Global Leaders in the HIV Response Call for Access to Long-Acting Medicines

Despite scientific breakthroughs, 1.3 million people contracted HIV in 2023, and there is still one AIDS-related deaths every minute.

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Today, at the 55th Programme Coordinating Board for the Joint United Nations Programme on HIV/AIDS (UNAIDS), HIV leaders from across the world called for access to long-acting medicines for everyone who would benefit from them, to build toward a new era in the AIDS response.

Over the last two years, scientific breakthroughs have brought to the fore a new class of anti-HIV medicines with long-acting effects, allowing people at risk of HIV infection and those living with the virus to take medicines every few months. One is injected just twice a year. Recent studies have shown these medicines to be among the most effective ever developed. One study showed zero new infections among young African women using long-acting prevention drugs, while a study among key populations showed them more effective than oral medicines. Another study highlighted at the session showed encouraging results using long-acting HIV treatment in low- and middle-income countries.

At the “Leadership in the AIDS Response” session at the UNAIDS board, government officials, researchers, manufacturers, and civil society called for accelerating global access to use these scientific breakthroughs to interrupt the continuing AIDS pandemic. Despite existing HIV prevention tools, in 2023 an estimated 1.3 million people newly contracted HIV – two every minute. Despite HIV treatment, there is still one AIDS-related deaths every minute.

Winnie Byanyima, Executive Director of UNAIDS, said: “We can usher in a new era by connecting technological innovation with access for all. Let us act boldly together, bring down the curve of new infections, and dramatically accelerate the HIV response.

“Let us learn from the painful lessons of the past so that we write a new story now. In the late 1990s and early 2000s, even after antiretroviral medicines were proven to be effective and rolled out in high-income countries, 12 million people on this continent still died waiting for those drugs. We can - and must – do better with long-actings. We urge the companies producing these medicines to expand their generics licenses. And we support governments making use of all their

legal flexibilities to get access to affordable medicines," she said. "The usual trajectory is that the Global South waits years before the science reaches them. What if we do not wait for years, what if we ensure that science is treated as the public good it is? What if we disrupt the far too slow trajectory we are on and shift to a trajectory that accelerates progress, ends the pandemic, enables sustainability, and can be a model for the world?"

Secretary Ethel Maciel, Secretary of Health of Brazil, said: "Brazil has a long history of making use of technology in the HIV response. The possibility of having new long-acting medicines in the global response is a great opportunity. But we have the huge challenge of the high cost of these medicines, and the difficulty for a range of countries, including ours, to access them. "Brazil is committed to work together in the fight to ensure that this new technology is made available to all people all over the world who are at risk of and living with HIV."

Dr Cissy Kityo, Executive Director of the Joint Clinical Research Centre, Uganda, a leading scientist working on trials of long-acting medicines said: "We have these fantastic new tools. The technology of long-acting ARV's antiretrovirals is remarkable. The evidence is now clear that long acting medicines will be game-changers for both prevention and treatment. The science is in, the question is how well we will use it."

Mr Javier Padilla Bernáldez, Secretary of State for Health, Spain, said: "This new long-acting technology puts us in an exceptional situation, not an ordinary one, an opportunity that we cannot afford to miss. Long-acting medicines can change the landscape of the HIV response. But if this game-changing innovation did not reach the people it would be a nothing-changer! "We need to remember the 2000s' fight for universal access. We cannot repeat the same mistakes and delays of before. We need to ensure that no countries should be pressured if they choose to use the safeguards in the TRIPS agreement. The inequality gap is a global problem. We need a universal perspective, so that all countries, including middle-income countries, are included."

Dr Sylvia Vito, Africa Head of EVA Pharma, a company in Egypt licensed to produce a generic version of lenacapavir, said: "We are a company that will not sit comfortably, but rather be in a good hurry to support the unmet HIV medical needs for our people. We intend to move fast on product development, production, and eventual registration. It is our intention that high quality long-acting generic ARV medicine will not only be available, but made accessible and affordable as well. We intend to beat the current standard of care in HIV treatment and prevention by going further to improve on the current options for patients in low and middle-income countries."

