Critical Analysis of Global Fund's Proposed Equitable Access Initiative: GF-B31-ER8

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INTRODUCTION

On May 15, 2014, Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria, issued a report to the Board of the Global Fund on a proposed "Equitable Access Initiative." This is the fourth draft of a proposal to establish a Blue Ribbon Task Force on what was first called a tiered-pricing initiative but has now evolved to "equitable access" nomenclature. This revised proposal, the first one that has been made publicly available, was issued one day after the broad circulation of a letter from 220 global civil society organizations calling for the Global Fund to abandon its proposed initiative based on their collective analysis of the third draft leaked on March 18, 20014. There had also been significant civil society and expert critique of the first three proposal drafts and there are also indications that some of the proposed partners (UNITAID, UNDP, UNICEF, GAVI, and the World Bank) were also highly critical.

Although there is evidence that Mark Dybul has responded to criticisms from civil society and proposed partners and although now public fourth draft is somewhat better than the prior drafts, there are still five major concerns with the proposal, including:

1. The under-inclusiveness of the problem definition, which focuses on countries transitioning from low- to middle-income status only rather than the broader problem of restricted donor health funding and unaffordability of medicines and other health technologies for poor people and resource-constrained low-, lower-middle, and even upper-middle income countries.
2. The continued prioritization of country-tiering, market segmentation, and tiered pricing solutions instead of other more country-led solutions including adoption, use, and expansion of TRIPS flexibilities and delinking the market for R&D from the market for manufacture/distribution.
3. Industry is given a privileged role on the Task Force and in input on the Task Force's concept note despite its obvious conflicts of interest.
4. Although country participation is clarified, the proposal does not provide for country leadership by the countries most affected by industry imposition of unaffordable prices and by ineligibility or limited eligibility for donor health funding.
5. The process for developing this proposed initiative has been closely held and secretive with no role for civil society and governments and only a limited role for a subset of proposed partner organizations.

This analysis focuses first on a section-by-section critique of the proposal and then on the flawed process by which it has been developed.

THE PROPOSED EQUITABLE ACCESS INITIATIVE

Problem definition:

The fundamental problems of affordability/access are still poorly defined: Paragraph 1.2 still erroneously defines the problem about country eligibility for global health funding and access to low prices as entailing only countries that move from low- to middle-income status. Contrary to this problem definition, many long-established middle-income countries face the problem of inadequate access to donor health funding and unaffordable medicines. Likewise, funding and affordability remains a concern in many low-income countries as well, including for newer AIDS, TB, and malaria medicines, but also for medicines addressing neglected and chronic, non-communicable diseases. The problem definition should include problem statements that:

- LMICs have not availed themselves of all lawful policies that might increase their access to affordable medical technologies.
- Donor countries and multilateral global health institutions frequently have funding policies that restrict funding to populations in low-income countries only and ignore poor populations in middle-income countries.
- The absence of generic competition for many medicines and the arbitrary pricing power of single-source suppliers to set prices primarily to maximize profits, usually to the detriment of the poor, routinely undermines equitable access.
- The current IP-based incentive system for funding medical innovations is inefficient and neglects many important therapeutic needs including neglected diseases, rational fixed-dose combination, and pediatric formulations.

The scope of diseases included is unclear, but should include all health conditions: The proposal addresses "life-saving health interventions, including diagnosis, immunization and treatment for HIV, TB and malaria," paragraph 1.1. In contrast, in paragraphs 1.3,1.5, and 2.7, there is a reference to "essential health commodities." A special emphasis on life-saving or essential health commodities only and a special listing of interventions for diagnosis, immunization and the treatment of HIV, TB, and malaria is undesirable. Poor populations in low- and middle-income countries need the full spectrum of preventative, curative, therapeutic, and palliative medicines available patients in rich countries. In addition, they may have special needs because of a unique burden of disease, including but not limited to diagnostics, vaccines, and medicines for neglected tropical diseases.

(Note: Paragraph 1.5 is confusing in that it discusses removal of donor/governmental institutional frameworks. There has been no previous mention, let alone description, what these frameworks might be.)

Why the initiative:

Focus is narrowly on the transition to domestic financing: Paragraph 2.1 says it "is not possible to have transition if countries cannot afford health commodities." Although transition is not defined, I assume that the term refers to the transition from receiving Global Fund and other donor funding, e.g., through GAVI, UNITAID, and others, to relying principally or solely on domestic resources. A clearer statement would therefore be: "Global health programming and responsibility for funding cannot be successfully transitioned from the Global Fund and other global health funders to middle-income countries if those countries cannot afford current prices for health commodities in middle-income countries."

