



QUALITY ISSUES

This report is a pricing guide, and as such does not include detailed information about the quality of the products listed. However, quality is important and price should not be the only factor determining procurement decisions.

Readers and purchasers wishing to obtain more information about drug quality are therefore encouraged to consult the WHO List of Prequalified Medicinal Products which contains the products that 'meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis medicines' or the US FDA Approved and Tentatively Approved Antiretrovirals List.

WHO PREQUALIFICATION

More commonly known as WHO Prequalification, the WHO List of Prequalified Medicinal Products was initiated by the WHO and developed in collaboration with other United Nations organisations, principally for procurement by UN agencies. The project evaluates pharmaceutical manufacturers and products according to WHO-recommended standards of quality and compliance with Good Manufacturing Practices.

WHO's Prequalification Programme is a benchmark for the identification of quality essential medicines and has significantly improved access to quality medicines over the past years. A key factor of success has been that financial support to national programmes has been dependent on purchasing medicines respecting clear quality assurance criteria. In this the WHO Prequalification Programme has played an important role, providing guidance to purchasers on the quality of medicines and thereby creating a positive market dynamic where manufacturers strive to reach WHO standards in order to comply with procurement policies.

US FDA

In May 2004, in support of the US President's Emergency Plan for AIDS Relief (PEPFAR), US FDA announced a new initiative to help ensure that those being served by PEPFAR would receive safe, effective, and quality manufactured antiretroviral drugs.

DONOR PROCUREMENT POLICIES

The Global Fund to Fight AIDS, Tuberculosis and Malaria has recently changed its quality assurance policy so that Global Fund grant funds may only be used to procure antiretrovirals, anti-tuberculosis and anti-malarial finished products that are either prequalified by the WHO Prequalification Programme, authorised for use by a Stringent Drug Regulatory Authority (SRA), or recommended for use by an Expert Review Panel (ERP).

Unfortunately, the majority of donors today do not have sufficient quality assurance criteria, giving a wrong signal to manufacturers by removing the incentive to comply with WHO norms and standards, and ultimately endangering patients' health in countries where the regulatory system remains weak. Donors and drug purchasers should take heed from the Global Fund's example and make sure that they implement an effective quality assurance policy for medicines bought on behalf of developing countries.

QUALITY OF DRUGS IN THE DATA PROVIDED IN UNTANGLING THE WEB

Manufacturers who have at least one antiretroviral quality-assured by WHO Prequalification or US FDA were invited to participate in this publication.

But not all the products listed in this report have been quality-assured by WHO Prequalification or US FDA, and only some of them are used by MSF in its own projects. Products included in the List of Prequalified Medicinal Products (as of May 2011), including the ones approved by Health Canada, the European Medicines Agency (EMA) through article 58, or in the US FDA Approved and Tentatively Approved Antiretrovirals List, appear in **bold** in the tables of drug prices.

Please consult the websites for WHO Prequalification¹⁷ and the US FDA Approved and Tentatively Approved Antiretrovirals¹⁸ for the latest list of prequalified products and for information on the status of dossier assessment.