor funding with very limited government investment. Unfortunately, donors aren't considerate of country priorities and community involvement and as a result, dictate where monies go and for what. Mr Maleche concluded by identifying the issues below in relation to the above mentioned heath trends;

a) The manner in which governments are thinking about UHC has been problematic, a number of health interventions are supported by donor funding including HIV, malaria, TB: biggest players are Global Fund, PEPFAR
b) Patients are being detained in health care facilities for not paying their bills, e.g. Directly observed therapy in TB (DOTs): people take medication in front of doctors – total breakdown of trust – developments in this field (in terms of planting chips in people in India) border on infringing on the right to privacy
c) Accountability, right to information and transparency is another issue in East African health sector, Main issues in EAC: UHC, public-private partnerships, corruption and transparency, working with donors
d) Result into patients being detained at hospitals because they can't afford to pay their medical bills which is not only a violation of human rights but also not in line with the aspect of UHC.
e) Breach the right to medicine through encouraging innovations that ensure that patients adhere to medication.
f) Result into government engagement in procurement arrangements without involving people at the grassroots or even training the health workers who are to use the equipment.
g) Encourage embezzlement of funds which restrains donor funding.

As recommendations to address the above issues, he suggested the following;

I. CSOs need to rethink how to push issues of access to medicines forward especially by holding governments accountable to set commitments and laws
II. For UHC to become a more progressive institute, it's important to encourage public-private involvement

3.2 Overview: The NCD scourge in East Africa

During this session, Mr David Mulabi of EAC NCD Alliance painted a picture of the NCD scourge in East Africa raising its impact on households (leads to catastrophic out of pocket expenditure to cater for patients as treatment is very expensive) and the nations (one of the leading cause of mortality and morbidity). However, he pointed out that from 1990 to 2015 only 1% of global resources had been allocated to Non Communicable Diseases (NCDs) care yet it contributes to 70% of global deaths. With specific reference to EA, he mentioned that health financing for NCDs is majorly out of pocket by patients or donor funded, encouraging CSOs to rethink ways of ensuring government involvement in this aspect. Speaking to key issues in terms of access to medicines for NCDs, Mr Mulabi noted the following;

- Lack of access to essential medicines and technologies that are essential for early detection and prevention which makes NCD care more expensive.
- Lack of training of health workers which leads to wrong treatment or diagnosis for patients.
- Late diagnosis which makes it almost impossible for patients to survive.
- The problem of counterfeit medicines on the market leading to escalation of NCDs.
- Limited involvement of the global community in funding NCD prevention and care.
- Majority of the governments focus on NCDs treatment as opposed to NCDs prevention which is unrealistic especially given the minimal resourcing of NCDs prevention.

He closed his presentation with emphasizing that NCDs are not only an issue of poverty, inequality but also social injustice. He therefore recommended the following action points to push forward the work on access to medicines for NCDs;

- Concretization of existing regional and country strategic plans that provide for proper response to NCDs care and treatment
- CSO engagement in especially holding government accountable to NCDs care and treatment commitments
- Capacity building of health workers on machines purchased to treat different NCDs
- Governments to push for prevention and health promotion in order to curb the growing rate of NCDs in the region

3.3 Current health trends and challenges within the SADC region

During her presentation, Ms Mabote gave an overview of the South African Development Community (SADC) region emphasising that the health department is understaffed with only

3 people that coordinate the various ministries of the member states. In regards to the health challenges in the region, she highlighted the following;

- She listed HIV, TB Malaria and Antimicrobial resistance as some of the greatest health challenges in the SADC region specifically singling out increased resistance to HIV and TB. Even with the new drugs being made available on the market, Ms Mabote stated that these were very expensive and could barely be afforded by patients
- HIV incidences and root causes are mostly embedded in structural inequalities and access to medicines
- Regional integrations to support HIV & TB prevention/care are unfortunately through bilateral agreements which on many occasions don't reflect country priorities.
- In the region, focus on disease area mainly leans towards HIV suffocating interventions on NCDs

Recommendations;

- Developing centres of research to treat antimicrobial resistance
- Increasing focus on Sexual Reproductive Health and Rights (SRHR) to increase access to preventive measures such as condoms
- Governments to push forward work on Universal Health Coverage to reduce out of pocket expenditure that in many cases results into increased inequality

During her presentation, Ms. Vicki of Atkinson, NCD Alliance started with sharing her personal experience with NCDs and the continuing battle in dealing with each of them. Pointing to the fact that NCDs are the leading cause of death among women in South Africa, Ms. Vicki went ahead to highlight the growing challenges in addressing NCD care and prevention in the SADC region including;

