

GLOBAL FUND OBSERVER (GFO) NEWSLETTER, a service of Aidspace.

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1. NEWS: Global Fund and Others Announce Cheaper Drug Possibilities for Grant Recipients
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The Global Fund and three other organizations today announced ways in which grant recipients can obtain high quality antiretroviral drugs and diagnostics at very low prices that previously were only available to a few countries.

The press statement by the four organizations is reproduced below, together with a supporting “Question and Answer” document. This article is based in part upon interviews that GFO conducted today with the Global Fund and the Clinton Foundation.

Under the plan, generic drugs made by four Indian companies and one South African company could eventually become available in over 120 countries eligible for Global Fund grants at prices as low as \$140 per patient per year.

The drugs in these agreements include two- and three-drug fixed dose combinations which have been certified by the WHO as being of acceptable quality and efficacy.

The four organizations that have agreed to work together are the Global Fund, the William J. Clinton Presidential Foundation, the World Bank, and UNICEF. The Clinton Foundation helps to negotiate price agreements with drug manufacturers; the Global Fund and the World Bank provide AIDS-related grants; and UNICEF offers a bulk procurement facility.

Last year, the Clinton Foundation negotiated agreements whereby suppliers of generic ARV drugs agreed to offer prices to a few countries in Africa and several in the Caribbean that were significantly lower than any prices previously available. The Foundation did so by pooling volumes across multiple countries, by moving to a system of multi-year tenders, and by finding ways in which the buyers could guarantee full and prompt payment. This gave the manufacturers the ability to plan their production more efficiently and to realize cost savings that they could pass on in the form of lower prices.

In today's agreement, these terms and prices will be made available, in principle, to all countries that have received Global Fund HIV/AIDS grants and that meet certain additional conditions for participation.

In each such country, the Clinton Foundation has negotiated or will negotiate a low "ceiling price" for each relevant ARV drug. Any company – be it a generic manufacturer or one of the original patent-holders – that is willing to produce these drugs to acceptable standards and to sell them at or below this price is welcome to compete for contracts within the program.

A Global Fund Principal Recipient (PR) that is administering an HIV/AIDS grant and that wishes to become eligible for these low prices should proceed as follows:

- First, as in the past, the PR should go through the arduous assessment process that comes after Global Fund grant approval and before signing of the Global Fund grant agreement. This assessment will be conducted by the relevant Local Fund Agent (LFA), and will include, in particular, the need to develop an acceptable Procurement Plan.
- During this process, the PR should make initial contact with the Clinton Foundation's HIV/AIDS Initiative (www.clintonpresidentialcenter.com/AIDS_overview.html) by sending an email to info@hivaidsinitiative.org and writing "Procurement expression of interest" in the Subject line, or by phoning +1-617-774-0110 and asking to speak with the Procurement Department. Foundation staff will ask for some basic information to get the process started.
- If technical assistance is needed during the development of the Procurement Plan, the PR can seek such help from the Clinton Foundation, the WHO, the World Bank, or others. (See, for instance, the 160 TA providers listed in *"The Aidspace Guide to Obtaining Global Fund-Related Technical Assistance"*, available at www.aidspace.org/guides. See also the *"The Aidspace Guide to Procurement and Supply Management for Recipients of Global Fund Grants,"* scheduled for release by July.)
- Once the Procurement Plan has been approved by the Fund, the PR should submit the plan to the Clinton Foundation. The Foundation will accept the Plan as valid, and will not require that the work it contains be repeated. However, to become eligible for the low prices that the Clinton Foundation has negotiated with the manufacturers, the PR will have to go through some extra steps, some of which will involve a country visit by a team from the Clinton Foundation.
- In particular, the PR will need to show that it is able and willing to move to a system of long-term tenders. And it should, at an appropriate moment in the negotiations, ask the Fund to place the relevant grant money in an escrow account (or to use the money to pay for a letter of credit) rather than sending the money to the PR. The escrow account or letter of credit will later be used to pay for the drug purchases.
- The PR will also need to prove that procedures will be put in place to ensure that the low-cost drugs will be given to the patients for whom they are intended and, in particular, that the drugs will not get stolen and/or sent to countries where these low prices are not available.
- If the PR ends up being able to purchase drugs and diagnostics at a significantly lower price than was anticipated when the original proposal was submitted to the Global Fund, the PR can, subject to agreement by the CCM (if it was a CCM proposal) use some of the savings to increase the scale of the original proposal, or to add modestly to the project's activities, so long as the objectives remain broadly consistent with the original approved proposal.

Starting in mid-2004, the Global Fund will publish information on the products purchased and the prices paid by all its grant recipients. This transparency will help to keep prices low.

