

Dear Reader,

We are pleased to welcome you to the March issue of AMDSmail.

This is the first issue of AMDSmail that will be delivered to you every 3 months throughout 2008. In addition, important new developments will be sent out separately as AMDSflash. If you need further information about AMDSmail and AMDSflash, please contact AMDS@who.int (attention Kenji Tamura).

In the news

Seven new Anti-Retrovirals (ARVs) added to the WHO list of pre-qualified medicinal products

WHO pre-qualification programme announced that they have added seven ARVs, three fixed-dose combinations (FDC) and four single ARVs, to the list of pre-qualified medical products for HIV/AIDS. Three FDCs include two triple combination tablets, lamivudine (3TC) + nevirapine (NVP) + zidovudine (ZDT) and abacavir (ABC) + 3TC + ZDT, by Ranbaxy (India) and one triple combination 3TC + NVP + stavudine (d4T) from Emcure (India). In addition, a film-coated tablet of 3TC (150mg) and two formulas of d4T (30 and 40 mg) manufactured by Matrix (India) and a protease inhibitor by Bristol Myers Squibb (USA), atazanavir, were added to the list. The latest version of the list of WHO pre-qualified HIV/AIDS products are available online.

(7 March 2008)

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

ARVs price reduction by GlaxoSmithKline (GSK)

GSK (UK) announced that new lower prices for its HIV medicines offered on a not-for-profit basis will become available to the developing countries. The price reductions will be applied for 14 ARVs including ABC oral solution (Ziagen®) for children and a commonly used two ARVs combination tablet (3TC + ZDV, Combivir®). The average price reduction for 14 ARVs is about 21 %. The new lower prices will take effect immediately for public sector customers and not-for-profit organizations in all the least developed countries and sub-Saharan Africa, as well as countries with eligible Global Fund and PEPFAR projects. The press release by GSK and the list of HIV medicines with lower prices is available online.

(19 February 2008)

▶ [GSK press release](#)

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Generic atazanavir and a new NNRTI approved by U.S. FDA

The U.S. Food and Drug Administration (FDA) granted tentative approval for a generic formulation of atazanavir sulfate manufactured by Emcure (India). Atazanavir is a member of the protease inhibitor class and prescribed for the treatment of HIV infection in combination with other ARVs. Tentative approval indicates that Emcure's atazanavir meets all FDA-required standards, but it cannot be sold in the U.S. because of existing patent protections. However, this approval makes the product eligible for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR) programme. The list of FDA-approved and tentatively approved ARVs in association with the PEPFAR is available online.

(4 February 2008)

▶ [FDA ARVs list](#)

The U.S. FDA also approved etravirine (TMC125, Intelence®) by Tibotec, a subsidiary of Johnson & Johnson (USA), for use in combination with other ARVs in adult HIV patients who are failing other therapies. Etravirine is the newest approved ARV in the class of non-nucleoside reverse transcriptase inhibitors (NNRTIs). The most common adverse effects caused by etravirine are rash and nausea. The safety and effectiveness of etravirine in children under 16 years and in pregnant women have not been studied. FDA news item on etravirine approval is available online

(18 January 2008)

▶ [FDA news](#)

Activities by AMDS and partners

Réseau Médicaments et Développement (ReMeD) : un réseau de formation et d'information pour les professionnels de santé du monde entier

ReMeD est une association française de solidarité internationale qui œuvre pour un meilleur accès à des médicaments de qualité dans les pays en développement. ReMeD coordonne un réseau de 2000 professionnels dans le monde engagés pour un développement durable en matière de santé. ReMeD met son expertise au service de l'échange d'informations sur le médicament entre professionnels du Nord et du Sud, notamment depuis 1997 via le forum Internet de discussion sur les médicaments essentiels, e-med. ReMeD coordonne des campagnes de sensibilisation des populations en France et en Afrique Francophone et organise des formations depuis de nombreuses années, notamment à la bonne gestion et à la bonne dispensation des antirétroviraux.

► <http://www.remed.org>

Réseau Médicaments et Développement (ReMeD) : a global information and training network for health professionals

ReMeD is an international organization based in France. It works for a better access to quality drugs in developing countries. ReMeD coordinates an international network of 2000 professionals working for sustainable health

development. ReMeD has been utilizing its expertise to facilitate information exchange in the field of

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pharmaceuticals, in particular, through a forum on the essential drugs on Internet, e-med since 1997. For many years ReMeD has been coordinating public awareness campaigns in France and in francophone Africa and has been organizing training courses, in particular, for the good management and dispensing of ARVs.

► [ReMeD web site - English version](#)

PSM Toolbox: Working Group meeting convened (31 January - 1 February 2008)

Representatives from four AMDS partner organizations, ESTHER, IDA Solutions, JSI (USAID | DELIVER PROJECT), ReMeD, and a PSM consultant met with AMDS secretariat in Woerden (Netherlands) to 1) review the PSM Toolbox website (www.psmtoolbox.org) and its off-line version on CD-ROM, 2) review new tools to be included in the toolbox, and 3) discuss the marketing strategy and expansion of the project. During the two-day meeting, it has been agreed to a) revise tool categories, 2) translate major documents and tool information into French, 3) include new tools, and 4) expand the toolbox for malaria medicines and diagnostics. The report of the PSM Toolbox working group meeting is available on the WHO HIV web site.

► [PSM toolkit site - www.psmtoolbox.org](http://www.psmtoolbox.org)

Publications

Interagency guidelines: A model quality assurance system for procurement agencies.

A comprehensive set of recommendations for quality assurance systems for procurement agencies. These recommendations are aimed to assist organizations purchasing pharmaceutical products, vaccines, or other health sector goods to design and implement a uniform and harmonized system that will ensure procurement of pharmaceutical products of defined quality for supply to patients on a mutually recognized process of prequalification.

► [Interagency Guidelines](#)

Electronic update for the 10th edition of 'Untangling the Web of Price Reductions' (September 2007 revision)

The objective of the electronic update is to have a flexible way of including all the new information on products and prices in real time. It will be updated and posted every time new information is obtained from companies. The main version of 'Untangling the Web of Price Reductions' will continue to be updated and published annually.

► [Electronic update2 \(March 2008\)](#)

► [English version \(September 2007 revision\)](#)

► [French version \(September 2007 revision\)](#)

Guidelines for the Implementation of Reliable and Efficient diagnostic HIV Testing (WHO PAHO)

The guidelines present simple and standardized testing strategies to be used as an entry point for HIV care, treatment, and prevention services in the Region of the Americas. The guidelines describe the actions that need to be taken to deliver HIV testing in voluntary testing and counseling settings (client-initiated testing) and in clinical settings (provider-initiated testing). This document emphasizes approaches that are most likely to have a broad public health impact while focusing on the implementation of reliable and cost-efficient HIV testing in existing health care settings.

► [English](#)

► [Spanish](#)

Event

- 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/>

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