



AIDS Medicines and Diagnostics Service (AMDS)



World Health Organization

About the AMDS

- The AMDS is a mechanism created to expand access to quality, effective treatment for HIV/AIDS by facilitating the increased supply of antiretrovirals (ARVs) and diagnostics in developing countries.
- The AMDS is the access and supply arm of UNAIDS/WHO 3 by 5 initiative, which aims to multiply eight-fold the number of people in poor countries receiving antiretroviral therapy by 2005.
- The AMDS builds on years of work by UNAIDS, WHO, UNICEF, the World Bank, and the global health community, as well as on some more recent initiatives, such as that by the Global Fund for AIDS, TB and Malaria, to address the AIDS treatment gap in developing countries. It brings together stakeholders and partners, pooling their capacities, in order to maximize impact towards meeting the 3 by 5 goal as rapidly as possible.
- The AMDS will be one of a trio of mechanisms, with secretariats housed at WHO, to improve access to treatment for HIV/AIDS, TB and malaria.

What the AMDS will offer

- Manufacturers currently have little idea of global market demand and its development over time. This situation affects both the price and volume of medicine production. AMDS will provide the necessary forecasting information to ensure that volumes produced reflect the real need at an affordable price.
- Buyers currently have little information on sources, prices and the patent and regulatory status of quality ARVs and diagnostics. The AMDS will gather and make available all the intelligence needed for buyers, specifically those at country level, to make informed choices on procurement.
- The AMDS will offer technical support to countries to improve drug procurement, in-country supply management services, and local production where applicable.
- At present, most medicine purchasing is done in a fragmented way. The AMDS will assist buyers to obtain best prices for individual or pooled demand, initially only for core ARVs and diagnostics. Where necessary, advice will be given on alternative sourcing options, for example through existing procurement agencies.
- The AMDS services will be available to governments, public-interest-nongovernmental organizations (NGOs), health insurance and employer-benefit schemes, and other not-for-profit supply channels.

AMDS structure

- The AMDS is operational since 1 December 2003.
- The AMDS is inviting a number of intergovernmental organizations, NGOs, foundations and governments to join WHO and its UN partners.
- Where partners already perform AMDS functions existing structures will be utilized and strengthened. Only where these are currently lacking will new structures or systems be developed.
- Partners will be fully represented in planning, prioritizing and potentially expanding the activities of the AMDS through participation in a steering committee.

Milestones: As of mid-2004, 20 countries are using the AMDS to help in procurement and/or distribution of medicines and/or diagnostics, and this number will rise to 50 countries by the end of 2005.

Specific services provided to countries

- *Selection of core ARVs, national acceptance*
Global guidance on simplified treatment guidelines and evidence on ARVs, on simplified treatment regimes, and on selection of essential HIV diagnostic tests; country-level technical support to promote clinical guidelines (see technical brief on ARV treatment guidelines) and to update the National Essential Medicines List.
- *Patent status and licensing*
Information on patent status of ARVs in the country; global guidance and country-specific support on the legal importation of generic medicines and voluntary/compulsory licensing.
- *Registration and quality assurance*
Global guidance and information on regulatory matters and registration status of ARVs; strengthening drug regulatory agencies in dealing with ARVs (registration, inspection, importation, local production and combination products).

- *Product specifications*
Global quality and product specifications for ARVs, to be used for procurement tenders and contracts; including quality specifications for new combination products.
- *Prequalification of ARVs and diagnostics*
Lists of products found to meet WHO standards for quality, safety and efficacy, including fixed-dose combinations, and their suppliers; operational standards for evaluating supply agencies and quality control laboratories.
- *Market intelligence on sources, prices, raw materials*
Access to information on sources and prices of ARVs, other AIDS-related medicines and diagnostics; price indicators for raw materials for local production.
- *Procurement of core ARVs and diagnostics*
Global guidance and training programmes on procurement; practical information for buyers; access to the services of the WHO/UNAIDS diagnostics buyers group; country assessments and country-specific technical support to improve procurement and distribution of ARVs; access to global procedures to obtain economies of scale through international rate contracts; procurement services by or through AMDS (if required).
- *Import taxes and margins*
Information on tariffs, taxes and margins in other countries; country-specific technical and political support in efforts to reduce them.
- *Supply management and monitoring*
Global guidance and training programmes in drug supply management and monitoring; country assessments and consultant support in improving national supply systems; methods and technical support in preparing institutional and national estimates of ARV quantities needed; full-time (inter)national technical staff to assist national authorities.
- *Local production and quality assurance*
Global guidance on Good Manufacturing Practices (GMP) standards; (inter)national training courses on Quality Assurance and GMP; technical support to the national drug regulatory agency in inspecting national production facilities.

PREQUALIFICATION PROJECT

Ensuring the quality, safety and efficacy of HIV/AIDS medicines and diagnostics

The Prequalification Project was created to provide a reliable source of information on the availability of quality, safe and effective HIV/AIDS medicines and diagnostics. It assesses products voluntarily submitted by companies around the world according to WHO recommended standards.

When products are found to meet those standards, they are added to a publicly accessible list of particular use to other United Nations agencies, countries and procurement agencies. Potential buyers thus have a growing, reliable inventory and range of prices to choose from when purchasing these vital products.

The HIV list as it stands contains 86 HIV/AIDS medicines, of which 48 are single-drug antiretrovirals (ARVs), five are two-drug combination ARVs and one is a triple-drug combination. Several other fixed-dose combinations are in the evaluation pipeline. These products are from both branded and generic manufacturers.

Parallel to the medicines scheme, a project run by WHO and UNAIDS assesses the quality, safety and suitability of HIV diagnostics for use in poor countries. Currently, 24 HIV test kits that have met the criteria are available at reasonable cost. Four of these are produced in transition economies. Information on the proprietary rights, licensing and patent issues related to these products is collected and made available.

WHO also evaluates CD4 and viral load tests to monitor the efficacy of HIV drug treatment. In addition, the health agency is helping countries to develop the skills to assess the quality of diagnostic technologies. The agency also provides training to health care workers to ensure correct use of diagnostic tests.

Managed by WHO, the prequalification project partners with the United Nations Children's Fund (UNICEF), UNAIDS and the United Nations Population Fund (UNFPA). It also receives support from the World Bank.

The list of prequalified products and suppliers is available on the WHO web site: <http://www.who.int/medicines/>