WHO prequalifies first hepatitis C generic

The World Health Organisation (WHO) has prequalified the first generic version of sofosbuvir, a critical medicine in treating hepatitis C.

“This is a breakthrough medicine with a 95% cure,” said Dr Suzanne Hill, director, essential medicines and health products at WHO. “The first WHO-prequalified generic of this product will give large procurers and countries the assurance of quality for an affordable product.”

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WHO prequalification means the product can now be procured by the United Nations and financing agencies such as UNITAID, which now includes co-infection with HIV and hepatitis C in the portfolio of diseases it covers. Countries such as Indonesia, Vietnam, Cambodia, Myanmar, Mongolia, Nepal, Rwanda, Uganda, Kenya, Zambia, Ethiopia, Pakistan and Egypt are already procuring generic versions of sofosbuvir. The fact that WHO has prequalified one of those generics will give them extra guarantee of the product’s quality, safety and efficacy.

“Direct acting antiviral medicines such as sofosbuvir are highly effective for treating and curing chronic hepatitis C infection. But, at best, one out of 10 people in need had access to these medicines in 2015,” said Dr Gottfried Hirnschall, WHO’s director of the HIV department.

The development could expand access to treatment by increasing the number of quality-assured generic medicines on the

market. Sofosbuvir, 400 mg tablet, is manufactured by Mylan Laboratories Ltd., India.

The average price of the required three-month treatment course of Mylan's sofosbuvir is around $260, a fraction of the medicine's market entry price in late 2013, and of the price set in the majority of high-income countries. The medicine remains highly expensive in many countries, but licensing agreements between Gilead Sciences, who developed sofosbuvir, and several generic manufacturers have made it possible for low-income and some middle-income countries to provide the medicine at more affordable prices.