

EU door opens for generic version of AIDS medicine Truvada

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European patents expired on July 25 for Truvada, allowing EU authorities to clear the way for cheaper generics to enter the market

Patient associations on Thursday lauded an EU decision to allow the sale of generic versions of Truvada, an anti-retroviral medicine used by those diagnosed HIV-positive, the virus causing AIDS.

"This decision is historic ... ending an inherent monopoly," said the Coalition PLUS and Aides associations in a statement.

Truvada, made by US lab Gilead, is one of the most widely used medicines to treat patients with the HIV virus and was to date the only one enjoying Europe-wide clearance for patients deemed high infection risk.

But European patents on the medicine expired on Wednesday, providing a window of opportunity for generics.

In some European states, however, Gilead retains a monopoly owing to a complementary certificate of protection (CCP) which extends the period of exclusivity afforded a product.

Four rival labs—Teva, Accord Healthcare, Lupin and Mylan—had sought to have that overturned in the courts in Britain—which called on the European Court of Justice to make a ruling.

The ruling, which came down on Wednesday, highlighted the fact that Truvada contains two active substances—emtricitabine and tenofovir disoproxil—but only the second of the two is explicitly mentioned in the basic patent.

The judge argued that as a result, the conditions for a CCP were not met.

French authorities had reached a similar conclusion last September in rejecting a Gilead demand to prevent commercialisation of a Truvada generic developed by France's Mylan laboratory.

Five generics are now available in France, resulting in a significant price drop—around 160 euros (\$190) a bottle compared with more than 400 euros for Truvada under its monopoly.

The Aides association said the appearance of generic options had resulted in more than 760 million euros of savings, adding that Europe-wide the benefit could run into the billions while offering heightened protection against infection for thousands of people.

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