- The systematic exclusion of people with NCDs to the extent that they can't get the right treatment.
- The gross inequality in NCDs care further leading to poverty due to out of pocket expenditure.
- The lack of clear plans and campaigns to fight or even fund NCDs care or treatment where less than 2% of donor funding ever goes to NCDs care/treatment
- The increasing rate of premature deaths as a result of NCDs where patient pass on before the age of 70 years
- 51% of deaths in South Africa are from NCDs, Cardio-vascular disease and strokes being some of the biggest killers

In her recommendations as response to the above issues, Ms. Vicki suggested as follows;

- Ensuring equitable access to medicines
- Ensuring accessibility to NCD medicines so that they can be afforded by people
- Continued advocacy for UHC and increases resourcing especially by governments to both NCD care and prevention

4. GLOBAL TRADE, HEALTH AND GENERIC MEDICINES

During his presentation on Global Trade, Health and Generic medicines, Mr Mulumba began with a narration of the "Modern Intellectual Property Battle in the sixth Century in Ireland" Mr Mulumba informed the meeting that IP should strike a balance between rewarding innovation and access to the product invented

In reference to the access to medicines index 2018, he highlighted that; 1) globally many people can't access the medicines they need because their prices are too high, 2) Pharmaceutical companies are more sophisticated in how they get essential products to the poor; 3) Cancer incidence continues to rise in LMIC, and 4) Access to pharmaceuticals is better guaranteed through models such as equitable pricing or licensing than through donations.

He then discussed the basics of Intellectual Property (IP); stating that IP are rights in property that are awarded to organizations, institutions or individuals for their creations and they take the form of copy rights, patents, and trademarks which are mainly to prevent new users from using a product without a licence or authorization. With specific reference to patent they must have industrial applicability to pass the test.

In relation to global trade, Mr Mulumba emphasized that since medicines are being dealt with as any other commodity in trade, they are therefore subject to principles of trade. However, the greatest challenge with patents is that they lead to monopoly which results into inventors setting prices that are too high to even be afforded by patients. However, it was emphasized that countries can leverage on TRIPs flexibilities including;

- No Obligation to implement beyond TRIPS (Art 1);
- Parallel Importation (Art 6);
- Freedom in formulating or amending national legislation and regulations (Art 8);
- Government use order;
- Compulsory license;
- Bolar provision
- Pre and post opposition procedures
- Countries determine the appropriate method of implementation (Art 1);

In conclusion, Mr. Mulumba painted a picture of the patent regime in EA highlighting the following;

1) LDCs in the region are taking advantage of the transition period (2030) hence incorporating the TRIPs flexibilities in their legislations,

2) None of the EAC partner states provide for post grant procedures,
3) In Tanzania-mainland, there are no specific provisions concerning the protection of natural substances,
4) In terms of new uses, the Ugandan law permits patents for new use,
5) In terms of patentability, the EAC partner states differ in scope of information taken into consideration to determine prior art,
6) For disclosure requirements, applicants in the region with the exception of Burundi must indicate the best mode for carrying out the invention and finally parallel importation also varies from state to state in the region with Uganda dependent on the consent of the owner of the patent while Rwanda principally follows the national exhaustion doctrine.

Mentioned below are reflections that were made after this presentation;

- Even if IP improves innovation, it's important to ensure exploitation of patents as this will only limit access to essential medicines.
- There is need to think of ways to engage government to implement IP policies that translate into affordable medicines for people
- CSOs should leverage on getting clear information on how international prices are concluded in an innovation so that these can be managed and not exaggerated by inventors
- Identify ways to add traditional medicines to the patent regime
- Proposed reconciliation of IP regime in the regions as countries have different levels of development
- Reconsider branding of medicines as this only makes them more expensive and less affordable

5. REGIONAL AND GLOBAL OPPORTUNITIES

During this session, speakers Mr Chikosa and Ms Tabitha Ha presented key regional and global opportunities and challenges to respond to the existing health challenges in improving access to medicines.

5.1 Regional opportunities

Mr Chikosa highlighted different regional opportunities (African Medicines Agency, African Medical Agency Business Plan, 2017, Resolution 141 of the African Commission on Human and People's Rights, Roadmap for Medicines Access, 2019-2023) as entry points for CSO advocacy with specific reference to the following;

- Road map for access to medicines 2019-2023 to promote medical research which will enhance a balanced IP system promoting both innovation
- Providing technical support and capacity building initiatives in IP to ensure balanced invention for public health needs

- Domesticating TRIPS flexibilities to promote both local productions and access to medicines
- Encouraging country procurements through continental and regional business initiative that encourage renegotiation of prices which will encourage importation of high quality products

He wrapped up his session by outlining some regional challenges such as;

- Lack of political will to incorporate the TRIPs flexibilities
- Inadequate knowledge on the part of technocrats
- Capacity constraints (such as weak legal and regulatory frameworks and weak supporting technical know-how and administrative capacity which remove any incentive or inclination to act on the "flexibilities[APMPA])
- Unbalanced technical support and cooperation
- Policy incoherence
- Unbalanced technical assistance where many of the provisions aren't sufficient for Low and Middle Income Countries (LMIC).

