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IMPROVING ACCESS TO DRUGS FOR HIV/AIDS IN THE
AFRICAN REGION - A PROGRESS REPORT

EXECUTIVE SUMMARY

1. The health systems of countries hit hardest by the HIV/AIDS epidemic are overwhelmed and the burden of the epidemic is increasing as people infected several years ago become ill. Given its global nature, the epidemic has been put high on the international agenda not only as a health issue, but also as a development and security concern requiring the collaboration of governments, development partners, the United Nations system, the private sector, nongovernmental organizations and civil society, with a view to combating it.
2. On 11 May 2000, the Joint United Nations Programme on HIV/AIDS (UNAIDS) issued a press release announcing that five drug companies have indicated their willingness to work with other stakeholders to find ways and means of broadening access to care and treatment, while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS related illnesses. A key aspect of this Initiative is that it envisages a huge reduction in the prices of antiretrovirals. The announcement was only a declaration of intent, and details of its implementation were yet to be collectively or individually discussed and agreed upon.
3. Following this announcement, further information on the Initiative was provided for ministers of health of countries of the African Region, at their usual meeting with the WHO Regional Director, and at a special meeting with the Director General of WHO and the Executive Director of UNAIDS during the 53rd World Health Assembly.
4. The present report gives an overview of issues related to the improvement of access to care and HIV/AIDS drugs, especially as regards new developments since the UNAIDS announcement in May 2000. It is acknowledged that price reduction for antiretrovirals is just one of the issues to be addressed in resolving the HIV/AIDS equation. Other issues also need to be considered in fighting the epidemic. They include prevention, treatment and care; availability of diagnostic facilities; treatment and care for opportunistic infections; psychosocial support and efforts to develop a vaccine for HIV infection. The report also outlines various initiatives undertaken by WHO and other UN agencies to improve access to care for HIV/AIDS. Finally, the report proposes some future actions.
5. This report is being submitted to the 50th session of the WHO Regional Committee for Africa following a request from a group of Member States for an update on progress made since the UNAIDS announcement in May 2000.

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INTRODUCTION

1. The HIV/AIDS epidemic in the African Region has been described as an emergency, a disaster and a security risk for the Region. The latest epidemiological data indicate that the demographic structure in severely affected countries will be significantly changed by the year 2020, from a pyramid to a column, with huge population losses among young adults. Approximately 24 million Africans are now living with HIV/AIDS. The situation has caused exponential increases in the demand and need for care, as the epidemic has matured and those who are infected have become ill with HIV-related diseases and opportunistic infections. Inadequate access to drugs for HIV/AIDS is a major constraint limiting the ability of countries to meet their citizen's human right to care and health. One of the main reasons for the limited availability of HIV-related drugs in developing countries is the high cost of drugs, particularly of antiretrovirals that require life-long use, where they are available. The thirteenth International Conference on HIV/AIDS held in Durban, South Africa, in July 2000 widely acknowledged the widening gap in access to lifesaving drugs between the developed and developing countries as a failure in international solidarity..

2. Access to health services and drugs is a basic human right, particularly for people with HIV/AIDS. The HIV/AIDS epidemic is complex, multifaceted and requires that there be access not only to drugs but also to health professionals, appropriate nutrition, home-based care and support as well as information to enable the infected people to prevent further spread of the disease. Although access to drugs is a crucial factor in improving the quality of life of people in general, and those with HIV/AIDS in particular, other equally important factors need to receive attention in the fight against the epidemic. These factors are prevention, treatment of opportunistic infections, strengthening of laboratory facilities, and psychosocial support.

3. This report is being submitted to the 50th session of the Regional Committee following a request for an update on progress made in drug price negotiations with pharmaceutical industries. The request was made by the ministers of health of the SADC countries at their meeting in Pretoria on 17 June 2000.