The strength of the plan announced today is that as more and more recipients of Global Fund and World Bank grants get involved, the procurement budgets that they have access to can, in effect, become aggregated and can make possible substantial competition and very large production runs.

This, in turn, means that the drug manufacturers can guarantee large long term contracts to their own suppliers, leading to yet further reductions in cost.

In the past, prices were kept high because low volume, uncertain demand and late payment led to inefficient production runs and high administrative costs per order. Today's agreement seeks to avoid all these problems, and to pass the benefits to those who need the drugs.

Stephen Lewis, the UN Secretary General's Special Envoy for HIV/AIDS in Africa, commented, "This is all tremendously exciting, and it will be made even more so if WHO finally receives the seed money it needs – \$200 million over two years – to help to coordinate the interventions at country level [and] to provide the emergency technical assistance [that is needed] to achieve '3 by 5.'

"The inexplicable financial torpor which has anaesthetized the donor world may now be broken, as the donor countries see the extraordinary opportunity to come in behind this initiative and give it an additional dramatic push. Surely the increasingly realistic prospect of prolonging and saving the lives of millions of men, women and children, will galvanize the international community."

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2. COMMENTARY: Plans Are Fine, But Who Has Been Helped?

by Richard Stern

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In the past few years we have heard many announcements – such as today's – about scaling up plans and programs regarding HIV/AIDS treatment. They have come from UNAIDS, WHO, PAHO and the Global Fund, as well as generic and originator drug companies. But after the press coverage dies down, things don't seem to change very much for the people who need these drugs. Lots of our AIDS leaders like to be in the headlines, but they don't seem to focus on the follow-up issues related to being sure that the promised medications actually reach the target populations.

I have seen little interest by the Global Fund in organizing a press conference that would point out that of the 30,000 people in Peru, Ecuador, Nicaragua and the Dominican Republic who could and should have received ARV therapy from Global Fund projects approved in Round Two, fourteen months ago, not one person has as yet received a single pill. Very likely a third of the people who needed treatment when the projects were approved have died. India is the same. Ironically, CIPLA's drugs, produced in India, do not reach India's 400,000 people who need treatment now, and a Global Fund grant to India worth \$100 million has yet to provide treatment for a single person.

To me these tragedies related to bureaucracy, negligence and indifference are newsworthy, but you don't see them in the New York Times.

Announcements such as this, coming one after the other, may actually be counterproductive in the sense that they give everyone a false sense of complacency. People reading about them think, "Well, the AIDS problem is solved in developing countries," and go on to some other issue. The media operates on one level, while the reality of the epidemic and the challenge of implementing effective solutions is often ignored. UNAIDS, PAHO, WHO, the Clinton Foundation and the Global Fund should start to hold press conferences focusing on why, with so much money available and prices so dramatically low, so few people are actually receiving treatment.

[Richard Stern (rastern@racsa.co.cr) is Director of Agua Buena Human Rights Association (www.aguabuena.org), based in Costa Rica. He travels widely in Latin America working with community groups on HIV/AIDS treatment issues.]

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3. PRESS RELEASE: The Press Release Announcing the Pricing Agreement
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[The following press release was issued on 6 April 2004 by the William J. Clinton Foundation, The Global Fund, UNICEF, and The World Bank.]

6 April 2004

New Agreements Aim to Make Lowest-Priced AIDS Drugs and Diagnostics Available to Hundreds of Thousands of Patients Throughout the Developing World

Global Fund, World Bank and UNICEF join with the Clinton Foundation to extend deep price reductions under Clinton-brokered agreements

Geneva, New York, Washington -- The Global Fund, the World Bank, UNICEF and the Clinton Foundation today announced agreements that will make it possible for developing countries to purchase high-quality AIDS medicines and diagnostics at the lowest available prices, in many cases for more than fifty percent less than is currently available.

Today's agreements will pave the way for countries supported by the Global Fund, the World Bank and UNICEF to gain access to drug and diagnostic prices negotiated by the Clinton Foundation. Beneficiaries of Global Fund and World Bank grants who are interested in accessing these agreements should contact the Clinton Foundation to initiate the process that is provided for under the Clinton Foundation's agreements with its suppliers. Countries will be required to provide guarantees of payment, to conduct long term tenders and to ensure the security of drug distribution. The Global Fund, World Bank and UNICEF will support their funding recipients in complying with these terms, as consistent with their policies and existing practices. As a result of these agreements, the Clinton Foundation will work with its suppliers to find ways to make the low-priced medicines and tests available to more countries as soon as feasible.