The importance of generic production was central to the interventions of speakers. Several speakers noted the obstacle that much of Latin America, a region of rising HIV infections, has been excluded from companies' voluntary licenses for generic versions. This is despite Brazil, Peru, Mexico and Argentina participating in clinical trials. Speakers highlighted the importance of using TRIPS flexibilities for enabling access under World Trade Organization rules, which can enable governments to supply its citizens with generic versions of patented treatments either through domestic production or imports. In the 2021 Political Declaration on HIV/AIDS, countries committed to make use of TRIPS flexibilities, specifically geared to promoting access to medicines.

Although Gilead Sciences, the producer of lenacapavir, one of the new class of long-acting medicines, has not yet announced the price of its product for use as PrEP, it costs around $40,000 per person per year in the United States where it is used for treatment. However, experts have estimated that it could be produced and sold for $40 per person per year, in line with UNAIDS estimates for sustainable pricing in low- and middle-income countries. Speakers highlighted opportunities to bring down the price of these medicines through generics, expanded local and regional production, and the use of TRIPS flexibilities by member states.

One important opportunity for progress emphasized by speakers was to build on the progress on multilateral collaboration made by Brazil, which as chair of the G20 in 2024, successfully secured worldwide support for the Global Coalition for Local and Regional Production, Innovation and Equitable Access, laying the foundations for a greatly expanded and more equitable access to medicines.

Speakers noted also the importance of choice, and of widening access to a range of new technologies, of which lenacapavir is just one. Speakers highlighted important current innovations including 2-monthly injectable cabotegravir and a three-month dapivirine vaginal ring, as well as new technologies currently in the pipeline including a once-a-month pill may move into phase 3 trials next year.

Reinforcing the importance of accelerating access to long-acting medicines, The New England Journal of Medicine has today published an article by UNAIDS Executive Director Winnie Byanyima, Linda-Gail Becker of the Desmond Tutu HIV Centre, and Matthew Kavanagh of Georgetown University's Center for Global Health Policy and Politics, entitled "Long-Acting HIV Medicines and the Pandemic Inequality Cycle — Rethinking Access".

The article showed that the "pandemic inequality cycle" in HIV has usually meant a decade delay between access to breakthrough HIV technologies in the global North and the global South.

In their article the authors write: "The world may look back on 2024 as a pivotal time in the fight against AIDS — the start of a revolution in the global biomedical response to HIV using long-acting antiretroviral medicines. Whether they will do so depends on whether policymakers and pharmaceutical companies avoid repeating past mistakes."

The authors call for "a nonlinear approach to global access to ARVs that combines far more rapid sharing of technology, decentralized global production, and research and development of products that meet the needs in Africa, Asia, Latin America, and the Caribbean."

They highlight the need for progress on long-acting treatment as well as prevention and "to break the long-standing pattern of failing to get HIV technologies to the people who need them most, to stop playing catch-up, stop accepting that innovations must reach people in the Global South years late, and use long-acting medicines to help end the pandemic." The article is available at https://www.nejm.org/doi/full/10.1056/NEJMms2412286.

The importance of long-actings, and what is at stake in the discussions on access, was summed up

by Jerop Limo, a 26 year old Kenyan activist born living with HIV who is Executive Director of the Ambassador for Youth and Adolescent Reproductive Health Program (AYARHEP).

“Taking a pill every day is not easy. It is a constant reminder of being different, and the stigmatising and shaming we experience because of it can discourage us from taking our medicines,” he said. “This is not just about convenience. Young people living with HIV, and young people at risk of HIV, are clear: with all the pressures we face, long-acting medicines would help us stay on the medicines and help transform, and save, our lives.

“We deserve to live, and to live fully. We can’t have access on paper only. We need access for all people in all countries. I am inspired to see leaders coming together to centre communities and to call for access to long-acting HIV medicines. With partnership we can do this. We don’t have time to wait.”

The UNAIDS Programme Coordinating Board brings together governments, civil society and the United Nations to help guide the HIV response. UNAIDS sees the development of long-actings as a vital disruptive innovation.

“The arrival of long-acting injections is a game-changer which can help prevent millions of new HIV infections, if we ensure access to all who would benefit from them,” said Ms Byanyima. “Today, in Nairobi, leaders in the global HIV response took a bold and vital step forward on the path to access for all.”

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http://beta.docker.poz.com/article/global-leaders-hiv-response-call-access-longacting-medicines