

Dear Reader,  
We are pleased to welcome you to the second issue of AMDSmail. The first issue of AMDSmail (June 2007) was distributed to and read by more than 1500 recipients. AMDSmail will be produced every 3 months. In addition, important new developments will be sent out separately as AMDSnewsflash. If you need further information, please contact us at [AMDS@who.int](mailto:AMDS@who.int) (attention Kenji Tamura).

## In the news

In the last few months there were important developments related to the regulatory status of ARVs and their proper use. Please share the following news items with those who are interested in these issues.

### Seven new ARVs added to the list of WHO pre-qualified HIV/AIDS products

The last two months saw the addition of seven new anti-retrovirals (ARVs) to the list of WHO pre-qualified HIV/AIDS products. They are two fixed-dose combination (FDC) tablets of stavudine (d4T) and lamivudine (3TC) by Cipla and three co-packaged ARVs from Ranbaxy: two with a FDC tablet of d4T and 3TC and a single tablet of efavirenz (EFV) and one with a FDC tablet of 3TC and zidovudine (AZT) with a single tablet of EFV. These five new products were added in 57th edition of the WHO pre-qualified list (31 August 2007). In addition, two Cipla-made paediatric FDCs with d4T, 3TC and nevirapine (NVP) that had been tentatively approved by US FDA (see below) were added in the 58th list as of 12 September 2007. The latest version of the list of WHO pre-qualified HIV/AIDS products is available [online](#).

### FDA Grants Tentative Approval for the paediatric FDC: stavudine/ lamivudine / nevirapine

The U.S. Food and Drug Administration (FDA) has granted tentative approval for the paediatric triple-FDC tablet of d4T, 3TC and NVP -- the first fixed-dose anti-HIV product designed to treat children under the age of 12 years. The FDC of d4T, 3TC and NVP by Cipla comprises a complete HIV regimen (6mg+30mg+50mg and 12mg+60mg+100mg tablet) to be taken twice daily. Patients can use it after they have tolerated 14 days of lead-in treatment with a half dose of NVP and full doses of other two ARVs. These tablets can also be dissolved in water for children who cannot swallow tablets (15 August 2007).

► [More information](#)

### Overdosing Kaletra® (lopinavir/ritonavir)

Abbott Laboratories, in a letter posted on FDA's web site, warned health care professionals that a child should receive less than five millilitre oral solution of Kaletra® (lopinavir/ritonavir) per dose and the proper dose of Kaletra for children should be based on body weight. This letter was issued following the death of an infant who was given ten times the proper dose.

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The death occurred after a 44 day-old infant was given 6.5ml of Kaletra® oral solution, the equivalent of 520mg of lopinavir and 130mg of ritonavir. Each millilitre of oral solution contains 80mg of lopinavir and 20mg of ritonavir. The infant died nine days later of cardiogenic shock. The letter will be distributed to health care providers to remind them about proper dosing of the drug for children.

### Suspension of Viracept® (nelfinavir) from the list of WHO pre-qualified products

Due to the presence of genotoxic impurity, Viracept® (nelfinavir) manufactured by Roche was suspended from the list of WHO prequalified products. The WHO judgement followed the decision by the European Union (EU) to suspend Viracept® marketing authorization. Viracept® has been pre-qualified by WHO based on scientific evaluation of the European Medicines Agency (EMA) and valid marketing authorisation by the EU. The presence of genotoxic impurity relates only to Viracept® marketed by Roche outside USA, Canada and Japan. WHO recommendations concerning measures to be taken with respect to Viracept® (quarantine of Viracept® and possible alternatives) are available [online](#). (21 July 2007)

Following the recall of Roche Viracept® in Europe, the U.S. Food and Drug Administration (FDA) announced that Pfizer Inc., the manufacturer of Viracept® in USA, has notified health care professionals that its HIV drug Viracept® contains traces of ethyl methanesulfonate (EMS), a potential human carcinogen. FDA has asked Pfizer to limit the presence of EMS, a process-related impurity, in Viracept®. (9 September 2007)

► [More information and recommendations for Viracept® in USA.](#)

## Activities by AMDS and partners

### Procurement Supply Management training for HIV/AIDS (IDA Solutions)

IDA Solutions started out as the training department of IDA Foundation, a large pharmaceutical wholesaler and exporter. Since 2005, IDA Solutions, an independent, not-for-profit organization, focused on capacity building in pharmaceutical supply chain management (SCM) for low- and middle- income countries. One of the offered training sessions is "SCM of HIV/AIDS Medicines & Supplies", which is available in English and French.

The English sessions are organized by IDA Solutions? South African division, ARV Access for Africa. The French training is organized by IDA Solutions in the Netherlands.