In conclusion, Mr. Chikosa encouraged CSOs to become more aggressive in pushing forward their agenda while being mindful of what's going on.

5.2 Regional and global opportunities and challenges

During her session Ms. Tabitha introduced the participants to human rights in relation to access to medicines highlighting that unfortunately as opposed to their role, patents mostly don't bring patients closer to the medicines that they need as they lead to excessively high prices that people can barely afford. In addition, the patent-based model for incentive research and development is not working for people living with poverty-related diseases or for areas that do not offer sufficient financial incentive for pharmaceutical companies. This leads to 'missing medicines' for tuberculosis, antibiotics, for example. With specific reference to global opportunities to enhance Ms Tabitha pointed to the following;

- Utilizing the TRIPS flexibilities to ensure access to medicines is key and is been pushed by civil society at the national level e.g. Malaysia, Chile
- International agreements like the 2005 Doha Declaration on TRIPS and Public health prioritized public health should be leveraged over financial profit to enhance access to medicines

In her recommendations for CSOs and governments to further work on access to medicines, Ms. Tabitha highlighted the recommendations of the UN High Level Panel on Access to Medicines (HLP), which includes the following;

- National governments should invest 0.01% in health research and Development
- Governments and WHO should explore research and development models that don't rely on intellectual property incentives and prioritize public Research and Development funding in public health

- Governments to call for and negotiate a global R&D agreement
- Enhance transparency including R&D costs
- Leverage the TRIPS flexibilities

She explained how the UN HLP report has received good support from countries in the 'Global South' but resistance from the US, and other countries that have a big pharmaceutical company lobby. Some of the recommendations are being included in the WHO's 'roadmap on access to medicines', however for this to move forward there needs to be more vocal support from southern countries at the WHO Executive Board meeting in January and the World Health Assembly in May. This would help defend against the US which is threatening to weaken the roadmap. The WHO also need countries to demonstrate progress at the next World Health Assembly on the Global Strategy and Plan of Action (GSPOA) on public health, innovation and intellectual property, so that WHO can continue to justify work in this area.

She concluded with recommendations for national governments:

- Use WHO Executive Board Meeting (Zambia And Tanzania Are Members) Or World Health Assembly To Call And Welcome A Strong Roadmap And Report On Their Progress On GSPOA
- Attend The WHO 'Fair Pricing Forum' In Early 2019, South Africa
- Support Civil Society Input And Participation In WHO Regional Committee For Africa Processes, Including Annual Meeting In August 2019 (TBC)
- Call for strong inclusion of Access to Medicines as part of UN High Level Meeting on UHC

6. NATIONAL EXPERIENCES IN ADVOCATING FOR ACCESS TO MEDICINES THROUGH THE UTILIZATION OF THE TRIPS FLEXIBILITIES

This was a panel session moderated by Mr. Paul Ogendi who is an IP expert. The panel consisted of Mr. Denis Kibira, the Executive Director HEPS Uganda, Mr. Simon Kabore, the Executive Director RAME Burkina Faso, Ms. Patricia Asero Ocheng from ICW Kenya and Ms. Lotti Ruther from Health Gap South Africa. In this session, the four panelists shared national experiences in advocating for access to medicines while identifying learnings and opportunities at national and regional level as highlighted below;

- Leveraging on regional regulations/laws for instance the TRIPS flexibilities in order to push forward access to medicines
- Leveraging on in-country policies for instance Buy Uganda Build Uganda (BUBU) to encourage local production and technological transfer
- Push for incorporation of substantive examination in laws/regulations to curb ever-greening
- Advocate for a stricter patentability criteria in terms of what medicines deserve patents
- Advocate for transparency at the patent offices

- Continuous patent opposition both pre and post granting of patents through CSO and activists intervention
- Advocating for parallel importation so as to ensure international exhaustions
- Leveraging on litigation to push forward policy reforms
- Advocate for increased government investment in IP as it's not a priority in majority of the countries in the region
- Capacity building of both CSOs and media so as to get a better understanding of issues related to Intellectual Property Rights and access to medicines
- Work closely with government (MoH) to ensure that anti-counterfeit laws are never regulated
- Leveraging on in-country government initiatives for instance the presidential initiative to issue research grants
- Publication of press articles to create public awareness
- Advocate and promote Research and Development

As way of wrapping up this session, the facilitator emphasized that it was of great importance to ensure constructive research to make policy and law makers interested in being champions in this field thus ensuring continued advocacy in access to medicines.