Industry is still given a privileged role despite its obvious conflict of interest: The document acknowledges that there have been concerns expressed about industry inclusion on the Expert Panel. Nonetheless, paragraph 2.5 specifically defends the continued inclusion of "Industry (i.e. representatives from both generic and innovator pharmaceutical manufacturers)" as necessary to "a comprehensive discussion." Contrary to the proposal, industry could be constructively consulted about its views and experiences without it having seats on the Panel. Moreover, industry will have more than a seat. Pursuant to Action Step 8, the Initiative's "concept note" would be shared with key suppliers of essential health commodities for feedback. This step gives industry privileged access to the conceptualization of the initiative despite its deep conflicts of interest.

Country participation is clarified, but there is still insufficient provision for country leadership: Paragraph 2.5 acknowledges that officials from affected countries would be on the expert panel, but does not define any privileged leadership role for countries. In addition, paragraph 2.6 describes a process of country engagement: "There would be a heavy emphasis on, and engagement of, countries – their experiences with the problem and solution, and their needs for the future," and paragraph 4.4 says that governments will be systematically included through the program of work, including regular stakeholder consultation. Despite membership on the Task Force and despite engagement and systematic inclusion, the proposed initiative remains fundamentally flawed to the extent that affected governments are not in a more defined leadership role – governments must define the role of global health agencies and initiatives and governments' engagement as stakeholders, whereas the Global Fund-led proposal has attempted to reverse these responsibilities for leadership.

Country-tiering is clarified, and tiered-pricing is deemphasized on paper but still central in concept: Paragraph 2.7 identifies the need for a more refined approach to income stratification of countries that goes beyond GDP or GNI. Such an approach could include percentage of people living in poverty, access to health commodities, etc. This is a needed clarification in the proposal, but it still gives the proposed initiative a primary focus on country-tiering practices, market

segmentation, and tiered-pricing rather than other potential solutions. In other words, a focus on the tiering problem – ability to pay – inevitably leads to prioritizing tiered-pricing as the solution to the access/affordability dilemma across the "continuum of development," in lieu of other solutions, including delinkage and IP reform, that might produce better and more durable solutions.

On the plus side, the Executive Director admits that his previous focus on tiered pricing was in error, paragraph 2.8. Indeed, the ED goes further than that acknowledging that industry-led tiered-pricing has been part of the problem: "It is important to note that a key impetus for the effort is the clear inadequacy of the current approach to tiered pricing in many settings with the unrefined income classification that leaves many persons in MICs vulnerable to inequitable access." However, even though the proposal has evolved dramatically in recent months, there is a strong possibility that focusing on market segmentation and income differentials between countries will lead to prioritizing solution whereby countries pay more graduated, but still higher-than-desirable prices, with the unstated assumption that heightened profits from higher-tiered countries are necessary to recoup R&D costs and to pay for ongoing innovation. This industry-dominated tiered-pricing price setting could occur even in the absence of full disclosure of a company's R&D costs and of its global earnings on a particular product. However, it may well be that a superior solution is to delink the incentives and rewards for innovation from the generic manufacture and low-price sale of resulting medical technologies. This solution is not even on the radar of this proposal.

Progress so far:

Civil Society participation is clarified and improved: A draft program of work has been developed, with early timelines established, but the timing of later steps not yet defined. In Step 4, there will be a consultation with Civil Society; in Step 7, the concept note will be formally shared with civil society for feedback. It should be noted as well that Civil Society representatives will be on the proposed task force, paragraph 2.5, and that civil society and communities living with, and most affected by the three diseases will be systematically included through the program of work including regular stakeholder consultation.

Exclusion of certain middle-income countries and questionable focus on introducing the initiative to Heads of State: In Action Step 6 of the Program of Work, there is a stated intent to introduce the Initiative to Heads of State from Africa, Asia, Latin- (sic) and South Africa. This description excludes low- and middle-income countries from the Caribbean and from Eastern Europe. The proposal should include countries from all low- and middle-income regions. In addition, the focus on heads of state may be unwise and presumptive. Countries should choose who they want send for such important consultations based primarily on knowledge and competence in the issues under discussion.