The Global Fund and the World Bank are among the world's largest sources of funding commitments to AIDS treatment. The Global Fund focuses more than 60 percent of the \$2.1 billion committed for two years to 122 countries to the fight against AIDS. The World Bank has currently committed \$1.6 billion to fight AIDS through the Multi-country HIV/AIDS Programs (MAP) and other AIDS operations, including grants for the poorest countries. UNICEF spent \$111 million during 2003 in the fight against AIDS and is rapidly accelerating the procurement of antiretroviral medicines (ARVs) and AIDS diagnostic equipment and tests for developing countries.

The prices have been negotiated by the Clinton Foundation with five manufacturers of ARVs and five manufacturers of HIV/AIDS diagnostic tests. These prices were announced originally in October 2003 and January 2004, and to date they have been available to the 16 countries in the Caribbean and Africa where the Clinton Foundation's HIV/AIDS Initiative is active.

The drugs in these agreements include individual formulations and two- and three-drug fixed dose combinations which have been pre-qualified by the World Health Organization to assure quality and efficacy. This standard is a prerequisite for procurement under Global Fund, World Bank and UNICEF policies.

These medicines are critical components of the four regimens recommended by the World Health Organization as "first line" treatment for AIDS in its 3x5 initiative. In developing countries outside of Brazil, such life-sustaining therapy is available to fewer than 200,000 people living with the virus, though almost six million require it. Recent commitments of financial support for treatment, along with these lower prices for drugs and tests, can expand this coverage significantly.

The pharmaceutical manufacturers included in these agreements are Aspen Pharmacare Holdings in South Africa; Cipla in India; Hetero Drugs Limited in India, Ranbaxy Laboratories in India; and Matrix Laboratories in India. The price for the most common first line formulation under these agreements is as low as \$140 per person per year, one-third to one-half of the lowest price otherwise available in most settings.

The diagnostic tests included in these agreements are offered by five leading medical technology companies and include CD4 tests from Beckman Coulter, Inc. and BD (Becton Dickinson and Company) and viral load tests from Bayer Diagnostics, bioMérieux and Roche Diagnostics. The prices available for these tests under the agreement include machines, training, reagents and maintenance and are up to 80% cheaper than otherwise available in the market.

Speaking about these agreements, former U.S. President William J. Clinton said, "I am grateful for this collective effort, which will soon help many hundreds of thousands of people, and eventually millions of people, live longer, healthier lives. With these agreements, we are one step closer to making sure future generations can live without the scourge of AIDS. We are hopeful that developing countries and those who support them in the fight against AIDS will take full advantage of this agreement and act quickly to do all they can to help in this fight."

Richard Feachem, Executive Director of the Global Fund, affirmed that, "Access to HIV treatment for all who need it is a moral imperative and now the target of growing financial commitments. Today's agreements build on sound science, agreed policy and market economics to maximize the reach of those commitments. As a result, hundreds of thousands of additional people will receive the drugs they need to stay alive and remain healthy."

According to the agreements announced today, the governments and NGOs supported by Global Fund, World Bank and UNICEF policies will be able to use the resources of these organizations to procure drugs and tests available under the Clinton Foundation arrangements. These agreements are consistent with existing policies of all three international organizations.

World Bank President James Wolfensohn said of today's announcement, "We regard AIDS as being the single most important issue at the moment in Africa because of the devastating effect that it has had throughout the Continent, and it is not something that is deferrable to discussions of economic or other issues. The emerging epidemic in Asia, Europe and Central Asia and the Caribbean is also a tremendous concern. This initiative will help to get treatment to those most in need - the world's poorest people. The World Bank is pleased to be a partner in the program and fully supports it."

The Executive Director of UNICEF, Carol Bellamy, added, "This new partnership works to break down some of the barriers - - such as price, supply and demand - - that are impeding access to life-saving AIDS medicines and diagnostics in developing countries. UNICEF is very proud to be part of this creative initiative that promises to save lives and bring hope to millions of children and families around the world."

The Clinton Foundation, Global Fund, World Bank and UNICEF are committed to exploring additional forms of cooperation to expand treatment access.

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The **Global Fund** is a unique and independent global public-private partnership dedicated to attracting and disbursing additional resources to prevent and treat AIDS, tuberculosis and malaria. This partnership between governments, civil society, the private sector and affected communities represents a new approach to international health financing. The Global Fund works in close collaboration with other bilateral and multilateral organizations to supplement existing efforts dealing with the three diseases.