Reflecting on the panel discussions, participants highlighted that public momentum in advocating for access to medicines is only maintained by continuous provision of information to the public while ensuring joint efforts from lawyers, CSOs and activists.

7. AN OVERVIEW OF THE FINDINGS OF THE EAC AND SADC TRIPS STUDIES

7.1 Utilization of the TRIPS flexibilities for access to medicines within the current intellectual property regime

In this plenary session, Mr Kibira from HEPS provided a synopsis of the results from the ongoing research by CEHURD and KELIN on utilization of the TRIPS flexibilities for access to medicines within the current intellectual property regime. From his presentation, he highlighted the goal/objectives of the study, methodology used, result in regards to patent information and prices. He then brought to the attention of the participants some of the emerging issues from the study that they could focus on as CSOs to ensure access to medicines;

- Limited institutional collaboration
- Low IP cognizance in the national policies
- Medicine ever-greening and over patenting
- Although patents had not been filed for some medicines, the prices in some cases were higher than that of medicines that were on patent.
- Older first line ARVs are being replaced by newer, safer medicines which are more expensive.

7.2 Breaking IP barriers: the SADC region

During her session, Ms Mabote from ARASA brought the participants up to speed in terms of the work that ARASA was doing in relation to IP including; offering of short online courses and Question and Answer options on IP issues on the ARASA website.

Referring specifically to the SADC study under industrialization, Ms Mabote pointed to the fact that the biggest issue realized was that local manufacturers don't feel that there is return on investments in medicines therefore it's of utmost importance for CSOs to understand their work and how to engage them.

8. COUNTRY SPECIFIC HEALTH RELATED CAMPAIGNS

This panel session was moderated by Ms Tabitha Ha from Oxfam. The panel consisted of Ms Sophie Kyagulanyi from Oxfam Uganda, Ms Candice Sehoma from MSF, Ms Leonora Matte from TAC, and Ms Maud Mwakasungula from WOCACA. In this session each panellist shared their success and learnings from specific campaigns in relation to access to medicines. Captured below are key points shared by panellists in running successful campaigns (Treatment for All campaign, Thobeka Daki campaign, Even It Up campaign, Fix the Patent Laws) in relation to access to medicines;

- The importance of carrying out trainings on Intellectual property when doing campaigns on access to medicines as majority of the people don't understand them
- The need to develop and share activists guides that can give people a sense of direction during the campaign
- The patient advocacy approach where you put a face to a campaign to make it more personal and appealing to the community
- The importance of pointing out pharmaceutical greed while advocating for access to medicines
- Need to push for change in laws that affect access to medicines
- The importance of mapping key stake holders/policy makers that can serve as champions for your campaign
- Carrying out research so that you have your facts rights and understand what has been done so far and what needs to be done moving forward
- Media involvement through training on IP and how they can report it but also through the day to day running of the campaign as they help put the word out
- Ensuring community involvement in campaigns
- Have clear goals and objectives of what you need to achieve from the campaign

In speaking to challenges, faced during campaigns, the panelists emphasized that campaigns don't happen overnight, they require a lot of patience, persistence and determination to ensure that they are successful.

Key points of reflection from the participant after this discussion included; leveraging on multi-sector campaigns while involving both CSOs and the private sector as well and

ensuring sustainability of a movement /campaigns and lastly ensuring that violation of human rights issues are clearly brought out in access to medicines campaigns.

9. PRIORITIZING AND DEVELOPING ADVOCACY STRATEGIES

This was an interactive session facilitated by Ms Mabote in which participants were able to identify national and regional advocacy priorities for access to medicines as well as opportunities and challenges. The participants were split into four different groups where they were allowed an hour long discussion in their different groups to identify 4 top regional gaps and areas of intervention. Issues that were raised during this session are clearly outlined in section 11 under "Way forward: Concretisation of Action Plans to promote advocacy for access to medicine".

There was general consensus that NDCs need to be a consistent focus in conversations regarding access to medicines. As we advocate for the incorporation of the TRIPS flexibilities in national legislations, countries need to ensure that local understanding and expertise on access issues are developed on an ongoing basis. This need to be undertaken at every level: among the public, civil society and government. Consistent training and support also needs to be provided in terms of the TRIPS flexibilities' implementation. As an additional point, the rhetoric that some of this information is "too complex" or "too difficult" to be understood and implemented locally needs to shift. If not, we remain handcuffed to a misconception of what African countries are capable.

Engagements with ARIPO should be informed by approved national and regional agreements on IP. Only by presenting ourselves as a collective force will CSOs able develop a coordinated response and to hold ARIPO accountable.

