



# ARV treatment guidelines and technical and operational recommendations for ART



World Health Organization

**B**ackground: Scaling up the delivery of ART in resource-poor settings in line with 3 by 5 requires simplified treatment regimes that can be used safely and effectively by a broad range of health professionals. ART programmes also require guidance on the key operational and technical issues related to scale-up.

The World Health Organization (WHO) manual *Scaling up ART in resource-limited settings—guidelines for a public health approach*, published in June 2002, has been updated and the recommendations simplified. Ongoing work to formulate operational guidelines on scaling up treatment access and then refine such guidelines as more experience is accrued, has been started.

## 1. ARV treatment guidelines for resource-limited settings

### a) Objectives of the document

The updated treatment guidelines are intended to support and facilitate the more universal access to antiretroviral treatment by proposing a public health approach. The key tenets of this approach are:

1. standardization and simplification of antiretroviral treatment regimens with the objective of 'universal access', i.e. that all those who need it will have access to antiretroviral treatment;
2. scaling up of antiretroviral treatment programmes to support the efficient implementation of long-term therapy programmes in resource-limited settings;
3. ensuring that antiretroviral treatment programmes are based on scientific evidence, in order to avoid the use of substandard treatment protocols, which compromise the treatment outcome of individual clients and create the potential for emergence of drug-resistant viruses.

### b) Description of content

The guidelines present options for first- and second-line regimens, and recommend when to start antiretroviral treatment, reasons for changing it, and what regimens to continue if treatment needs to be changed. They also address how treatment should be monitored, with specific reference to the side effects of antiretroviral treatment, and make specific recommendations for certain patient subgroups. All recommendations are made bearing in mind the needs of health systems that often lack sophisticated manpower and monitoring facilities, without compromising the quality and outcomes of the treatments offered.

A first innovative feature is significant simplification of the recommendations for the treatment regimen, with a recommendation to opt for one, single three-drug first-line treatment regimen, using either d4T or ZDV, 3TC, and either NVP or EFV as the first-line drugs. Further new features include more liberal recommendations on when to start treatment, new definitions of treatment failure, new recommendations on second-line treatment, increased clarity in the laboratory monitoring section, and a new section on adherence support.

### c) Utility and usefulness at country level

While it is hoped that the treatment guidelines will be useful for clinicians in resource-limited settings, it is intended primarily for use by treatment advisory boards, national AIDS programme managers, and other senior level policy-makers involved in the planning of national and international HIV care strategies in developing countries. The treatment guidelines serve as a framework for selecting the most potent and feasible antiretroviral regimens as a component of an expanded national response for care of HIV-infected individuals. The framework aims to 'standardize' and simplify antiretroviral therapy, much like TB treatment in National TB control programmes, while acknowledging the relative complexity of HIV treatment.



## d) The role and function of partners in the development of the guidelines

The treatment guidelines developed for release on 1 December 2003 were prepared by a writing committee which included experienced physicians, nongovernmental organizations (NGOs), and AIDS activists from both the northern and southern hemisphere. The consensus draft was forwarded for review to all WHO regional offices, to over 130 partners in the International Treatment Access Coalition, and was posted for public comment on the WHO web site. The final version was posted on the WHO website on World AIDS Day, 2003.

**Milestone:** The guidelines will be available in print before end of March 2004, and will be revised on our annual basis, with expected web release on World AIDS Day 2004 and 2005.

## 2. Technical and operational recommendations for scaling up access to ART in resource limited settings

### a) The consultative process

To support the 3 by 5 strategy, a consultation took place in Lusaka, Zambia (18–21 November 2003), which aimed to bring about consensus on operational and technical issues related to scale up. The Zambia consultation has built on the experiences of implementers in the field, partner organizations and previous consultations.

The consultation covered five operational and technical areas:

- The Essential service package
- Human resource, training and service delivery
- Commodity management
- Strategic information
- Involving communities

### b) Process

- Each of the five areas in which recommendations were produced were covered by a working group, chaired by two representatives from organizations other than WHO, at least one of whom represents an organization based in a developing country, and in which there is representation from different geographic areas and stakeholder groups.
- Each group was supported by a key point-person within WHO, involved with the development of the 3 by 5 strategy.
- WHO has been responsible for ensuring completion of the draft documents and final outputs.

### c) Outputs

- Operational and technical recommendations for scaling up ARV treatment aimed specifically at implementers (the public, NGOs, private practitioners and industry) at service-delivery points and district health teams.
- Start of a network of implementers of ART in resource-limited settings, with a mechanism to share more information as they 'learn by doing' over the course of the next two years.

**Milestone:** The operational and technical recommendations of the consultation were released on the web in December 2003, and the electronic forum was launched on 1 December. The recommendations will be used to develop our operational manual for scale up, which will be available at the end of March 2004.