In 2003 the **World Bank** provided \$18.5 billion and worked in more than 100 developing countries, bringing finance and/or technical expertise toward helping them reduce poverty. In addition to financial assistance, the Bank is also a major provider of implementation support for HIV/AIDS programs through direct provision of expertise (especially fiduciary), dissemination of good practice and lessons learned, and sponsorship of country-to-country learning. The World Bank is also working with all major stakeholders in scaling up antiretroviral therapy and its recently issued technical guide, "HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement" sets out principles and advice to countries and has generated many messages of support and appreciation from UN agencies, donors, policymakers, and NGOs. For more on the Bank's work in the area of HIV/AIDS, visit: www.worldbank.org/aids

UNICEF works in 158 countries to ensure that all children survive and thrive through adolescence. UNICEF's efforts on the ground emphasize immunization and micronutrients; the best start in life, including safe water and sanitation, basic health and nutrition, and loving interaction; education for all children; fighting HIV/AIDS and caring for children orphaned by the disease; and a protective environment that shields children from abuse, exploitation and violence. UNICEF is funded entirely by voluntary contributions from governments, foundations, businesses and individuals.

The **Clinton Foundation** HIV/AIDS Initiative has been at work for more than a year helping individual governments in Africa and the Caribbean to develop scalable AIDS care, treatment and prevention strategies. In the Caribbean, the Foundation is working with nine countries and three territories which together have over 90% of people living with AIDS in the Caribbean. In Africa, the Foundation is working with Mozambique, Rwanda, South Africa and Tanzania which together have about 33% of all people living with AIDS in Africa. The Foundation is also working to change the economics of HIV/AIDS care and treatment. The first agreements it has brokered have dramatically reduced the prices of ARVs and AIDS diagnostics.

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4. Q&A: Further Details Regarding Pricing Agreement, Released by the Four Participants

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[The following Q&A regarding the pricing agreement was released on 6 April 2004 by the same four organizations as the above press release.]

Questions & Answers

1. Who will actually conduct procurement under these agreements?

Governments and nongovernmental organizations (NGOs) purchase the drugs and diagnostics or outsource this task to procurement agents, such as UNICEF. In some cases as in South Africa or China, the governments use their own funds to make the purchases. In most cases, they receive funds from donors to support procurement for national scale programs.

Right now, the Global Fund and World Bank are by far the largest sources of funds for AIDS treatment in the world. A number of donor governments including Ireland, Canada, Norway, Sweden, France and Great Britain along with a number of private donors are also funding governments to carry out AIDS treatment programs in cooperation with the Clinton Foundation.

2. What steps must recipients take to obtain the prices made possible by these agreements?

HIV/AIDS programs wishing to access these agreements should contact the Clinton Foundation to express their interest to become a Member Purchaser. Each applicant will be considered on a case-by-case basis. Once a Member Purchaser, recipients will conduct their normal tender processes to buy drugs and tests. There are only a few additional requirements that must be met. They must secure letters of credit or other guarantees that ensure that the funds are available to pay for the drugs or tests. They must make tenders for extended periods and they must have sufficient security in their distribution and storage systems to ensure that the drugs and reagents are not stolen or diverted to unauthorized sources. In the case of Global Fund grantees, consistent with current Global Fund policies, assessments conducted by Local Fund agents will be used to determine the grantee's capacity to meet procurement and supply management requirements.

3. What countries are likely to benefit from these arrangements?

Countries that have received World Bank or Global Fund funds can potentially participate. Their participation will happen in a gradual fashion as they implement the systems necessary to meet the procurement and distribution terms of the Clinton Foundation's agreements.

4. Do these agreements endorse the use of generics? Of fixed-dose combinations?

The Clinton Foundation, Global Fund, World Bank and UNICEF all rely upon the World Health Organization to assess the quality of drugs and the suppliers of those drugs. The WHO has prequalified fixed dose combinations produced by high quality generic suppliers.

The Clinton Foundation would be happy to make agreements with patent-holding manufacturers of antiretroviral drugs to include them in its drug agreements. Patent-holding companies based in the United States and Europe have partnered with the Clinton Foundation on HIV/AIDS diagnostic tests.

5. Does this undermine the intellectual property of patent-holding manufacturers?

No. All four organizations support strong protection of intellectual property. However, the world community has recognized the emergency of the global AIDS health crisis and made provisions in world trade agreements for the use of generic drugs to fight AIDS. All countries will act according to their own laws and in the context of international laws and agreements in purchasing drugs. For diagnostic tests, the agreement includes the major patent-holding manufacturers.

6. If Governments are authorized to buy medicines from generic producers without the consent of the patent holder will not this undermine the ability of pharmaceutical industry to pursue research and development on the treatments?

