World Health Organization Prequalifies Its First Generic Hepatitis C Cure

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Last week, the World Health Organization (WHO) prequalified its first generic hepatitis C virus (HCV) treatment, a move that could help dramatically expand access to affordable HCV cures around the world, according to a recent press release from the agency.

The WHO prequalification essentially green-lights increased production of a generic version of sofosbuvir (known in the United States under its brand name, Sovaldi) by the Indian drug manufacturer Mylan Laboratories and gives an extra guarantee of the product's quality, safety and efficacy. The also allows the United Nations and financing agencies such as UNITAID to procure the cheaper version of the medication for their HCV treatment programs.

The prequalification also has the potential to save these agencies millions of dollars. The average price of a standard 12-week course of hepatitis C treatment with Mylan's version of sofosbuvir costs around $260, a small fraction of the medicine's $1,000-per-pill market entry price in late 2013.

Since then, international health officials say the drug remains highly expensive in many countries, rendering it unaffordable for many individuals and agencies. Licensing agreements between Gilead Sciences, which developed sofosbuvir, and a number of generic manufacturers have made it possible for low-income and some middle-income countries to provide HCV treatment at more affordable prices. However, those deals have not been made universally.

Countries such as Indonesia, Vietnam, Cambodia, Myanmar, Mongolia, Nepal, Rwanda, Uganda, Kenya, Zambia, Ethiopia, Pakistan and Egypt are already accessing cheaper generic versions of sofosbuvir. WHO's prequalification of one of these generics will likely open up access to far more countries.

WHO said it made its decision to prequalify generic sofosbuvir in advance of World Hepatitis Day, which takes place every year on July 28. This year's theme is "Eliminate Hepatitis," a nod to the agency's vow to eliminate viral hepatitis worldwide by 2030.

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