FDA Approves Generic Truvada for HIV Treatment and PrEP

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In a move that has taken HIV advocates by surprise and stewed considerable confusion, the U.S. Food and Drug Administration (FDA) has approved a generic formulation of Gilead Sciences' blockbuster antiretroviral (ARV) Truvada (tenofovir disoproxil fumarate/emtricitabine). This decision could have major implications for the future cost of Truvada, to insurers and consumers alike.

However, Gilead insisted in a statement, "A generic version of Truvada will not be immediately available. It's important to note that there are a number of factors involved in commercialization that are not tied directly to FDA approval."

"It's not uncommon in patent settlement agreements for generics to negotiate language permitting full approvals months and years in advance of the settlement license date," Tim Horn, deputy executive director of HIV and HCV programs at Treatment Action Group, told POZ. "Regardless, now is the time to start thinking seriously about the advantages, as well as the drawbacks, of generic products to prevent and treat HIV."

The Gilead statement noted that the patent for the tenofovir disoproxil fumarate component of Truvada expires in July 2017 and that Gilead retains exclusive rights for the drug's pediatric use until January 2018. Meanwhile, the patent for emtricitabine, the other medication in Truvada, does not expire until 2021, according to Gilead.

The FDA approval grants Teva Pharmaceuticals the right to produce generic Truvada for the combination tablet's use as a component of an HIV treatment regimen and as pre-exposure prophylaxis (PrEP). Generic Truvada would come in the same form as the brand-name version: as a fixed-dose combination tablet, although the famous powder-blue color may change.

A Teva spokesperson confirmed the generic Truvada approval but said no further related information was available at this time. Consequently, it remains unclear what sort of exclusivity Teva may have to produce generic Truvada. Generic manufacturers often hold such exclusive rights for an initial period before competitors can also begin producing a particular generic

medication and thus drive down prices.

As discovered by activist James Krellenstein, a June 5 FDA document added Truvada to the agency's list of medications that have been granted what is known as a paragraph IV patent certification. According to Martin Shimer, RPh, deputy director of the Office of Generic Drug Policy at the FDA, the paragraph IV certification for Truvada indicates that Teva applied for an abbreviated new drug application (ANDA), challenging Gilead's patent on the combination tablet and seeking the rights to produce a generic equivalent.

The paragraph IV certification does not mean the FDA has invalidated Truvada's patent. However, such an ultimate result is not necessarily off the table.

Addressing questions about the timing of generic Truvada's availability, Shimer said that the "FDA's ability to approve an ANDA often does not result in immediate marketing by the ANDA applicant that just gained approval."

Shimer suggests that Teva and Gilead may ultimately develop private legal settlements that will spell out the near-term availability of generic Truvada. The FDA is often not privy to such settlement agreements, according to Shimer.

ACT UP and Treatment Action Group veteran Peter Staley expresses concern about how the introduction of a generic version of Truvada may affect out-of-pocket costs for individuals taking the tablet. "Gilead's patient and copay assistance programs have become central pillars in patient access," he said. "They must maintain these programs, and Teva must establish equivalent or better assistance programs for their generic version."

Signs look promising that Gilead will indeed continue supporting PrEP use among individuals at risk for HIV, at least in the near term. According to the company's statement, "Gilead believes Truvada for PrEP is an important HIV prevention tool and we remain committed to helping ensure access to our medications for people both at risk of or living with HIV."

To see the FDA generic approval page, click here.

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