A very small portion of pharmaceutical industry income comes from sales to the countries that form part of this initiative. The prices that are provided for in the agreements are very low and intended to provide maximum access for patients in need. Mechanisms are in place to prevent the sale of these low cost medicines in the major developed country markets so this will not have an impact on profit margins of the research-based pharmaceutical industry in the high-income countries. This initiative should have very little or no impact on research and development efforts. It is intended to benefit people in need.

7. How will it be assured that the drugs get to the people that need them and that they are of good quality?

The World Bank, the World Health Organization (WHO), the Clinton Foundation and many additional organizations provide technical assistance to countries to strengthen their supply chain management and to ensure secure and timely distribution. This includes training and the engagement of specialized agencies to assist recipient countries. Global Fund and World Bank funding is conditioned on the adoption and implementation of adequate fiduciary controls and evidence of mismanagement will lead to the suspension of that funding. The WHO is collaborating with countries to address weaknesses of the national and regional laboratory capacities and assisting countries to ascertain the quality of the batches.

Moreover, both the Global Fund and the World Bank have mechanisms to monitor compliance with their policies and agreements in countries where they are dispensing funds. This includes a price reporting mechanism that the Global Fund will use, beginning in the summer of 2004, to publish transparently the products procured and prices paid by its recipients. In partnership with these organizations, the Clinton Foundation will monitor the progress of countries in developing efficient tendering processes and efficient and secure drug and diagnostic test distribution processes.

8. Have any of the partners involved changed their policies to make this possible?

These agreements are consistent with the overall policies established by each of the participating organizations to accelerate access to AIDS treatment for the developing world.

The relationship with the Global Fund, World Bank, UNICEF, and the Clinton Foundation is entirely consistent with its existing policies, which require recipients to purchase quality-assured medicines at the lowest available prices, consistent with national laws and international agreements. This policy will be maintained under this agreement. The World Bank has adapted a

few of its procurement procedures to make them consistent with the principles that underlie the agreements between the countries and the Clinton Foundation to accommodate the special circumstances associated with the AIDS epidemic.

9. What will be the most immediate impacts of these agreements?

These agreements will mean that hundreds of thousands of additional people will be able to receive treatment for AIDS with funds already allocated to countries by the Global Fund and the World Bank. As additional grants are made, millions of patients may benefit from these procurement arrangements and their associated prices.

10. Is the Clinton Foundation competing for resources with the Global Fund and World Bank?

No. The Clinton Foundation provides technical assistance to countries interested in scaling up care and treatment and establishes programs to change the economics of AIDS treatment in resource poor settings by lowering the costs of treatment. The Clinton Foundation's work therefore complements the financing role of the Global Fund and the World Bank. This technical assistance may involve helping the government to prepare applications for funds to the Global Fund or World Bank. Fundraising is not the primary mission of the Foundation, which recognizes and affirms the central financing role of mechanisms like the Global Fund and the World Bank. The Global Fund, in particular, as an independent foundation relying on ad hoc contributions for resource mobilization, has urgent fundraising needs that all four collaborating partners support. In addition to its role as procurement agent, UNICEF supports significant programs in developing countries to stop the spread of AIDS and care for those affected by it, particularly children and families. UNICEF is funded entirely by voluntary contributions and has continued funding needs for its HIV/AIDS programs.

11. What are the price savings associated with these agreements?

For the four regimens recommended by the World Health Organization as first line responses to HIV/AIDS treatment, the drug prices available through these arrangements save up to \$130 per patient per year when compared to the lowest price generic equivalent (or about half of the cost) and up to \$420 per patient per year when compared to the lowest price branded equivalent (or about two-thirds of the cost). The diagnostic savings range from \$8 to as much as \$80 per test depending on the country and the particular test.

12. Do these agreements make unnecessary the availability in developing countries of antiretrovirals manufactured by patent holders?

No. While some compounds are available at high and assured quality at the lowest possible price from generic manufacturers, others are not. Some compounds can be purchased most cheaply through procurements from patent-holding manufacturers. Countries may also be required to purchase originator products depending on national laws and international agreements.

In all cases, the four collaborating organizations encourage patent-holding pharmaceutical manufacturers to make their products available at low prices to poor countries and to sustain research and development investments to improve the scientific basis of fighting HIV/AIDS and other infectious diseases.

Consistent with this spirit, GlaxoSmithKline has made available to all Global Fund Principal Recipients the deepest discounts it offers on products to fight HIV/AIDS and malaria. The Global Fund is also drawing on the inputs and additional manufacturers to explore the feasibility of channeling in-kind donations of medicines to its recipients as a voluntary option for meeting grant obligations.

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This is an issue of the GLOBAL FUND OBSERVER (GFO) NEWSLETTER.

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