

**CIVIL SOCIETY OPEN LETTER ON IMPLEMENTATION OF PUBLIC
HEALTH SENSITIVE TRIPS FLEXIBILITIES IN ARIPO's HARARE
PROTOCOL**

15th November 2019

Dear Honourable Ministers,

The undersigned civil society organizations (CSOs) call on Ministers participating in the ARIPO Ministerial Meeting next week in Liberia to establish a transparent Member State TRIPS Flexibilities Working Group that includes participation of civil society as well as public health and development experts from UNDP, WHO, UNCTAD and UNAIDS to discuss implementation of public health sensitive TRIPS flexibilities in the Harare Protocol in particular the detailed proposals that have been presented by civil society.

The 16th Session of the Council of Ministers of ARIPO mandated the Secretariat to “explore and formulate concrete proposals aimed at addressing policy and legal incoherencies that impact access to health technologies and in the Member States of ARIPO, take actions accordingly and report to the Governing Bodies of the Organization”.

This mandate followed from the 2017 High-Level Meeting on Promoting Policy Coherence on Health Technology Innovation and Access (HLM) in the ARIPO region organized by the Government of Malawi with the support of the United Nations Development Program (UNDP). The HLM identified the following as critical at the Regional Level for improving policy coherence:

- The need for ARIPO Member States to align the Harare Protocol and ARIPO patent practices with the national public health and industrial policy objectives of ARIPO Member States, including the 13 which are least developed countries, recognizing that all ARIPO Member States have the need to increase affordable access to medicines and vaccines and that some have prioritized local pharmaceutical production.
- Examining ways of incorporating TRIPS flexibilities including the WTO LDC Waiver;
- Strengthening the ARIPO patent examination guidelines and practices to incorporate a public health perspective; and
- Including a regional patent opposition mechanism.

Multiple health challenges affect African countries with severe financial constraints being a major obstacle for African nations. This is especially true as countries move towards Universal Health Coverage, and countries transition out of eligibility of various global health financing programs such as the Global Fund to Fight AIDS, Tuberculosis

and Malaria and GAVI and will be expected to increase domestic spending on health and bear the full cost of drugs, vaccines, and other medical technologies.

In addition, African Heads of States have also adopted several regional instruments such as the African Union Commission's Pharmaceutical Manufacturing Plan for Africa, the East African Community (EAC) and the Southern African Development Community (SADC) pharmaceutical business plans. These strategies and plans aim to address the challenge of access to affordable medicines in the region and increase self-reliance by promoting regional/local generic production.

Numerous international instruments and expert reports call on countries to make full use of TRIP flexibilities to promote access to health technologies. This includes the 2016 UN Secretary General's High-Level Panel on Access to Medicines, the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020, the RIO+20 United Nations Conference on Sustainable Development (UNCSD), the 2018 UN General Assembly Declaration on the Prevention and Control of Non-communicable Diseases and the 2018 UN General Assembly Declaration on the Fight Against Tuberculosis.

For ARIPO's 18 Members States, national implementation of TRIPS flexibilities is insufficient. The majority of pharmaceutical patents are processed by ARIPO, which also administers the granting of patents. Hence Harare Protocol's rules and ARIPO's practices have a direct impact on whether a country's population has access to affordable medicines and whether the ambition of a robust generic industry as envisaged in multiple national and regional pharmaceutical business plans will be realized.

In this context, we are extremely concerned that ARIPO is failing. Key TRIPS flexibilities such as the Least Developed Country (LDC) patent exemption for pharmaceutical products has not been operationalized in the Harare Protocol. In addition, worryingly despite pharmaceutical patents being excluded in some jurisdictions e.g. in Uganda, Rwanda and Liberia, ARIPO continues to persist with granting such patents at the regional level, hence undermining national implementation of the pharmaceutical exemption.

We are also very concerned by the extremely permissive patent examination rules and lax practices in ARIPO, which has facilitated and supported patent holding companies to continue their notorious practice of 'patent evergreening' i.e. prolonging their market monopoly by obtaining patents on simple changes to known compounds. This is an abuse of the patent system for it unduly blocks generic competition, severely undermining access to medicines and public health. Numerous frivolous patents have been granted due to the absence of rigorous patent examination standards and practises.

Further, administrative third party pre and post grant opposition systems, commonly implemented in other countries are absent from the Harare Protocol.

To address these policy and legal incoherencies, in June 2019, sixty-one civil society organizations presented concrete proposals to the ARIPO Secretariat building on the discussions and outcome of the 2017 HLM in Malawi.¹ However disappointingly to-date, no action has been taken to initiate a discussion on these proposals, although civil society has expressed a sincere desire to constructively engage with ARIPO Member States on possible changes to the Harare Protocol to take advantage of public health sensitive TRIPS flexibilities.

Hence, we call on Ministers participating in the upcoming ARIPO Ministerial Meeting to establish a transparent Member State TRIPS Flexibilities Working Group that includes participation of civil society as well as public health and development experts from UNDP, WHO, UNCTAD and UNAIDS to discuss implementation of public health sensitive TRIPS flexibilities in the Harare Protocol in particular the detailed proposals that have been presented by civil society.²

