

Dear Reader,

Welcome to the December issue of AMDSmail!

In this issue, you will find some important developments in the regulatory status of HIV medicines. We also have some updates on new projects initiated by the WHO/AMDS and its partner organizations. Please visit our new project pages that are available on the AMDS website. If you need further information about AMDSmail and AMDSflash, please contact contact [AMDS@who.int](mailto:AMDS@who.int) (attention Boniface Dongmo Nguimfack or Maryann Akpama).

## In the news

### Fourteen new ARVs added to the WHO list of pre-qualified medicinal products

The WHO Pre-qualification Programme has added fourteen antiretroviral medicines (ARVs), eight fixed-dose combinations (FDCs) and six single ARVs, to the list of pre-qualified medicinal products for HIV/AIDS. The eight FDCs include four triple combinations of lamivudine (3TC) + nevirapine (NVP) + stavudine (d4T) with two different strengths (150 + 200 + 30 mg and 150 + 200 + 40 mg) for adult treatment manufactured by [Actavis Pharma Ltd - India](#) and [Matrix -India](#), two lamivudine (3TC) + stavudine (d4T) combination (150+30mg and 150+40mg) for adults by [Matrix \(India\)](#), one Lopinavir (LPV) + Ritonavir (RTV) (100 +25 mg) by [Abbott Laboratories - Germany](#) and Efavirenz (EFV)+[Lamivudine (3TC)+Zidovudine(ZDV)] 600 mg+[150m+300mg] by [Aurobindo Pharma Ltd - India](#). Six single ARVs include formulation of abacavir (ABC) (300 mg) manufactured by [Matrix Laboratories Limited](#) and [Ranbaxy Laboratories Ltd](#), EFV, NVP and ZDV (600mg, 200mg, and 300mg respectively) manufactured by [Matrix \(India\)](#) and a Stavudine Powder for oral solution (d4T 1 mg/ml) by [Aurobindo Pharma Ltd](#). The latest version of the list of WHO pre-qualified HIV/AIDS products is available online.

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▶ [WHO List of Prequalified Medicinal Products](#)

# AMDSmail

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### Eleven new ARVs tentatively approved and six new generic ARVs approved by U.S. Food and Drug Administration (FDA)

The Food and Drug Administration (FDA) has granted since April 2008 eleven new tentative approval to ARV formulations of which six are FDC (3TC+Tenofovir Disoproxil Fumarate (TDF) (300+300mg) by [Matrix Laboratories](#); Abacavir Sulfate (ABC)+3TC (600+300mg) by [Aurobindo Pharma Ltd](#); 3TC + d4T (60+12mg and 30+6mg) by [Cipla Limited](#), 3TC+ZDV (150+300mg) by [Hetero Drugs](#) and 3TC+NVP+ZDV (150+200+300mg) by [Matrix Laboratories](#)) and five single formulations (3TC (150mg, 300mg) ABC (60mg), emtricitabine (FTC) (200mg), NVP (200mg) and ZDV (300mg) under the procedures established for the President's Emergency Plan for AIDS Relief (PEPFAR) program. FDA's "tentative approval" means that although a product meets all of the safety, efficacy, and manufacturing quality standards required for marketing in the U.S., existing patents and/or proprietary issues currently prevent marketing of the product in the United States. Tentative approval, however, does qualify the product for consideration for purchase under the PEPFAR program.

FDA has also granted approval to didanosine (ddI) (125mg, 200mg, 250mg, 400mg) produced by [Aurobindo Pharma Ltd](#) and ZDV (50mg/ml and 300mg) produced respectively by [Cipla](#) and [Hetero Drugs](#).

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## Activities by AMDS and partners

### AMDS website

#### 1) New electronic platform for ARV demand forecasting

Accurate forecasting of market trends for ARVs and active pharmaceutical ingredients (APIs) for ARV production is essential for brand-name pharmaceutical companies as well as for generic companies in order to design a long-term expansion programme for their production capacity. In order to make available the data for ARV production forecast and to publicize the global rolling demand to the public and in collaboration with [Clinton Foundation HIV/AIDS Initiative](#), [Future Institute](#), [the Global Fund](#), [John Snow Inc](#), [Supply Chain Management System](#), [UNAIDS](#), [UNICEF](#), [UNITAID](#), and [USAID](#), the AMDS/WHO has set up an electronic platform on AMDS website.

▶ [Electronic platform for ARV demand forecasting](#)

#### 2) New database of controlled medicines

In collaboration with the WHO Department of Mental Health and Substance Abuse and the Department of Medicines Policy and Standards, has developed the database on buprenorphine and methadone which are used for the opioid substitution therapy, and morphine which is used for the relief of pain. The data included in this database, available forms and formulations, procurement issues, registration procedures and prices, are collected from the pharmaceutical companies producing and distributing these medicines. This database will provide countries and organizations purchasing these essential medicines with information to improve access to these medications.

▶ [AMDS database of controlled medicines](#)

## Publications

### New summary report from the Global Price Reporting Mechanism (GPRM) - October 2008 version

New summary reports on the GPRM (October 2008) is now available on the AMDS website. The October version covers the transaction prices of ARVs for adult and children 1st and 2nd-line regimens for low, lower-middle and upper-middle income countries for the first time. It also covers the trend analysis of the HIV diagnostics such as rapid, ELISA and confirmatory test.

The next summary report will be published in February 2009 and will cover the price data of ARVs for adult and children and HIV diagnostics such as rapid, ELISA and confirmatory test.

▶ [GPRM summary report \(October 2008\)](#)

### Revised version of AMDS checklist developed for the Global Fund proposal

The revised versions of the check list developed by the Global Fund and the AMDS secretariat for procurement and supply management issues to be considered in preparation of the Global Fund proposal has been revised. The new version is now available on [AMDS website](#) in both English and French.

▶ [AMDS website](#)

## Event

- Joint WHO/UNAIDS informal consultation with pharmaceutical companies - forecasting ARV demand 2008-2010 and improving paediatric and second line ARV options - 15-16 December 2008

### [Electronic platform for ARV demand forecasting](#)

This consultation was a follow-up of the [meeting of the United Nations Secretary General](#) with the pharmaceutical and diagnostic companies on 9 October 2008 in New York. The aim was to engage the pharmaceutical companies in a dialogue on global ARV demand forecasts for 2008-2010 and paediatric and second-line medicines as well as discussion on how to improve availability of suitable formulations.

All powerpoint presentations and information related to the meeting are now available on the [AMDS website](#).