DRL, Emcure get approval to make breakthrough HIV drug

In a meeting held this month, the subject expert committee recommended local phase III and bioequivalence-trial waivers for generic lenacapavir by Dr Reddy's Laboratories and Emcure. It has, however, asked the companies to conduct a phase IV efficacy study.

New Delhi: Lenacapavir, a breakthrough twice-a-year injection used in the prevention of HIV infections, could soon be available in India.

India's drug regulator has cleared the path for two Indian pharmaceutical companies to manufacture it, a move that could dramatically improve access to the drug for millions in India and other low- and middle-income countries.

In a meeting held this month, the subject expert committee under the Central Drugs Standard Control Organisation (CDSCO) recommended local phase III and bioequivalence-trial waivers for generic lenacapavir by Dr Reddy's Laboratories and Emcure Pharmaceuticals. It has, however, asked the companies to conduct a phase IV efficacy study.

During the meeting, Dr Reddy's presented its proposal for grant of permission for manufacturing and marketing the injection in 463.5 mg/1.5 ml strengths along with justification for phase III clinical trial and bioequivalence-study waivers.

The committee noted that the drug was approved in the US, UK, Canada, the European Union, Australia and a few other countries, according to the minutes of the meeting that ET has seen. The committee reviewed the data presented by Dr Reddy's from the innovator, agreed that pre-exposure prophylaxis, or preventive measures, to reduce the risk of sexually acquired HIV in adults and adolescents weighing at least 35 kg who are at increased risk was an unmet medical need in India, and recommended the waivers, the minutes showed.

Emcure also presented its proposal and received similar waivers.

The waiver comes with a condition. The companies must conduct a phase IV post-marketing study in India with efficacy as the primary endpoint and must submit the study protocol to CDSCO within three months of receiving marketing authorisation.

On the question of using lenacapavir for heavily treatment-experienced patients with multidrug-resistant HIV, the committee did not recommend a waiver, citing insufficient evidence on how the drug behaves in the Indian population in terms of pharmacokinetics and ethnicity-related factors.

Patient groups and civil society organisations working on HIV and AIDS across the Asia-Pacific region, including Third World Network, earlier wrote to CDSCO urging it to waive the local trial requirements for generic lenacapavir, arguing that the extensive international evidence already available made duplicating those trials unnecessary and that any delay would only push back access to a drug that people urgently need.

In 2024, half a dozen drug makers including four Indian companies entered into nonexclusive, royalty-free licensing agreements with the drug's developer, Gilead Sciences, to manufacture its generic versions and market it locally and in 120 low- and middle-income countries.

While Gilead filed patents widely on the drug, the voluntary licence was meant to overcome the patent barriers for sale in identified low- and middle-income countries.

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