



## Pan American Health Organization

Regional Office of the  
World Health Organization

### Tools to determine quality of antiretrovirals

The quality of pharmaceutical products in the Americas is normally ensured through the application of a regulatory and normative framework at the country level that assesses medicines used by the population in terms of quality, safety and efficacy. The application of Good Manufacturing Practices by the producers of pharmaceutical products, combined with the regulatory systems put in place by public health authorities establishes an effective framework in which product quality can be guaranteed.

HIV/AIDS Antiretroviral medicines exist within the Latin American and Caribbean markets however as multisource (originator and generic) pharmaceutical products for which there are limited publicly available quality assurance standards, analytical methods and reference standards. Before countries move to procure ARV, a process must be initiated at the country to determine the acceptable quality reference and criteria. A number of international quality references are available to countries including:

1. The WHO Pilot Procurement Quality and Sourcing Project / Suppliers whose HIV related medicines (including ARV) have been found acceptable, in principle, for procurement by UN agencies (<http://www.who.int/medicines/organization/gsm/activities/pilotproc/suppliers.doc>)
2. Assessment and registration of the ARV by the regulatory authority of a member of the Pharmaceutical Inspection Convention or an entity participating in the Pharmaceutical Inspection Cooperation Scheme (<http://www.picscheme.org/index.htm>)
3. A product authorized by the regulatory authority of a member of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (<http://www.ich.org/>)

In addition to the above, and irrespective of the quality reference standard selected, the ARV must be assessed and registered by the National Drug Regulatory Authority in accordance with the requirements detailed in national legislation.

For further and more detailed information on quality of products used in the treatment of HIV/AIDS, please refer to the WHO Essential Drugs and Medicines Policy webpage, access to HIV-related medicines at <http://www.who.int/medicines/organization/par/edl/access-hivdrugs.shtml> .