'ACCESS' – AN INITIATIVE TO IMPROVE DRUG AFFORDABILITY

4. The ministers of health of countries of the African Region, through Resolution AFR/RC49/R5 which was adopted at the 49th session of the Regional Committee in 1999, requested the Regional Director to provide support to countries in their effort to improve the affordability of essential drugs, particularly for HIV/AIDS and related conditions. In response to this resolution and to discussions at the 52nd session of the World Health Assembly, the World Health Organization and the UNAIDS Secretariat embarked upon negotiations with pharmaceutical companies in order to obtain price reductions and improve the affordability of HIV/AIDS-related drugs for developing countries. On 11 May 2000, WHO and UNAIDS issued a joint statement announcing that five pharmaceutical companies had indicated their willingness to work with other stakeholders to find ways to broaden access to care and treatment. This initiative, named 'Accelerating ACCESS', is being coordinated by a task force involving WHO, the UNAIDS Secretariat, UNICEF and the World Bank.

5. The five companies initially involved were Boehringer Ingelheim, Bristol-Myers Squibb, Glaxo Wellcome, Merck & Co. Inc., and F. Hoffman- La Roche. The announcement was a declaration of intent, and the details of its implementation have yet to be collectively or individually discussed and agreed upon. Further information on the negotiations was provided to ministers of health of countries of the African Region, at their briefing with the WHO Regional Director, and at a special meeting with the Director-General of WHO and the Executive Director of UNAIDS during the 53rd session of the World Health Assembly.

6. The ministers issued a statement in response to the announcement, welcoming any initiative to improve access to HIV/AIDS care in the African Region. They emphasised that any attempt to improve drug affordability needed to be placed in the context of actions to improve access to care and strengthen health

systems. The ministers of health of South Africa, Uganda, Mali and Congo were designated to represent subregional groups of countries in further discussions and negotiations. In addition, the World Health Assembly adopted resolution WHA 53.14, requesting the Director General of WHO to ensure that, together with the UNAIDS Secretariat and other interested UNAIDS cosponsors, the World Health Organization proactively and effectively pursues a dialogue involving the pharmaceutical industry, jointly with Member States and Associations of People Living With HIV/AIDS.

7. Four ministers are members of a Contact Group established to provide a forum on negotiation process for the representatives of governments, People Living With HIV/AIDS (PLWAs), nongovernmental organisations (NGOs) and other parties including the pharmaceutical industry. The Group will provide guidance to WHO, the UNAIDS Secretariat and other UN agencies on the principles, policy and practice applicable for accelerating access to drugs. The discussions of the group are meant to assure a well-coordinated, participatory and transparent approach to accelerating access to drugs and care for HIV/AIDS management.

8. Discussions will include all substantive issues concerning the Accelerating ACCESS Initiative at the global, regional and subregional levels, including (i) programming of HIV/AIDS prevention, care and treatment; (ii) affordability of health technology; (iii) health systems infrastructure; (iv) modalities for participation in the Initiative; (v) procurement arrangements; and (vi) financing. The Group held a first informal meeting in Geneva on 30 June 2000, and will convene its inaugural formal meeting in September.

9. Issues of importance concerning the improvement of affordability and accessibility of drugs and care include:

- (a) The current basic price of antiretroviral drugs (ARVs) based on which percentage reductions will be made.
- (b) The current annual cost of ARV treatment per individual, estimated at around US\$10,000 compared to US\$4 which is the annual average per capita expenditure on health in most countries in the Region.
- (c) The capacity of countries to meet the preconditions that may accompany offers of drug price reductions and donations.
- (d) The financial capacity of countries to import drugs, as well as establish and maintain their capacity to meet other technological requirements related to the use of antiretrovirals, including laboratory monitoring.
- (e) The implications for the strengthening of health systems.
- (f) Other aspects of access to care, including geographic barriers to access to health services; the attitudes and skills of health care workers and the training, support and supervision necessary for improvement.
- (g) Equity and solidarity in access to drugs and care.

Accelerating ACCESS – PROGRESS SINCE THE 53rd SESSION OF THE WORLD HEALTH ASSEMBLY

10. There have been some initial developments in the Accelerating Access Initiative since May 2000, and more information and details are emerging. These developments which are in their early stages are listed below.

