



Independent observer  
of the Global Fund

## Further Details Regarding Pricing Agreement, Released by the Four Participants

[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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

1. Who will actually conduct procurement under these agreements?
2. What steps must recipients take to obtain the prices made possible by these agreements?
3. What countries are likely to benefit from these arrangements?
4. Do these agreements endorse the use of generics? Of fixed-dose combinations?
5. Does this undermine the intellectual property of 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?
7. How will it be assured that the drugs get to the people that need them and that they are of good quality?
8. Have any of the partners involved changed their policies to make this possible?
9. What will be the most immediate impacts of these agreements?

10. Is the Clinton Foundation competing for resources with the Global Fund and World Bank?
11. What are the price savings associated with these agreements?
12. Do these agreements make unnecessary the availability in developing countries of antiretrovirals manufactured by patent holders?

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