



WORLD HEALTH ORGANIZATION

NOTE FOR THE PRESS

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Note for the media WHO/25
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WHO INCLUDES ADDITIONAL ANTIRETROVIRAL PRODUCTS IN LIST OF PREQUALIFIED MEDICINES

Geneva - The World Health Organization (WHO) today lists seven HIV/AIDS medicines that have received approval or tentative approval by the United States Food and Drug Administration (FDA).

The additions follow an agreement signed earlier this year between the two organizations to facilitate the exchange of quality-related information on HIV/AIDS medicines for procurement. WHO's inclusion of the FDA approved medicines adds value to the process by providing a wider selection of products of assured quality into a single comprehensive list.

"The listing of FDA tentative approvals makes the task of procurement agencies easier so that they only need to consult one list when buying," says Dr Lembit Rägo, head of the prequalification project. "In the long term, the US FDA tentative approval process for antiretrovirals can also help to reduce WHO's work load in prequalifying medicines, thus allowing the health agency to devote more attention to products that have not been assessed by any other stringent regulatory agency."

There are no major differences between the FDA and WHO medicines assessment systems. The standards against which the WHO assessment teams evaluate both the quality specifications of medicines and the manufacturing sites are based on the principles and practices agreed by the world's leading regulatory agencies, including the FDA, and adopted by the WHO Expert Committee on Specification for Pharmaceutical Preparations.

The medicines listed today are six antiretrovirals from Indian generic manufacturer Aurobindo, including a double fixed-dose combination (a two in one pill); and a co-blister pack of a double fixed-dose combination plus a single-ingredient product from Aspen, South Africa.

Medicines listed today:

- Efavirenz, 600 mg Tablets, Aurobindo, Hyderabad, Andhra Pradesh, India
- Lamivudine, 10mg/ml Oral solution, Aurobindo Hyderabad, Andhra Pradesh, India
- Lamivudine/zidovudine, 150/300 mg Tablets, Aurobindo, Hyderabad, Andhra Pradesh India
- Lamivudine/zidovudine + nevirapine, 150/300 mg + 200 mg Tablets, Aspen Pharmacare, South Africa
- Stavudine, 30 mg Capsules, Aurobindo, Hyderabad, Andhra Pradesh India
- Stavudine, 40 mg Capsules, Aurobindo, Hyderabad, Andhra Pradesh, India
- Zidovudine, 50 mg/5 ml Oral solution, Aurobindo, Hyderabad, Andhra Pradesh, India

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