

MEDIA RELEASE**ZIMBABWE FAST-TRACKS APPROVAL OF LENACAPAVIR IN JUST 23 DAYS****Embargo: Immediate Release**

Harare, 22 November 2025 – The Medicines Control Authority of Zimbabwe (MCAZ) announces the expedited approval of Lenacapavir, an innovative long-acting medicine for pre-exposure prophylaxis (PrEP) to prevent HIV-1 infection. Lenacapavir was assessed and approved by the Registration Committee of the Authority under the expedited review process, as it is considered to be of major public health importance both in Zimbabwe and globally. The application, submitted by Gilead on the 29th of October 2025, underwent a rigorous evaluation and was finalised in twenty-three (23) days, demonstrating the Authority's commitment to ensuring timely access to essential, life-saving health products.

Lenacapavir is recommended, together with safer sex practices, for PrEP in adults and adolescents weighing at least 35 kg. The product is administered as a six-monthly subcutaneous injection following an initiation phase that includes one injection and oral tablets taken on Days 1 and 2. It is intended for individuals who are HIV-negative and at substantial risk of HIV infection. Lenacapavir must always be used alongside safer sex practices, including condom use and behavioural risk-reduction measures.

The registration of Lenacapavir marks a significant advancement in Zimbabwe's HIV prevention strategy. By providing a long-acting alternative to daily oral PrEP, this product has the potential to improve adherence and expand prevention options for populations most vulnerable to HIV infection.

The MCAZ Director-General, Mr. Richard T. Rukwata, said, "The rapid approval of Lenacapavir reflects MCAZ's dedication to accelerating access to trusted, high-quality health products. This milestone brings new hope for HIV prevention and reinforces our commitment to safeguarding public health."

In line with its mandate, MCAZ conducted a comprehensive assessment of the product's safety, efficacy, and quality. The Authority applied a regulatory reliance approach, drawing on scientific assessments from the World Health Organization Prequalification (WHO PQ) programme to support an efficient and robust review process.

MCAZ remains committed to ensuring access to high-quality, safe, and effective medical products that strengthen public health and contribute to Zimbabwe's fight against HIV/AIDS.

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About MCAZ:

Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an Act of Parliament, The Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03]. MCAZ is a successor of the Drugs Control Council (DCC) and the Zimbabwe Regional Drug Control Laboratory (ZRDCL). DCC was established by an Act of Parliament in 1969: Drugs and Allied Substances Control Act [Chapter 15:03], following which ZRDCL became operational in 1989.

MCAZ is responsible for protecting public and animal health by ensuring that accessible medicines and allied substances and medical devices are safe, effective and of good quality through enforcement and adherence to standards by manufacturers and distributors.

The Medicines Control Authority of Zimbabwe (MCAZ), which is the National Pharmacovigilance Centre of Zimbabwe, is a participating country of the WHO International Drug Monitoring Program since 1998. The National Pharmacovigilance Centre is responsible for monitoring the safety of medical products and allied substances in Zimbabwe.

The mandate of MCAZ is to protect public health, ensuring that medicines and medical devices on the market are safe, effective, and of good quality.

Notes to Editors:

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