- During the thirteenth International Conference on AIDS in July 2000, Boeringher-Ingelheim made a public offer to provide Nevirapine free of charge through WHO for the prevention of mother-to-child transmission of HIV; details of this offer have yet to be discussed and agreed upon.
- Glaxo Wellcome has stated that the reduction of the prices of Retrovir, Eпивir and Combivir will be between 75% and 85% compared to average global market prices (e.g. a price reduction for Combivir which will lower the price of dual therapy from \$16 to \$2 per day).
- Merck and the Gates Foundation has signed a memorandum of understanding with the Government of Botswana for a US\$100 million project on comprehensive care including the use of antiretrovirals, over 5 years.
- The Import/Export Bank of the United States has announced the availability of a US\$1 billion loan to enable African countries to import antiretrovirals from American pharmaceutical companies.
- Following the meeting of the Programme Coordination Board of UNAIDS on 12 June 2000, a number of countries were contacted to ascertain their interest in rapid implementation of interventions for improving access to care, including to antiretrovirals. As at 30 June 2000, Botswana, Burundi, Chile, Cote d'Ivoire, Ghana, Kenya, Lesotho, Mali, Rwanda, Senegal, Swaziland, Uganda and Zambia had sent written requests for cooperation within the context of the Initiative.

IMPROVING ACCESS TO CARE – THE FRAMEWORK FOR THE IMPLEMENTATION OF THE REGIONAL STRATEGY ON HIV/AIDS/STI

11. The current session of the Regional Committee will discuss a Framework for the acceleration of the implementation of the Regional Strategy on HIV/AIDS. The Framework underscores the importance of strengthening health systems as vehicle for the delivery of a critical component of the national response to HIV/AIDS. Equity and solidarity, strengthening national capacities and integration at the operational level are cornerstones of the Framework. The improvement of access to drugs and care for HIV/AIDS and related opportunistic infections are being pursued within this context. The actions undertaken and planned by WHO and other UN agencies within this broad framework are as follows:

UN Strategy on Access to HIV-related Drugs

12. A UN interagency task force established in 1999 has developed a strategy on access to HIV-related drugs, which emphasises rational use and selection of HIV-related drugs; affordable prices; sustainable financing and reliable supply systems. Rational selection focuses therapeutic decisions, professional training, public information, financing, supply and quality assurance efforts on those drugs which will have the greatest impact in a given health care setting. At country level, the selection of HIV-related drugs (for providing palliative and supportive care and for treating and preventing opportunistic infections, sexually transmitted diseases and HIV-related malignancies) should be based on locally developed treatment guidelines, drawing on the best available evidence concerning efficacy, safety, quality, and cost effectiveness. The current WHO Model Essential Drug List includes 2 antiretroviral drugs, Nevirapine and Zidovudine, for use in the prevention of mother-to-child transmission of HIV. The next meeting of the WHO Expert Committee on Essential Drugs will consider concerns expressed in relation to the inclusion of HIV-related drugs, as well as issues related to the frequency of updates of the list, procedures for external review of proposed amendments, how best to reflect cost and cost effectiveness considerations as well as linkages to the WHO standard treatment guidelines.

13. UNICEF, WHO and the UNAIDS Secretariat are providing *Price Information* to help countries in price negotiations and in locating and assessing the efficacy of new supply sources. The database on drug prices which is available on the WHO website will be expanded to include antiretroviral drugs. The competitiveness of generic drugs in terms of their prices and their use for therapy is also a strong price-reduction tool that can be used to achieve price reductions of up to 95% compared to the initial brand prices in the developed countries. The elimination of import duties and taxes, local production of quality drugs and application of TRIPS safeguards (compulsory licensing, parallel importing) are recommended in the Strategy.

14. WHO and UNAIDS have produced information documents and guidelines on issues related to access to HIV/AIDS care and treatment. These documents are either available or are being finalized for distribution to countries.

