# Cut-Price HIV Meds

The FDA approves three new, cheaper combination ARV tablets.

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The Food and Drug Administration (FDA) has approved three new antiretroviral (ARV) combination tablets from Mylan that are not generic drugs but that the company has priced at about a 40 percent discount compared with comparable antiretroviral (ARV) treatments.

First, there are the single-tablet regimens Symfi and Symfi Lo, which each contain efavirenz, lamivudine and tenofovir disoproxil fumarate; the difference between them is that the dose of efavirenz is 600 milligrams in Symfi and just 400 mg in Symfi Lo. The tablets are approved for the treatment of HIV among adults and children, who must weigh at least 40 kilograms (88 pounds) to take Symfi and 35 kg (77 lbs.) to take Symfi Lo.

Recent research has indicated that treating HIV with tenofovir and emtricitabine is comparably effective regardless of whether individuals also receive 400 mg or 600 mg of efavirenz.

Sold under the brand name Sustiva, efavirenz is associated with various troubling side effects, including nightmares. A recent study backed up previous findings that the drug is associated with an increased risk of suicidal behaviors.

Symfi and Symfi Lo have the same components as Atripla (efavirenz 600 mg/tenofovir disoproxil fumarate/emtricitabine) but swap lamivudine for emtricitabine; both of those drugs are in the nucleoside/nucleotide reverse transcriptase inhibitor class of ARVs.

The FDA has also approved Mylan's Cimduo (lamivudine/tenofovir disoproxil fumarate), which is similar to Truvada (tenofovir disoproxil fumarate/emtricitabine) and also swaps lamivudine for emtricitabine. (Cimduo was not yet available as of press time.) The tablet is approved for use in combination with other ARVs for the same population as Symfi Lo. It is not approved for use as pre-exposure prophylaxis.

Tim Horn, MS, deputy executive director of HIV and HCV programs at Treatment Action Group, says the introduction of these cut-price tablets is "a step in the right direction" that should save some insurers money. But for considerable cost savings, he says, true generic competition "is a must—and is encouraged."

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