The Pharmaceutical industry needs to be increasingly transparent, and civil society needs to be granted access to a range of information. These include the policies and practices of pharmaceutical companies working in our countries, the tax regimes they operate under, and the by-lateral trade agreements that limit any kind of productive and proactive change. Transparency is essential.

10. MOVING BEYOND IP- DE-LINKAGE MODELS FOR RESEARCH AND DEVELOPMENT

During this session, Ms Tabitha Ha from Oxfam discussed the current de-linkage model of research and development. She highlighted how to move beyond IP while using the De-Linkage model of research and Development (R&D) and notedthat R&D costs involve a wide range of estimates, therefore, it was crucial to ensure transparency so that prices aren't hike in the disguise of high R&D costs. Furthermore, she stated that while R&D is funded by the private sector, public funding is also expended especially at the most risky point of the research through tax payers' monies. Therefore, it was of utmost importance to safe guard public funding through ensuring that R&D is;

- Needs driven
- Equitable

- Effective
- Transparent
- Efficient
- Accessible/Available

Ms. Tabitha explained that De-Linkage is merely a change in the way we finance R&D where "temporary monopolies and the associated high drug prices should not be used to fund pharmaceutical research and development, as well as a set of policy proposals that would replace monopolies and high prices with alternative incentives based upon cash rewards, and expanded funding for research, drug development, and clinical trials through a combination of grants, contracts, tax credits, and other subsidies". De-linkage is therefore about sharing resources, risks and rewards. The benefits of De-Linkage, include;

- Lowers prices and expands access.
- Eliminates price sensitive formularies and high co-payments
- Enhances efficient incentives that target health outcomes, and free access to data
- Enhances fairness in R&D
- Policy coherence

In conclusion, Ms Tabitha recommended the following next steps in ensuring access to medicines; a) National level investment in research and development, b) Transparency of prices for R&D and production costs) Move towards R&D models that 'de-link' the costs of R&D from high prices or sales of the medicines.

11. THE ARIPO PLATFORM, CHALLENGES AND OPPORTUNITIES OF ENGAGING AT THE REGIONAL LEVEL

This session examined the working of ARIPO in terms of support and facilitation of member states in the utilization of the TRIPS flexibilities with specific reference to other regional bodies highlighting challenges and opportunities they offer to promote access to medicines. There were two speakers during this session who addressed the stated topics.

11.1 The ARIPO platform, challenges and opportunities of engaging at the regional level

Ms Sangeeta endeavoured to explain to the meeting about the workings of ARIPO (African Regional Intellectual Property Office) which is comprised of 19 member states 13 of which are from Least Developed Countries (LDCs). Even when this regional body was formed to address issues of World Trade Organization (WTO) member states, it has some countries that aren't WTO member states like Liberia and South Sudan. The body is comprised of different organs; Supreme Decision making body, Administrative Council, working group and the ARIPO secretariat. Basic documents for patents in ARIPO include; Harare protocol, Implementing regulations, administrative instructions and guidelines for examination. Pointing to some of the ARIPO **issues/challenges**, Ms Sangeeta mentioned the following;

- Some of the members of the Harare protocol although WTO member states, are still categorised as Least Developed Countries, which means that they are exempted from having to grant pharmaceutical patents until 2033.

- There is lack of transparency which creates a lot of uncertainty regarding patent status of different products
- Although patents are exempted at national level, they are usually granted at regional level due to lack of substantive examinations with majority of the patents granted by ARIPO rejected by other systems.
- ARIPO grants many secondary patents since the Harare protocol patent examination process isn't rigorous. This results into ever-greening of original patents
- Harare protocol doesn't provide for the post-grant opposition procedure with most of the opposition procedures in national patent legislation being directed at patent fillings processed nationally.
- Lack of transparency and accountability by the ARIPO secretariat
- ARIPO doesn't encourage engagements at national level including ministerial involvement with for instance Ministry of Health
- Limited CSO engagement on ARIPO issues as majority of the member states lack interest.

In addressing way forward to improve ARIPO workings, Ms Sangeeta made the following recommendations for CSOs;

- More organized CSO engagement at both national and regional level in order to hold ARIPO accountable to its commitments
- Advocating for more detailed disclosure of inventions to curb ever-greening
- Encouraging patent applicants to declare International Non-Proprietary Names (INN) issued by World Health Organization (WHO) at the time of filing.
- Advocating for the operationalization of the TRIPS flexibilities in countries where this is applicable
- Advocating for the adoption of more rigorous patentability standards and guidelines for examination of filed pharmaceutical patents
- Lobbying ARIPO secretariat especially at national level through the Ministry of Health and Ministry of Trade, Industry and Economic Development to ensure change for better implementation of patents through ARIPO
- Placement of submission to the ARIPO administrative council to clarify areas of concern
- Documenting of concrete evidence of the impact of patents on access to medicines

11.2 The ARIPO platform, challenges and opportunities of engaging at the regional level

In addressing issues in this regard, Mr Chikosa Banda made reference to the Malawi High Level meeting and council of ministers meeting as great opportunities for engagement to enhance access to medicines in the regions. He made the following recommendations for CSOs to further enhance access to medicines;

- Collaboration with ministries departments and IP responsible agencies.
- Examining ways to incorporate waivers on TRIPS flexibilities.

