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90 organisations demand reform of African Regional Patent Office (ARIPO) to improve access to medicines

ARIPO's rules on granting patents favours the interests of pharmaceutical companies over peoples' right to access to affordable medicines

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Monrovia, Liberia, 18th November 2019 — More than 90 civil society organisations are today calling for urgent reform of the Harare Protocol of the African Regional Intellectual Property Organization (ARIPO) in order to ensure people have access to more affordable medicines. The organisations demand that Ministers representing ARIPO Member States — who are meeting for the ARIPO Administrative and Ministerial Councils from 18 to 21 November in Liberia to change how they grant patents on medicines, in order to promote cost cutting generic competition.

ARIPO is a regional mechanism that administers the filing, examination and grant of pharmaceutical patents for 18 countries in the region that are contracting parties to the Harare Protocol. This Protocol is the legal framework that sets out the rules for the administration of patents, utility models and industrial designs for parties to the Protocol.

"To combat growing epidemics such as drug-resistant tuberculosis, diabetes and cancer — where a single drug can cost hundreds or thousands of dollars to treat just one person — ARIPO's rules for granting patents, laid out in the "Harare Protocol," must be changed in order to facilitate access to more affordable generics, rather than granting undeserving patent monopolies to multinational pharmaceutical companies," explained Lotti Rutter from Health GAP, a global HIV advocacy organisation working across several countries in the region. "ARIPO Member States have some of the highest burdens of disease in the world. The price of medicines in these countries determines whether the government will be able to provide treatment for these diseases to its people or not. When medicines are unaffordable, people pay with their lives."

To date ARIPO has failed to utilise many of the key public health safeguards allowed under international law and championed by national and regional bodies throughout Africa. Instead, ARIPO continues to grant multiple unworthy pharmaceutical patents that make medicines unaffordable to patients and governments. Not only does excessive, unnecessary patenting have a direct impact on whether countries have access to affordable medicines, but also on whether the ambition of a robust generic industry in the region will be realised.

"We are gravely concerned that governments who make ARIPO's rules are failing to promote public health and are prioritising patent fee collection instead. While global patent laws recognise and exempt least developed countries (LDCs) from granting any pharmaceutical patents, ARIPO continues to undermine this right by granting patents at the regional level despite the fact that the vast majority of ARIPO member states are LDCs. ARIPO's grant of pharmaceutical product patents is also inconsistent with national patent laws such as in Uganda, Rwanda and Liberia that have nationally implemented the pharmaceutical exemption," argued Moses Mulumba from the Centre for Health, Human Rights and Development (CEHURD) in Uganda.

Furthermore, the lax application of patentability standards and the absence of rigorous substantive examination in ARIPO has allowed pharmaceutical companies to continue their notorious practice of "patent evergreening". By obtaining patents over minor changes to known compounds, pharmaceutical companies prolong their market monopoly beyond the initial 20 year patent term. This type of excessive patenting — including granting multiple patents on new forms, new uses and new formulations of a known compound — blocks competition from more affordable generic versions and maintains artificially high prices for extended periods of time. This is hugely problematic for public health.

The situation is worsened, as other key public health safeguards that are common in countries — such as administrative procedures to allow third parties to oppose the grant of pharmaceutical patents — are absent from the Harare Protocol.

In 2017 the Council of Ministers mandated the ARIPO 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". However, to date no action has been taken to reform the Harare Protocol and improve ARIPO's practices and procedures that will rectify this situation.

"Civil society have presented concrete proposals to the ARIPO Secretariat on what reforms need to take place¹. However disappointingly to date, no action has been taken to discuss these proposals. We have repeatedly attempted to engage constructively in the process and have presented multiple requests to participate, but have been shut out despite early promises that ARIPO would engage with civil society stakeholders and experts," says Allan Maleche, from the Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN).

"Now is the time for urgent action. This is not just about legal technicalities — ARIPO's decisions affect the lives of many people living across the region. In particular, we call on Ministers and Heads of Patent Offices attending the ARIPO Governing Body meetings in Liberia to ensure that ARIPO establishes a credible and transparent "TRIPS Flexibilities Working Group" to discuss and develop proposals to implement public health safeguards in the Harare Protocol, including those recommended by civil society. Further they must ensure civil society — as well as public health and development experts such as UNDP, WHO, UNAIDS and UNCTAD — are permitted to participate and sufficiently represented, with timely access to information about meetings and documents."

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 $^{^{1}\} https://www.kelinkenya.org/wp-content/uploads/2019/06/CSO_TRIPSFlexibilitiesProposalsForARIPOFinal-\ with-sign-ons-4-6-19.pdf$