

**Policy on anti-retroviral
drugs supply and use
OF
THE FEDERAL DEMOCRATIC REPUBLIC OF
ETHIOPHIA**

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POLICY ON ANTI-RETROVIRAL DRUGS SUPPLY AND USE OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA

INTRODUCTION

Policies and strategies that improve the prevailing low socio-economic status of the country, ensuring rapid economic growth that benefit the whole of the Ethiopian citizens and building well established free market economy through integrating the overall development capacities and efforts, have already been formulated. Capacity building implementation programs and strategies, enabling rapid growth of well-developed free market economy benefiting the general population have also been in place.

Thus far in Ethiopia, inadequately organized and coordinated efforts that have been applied to curb the spread of the HIV/AIDS epidemic and its socio-economic impacts have not produced significant effects. This deadly epidemic, without curative drugs or protective vaccine, has hit the country hard.

Unless robust actions to prevent and control this epidemic are executed, the epidemic will blur our development vision, exert strong negative impact on socio-economic, peace and stability and psychosocial life of the Nation. 7

In order to curb the spread of the epidemic and mitigate its impacts prevention and control measures with strong social mobilization that is given dedicated leadership by the Government and involving the whole of the Ethiopian people is mandatory.

Providing care and support to infected and affected citizens are not dichotomous with prevention and control, in actual fact they are synergistic and enable human handling of the epidemic. Therefore, care and support have important role in preventing the spread of the epidemic.

One of the major components of care, in actual fact prevention, is prevention of mother to child transmission of the virus using antiretroviral drugs. Furthermore, these drugs play important role in minimizing HIV transmission in health care institution settings. The other major use of these drugs is in the treatment of People Living with HIV/AIDS (PLHA). These agents, by improving the quality and length of life, enable patients to contribute to the well being of their families and development of their country.

In Ethiopia the number of PLHA is high, therefore, the demand for the drugs is high. However, because the country is among the least developed countries with very low per capita, taking into account the high price of the drug, it becomes very difficult to meet this high demand without concerted efforts of the government and other stakeholders. Moreover, even if the advantages of the drugs when appropriately used have been established beyond any shadow doubt, they have also frequent adverse effects and other problems. First of all they can never eradicate the virus from the body, hence they have to be taken lifelong.

In addition to these, the drug regimens are complicated, require high degree of adherence, they interact with other drugs, food and recreational beverages, therefore the compliance by patients, in particular under our circumstances is exceedingly low. Poor compliance means emergence of viruses resistant and cross-resistant to these drugs. This is a disaster not only for the individual user of the drugs but also for the community because of increased circulation of drug resistant strains of the virus.

Taking into account the multitude of problems that are related with the introduction of programs pertaining to use of antiretroviral drugs, in particular the immense technological, financial and institutional capacities demanded for safe and effective use of antiretroviral drugs; “Antiretroviral Drugs Supply and Use Policy”, which is a component of other policies that have been formulated to prevent and control HIV/AIDS, such as the “Health Policy”. The “National AIDS Policy” and the “Drug Policy”, has been formulated.

The Ethiopian Federal Democratic Republic:

1. Realizing, the degree of socio-economic damage posed by HIV/AIDS and the roles of antiretroviral drugs in the prevention and control of the epidemic;
2. Cognizant of the high cost of introducing the use of these drugs in face of very low capacity that the country can contribute, and such undertaking cannot be effective without the concerted efforts of many stakeholders;
3. Recognizing very crucial role of regulation because of the complicated nature of the regimens of the antiretroviral drugs, problems related with use of the drugs in the community, the emergence of resistance, cross resistance and their individual and

community consequences, and adverse effects of the drugs has formulated “Antiretroviral Drugs Supply and Use Policy”.

Objectives of the Policy

By ensuring sustainable supply of safe, effective, quality and affordable antiretroviral drugs and promoting their proper use:

- A. Reduce transmission of HIV from Mother to Child.
- B. Prolong and improve the quality of lives of PLHA thereby making them productive and contribute to the well being of their families and development of their country.
- C. Reduce accidental HIV infection within health care institutions.