SIGNATORIES

1. Africa Young Positives Network (AY+) (regional network).
2. AIDSLaw Project, Kenya
3. Alliance of Women Advocating for Change (AWAC), Uganda
4. Achikondi Women's Health Clinic, Malawi
5. AIDS and Rights Alliance for Southern Africa, Namibia.
6. AIDS Information Centre (AIC), Uganda
7. Angaza Foundation, Malawi
8. Association of Liberian People Living with HIV and AIDS (ALL+), Liberia
9. Bwalo Initiative, Malawi
10. Centre for Development, Malawi
11. Cancer Survivors Quest, Malawi
12. Centre for the Development of People (CEDEP) Malawi
13. Center for Health, Human Rights & Development (CEHURD), Uganda
14. Centre for Participatory Research and Development (CEPARD), Uganda
15. Centre for Human Rights Education Advice and Assistance (CHREAA), Malawi
16. Child Rights Information and Documentation Centre (CRIDOC), Malawi
17. Coalition for Health Promotion and Social Development (HEPS Uganda)
18. Collective Action for Sustainable Community Development (CASCOD), Malawi
19. Dandora Community AIDS Support Association (DACASA), Kenya

¹ https://www.kelinkenyia.org/wp-content/uploads/2019/06/CSO_TRIPSFlexibilitiesProposalsForARIPOFinal-with-sign-ons-4-6-19.pdf

² https://www.kelinkenyia.org/wp-content/uploads/2019/06/CSO_TRIPSFlexibilitiesProposalsForARIPOFinal-with-sign-ons-4-6-19.pdf

20. Development for Peace Education, Lesotho
21. Drug Fight Malawi
22. East African Health Platform (EAHP) (regional network), Tanzania
23. Female Sex Workers Association (FSWA), Malawi
24. Health GAP, Kenya, Malawi, Mozambique, Tanzania, Uganda, Zimbabwe
25. Human Rights Research Documentation Center (HURIC), Uganda
26. Human Rights Awareness and Promotion Forum (HRAPF), Uganda
27. International Community of Women Living with HIV/AIDS, East Africa (ICWEA)
28. International Community of Women Living with HIV, Kenya
29. International Treatment Preparedness Coalition (ITPC) Kenya
30. Jiya-Vannie Diabetic Foundation, Malawi
31. Karonga Debate Club, Malawi
32. Kasese Women's Health Support Initiative, Uganda
33. Kenyan Network of Cancer Organizations (KENCO), Kenya
34. Kenya Legal & Ethical Issues Network on HIV and AIDS (KELIN), Kenya
35. Kenya Sex Workers Alliance (KESWA), Kenya
36. Kenya Treatment Access Movement (KETAM), Kenya
37. Kisumu Post Test Club, Kenya
38. Kenya Cancer Association, Kenya
39. Ladder for Rural Development Organization, Malawi
40. Lean on Me Foundation, Kenya
41. Liberia Initiative for the protection of Rights, Identities, Diversity and Equality (LIPRIDE), Liberia
42. Liberia National Network of Person Living with HIV and AIDS (LIBNEP+), Liberia
43. Liberia Network of Young People and Adolescents Living with HIV (LNYA+), Liberia
44. Malawi Network of Religious Leaders Living with or Personally Affected by HIV and AIDS (MANERELA+), Malawi
45. Malawi Health Equity Network, Malawi
46. Mama's Club, Uganda
47. Most at Risk Populations' Society in Uganda
48. National Cancer Association of Malawi
49. National Community of Women Living with HIV, Uganda
50. National Forum for People Living with HIV/AIDS (NAFOPHANU), Uganda
51. National Network of TB Champions in Kenya
52. National Empowerment Network of PLHIV in Kenya (NEPHAK)
53. Network of Post Test HIV and Aids Community Organization
54. NGO Gender Coordination Network, Malawi
55. Nitwiriza Counseling Centre, Uganda
56. Palliative Care Association of Malawi (PACAM), Malawi
57. Pan-African Treatment Access Movement (PATAM), Zimbabwe
58. Peer to Peer Uganda
59. Positive Women with Disabilities Uganda (POWODU), Uganda
60. Peoples Health Movement Kenya
61. People's Health Movement Tanzania
62. People's Health Movement Uganda
63. People's Health Movement Zambia
64. Positive Men's Union, Malawi

65. Prevention Care International (PCI), Uganda
66. Reaching the Unreached Tanzania (RUT), Tanzania
67. Reproductive Health Uganda
68. Sauti Skika, Kenya
69. Sexual Minorities Uganda (SMUG), Uganda
70. Sisters for Sisters, Liberia
71. Southern African Programme on Access to Medicines and Diagnostics (SAPAM)
72. Southern and Eastern Africa Trade Information and Negotiations Institute (SEATINI), Uganda
73. STIGMALESS, Uganda
74. Stop AIDS in Liberia (SAIL), Liberia
75. Swaziland Positive Living (SWAPOL), Eswatini
76. Tanzania Network of Women Living with HIV and AIDS, Tanzania
77. TB Pamoja group, Kenya
78. The Action Group for Health, Human Rights and HIV/AIDS
79. The People's Matrix Association, Lesotho
80. Treatment Advocacy and Literacy Campaign (TALC), Zambia
81. Treatment Action Campaign, Kenya
82. Uganda National Health Consumers Organisation, Uganda
83. Uganda Harm Reduction Network, Uganda
84. Uganda Health Sciences Press Association, Uganda
85. Uganda Network on Law Equality and Ethics (UGANET), Uganda
86. Uganda Network of AIDS Services Organization (UNASO), Uganda
87. Uganda's young positive networks (UNYPA), Uganda
88. Uganda Young Positives, Uganda
89. United Sisters, Liberia
90. Womenplus Against TB & HIV, Kenya
91. Women's Coalition Against Cancer (WOCACA), Malawi
92. Women for Fair Development (WOFAD), Malawi
93. Women Fighting AIDS in Kenya (WOFAK), Kenya
94. Women's Probono Initiative (WPI), Uganda
95. Kasese Women's health support Initiative, Uganda
96. White Ribbon Alliance (WRA), Uganda
97. Youth Alliance for Social Empowerment and Development, Malawi
98. Zimbabwe National Network of People Living with HIV (ZNNP+)