

Dear Reader,

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

This is the third in this series and the last issue of 2007. The AMDS team at WHO's HIV/AIDS department would like to take this opportunity to thank you for continuing to support its work. The AMDSmail and AMDSflash project has been a great success. The July summary report of the Global Price Reporting Mechanism (GPRM) announced by AMDSflash was downloaded extremely quickly from the AMDS website; 1200 times in a month!!

If you need further information about AMDSmail and AMDSflash, please contact AMDS@who.int (attention Kenji Tamura).

In the news

New scored-tablet formulations for pediatric treatment

GlaxoSmithKline (GSK) has announced that it has received approval from the European Commission (EC) for new scored tablet formulations of its medicines for HIV treatment including Combivir® (lamivudine 150mg + zidovudine 300mg), Epivir® (lamivudine 150mg) and Ziagen® (abacavir 300mg) for use in children (≥ 14 kg). Up until now Combivir® has only been prescribed for adults and children over 12 years of age. The approval of the new scored-tablets of Combivir®, a fixed-dose combination of HIV medicines, will allow a shift to new weight-based prescriptions of the drug to be dispensed to much younger children.

(6 December)

▶ [GSK press release](#)

Generic version of Tenofovir tentatively approved by U.S. Food and Drug Administration (FDA)

Mylan Incorporated has announced that the tenofovir disoproxil fumarate tablet (300mg) produced by Matrix, a Mylan subsidiary, has received tentative approval from the U.S. FDA. Matrix's tenofovir is the first generic version of tenofovir approved by the U.S. FDA. A tentative approval means that Matrix can sell the product in certain countries outside of the United States.

(4 December)

▶ [Mylan press release](#)

New HIV integrase inhibitor approved by the European Union and the U.S. FDA

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use has recommended that a conditional marketing authorization

AMDSmail

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be granted for Isentress® (raltegravir) produced by Merck Sharp & Dohme Ltd. Isentress® is the first agent of the pharmacological class of antiretroviral agents known as HIV integrase strand transfer inhibitors, commonly referred to as integrase inhibitors. In October 2007, the U.S. FDA already granted accelerated approval for Isentress® tablets (400 mg).

(16 November)

▶ [Press release by EMEA](#)

New lower-strength Kaletra® (lopinavir + ritonavir) tablet for pediatric HIV patients

Abbott laboratories has announced that it has received U.S. FDA approval for a new lower strength tablet formulation of Kaletra® (lopinavir 100mg + ritonavir 25mg). A heat-stable form of Kaletra® is also marketed as Aluvia® in low- and middle-income countries. For pediatric patients, lower strength Kaletra tablets will offer more dosing flexibility compared with the original tablet for adults (lopinavir 200mg + ritonavir 50mg). Abbott expressed its intention to register and make the new lower-strength Kaletra®/ Aluvia® tablet available in more than 150 countries.

(12 November)

▶ [Abbott press release](#)

Global Fund's interim quality assurance policy for multi-source products

The governing Board of the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) has decided that its quality assurance policy for all pharmaceutical products will be reviewed and a report of review will be submitted to the Board at its 18th meeting in November 2008. In the meantime, the Board has decided to set up an interim quality assurance policy for multi-source products. It took this action in order to address concerns raised about the risk of quality assurance problems with drugs previously covered by the Global Fund's quality assurance policy for single and limited source products that have recently been re-categorized as multi-source products.

As an interim measure to address this risk pending the outcome of the review of quality assurance policy, the Board decides that any drugs for the treatment of HIV/AIDS, TB and malaria for which the formula has been published since the 3rd Board Meeting (October 2002) shall be subject to the single and limited source quality assurance policy. This change will take effect immediately.

(13 November)

▶ [Information note of the board decision on policy](#)

Registration status of Viread® (tenofovir) and Truvada® (tenofovir + emtricitabine) released
Gilead Sciences Incorporated, the original manufacturer of Viread® (tenofovir) and Truvada® (tenofovir + emtricitabine), has posted the country-by-country registration status list for both products on its website. According to this registration status list, as of November 2007, Viread® has already been registered in 43 countries and requests for approval to use it had been filed in 35 countries. On the other hand Truvada® has been approved for use by 36 countries and submitted for registration in 34 countries.

(November 2007)

▶ [Country-by-country registration status of Viread® and Truvada®](#)

Canada is first to notify compulsory license to export generic drug

The World Trade Organization (WTO) has announced that on 4 October 2007 it received from Canada a notification that it has authorized a company to make a generic version of a patented medicine for export under special WTO provisions agreed in 2003. The triple combination, TriAvir (zidovudine + lamivudine + nevirapine) can now be manufactured and exported to Rwanda which has no facilities to manufacture the medicine itself. According to the WTO, Canada will be the first country to authorize a manufacturer to make a generic copy of a patented AIDS drug for export.