Accelerated country support - the International Partnership Against AIDS in Africa (IPAA)

15. The World Health Organization, in the context of the IPAA, held a meeting in South Africa from 18 to 22 June 2000 with 8 countries in order to plan support for accelerated efforts to improve access to HIV/AIDS drugs, as part of National Essential Drugs Programmes. The participating countries were Chad, Ghana, Ethiopia, Malawi, Mali, Mozambique, South Africa and Tanzania. Highlights of the discussions include the following:

- Most antiretrovirals and other drugs for opportunistic infections are not patented in many countries and can therefore be freely imported from many sources.
- Countries should study the patent status of HIV/AIDS drugs in order to determine whether to access these drugs through direct importation, parallel importation or compulsory licensing so as to reduce costs.
- Public and donor funds need to be pooled and directed towards the most cost-effective interventions including prevention of HIV transmission.
- Debt relief should be used for health and social development including the procurement of drugs.
- HIV/AIDS subcommittees should be established within national drug committees.
- National strategic plans and national drug policies, especially in regard to access to HIV/AIDS drugs, should be closely coordinated.

16. Country plans were initiated and WHO provided support for the implementation of activities in the following key areas: provision of price information and supplier details; information on the negative implications of WTO/ TRIPS agreements for access to HIV/AIDS drugs; conduct of needs assessment; training and re-training of health personnel; technical assistance for incorporating appropriate legal provisions for WTO / TRIPS compliance; technical assistance for the preparation of frameworks of negotiation with drug companies; strengthening home-based care; prevention interventions; resource mobilisation; revision of essential drug lists and standard treatment guidelines; and assistance for the development of drug quality assurance systems. Country support missions to finalize plans will be initiated in August 2000. The first joint WHO/UNAIDS Secretariat mission to Swaziland was fielded in July 2000 with the aim of mapping out key areas for intervention and proposing the way forward to increase access to HIV/AIDS care and drugs.

Drug Kits for Home-based Care

17. The WHO Regional Office for Africa carried out a needs assessment on HIV/AIDS-related care in nine countries – Botswana, Malawi, South Africa, Swaziland, Mauritius, Tanzania, Zambia and Zimbabwe. The information collected was used to plan interventions for improving care within the continuum from health institutions to the community. The training needs of health care providers, particularly nurses, were identified. A Fact Sheet for Nurses, covering all aspects of HIV/AIDS care, was developed and launched at the thirteenth International Conference on AIDS and will be made widely available in countries in the next few months.

18. The extensive needs yet to be met in the provision of care in homes prompted the initiation of an intervention to provide drug kits to home-based care providers. Drugs have been provided in the nine countries, in addition to training and support from health care workers. Early and anecdotal indications are that the provision of kits adds value to the quality and appreciation of home-based care. The Initiative will be evaluated to assess its cost, relevance and effectiveness and its results used for modelling, adaptation, resource mobilisation and expansion. Drug supply, human resources and training needs for home-based care will be integrated into national treatment guidelines and HIV/AIDS strategic plans and budgets. The possibility of developing standardised kits on a wide scale, and for which price reduction may be obtained through bulk purchasing will be actively explored.

Strengthening laboratory capacity to monitor the use of antiretrovirals

19. The WHO Regional Office organised in Dakar, Senegal, the first regional consultation on the strengthening of laboratories in the context of the use of antiretrovirals. A network for this purpose is being established. Through the network, countries will be supported to share expertise, experience and technical resources.

FUTURE ACTIONS

20. WHO and the UNAIDS Secretariat will continue to facilitate and support negotiations between countries and pharmaceutical companies in the context of the Initiative. The Contact Group will meet regularly and focus on key areas including monitoring of achievements in, and challenges to, the effort to improve access to HIV-related drugs. Reports on meetings of the Contact Group will be communicated regularly to members of the Group, governments in participating countries, the NGO/PLWA community, executive heads of participating UN agencies and members of the UNAIDS Programme Coordinating Board.

21. Technical support will be provided to countries, in the context of the Regional HIV/AIDS/STI Strategy and the International Partnership Against HIV/AIDS in Africa. The key areas of support will be as listed in paragraph 15 of this document. Support will also be provided for countries to enable them to adapt guidelines and tools for clinical, nursing and psychosocial care for HIV/AIDS, as well as for the prevention of mother-to-child transmission. Functional links between the different components of community and health facility-based care services will be strengthened through supporting countries to define and provide a package of care and prevention services for HIV/AIDS. Diagnostic technologies and facilities including the improvement of the affordability of reagents will be incorporated into the related activities.

22. The Regional Director will provide regular update on progress to ministers of health and will report annually to the Regional Committee.