- ▶ English training programme and information on the recent emergency buffer stock project
- ▶ Programme of the upcoming French training sessions

### Comprehensive Condom Programming (UNFPA)

Comprehensive Condom Programming (CCP) is based on the social marketing concept of demand, supply and support to expand access to and use of condoms to prevent unintended pregnancies and the spread of HIV. Condom programming aims to integrate with and complement other components of adequately-funded, comprehensive, locally-developed HIV prevention strategies. As a management concept that functions within an integrated or linked sexual and reproductive health and HIV prevention strategy, the array of condom

programming components helps managers to: a) assess whether sufficient capacity exists in the main areas of CCP work; and b) plan how to fill observed gaps to achieve a comprehensive programme. An interagency core group meeting to scale up male and female condom programming for HIV prevention, will take place in 2-4 Oct 2007, at UNFPA New York USA.

- ▶ [More information](#)

## Stories from the field

### Good Distribution Practices Certification granted to Missionpharma Logistics India

Missionpharma announced that its pharmaceutical logistics platform in India, Missionpharma Logistics India (MPL), has been certified by Bureau Veritas as being in accordance with the technical guide by WHO for good distribution practices. The standard operating procedures and overall quality management system used at MPL for storage, consolidation, kit packing and distribution of pharmaceutical products have been

evaluated methodically and found to be in accordance with the annex 5 of WHO technical Report Series no. 937, 2006. The main evaluation components by WHO good distribution practices are 1) Quality management, 2) Storage of pharmaceutical products, 3) Training of personnel, 4) Order preparation, 5) Pharmaceutical inventory management, 6) Shipment and dispatch, 7) Traceability and batch tracking, and 8) Documentation.

- ▶ [More about Missionpharma Logistics India \(MPL\)](#)

## Publications

### AMDS checklist developed for Global Fund To Fight AIDS, TB and Malaria (GFATM) proposal

In collaboration with WHO/AFRO, the UN Procurement and Supply Management working group and GFATM, the AMDS secretariat has prepared a checklist for procurement and supply management issues to be considered in preparation of GFATM proposal. Both English and French versions of the check list are now available on AMDS web site.

### Use of antiretroviral therapy in resource-limited countries in 2006: distribution and uptake of first- and second-line regimens (abstract)

The AMDS/WHO carried out a multi-country survey on the use of first- and second-line regimens in adults and children, and the rates of switching from first-line to second-line regimen. Based on this survey, weighted percentages of ARVs' use across the cohort of adults and children were calculated and correlated with 2006 WHO ART guidelines.

- ▶ [More information](#)

## Forecast of demand for antiretroviral drugs in low- and middle-income countries: 2007–2008 (abstract)

Using regression analysis and documented assumptions, the number of individuals to receive antiretroviral drugs in 2007–2008 was estimated. The volume of active pharmaceutical ingredients was calculated by using two methods: a normative approach modeling implementation of country-specific guidelines, and an empirical model projecting current trends in drug use estimated by a survey of country HIV programmes.

▶ [More information](#)

## Untangling the web of prices (10th version, Médecins Sans Frontières)

The 10th version of 'Untangling the web of prices: a pricing guide for the purchase of ARVs for developing countries' is now available at [online](#). This report includes the price information on all major ARVs and analysis of the impact of new WHO treatment guidelines on the prices of first- and second-line regimens.

▶ [MSF Access initiative](#)

## WHO Pre-qualification Annual Report 2006 available in other languages

WHO Prequalification Annual Report 2006 originally published in English is now translated and available in French (français), Spanish (Español), Arabic [عربي](#) and Chinese [中文](#)

▶ [WHO Prequalification web site](#)

## Laboratory guideline for CD4 enumeration (WHO/SEARO)

CD4 T lymphocytes enumeration is essential for initiation of antiretroviral therapy for an HIV-positive patient as well as for monitoring the response to treatment. The techniques for enumeration of CD4 T lymphocytes are evolving. Guidelines on use of various techniques, the selection of technology, procurement of equipment and their maintenance; ensuring continuous supply and economical use of reagents and bio-safety in laboratory have been discussed in this document.

▶ [Laboratory Guidelines for enumerating CD4 T Lymphocytes in the context of HIV/AIDS](#)

## Antiretrovirals for HIV: A compilation of facts and product information

This document is a compilation of current facts and product information about antiretroviral (ARV) drugs that are commonly used for the treatment of HIV infection in resource-constrained settings. The chapters about individual drugs include information about the class of the drug, available formulations, storage, dosage, known interactions with other drugs (including other ARVs) and main side-effects.

▶ [Antiretrovirals for HIV: A compilation of facts and product information](#)

### 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/>