

Critical Issues Surrounding an International Fund for HIV/AIDS and Other Infectious Diseases



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Wealthy nations and donors are being pressured to fund an overdue comprehensive response to the global AIDS catastrophe.

Will people with AIDS, TB, and malaria be served by a fund that includes resources for an efficient bulk medicine procurement and distribution system?

Or will lives be ransomed to protect the pharmaceutical industry interests?

Introduction

A multilateral fund addressing care, treatment and prevention for HIV/AIDS, tuberculosis and malaria is a necessary response to the global AIDS catastrophe. At the Abuja, Nigeria OAU meeting, UN Secretary General Kofi Annan announced the creation of such a Global AIDS and Health Trust Fund (hereinafter the "Fund") and called for US\$7-\$10 billion in donations from rich countries, foundations, and private donors. The Health GAP Coalition has campaigned for such a fund since for over two years.

The fund will not be limited to AIDS, nor will it exist solely to purchase drugs.

Currently, all decisions are being made in non-transparent negotiations between the US, EU and various UN Agencies. By the UN Special Session on HIV/AIDS (25-27 June) most of the fund's parameters and policies will have been established, and will be announced to the delegations.

The United States is opposing bulk procurement of medicines through competitive bidding. The U.S. is also working hard to exclude generic drug manufacturers. Governance plans emerging reserve seats for the pharmaceutical industry on governance and advisory boards. These conditions are not guided by health or humanitarian concerns. The negotiating stance of the U.S. must be opposed.

This document provides policy recommendations and a principled foundation for negotiations on the Fund. We focus primarily on the politicized issues surrounding procurement and delivery of medications, governance, the role of wealthy nations, and the role of generic competition. Additional important concerns, such as the role of the fund in fortifying and expanding local capacity in developing country health sectors, are not fully addressed in this document.

In order to mount an adequate response to the global AIDS crisis, it is imperative that medicines and medical products be available to poor (non-OECD) countries at-or-near marginal costs of production. Generic competition and the creation of economies of scale are key components of a dynamic process that will exert sustainable downward pressure on drug prices.

A function of the Fund must be to finance a global and regional health commodities bulk procurement and delivery systems, *in addition to* funding disease prevention and care. Commodities purchased and distributed must include medicines. Bulk procurement coordinated by a large-scale purchaser will allow the most efficient use of limited, desperately needed resources. Generic manufacturers must be included as bidders in the bulk procurement process.

Drug acquisition schemes dependent upon pharmaceutical industry charity or on country-by-country, drug-by-drug, company-by-company negotiations is inefficient and unacceptable. Sustainable access to affordable medication has been too-long waylaid by the profit and public relations concerns of the pharmaceutical industry.

In accordance with Secretary General Annan's recommendation, first-year funding should be US\$10 billion. New US contributions should total US\$2 billion. Other G8, OECD governments and multilateral agencies should provide an additional \$6 billion, with the balance supplied from foundations and other private sources. Wealthy countries must commit to support this program by UNGASS. Substantial financial support should be available by the G8 meeting in Genoa (20-23 July). Commitments of inadequate resources will guarantee inadequate responses. For example, the small inaugural donation from the United States announced May 11 undermines momentum and sets an unacceptably low standard for other wealthy nations and foundation donors.

The Health GAP Coalition is a network of U.S.-based AIDS activists, public health experts, human rights groups, fair trade advocates and individuals dedicated to eliminating barriers to access to affordable life-sustaining medicines for people living with HIV/AIDS in impoverished countries. Access to medication is a fundamental human right that supersedes the commercial interests of the pharmaceutical industry.

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Summary of Recommendations:

- A. The Fund's health commodities procurement program should be housed within the UN system, expanding upon existing bulk procurement expertise within UNICEF, WHO and other agencies.
- B. The Fund must purchase drugs and other health commodities at the best world prices, regardless of patent status.
- C. The drug delivery system should coordinate and build upon existing public and private distribution networks, including those used by UNICEF, WHO, PAHO, mission hospital systems, work place programs, certain private insurers, national and regional government health systems, and certain NGOs. While existing distribution channels are being filled, additional distribution networks should be built or expanded, and funded as well.
- D. Funders must not attach strings or impose conditions upon donations. Priorities and decisions must be made solely by a governing body.
- E. Governance and advisory bodies of the Fund must be composed entirely of international health experts. A majority of board members must be representatives of governments and civil society representing developing countries. Fundamental conflicts of interest preclude any governance or advisory role for pharmaceutical corporations, or philanthropic foundations created by drug companies.
- F. The Fund should assign equal priority to prevention and treatment services. Sustainable access to treatment is integral to the viability and efficacy of prevention programs. In some cases, political considerations of wealthy nations entirely unrelated to public health have created pressure to avoid funding for treatment.
- G. Investments in infrastructure afforded by the Fund should prioritize building or restoring sustainable primary care system projects that plan to deliver medicines as rapidly as possible.
- H. The program should facilitate and provide assistance with country-level drug registration procedures for medicines provided by the Fund.
- I. The UN system should provide workshops and technical assistance to facilitate drafting and passage of intellectual property legislation allowing rapid and efficient implementation of compulsory licensing and parallel importing when necessary.
- J. The Fund should avoid burdening applicants with unnecessary administrative requirements. The Fund should facilitate or provide necessary and appropriate technical assistance to all applicants, without diverting resources to consultants, vendors, and NGOs in developed countries.
- K. The Fund must be a sustained program. Measurable health outcome goals such as a increasing life expectancy must be established. Member states should receive assurances that the fund will be maintained until goals are met.