- Regarding the ARIPO problems, he encouraged that CSOs first establish what the problem is then establish how they can hold it accountable to its commitments and continuously follow up to ensure that they come through on their commitments.
- Further still, he emphasized that it was of great importance to always engage government in interventions to push for reforms in IPR especially by mapping government champions
- Working closely with development partners like UNDP who can help us push our agenda forward
- Prepare policy briefs on key issues were are working on
- Involvement of patient groups that are affected by the issues that we are trying to advocate for
- Convene capacity building meetings with stakeholders like the administrative council for them to better understand our issues and why it's of great importance for them to respond to them positively

12. FEEDBACK FROM POLICY LEADERS

During this session, Mr Mulumba allowed the policy makerspresent in the meeting to give their thoughts on the issues that had been raised during the two day discussion. Below are some of the issues raised by the two officials;

12.1 Uganda Registrations Services Bureau (URSB)

Mr Agaba the IP Manager at URSB started his presentation by explaining to the meeting what URSB is, stating that it's an agency of the government under the Ministry of Justice doing company registry, official receivers and registers of marriage among others. He then informed the meeting that the Industrial Property Act in Uganda is one of the most progressive Act especially in terms of technology. In relation to the meeting, he recommended the following in order to push this agenda forward:

- In terms of accountability, he encouraged CSOs in Uganda to always raise their concerns to URBS as they are willing to intervene and work with citizens to improve services in the country.
- He further encouraged all CSOs to work diligently with their governments so as to push forward matters of IPR ensuring that they are on the same page with government and only then can we realise change in these issues.
- He also advised CSOs to be more comprehensive in their approaches while dealing with government encouraging incorporation of different aspects in dealing with particular sector needs.
- Lastly he emphasized the importance of inviting more policy makers to future convenings such as this to not only build their capacities in areas of interest but also build champions that can rally for our needs.

12.2 Ministry of Health

Mr Morries Seru the head of Pharmaceutical Department under the Ministry of Health informed the meeting that there was no activity to deal with IP incorporated in the strategic plan even on the component of R&D. He therefore encouraged CSOs especially in Ugandan to;

- Lobby for meetings with government to ensure that IP issues quickly become one of the priorities in the Ministry of Health and are reflected in the strategic plan
- Push forward access to medicines issues through the Medicines Transparency Alliance (MeTA) through the Coalition for Health Promotion and Social development (HEPS) secretariat
- Encourage the government to allocate resources to NDCs prevention since there are barely any funds to enhance preventive strategies of NCDS
- Always speak from an informed point of view where CSOs first understand the policies, challenges and government position on an issue so that they know how best to engage government.

13. WAY FORWARD: CONCRETISATION OF ACTION PLANS (INCLUDING TIMELINES, KEY MILESTONES AND RESOURCE NEEDS) TO PROMOTE ADVOCACY FOR ACCESS TO MEDICINE

As a follow up from the group discussions, Mr Maleche and Ms Mabote presented to the participants pertinent issues emanating from the four groups.

The areas included;

- **Capacity building** of law makers, decision makers, CSOs and communities around IP and access to medicines through; trainings, building a platform to share in country advocacy /litigation experiences to further coalition building and joint campaigns
- **National and regional Law reforms** through; 1) incorporating of TRIPS flexibilities in national laws and see to it that they are utilized, 2) identifying of national laws that can be used to promote traditional knowledge advocacy, 3) ARIPO law reform through making recommendations on how to take this forward, and 4) analyzing of regional level registration issues
- **National, regional and Global level advocacy** through**;** Analysis of drugs that aren't easily accessible to people mostly due to ARIPO processes, in country advocacy for countries that have IP waivers until 2033 to leverage on this opportunity to establish reforms, advocacy for accountability and transparency at ARIPO level, leveraging on recommendations from high level meetings to ensure that they are applied in country. Regionally; Capacity building of ARIPO patent examiners, Lobbying ARIPO secretariat to be transparent, map governments that can champion advocacy for access to medicines at ARIPO level, and prepare policy briefs that can be shared with members of administrative council. Globally; build a strong movement, CSO position paper on issues of access to medicines, following up with WHO regarding

commitments made at high level meetings, and participation in WHO meeting in South Africa in 2019.