Update on Program of work:

Convening partners: Paragraph 4.1 identifies convening partners as GAVI, the Global Fund, the World Bank, UNICEF, and UNITAID. WHO's participation as a convener is precluded because of alleged legal reasons, but the WHO will nonetheless be an observer. (Greater clarity should be provided why WHO is legally precluded; if it is because of the presence of conflicted industry representatives, then WHO's partnership role is vastly more appropriate than industry's membership on the task force.) The initiative will build on previous work by Partners, including the Middle Income Country consultation in June 2013.

"Access levers": The revised proposal has a more comprehensive list of measures that could be explored by the expert panel, including:

- Economic Classifications of Countries – To facilitate policy making, revisit income stratification to align middle-income economic concept(s) to realities on the ground, around poverty and disease burden;
- Affordability and mechanisms of support for the poorest, the marginalized and criminalized;
- The use of public health related TRIPS Flexibilities;
- Explore improvements on elements of TRIPS;
- Regulatory improvements;
- Enhanced Procurement and Supply Chain processes – e.g. forecasting; coordinated procurement; greater transparency and integration of markets through e-procurement; quality assurance;
- Market analysis:
- Competition – creating favorable conditions for both innovator and generic competition;
- Licensing and royalties, including tiered royalties with a more refined economic classification;
- Pricing solutions – including increased transparency about pricing, price negotiations and tiered pricing; assuming a more refined income classification to better protect countries as the move along the development continuum;
- Mechanisms for technology transfer – to generic companies and to local manufacturers;
- Advance Market Commitments;
- Role of insurance in commodities financing – (plays a role in Rwanda and Ghana);
- Support for prevention strategies;
- Support for patient adherence; and
- Adoption of regional equitable access strategies e.g. in Africa, Eastern Europe and Latin America.

This list is incomplete is some regard and over-inclusive in others. A major omission is the topic of delinkage and alternative incentive systems for innovation. There is a discussion of pricing transparency, but not of other key market information like R&D costs, company earnings, etc. In terms of over-inclusiveness, some of the topics concern internal domestic issues, e.g., support for prevention and adherence strategies and role of insurance. Others are already being addressed elsewhere, e.g., regulatory improvements (WHO), enhanced procurement and supply chain processes (Global Fund and WHO), and market analysis (UNITAID). In other words, this list still needs lots of work and refinement, and eventually prioritization.

Process concerns:

The process for seeking input into this proposed initiative has been deeply flawed. There have been a series of secret draft proposals, shared with proposed partners and perhaps some other limited stakeholders, including industry, but the proposals have not been shared with affected governments, civil society, and communities affected by unmet health needs. Fortunately, civil society has been proactive in responding to leaks of the earlier proposals and experts have written critical analyses, but governments have had trouble responding to unofficial documents. Similarly, this proposal has not been submitted for approval to the Board of the Global Fund, though it has been discussed at the Board level at UNITAID. It is also not clear whether it has been approved by the GAVI Board.

As stated previously, there is a fundamental question about the role that convening partners, especially the Global Fund, are playing and whether they should instead be trying to convene a more country-led process – a process that allows countries to set the substantive agenda and to lead the development and implementation of the initiative. This kind of process might well help countries to focus on the critical question of whether an initiative like this will help countries to define and adopt policy options collectively, or whether they would be better off implementing some well-known strategies on their own like pro-public health IP reform. Countries could also confront the critical question of whether an initiative like this will produce any credible and enforceable outcomes. For example, they might conclude that a mere framework on country tiers and voluntary tiered-pricing would create no binding norms on pharmaceutical companies' pricing decisions, especially in more lucrative, middle-income country markets.

Conclusion:

In sum, the list of policy options in the proposed Equitable Access Initiative is improved, but not perfect, partially because the "gist" of the proposal still focuses upon country tiers and tiered-pricing instead of the many other country-controlled policy levers that might yield greater results. Given the continued risk of industry-domination and the lack of a formal leadership role for affected countries, there is a significant political risk that the proposed initiative will resulted in an unenforceable "framework" for better differentiating countries' funding and

commodity pricing needs to which industry will respond, per usual, with unilaterally imposed, unjustifiably high pricing, even though there might be more finely tuned scaling.

The proposal and the process still have to be flipped on their heads – countries and civil society should lead, global health institutions like the Global Fund should assist, and much greater focus should be paid to options that will increase and sustain competition while ensuring quality, most notably adoption and use of TRIPS public health flexibilities and exploration of opportunities for delinkage. Unless such dramatic changes are made, the demand of 220 civil society organizations to abandon the proposed initiative should still be followed.