Discussion of fund principles:

1. Health Commodities Bulk Procurement Program:

The Fund must fund a global procurement program. This public sector program will create sustainable downward pressure on drug prices. Drug company offers of price reductions or donations have generated far more publicity than justified by the extremely limited quantity of medicine that has reached people with AIDS in impoverished countries. Typically, industry has used country-by-country negotiations to extract conditions, incur delays, and impose limitations while obscuring price transparency and discouraging sustainable responses not dependent on corporate charity.

- A. Medicines and other competitively available commodities must be purchased at best world prices, regardless of patent status.
- B. Commodities including medicines should be purchased through a transparent competitive bidding process that can be reopened as market conditions alter in ways that reduce market prices.
- C. The procurement system should purchase from multiple suppliers where possible, including generic manufacturers, to ensure adequate supply security and manufacturing capacity. Capacity building of local generic drug production must be supported.
- D. The program must encourage cooperation and coordination among participating manufacturers.
- E. The program must attempt to coordinate purchases and raw materials supply networks to optimize manufacturing capacity in correlation with need, to enhance buying power, and to maximize economies of scale.

- F. The program must provide procurement services for global regional entities, but also be extended to governments and other providers including non-governmental and work place programs, and mission hospitals.
- G. The low-cost medicines shall be for distribution for free to people in non-OECD countries, plus Mexico.
- H. Medicines for HIV and its opportunistic infections, treatments for tuberculosis, malaria and other life threatening illnesses affecting poor countries must be eligible for purchase. In addition to medicines, the program should also purchase diagnostics and monitoring tools necessary for disease management and micronutrients known to improve health outcomes.
- I. The purchasing program and any subcontractors must not fund or be used in connection with pharmaceutical donation programs that place restrictions, implied or explicit, on a nation's trade or patent policy.

2. Delivery of medicines: coordinating and building outward from existing capacity

- A. The drugs should be distributed through an expanded and coordinated network based on the combined strengths of existing channels such as the WHO's TB program, UNICEF's vaccine program and the network of mission hospital drug delivery systems. Work place programs must also be eligible.
- B. The drug distribution system should be secure and flexible, and quick to repair weak or damaged links.
- C. Medicines should be delivered to a mix of public, private, and government sectors including member state health systems, NGOs, mission clinics and hospitals, and work place programs. Drug delivery partners should vary as needed for maximum effectiveness by region.
- D. Capacity building is a goal. When existing channels for drug delivery are filled, new NGOs, public health systems, or work place programs in participating regions may apply to receive medicines.
- E. Inventory check-points must be established at multiple points in the distribution chain to minimize drug leakage.

3. Governance

- A. International health experts and representatives from civil society including PLWHIV and other consumer organizations should compose the governing body. The decision making board should also consist largely of individuals from the global South.
- B. Decision-making must be transparent. All decisions relating to the creation, governance, and activities of the fund must be made with active participation by people with HIV/AIDS, affected communities, developing country governments, and NGOs. All information related to this fund must be accessible to the public.
- C. Governance rules must include provisions guarding against conflicts of interests. Foundations, NGOs or businesses should not be able to participate in funding decisions that would directly benefit them.
- D. Commercial interests shall not be represented on governing or advisory bodies. Pharmaceutical interests in particular have no role in governance of the fund, due to conflicts of interest with relation to purchase of pharmaceutical products as well as training of health care workers. In addition, the pharmaceutical industry's contribution to devastating inequities in access to medicine renders an advisory role suspect.

4. Appropriate Role of Donors

- A. Donors should provide unrestricted support to the Fund. Funding decisions should be guided by the needs of the epidemic determined by transparent governing and advisory bodies to ensure that the Fund's grants are balanced and comprehensive.
- B. Donors should contribute *new* resources towards the Fund. Useful programs currently underway must not be threatened by the emergence of the Fund.
- C. Vendors from donor-countries must not be shown preferential treatment. All health commodities including drugs should be procured at best world prices, regardless of vendor home countries.
- D. All financial assistance should be made without regard to recipient countries' trade policies, including internal laws and decisions regarding compulsory licensing and parallel importing.