Additional steps moving forward

- Mapping key dates at EAC and SADC level and leverage on them as important areas of CSO intervention
- Identify key regional Acts that can be used by all countries to push for access to medicines
- Capacity building for media on how to report on IP issues
- Establish ways in which South African CSOs can support CSOs in other countries within the region in IP campaigns
- Advocate for issues around De-linkage, registration and Research and Development.

14. WRAP UP AND NEXT STEPS

This being the final session, Mr Maleche facilitated an engaging discussion with participants probing for organizational and country commitments as next steps to take this work forward with identifying potential areas of collaboration. Illustrated in the table below are the commitments from some of the participants;

ORGANIZATION/COUNTRY	COMMITMENT	PRESENTED BY
Kenya and Uganda	➢ To integrate voices from this process to finalize TRIPS flexibilities study ➢ 2 national consultations on issues emerged (ARIPO & specific medicines) from the meeting to feed into the study and concretize advocacy plan ➢ Regional consultations that will support advocacy campaign ➢ Identify opportunities to engage ARIPO ➢ Campaigns on access to medicines in partnership with OXFAM ➢ EAC STRIPS protocol to explore opportunities directly out of the current study and engage policy makers	Mr Mulumba
Health Gap South Africa	➢ ARIPO reform ➢ Registration issues ➢ Through the "Fix a patent law reform" to engage policy makers, parliament to lobby for policy reform ➢ Patent analysis for medicines	Ms Lotti Rutter
OXFAM	➢ Conduct capacity building for activists to ensure they get a better understanding of IP issues and	Ms Sophie Kyagulanyi (Oxfam Uganda) and

	how to intervene and advocate for change ➢ Supports CSOs/activists to connect at global level ➢ Coordinate and support international campaigns	Ms Tabitha Ha (Oxfam International)
ARASA	➢ Convene meeting with SADC members of parliament to push forward policy reform recommendations ➢ Continue to offer online IP short courses on introduction to IP ➢ Strengthen the capacities of CSOs in Zimbabwe and Mozambique on IP	Ms Lynette Mabote
Bonela	➢ Advocacy to push government to implement policies in relation to Intellectual Property Rights	Ms.Tebogo Carensanye

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ANNEX 1: AGENDA

DAY 1 Overall facilitator: Anne Lumbasi	
Overview of health indicators and trends in the region and recent developments on intellectual property, innovation and access to medicines	
8:00am – 08:30am	**Registration**
8:30am – 09:30am	**Session 1: Opening remarks** Welcome note: Executive Director, CEHURD Opening remarks: Country Director, OXFAM Introduction to the meeting agenda and objectives: Executive Director, KELIN
9:30am – 10:30am	**Session 2: Current health trends and challenges within the EAC and SADC region** **Speakers:** Mr David Mulabi, EAC NCD Alliance Mr Allan Maleche, KELIN- EAC (HIV & TB) Ms Lynette Mabote, ARASA – SADC region (HIV, TB) Ms Vicki Pinkney-Atkinson , SA NCD Alliance
10:30am – 11:00am	**Tea Break**
11:00am – 12:00pm	**Session 4: Tackling access to medicines issues through intellectual property** **Speaker:** Mr Moses Mulumba, CEHURD
12:00pm – 13:00pm	**Session 3: Regional and Global Opportunities** **Speakers:** Mr Chikosa Banda, IP consultant Ms Tabitha ha, Oxfam
13:00pm – 14:00pm	**Lunch**
14:00pm – 15:00pm	**Session 5: National Experiences in advocating for access to medicines through the utilization of TRIPs flexibilities** **Facilitator:** Mr Paul Ogendi, IP expert **Speakers:** Mr Denis Kibira – HEPS

	Ms Patricia Asero Ochieng – ICW, KENYA Ms Lotti Rutter – Health Gap South Africa Mr Simon Kabore – RAME, BURKINA FASO
15:00pm – 16:00pm	**Session 6: An overview of the findings of the EAC & SADC TRIPs studies** **Speakers:** Mr Denis Kibira – HEPS Ms Lynette Mabote – ARASA Plenary
16:00pm – 16:30pm	**Tea break**
16:30pm – 17:30pm	**Session 7: Specific health related campaign** **Facilitator:** Ms Tabitha Ha **Organizations:** Ms Sophie Kyagulanyi, Oxfam Uganda MSF/TAC- Treatment Action Campaign, Fiscal justice for health Ms Maud Mwakasungula, Women's coalition Against Cancer in Malawi: UICC's treatment for all campaign
18:00pm – 20:00pm	**Group Dinner**
DAY 2 Overall facilitator: Lucy Ghati, KELIN	
Galvanising regional forums to harness full utilisation of the TRIPS flexibilities	
8:30am – 8:45am	**Session 8: Recap key points from day 1** **Facilitator**: Ms Joselyn Nakyeyune, CEHURD
8:45am – 9:45am	**Session 9: Prioritizing and developing advocacy strategies** Group discussion facilitated by Ms Lynette Mabote, ARASA
9:45am – 10:30am	**Session 10: Moving IP – De-linkage models for research and development (R&D)** **Speaker:** Ms Tabitha Ha, Oxfam **Plenary**
10:30am – 11:00am	**Coffee Break**
11:00am – 12:00pm	**Session 11: The ARIPO platform, challenges and opportunities of engaging at the**

