

Dear Reader,

Welcome to the July 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 AMDS@who.int (attention Boniface Dongmo Nguimfack or Maryann Akpama).

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IN THE NEWS

PEPFAR procurement data (2007–2008) provided to AMDS

The AMDS, through their close collaboration with the Supply Chain Management System of PEPFAR has now received all ARV procurement of PEPFAR for fiscal year 2007 and 2008. After these data will have been uploaded in the GPRM, more than 75 percent of all ARV procurement in low and middle income countries will be in the public domain. GPRM is currently working on the data, so as to avoid duplicate reporting in the GPRM database. We will inform you through AMDS Mail when this important dataset has been uploaded and is available for analysis.

The GRPM now collecting transaction information for TB commodities

The AMDS has agreed with the Global Drug Facility (GDF), the Global Fund (GFATM) and International dispensary Association (IDA) to use the GPRM as the portal to make the information on the procurement of TB commodities available in the public domain. To date AMDS has received their TB transaction data from 2000. The data will be released in GPRM as soon as the data sets have passed the quality control and duplicate removal process.

Fifteen new ARVs prequalified by the WHO pre-qualification programme

Since December, 2008, the WHO Pre-qualification Programme has added fifteen antiretroviral medicines (ARVs), eight fixed-dose combinations (FDCs) and seven single ARVs, to the list of pre-qualified medicinal products for HIV/AIDS. The eight FDCs include two triple combinations of lamivudine (3TC) + nevirapine (NVP) + zidovudine (ZDV) (150 + 200 + 300 mg) for adult treatment manufactured by [Cipla Ltd](#) and [Matrix Laboratories \(India\)](#), one triple combination of lamivudine (3TC) + abacavir (ABC) + zidovudine (ZDV) (30 + 60 + 60 mg) for infant treatment manufactured by [Matrix Laboratories \(India\)](#), two lamivudine (3TC) + stavudine (d4T) combination (150+30mg and 150+40mg) for adults treatment by [Aurobindo Pharma Ltd](#) (India), two Lopinavir (LPV) + Ritonavir (RTV) (100 +25 mg and 200 + 50 mg) by [Matrix Laboratories \(India\)](#) and Lamivudine (3TC) + Zidovudine (ZDV) 30 + 60 mg by [Matrix Laboratories \(India\)](#). The seven single ARVs include three formulations of efavirenz (EFV) (600 mg) manufactured by [Cipla Ltd](#), [Hetero Drugs Limited](#) (India) and [Strides Arcolab Ltd](#) (India), one formulation of efavirenz (EFV) (200 mg) manufactured by [Strides Arcolab Ltd](#), one formulation of lamivudine (3TC) (300 mg) by [Matrix Laboratories](#), one formulation of nevirapine (NVP) 50 mg/5ml and the first generic version of tenofovir (TDF) (300 mg) by [Cipla Ltd.](#) 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. (01 July 2009).

- [WHO list of prequalified Medicinal Products](#)

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

Since December 2008 The Food and Drug Administration (FDA) has granted nineteen new tentative approval to ARV formulations of which thirteen are FDC and six single dose formulations. The thirteen FDC include two two triple combinations of 3TC + d4T + NVP (150 + 30 + 200 mg and 150 + 40 + 200 mg) by [Strides Arcolab Ltd](#), 3TC + ZDV co-packaged with NVP ([150 + 300mg] and 200 mg) by [Hetero Drugs Limited](#) (India), two double combinations of emtricitabine (FTC) + TDF (200 + 300 mg) by [Aurobindo Pharma Ltd](#) and [Matrix Laboratories \(India\)](#), two 3TC+ d4T (150 +30 mg and 150 + 40 mg) by [Strides Arcolab Ltd](#), two LPV + RTV (200 + 50 mg) by [Matrix Laboratories](#) and [Aurobindo Pharma Ltd](#), one LPV + RTV (100 + 25 mg) by [Aurobindo Pharma Ltd](#); Abacavir Sulfate (ABC)+3TC (600+300mg) by [Matrix Laboratories \(India\)](#); ABC + 3TC (60 + 30 mg) by [Aurobindo Pharma Ltd](#) and 3TC + ZDV (150 + 300 mg) by [Macleods Pharmaceuticals Limited](#). Six single formulations 3TC (150 mg) ([Alkem Laboratories Limited](#)), TDF (300 mg) ([Cipla Ltd](#) and [Aurobindo Pharma Ltd](#)), NVP (200 mg) ([Macleod's Pharmaceuticals Limited](#)), FTC (200 mg) ([Matrix Laboratories Limited](#) and [Aurobindo Pharma Ltd](#)), EFV (100 mg) by [Aurobindo Pharma Ltd](#).

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.

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ACTIVITIES BY AMDS AND PARTNERS

AMDS website

1) Standardization of laboratory items

As a follow up to the recommendations of the Maputo consultative meeting whose objectives were, inter alia, to develop a consensus to guide standardization of laboratory equipment at each level of the national laboratory system, several countries have undertaken the standardization of laboratory equipment. Different partners have made available to AMDS country case studies on laboratory standardization from Botswana, Tanzania and Zambia. They illustrate the significant financial and operational benefits that countries gain from standardizing laboratory equipment. The case studies are available at the following webs

- [AMDS diagnostics](#)

2) New database of controlled medicines

With the objective to support access to opioid substitution therapy and oral morphine, AMDS, in collaboration with the WHO Department of Mental Health and Substance Abuse and the Department of Medicines Policy and Standards, developed a database on sources and prices of buprenorphine and methadone, and morphine. The database includes information on available forms and formulations, procurement issues, registration procedures and prices, collected from the pharmaceutical companies producing and distributing them.

- [AMDS database of controlled medicines](#)

PUBLICATIONS

New summary report from the Global Price Reporting Mechanism (GPRM) June 2009 version

A new summary report on the GPRM (June 2009) is now available on the AMDS website. The June version covers recent transaction prices of ARVs for adult and children for low, lower-middle and upper-middle income countries. It also includes information on the procurement of HIV serological tests. The next summary report will be published in October 2009.

- [GPRM summary report \(June 2009\)](#)

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 Global Fund proposals has been revised. The new version is available on the AMDS website in [English](#) and in [French](#).

- [AMDS website](#)