- E. Decisions regarding grant awards should be determined by the governance or advisory boards, and driven by country need. Strategic and economic factors including military alliances and trade partner status with should have no bearing on these decisions.
- F. Fund donations should constitute new foreign aid expenditures by the United States government. Systematic under-spending and lack of attention to developmental needs have greatly contributed to the AIDS pandemic, particularly in sub-Saharan Africa where the majority of this new funding must now be directed. To take financial resources from other regions and needs will simply replicate this deadly practice.
- G. Financial assistance must be part of a sustained commitment. Authorizing legislation and/or private donations should reflect at least a five-year cycle of spending with the need for renewal at the end of the original cycle.

5. Grants for Treatment and Prevention

- A. Access to treatment is integral to effective prevention programs. Without access to medicine, there is little motivation to seek testing. With reduced viral burdens, HIV positive individuals are less infectious. Access to anti-HIV medications can dramatically reduce mother-to-child transmission of HIV.
- B. Funds must be available for purchase and distribution of HIV/AIDS treatment, including antiretroviral medications, drugs for prophylaxis and treatment of opportunistic infections, tuberculosis, sexually-transmitted diseases (STDs), supportive and palliative care;
- C. Funds should be granted to prevention services, including the distribution of barrier methods to HIV transmission; methods to screen blood for HIV, HCV and other pathogens; voluntary testing and counseling (VCT); and prevention of mother-to-child transmission (MTCT). Bulk purchase and distribution of safe and effective HIV vaccines and microbicides should be subsidized by the Fund as soon as such products exist.
- D. HIV vaccine and microbicide research should be supported by wealthy countries.

6. Primary Care Investments

- A. Funds should be made available to strengthen primary health care systems, including reproductive health systems, programs to treat and prevent respiratory and diarrheal diseases, malaria, primary obstetrical and pediatric care, including prevention and treatment of childhood infections, and programs to improve food security and purify water supplies.
- B. Infrastructure investments should prioritize grants to projects that build or restore sustainable primary care systems, with preference given to plans that will properly deliver medicines as rapidly as possible.

7. Drug Registration

- A. Bulk procurement programs receiving grants from the Fund should consider 'safe and effective' -- and therefore distribute -- medicines that have already been registered and approved for sale by any of a number of acceptably rigorous national drug licensing agencies. Bio-equivalent generics must also be accepted. Acceptable drug registration data must not be limited to the standards of a single nation.
- B. A bulk procurement and distribution program(s) should assist countries in streamlining and expediting licensing and registration of medicines in participating countries. The program should work with suppliers to develop and maintain a common dossier of product information that would include information typically required for drug registration.
- C. Nations that receive medicines from the program may conserve resources and expedite registration procedures by accepting without review the merits of data and the determinations of drug approval agencies from a range of acceptably rigorous national drug licensing agencies.

8. Intellectual property legislation

- A. International agencies should provide workshops and technical assistance for nations states on the creation of TRIPs-compliant intellectual property legislation allowing rapid and efficient implementation of compulsory licensing and parallel importing when necessary to drive down prices.
- B. WHO must immediately respond to its sixteen month old expanded mandate and draft sample intellectual property legislation for member states that want to maximize WTO-legal tools such as compulsory licensing and parallel importing to drive down drug prices.
- C. Impoverished countries should have access to data from patent processing systems in place in wealthy nations.

Background on recent developments relating to the pharmaceutical industry:

- The cycles of pharmaceutical industry price reductions announcements are an artifact of campaigns to win sustainable, self sufficient production and importation of critical medicines at best world prices.
- World-wide activist protests coupled with the entry of public and private sector generic drug manufacturers -- and threats from governments of the global south to break drug company monopolies -- are responsible for the price reduction announcements.
- Drug companies already have substantial tax incentives to donate medicines. Such donations would come at a greater expense to the U.S. tax base than an outright purchase of generic drugs.
- The fear of re-importation into primary markets (rich countries) is an empty fallacy. The U.S., EU, and Japan are capable of controlling their borders. In addition, drug makers with a large primary market in OECD countries already have experience monitoring movement of their commodities
- The industry frequently overstates the complexity of HIV treatment regimens and pill burden. Despite industry rhetoric, patients initiating therapy currently would likely take one to three anti-HIV pills in the morning, and the same number at night. Given a full array of treatment options, it would be unusual for patients to choose unnecessarily complex treatment regimens. Food restrictions, refrigeration, very high pill burdens, and tight pill-taking schedules are difficulties suffered primarily by very "treatment experienced" people with HIV who have already spent years working through combinations of therapies.
- Industry spends far less than the frequently cited \$500 million bringing a drug to market; current first world prices bear no relation to cost of drug production. Many HIV antiviral and other treatments approved by FDA were invented or otherwise were heavily subsidized with U.S. tax dollars. Industry spends on average at least twice as much on marketing, especially direct to consumer marketing, than is spent on research and development.

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