	regional level **Speakers:** Ms Sangeeta Shashikant, Third World Network Mr Chikosa Banda, IP consultant
12:00pm – 13:00pm	**Session 12: Feedback from Policy Leaders** **Speakers:** Mr Agaba Gilbert, URSB Mr Seru Marries, MoH
13:00pm – 14:00pm	**Lunch Break**
14:00pm – 15:00pm	**Session 13: Way forward; Concretisation of Action plans (including timelines, key milestones and resource needs) to promote advocacy for access to medicines** **Facilitator:** Mr Moses Mulumba, CEHURD
15:00pm – 16:00pm	**Wrap up and next steps** **Facilitator:** Mr Allan Maleche
Logistics & Networking **Departure at Leisure**	

ANNEX 2: LIST OF PARTICIPANTS

No	Name	Organisation
1.	Mr Moses Mulumba	CEHURD
2.	Mr Maleche Allan	KELIN
3.	Mr Denis Kibira	HEPS
4.	Mr Vincent Koch	OXFAM
5.	Ms Lynette Mabote	ARASA
6.	Ms Tabitha Ha	OXFAM
7.	Ms Vicki Pinkney	Atkinson, SA NCD Alliance
8.	Mr Chikosa Banda	IP consultant
9.	Mr David Mulabi	EAC NCD Alliance
10.	Mr Paul Ogendi	IP expert
11.	Ms Patricia Asero Ochieng	ICW Kenya
12.	Ms Lotti Rutter	Health Gap
13.	Mr Simon Kabore	RAME Burkina Faso
14.	Ms Sophie Kyagulanyi	OXFAM
15.	Ms Maud Mwakasungula	WOCACA
16.	Ms Candice Sehoma	MSF
17.	Ms Leonora Matte	TAC
18.	Ms Ela Kasirye	VPCDN
19.	Mr Seru Morries	MoH
20.	Mr Agaba Gilbert	URSB
21.	Mr Christopher Kwizera	UNCDA
22.	Ms Catherine Karekezi	NCDA- Kenya
23.	Ms Cassidy Parker	Put/ARASA
24.	Ms Gloria M. Kida	Tanzania Breast Cancer Foundation
25.	Ms Esta Mnzava	East African Health Platform

26.	Ms Jacinta Nyochae	AIDS Law project
27.	Ms. Tebego Carensanye	BONECA
28.	Ms. Rose Kaberra	ITPC-EA
29.	Mr. Kenneth Muhangi	KTA Advocates
30.	Mr. Edgar Tabaro	KTA Advocates
31.	Mr. Mbabazi Norman	IP Centre
32.	Ms. Lucy Ghati	KELIN
33.	Ms. Anne Lumbasi	CEHURD
34.	Mr. Richard Hasunira	CEHURD
35.	Ms. Joselyn Nakyeyune	CEHURD

ANNEX 3: RELATED DOCUMENTS

a. Power point presentation of “Advocacy against Bangui Agreement of 1999”
b. Power point presentation of “Patent Law Reform in South Africa: Lessons for activists”
c. Power point presentation of “Patent law reform in South Africa”
d. Power point presentation of “Regional opportunities”
e. Power point presentation of “The ARIPO platform, challenges and opportunities of engaging at the regional level”
f. Power point presentation of “The ARIPO platform, challenges and opportunities of engaging at the regional level”
g. Power point presentation of CEHURD and KELIN study “opportunities and gaps in utilizing trips flexibilities on access to medicines for HIV, TB and NCDS”
h. Power point presentation on “De-linkage”
i. Power point presentation on “Global trade, health and generic medicines for Africa”
j. Power point presentation on “Inequality and public spending- Fiscal Justice”
k. Power point presentation on “Overview: NCD Scourge in East Africa”
l. Power point presentation on “Regional & global Opportunities and challenges”
m. Power point presentation on “UICC treatment for all”
n. The ARIPO-protocol on patents
o. www.delinkage.org