General Policy

1. Determining the type of antiretroviral drugs that will be used in the health care services;
2. The Government, because of its responsibility to safeguard the health and well being of its citizens, shall coordinate and facilitate the supply of antiretroviral drugs.
3. Build capacity of making available safe, effective and quality antiretroviral drugs, and proper use of these drugs;
4. Ensure sustainable supply of antiretroviral drugs through encouraging involvement of all stakeholders;
5. Nurture international relationship diligently, in order to strengthen and expand the continuous supply and use of antiretroviral drugs;
6. Conduct integrated research on modern and traditional treatments given to patients with HIV/AIDS, and disseminate the outcomes for all stakeholders;
7. Establish a system of monitoring supply, and use of Anti-retroviral drugs.

General Strategies

1. Selection of Antiretroviral Drugs

- 1.1 Taking into account the availability of trained human resource, financial capabilities and the nature of the drugs, determine the type of antiretroviral drugs to be used in the country.
- 1.2 A list of antiretroviral drugs which is part and parcel of the national drug list shall be prepared and regularly updated.
- 1.3 Import of antiretroviral drugs that are not included in the national drugs list for research and other purpose shall be facilitated by responsible government office.

2. supply of Antiretroviral Drugs

- 1.4 The Government shall supply antiretroviral drugs used for prevention of mother to child transmission (MTCT) to the appropriate health care institutions through coordination of all stakeholders.

2.2 Antiretroviral drugs for ART:

- a. Shall be exempted from taxation.
- b. Shall be supplied at a reduced price through Government's negotiation with manufactures, importers and distributors.
- c. Shall be purchased through a system of bulk and generic substitutions.

2.3 Government shall encourage local production of Anti-retroviral drugs.

2.4 Government shall facilitate a conducive environment for benefaction of antiretroviral drugs.

2.5 By making use of its International links, the Government shall encourage the establishment of International antiretroviral initiatives and programs in Ethiopia, so that the community benefits out of these initiatives and programs.

2.6 Government creates enabling environment for international research to come in and work in Ethiopia, so that citizens access antiretroviral drugs by willingly participating in this research projects.

2.7 The private sector will be encouraged to be involved in locally manufacturing, importing and distributing antiretroviral drugs.

2.8 All other stakeholders that will play important role in making antiretroviral drugs available to the community shall be encouraged to do so.

2.9 In order to reduce accidental HIV transmission in health care institutions.

- a. Health care workers will be given sustainable training on universal precaution and appropriate efforts will be made in order to supply protective materials in sufficient amounts.
- b. Based on the country's financial ability and research/surveillance on accidental blood exposures (AEBs), post-exposure prophylaxis (PEP) will gradually be introduced.

3. Drug use

3.1 Standardized antiretroviral prescription paper shall be prepared and put in action;

3.2 National guideline for safe and effective use of antiretroviral drugs shall be prepared and implemented;

- 3.3 Sustainable public education on proper use of antiretroviral drugs shall be given to the community;
- 3.4 Antiretroviral drugs
 - a. Shall be prescribed in authorized health care institutions by trained physicians using the National treatment guideline;
 - b. Shall be dispensed in authorized retail outlets by trained pharmacy personnel/ pharmacists;

4. Research and Development

- 4.1 Government encourages institutions and individuals that conduct research on modern and traditional HIV/AIDs treatment and related issues;
- 4.2 The government shall make all efforts to strengthen the capacity of research institutions that will have significant contribution in program implementation;
- 4.3 The rights and benefits of citizens that enroll in researches concerning Antiretroviral drugs and vaccines shall be respected;
- 4.4 The necessary national and international legal and ethical norms shall be observed in conduct of research on AIDS treatment including researches involving antiretroviral drugs.

5. Implementation of the Policy

- 5.1 The implementation of the program of antiretroviral drugs shall be facilitated to conform phased, step-by-step fashion;
- 5.2 Appropriate guidelines that will enable implementation of the program shall be formulated and put into action;
- 5.3 In order to implement the policy all stakeholders shall act together depending on the prevailing circumstances.
- 5.4 In order to establish an enabling environment for implementation of the policy, the Government shall nurture international relations;
- 5.5 In order to strengthen and expand the program a system of sustainable monitoring and evaluation shall be in place.

6. Capacity building to implement programs

- 6.1 Based on the nature of the drugs and adverse effects they incur,
- a. Strengthening a system of drug supply, storage, and distribution;
 - b. Provide sustainable training for health care workers that will be deployed in different aspects of program implementation;
 - c. Strengthening a system of management including information management system;
 - d. Quality assurance system;

Capacities shall be built in.

- 6.2 In order to implement programs in health institution, capacity pertaining to Laboratory equipment and related materials shall be built.