Merck's alimatravir licensing deal receives mixed response

In July 2026, Merck announced licensing agreements with seven manufacturers for generic production of its HIV drug alimatravir, though access and equity concerns remain. Ed Holt reports.

Pharmaceutical company Merck (or MSD) is facing criticism after granting voluntary licences to produce generics of its once-monthly oral HIV pill alimatravir, which is still in clinical trials. The firm announced on July 24 royalty-free voluntary licensing agreements with seven producers for the manufacture and sale of generics of the drug in 129 low-income and middle-income countries (LMICs), should the product be approved. The company said they had been agreed with the aim of making alimatravir available in LMICs as broadly and as quickly as possible. The announcement comes after engagement with HIV communities during the drug's development.

There has been widespread praise for the company's decision to grant the licences now, but campaigners have criticised the company over the exclusion of some countries from the agreements, including those participating in one of the two ongoing phase 3 trials. These include Brazil, Colombia, Mexico, Peru, and Chile.

"This is extremely unethical. Brazilians are participating in the clinical trials to generate evidence and support regulatory approval, but our communities are … excluded from the benefits", Susana Van der Ploeg of the Brazilian Interdisciplinary AIDS Association told *The Lancet Infectious Diseases*. Other experts pointed to the potential public health threat of the exclusions.

"Merck's current access plan excludes LMICs accounting for approximately 230 000 new HIV acquisitions each year. In Latin America alone, excluded countries account for approximately 112 000 infections annually—around 80% of the region's HIV incidence. Broader licensing could prevent very large numbers of infections", Andrew Hill, Senior Visiting Research Fellow, Department of Pharmacology and Therapeutics, University of Liverpool, UK, told *The Lancet Infectious Diseases*.

Following the criticism, on July 28 Merck announced a memorandum of understanding (MOU) had been signed between the company, the Minister of Health of Brazil, and the Oswaldo Cruz Foundation (Fiocruz)—the Brazilian government's research and medicine production agency. No specific details of the MOU have been released, but a Merck spokesperson told the journal it "establishes a framework for collaboration between MSD and Fiocruz to explore opportunities that could help accelerate access, availability, and potential future supply of alimatravir in Brazil and potentially more broadly across Latin America". But concerns remain over what any such deal will ultimately entail.

"We have no information about the terms of the agreement, the royalties that will be paid, the pricing, or the obligations involved. The real solution is to remove patent barriers—either by preventing unjustified patents from being granted or by using compulsory licences—so that genuine competition can reduce prices and expand access", Van der Ploeg said.

Campaigners have also raised concerns over transparency around the company's pricing policy for the drug. Research presented at the 26th International AIDS Conference in Rio de Janeiro, Brazil, during July 26–31 suggested it could be produced for just US$3 per person per year, which would make it one of the cheapest HIV drugs ever produced. Hill, one of the co-authors of the presentation, said reaching that low price would require competitive mass production, large and predictable orders, reliable demand forecasts, and long-term financing, but that "there is no obvious manufacturing reason why the price should remain high once production reaches scale".

A spokesperson for Merck said the company could not give any details of its LMIC access strategy, including pricing, but confirmed it intended to provide alimatravir at no profit in all countries included under the voluntary licensing while generic supply is being established.

The announcement of the licence agreements comes amid warnings the potential of innovative prevention medicines is in danger of being lost. Activists point to what they say have been problems in some countries with roll-outs of the twice-yearly injectable pre-exposure prophylaxis product lenacapavir due to aid cuts that have hit HIV/AIDS programmes and backsliding on delivery commitments by the drug's manufacturer, Gilead. They want to avoid a repeat of this with alimatravir.

The HIV advocacy group AVAC said it wanted to see Merck pledge to reach at least 2 million people with alimatravir within the first year of product launch and 5 million within the first 2 years, and guarantee it will be available in LMICs within 3 months of first approval. "These targets are a bare minimum and entirely feasible. We need this to jump-start the scale of the market, drive down prices and, most importantly, deliver impact", Mitchell Warren, Executive Director at AVAC, told *The Lancet Infectious Diseases*.

"We … appreciate the perspective of HIV advocacy groups in setting ambitious goals. While we are not announcing specific manufacturing volumes or timelines today, our multi-faceted strategy is designed to support these goals", the Merck spokesperson said.

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