

Dear Reader,

Welcome to the June 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 Kenji Tamura or Maryann Akpama).

In the news

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

The WHO Pre-qualification Programme has added six anti-retroviral medicines (ARVs), three fixed-dose combinations (FDC) and three single ARVs, to the list of pre-qualified medicinal products for HIV/AIDS. Three FDCs include a triple combinations of lamivudine (3TC)+nevirapine (NVP)+stavudine (d4T) with two different strengths (30+50+6mg and 60+100+12mg) for paediatric treatment manufactured by [Cipla \(India\)](#) and one 3TC+zidovudine (ZDV) combination (150+300mg) for adults by [Matrix \(India\)](#). Three single ARVs include two formulations of efavirenz (EFV, 50 and 200 mg) manufactured by [Merck Sharp and Dohme \(Australia\)](#) and abacavir (ABC, 300mg) by [Cipla](#). The latest version of the list of WHO pre-qualified HIV/AIDS products is available online.

(14 May 2008)

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

Apotex received final tender approval from Rwanda for a generic FDC

The Government of Rwanda has announced purchase of a generic FDC for HIV/AIDS treatment from Toronto-based generic pharmaceutical manufacturer [Apotex, Inc.](#), using the provisions of Canada's 2004 law on compulsory licensing of patented pharmaceuticals for export to eligible developing countries. Apotex is the first company to provide generic ARVs to African countries under this law. This has been made possible thanks to a decision arrived at by the [World Trade Organization](#) on the implementation of paragraph 6 of the Doha declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and public health ([the 30 August 2003 decision](#)). Apotex will export 15,600,000 tablets of 'Triavir®', a combination tablet of 3TC+NVP+ZDV (150+200+300mg), to Rwanda at the price quoted in the tender, US\$0.195 per tablet.

(7 May 2008)

▶ [Purchase of Apotex ARVs by Rwanda](#)

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Introduction of BCS-based biowaiver application system by WHO Pre-qualification Programme

The WHO Pre-qualification Programme has started implementing the Biopharmaceutics Classification System (BCS)-based biowaiver application system. The term "biowaiver" is applied to a regulatory drug approval process where the efficacy and safety part of the dossier (application) is approved based on evidence of equivalence other than through *in vivo* equivalence testing. The programme has identified 3TC, d4T and ZDV as the active pharmaceutical ingredients for ARVs to be eligible for BCS-based biowaiver applications. The new section on bioequivalence studies on the [WHO Pre-qualification Programme web site](#) can be found on the left-hand side menu under "Information for Applicants" and "Guidance on bioequivalence studies".

(1 May 2008)

▶ [WHO Pre-qualification Programme web site](#)

Two FDCs tentatively approved by U.S. FDA

The U.S. Food and Drug Administration (FDA) granted tentative approval to two formulations of FDCs with a combination of 3TC+NVP+d4T (150+200+30mg and 150+200+40mg) under the procedures established for the President's Emergency Plan for AIDS Relief (PEPFAR) programme. [Strides Arcolab \(India\)](#) manufactures both FDCs. FDA's "tentative approval" means that although a product meets safety, efficacy, and manufacturing quality standards required for marketing in the USA, 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 programme. (24 March 2008)

- ▶ [FDA's list of ARVs approved and tentatively approved for PEPFAR programme](#)

Safety review of ABC and didanosine by U.S. FDA

The U.S. FDA announced that it would review the safety of two ARVs, ABC manufactured by [GlaxoSmithKline](#) and didanosine (ddl) by [Bristol-Myers Squibb](#). A recent study involving more than 33,000 HIV-positive persons indicated that these ARVs might be linked to an increased risk of heart attack among some of the participants. Both medicines are used in combination with other ARVs for the treatment of HIV infection. (27 March 2008)

- ▶ [Early communication of U.S. FDA about an ongoing safety review of ABC and ddl](#)

Activities by AMDS and partners

John Snow, Inc. (JSI)

JSI is an international public health firm with expertise in supply chain management, drug procurement, health systems strengthening and health services management. JSI currently operates from seven U.S. and forty-three international offices, with an in-house team of more than 550 professional staff. JSI's expertise in supply chain management of health commodities is implemented through the [USAID | DELIVER PROJECT](#), the JSI Center for Logistics Services and the [Supply Chain Management System \(SCSM\)](#) project. The major focus of this work is to sensitize partners and clients about the critical role and importance of supply chains in the success of public health programmes based on the concept of "commodity security", and to strengthen national and international supply chains to be able to increase the availability of essential health commodities to the people that need them, when and where they need them. A variety of tools for procurement and supply management (PSM) of HIV-related commodities, developed by JSI and through the above-mentioned projects, are available online:

- ▶ [USAID | DELIVER PROJECT website](#)
- ▶ [PSM toolbox website.](#)

AMDS website

1) New electronic platform for ARV demand forecasting

Accurate forecasting of global demand for ARVs and active pharmaceutical ingredients for ARV production is essential for brand name and generic pharmaceutical companies in order to design a long-term programme for their production capacity. In order to make available the data necessary for the production of ARV forecasts and to publicize demand forecasts for ARVs to the public, the WHO/AMDS has set up an electronic platform on AMDS website 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](#).

- ▶ [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, the WHO/AMDS has developed a database on buprenorphine and methadone that are used for the opioid substitution therapy. Morphine which is used for the relief of pain is also included in the database. The information in this database including available forms and formulations, procurement issues, registration procedures and prices, is collected from the pharmaceutical companies producing and distributing these medicines. This database will provide countries and organizations purchasing relevant controlled medicines with information designed to improve access to these medications.

- ▶ [AMDS database of controlled medicines](#)

Publications

New summary report from the Global Price Reporting Mechanism (GPRM) (February 2008 version)

New summary report on the procurement data from the GPRM is now available on the AMDS website. The February version covers the transaction prices of ARVs for adult 1st- and 2nd-line regimens. The next summary report will be published in August and will cover the price information of ARVs for adults and children as well as HIV diagnostics including rapid, ELISA and confirmatory tests.

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

Harmonization of Monitoring and Evaluation Indicators for ARV Procurement and Supply Management Systems

This working document for field-testing was developed by the WHO/AMDS and its partner organizations for monitoring and evaluation (M & E) of PSM systems for ARVs. The WHO/AMDS is also developing a field-testing methodology which will be used by partners who have technical capacity and financial resources to carry out field-test activities. The English version of the M & E indicators can be found on the AMDS website and French version will be available soon on the same page.

▶ [M & E indicators for ARV PSM](#)

AMDS checklist for the Global Fund proposal (revised version, May 2008)

The AMDS check list, developed by the Global Fund and the WHO/AMDS, for PSM issues to be considered in preparation of the Global Fund proposal, has been revised. The new version is now available on the [AMDS website](#) in [English](#) and in [French](#).

▶ [AMDS website](#)

Events

- 2008 HIV/AIDS Implementers' Meeting
3-7 June 2008, Kampala, Uganda
<http://www.hivimplementers.com/>
- XVII International AIDS Conference (AIDS 2008)
3-8 August 2008, Mexico City, Mexico
<http://www.aids2008.org/>