Procurement of ARVs and roles of AIDS Medicines and Diagnostics Service (AMDS)

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Obstacles

- High prices
- International patent agreements (WTO, TRIPS) and domestic laws and regulations
- Selection of appropriate products
- Life-long procurement
- Difficult to forecast
- Different funding sources (GFATM, PEPFAR, etc.)
What is the AMDS

The AMDS supports countries to procure HIV medicines and diagnostics and strengthen their supply management through collaboration between the UN, Technical and Donor Partners.

Created as the 4th Pillar of the 3 by 5 Strategy.

Components are:
- Technical departments of the WHO, UNICEF, WORLD BANK, UNAIDS
- AMDS team (WHO/HIV) = AMDS secretariat
- Technical and donor partners with HIV-specific Procurement and Supply Management (PSM) activities
Partners and levels of cooperation being sought

**PARTNERS**

- Technical partners (MSH, JSI, MSF, …)
- AAI companies (R & D)
- Companies of the International Generic ARV Manufacturers Association
- Diagnostics manufacturers
- Global Drug Facility (GDF) for TB
- Malaria Medicines and Supplies Service (MMSS)

**Levels of cooperation**

- Country level
  - Regional
  - Global
AIDS Medicines and Diagnostics Service

Objectives

- Ensure that the supply of quality commodities is never an obstacle to rapid expanding treatment, care and support, and to 3 by 5

- Improve commodity supply to catalyze rapid expansion of treatment, to promote equity, to support prevention
AIDS Medicines and Diagnostics Service

General Principles

- Use all available channels (government, NGOs, insurances), build on existing structures/systems when possible
- Use partners to best capacity
- Involve all partners in planning and further expansion
What the AMDS does not plan to do........

- No procurement itself
  - but
    - Support countries to buy/manage supplies
    - Direct to appropriate services
      - ARVs: UNICEF, IDA, WHO supply service
      - Diagnostics: WHO procurement service

- No repeat / duplicate effort
  - Use ongoing work and available expertise
  - No new structures

- No funding to purchase commodities
AMDS Functions (1)

- Support WHO prequalification for ARVs and diagnostics
  - WHO Essential Health Technology (diagnostics)
  - WHO Essential Drugs and Medicines (medicines)

- Support procurement for ARVs and diagnostics
  1) UNICEF
  2) International Dispensary Agency (IDA)
  3) WHO supply service

- Support in-country capacity building for procurement service management (PSM), development of technical tools for rational use, and forecasting of the demands, etc. (http://www.who.int/3by5/library/en/)
AMDS Functions (2)

- Build and expand alliances with:
  - (1) WHO (HIV, EDM, EHT) at HQ, RO and Country
  - (2) Interagency Pharmaceutical Co-ordinating (IPC) Group
    - UNAIDS, UNICEF, UNFPA, World Bank, GFATM
    - PEPFAR, Clinton Foundation, Gates foundation
  - (3) NGOs: missions, MSH, MSF, JSI
  - (4) Suppliers and producers

- Disseminate strategic information
  - **On** AIDS medicines and diagnostics: e.g. prices & sources, patent, legal and regulatory information
  - **Through** a web page embedded in HIV, EDM and possibly UNICEF and World Bank, a newsletter
Disseminate information

"Removal of AIDS medicines from the list of WHO prequalified products"

June 17\textsuperscript{th}, 2004 (2 Cipra products)
August 4\textsuperscript{th}, 2004 (3 Ranbaxy products)

- Lack of appropriate data on BioEquivalence (BE)
- BE is not required by many drug regulatory authorities
- May or may not be the same efficacy as their originals
- Does not necessarily mean poor quality
- Risk of interruption vs. Possible poor quality
- Prequalified alternatives are available
- Do not replace with lower quality products
FDCs prequalified by WHO

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<th>strength</th>
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<th>*Possible lowest cost/year (USD)</th>
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* not applicable for all countries
Pooled procurement and Centralized price negotiation (1)

Organization of Eastern Caribbean States /Pharmaceutical Procurement Services (OECS/PPS)

- Negotiation and monitoring of drug supply
  ➔ Regional Price Contract (RPC)
- Single supplier for each item on the contract
- Special reserve drug account
- Purchase order on behalf of participating countries
- No warehouse or re-distribute

Antigua and Barbuda       St. Kitts and Nevis
Dominica                  St. Lucia
Grenada                   St. Vincent and the Grenadines
Montserrat, St. Vincent and the Grenadines
Montserrat, British Virgin Islands and Anguilla (associate members)
Pooled procurement and Centralized price negotiation (2)

Lima Negotiation (July '02 - June '03)

- Supported by WHO/UNAIDS
- 1st line regimen (AZT, 3TC and EFV/NVP)
  (from 1,000-5,000USD to 350-690 USD)
- 2nd line regimen D4T, DDI and IDV/rtv or LPV/rtv
  (from 1,600-7,600USD to 1,400-4,600USD)
- Price reduction of Rapid test (62-81%), ELISA (13-33%), CD4 (5-70%), and Viral Load (22-82%)

Argentina Bolivia Chile Colombia Ecuador
Mexico Paraguay Peru Uruguay Venezuela
How to prepare pooled procurement

- Standardize regimens and diagnostics
- Align domestic drug regulations
- Establish single negotiating and ordering agency
  - Inter-country agency (regional AMDS or SPC?)
  - WHO WPRO and its procurement service?
    (w/support of AMDS/WHO)
- Revolving fund for small quantity orders
- May not be the lowest for all countries !!!
Further information is available:

WHO AMDS  www.who.int/3by5/amds/en/
WHO EDM   www.who.int/medicines

THANK YOU