Introduction

The availability of low-cost, high-quality, child-friendly ARV formulations, particularly FDC products, has had a significant impact on the scale-up of ART for children.

WHO strongly endorses the use of these products, and encourages the continued development of improved formulations appropriate for paediatric use.

This Annex contains information on antiretroviral (ARV) drugs for which there are paediatric indications, formulations or sufficient information and evidence to provide guidance on prescribing and dosing. Situations that are frequently encountered in resource-limited settings are taken into consideration, including the possible lack of refrigeration and the lack of liquid or formulations of ARVs for small children. For simplification, doses are provided in ranges based on children's weights. Although weight and height can both be measured, it may be impractical to expect providers in many settings to accurately calculate body surface area (BSA). When determining weight-band-based dosing for drugs that are usually dosed by BSA, careful consideration was given to the usual surface area for children of that weight in cohorts from developing countries.

WHO began the work of developing simplified guidance on ARVs for use in children as a result of recommendations made at a technical consultation in November 2004. Since then, the guidance has been regularly updated by the Paediatric ARV Working Group. Members of this working group are listed in Annex A.

The Paediatric ARV Working Group reviews current scientific data and uses pharmacokinetic modelling data to develop guidance to manufacturers on which ARV medicines are likely to be required.

The primary sources of information for the guidance are the package inserts from the innovator for each drug at the time of writing. This information is supplemented with data from other authoritative publications and expert consultation. Providers are advised to consider the most recent guidelines and product labelling as this information may have been updated.

Generic (multisource) ARV drugs are manufactured by several companies. These products include a number of important paediatric fixed-dose combination (FDC) tablets that contain doses of drugs appropriate for small children. Paediatric FDCs are preferable for implementation in resource-limited settings, and while most of them are of acceptable quality, providers should consult the WHO document *Access to HIV/AIDS drugs and diagnostics of acceptable quality* for guidance (http://www.who.int/hiv/amds/selection/en/index.html).

WHO operates a voluntary prequalification system that was set up in 2001. This service facilitates access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis (TB). Manufacturers (including manufacturers of generic products) who wish their medicines to be included in the prequalified products list are invited to apply. Each manufacturer must present extensive information on the product (or products) submitted to allow qualified assessment teams to evaluate quality, safety and efficacy. The manufacturer must open its manufacturing sites to an inspection team that assesses working procedures for compliance with WHO Good

Manufacturing Practices. Alternatively, the inspections carried out by stringent regulatory bodies are recognized and their work is not duplicated by WHO. A list of WHO-prequalified products is continuously updated and is available at http://mednet3.who.int/prequal/.

This Annex will be updated regularly as new data become available and readers are recommended to check the WHO website on paediatric HIV care (http://www.who.int/hiv/topics/paediatric/en/index.html).