(5 October)

▶ [More information](#)

Activities by AMDS and partners

Meeting of AMDS partners and stakeholders (12-13 December, 2007)

During a two-day meeting in Geneva, Switzerland, AMDS partners and stakeholders shared the outcomes of various AMDS projects in the area of procurement and supply management (PSM) and discussed on future collaboration within the AMD network.

1. Global Price Reporting Mechanism (GPRM)
2. Forecasting the demand for antiretrovirals (ARVs)
3. PSM toolbox
4. PSM training and capacity building.
5. Harmonization of Monitoring & Evaluation requirements for PSM systems
6. Handbook of supply management at first-level health facilities

▶ [More information](#)

Joint WHO/UNAIDS informal consultation meeting with pharmaceutical companies on forecasting global demand for adult and pediatric ARVs (11 December 2007)

The innovator and generic producers of ARVs, the producers of active pharmaceutical ingredients for ARVs, and the technical partners of AMDS discussed on the following issues related to the forecasting of global demand for adult and pediatric ARVs.

1. The report on demand forecast for antiretroviral drugs in low and middle-income countries, 2007-2008 (WHO, UNAIDS, Clinton Foundation, Mexican Institute of Public Health)
2. The report on forecasting global demand for pediatric ARVs (Supply Chain Management System)
3. WHO recommendations on 2nd line and pediatric ARVs: Current use of ARVs and future trends
4. The creation of an electronic information platform for the production and access to global ARV forecast

▶ [More information](#)

Launch of new PSM toolbox website

In November 2007, AMDS launched a new website for the PSM toolbox which you can use to find tools developed for PSM of HIV commodities. This new website is equipped with a sophisticated search engine so that users can easily identify a specific PSM tool for their daily supply management work. The website also has a forum for exchanging views and valuable experience about PSM tools. New or un-listed tools can be submitted

through the website for a review by the technical working group and for possible inclusion on the website. An off-line version of PSM toolbox on CD is also available upon request. Please contact Ms Clarisse Morris at cmorris@idasolutions.org or Dr. Kenji Tamura at AMDS@who.int.

▶ [PSM toolbox website - www.psmtoolbox.org](http://www.psmtoolbox.org)

Publications

New summary report from the GPRM (October 2007 version)

A new summary report on the GPRM (October 2007) is now available on the AMDS website. The value of the procurement transactions included in the GPRM for antiretroviral medicines since January 2004 is now over US\$ 1 billion in more than 15,000 procurement transactions. This represents approximately 44% of the volume of ARVs in transactions with low- and middle-income countries.

▶ [GPRM summary report \(October 2007\)](#)

New WHO HIV publication: Demand forecast for antiretroviral drugs in low and middle-income countries, 2007–2008

Based on scale-up observed during 2006, the publication's forecasts provide 2007–2008 estimates of the number of people receiving antiretroviral therapy. The volume of current and future demand for active pharmaceutical ingredients (API) for first- and second-line antiretroviral drugs is calculated using two methods: a normative approach which models implementation of country-specific guidelines, and an empirical model which projects 2006 trends in drug use determined by a survey of national HIV programmes.

▶ [Report on demand forecast](#)

Survey of the quality of antiretroviral medicines circulated in selected African countries (WHO)

This report summarizes results of the survey performed in Cameroon, the Democratic Republic of Congo, Kenya, Nigeria, United Republic of Tanzania, Uganda and Zambia to assess the quality of antiretroviral medicines. The collected samples of ARVs at public and private sector procurement organizations and treatment centres around the capital cities were assessed for quality using a variety of assessment methods.

▶ [Report on survey of quality of antiretroviral medicines](#)

September revision of Untangling the Web of Price Reductions (10th Edition) by Médecins sans Frontières (MSF)

This 10th edition of 'Untangling the web of price reductions', a pricing guide for ARVs for developing countries, has been revised to reflect a withdrawal of the previously published prices by Cipla limited for the tenofovir-based fixed-dose combination.

▶ [UTW 10th version \(revised September 2007\)](#)

A 'Step-by-step' algorithm to procure controlled substances for drug substitution treatment

This brochure provides guidance to national governments which have decided to procure drugs for substitution treatment for heroin dependence, including methadone and buprenorphine.

▶ ['Step-by-step' brochure](#)

Events

- 15th Conference on Retroviruses and Opportunistic Infections (CROI 2008), 3-6 February 2008, Boston, USA. <http://www.retroconference.org/2008/>
- XVII International AIDS Conference (AIDS 2008), 8 August 2008, Mexico City, Mexico. <http://www.aids2008.org/>