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MediaTitle	New Sarawak Tribune		
Date	18 Jul 2012	Color	Black/white
Section	World	Circulation	46,471
Page No	w13	Readership	164,773
Language	English	ArticleSize	362 cm²
Journalist	N/A	AdValue	RM 1,053
Frequency	Daily	PR Value	RM 3,159

US approves first-ever pill for HIV prevention

WASHINGTON: The first-ever daily pill to help prevent HIV infection was approved Monday by US regulators for use by healthy adults who are at risk for getting the virus that causes AIDS.

Truvada, made by Gilead Sciences in California, has been on the market since 2004 and was approved by the Food and Drug Administration for a new use as a tool to help ward off HIV, in combination with safe sex and regular testing.

The pill as pre-exposure prophylaxis (PrEP) has been hailed by some AIDS experts as a potent new tool against human immunodeficiency virus, while other health care providers are concerned it could encourage risky sex behavior.

In addition, the regimen is estimated to cost around $14,000 per year, making it out of reach of many."Truvada alone should not be used to prevent HIV infection," said Debra Birnkrant, director of the division of antiviral products at the FDA.

"Truvada as PrEP represents another effective, evidence-based approach that can be added to other prevention methods to help reduce the spread of HIV."

The FDA said Truvada should be used as "part of a comprehensive HIV prevention strategy that includes other prevention methods, such as safe sex practices, risk reduction counseling, and regular HIV testing."

Truvada was previously approved as a treatment for people infected with HIV to be used in combination with other antiretroviral drugs.

The decision by the FDA followed the advice of an independent panel in May that supported Truvada for prevention in uninfected people, after clinical trials showed it could lower the risk of HIV in gay men and heterosexual couples.

One study of men who were sexually active with other men but were not infected with the virus that causes AIDS found 44 percent fewer infections in those taking Truvada versus a placebo.

Those in the study who took the drug regularly had almost 73 percent fewer infections.

A second study on heterosexual couples in which one partner was infected with HIV and the other was not showed that Truvada reduced the risk of becoming infected by 75 percent compared with a placebo.

Common side effects were the same as experienced by people with HIV who were taking Truvada, and included diarrhea, nausea, abdominal pain, headache, and weight loss.

However, the adherence rate -- meaning how often people in the study actually took the drug daily -- was low in the study of men who have sex with men, at just 30 percent, Birnkrant said.

In the study of heterosexual partners, adherence was much higher, at between 80 and 90 percent.

Therefore, the drug label must include special instructions for health care providers on how to counsel potential users of the drug.

The drugmaker must also include a warning that Truvada for PrEP "must only be used by individuals who are confirmed to be HIV-negative prior to prescribing the drug and at least every three months during use."

The goal of the approval is to eventually cut back on the rate of new infections in the United States, which have stayed steady in recent years at about 50,000 annually, she said.

A key goal of the US strategy against HIV/AIDS, set forth in 2010, is to decrease the number of new infections by 25 percent by 2015.

"The hope is that over time it will decrease the rate of new infections or incidence in the United States," Birnkrant said.

The FDA approval drew the support of amfaR, The Foundation for AIDS Research.

"We know that Truvada, when taken as directed, works. Now we need to figure out how to properly use it to change the course of the epidemic," said a statement by amfaR chief executive Kevin Robert Frost.

However, the AIDS Healthcare Foundation described the move as "reckless," largely because the FDA recommends but does not explicitly require a negative HIV test prior to use. - AFP

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BOTTLES of antiretroviral drug Truvada are displayed in 2010 in San Anselmo, California. PHOTO: AFP